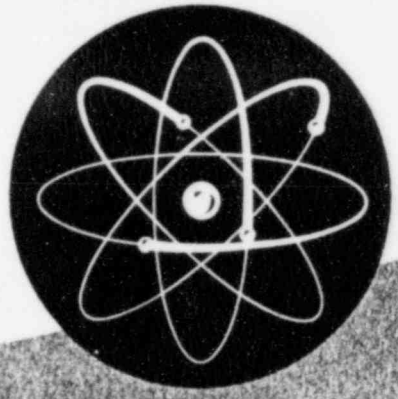


# AEC LICENSING GUIDE

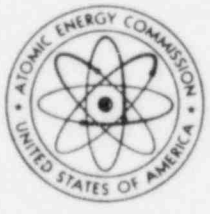
# MEDICAL PROGRAMS

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

★ DIVISION OF MATERIALS LICENSING ★

UNITED STATES ATOMIC ENERGY COMMISSION

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




April 1972

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

## 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 November 1965.

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 - Price 55 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:

| REGION | ADDRESS |
|---|---|
| I | Region I, Division of Compliance, USAEC<br>970 Broad Street<br>Newark, New Jersey 07102 |
| II | Region II, Division of Compliance, USAEC<br>Suite 818, 230 Peachtree St. N.W.<br>Atlanta, Georgia 30303 |
| III | Region III, Division of Compliance, USAEC<br>799 Roosevelt Road<br>Glen Ellyn, Illinois 60137 |
| IV | Region IV, Division of Compliance, USAEC<br>10395 West Colfax Avenue<br>Denver, Colorado 80215 |
| V | Region V, Division of Compliance, USAEC<br>2111 Bancroft Way<br>Berkeley, California 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.

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## APPENDICES

# 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 a 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 required that the physician so licensed personally conduct the program. Section 35.12, 10 CFR 35, outlines specific requirements for this type of 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

**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.*

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. 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. In addition, Form AEC-313a must be filed in duplicate for each physician. The application forms, with supporting documents, should be mailed to the Materials Branch, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545. Item 1(a) of Form AEC-313 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 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 Form 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 a diagnostic program under a general license must file Form AEC-482 in triplicate. The registration form should be mailed to the Materials 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.

# III. INFORMATION TO BE SUBMITTED

The information contained in an application must be sufficient to allow the Commission to determined 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 APPLICATION FOR BYPRODUCT MATERIAL LICENSE

*Item No.*

1(a) Explained in section II.

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 CFR 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 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 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.

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

*Item No.*

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 II

## 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. 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.

5(b) See appendix F.

6 Self-explanatory.

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 State the name and address of the physician in item 4 of Form AEC-313. If more than one physician is named in item 4 of Form AEC-313, 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 radioisotope training. Also state the name of

*Item No.*

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.

*Item No.*

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.

# IV. 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.)

## APPENDIX A

## SAMPLES OF TYPICAL LICENSES

I. **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. A physician is named as the licensee.

B. Condition 10 may provide for the use of byproduct material at more than a single address.

C. Condition 12 of the license limits the use of byproduct material to the physician. This condition should be interpreted to mean that the physician must (1) select patients for radioisotope diagnosis or treatment, (2) prescribe the radioisotope and dosage to be administered, and (3) interpret the results of the diagnosis and treatment. A technician may (a) prepare the radioisotope dosage prior to administration, (b) administer the material to the patient as directed by the physician, and (c) use counting or scanning equipment to obtain necessary data for the responsible physician.

D. This license may authorize diagnostic uses of radioisotopes which may not have been specifically requested by the applicant. Section 35.14 and 35.100, Schedule A, 10 CFR 35, allows the AEC to approve all diagnostic uses in a specific group of uses provided appropriate clinical experience and radiation detection instruments are evident. The diagnostic uses covered by Section 35.100 are as follows:

