designate a transition area at Fort Madison, Iowa.

Interested persons may participate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Director, Central Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, Federal Building, 601 East 12th Street, Kansas City, Mo. 64106. All communications received within 45 days after publication of this notice in the FEDERAL REGISTER will be considered before action is taken on the proposed amendment. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Regional Air Traffic Division Chief.

Any data, views or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

A public docket will be available for examination by interested persons in the Office of the Regional Counsel, Federal Aviation Administration, Federal Building, 601 East 12th Street, Kansas City, Mo. 64106.

A public use instrument approach procedure has been developed to serve the Fort Madison, Iowa, Municipal Airport, using the Burlington, Iowa, VORTAC as a navigational aid. Consequently, it is necessary to designate a 700-foot floor transition area at Fort Madison to provide protection for aircraft that will be executing this approach procedure. With the designation of controlled airspace for its protection, the new approach procedure will be effective. IFR air traffic into and out of Fort Madison Municipal Airport will be controlled by the Chicago ARTC Center through the Burlington Flight Service Station.

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations as hereinafter set forth:

In § 71.181 (33 F.R. 2137), the following transition area is added:

FORT MADISON, IOWA

That airspace extending upward from 700 feet above the surface within a 5-mile radius of Fort Madison Municipal Airport (latitude 40°39'00" N., longitude 91°19'20" W.); and within 2 miles each side of the Burlington, Iowa VORTAC 258° radial, extending from the 5-mile radius area to 12 miles west of the VORTAC excluding the portion which overlies the Burlington, Iowa, transition area.

This amendment is proposed under the authority of section 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348).

Issued at Kansas City, Mo., on April 11, 1968.

DANIEL E. BARROW,
Acting Director, Central Region.

[F.R. Doc. 68-5040; Filed, Apr. 25, 1968; 8:49 a.m.]

ATOMIC ENERGY COMMISSION

[10 CFR Parts 31, 32]

IODINE-125 OR IODINE-131

General Licensing for Use in Clinical or Laboratory Tests Not Involving Administration to Human Beings

By letter dated October 20, 1966, the Jones Medical Instrument Co. filed a petition (PRM-30-26) with the Atomic Energy Commission requesting issuance of a general license for use of iodine-125, in prepackaged units, not to exceed 10 microcuries each, for in vitro testing of thyroid functioning.

Such testing has been performed for several years with iodine-131 under the general license provided in § 31.4, 10 CFR Part 31, and, with iodine-125 under specific license. The usefulness of these isotopes in medical tests and the similarity of radiological safety considerations between in vitro thyroid function tests and other in vitro tests have led the Commission to consider the issuance of a separate general license, in a new § 31.11, to physicians, clinical laboratories, and hospitals, authorizing the receipt, acquisition, possession, use or transfer of iodine-125 or iodine-131 for in vitro clinical or laboratory tests.

The tests, which do not involve administration of radioactive material to human beings, are performed by physicians and clinical and laboratory personnel who generally are trained to perform the tests with care and precision.

The general licensee would be required to register with the Commission and to receive an acknowledgment of his registration and a registration number before receiving iodine-125 or iodine-131 pursuant to the general license. The objectives of the registration requirement are: (1) To provide a means of identifying the general licensee, (2) to provide assurance that the general licensee is aware of the terms and conditions of the general license prior to receipt of material, and (3) to facilitate communication with the general licensee.

A new § 32.71 would be added to 10 CFR Part 32 to set out requirements for issuance of specific licenses to manufacture or distribute iodine-125 or iodine-131 for use under the proposed general license. These requirements are intended to assure that general licensees receive properly packaged products, labeled to identify the radioactive contents and to specify that use is restricted to in vitro clinical or laboratory tests.

Pursuant to the Atomic Energy Act of 1954, as amended, and section 553 of Title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Parts 31 and 32 is contemplated. All interested persons who desire to submit written comments or suggestions should send them to the Secretary, U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Chief, Public Proceedings Branch, within 30 days after publication of this notice in the FEDERAL REGISTER. Comments received after that period will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed within the period specified. Copies of comments on the proposed rule may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

1. A new § 31.11 is added to 10 CFR Part 31 to read as follows:

§ 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-____, "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-____ with registration number assigned. The registrant shall furnish on Form AEC-____ 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,[1] 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 § 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.

