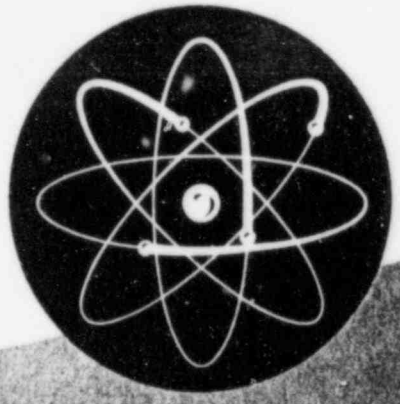


AEC LICENSING GUIDE

MEDICAL PROGRAMS

● A Guide For The Preparation Of Applications For The Medical Use Of Radioisotopes.

★ DIVISION OF MATERIALS LICENSING ★
UNITED STATES ATOMIC ENERGY COMMISSION

NOTE

This document has been compiled by the United States Atomic Energy Commission as an aid in the preparation of applications for byproduct material licenses to receive, possess, and use radiopharmaceuticals. It is not intended as an interpretation of Commission regulations within the meaning of Section 30.5 of Title 10, Code of Federal Regulations, Part 30. Nothing contained in this guide may be construed as having the force and effect of United States Atomic Energy Commission regulations; nor as indicating that applications which follow the recommendations of this document necessarily will be approved; nor as relieving any licensee from the requirements of Title 10, Code of Federal Regulations, Parts 20 and 30, or other pertinent regulations.

This guide supersedes the previously issued booklet with the same title, dated February 1957 and designated RC-12.

AEC LICENSING GUIDE ● MEDICAL PROGRAMS

A GUIDE FOR THE PREPARATION OF APPLICATIONS FOR THE MEDICAL USE OF RADIOISOTOPES

November 1965

DIVISION OF MATERIALS LICENSING
U.S. ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C., 20402 - Price 45 cents

PREFACE

The Atomic Energy Act of 1954, as amended, charges the United States Atomic Energy Commission with, among other things, responsibility for regulating the receipt, possession, and use of byproduct material. The Commission is authorized to establish by rule, regulation, or order, such standards, instructions and procedures to govern the possession and use of byproduct material as it may deem necessary or desirable to protect health or to minimize danger to life or property.

In the performance of its regulatory functions, the Commission has promulgated the regulations contained in Title 10 of the Code of Federal Regulations. The following regulations are included in Title 10 and are particularly pertinent to the subject of this guide:

1. Part 20, "Standards for Protection Against Radiation" (10 CFR 20).

2. Part 30, "Rules of General Applicability to Licensing of Byproduct Material" (10 CFR 30).

3. Part 35, "Human Uses of Byproduct Material" (10 CFR 35).

Current copies of Commission regulations may be obtained from the Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545, or from any of the following U.S. Atomic Energy Commission Regional Compliance Offices:

Director, Region I
Division of Compliance, USAEC
376 Hudson Street
New York, N.Y. 10014

Director, Region II
Division of Compliance, USAEC
50 Seventh Street, Northeast
Atlanta, Ga. 30323

Director, Region III
Division of Compliance, USAEC
Oakbrook Professional Building
Oak Brook, Ill. 60523

Director, Region IV
Division of Compliance, USAEC
10395 W. Colfax Avenue
Denver, Colo. 80215

Director, Region V
Division of Compliance, USAEC
2111 Bancroft Way
Berkeley, Calif. 94704

This guide describes the kinds of information to be submitted in applications for the possession and use of radiopharmaceuticals. Its use should result in the submission of more complete applications. The Commission will request additional information if necessary in order to provide reasonable assurance that the applicant has established an adequate radiation safety program. (See Sec. 30.32(b) of 10 CFR 30.) Requests for additional information delay final action on the application and may be avoided by a thorough study of Commission regulations and this guide prior to filing the application.

This guide is intended only for general information and should not be considered a substitute for the applicant's careful evaluation of the proposed use of byproduct material or for assuring that the application correctly and adequately describes the radiation safeguards and procedures to be followed.

TABLE OF CONTENTS

	Page
I. Byproduct Material Licenses for the Medical Use of Radioisotopes	1
II. Types of Application Forms	3
III. Filing an Application	5
IV. Information To Be Submitted	7
V. Requirements of the Regulations	11

APPENDICES

Appendix A. Samples of Typical Licenses	13
Appendix B. Medical Isotopes Committee	25
Appendix C. Acceptable Training and Experience for Medical Uses of Byproduct Material	27
Appendix D. A List of Well Established Medical Uses	29
Appendix E. Sample Applications	31
Appendix F. Non-Routine Medical Uses of Byproduct Material	47
Appendix G. Types of Instruments Needed for Medical Programs	49
Appendix H. Information on Facilities and Equipment and Operating Procedures To Be Included With the Application	51
Appendix I. Information for Commission Approval of Treatment or Disposal by Incineration	53

I. BYPRODUCT MATERIAL LICENSES FOR THE MEDICAL USE OF ISOTOPES

The purpose of the guide is to assist persons desiring to use radioactive materials in the practice of nuclear medicine to obtain a byproduct material license. The format of the guide has been established in such a way that it describes the various types of licenses, the types of applications which should be submitted to obtain a license, and the information which should be included in the application.

Licenses may be issued to institutions or to private practitioners. The various types of licenses and their characteristics are as follows:

A. Specific licenses issued to institutions.*

Specific licenses issued to institutions specify the radioisotopes and the clinical uses which can be performed by physicians named on the institution's license. The regulations in Section 35.11(b) of 10 CFR 35 require that an institutional licensee have a medical isotope committee to evaluate all proposals for clinical research, diagnostic, and therapeutic uses of radioisotopes within the institution. The physicians named on the institution's license conduct their programs with the approval of the isotopes committee. Institutional licenses provide a means whereby nonapproved physicians under the supervision of physicians named on the license may obtain basic and clinical radioisotope training and experience which may enable them to qualify as individual users. Acceptable physician training and experience for the well established uses of radioisotopes in medicine are outlined in appendix C.

B. Broad medical licenses issued to institutions.

Broad medical licenses, i.e. licenses authorizing multiple quantities and types of byproduct material for unspecified uses, are issued to institutions which (1) have had previous experience operating under a specific institutional license and (2) are engaged in medical research, as well as routine diagnosis and therapy using radioisotopes. Such programs operate under the supervision of a medical isotopes committee. No physicians are named as individual users on the license, nor are radioisotopes limited to specified uses. As is the case with specific institutional licenses, physicians may obtain basic and clinical radioisotope training and experience in the use of radiopharmaceuticals in such programs. Since this type of license is not appropriate for most institutions using byproduct material in medical programs and is discussed in a licensing guide dealing specifically with broad licenses now in preparation, no further specific mention will be made of the broad license in this guide.

C. Specific licenses issued to physicians for their private practice.

Licenses issued to physicians for private practice specify the types of isotopes and the clinical uses which may be performed by the physician to whom the license is issued. Usually, private practitioners to whom such licenses are issued are located in offices not on hospital premises. However, this type of license may be appropriate for a physician who conducts a private practice in institutional facilities. It is not required that a medical isotopes committee be formed. The private practice license does not permit other physicians to obtain basic and clinical radioisotope training and experience under it. These licenses are limited to well established uses of byproduct materials and require that the physician so licensed personally conduct the program. Section 35.12, 10 CFR 35, outlines specific requirements for this type of license.

*While the "Specific" licenses and the "Broad" licenses referred to in paragraphs A and B are both specific licenses, for purposes of simplicity in this guide only, the former will be referred to as a specific license.

D. General license for certain diagnostic uses. The general license provided in Section 35.31, 10 CFR 35, authorizes the registrant physician to possess and use limited quantities of prepackaged individual doses of Iodine 131 for measurement of thyroid uptake; Iodine 125 and Iodine 131 for blood and plasma volume determinations; Cobalt 60 and Cobalt 58 for intestinal absorption of cyanocobalamin; and Chromium 51 for red blood cell volume and survival time determinations. Section 35.31 explains the general license requirements and requires the physician to register with the Commission prior to receiving or using the diagnostic radiopharmaceuticals covered.

E. Specific licenses for the teletherapy use of radioisotopes. See licensing guide "AEC Licensing Guide—Teletherapy Programs." These are not discussed herein.

Over 90 percent of the licenses issued for the medical use of radioisotopes are specific licenses to institutions or specific licenses to physicians for their private practice. Accordingly, this guide is orientated toward the needs of these persons. Refer to appendix A for samples of such specific licenses issued to institutions and specific licenses issued to physicians. Note that conditions placed on the licenses vary somewhat depending on whether it is an institutional or private practice license and depending on the scope of the license.

II. TYPES OF APPLICATION FORMS

There are three application forms on which information about a proposed medical radioisotope program may be submitted. The basic information may be submitted on Form AEC–313 or Form AEC–313MC. In addition, separate Forms AEC–313a must be used to describe each physician's training and experience for both specific licensed institutional programs or specific licensed private practitioners' programs. A special registration certificate, Form AEC–482, is available for private practitioners desiring to register for the general license authorizing specified diagnostic uses.

A. Form AEC–313MC.

The Form AEC–313MC categorizes the well established medical uses of byproduct materials into (1) diagnostic procedures, (2) diagnostic procedures requiring scanning devices, (3) most therapy involving Phosphorus 32 and Iodine 131, and (4) Iodine 131 for the treatment of thyroid carcinoma and Gold 198 and Phosphorus 32 intracavitary uses. The categories are based on the similarity of acceptable training and experience for physicians, facilities and equipment, and radiation safety practices.

Use of the Form AEC–313MC may be appropriate for a specific institutional or for a specific private practice license. It is not appropriate for any other type of medical license. It is designed to reduce the number of amendments to a license which may be required in an expanding radioisotope program. Portions of the application form are preprinted in order to conserve the physician's time in preparation of the application and to facilitate Commission review. *The Form AEC–313MC should be used only by physicians who qualify through training and experience for all uses in at least one of the categories of uses.* If the physician does not qualify for all uses in at least one category of use, the Form AEC–313 should be used. When application for particular categories is made, the licensee may be authorized to use more radioisotopes, and for other purposes, than those for which he has an immediate need. However, he is not obliged to obtain additional facilities or equipment which may be necessary for the additional uses until such time as he wishes to take advantage of the additional uses authorized.

The applicant has a choice of submitting the Form AEC–313MC or the Form AEC–313, which is described in the next paragraph. It is recommended that the applicant use the Form AEC–313MC rather than the Form AEC–313 wherever possible.

B. Form AEC–313

The Form AEC–313, rather than the Form AEC–313MC, should be used under the following conditions:

1. If the license desired is other than a specific institutional or a specific private practice license or;

2. If the individual physician(s) to be named on the institutional license or a physician in private practice does not have acceptable training and experience for an entire category of uses outlined in the Form AEC–313MC or;

3. If the medical uses of byproduct material are for nonroutine or experimental purposes (other than those listed in app. D) or;

4. If the preprinted Form AEC–313MC does not meet the needs of the applicant's proposed radioisotope program.

C. Form AEC–313a.

In addition to the Form AEC–313MC or AEC–313, a separate Form AEC–313a must be completed by each physician who is to be listed on an institutional license or by each physician applying for a private practitioner's license.

D. Form AEC–482

Form AEC–482 "Registration Certificate—Medical Use of Byproduct Material Under A General License" is used by physicians to register for the diagnostic general license provided in Section 35.31, 10 CFR 35.

III. FILING AN APPLICATION

An application for medical uses of byproduct material must be filed in duplicate on the "Application for Byproduct Material License," Form AEC–313, or Form AEC–313MC, which were described in section II above. In addition, Form AEC–313a must be filed in duplicate for each physician as described in section II. The application forms, with supporting documents, should be mailed to the Isotopes Branch, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545. Item 1(a) of Form AEC–313 or –313MC must name the person (hospital, corporation, partnership, individual, etc.) who will be responsible, as the licensee, for assuring that the byproduct material is used in compliance with the conditions of the license and with the Commission's regulations and the Act. For institutions such as medical schools or hospitals, the applicant will usually be the hospital, medical center, clinic, etc. The name of the applicant must be entered both in items 1(a) and 16 of the Form AEC–313 or –313MC and the application must be signed by the applicant, or, if the applicant is an institution, by an individual who is authorized to sign on behalf of the institution. *Where a hospital is the applicant, the hospital administrator is normally the individual who signs the application.*

A physician requesting use of byproduct material in private practice or under contract with an institution should be the applicant; his name should be stated in items 1(a) and 16, and the application should be signed by the physician. In case two or more physicians are in a partnership, items 1(a) and 16 should state the name of the partnership and bear the signatures of the partners or the signature of an individual authorized to sign on behalf of the partnership.