GROUP I

| ISOTOPE | CHEMICAL FORM | USE |
|---|---|---|
| Iodine 131 or iodine 125 | Sodium Iodide | Thyroid function studies |
| Iodine 131 or iodine 125 | Iodinated Human Serum Albumin (IHSA) | Determinations of blood plasma volume |
| Iodine 131 or iodine 125 | Rose Bengal | Liver function studies. |
| Iodine 131 or iodine 125 | Fats or Fatty Acids | Fat absorption studies. |
| Iodine 131 or iodine 125 | Iodopyracet, Sodium Iodohippurate, Sodium Diatrizoate, Diatrizoate Methyl-glucamine, Sodium Diprotrizoate, Sodium Acetrizoate, or Sodium Iothalamate | Kidney function studies |
| Chromium 51 | Human Serum Albumin | Gastrointestinal protein loss studies |

| ISOTOPE | CHEMICAL FORM | USE |
|---|---|---|
| Chromium 51 | Sodium Chromate | Determination of red blood cell volumes and studies of red blood cell survival time |
| Cobalt 58 or cobalt 60 | Cyanocobalamin (Vitamin B-12) | Intestinal absorption studies |
| Potassium 42 | Chloride | Potassium space determinations |
| Iron 59 | Chloride, Citrate or sulfate | Iron turnover studies |
| | **GROUP II** | |
| Iodine 131 | Iodinated Human Serum Albumin (IHSA) | Brain tumor localizations<br>Cardiac imaging |
| Iodine 131 | Sodium Iodide | Thyroid imaging |
| Iodine 131 | Macroaggregated Iodinated Human Serum Albumin | Lung imaging |
| Iodine 131 | Colloidal (microaggregated) Iodinated Human Serum Albumin | Liver imaging |
| Iodine 131 | Rose Bengal | Liver imaging |
| Iodine 131 | Iodopyracet, Sodium Iodohippurate, Sodium Diatrizoate, Diatrizoate Methylglucamine, Sodium Diproprizoate, or Sodium Acetrizoate | Kidney imaging |
| Iodine 131 | Sodium Iodipamide | Cardiac imaging |
| Chromium 51 | Sodium Chromate | Spleen imaging |
| Gold 198 | Colloidal Form | Live imaging |
| Mercury 197 | Chlormerodrin | Kidney imaging<br>Brain imaging |
| Mercury 203 | Chlormerodrin | Brain imaging |
| Strontium 85 | Nitrate or Chloride | Bone imaging in patients with known or suspected cancer |
| Technetium 99m | Pertechnetate | Brain imaging and thyroid imaging<br>Blood pool imaging<br>Salivary gland imaging |

E. This license does not include a specific possession limit for the radioisotopes authorized in Schedule A. The quantities possessed should be those required for the clinical program.

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

A. The license is issued to a hospital and condition 10 names the physicians under whose direction the radioisotopes may be used.

B. Condition 13 requires the sealed sources containing byproduct material to be leak tested every six months.

**III. 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 (M-3)
(2/70)
10 CFR 30

# U. S. ATOMIC ENERGY COMMISSION
## BYPRODUCT MATERIAL LICENSE
(Medical - Groups I & II)

Page 1 of 1 Pages

## LICENSE SAMPLE (1) - PRIVATE PRACTICE LICENSE

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 32, 33, 34, and 35, 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 as amended, 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. John H. Smith, M. D. | 3. License Number 37-00101-01 |
| 2. 606 Orchard Street<br>Pittsburgh, Pennsylvania 12221 | 4. Expiration date June 30, 1973 |
| | 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. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35 | A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35 | A. As necessary for uses authorized in Subitem 9. A. |
| B. Iodine 125 or 131 | B. Triiodothyronine | B. 1 millicurie |

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
B. In vitro studies.

CONDITIONS

10. Byproduct material may only be used at 606 Orchard Street, Pittsburgh, Pennsylvania; Mercy Hospital, 204 Mercy Street, Pittsburgh, Pennsylvania; and St. Joseph Hospital, 205 Allen Street, Monroeville, Pennsylvania.

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

Conditions numbered 2, 3, and 4 printed on the reverse side of this page shall apply to this license.

For the U. S. Atomic Energy Commission

Date _____

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

## CONDITIONS

1. Byproduct material may only be used at the licensee's address stated in Item 2 above.

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

3. Except as otherwise specifically provided by this license, byproduct material to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity.

4. Iodine 131 labeled Macroaggregated Iodinated Human Serum Albumin, Chromium 51 labeled Human Serum Albumin, and Iodine 131 labeled Colloidal (Microaggregated) Human Serum Albumin shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary, Department of Health, Education, and Welfare, to propagate or manufacture and prepare, label, or distribute this material pursuant to Title 42, Chapter 1, Code of Federal Regulations, Part 73, "Biological Products."