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-_____. The report shall be furnished within 30 days after the 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.

2. A new § 32.71 is added to 10 CFR Part 32 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:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

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

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form, radionuclide, activity and date of determination of activity; and

(2) Displaying the radiation caution symbol described in § 20.203(a)(1) of this chapter and the words, "Caution, Radioactive Material", and "Not For Internal or External Use in Humans or Animals."

(d) 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.

Name of manufacturer

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material.

(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 12th day of April 1968.

For the Atomic Energy Commission.

W. B. McCool,
Secretary.

[F.R. Doc. 68-5018; Filed, Apr. 25, 1968; 8:48 a.m.]

[1] 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.

PROPOSED RULE PR-31,32

Iodine

NOV 7 1968

Dr. Paul C. Tompkins
Executive Director
Federal Radiation Council
Washington, D. C. 20449

Dear Dr. Tompkins:

Enclosed are five copies of a notice of rule making amending the Commission's regulations, "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items," 10 CFR Part 31 and "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material," 10 CFR Part 32.

The amendments issue a new general license to physicians, clinical laboratories, and hospitals for the possession and use of iodine-125 and iodine-131 for in vitro clinical or laboratory tests and set forth requirements for issuance of specific licenses to manufacture or distribute iodine-125 or iodine-131 for use under the general license.

The notice of rule making is being transmitted to the Office of the Federal Register. The amendments will become effective sixty days after publication in the Federal Register.

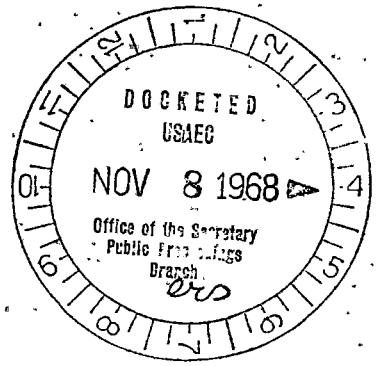
Distribution:
Formal File
Supplemental File
Secretariat w/cy for
Public Document Room
Attn: Stan Robinson
Program Assistance Branch, RPS
Radiation Standards Branch, RPS

Enclosures:
Notice of Rule Making (5)

Sincerely,

Original signed by
Forrest Western

Forrest Western, Director
Division of Radiation Protection
Standards



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DOCKET NUMBER
PROPOSED RULE PR-31,32
Iodine

NOV 7 1968

Mr. James G. Terrill, Jr.
Director, National Center for
Radiological Health
U.S. Public Health Service
12720 Twinbrook Parkway
Rockville, Maryland 20852

Dear Mr. Terrill:

Enclosed are five copies of a notice of rule making amending the Commission's regulations, "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items," 10 CFR Part 31 and "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material," 10 CFR Part 32.

The amendments issue a new general license to physicians, clinical laboratories, and hospitals for the possession and use of iodine-125 and iodine-131 for in vitro clinical or laboratory tests and set forth requirements for issuance of specific licenses to manufacture or distribute iodine-125 or iodine-131 for use under the general license.

The notice of rule making is being transmitted to the Office of the Federal Register. The amendments will become effective sixty days after publication in the Federal Register.

Sincerely,

Original signed by
Forrest Western

Forrest Western, Director
Division of Radiation Protection
Standards

Distribution:
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Public Document Room
Attn: Stan Robinson
Program Assistance Branch, RPS
Radiation Standards Branch, RPS
Enclosures:
Notice of Rule Making (5)

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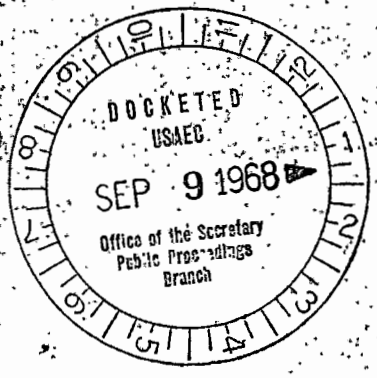
DOCKET NUMBER
PROPOSED RULE PR-31,32
Iodine

DOCKET NUMBER
PROPOSED RULE PR-30,31,32,35
Exemption of Small Quantities

SEP 3 1968



Mr. R. J. Adams, President
Curtis Nuclear Corporation
1948 East 46th Street
Los Angeles, California 90058

Dear Mr. Adams:

Thank you for your letter of August 29, 1968, commenting on the Commission's proposed exemption of small quantities of byproduct material.