Applications for amendments to existing byproduct material licenses are also filed on the Forms AEC–313MC or AEC–313 and the Form AEC–313a. The application for amendment should be completed and signed in the same manner as an initial application except that pertinent information submitted on previous applications may be incorporated by reference. The license number of the license to be amended should be clearly stated in the application. A physician applying for registration to use byproduct material in a diagnostic program under a general license must file Form AEC–482 in triplicate. The registration form should be mailed to the Isotopes Branch, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545. Possession and use of the radiopharmaceuticals covered in the license is not authorized until the physician has filed Form AEC–482 and received from the Commission a validated copy of the form with a registration number assigned.

IV. INFORMATION TO BE SUBMITTED

The information contained in an application must be sufficient to allow the Commission to determine that the applicant's proposed equipment, facilities, procedures, and the training and experience of users are adequate to protect health and minimize danger to life and property. Attached as appendix E are sample applications typical of those appropriate for most medical programs.

The applicant may incorporate by reference information contained in applications, statements, and reports previously filed with the Commission's Division of Materials Licensing or with the former Division of Licensing and Regulation, provided that such reference is clear and specific, indicating the date, page, and paragraph.

FORM AEC-313 AND-313MC APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Item No.

1(*a*) Explained in section III.

1(*b*) Self-explanatory. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use.

2 Self-explanatory.

3 Self-explanatory.

4 To use byproduct material in humans, an individual must be licensed by a State or territory of the United States, District of Columbia, or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine (see sec. 30.4(*l*) of 10 CRF 30) and have basic and clinical radioisotope training and experience commensurate with the proposed use of byproduct material. Acceptable training and experience is specified in appendix C for routine medical uses and appendix F for experimental or nonroutine uses.

5 Self-explanatory.

6–7 *Form AEC-313MC.*

Items 6 (*a*), (*b*), and (*c*) and 7 of Form AEC-313MC are divided into four categories designated by roman numerals I, II, III, and IV. Check the category or categories for which the physician listed in item 4 has acceptable training and experience for all uses listed in the category and specify anticipated dose ranges.

Form AEC-313.

When using the Form AEC-313, list each isotope, chemical and/or physical form, and possession limit. If the byproduct material is a sealed source, state the name of manufacturer and model number and maximum activity. Under item 7 list each type of *nonhuman* use requested. A specific authorization must be obtained from the AEC to perform studies involving the use of byproduct material in animals. For human uses, refer to item 4 of the instructions for preparing the Form AEC-313.

8–9 See appendix C for the acceptable basic radioisotope training for an institutional user or individual user in a medical radioisotope program. If the Radiation Protection Officer is not a user, list his qualifications to act as Radiation Protection Officer. If the Radiation Protection Officer is a user, his qualifications will be listed elsewhere in the application.

10 List all radiation monitoring or measuring instruments that will be available for the proposed use(s) of byproduct material. This should include

Item No.

instruments for measuring uptake of the isotopes, assaying biological specimens, and making radiation surveys. The manufacturer's name and model number of each instrument should be listed with the number of instruments available, type of radiation detected (beta, gamma, etc.), the sensitivity range (mr/hr, cpm/, etc.), window thickness, if applicable, and use, such as measuring, surveying, etc.

Appendix G contains a list of the types of instruments needed for various medical uses of byproduct material.

An applicant who submits a Form AEC–313MC may request more uses of radioisotopes than are contemplated for the initial program. It is not necessary to have on hand appropriate instruments for all the requested uses until such time as they are to be used. The license will specify the instruments for categories of licensed uses.

11 Self-explanatory.

12 State the name of the organization furnishing film badge service and specify the frequency for changing the badges. If pocket chambers or pocket dosimeters are used, indicate the useful range, frequency of reading the monitoring devices, and the procedures for maintaining the dosimeters.

13–14 Submit sufficiently detailed information about the facilities and equipment and the radiation protection program to be in effect during use of byproduct materials to permit the Commission to make a determination that the applicant has established an adequate radiation safety program. The degree of detail required depends on the scope of the proposed byproduct material program. See appendix H for guidelines.

15 A specific method for disposing of byproduct material waste should be submitted. A licensee may dispose of waste in the following ways—

(*a*) Transfer to a person appropriately licensed to receive such waste.

(*b*) Release into the sanitary sewerage system in conformance with section 20.303 of 10 CFR 20.

(*c*) Burial in soil in conformance with section 20.304 of 10 CFR 20.

(*d*) Release into the air in concentrations conforming with section 20.106 of 10 CFR 20.

(*e*) Other methods specifically approved by the Commission pursuant to section 20.302.

Requests for incineration of byproduct material are handled in accordance with sections 20.106(b) and 20.302 and should include the information outlined in appendix I and section 20.106(c) of 10 CFR 20.

16 Refer to section III.

FORM AEC-313a, APPLICATION FOR BYPRODUCT MATERIAL LICENSE—SUPPLEMENT A-HUMAN USE

Item No.

1–3 Self-explanatory.

4 When the Form AEC–313a is used in conjunction with Form AEC–313, state the clinical use and chemical form of each radioactive material. Items 4 (*a*) and (*b*) need not be completed if Form AEC–313MC, rather than Form AEC–313, is used. For item 4(*c*), see appendix H.

5(*a*) The applicant should state the isotope, chemical and physical form, and dosage range for each condition to be diagnosed or treated. When a byproduct material is proposed for both diagnosis and therapy, the dosage range for each should be stated separately. The statement of dosage is reviewed for appropriateness of the dose range rather than as a specific dosage. In case the application is for use in infants, children, or pregnant women, the request should be submitted in accordance with procedures for nonroutine use of isotopes (see app. F). Item 5(*a*) need not be completed if Form AEC–313MC, rather than Form AEC- 313, is used.

5(*b*) See appendix F.

6 Self-explanatory.

Item No.

7 There should be attached either a statement indicating that this application has been reviewed by the institution's medical isotope committee and stating the basis for their action, or a statement indicating that it will be reviewed.

8(*a*) For private practice programs, state the name and address of the hospital(s) which will admit patients should it become necessary during or after administration of the radioactive material.

8(*b*) For programs covering more than diagnostic prepackaged doses, the applicant should submit appropriate housekeeping and radiological protection rules to be observed by individuals who must handle radioisotopes or care for patients treated with radioactive pharmaceuticals. Where appropriate, these rules should contain procedures pertaining to surveys, spills, handling of contaminated linens, precautions to be taken with visitors and hospital personnel, collection of urine and excreta, and other radiological safety measures tailored to specific programs and facilities. See appendix E for sample instructions.

9 (*a*) State the name and address of the physician in item 4 of Form AEC–313 or Form AEC–313MC. If more than one physician is named in item 4 of Form AEC–313 or Form AEC–313MC, a separate page 3 of Form AEC–313a (preceptor statement) must be submitted for each individual user.

10 In item 10 (*a*), (*b*), (*c*), and (*d*), indicate the type of clinical training, the isotope used, condition(s) diagnosed or treated, number of cases observed and the number of cases involving personal participation. If additional space is needed, continue on page 4 of Form AEC–313a.

11 Self-explanatory.

12 State the name of the physician under whom the clinical training was received and the dates of the trainee physician's clinical radiosotope training. Also state the name of the preceptor's institution and its byproduct material license number. *Item 12 must be signed by the physician(s) under whom the clinical training was received.* This item may not be signed by the individual named in item 9(*a*).

Refer to appendix C for the minimum acceptable clinical experience for the well established diagnostic and therapeutic uses and appendix F for nonroutine uses.

FORM AEC-482, APPLICATION FOR REGISTRATION CERTIFICATE—MEDICAL USE OF BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Self-explanatory. A sample certificate is printed in Appendix A. The reverse side of the certificate contains the conditions and limitations of the general license.

V. REQUIREMENTS OF THE REGULATIONS

Byproduct material programs must be conducted in compliance with 10 CFR 20, "Standards for Protection Against Radiation"; 10 CFR 30, "Rules of General Applicability to Licensing of Byproduct Material"; 10 CFR 35, "Human Uses of Byproduct Material"; the following listed specific requirements in these regulations are not normally submitted with the application; however, attention is directed to these requirements so that they may be considered and procedures adopted to assure compliance with them.

A. *Caution signs, labels, and signals.* (See sec. 20.203 of 10 CFR 20.)

B. *Records of surveys, radiation monitoring, and disposal.* (See sec. 20.401 of 10 CFR 20.)

C. *Reports of theft or loss of licensed material.* (See sec. 20.402 of 10 CFR 20.)

D. *Notifications of incidents.* (See sec. 20.403 of 10 CFR 20.)

E. *Report to former employees of exposure to radiation.* (See sec. 20.404 of 10 CFR 20.)

F. *Reports of overexposures and excessive levels and concentrations.* (See sec. 20.405 of 10 CFR 20.)

G. *Notice to employees of exposure to radiation.* (See sec. 20.406 of 10 CFR 20.)

H. *Records.* (See sec. 30.51 of 10 CFR 30.)

797-262 O—66——2

APPENDIX A

SAMPLES OF TYPICAL LICENSES

1. *A Specific License Issued to an Institution.*

This sample has the following characteristics which differ in some respects from the other sample licenses listed.

a. The license authorizes the use of categories of radioisotopes which are printed on Form AEC-313MC. The issuance of the license is a result of the submission of the Form AEC-313MC.

b. The license is issued to a hospital and condition 12 names the physicians under whose direction the radioisotopes may be used.

2. *A specific License Issued to an Institution.*

This sample has the following characteristics which differ in some respects from the other sample licenses listed.

a. Issuance of this license is based on the submission of a Form AEC-313. The form AEC-313 is necessary rather than the Form AEC-313MC since the possession limits are larger in some instances than those printed on the Form AEC-313MC. There are also radioisotopes and authorized uses which are not included on the preprinted Form AEC-313MC.

b. License Condition No. 20 requires leak testing of sealed sources.

3. *A Specific License Issued to a Physician in Private Practice.*

This sample has the following characteristics which differ in some respects from the other sample licenses listed.

a. As in the case of sample No. 1 above, this license is the result of the submission of a Form AEC-313MC.

b. A physician is named as the licensee rather than a hospital as is the case with the two preceding sample licenses.

c. Condition No. 12 of the license limits the use of the license to the physician who is named as the licensee.

4. *General License Registration Certificate Issued to a Physician in Private Practice.*

This certificate authorizes the use of Iodine 125, Iodine 131, Cobalt 58, Cobalt 60, and Chromium 51 for specific diagnostic purposes provided under the general license in Section 35.31, 10 CFR 35.

FORM AEC-374
(12-57)

LICENSE SAMPLE (1) - INSTITUTIONAL LICENSE

U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE

Page 1 of 3 Pages

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Part 30, Licensing of Byproduct Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below; and to use such byproduct material for the purpose(s) and at the place(s) designated below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Name: Sisterville Hospital	3. License number: 12-345-67 (E69)
2. Address: 100 E. Morgan Street Sisterville, Indiana	4. Expiration date: May 31, 1969
	5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
A. Iodine 131 B. Iodine 131 (See Page 2)	A. Iodide B. Iodinated Human Serum Albumin (See Page 2)	A. 100 millicuries B. 1 millicurie (See Page 2)

9. Authorized use

A. Diagnosis of thyroid function. Treatment of hyperthyroidism, cardiac conditions, and thyroid carcinoma.
B. Plasma and blood volume determinations.
C. Liver function studies.

(See Page 2)

CONDITIONS

10. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above.

11. The licensee shall comply with the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation."

12. Byproduct material shall be used by, or under the supervision of, Dr. Robert B. Cross, Dr. James E. Moran, or Dr. Edward J. Brown.

13. Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.

14. A. For diagnostic uptake and function measurements, the licensee shall have available a Geiger Mueller or scintillation probe and scaler(s).

B. For diagnostic studies depending upon the measurement of biological specimens (blood, urine, etc.), the licensee shall have available a well-type scintillation detector and shield.