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

6. Patients containing Cobalt 60, Cesium 137, and/or Iridium 192 implants shall remain hospitalized until the implants are removed.

7. 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.

FORM AEC-374 (M-3)
(2/70)
10 CFR 30

# U. S. ATOMIC ENERGY COMMISSION
## BYPRODUCT MATERIAL LICENSE
(Medical - Groups I & II)

Page 1 of 3 Pages

## LICENSE SAMPLE (2) - INSTITUTIONAL LICENSE

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 32, 33, 34, and 35, 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 as amended, 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. Good Hope General Hospital | 3. License Number 45-00543-21 |
| 2. 2005 South Buran Avenue<br>Richmond, Virginia 22231 | 4. Expiration date June 30, 1975 |
| | 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. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35 | A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35 | A. As necessary for uses authorized in Subitem 9. A. |
| B. Iodine 131 | B. Iodide | B. 200 millicuries |
| C. Iodine 125 or 131 | C. Triiodothyronine | C. 1 millicurie |
| D. Phosphorus 32 | D. Soluble Phosphate | D. 25 millicuries |
| E. Phosphorus 32 | E. Colloidal Chromic Phosphate | E. 25 millicuries |
| F. Gold 198 | F. Colloidal | F. 300 millicuries |
| G. Cobalt 60 | G. Wire (Manufacturer and Model No.) | G. 200 millicuries |
| H. Strontium 90 | H. Sealed Source (Manufacturer and Model No.) | H. 50 millicuries |
| I. Cesium 137 | I. Chloride | I. 10 millicuries |
| J. Molybdenum 99 | J. Molybdenum 99/ Technetium 99m Generator (Manufacturer and Model No.) | J. 200 millicuries |

Conditions numbered 1, 2, 3, 4 printed on the reverse side of this page shall apply to this license.

For the U. S. Atomic Energy Commission

Date _____

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

## CONDITIONS

1. Byproduct material may only be used at the licensee's address stated in Item 2 above.

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

3. Except as otherwise specifically provided by this license, byproduct material to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity.

4. Iodine 131 labeled Macroaggregated Iodinated Human Serum Albumin, Chromium 51 labeled Human Serum Albumin, and Iodine 131 labeled Colloidal (Microaggregated) Human Serum Albumin shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary, Department of Health, Education, and Welfare, to propagate or manufacture and prepare, label, or distribute this material pursuant to Title 42, Chapter 1, Code of Federal Regulations, Part 73, "Biological Products."

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

6. Patients containing Cobalt 60, Cesium 137, and/or Iridium 192 implants shall remain hospitalized until the implants are removed.

7. 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.

FORM AEC-374A
(8-65)
10 CFR 30

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



License Number 45-00543-21

LICENSE SAMPLE (2) (continued)

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
B. Treatment of hyperthyroidism, cardiac conditions, and thyroid carcinoma.
C. In vitro studies.
D. Treatment of polycythemia vera and leukemia.
E. and F. Intracavitary treatment of malignant effusions.
G. Interstitial and intracavitary treatment of cancer as a replacement of radium.
H. Treatment of superficial eye diseases.
I. Brain imaging in 12 patients. Within six weeks after the completion of this study, the licensee is requested to furnish a report to the Commission which briefly summarizes the results of the study.
J. Production of Technetium 99m pertechnetate.

CONDITIONS

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

11. Technetium 99m Pertechnetate may be eluted and prepared from a Molybdenum 99/Technetium 99m generator in accordance with statements, representations, and procedures contained in application dated June 4, 1968.

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

13. 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.

For the U. S. Atomic Energy Commission

te _____

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

FORM AEC-374A
(2-68)
10 CFR 30

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

Page 3 of 3 Pages

License Number 45-00543-21

LICENSE SAMPLE (2) (continued)

13. continued

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 5 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, Suite 818, 230 Peachtree Street, Northwest, Atlanta, Georgia, 30303.

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

14. Sealed sources containing byproduct material shall not be opened.

For the U. S. Atomic Energy Commission

te _____

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

LICENSE SAMPLE (3)

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

U.S. ATOMIC ENERGY COMMISSION

FORM APPROVED
BUDGET BUREAU NO.
38 R-027

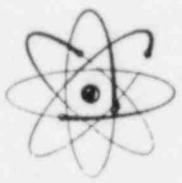
## REGISTRATION CERTIFICATE—MEDICAL USE OF BYPRODUCT MATERIAL UNDER GENERAL LICENSE

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 in 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.