We appreciate your request for reconsideration of the quantities of iodine-125 and iodine-131 proposed for exemption in order to facilitate the use of those nuclides for in-vitro diagnostic tests. The Commission, recognizing this use, and in response to a petition for rule making from the Jones Medical Company of Chicago, Illinois, published a notice of proposed rule making on April 26, 1968, to provide a general license for the in-vitro tests. A copy of the notice is enclosed. We are evaluating the comments received in response to the notice of proposed rule making prior to submitting the amendments to 10 CFR Parts 31 and 32 to the Commission for their consideration for publication in effective form.

We will advise you of further action on the general license for in-vitro diagnostic tests.

Sincerely,

Forrest Western, Director
Division of Radiation Protection Standards

Enclosure:
Notice of Proposed Rule Making

Distribution:
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Supplemental File
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Public Document Room
Attn: Stan Robinson

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Form AEC-318 (Rev. 9-53)

U.S. GOVERNMENT PRINTING OFFICE : 1966—O-214-629

Curtis Nuclear Corporation
1948 EAST 46TH STREET • LOS ANGELES, CALIFORNIA 90058 • TELEPHONE (213) 232-3531

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DOCKET NUMBER
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August 29, 1968

The Secretary
UNITED STATES ATOMIC ENERGY COMMISSION
Washington, D.C. 20545

ATTENTION: Chief, Public Proceedings Branch

RE: Proposed Amendments to 10 CFR Part 30, 31, 32, 35.

Gentlemen:

We respectfully request your reconsideration of maximum exempt quantities of Iodine 125 and Iodine 131.

In view of the wide acceptance of the T-3 thyroid diagnostic test as the test for thyroid clinical status, a restriction of less than 100 microcuries would cause an extreme hardship on both the patient and the medical laboratory.

The hazard to humans is especially low with this in-vitro test and should not impose a safety problem.

We are all concerned with giving the medical profession the best "tools" to work with and at the same time keep medical cost down.

Your cooperation and consideration is appreciated.

Very truly yours,

R.J. ADAMS
President

RJA:bf

Air Mail

DOCKET NUMBER
PROPOSED RULE PR-31,32
Iodine

JUN 20 1968

Mr. Robert C. Hill, Chief
Radiological Health Section
Industrial, Radiation and
Air Hygiene Program
The Kansas State Department of Health
Topeka, Kansas 66603

Dear Mr. Hill:

Thank you for your letter of June 12, 1968 addressed to Mr. Harlese, commenting on the Commission's proposals to amend (1) 10 CFR Parts 31 and 32 to provide a general license to physicians, clinical laboratories or hospitals for the use of iodine 125 or iodine 131 in clinical or laboratory tests not involving administration of radioactive materials to human beings, and (2) 10 CFR Part 33 to provide the wider use of "broad licenses."

Your comments have been noted and will receive careful consideration prior to taking further action on the proposed rule.

Sincerely,
Original signed by
Forrest Western

Forrest Western, Director
Division of Radiation Protection
Standards

Distribution:
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Secretariat w/copy for
Public Document Room
Attn: Stan Robinson
Radiation Standards Branch, RPS
Eber R. Price, SLR

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DOCKET NUMBER
PROPOSED RULE PR-31,32
Iodine

THE KANSAS STATE DEPARTMENT OF HEALTH

TOPEKA
KANSAS

June 12, 1968

HUGH DIERKER, M. D., M. P. H.
Director of Health

Mr. B. L. Harless, Chief
State Agreements Branch
Division of State and Licensee Relations
USAEC
4915 St. Elmo Street
Bethesda, Maryland

Dear Mr. Harless:

This letter is in reference to your memorandum to all agreement states, dated April 23, 1968, enclosing approved and proposed amendments to the AEC regulations.