(See Page 2)

For the U. S. Atomic Energy Commission

Date _____ by _____

Division of Materials Licensing
Washington, D. C. 20545

FORM AEC-374B (10-61)

SAMPLE LICENSE
U. S. ATOMIC ENERGY COMMISSION
MATERIAL LICENSE
Supplementary Sheet

Continued From Page 1

License Number 12-345-67 (E69)

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
C. Iodine 131	C. Rose Bengal	C. 1 millicurie
D. Iodine 131	D. Labeled Renal Function Compounds	D. 2 millicuries
E. Iodine 131	E. Triiodothyronine	E. 1 millicurie
F. Iodine 131	F. Labeled Fats and/or Fatty Acids	F. 1 millicurie
G. Phosphorus 32	G. Soluble Phosphate	G. 25 millicuries
H. Phosphorus 32	H. Colloidal Chromic Phosphate	H. 25 millicuries
I. Gold 198	I. Colloidal	I. 200 millicuries
J. Chromium 51	J. Chromate	J. 5 millicuries
K. Cobalt 58	K. Labeled Vitamin B-12	K. 1 millicurie
L. Cobalt 60	L. Labeled Vitamin B-12	L. 1 millicurie
M. Iron 59	M. Chloride and/or Citrate	M. 1 millicurie

9. Authorized Use

D. Kidney function studies.
E. In vitro study of thyroid function.
F. Fat absorption studies.
G. Treatment of polycythemia vera and leukemia.
H. and I. Intracavitary treatment of pleural effusions and/or ascites.
J. Red blood cell labeling and survival studies.
K. and L. Diagnosis of pernicious anemia.
M. Iron turnover studies.

CONDITIONS

14. Continued:

C. For diagnostic studies to determine relative localization of a radioisotope, the licensee shall have available a scanner.

D. For therapy the licensee shall have available a low range survey meter capable of detecting low level contamination.

E. For treatment of thyroid carcinoma with Iodine 131 and treatments with Gold 198, the licensee shall have available a survey meter capable of detecting up to one roentgen per hour.

(See Page 3)

For the U. S. Atomic Energy Commission

Date_____

by_____
Division of Licensing and Regulation
Washington 25, D. C.

FORM AEC-574A
(2-68)

SAMPLE LICENSE
U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE
Supplementary Sheet

License Number 12-345-67
(E69)

Continued from Page 2:

CONDITIONS

15. Except as specifically provided otherwise by this license, the licensee shall possess and use byproduct material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated March 1, 196X.

16. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

For the U. S. Atomic Energy Commission

Date _____

by _____
Division of Materials Licensing
Washington, D. C. 20545

LICENSE SAMPLE (2) - INSTITUTIONAL LICENSE

FORM AEC-374
(12-57)

U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE

Page 1 of 3 Pages

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Part 30, Licensing of Byproduct Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below, and to use such byproduct material for the purpose(s) and at the place(s) designated below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Name: Good Hope General Hospital	3. License number: 76-543-21 (F69)
2. Address: 2005 South Buran Avenue, Richmond, Virginia	4. Expiration date: June 30, 1969
	5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
A. Iodine 131	A. Iodide	A. 200 millicuries
B. Iodine 131	B. Iodinated Human Serum Albumin	B. 10 millicuries
(See Page 2)	(See Page 2)	(See Page 2)

9. Authorized use

A. Diagnosis of thyroid function and thyroid scans. Treatment of hyperthyroidism, cardiac conditions, and thyroid carcinoma.

B. Plasma and blood volume determinations. Brain scans.

C. Liver function studies and liver scans.

(See Page 2)

CONDITIONS

10. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above.

11. The licensee shall comply with the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation."

12. Byproduct material shall be used by, or under the supervision of, Dr. Gerald M. Good, Dr. Franklin D. Lawson, or Dr. Daniel H. Harrington.

13. Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.

14. A. For diagnostic uptake and function measurements, the licensee shall have available a Geiger Mueller or scintillation probe and scaler(s).

B. For diagnostic studies depending upon the measurement of biological specimens (blood, urine, etc.), the licensee shall have available a well-type scintillation detector and shield.

(See Page 3)

For the U. S. Atomic Energy Commission

Date_____ by_____

Division of Materials Licensing
Washington, D. C. 20545

FORM AEC-374B (10-61)

SAMPLE LICENSE
U. S. ATOMIC ENERGY COMMISSION
MATERIAL LICENSE
Supplementary Sheet

Continued From Page 1

License Number 76-543-21 (F69)

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
C. Iodine 131	C. Rose Bengal	C. 5 millicuries
D. Iodine 131	D. Labeled Renal Function Compounds	D. 10 millicuries
E. Iodine 131	E. Triiodothyronine	E. 1 millicurie
F. Iodine 131	F. Labeled Fats and/or Fatty Acids	F. 4 millicuries
G. Phosphorus 32	G. Soluble Phosphate	G. 25 millicuries
H. Phosphorus 32	H. Colloidal Chromic Phosphate	H. 25 millicuries
I. Gold 198	I. Colloidal	I. 300 millicuries
J. Chromium 51	J. Chromate	J. 5 millicuries
K. Cobalt 58	K. Labeled Vitamin B-12	K. 1 millicurie
L. Cobalt 60	L. Labeled Vitamin B-12	L. 1 millicurie
M. Iron 59	M. Chloride and/or Citrate	M. 1 millicurie
N. Cobalt 60	N. Wire (Manufacturer and Model No.)	N. 200 millicuries
O. Strontium 90	O. Sealed source (Manufacturer and Model No.)	O. 50 millicuries
P. Chromium 51	P. Labeled Human Serum Albumin	P. 10 millicuries
Q. Iodine 125	Q. Iodide	Q. 10 millicuries
R. Mercury 203 or 197	R. Chlormerodrin	R. 10 millicuries
S. Cesium 131	S. Chloride	S. 10 millicuries

9. Authorized Use

D. Kidney function studies.
E. In vitro study of thyroid function.
F. Fat absorption studies.
G. Treatment of polycythemia vera and leukemia.
H. and I. Intracavitary treatment of pleural effusions and/or ascites.
J. Red blood cell labeling and survival studies. Spleen scans.
K. and L. Diagnosis of pernicious anemia.
M. Iron turnover studies.
N. Interstitial and intracavitary treatment of cancer as a replacement for radium.
O. Treatment of superficial eye diseases.
P. Study gastrointestinal protein loss in 30 patients over 40 years of age.
Q. Study of thyroid function.
R. Brain and renal scans.
S. Brain scans in 12 patients. Within six weeks after the completion of this study, the licensee is requested to furnish a preliminary report to the Commission which briefly summarizes the results of the study.

(See Page 3)

For the U. S. Atomic Energy Commission

Date_____

by_____

Division of Licensing and Regulation
Washington 25, D. C.

FORM AEC-374A (2-65)

SAMPLE LICENSE
U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE
Supplementary Sheet

License Number 76-543-21 (F69)

14. Continued:

C. For diagnostic studies to determine relative localization of a radioisotope, the licensee shall have available a scanner.

D. For therapy, the licensee shall have available a low range survey meter capable of detecting low level contamination.

E. For treatment of thyroid carcinoma with Iodine 131 and treatments with Gold 198 or Cobalt 60, the licensee shall have available a survey meter capable of detecting up to one roentgen per hour.

15. Except as specifically provided otherwise by this license, the licensee shall possess and use byproduct material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated June 1, 196X.

16. Patients administered Iodine 131 for the treatment of thyroid carcinoma and Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

17. Patients containing Cobalt 60 as implants shall remain hospitalized until the implants are removed.

18. Sealed sources containing byproduct material shall not be opened by the licensee.

19. Needles or standard medical applicator cells containing Cobalt 60 as wire shall not be opened by the licensee unless specifically authorized by a condition of this license.

20. A. Each sealed source containing byproduct material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas 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, the sealed source shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. 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 0.005 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 days of the test with the Director, Division of Materials Licensing, U. S. Atomic Energy Commission, Washington, D. C., 20545, describing the equipment involved, the test results, and the corrective action taken. A copy of such report shall also be sent to the Director, Region II, Division of Compliance, USAEC, 50 Seventh Street, Northeast, Atlanta, Georgia, 30323.

D. Tests for leakage and/or contamination shall be performed by Dr. Gerald M. Good, or by other persons specifically authorized by the Commission of an Agreement State to perform such services.

For the U. S. Atomic Energy Commission

Date_____ by_____

Division of Materials Licensing
Washington, D. C. 20545

LICENSE SAMPLE (3) - PRIVATE PRACTICE LICENSE

FORM AEC-374
(12-57)

U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE

Page 1 of 3 Pages

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Part 30, Licensing of Byproduct Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below, and to use such byproduct material for the purpose(s) and at the place(s) designated below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Name: Dr. John H. Smith	3. License number: 10-101-10 (P69)
2. Address: 506 Orchard Street Pittsburgh, Pennsylvania	4. Expiration date: June 30, 1969
	5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
A. Iodine 131	A. Iodide	A. 100 millicuries
B. Iodine 131	B. Iodinated Human Serum Albumin	B. 1 millicurie
(See Page 2)	(See Page 2)	(See Page 2)

9. Authorized use

A. Diagnosis of thyroid function. Treatment of hyperthyroidism, cardiac conditions, and thyroid carcinoma.

B. Plasma and blood volume determinations.

C. Liver function studies.

(See Page 2)

CONDITIONS

10. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above.

11. The licensee shall comply with the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation."

12. Byproduct material shall be used by John H. Smith, M. D.

13. Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.

14. A. For diagnostic uptake and function measurements, the licensee shall have available a Geiger Mueller or scintillation probe and scaler(s).

B. For diagnostic studies depending upon the measurement of biological specimens (blood, urine, etc.), the licensee shall have available a well-type scintillation detector and shield.

(See Page 2)

For the U. S. Atomic Energy Commission

Date_____ by_____

Division of Materials Licensing
Washington, D. C. 20545

SAMPLE LICENSE

FORM AEC-374B (10-61)

U. S. ATOMIC ENERGY COMMISSION

MATERIAL LICENSE

Supplementary Sheet

Continued From Page 1

License Number 10-101-10 (F69)

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
C. Iodine 131	C. Rose Bengal	C. 1 millicurie
D. Iodine 131	D. Labeled Renal Function Compounds	D. 2 millicuries
E. Iodine 131	E. Triiodothyronine	E. 1 millicurie
F. Iodine 131	F. Labeled Fats and/or Fatty Acids	F. 1 millicurie
G. Phosphorus 32	G. Soluble Phosphate	G. 25 millicuries
H. Phosphorus 32	H. Colloidal Chromic Phosphate	H. 25 millicuries
I. Gold 198	I. Colloidal	I. 200 millicuries
J. Chromium 51	J. Chromate	J. 5 millicuries
K. Cobalt 58	K. Labeled Vitamin B-12	K. 1 millicurie
L. Cobalt 60	L. Labeled Vitamin B-12	L. 1 millicurie
M. Iron 59	M. Chloride and/or Citrate	M. 1 millicurie

9. Authorized Use

D. Kideny function studies.
E. In vitro study of thyroid function.
F. Fat absorption studies.
G. Treatment of polycythemia vera and leukemia.
H. and I. Intracavitary treatment of pleural effusions and/or ascites.
J. Red blood cell labeling and survival studies.
K. and L. Diagnosis of pernicious anemia.
M. Iron turnover studies.

CONDITIONS

14. Continued:

C. For diagnostic studies to determine relative localization of a radioisotope, the licensee shall have available a scanner.

D. For therapy, the licensee shall have available a low range survey meter capable of detecting low level contamination.

E. For treatment of thyroid carcinoma with Iodine 131 and treatments with Gold 198, the licensee shall have available a survey meter capable of detecting up to one roentgen per hour.

15. Except as specifically provided otherwise by this license, the licensee shall possess and use byproduct material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated June 1, 196X. (See Page 3)

For the U. S. Atomic Energy Commission

Date_____

by_____

Division of Licensing and Regulation
Washington 25, D. C.

FORM AEC-374A
(2-65)

SAMPLE LICENSE
U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE
Supplementary Sheet

Page 3 of 3 Pages

License Number 10-101-10
(F69)

Continued from Page 2:

CONDITIONS

16. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual radioactivity is 30 millicuries or less.

17. Iodine 131 for the treatment of thyroid carcinoma and Gold 198 shall only be used at the hospital(s) listed below.

    A. XYZ Hospital, Pittsburgh, Pennsylvania

    B. Metropolitan Hospital, Isotope Clinic, Pittsburgh, Pennsylvania

    C. University Hospital, Pittsburgh, Pennsylvania.

For the U. S. Atomic Energy Commission

Date_____

by_____
Division of Materials Licensing
Washington, D. C. 20545

SAMPLE

Form AEC-482
(7-65)
10 CFR 35

U.S. ATOMIC ENERGY COMMISSION

FORM APPROVED
BUDGET BUREAU NO.
38 R-027

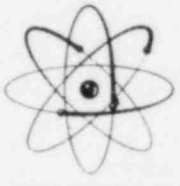
REGISTRATION CERTIFICATE—MEDICAL USE OF BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Section 35.31 of 10 CFR 35 establishes a general license authorizing physicians to possess certain small quantities of I 125, I 131, Co 58, Co 60, and Cr 51 for specified diagnostic uses. Possession of byproduct material under 10 CFR 35.31 is not authorized until the physician has filed Form AEC-482 and received from the Commission a validated copy of Form AEC-482 with registration number assigned.