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(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.

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**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, specialities, 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 uses 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 instituion.

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 organizations 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 the 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 Associated Universities "Basic Course in Radioisotope 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. 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 labeled human

serum albumin for gastrointestinal protein loss studies; cobalt 60 or 58 labeled cyanocobalamin for intestinal absorption studies; iron 59 as chloride, citrate and/or sulfate for iron turnover studies; potassium 42 as chloride for potassium space determinations; krypton 85 as gas for diagnosis of cardiac abnormalities; and xenon 133 as free gas or in solution for diagnosis of cardiac abnormalities, blood-flow studies and pulmonary function studies. 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.

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

The specialized diagnostic procedures covered by Category II are iodide for thyroid imaging; iodinated human serum albumin for brain tumor localization, cardiac imaging for determination of pericardial effusions, and placenta localization; sodium iodipamide for cardiac imaging for determination of pericardial effusions; labeled renal function compunds for kidney imaging; chromium 51 for spleen imaging and placenta localization; macroagregated iodinated human serum albumin for lung imaging; microaggregated (colliodal) human serum albumin for liver imaging; strontium 85 as nitrate or chloride for bone imaging in patients with known or suspected cancer; selenium 75 as selenomethionine for pancreas imaging; and mercury 197 for brain and renal imaging; and mercury 203 for brain imaging; technetium 99m as sulfur colloid for liver and spleen imaging; and technetium 99m as pertechnetate for brain, thyroid, salivary, blood pool imaging, and placenta localization.

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

2. Active participation in the performance of three tumor localizations or organ images using byproduct material, except that for pancreas imaging the physician must have been actively engaged in conducting images for at least six months and have participated in at least three (3) pancreas images under the supervision of a physician already experienced in this procedure.

*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. The applicant requesting iodinated human serum albumin, chromium 51, or technetium 99m for placenta localization should confirm that the procedure will be performed only if:*

*1. The patient is in the third trimester of pregnancy;*
*2. The pateint is bleeding; and*
*3. The obstetrician recommends the study for the management of the patient.*

*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.

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

1. Thirty hours of training in basic radioisotope 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. Treatement 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 determination 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 |
|---|---|---|
| Cesium 137 | Encased in Needles and/or Applicator Cells | Interstitial or intracavitary treatment of cancer |
| Cesium 137 | Teletherapy Source | Treatement of cancer |
| Chromium 51 | Chromate | Spleen imaging |
| Chromium 51 | Chromate | Placenta localication |
| Chromium 51 | Chromate | Red blood cell labeling for volume and survival studies |
| Chromium 51 | Labeled Human Serum Albumin | Gastrointestinal protein loss studies |
| Chromium 51 | Labeled Human Serum Albumin | Placenta localization |
| Chromium 51 | Labeled Red Blood Cells | Placenta localization |
| Cobalt 58 or Cobalt 60 | Labeled Cyanocobalamin | Intestinal absorption studies |
| Cobalt 60 | Teletherapy Source | Treatment of cancer |
| Cobalt 60 | Encased in Needles and/or Applicator Cells | Interstitial or intracavitary treatment of cancer |
| Gold 198 | Colloidal | Liver imaging |
| Gold 198 | Colloidal | Intracavitary treatment of malignant effusions |
| Gold 198 | Colloidal | Interstitial treatment of cancer |
| Gold 198 | Seeds | Interstitial treatment of cancer |
| Iodine 131 | Iodide | Diagnosis of thyroid function |
| Iodine 131 | Iodide | Thyroid imaging |