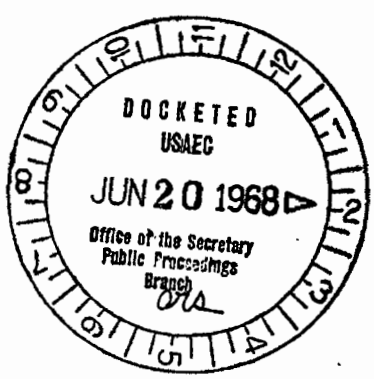
Relative to numbered paragraph 1, this department has no further comment.

In view, particularly, of the requirement for registration of the general licensee as set forth in the proposed paragraph 31.11 (b) of 10 EFR Part 31, this department is in full accord with the purpose and intent of the proposed amendment to the AEC regulations pertaining to a general license for iodine 125, and the change to the existing license for iodine 131, both for use in in vitro clinical or laboratory tests.

Item 3 of your memorandum discusses a proposed amendment to 10 CFR 33 to establish three types of specific byproduct material licenses of broad scope. It is considered that the addition of broad scope types B and C licenses, and redefinition of the type A license constitute a most useful addition to existing regulations.

In view of this department's concurrance with the referenced amendments of the AEC regulations, recommendation will be made for similar amendment of the Kansas Radiation Protection Regulations to the State Board of Health at an appropriate time.

It is hoped that the three amendments will be included in the forthcoming reissue of the Suggested States Regulations for Control of Radiation as published by the Council of State Governments, thereby facilitating a long-overdue review and change to this State's regulations, last amended in 1966.



Sincerely yours,

ENVIRONMENTAL HEALTH SERVICES

Robert C. Will, Chief
Radiological Health Section
Industrial, Radiation and
Air Hygiene Program

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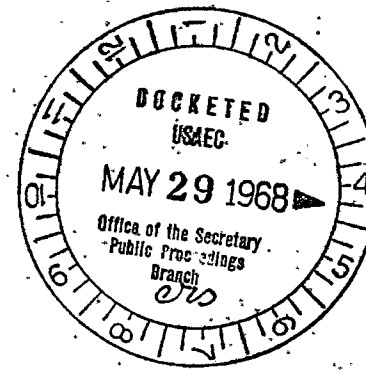
DOCKET NUMBER
PROD. & UTIL. FAC. PR-31,32
PROPOSED RULE

MAY 29 1968



Dr. E. R. Farmer, Director
Radiological Health Section
Oregon State Board of Health
P. O. Box 231
Portland, Oregon 97207

Dear Dr. Farmer:

Thank you for your letter of May 21, 1968, commenting on the Commission's proposal to amend 10 CFR Parts 31, 32, to issue a general license authorizing the use of iodine 125 or iodine 131 for in vitro clinical or laboratory tests.

Your comments have been noted and will receive careful consideration prior to taking further action on the proposed rule.

Sincerely,

Forrest Western, Director
Division of Radiation Protection
Standards

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Public Document Room
Attn: Stan Robinson
E. R. Price, SLR
Radiation Standards Branch, RPS

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ABBOTT

LABORATORIES NORTH CHICAGO, ILLINOIS 60064

May 27, 1968

Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Gentlemen:

Re: Proposed General License for in Vitro Use of Iodine-125 and Iodine-131

In accordance with the notice published in the Federal Register of April 26, 1968, (33 FR 6375), Abbott Laboratories, a major producer of Iodine-125 and Iodine-131 diagnostic kits, hereby submits its comments to the proposed amendment to 10 CFR Part 31 concerning Iodine-125 and Iodine-131 - General Licensing for Use in Clinical or Laboratory Tests Not Involving Administration to Human Beings.

While Abbott believes that the generally licensed quantity of Iodine-125 for in vitro thyroid testing should be increased, it is strongly opposed to the proposed regulation insofar as it separates the licensing of Iodine-125 and Iodine-131 for in vitro testing from the licensing of other isotopes for in vitro testing. The generally licensed quantity of Iodine-125 could more appropriately be increased by amending Schedule A of Section 31.100. Further, we do not believe that the additional requirements placed upon the in

vitro use of these isotopes are either needed or desirable.

The proposed regulation contemplates the general licensure of Iodine-125 for in vitro testing, an increase in the generally licensed quantity of Iodine-131 for in vitro testing, the registration of general licensees and greater control over the labeling of both Iodine-125 and Iodine-131 for such purposes.