INSTRUCTIONS

Submit this Form in triplicate to: United States Atomic Energy Commission, Washington, D.C., 20545, Attention: Director, Division of Materials Licensing. *A registration number will be assigned and a validated copy of Form AEC-482 will be returned. Please print or type your name and address* (including ZIP code), *within the shaded area.*

Registration number:



(Leave this space blank—number to be assigned by AEC)

I am a duly licensed physician authorized to dispense drugs in the practice of medicine. My license(s) is (are) valid under the laws of:

STATE(S) OF LICENSURE	LICENSE NUMBER(S)

CERTIFICATE

I hereby certify that:

1. All information in this registration certificate is true and complete.
2. I have appropriate radiation measuring instruments to carry out the diagnostic procedures for which I will use byproduct material under the general license of 10 CFR 35.31 and I am competent in the use of such instruments.
3. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director, Division of Materials Licensing, within 30 days from the date of such change.
4. I have read and understand the provisions of Section 35.31 of AEC regulations (10 CFR 35) reprinted on the reverse side of this form; and I understand that I am required to comply with those provisions as to all byproduct material which I receive, possess, use, or transfer under the general license for which this Registration Certificate is filed with the Atomic Energy Commission:

Date _____ By _____
(Signature of Registrant)

WARNING.—18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 35.31

§ 35.31 General License for Medical Use of Certain Quantities of Byproduct Material.

(a) A general license is hereby issued to any physician to receive, possess, transfer, or use for any of the following stated diagnostic uses, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, the following byproduct materials in capsules, disposable syringes or other forms of prepackaged individual doses;

(1) Iodine 131 as sodium iodide (NaI^{131}) for measurement of thyroid uptake;

(2) Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(3) Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(4) Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;

(5) Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin;

(6) Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

Note: Section 32.70 of this chapter requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include the following statement in the label affixed to the container or to the leaflet or brochure which accompanies the radiopharmaceutical;

This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license of the United States Atomic Energy Commision or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

.....
(Name of manufacturer)

(b) No physician shall receive, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form AEC-482, "Registration Certificate—Medical Use of 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 the Form AEC-482 with registration number assigned. The registrant shall furnish on Form AEC-482 the following information and such other information as may be required by that form:

(1) Name and address of the registrant;

(2) A statement that the registrant is a duly licensed physician authorized to dispense drugs in the practice of medicine, and specifying the license number and the State in which such license is valid; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use byproduct material under the general license of § 35.31 of this chapter and that he is competent in the use of such instruments.

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

(1) He shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, more than:

(i) 200 microcuries of iodine 131,

(ii) 200 microcuries of iodine 125,

(iii) 5 microcuries of cobalt 58,

(iv) 5 microcuries of cobalt 60, and

(v) 200 microcuries of chromium 51.

(2) He shall store the pharmaceutical until administered in the original shipping container or a container providing equivalent radiation protection;

(3) He shall use the pharmaceutical only for the uses authorized by paragraph (a) of this section;

(4) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age;

(5) He 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, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The registrant possessing or using byproduct material under the general license of paragraph (a) shall report in duplicate to the Director, Division of Materials Licensing, any changes in the information furnished by him in the "Registration Certificate—Medical Use of Byproduct Material Under General License," Form AEC-482. The report shall be submitted within 30 days after the effective date of such change.

(e) 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 the byproduct materials covered by the general license.

NOTE

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 35.31 are required, the physician should file an "Application for Byproduct Material License," Form AEC-313 and 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.

APPENDIX B

MEDICAL ISOTOPES COMMITTEE

Section 35.11(b), 10 CFR 35, requires the applicant for an institutional license to appoint a medical isotope committee to evaluate all proposals for research, diagnostic, and therapeutic uses of radioisotopes within the institution. The medical isotope committee shall consist of at least three members. This membership should include physicians expert in internal medicine or hematology (or pathology), therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiation.

The application should give the names, specialties, and radioisotope experience of each committee member and describe the functions, responsibilities, authority, and administrative procedures of the committee. The following is presented as a typical assignment given to a committee:

A. *Committee Authority.*

The committee is established by authority of the Hospital Administrator (or Hospital Director) as the administrative body responsible for the safe use of radioisotopes within the institution.

B. *Committee Responsibilities.*

1. Review and grant permission for, or disapprove, the use of byproduct material for experimental or nonroutine uses within the institution from the standpoint of radiological health and safety of patients or working personnel and other factors which the committee may wish to establish for medical use of byproduct materials prior to submission of an application to the Commission for licensing action.

2. Prescribe special conditions that will be required during a proposed use of byproduct material such as requirements for bioassays and physical examinations of users, minimum level of training and experience of users.

3. Receive and review records and reports from the radiological safety officer or other individuals delegated responsibility for health safety practices in the institution.

4. Recommend remedial action to correct safety infractions.

5. Formulate and review the institutional training programs for the safe use of radioisotopes.

6. Maintain written record of actions taken by the committee.

7. Coordinate and supervise the use of isotopes under private practice license. (Although it is not a requirement, the institution may desire to establish a radioisotope committee to assist in the control of radioisotope use if there are multiple private practice licensees permitted to use materials within the institution.)

8. Inform the Commission of any changes in committee membership.

C. *Committee Administrative Procedures.*

The scope of administrative procedures will depend primarily on the radioisotope program to be undertaken. If the program is initiated on a modest scale, revisions of procedures and organization may become appropriate, as the program grows over a period of time. The procedures may include—

1. A meeting schedule to review safety aspects of present programs and to consider special cases or problems.

2. Record keeping procedures for committee meetings, actions, recommendations, and decisions.

3. A program for the preparation and dissemination of information pertaining to radiation safety.

4. The delegation of responsibility to a specific individual for the conduct of the day-to-day radiation safety program, including appropriate surveys and maintenance of records.

5. Maintenance of written records of receipts, transfers, and disposal of all radioactive isotopes in the institution and maintenance of an inventory of the total quantity of each radioisotope possessed at the institution.

6. Provisions for initiating corrective action as necessary to assure radiation safety.

APPENDIX C

ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF BYPRODUCT MATERIAL

I. *GENERAL TRAINING.*

Section 35.11(d) of 10 CFR 35 provides that the Commission will approve a license application by an institution for medical use of byproduct material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (a) basic radioisotope handling techniques and (b) the clinical use of byproduct material proposed in the application. Similar criteria are established in section 35.12(c) of 10 CFR 35 for approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria which the Commission, with the assistance of its Advisory Committee on Medical Uses of Isotopes, has found acceptable for physicians who use radiopharmaceuticals. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radiopharmaceuticals but does not have the training and experience described, he may submit an application listing his specific qualifications and this will be reviewed by the Commission with the assistance of the Medical Advisory Committee.

Training may be obtained in a residency, formal training course, or collaboration in a program using byproduct material. To qualify as adequately trained, a physician's background should include:

A. *General Training in Basic Radioisotope Handling Techniques Including—*

1. *A Working Knowledge of—*

a. Principles and practices of radiological health safety;

b. Radioactivity measurements, standardization, and monitoring techniques and instruments;

c. Mathematics and calculations basic to the use and measurement of radioactivity;

d. Biological effects of radiation; and

2. *Experience in the Use of Byproduct Material for the Types and Quantities for Which the Application Is Being Made, or Equivalent Experience.*

NOTE: Satisfactory completion of the Oak Ridge Institute of Nuclear Studies "Basic Course in Radioisotopes Techniques," or its equivalent, in practical training will serve as evidence of acceptable basic training.

B. *Clinical Radioisotope Training Consisting of—*

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed;

2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data;

3. Adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment;

4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic and/or therapeutic procedures, limitations, contraindications, etc.

II. *SPECIFIC TRAINING—BASIC AND CLINICAL.*

The following relates to well-established medical uses. These uses are divided into the same categories as Form AEC–313MC and are followed by other specialized uses. Training requirements are the same for physicians in institutional or in private practice programs. See appendix F for suggested training and experience for nonroutine or experimental medical uses. Training and experience for the specific clinical uses are as follows:

A. *Category I—Diagnostic Procedures.*

The diagnostic procedures covered by category I are Iodide for diagnosis of thyroid function; Iodinated Human Serum Albumin for plasma and blood volume determinations; Rose Bengal for liver function studies; Labeled Renal Function Compounds for kidney function studies; Triiodothyronine for *in vitro* study of thyroid function; Labeled Fats and/or Fatty Acids for fat absorption studies; Chromium 51 as Chromate for red blood cell labeling and survival studies; Chromium 51 labeled Human Serum Albumin for gastrointestinal protein loss studies; Iron 59 as Chloride and/or Citrate for iron turnover studies; and Cobalt 60 or 58 as Labeled Vitamin B–12 for diagnosis of pernicious anemia. Training and experience criteria for these procedures are—

1. Thirty hours of training in basic radioisotope handling techniques, and

2. Active participation in the performance of five uptake studies, three dilution studies, and three excretion studies involving the use of radiopharmaceuticals on humans.

To be licensed for one or more of the diagnostic procedures listed in category I, but not the entire category, training and experience should include:

1. Thirty hours of training in basic radioisotope handling techniques, and

2. Active participation in three cases each of the specific diagnostic procedure(s) requested, except that for diagnosis of thyroid function the physician should have actively participated in five cases.

797–262 O—66——3

B. *Category II—Specialized Diagnostic Procedures (Scans or Tumor Localization).*

The specialized diagnostic procedures covered by category II are Iodide for thyroid scans; Iodinated Human Serum Albumin for brain tumor localization; Cholografin for cardiac scans for determination of pericardial effusions; Rose Bengal for liver scans; Labeled Renal Function Compounds for kidney scans; Gold 198 as Colloidal for liver scans; Mercury 197 or 203 as Chlormerodrin; for kidney and brain scans; Chromium 51 as Chromate for spleen scans; Strontium 85 as Nitrate or Chloride for bone scans in patients with diagnosed cancer; and Iodine 131 labeled Macroaggregated Iodinated Human Serum Albumin for lung scans.

Training and experience for these procedures are—

1. Thirty hours of training in basic radioisotope handling techniques, and

2. Active participation in the performance of three tumor localizations or organ scans using byproduct material.

NOTE: Category II procedures require specialized instrumentation and techniques. The physician should therefore be familiar with the use of instrumentation for each specialized procedure he requests. In lieu of the above experience, the physician should have broad diagnostic radioisotope experience and submit evidence that he is familiar with the instrumentation to be used and cite a literature reference for the procedure to be followed.

C. *Category III—Iodine 131—Treatment of Hyperthyroidism and/or Cardiac Conditions; Phosphorus 32—Treatment of Blood Dyscrasias.*

1. Thirty hours of training in basic radioisotope handling techniques, and

2. For the treatment of hyperthyroidism and/or cardiac dysfunction, clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients with hyperthyroidism and/or cardiac dysfunction using Iodine 131.

3. For the treatment of polycythemia vera, leukemia, and bone metastases, active participation in the treatment of three patients with one of these conditions using Phosphorus 32.

D. *Category IV—Treatment of Thyroid Carcinoma; Phosphorus 32 and Gold 198 Intracavitary Therapy.*

1. Thirty hours of training in basic radioisotope handling techniques.

2. For the treatment of thyroid carcinoma, clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of three patients with thyroid carcinoma using Iodine 131.

3. For the intracavitary treatment of carcinomatous patients with Gold 198, active participation in three cases.

4. For the intracavitary treatment of carcinomatous patients with Phosphorus 32, active participation in three cases.

NOTE: In lieu of the experience for the treatment of thyroid carcinoma, the physician should have broad experience with the use of Iodine 131 for the treatment of hyperthyroidism and/or cardiac dysfunction and cite a literature reference to the clinical procedures that will be followed.

E. *Interstitial Treatment of Carcinomatous Patients With Colloidal Phosphorus 32.*

1. Thirty hours of training in basic radiosotope handling techniques.

2. Active participation in the interstitial treatment of three carcinomatous patients with Colloidal Phosphorus 32 or Colloidal Gold 198.

NOTE: The interstitial use of colloidal chromic phosphate in the treatment of cancer entails a specialized procedure. Such treatment should, therefore, be carried out only by an appropriate team of specialists including a therapeutic radiologist.

F. *Interstitial Treatment of Carcinomatous Patients With Colloidal Gold 198.*

1. Thirty hours of basic training in radioisotope handling techniques.

2. Active participation in the interstitial treatment of three carcinomatous patients with Colloidal Gold 198.

NOTE: The interstitial use of colloidal gold in the treatment of cancer entails a specialized procedure. Such treatment should, therefore, be carried out only by an appropriate team of specialists, including a therapeutic radiologist.