At the present time, up to 10 microcuries of Iodine-125 in units of 1 microcurie is generally licensed for in vitro testing under Section 31.4 (10 CFR Part 31). Thus, the proposed regulation only increases the quantity of the isotope which is already generally licensed.

While an increase in the generally licensed quantities of Iodine-125 and Iodine-131 for in vitro testing is a further step in the availability in these isotopes for medical use, this step could more appropriately be taken by simply amending Schedule A of Section 31.100. Instead of generally including Iodine-125 as Gamma emitting byproduct material, it could be specifically listed with a 10 microcurie limit as is Iodine-131.

The proposed regulation removes Iodine-125 and Iodine-131 from the general license of Section 31.4 and sets up a separate general license under Section 31.11. However, according to the Notice of Proposed Regulation, the proposed regulation is based upon recognition

of the "usefulness of these isotopes in medical tests and the similarity of radiological safety considerations between in vitro thyroid function tests and other in vitro tests." This premise which is wholly consistent with the scientific evidence does not support the removal of Iodine-125 and Iodine-131 from the Section 31.4 general license and the promulgation of a separate licensing procedure. Rather it supports the continued inclusion of these isotopes within Section 31.4.

The proposed regulation provides for the registration of general licensees and sets forth specific labeling requirements with which the manufacturer must comply. Abbott has not received, nor is it aware of, any reports that the use or labeling of Iodine-125 and Iodine-131 for in vitro testing has been abused. However, if the registration and labeling requirements are necessary to protect the public safety, then such requirements should also be placed upon the in vitro testing of the other isotopes listed in Schedule A. If it is the increase in the quantity limit to 200 microcuries which warrants the separate and additional requirements, then Sections 31.11 and 32.71 of the proposal should only apply to quantities in excess of the quantities licensed under Section 31.4.

Sections 31.11(d)(2) and 32.71(d)

Because Iodine-125 and Iodine-131 may be subject to a specific license of broad scope under regulations proposed on April 30, 1968 (33 F.R. 6551), the words "a

general" should be deleted from the second sentence of the required statement in Sections 31.11(d)(2) and 32.71(d).

Section 32.71(c)(1)

It is a common practice of the industry to state the quantity of activity in a unit of Iodine-125 or Iodine-131 for in vitro thyroid testing in terms of maximum activity rather than absolute activity. The amount of activity needed for in vitro testing of the thyroid function is extremely small. Further, when Iodine-125 or Iodine-131 are used for such testing, two activity measurements are taken. The difference is used to determine the condition of the thyroid. The absolute activity of either measurement is meaningless. While the absolute activity and the date of determination would enable the user to calculate the amount of activity as of the test date, no useful purpose would be served by such a calculation. Therefore, since a statement of the maximum activity such as "one microcurie or less" provides the information needed by the user and since the user is already familiar with such a designation of activity, we suggest that Section 32.71(c)(1) be amended to read:

> "(1) identifying the radioactive contents as to chemical form, radionuclide and maximum activity;"

Enclosed is a copy of the labeling presently used by Abbott for Triosorb® 131 diagnostic kits.

Respectfully submitted,

ABBOTT LABORATORIES

Laurence R. Lee
Secretary

TRIOSORB®-131 T-3 DIAGNOSTIC KIT

10 Test Units

No. 7797

10 Test Units

No. **7797**

TRIOSORB®-131 T-3 DIAGNOSTIC KIT

Caution:
Radioactive
Material

Combination Package of Triosorb Resin-Sponge and Triomet®131 (Liothyronine I 131)

Kit, for determining **in vitro T-3** uptake, consists of:

10 Syringes Triomet-131 (Liothyronine I 131) diagnostic solution. Each syringe containing 0.1 μc., or less, adjusted to pH 5.2. **Not for injection.**

10 Triosorb Resin-Sponges
10 Plastic Test Tubes with Caps
1 Plunger
1 Aspirator Tip

See accompanying directions for use. Store at 5°C. (±3°C.). Avoid freezing and excessive exposure to light.

ABBOTT

Sponge Uptake* % Exp. Date

Conversion Factor** Lot No.

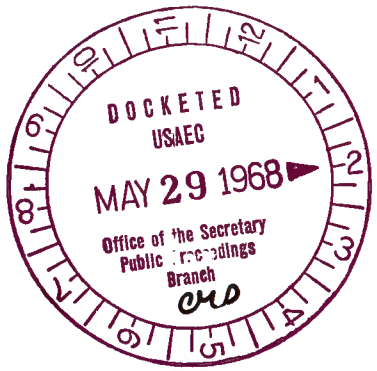
09-7807—3/R
Printed in U.S.

*Average value determined at 25° C. with normal pooled sera for the sponges in this kit.

**Factor which may be used to convert uptake determinations to a normal control serum value of 30%. (Uptake x Factor)

U. S. Pat. Nos. 2,695,612; D-174,985; 3,024,207; 3,094,494; 3,206,602; patented 1963 (Canada).

Abbott Laboratories, North Chicago, Illinois 60064, U.S.A.



Iodine 125 & 131

DOCKET NUMBER PR -31 & 32

MAY 22 1968

Mr. Jon D. Anderson
Deputy Director
State of New York
Executive Department
Office of Atomic and Space Development
P.O. Box 7036
Albany, New York 12225

Dear Mr. Anderson:

Thank you for your letter of May 15, 1968, commenting on the Commission's proposal to amend 10 CFR Parts 31, 32, to issue a general license authorizing the use of iodine 125 or iodine 131 for in vitro clinical or laboratory tests.

Your comments have been noted and will receive careful consideration prior to taking further action on the proposed rule.

Sincerely,

Forrest Western, Director
Division of Radiation Protection
Standards

Distribution:
Formal File
Supplemental File
Secretariat w/cy for
Public Document Room
Attn: Stan Robinson
Radiation Standards Branch, RPS

RPS:PAB	RPS:DIR
GLHutton:mfs	FWestern
5/22/68	5/ /68

DOCKET NUMBER
PROPOSED RULE PR-31,32
Iodine

FORM S 25

STATE OF OREGON
OREGON STATE BOARD OF HEALTH
STATE OFFICE BUILDING
1400 S W 5TH AVENUE
PORTLAND, OREGON 97201

MAILING ADDRESS
P O BOX 231
PORTLAND OREGON 97207

TELEPHONE
AREA CODE 503
DAYS—226-2161
AFTER HOURS—222-1500

May 21, 1968

Mr. Woodford B. McCool
Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Mr. McCool:

A review has been completed of the proposed amendment to 10 CFR, parts 31 and 32, to provide a general license for in vitro clinical and laboratory tests, 125 I and 131 I, which were published in the Federal Register on April 26, 1968 (33 F.R. 6375-6376). We understand this amendment would provide for the general licensing of innocuous quantities of 125 I and 131 I in medical diagnostic procedures, not involving the administration of the radiopharmaceutics to humans.

We have no objections to the concepts of the proposed amendments. We feel we have no real need in Oregon for this licensing change since our present licensing procedures for medical use appear adequate. We feel the relatively few requests for such licenses would not justify the administrative overburden to implement it.

We are pleased to have had the opportunity to comment on these proposed amendments.

Sincerely,

G. R. Farmer
Director
Radiological Health Section

GF:ln

Iodine 125 + 131

DOCKET NUMBER
PROPOSED RULE PR -31032

MAY 22 1968

Mr. David B. Reader
Division Manager
Nuclear Science Division
P.O. Box 10901
Pittsburgh, Pennsylvania 15236

Dear Mr. Reader:

Thank you for your letter of May 16, 1968, commenting on the Commission's proposal to amend 10 CFR Parts 31, 32, to issue a general license authorizing the use of iodine 125 or iodine 131 for in vitro clinical or laboratory tests.

Your comments have been noted and will receive careful consideration prior to taking further action on the proposed rule.

Sincerely,

Forrest Western, Director
Division of Radiation Protection
Standards

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Public Document Room
Attn: Stan Robinson
Radiation Standards Branch, RPS

RPS:PAB	RPS:DIR
GLHutton:mfs	FWestern
5/21/68	5/ /68

Stan Robinson

Iodine 125 & 131

DOCKET NUMBER
PROPOSED RULE PR - 31 & 32

MAY 20 1968

Dr. Philip C. Johnson
Professor of Medicine
Baylor University College of Medicine
Texas Medical Center
Houston, Texas 77025

Dear Dr. Johnson:

Thank you for your letter of May 8, 1968, commenting on the Commission's proposal to amend 10 CFR Parts 31, 32, to issue a general license authorizing the use of iodine 125 or iodine 131 for *in vitro* clinical or laboratory tests.