G. *Interstitial, Intracavitary, or Surface Treatment of Cancer With Radiation Sources.*

Active practice in therapeutic radiology with a minimum of three years' experience.

NOTE: In lieu of the above experience, the physician should be a qualified specialist in a field appropriate to the proposed use with specialized training and experience in radiation dosimetry and at least three years' experience in interstitial, surface, or intracavitary use of radiation sources.

H. *Treatment of Superficial Eye Disease With Beta Ray Applicators.*

Active practice in therapeutic radiology or ophthalmology and experience in the therapeutic use of beta rays or soft x-rays.

NOTE: In lieu of the above experience, the physician should have at least three years' experience in the therapeutic use of beta rays or soft x-rays and furnish evidence of knowledge and experience concerning beta ray depth dosage. Such physicians should have actively participated in the treatment of at least three cases of superficial eye diseases.

I. *Determination of Blood Volume With Automatic Blood Volume Instruments.*

This procedure involves the use of an instrument which automatically measures and directly indicates isotopic dilution and blood volume after injection of prepackaged doses of I-131 as Iodinated Human Serum Albumin.

Training and experience criteria for this procedure are—

1. Three hours of training in the use of the instrument and basic radioisotope handling techniques.

2. Active participation in the performance of three blood volume determinations with the instrument.

Uses of other byproduct material not listed in appendix C are considered to be nonroutine. See appendix F for experimental and nonroutine uses of byproduct material.

APPENDIX D

A LIST OF WELL-ESTABLISHED MEDICAL USES

Isotope	Chemical form	Use
Iodine 131	Iodide	Diagnosis of thyroid functions. Thyroid scans. Treatment of hyperthyroidism and/or cardiac dysfunction. Treatment of thyroid carcinoma.
Iodine 131	Iodinated Human Serum Albumin.	Blood volume determinations. Brain tumor localization.
Iodine 131	Rose Bengal	Liver function studies. Liver scans.
Iodine 131	Labeled Renal Function Compounds.	Kidney function studies. Kidney scans.
Iodine 131	Labeled Fats and/or Fatty Acids	Fat absorption studies.
Chromium 51	Chormate	Red blood cell labeling and survival studies. Spleen scans.
Iron 59	Chloride and/or Citrate	Iron turnover studies.
Cobalt 58 or 60	Labeled Vitamin B-12	Diagnosis of pernicious anemia.
Gold 198	Colloidal	Liver scans. Intracavitary treatment of pleural effusions and/or ascites. Interstitial treatment of cancer.
Mercury 203 or 197	Chlormerodrin	Kidney scans. Brain scans.
Phosphorus 32	Soluble Phosphate	Treatment of polycythemia vera. Treatment of leukemia and bone metastasis.
Phosphorus 32	Colloidal Chromic Phosphate	Intracavitary treatment of pleural effusions and/or ascites. Interstitial treatment of cancer.
Iodine 125	Iodide	Diagnosis of thyroid function.
Iodine 125	Iodinated Human Serum Albumin.	Blood volume determinations.
Iodine 125	Rose Bengal	Liver function studies.
Iodine 125	Labeled Renal Function Compounds.	Kidney function studies.
Iodine 125	Labeled Fats and/or Fatty Acids	Fat absorption studies.
Iodine 131	Cholografin	Cardiac scans for determination of pericardial effusions.
Strontium 85	Nitrate or Chloride	Bone scans on patients with diagnosed cancer.
Iodine 131	Macroaggregated Iodinated Human Serum Albumin.	Lung scans.
Chromium 51	Labeled Human Serum Albumin	Gastrointestinal protein loss studies.

APPENDIX E

SAMPLE APPLICATIONS

1. Sample application No. 1 is a blank Form AEC-313MC. This form has preprinted under items 6 (a), (b), (c), and 7 isotopes, chemical form, possession limit and use. The remainder of the application form is identical to Form AEC-313 and should be filled out similar to Sample Application No. 2 or 3 below. All items of Form AEC-313a must be also completed for each use in a checked category in a manner similar to the form included in 2 or 3 below.

2. Sample Application No. 2 is a Form AEC-313 and -313a request for institutional use.

3. Sample Application No. 3 is a Form AEC-313 and -313a request for private practice use.

Form AEC-313 MC (12/65) 10 CFR 30	UNITED STATES ATOMIC ENERGY COMMISSION **APPLICATION FOR A BYPRODUCT MATERIAL LICENSE FOR THE MEDICAL USE OF RADIOISOTOPES**	Form approved Budget Bureau No. 38-R142

INSTRUCTIONS. This form may be used instead of basic Form AEC 313. Check the category or categories for which the physician listed in Item 4 is qualified by training and experience to use. Use supplement sheet where necessary. Be sure all items are completed. If you desire to be licensed for one modality within a category but not the whole category, use the basic Form AEC 313. Complete all items of Form 313a for each category checked. For preparation see "Guide for Preparation of Applications for the Medical Use of Radioisotopes."

1. (a) NAME AND STREET ADDRESS OF APPLICANT *(Including ZIP Code)*	(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1.(a).)*
2. DEPARTMENT TO USE BYPRODUCT MATERIAL *(If applicant is an institution)*	3. PREVIOUS LICENSE NUMBER(S). *(If this is an application for renewal of a license, please indicate and give number.)*
4. INDIVIDUAL USER(S). *(Name and title of physician(s) who will use or supervise use of byproduct material. Give training and experience in Items 8 and 9.)*	5. RADIATION PROTECTION OFFICER. *(Name of person designated as radiation officer, if other than individual user. Attach résumé of his training and experience as in Items 8 and 9.)*

6. (a) BYPRODUCT MATERIAL	(b) CHEMICAL AND/OR PHYSICAL FORM	(c) POSSESSION LIMIT	7. (a) USE	7. (b) ANTICIPATED DOSES (in microcuries or millicuries)
☐ Category I				
Iodine 131 or 125	Iodide	2 millicuries	Diagnosis of thyroid function.	
Iodine 131 or 125	Iodinated Human Serum Albumin	1 millicurie	Plasma and blood volume determinations.	
Iodine 131 or 125	Rose Bengal	1 millicurie	Liver function studies.	
Iodine 131 or 125	Labeled Renal Function Compounds	2 millicuries	Kidney function studies.	
Iodine 131 or 125	Triiodothyronine	1 millicurie	*In vitro* studies.	
Iodine 131 or 125	Labeled Fats and/or Fatty Acids	1 millicurie	Fat absorption studies.	
Chromium 51	Chromate	5 millicuries	Red blood cell labelling and survival studies.	
Chromium 51	Labeled Human Serum Albumin	5 millicuries	Gastrointestinal protein loss studies.	
Iron 59	Chloride and/or Citrate	1 millicurie	Iron turnover studies.	
Cobalt 58 or 60	Labeled Vitamin B-12	1 millicurie	Diagnosis of pernicious anemia.	
☐ Category II				
Chromium 51	Chromate	5 millicuries	Spleen scans.	
Iodine 131	Iodide	2 millicuries	Thyroid scans.	
Iodine 131	Iodinated Human Serum Albumin	1 millicurie	Brain tumor localization.	
Iodine 131	Macroaggregated Iodinated Human Serum Albumin	5 millicuries	Lung scans.	
Iodine 131	Rose Bengal	1 millicurie	Liver scans.	
Iodine 131	Labeled Renal Function Compounds	2 millicuries	Kidney scans.	
Gold 198	Colloidal	20 millicuries	Liver scans.	
Mercury 203 or 197	Chlormerodrin	5 millicuries	Kidney and brain scans.	
Iodine 131	Cholografin	5 millicuries	Cardiac scans for determination of pericardial effusions.	
Strontium 85	Nitrate and/or Chloride	1 millicurie	Bone scans in patients with diagnosed cancer.	
☐ Category III				
Iodine 131	Iodide	30 millicuries	Treatment of hyperthyroidism and/or cardiac dysfunction.	
Phosphorus 32	Soluble Phosphate	25 millicuries	Treatment of polycythemia vera and leukemia.	
☐ Category IV				
Iodine 131	Iodide	100 millicuries	Treatment of thyroid carcinoma.	
Gold 198	Colloidal	200 millicuries	Intracavitary treatment of pleural effusions and/or ascites.	
Phosphorus 32	Colloidal Chromic Phosphate	25 millicuries	Intracavitary treatment of pleural effusions and/or ascites.	

(Continued on reverse side)

APPLICATION - SAMPLE 2

Form AEC-313 (11-63) 10 CFR 30	ATOMIC ENERGY COMMISSION **APPLICATION FOR BYPRODUCT MATERIAL LICENSE**	Form approved. Budget Bureau No. 38-R027.4.

INSTRUCTIONS. — Complete Items 1 through 16 if this is an initial application. If application is for renewal of a license, complete only Items 1 through 7 and indicate new information or changes in the program as requested in Items 8 through 15. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail three copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Isotopes Branch, Division of Materials Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30 and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20.

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital, person, etc.)*	(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1 (a).)*
XYZ Hospital Radioisotope Service 234 West Main Street Colesville, Illinois	(Same)
2. DEPARTMENT TO USE BYPRODUCT MATERIAL	**3. PREVIOUS LICENSE NUMBER(S).** *(If this is an application for renewal of a license, please indicate and give number.)*
Radioisotope Service	
4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*	**5. RADIATION PROTECTION OFFICER** *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*
John A. Doe, M.D.	Roger D. Doe, M.S.

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*	(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*
A. Iodine 131	A. Iodide (Liquid) 100 millicuries
B. Iodine 131	B. Iodide (Capsules) 5 millicuries
C. Iodine 131	C. IHSA (Capsules) 1 millicurie
D. Iodine 131	D. Labeled Renal Function Compounds (Capsules) 5 millicuries
E. Phosphorus 32	E. Soluble Phosphate (Individual Preparation Doses) 20 millicuries
F. Gold 198	F. Colloidal (Liquid-Individual Prepared Doses) 200 millicuries
G. Cobalt 60	G. Sealed Needles (X Company, Model Z) 200 millicuries
H. Strontium 90	H. Sealed Medical Applicator (X Company, Model B) 1 source of 50 millicuries

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

See Supplement 313a for human use.

A-G Research studies in animals.

(Continued on reverse side)

Form AEC-313 (11-63) Page Two

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	University Hospital Durham, Missouri	3 yrs.	(Yes) No	Yes (No)
b. Radioactivity measurement standardization and monitoring techniques and instruments	"	"	(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	"	"	(Yes) No	(Yes) No
d. Biological effects of radiation	"	"	(Yes) No	Yes (No)

9. EXPERIENCE WITH RADIATION. *(Actual use of radioisotopes or equivalent experience.)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-131	100 mc.	University Hospital	3 yrs.	Diagnosis, Therapy
P-32	30 mc.	" "	"	Therapy
Au-198	200 mc.	" "	"	Therapy
Co-60	200 mc.	" "	"	Diagnosis, Therapy
Cr-51	100 uc.	" "	"	Diagnosis
Fe-59	100 uc.	" "	"	Diagnosis

10. RADIATION DETECTION INSTRUMENTS. *(Use supplemental sheets if necessary.)*

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
Z Instr. Co. Model 1 GM Survey Meter	1	β, γ	0 - 20	3.5	Surveying
Z Instr. Co. Model 5 Ionization Chamber	1	β, γ	0 - 5000	20	Monitoring
Z Instr. Co. Model 21 Scaler	1	-	-	-	Measuring
Z Instr. Co. Model 18 Well Scintillation	1	γ	-	-	Measuring
Z Instr. Co. Model 23 Scintillation Probes	2	γ	-	-	Uptake

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.
Survey Instruments Monthly, Cobalt 60 standards
Measuring and Uptake weekly, Standard Solutions

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. *(For film badges, specify method of calibrating and processing, or name of supplier.)*
Film badges by Johnson Co. (Frequency once per month)
XYZ Co. Dosimeters worn in therapeutic work. Range 0-200 mr/hr (Frequency read daily)

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) (Yes) No See Attached.

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.
See Attached

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. See Section 20.303 of 10 CFR 20
Cobalt 60 and Strontium 90 sources returned to mfg. for disposal. SEE ATTACHED SHEET

CERTIFICATE (This item must be completed by applicant) FOR ANNUAL USES

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

XYZ Hospital
Applicant named in item 1

Date January 3, 1962

By: Jack R. Jones
Hospital Administrator
Title of certifying official

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

* U.S. GOVERNMENT PRINTING OFFICE: 1963 O—708-465

FORM AEC-313

Item 13

All isotopes are received and stored in the Radioisotope Laboratory. This facility is equipped with lead storage containers, portable lead bricks for shielding, remote handling tongs, work benches, sinks, trays, waste containers, and similar equipment. See attached sketch of layout.

The isotopes treatment room is used for the administration of isotopes and for the uptake measurements. The uptake and measuring instruments are located in this room. The room is equipped with examining tables, laboratory bench, sink, and waste container. See attached sheet for animal uses.

Item 14

All isotopes must be procured by the Chief, Radioisotope Service.

Isotopes will be stored in a locked storage container in the Radioisotopes Laboratory. Only persons authorized by the Medical Isotopes Committee shall have access to the storage container.

Weekly surveys will be made with a GM survey meter in all areas where isotopes are handled, stored, or dispensed. In addition, each room vacated by a patient having received therapeutic doses of material will be surveyed and decontaminated if necessary before occupancy by another patient.

All repair and maintenance of sealed sources as well as leak testing will be performed by the X Company.

When not in use, the Cobalt 60 needles will be stored in containers which limit the radiation level at the surface of the container to 200 mr/hr or less and to 10 mr/hr or less at one meter from the center of the container. For portable containers, the radiation level will not exceed 50 mr/hr at six inches from the surface of the container. Portable containers will be equipped with a secure locking device. All transfers of needles from storage containers to transfer containers shall be done behind lead shielding using remote handling equipment. See attached sheet for animal uses.

PROCEDURES FOR USE OF BYPRODUCT MATERIAL IN ANIMAL RESEARCH PROGRAMS

All samples of byproduct materials to be administered to animals will be prepared in the radioisotope laboratory on easily decontaminated surfaces or in a ventilated hood if necessary. Rubber gloves and laboratory coats will be worn by personnel during these preparations. Remote handling tools are available and will be used when necessary. All pipetting of radioactive material will be performed with a remote pipetting device.

Experimental animals will be caged in a room adjacent to the radioisotope laboratory. The animals will be injected with byproduct materials either in the animal room or the radioisotope laboratory. The animals will remain in cages until their excretions contain only background amounts of byproduct material, or until they are sacrificed.

The excreta from the animals will be disposed of into the sanitary sewer in concentrations not exceeding those specified in section 20.303 of 10 CFR 20, with a total disposal not to exceed 1 curie per year.

All dry byproduct material waste will be deposited in properly labeled metal cans provided in the laboratory and animal room. The cans will be lined with disposable polyethylene bags. Short-lived waste will be stored until it emits only background levels of radiation as measured with a survey meter at contact. The waste will then be disposed of in normal trash after all labels denoting radioactivity have been removed.

Sacrificed animals containing byproduct material will be stored in a freezer until they have decayed to background and then buried on hospital property.

Animal cages will be decontaminated with detergent and scrub brushes. Rubber gloves will be worn by personnel. Contaminated water will be flushed down the sink or floor drains in the animal room.

The animal room and laboratory will be surveyed for contamination and radiation levels after each preparation and/or administration of radioisotope(s). The animal room will be locked unless attended by authorized user of byproduct material or the radiation protection officer.

FORM AEC-313a

Item 7

MEDICAL ISOTOPES COMMITTEE

Established by authority of Jack R. Jones, Administrator of XYZ Hospital as the administrative body responsible for safe use of radioisotopes and radiation devices within the XYZ Hospital.

A. *Membership:*

JOHN A. D. DOE, M.D., *Chairman*
JOHN Q. PUBLIC, M.D., *Pathologist*
THOMAS N. ANDREWS, M.D., *Internist*
ROGER D. DOE, M.S., *Radiation Protection Officer*

B. *Experience:*

(1) JOHN A. D. DOE, M.D., *Chairman*
1947—Medical Degree, University of Arkansas School of Medicine.
1952—Diplomate American Board of Radiology with the Medallion in Nuclear Medicine. Attended the Oak Ridge Institute of Nuclear Studies in 1951.
1952-1962—Used Iodine 131, Phosphorus 32, Gold 198, for diagnosis and treatment, Cobalt 60 implants, and Iridium 192 as encased seeds in nylon ribbon in treatment, and Chromium 51 and Cobalt 60 for diagnostic procedures.

(2) JOHN Q. PUBLIC, M.D.
1949—B.S. Degree, University of Pittsburgh

1951—M.D. Degree, University of Pittsburgh
1957—Diplomate of American Board of Pathology.
1958—Attended the Oak Ridge Institute of Nuclear Studies basic radioisotope technique course and in 1959 attended the Oscar B. Just Clinical Training Course for Pathologists.
1959—Present—Used Iodine 131, Chromium 51, Cobalt 60, Cobalt 58, and Iron 59 for diagnostic studies.

(3) THOMAS N. ANDREWS, M.D.
1949—B.A. Degree, University of Rochester, Rochester, New York.
1953—M.D. Degree, Rochester School of Medicine.
1954—Attended the 1954 class of Oak Ridge Institute of Nuclear Studies.
1958—Attended the Columbus University postgraduate course and the clinical use of isotopes under Drs. Feidelberg and Quimby.
1959—Diplomate of American Board of Internal Medicine.
1959—Present—Used Iodine 131 and Phosphorus 32 for diagnosis and therapy.

(4) ROGER D. DOE, M.S., *Radiation Protection Officer*
1956—Attended the Oak Ridge Institute of Nuclear Studies basic radiation protection course and attended a 16-week course at Purdue University on counting techniques and research uses of radioisotopes.
1957—Received a M.S. Degree in Health Physics from Vanderbilt University.
1957–1959—Directed graduate students research and use of isotopes at Purdue University.
1959–1960—Taught the staff and graduate special counting techniques; radiation protection, and radioisotope Methodology.

C. *Committee Responsibilities:*

See appendix B of this guide for typical committee responsibilities.

D. *Committee Administrative Procedures:*

See appendix B of this guide for subjects to be covered in submitting application.

FORM AEC–313a

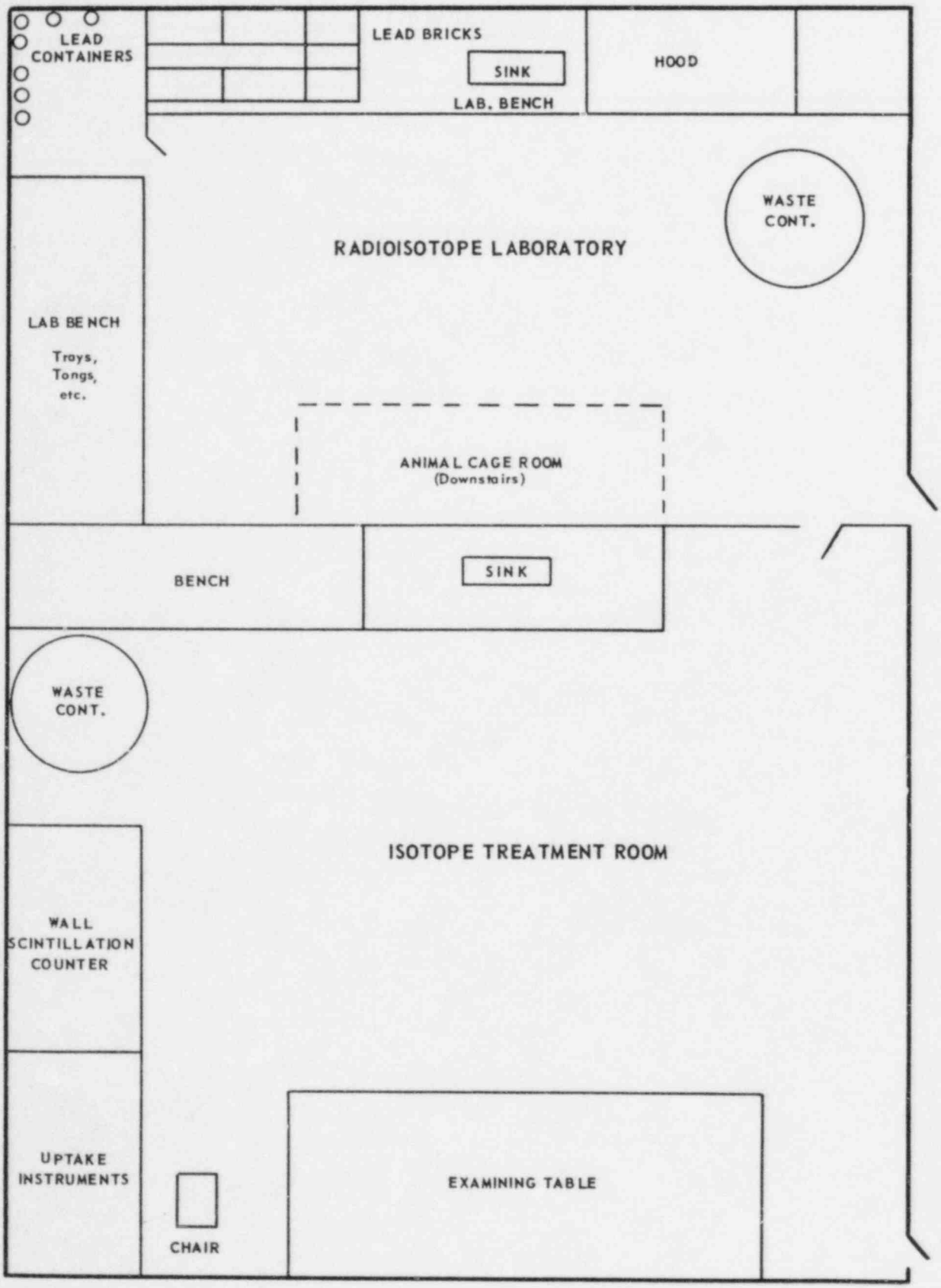
Item 4.c

SAMPLE

NURSING INSTRUCTIONS FOR PATIENTS RECEIVING COBALT 60

Patient _____
_____ me of *Cobalt 60* was inserted on _____ (date)
a.m.
at _____ p.m. _____ (name of physician)

(1) No patient is to be released from the hospital until all radioactive Cobalt is removed.
(2) No adjacent patient or visitors shall be within _____ feet of this patient.
(3) Nurses or other attendants shall not remain in the immediate proximity of the patient for more than a total of _____ hours per day.
(4) Unless otherwise notified, all excreta may be disposed of in the normal manner.
(5) No needles are to be removed by anyone other than the physician(s) named above.
(6) If a source needle is accidentially removed or works itself out, do not handle; immediately contact Dr. Roger D. Doe (Extension 3680).
(7) In the event of death, immediately notify Dr. Roger D. Doe (Extension 3680) or Dr. John A. Doe (Extension 5122) and do not remove the body from the room.


LEAD CONTAINERS
LEAD BRICKS
SINK
LAB. BENCH
HOOD
WASTE CONT.
RADIOISOTOPE LABORATORY
LAB BENCH
Trays, Tongs, etc.
ANIMAL CAGE ROOM (Downstairs)
BENCH
SINK
WASTE CONT.
ISOTOPE TREATMENT ROOM
WALL SCINTILLATION COUNTER
UPTAKE INSTRUMENTS
CHAIR
EXAMINING TABLE

FORM AEC–313a
Item 4.c

SAMPLE

NURSING INSTRUCTIONS FOR PATIENTS RECEIVING GOLD 198 AND THERAPEUTIC DOSES OF IODINE 131

Patient _____

This patient was administered _____ mc of _____
(isotope)

on _____ at _____ a.m. p.m.
(date)

_____
(name of physician)

(1) If patient's clothes or bed linens are contaminated by fluid originating in the patient, notify the above physician.

(2) Wear rubber gloves while handling contaminated objects. Place gloves in "contaminated" container after use.

(3) Nurses or other attendants shall not remain in the immediate proximity of the patient for more than a total of _____ hours during _____
(period)

(4) Visitors must remain outside of tape on floor and patient must remain in bed while visitors are in the room during _____
(period)

(5) Unless otherwise notified, all excreta may be disposed of in the normal manner.

(6) The patient may be released from the hospital after _____ days. The above named physician will make this calculation.

(7) In the event of death, immediately notify Dr. Roger D. Doe (Extension 3680) or Dr. John A. Doe (Extension 5122) and do not remove the body from the room. Dr. Doe will issue appropriate instructions for handling cadaver.

(8) When patient is discharged, room will be surveyed for contamination before remaking room.

SUPPLEMENT SHEET

Item 13

Facilities and Equipment

Facilities consist of an isotope preparation and storage room and a diagnostic room where doses are administered, uptakes measured, and samples counted.

The storage and preparation room contains a stainless steel table covered with absorbent paper, sink, remote handling equipment, labeled waste disposal containers, and closet where isotopes are stored in shielded containers and behind lead bricks.