Your comments have been noted and will receive careful consideration prior to taking further action on the proposed rule.

Sincerely,

Forrest Western, Director
Division of Radiation Protection
Standards

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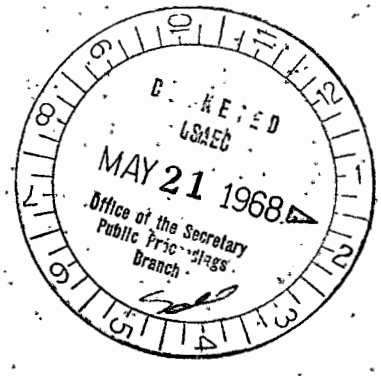
Secretariat w/copy for
Public Document Room
Attn: Stan Robinson
Radiation Standards Branch, RPS



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5/ /68	5/ /68

DOCKET NUMBER
PROPOSED RULE PR-31,32
Iodine

STATE OF NEW YORK
EXECUTIVE DEPARTMENT
OFFICE OF ATOMIC AND SPACE DEVELOPMENT

P. O. Box 7036

ALBANY, N.Y. 12225

May 15, 1968

Mr. Woodford B. McCool
Secretary
U.S. Atomic Energy Commission
Washington, D.C. 20545

Dear Mr. McCool:

The principal agencies within the State of New York that are engaged in the regulatory control of ionizing radiation have reviewed the proposed amendments to Parts 31 and 32 of the U.S. Atomic Energy Commission regulations, which were published in the Federal Register on April 26, 1968 (33 F.R. 6375-6376). As proposed, these new amendments provide a mechanism for the general licensing of certain quantities of iodine^{125} and iodine^{131} for use in medical diagnostic tests that do not involve the administration of the material to human beings.

The regulatory agencies of the State of New York support the basic concepts outlined in the proposed modification. However, there appears to be general agreement that if these changes are adopted by the Commission, the State of New York will not establish a general license approach since it would require another form of registration. Instead, the agencies intend to simplify the licensing review process in an effort to expedite the issuing of licenses.

We appreciate the opportunity you have provided the State of New York to comment on these proposed amendments.

Very truly yours,

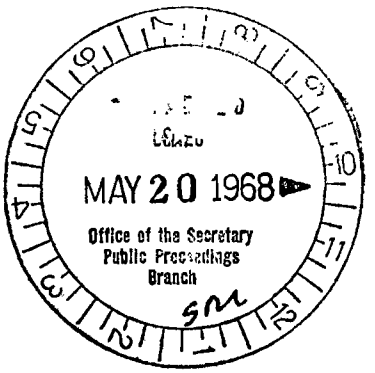
Jon D. Anderson
Deputy Director

Iodine 125 & 131

PROPOSED RULE PR 31 & 32

ICN Nuclear Science Division

A Division of International Chemical & Nuclear Corporation
P O Box 10901
Pittsburgh, Pennsylvania 15236
Tel 412-462-4000



May 16, 1968

Secretary
U.S. Atomic Energy Commission
Washington, D.C. 20545

Attention: Chief Public Proceedings Branch

Subject: "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items", 10 CFR Part 31, and "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material", 10 CFR Part 32.

Gentlemen:

The information we have leads us to believe that Jones Medical Instrument Company has developed a useful laboratory technique that utilizes iodine-125 and iodine-131. With proper instructions supplied by the vender clinicians exercising reasonable care should be able to safely contain and use the quantities proposed in the new general license without difficulty.

Therefore, we recommend your approval of amendments to the subject Commission regulations.