Item 14

Radiation Protection Program

All radioisotopes are procured in pre-calibrated assayed individual doses and stored prior to use behind lead shields in a closet in the preparation room. During administration of doses to patients, rubber gloves will be worn. The preparation room, storage area, and diagnostic room will be monitored daily or after administration of isotopes to patients. Uptake equipment and portable survey meter will be checked daily and calibrated monthly. Isotope shipments are monitored immediately upon receipt as a check for damage, leakage, or contamination. Permanent records are maintained on all radioisotopes, shipments, doses administered, waste disposal, exposure of individual users, and any transfers of material to other authorized persons.

Item 15

Waste Disposal

Liquid waste will be disposed of in accordance with section 20.303 of 10 CFR 20.

Solid wastes such as paper cups, tissues, empty isotope containers, etc., will be deposited in labeled waste containers. Contents of containers will be removed daily by user and stored in locked closet for decay to background level as measured by GM survey meter. These articles will be disposed in normal trash after removal or destruction of radiation labels. Contaminated instruments, syringes, etc., stored for decay to background in same closet.

Form AEC-313a (11-63) 10 CFR 30 PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R080.2.

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME

John A. Doe, M.D.

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a))

Same as Item 1(a) of Form AEC-313

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER — (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER — (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary):

See page 2.

(b) CHEMICAL FORM ADMINISTERED:

See page 2.

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

1. Stored in lead containers in locked stored area.
2. Handling by remote control and shielded dose cups.
3. Disposal via sanitary sewer system, Cobalt 60 and Strontium 90 returned to supplier for disposal.
4. Sealed sources will not be opened.
5. See attached nursing instructions.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER — YES (NO)

(2) ON FILE WITH THE ISOTOPES BRANCH REFER TO APPLICATION NO. _____ CIRCLE ANSWER — YES (NO)

5. PROPOSED DOSAGE SCHEDULE

(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

See page 2.

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER — YES (NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

Obtained in precalibrated form.

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. CIRCLE ANSWER — (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. CIRCLE ANSWER — YES NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. CIRCLE ANSWER — YES NO

PAGE 2

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

This page may be used for providing additional information. Please cross reference to specific items.

Items 4 a, 4 b, and 5 a

Isotope	Form	Purpose	Dosage Rates
Iodine 131	Iodide	Diagnosis of thyroid function.	Up to 25 microcuries
Iodine 131	Iodide	Treatment of thyroid carcinoma.	Up to 100 millicuries per dose. Total dose 300 to 600 millicuries
Iodine 131	Iodide	Treatment of hyperthyroidism and cardiac dysfunction.	4 to 10 millicuries per administration Total dose 30 to 40 millicuries
Iodine 131	IHSA	Blood and plasma volume determination.	Up to 20 microcuries
Iodine 131	Labeled Renal Function Compounds	Kidney function studies.	20 to 50 microcuries
Phosphorus 32	Soluble Phosphate	Treatment of polycythemia and leukemia.	3 to 7 millicuries per dose Total dose 10 millicuries
Gold 198	Colloidal	Intracavitary treatment of pleural effusions and ascites.	Chest - 125 millicuries Abdomen - 160 millicuries
Strontium 90	Eye Applicator	Treatment of diseases of the eye	
Cobalt 60	Needles	Interstitial treatment of cancer.	

* U.S. GOVERNMENT PRINTING OFFICE : 1964 O—748-382

Form AEC-313a (11/63) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Back of page may be used for comments.

9. NAME AND ADDRESS OF APPLICANT PHYSICIAN

John A. D. Doe, M.D.
XYZ Hospital
Colesville, Illinois

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131	Diagnosis of thyroid function	3	17
	Dilution studies	1	3
	Excretion studies	1	3
	Brain tumor localization	2	5
	Scanning studies	2	10
	Treatment of hyperthyroidism	3	15
	Treatment of cardiac conditions	2	12
	Treatment of thyroid carcinoma	1	3
P-32 Soluble	Treatment of polycythemia	1	3
	Treatment of leukemia	1	2
	Treatment of bone metastases	2	5
	Tumor localization		
	Intracavitary treatment	0	3
	Interstitial treatment		
Au-198	Intracavitary treatment	2	6
	Interstitial treatment		
	Scanning studies	1	4
Cr-51	Blood determinations	0	5
	Scanning studies		
Co-58 or Co-60	Diagnosis of pernicious anemia	1	3
Co-60	Interstitial treatment	5	15
I-192	Intracavitary treatment	5	22
Co-60 or Cs-137	Teletherapy treatment	3	40
Sr-90	Treatment of superficial diseases of the eye	2	15
Other Isotopes Use back of page			

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data, and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

11. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING

June 1958 to June 1961 1,000 hours +

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF John F. Smith, M.D.,

AT University Hospital, Durham 1-21-1
(Institution) Name and Address Missouri (Byproduct Material License Number)

John F. Smith
John F. Smith, M.D.
Chairman, Isotope Committee
(Signature of Preceptor) (Title)

APPLICATION SAMPLE 3 - PRIVATE PRACTICE

Form AEC-313 (11-63) 10 CFR 30	ATOMIC ENERGY COMMISSION **APPLICATION FOR BYPRODUCT MATERIAL LICENSE**	Form approved. Budget Bureau No. 38-R027.4.

INSTRUCTIONS. — Complete Items 1 through 16 if this is an initial application. If application is for renewal of a license, complete only Items 1 through 7 and indicate new information or changes in the program as requested in Items 8 through 15. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail three copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Isotopes Branch, Division of Materials Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30 and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20.

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital, person, etc.)*	(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1 (a).)*
John A. D. Doe, M.D. 502 Medical Plaza Colesville, Illinois	(Same)
2. DEPARTMENT TO USE BYPRODUCT MATERIAL	**3. PREVIOUS LICENSE NUMBER(S).** *(If this is an application for renewal of a license, please indicate and give number.)*
Private Use	
4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*	**5. RADIATION PROTECTION OFFICER** *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*
John A. D. Doe, M.D.	Roger D. Doe, M.S.

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*	(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*
Iodine 131	Iodide (Capsule form) 2 millicuries
Iodine 131	Iodinated Human Serum Albumin (vial) 1 millicurie
Iodine 131	Labeled Renal Function Compound (vial) 1 millicurie

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

Human Use - See Form AEC 313a (attached).

(Continued on reverse side)

Form AEC-313 (11-63) Page Two

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	Oak Ridge Institute of Nuclear Studies, Metropolitan Hosp., Colesville, Illinois	1 mo. '54 3 wks '53	(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Same	Same	(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Same	Same	(Yes) No	(Yes) No
d. Biological effects of radiation	Same	Same	(Yes) No	(Yes) No

9. EXPERIENCE WITH RADIATION. *(Actual use of radioisotopes or equivalent experience.)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-131	30 mc.	Metropolitan Hosp., Radioisotope Clinic	3 weeks	Human - Diagnostic and Therapeutic
P-32	5 mc.	State Medical School	1 yr. ('51)	Animal Research
C-14	5 mc.	State Medical School	1 yr. ('51)	Animal Research

10. RADIATION DETECTION INSTRUMENTS. *(Use supplemental sheets if necessary.)*

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
Model XX Scaler	1				Measuring
Model YY Scint. Detector	1	Gamma			Measuring
Lab. Monitor	1	Beta, Gamma	30,000 cpm	1.2 - 2mg/cm²	Monitoring
Survey Meter	1	Beta, Gamma	0 - 50 mr/hr	50 mg/cm²	Surveying

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.
Calibrated against Simulated I-131 Std. each day.
Calibrated against certified Standard once each month.

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. *(For film badges, specify method of calibrating and processing, or name of supplier.)*

XYZ Company Film Badge Service - Frequency -- once per month.

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) (Yes) No

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.
See attached sheet

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. See attached sheet

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

John A. D. Doe, M.D.
Applicant named in item 1

Date January 30, 1962

By John A. D. Doe, M.D.

Title of certifying official

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

* U.S. GOVERNMENT PRINTING OFFICE: 1963 O—708-865

797-262 O—66——4

Form AEC-313a (11-63) 10 CFR 30 PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R080.2

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME: John A. D. Doe, M.D.

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a)): Same

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER: (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER: (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary): I-131 as Iodide - Diagnosis of thyroid function; IHSA - blood volume determinations; labeled renal function compounds for renal function studies.

(b) CHEMICAL FORM ADMINISTERED:

Iodine 131 Iodide
Iodine 131 Iodinated Human Serum Albumin
Iodine 131 Labeled Renal Function Compounds

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL: Byproduct material procured in individual pre-calibrated and assayed doses. Doses stored behind lead shield in original shipping container prior to use. Handling by remote instruments or in shielded containers. Labeled waste disposal container available. For additional information see attached sheet.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER: YES (NO)

(2) ON FILE WITH THE ISOTOPES BRANCH REFER TO APPLICATION NO. _____ CIRCLE ANSWER: YES (NO)

5. PROPOSED DOSAGE SCHEDULE

(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

Iodine 131	Iodide	Up to 25 microcuries
Iodine 131	IHSA	Up to 20 microcuries
Iodine 131	Labeled Renal Function Compounds	Up to 40 microcuries

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER: YES (NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES: Not applicable.

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. NONE CIRCLE ANSWER: YES NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. See attached sheet CIRCLE ANSWER: (YES) NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. CIRCLE ANSWER: YES (NO)

Form AEC-313a (11/63) PAGE 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Back of page may be used for comments.

9. NAME AND ADDRESS OF APPLICANT PHYSICIAN

John A. D. Doe, M.D.
502 Medical Plaza
Colesville, Illinois

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131	Diagnosis of thyroid function	5	15
	Dilution studies	1	5
	Excretion studies	1	6
	Brain tumor localization		
	Scanning studies		
	Treatment of hyperthyroidism	2	0
	Treatment of cardiac conditions		
	Treatment of thyroid carcinoma	1	0
P-32 Soluble	Treatment of polycythemia		
	Treatment of leukemia		
	Treatment of bone metastases		
	Tumor localization		
	Intracavitary treatment		
	Interstitial treatment		
Au-198	Intracavitary treatment		
	Interstitial treatment		
	Scanning studies		
Cr-51	Blood determinations		
	Scanning studies		
Co-58 or Co-60	Diagnosis of pernicious anemia		
Co-60	Interstitial treatment		
I-192	Intracavitary treatment		
Co-60 or Cs-137	Teletherapy treatment		
Sr-90	Treatment of superficial diseases of the eye		
Other Isotopes Use back of page			

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

11. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING June 30, 1962 to July 21, 1962 120 hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF John Jones, M.D.

AT Metropolitan Hospital (Institution) Name and Address
Colesville, Illinois

2-34-1 (Byproduct Material License Number)

John Jones, M.D. (Signature of Preceptor)
Chairman, Isotope Committee

C I T Y H O S P I T A L

January 2, 1962

John A. D. Doe, M.D.
502 Medical Plaza
Colesville, Illinois

Dear Dr. Doe:

We are pleased to advise you that the City Hospital Board of Directors has approved your request for permission to admit patients containing radioactive materials in this hospital.

This agreement is made with the understanding that you will provide the necessary instrumentation, radiological safety and nursing instructions for hospital personnel.

Very truly yours,

J. J. Reem

J. J. Reem, M.D.
Hospital Administrator

APPENDIX F

NON-ROUTINE MEDICAL USES OF BYPRODUCT MATERIAL

Experimental and nonroutine medical uses of byproduct materials include all human uses not specified in appendix D. Such uses may be classified into one of two phases of development:

Clinical Research applies to a new use of byproduct material in humans. Little or nothing is known about the procedure and little or nothing has been published on the subject. The basis for proceeding with the new use in humans is derived from knowledge obtained from animal studies. This phase of development includes the initial introduction into humans and initial trials on a limited number of patients.

Clinical Evaluation applies to the planned testing of a new diagnostic or therapeutic procedure in an appropriate series of control and diseased humans. The procedure and results of clinical research will ordinarily have been reported in the literature or at meetings. If adequate information has not been published, the applicant should have spent sufficient time with those who developed the test, to be thoroughly familiar with the details.

The *clinical research* phase of experimental or nonroutine medical use of byproduct material is normally limited to licensees who have broad experience in the use of radioisotopes and who have appropriate facilities and equipment available to conduct research. Research should be pursued by groups of competent investigators representing different disciplines rather than by single individuals. The individual physician to be designated on the license as the authorized user should normally have broad and varied experience in the use of radioisotopes and in clinical research investigation.

The clinical evaluation phase of experimental or nonroutine medical use of byproduct material is normally limited to licensees under the supervision of an individual physician with broad experience in clinical evaluation and the use of radioisotopes and under the guidance of a radioisotope committee representing a number of disciplines. Adequate resources to conduct the trials shall be available.

Applications for experimental or nonroutine uses of byproduct material in humans are reviewed with the assistance of the Commission's Advisory Committee on the Medical Use of Isotopes. Applications should be supported by a research protocol which includes:

1. Title of study.

2. The purpose for conducting the study. Indicate whether the study is to be clinical research or clinical evaluation and explain why.

3. The plan of investigation in sufficient detail to permit a critical evaluation of the methods for conducting the experiments and the controls established.

4. A statement as to whether any planned complementary drug or radioisotope administration is contemplated in conjunction with the study.

5. A statement about the expected fate of the isotope administered and if the procedure is for therapy, a statement about the expected effects.

6. A. *If the application is for clinical research,* an outline of related work conducted by the applicant or others in laboratory animals and in humans, including data on localization, effective half-life, and radiation dosage. If no work has been conducted in animals, explain why. Pertinent references and a brief abstract prepared by the applicant of published or unpublished material should be submitted. (The brochure of a commercial supplier is not a satisfactory authority for this purpose. It is not necessary to include with the application reprints of references.)

B. *If the application is for clinical evaluation,* pertinent references and a brief abstract prepared by the applicant of published or unpublished material, including information on localization, effective half-life, and radiation dosage. (The brochure of a commercial supplier is not a satisfactory authority for this purpose. It is not necessary to include with the application reprints of references.)

7. A description of the human subjects to be studied:

A. Persons without manifest disease—number, method of selection, age range.

B. Persons with manifest disease—number, nature of pathology, method of selection, age range.

C. Pregnant women shall ordinarily be excluded from any test not involving the condition of pregnancy itself. Specify whether or not pregnant women will be tested and if so, explain why.

8. Confirmation that consent of human subjects, or their representatives, will be obtained to participate in the investigation except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

9. The dose range (microcuries or millicuries) to be administered and the method of administration.

10. Calculations of the radiation doses delivered to the whole body and to the critical organ(s). The calculations shall contain information about:

A. The expected half-life in various organs.

B. The relationship between the retained isotope and the permissible body burden for occupational exposure (except for therapy).

C. The rationale for using the dose selected.

D. The radiation dose due to other simultaneous or accompanying radioactive isotope test which may be administered.

11. A statement of the institutional resources available to support the study including:

A. Physical facilities and equipment especially suited for the study under consideration.

B. Availability of clinical material.

C. Types of consultation or collaboration available including the name of the sponsor of the study if other than the applicant.

12. Qualifications of the individual physician who will be responsible for the study, including a summary of research training and experience and pertinent training or experience in the use of radioisotopes.

13. Estimated time needed to complete the study.

14. A schedule for reporting results of the study, and an outline of the type of information to be included in the report. The schedule can be in terms of time intervals or number of subjects studied. If studies are to be long range, interim reports should be provided.

APPENDIX G

TYPES OF INSTRUMENTS NEEDED FOR MEDICAL PROGRAMS

The type and quantity of radiation detection instrumentation for a clinical radioisotope program depends upon (1) type and quantity of radioisotopes possessed and the nature of their use, (2) chemical and physical form of the isotopes, and (3) type and volume of work. Certain diagnostic and therapeutic uses of isotopes may involve specialized instrumentation. For example, Iodine 131 as Iodinated Human Serum Albumin for brain tumor localization and Phosphorus 32 for localization of brain and eye tumors involved the use of highly specialized scanning instrumentation including directional collimators or probes.

The attached table lists radiation detection instruments needed for various isotopes and uses.

INSTRUMENTATION NEEDED FOR MEDICAL USES OF BYPRODUCT MATERIAL

Item	I-131		P-32	Au-198	Co-60		Cr-51 Fe-59 S-35	H-3 C-14	Na-24 K-42	Co-58	Sr-85 Hg-197 Hg-203	Remarks
	Diag.	Ther.	Ther.	Ther.	Diag.	Ther.	Diag.	Diag.	Diag.	Diag.	Diag.	
Instrumentation:												
A. Measurement:												
1. Uptake	X	X	—	—	—	—	—	—	—	—	X	GM or scintillation. Detector and scalers (specialized scanning equipment for special diagnostic procedures).
2. Biological specimens.	X	—	—	—	X	—	X	X	X	X	—	Well-type scintillation detection and scaler—Liquid scintillation for H–3 & C–14.
B. Radiation survey:												
1. Low level	X	X	X	X	X	X	X	X	X	X	X	GM survey meter.
2. High level	—	X	—	X	—	X	—	—	—	—	—	Survey meter capable of measuring up to 1 roentgen per hour.
C. Personnel monitoring:												
1. Film badge	—	X	—	X	—	X	—	—	—	—	—	
2. Pocket meters	—	X	—	X	—	X	—	—	—	—	—	

X = Needed.
— = Not necessary.

APPENDIX H

INFORMATION ON FACILITIES AND EQUIPMENT AND OPERATING PROCEDURES TO BE INCLUDED WITH THE APPLICATION

The following indicates the areas in which detailed descriptive information should be submitted in the application.

1. The procedures that ensure that responsible persons are promptly notified of receipt of byproduct material.

2. The method of monitoring packages containing byproduct material to ensure that the contents have not been spilled during transport.

3. The procedures and facilities used to move the byproduct material to storage or the place of use.

4. The storage facilities and security procedures used to restrict access to the byproduct material to authorized users.

5. The facilities, equipment, and procedures that will be available for handling and storage of radioactive material. An explanatory sketch of the work areas and a listing of fume hoods, remote handling equipment, lead brick, or barrier shields, and storage containers.

6. The facilities and procedures for storing waste byproduct material prior to disposal.

7. The procedures for removing from storage, transporting, and returning to storage radiation sources for interstitial and intracavitary treatments and the accountability methods used to ensure that all sources are returned to storage.

8. Routine visual and radiation surveys that will be made of areas where byproduct material is used and stored.

9. Since sealed sources of radioactive material are tested for leakage at periodic intervals, submit information about how the leak test will be conducted.

NOTE: The application should specify that the leak test shall (1) be made by a person presently authorized by the Commission to perform such leak tests, or (2) describe how the test sample will be taken and confirm that the test will detect 0.005 microcuries of removable activity from the test sample. The applicant can obtain from the supplier of the sealed source information relative to persons and firms authorized to perform leak testing. Radioactive sources such as wire, needles, medical applicator capsules containing wire or needle sources, and metallic seeds do not require leak testing. Beta applicators and encapsulated radioactive material used in radiation effects studies and as calibration sources require leak testing.

10. The method used to keep records of receipt, transfer, and disposal of byproduct material, surveys, and personnel exposures.

11. If therapeutic doses of Iodine 131 and Gold 198 or Cobalt 60 are requested, include a copy of the operating instructions to nurses and hospital personnel concerning how to handle these patients and visitors to such patients.

APPENDIX I

INFORMATION FOR COMMISSION APPROVAL OF TREATMENT OR DISPOSAL BY INCINERATION

I. *For compounds containing isotopes such as Carbon 14, Hydrogen 3, Sulfur 35, etc., which volatilize at the temperature at which the incinerator operates.*

A. Quantity of each isotope to be disposed of in terms of microcuries per day or similar units.

B. Characteristics of the incinerator such as height of the stack, height of and distance to buildings in the surrounding area, rated air flow of the incinerator in cubic feet per hour or similar units, and expected dilution factors (if necessary).

C. The method of measurement of, or estimation of, the average concentration of radioactive material in the effluent at the point it leaves the stack.

II. *For compounds where significant portions of the isotopes may remain in the ash residue.*

A. The type, quantity, and chemical form of by-product material to be incinerated in terms of microcuries per day or similar units.

B. Characteristics of the incinerator such as height of the stack, height of and distance to buildings in the surrounding area, rated air flow of the incinerator in cubic feet per hour or similar units, and expected dilution factors (if necessary).

C. The method or measurement of, or estimation of, the average concentration of radioactive material in the effluent at the point it leaves the stack.

D. Describe the method of measurement or estimation of the concentration of radioactive material appearing in the ash residue.

E. The procedures which will be followed to prevent overexposure of personnel during all phases of the operation. Include instructions given to persons handling the combustibles and the ashes.

F. The method of disposing of contaminated ash.

U.S. GOVERNMENT PRINTING OFFICE: 1966 O—797-262

APPENDIX G

TYPES OF INSTRUMENTS NEEDED FOR MEDICAL PROGRAMS

The type and quantity of radiation detection instrumentation for a clinical radioisotope program depends upon (1) type and quantity of radioisotopes possessed and the nature of their use, (2) chemical and physical form of the isotopes, and (3) type and volume of work. Certain diagnostic and therapeutic uses of isotopes may involve specialized instrumentation. For example, Iodine 131 as Iodinated Human Serum Albumin for brain tumor localization and Phosphorus 32 for localization of brain and eye tumors involved the use of highly specialized scanning instrumentation including directional collimators or probes.

The attached table lists radiation detection instruments needed for various isotopes and uses.

INSTRUMENTATION NEEDED FOR MEDICAL USES OF BYPRODUCT MATERIAL

Item	I-131		P-32	Au-198	Co-60		Cr-51 Fe-59 S-35	H-3 C-14	Na-24 K-42	Co-58	Sr-85 Hg-197 Hg-203	Remarks
	Diag.	Ther.	Ther.	Ther.	Diag.	Ther.	Diag.	Diag.	Diag.	Diag.	Diag.	
Instrumentation:												
A. Measurement:												
1. Uptake	X	X	—	—	—	—	—	—	—	—	X	GM or scintillation. Detector and scalers (specialized scanning equipment for special diagnostic procedures).
2. Biological specimens.	X	—	—	—	X	—	X	X	X	X	—	Well-type scintillation detection and scaler—Liquid scintillation for H–3 & C–14.
B. Radiation survey:												
1. Low level	X	X	X	X	X	X	X	X	X	X	X	GM survey meter.
2. High level	—	X	—	X	—	X	—	—	—	—	—	Survey meter capable of measuring up to 1 roentgen per hour.
C. Personnel monitoring:												
1. Film badge	—	X	—	X	—	X	—	—	—	—	—	
2. Pocket meters	—	X	—	X	—	X	—	—	—	—	—	

X = Needed.
— = Not necessary.

APPENDIX I

INFORMATION FOR COMMISSION APPROVAL OF TREATMENT OR DISPOSAL BY INCINERATION

I. *For compounds containing isotopes such as Carbon 14, Hydrogen 3, Sulfur 35, etc., which volatilize at the temperature at which the incinerator operates.*

A. Quantity of each isotope to be disposed of in terms of microcuries per day or similar units.

B. Characteristics of the incinerator such as height of the stack, height of and distance to buildings in the surrounding area, rated air flow of the incinerator in cubic feet per hour or similar units, and expected dilution factors (if necessary).

C. The method of measurement of, or estimation of, the average concentration of radioactive material in the effluent at the point it leaves the stack.

II. *For compounds where significant portions of the isotopes may remain in the ash residue.*

A. The type, quantity, and chemical form of by-product material to be incinerated in terms of microcuries per day or similar units.

B. Characteristics of the incinerator such as height of the stack, height of and distance to buildings in the surrounding area, rated air flow of the incinerator in cubic feet per hour or similar units, and expected dilution factors (if necessary).

C. The method or measurement of, or estimation of, the average concentration of radioactive material in the effluent at the point it leaves the stack.

D. Describe the method of measurement or estimation of the concentration of radioactive material appearing in the ash residue.

E. The procedures which will be followed to prevent overexposure of personnel during all phases of the operation. Include instructions given to persons handling the combustibles and the ashes.

F. The method of disposing of contaminated ash.

U.S. GOVERNMENT PRINTING OFFICE: 1966 O—797-262

OTHER AEC LICENSING GUIDES

1. Plutonium-Beryllium Neutron Sources for Uses Other Than Well-Logging
2. Fabricated Plutonium Alpha Sources
3. Plutonium-Beryllium Neutron Sources for Well-Logging
4. Fabrication of Thorium-Magnesium Alloys Containing Not More Than 4 Percent Thorium
5. Processing Plutonium and Uranium 233
6. Processing Source Material
*7. Medical Standards for Reactor Operators
*8. Transportation of Irradiated Fuel Elements
*9. General Aspects of Byproduct Material Licensing
*10. Broad Byproduct Material Licenses
11. AEC Licensing Guide—Teletherapy Programs
12. The Purpose, Organization and Contents of Hazards Summary Reports for Power Reactors
13. AEC Licensing Guide—Industrial Radiography

*In preparation.