Very truly yours,

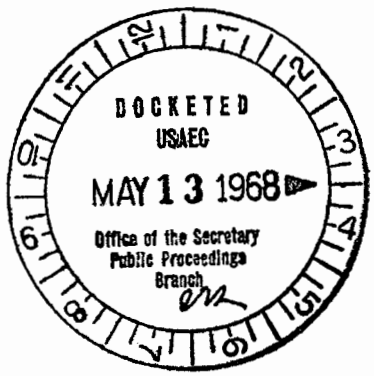
David B. Reader
Division Manager

vh

DOCKET NUMBER
PROPOSED RULE PR-31,32
Iodine 125

Baylor University College of Medicine
Texas Medical Center
Houston, Texas 77025
Department of
Internal Medicine

May 8, 1968



W. B. McCool, Secretary
U.S. Atomic Energy Commission
Washington, D.C. 20545

Dear Mr. McCool:

In general I agree with the suggested change in 10 CFR 31, 32 published in the Federal Register Vol. 33, pg. 6375, April 26, 1965. However, section d in 31.11, paragraph 4 seems unnecessarily restrictive when it prevents "transfer in any manner other than in the unopened labeled shipping container". From a radiological health standpoint transfer could safely be accomplished in its closed, sealed labeled shipping container. In its present form the opened package could not be legally transferred even if there were no need for the product at that location.

Thank you for considering this change.

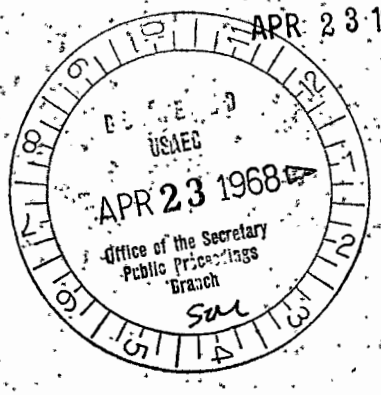
Sincerely,

Philip C. Johnson, M.D.
Professor of Medicine

PCJ:gs
cc: Martin Wukasch
Charles Barden

Iodine 125
31+32
Rebuttal
PRM-30-26

~~PRM-30-25~~



Dr. Paul C. Tompkins
Executive Director
Federal Radiation Council
7th Floor
1800 G Street, N. W.
Washington, D. C. 20006

Dear Dr. Tompkins:

Enclosed for your information are five copies of a notice of proposed rule making to amend the Commission's regulations, "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items", 10 CFR Part 31, and "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material", 10 CFR Part 32.

The proposed amendment to Part 31 would issue a new general license to physicians, clinical laboratories or hospitals for the possession and use of iodine 125 or iodine 131 in prepackaged units not to exceed 10 microcuries each, with a total possession limit of 200 microcuries, for in vitro clinical or laboratory tests. A related amendment to Part 32 setting forth requirements for issuance of specific licenses to manufacture or distribute iodine 125 or iodine 131 for use under the general license is also proposed.

The notice is being transmitted to the Office of the Federal Register and will allow 30 days for public comment after publication in the Federal Register.

Sincerely yours,

Forrest Western, Director
Division of Radiation Protection
Standards

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Public Document Room
Attn: Stan Robinson
Radiation Standards Branch, RPS
Enclosures:
Notice of Proposed Rule
Making (5)

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CLEutton	WSCool	FWestern
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~~Federal~~ 31 + 32
~~31 + 32~~
~~PRM-30-26~~

Mr. George Taylor, Secretary
Staff Subcommittee on Atomic Energy
and Natural Resources
Department of Legislation, AFL-CIO
815 Sixteenth Street, N.W.
Washington, D. C. 20006

Dear Mr. Taylor:

Enclosed for your information are three copies of a notice of proposed rule making to amend the Commission's regulations, "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items", 10 CFR Part 31, and "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material", 10 CFR Part 32.

The proposed amendment to Part 31 would issue a new general license to physicians, clinical laboratories or hospitals for the possession and use of iodine 125 or iodine 131 in prepackaged units not to exceed 10 microcuries each, with a total possession limit of 200 microcuries, for in vitro clinical or laboratory tests. A related amendment to Part 32 setting forth requirements for issuance of specific licenses to manufacture or distribute iodine 125 or iodine 131 for use under the general license is also proposed.

The notice is being transmitted to the Office of the Federal Register and will allow 30 days for public comment after publication in the Federal Register.

Enclosed also is a copy of a draft public announcement which will be released by the Commission on this matter in the next few days.

Sincerely yours,

C. L. Henderson
Assistant Director of Regulation
for Administration

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Public Document Room
Attn: Stan Robinson
Radiation Standards Br., RPS

Enclosures:
1. Notice of Proposed Rule Making (3)
2. Draft Public Announcement

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