| ISOTOPE | CHEMICAL FORM | USE |
|---|---|---|
| Iodine 131 | Iodide | Treatment of hyperthyroidism and/or cardiac dysfunction |
| Iodine 131 | Iodide | Treatment of thyroid carcinoma |
| Iodine 131 | Iodinated Human Serum Albumin | Blood volume determination |
| Iodine 131 | Iodinated Human Serum Albumin | Brain tumor localization |
| Iodine 131 | Iodinated Human Serum Albumin | Placenta localization |
| Iodine 131 | Iodinated Human Serum Albumin | Cardiac imaging for determination of pericardial effusions |
| Iodine 131 | Iodinated Human Serum Albumin | Cisternography |
| Iodine 131 | Rose Bengal | Liver function studies |
| Iodine 131 | Rose Bengal | Liver imaging |
| Iodine 131 | Iodopyracet, Sodium Iodohippurate Sodium Diatrizoate, Diatrizoate Methyl-glucamine, Sodium Diprotrizoate, Sodium Acetrizoate, or Sodium Iothalamate | Kidney function studies and kidney imaging |
| Iodine 131 | Labeled Fats and/or Fatty Acids | Fat absorption studies |
| Iodine 131 | Sodium Iodipamide | Cardiac imaging for determination of pericardial effusions |
| Iodine 131 | Macroaggregated Iodinated Human Serum Albumin | Lung imaging |
| Iodine 131 | Colloidal Microaggregated Human Serum Albumin | Liver imaging |
| Iodine 125 | Iodide | Diagnosis of thyroid function |
| Iodine 125 | Iodinated Human Serum Albumin | Blood volume determination |
| Iodine 125 | Rose Bengal | Liver function studies |

| ISOTOPE | CHEMICAL FORM | USE |
|---|---|---|
| Iodine 125 | Iodopyracet, Sodium Iodohippurate, Sodium Diatrizoate, Diatrizoate Methyl-glucamine, Sodium Diprotrizoate, Sodium Acetrizoate, or Sodium Iothalamate | Kidney function studies |
| Iodine 125 | Labeled Fats and/or Fatty Acids | Fat absorption studies |
| Iron 59 | Chloride, Citrate and/or Sulfate | Iron turnover studies |
| Iridium 192 | Seeds Encased in Nylon Ribbon | Interstitial treatment of cancer |
| Krypton 85 | Gas | Diagnosis of cardiac abnormalities |
| Mercury 197 | Chlormerodrin | Kidney imaging |
| Mercury 197 | Chlormerodrin | Brain imaging |
| Mercury 203 | Chlormerodrin | Brain imaging |
| Phosphorus 32 | Soluble Phosphate | Treatment of polycythemia vera |
| Phosphorus 32 | Soluble Phosphate | Treatment of leukemia and bone metastasis |
| Phosphorus 32 | Colloidal Chromic Phosphate | Intracavitary treatment of malignant effusions |
| Phosphorus 32 | Colloidal Chromic Phosphate | Interstitial treatment of cancer |
| Potassium42 | Chloride | Potassium space studies |
| Selenium 75 | Selenomethionine | Pancreas imaging |
| Strontium 85 | Nitrate or Chloride | Bone imaging on patients with known or suspected cancer |
| Strontium 90 | Medical Applicator | Treatment of superficial eye conditions |
| Technetium 99m | Pertechnetate | Brain imaging |
| Technetium 99m | Pertechnetate | Thyroid imaging |
| Technetium 99m | Sulfur Colloid | Liver and Spleen imaging |

| ISOTOPE | CHEMICAL FORM | USE |
|---|---|---|
| Technetium 99m | Pertechnetate | Placenta localization |
| Technetium 99m | Pertechnetate | Blood pool imaging |
| Technetium 99m | Petechnetate | Salivary gland imaging |
| Technetium 99m | Iron-Ascorbate-Diethylenetriamine Pentaacetic Acid Complex | Kidney imaging |
| Xenon 133 | Free Gas or in solution | Diagnosis of cardiac abnormalties<br>Blood-flow studies<br>Pulmonary function studies |

## APPENDIX E

## SAMPLE APPLICATIONS

1. Sample Application No. 1 is a Form AEC-313 and -313a request for an institutional license.
2. Sample Application No. 2 is a Form AEC-313 and -313a request for a private practice license.

APPLICATION - SAMPLE 1.

| 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<br>Radioisotope Service<br>234 West Main Street<br>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)

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 | beta, gamma | 0 - 20 | 3.5 | Surveying |
| Z Instr. Co. Model 5 Ionization Chamber | 1 | beta, gamma | 0 - 5000 | 20 | Monitoring |
| Z Instr. Co. Model 21 Scaler | 1 | - | - | - | Measuring |
| Z Instr. Co. Model 18 Well Scintillation | 1 | gamma | - | - | Measuring |
| Z Instr. Co. Model 23 Scintillation Probes | 2 | gamma | - | - | 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 IN DUPLICATE**

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, 1972

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 : 1968 O—322-213

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 Medial 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 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 technique 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*

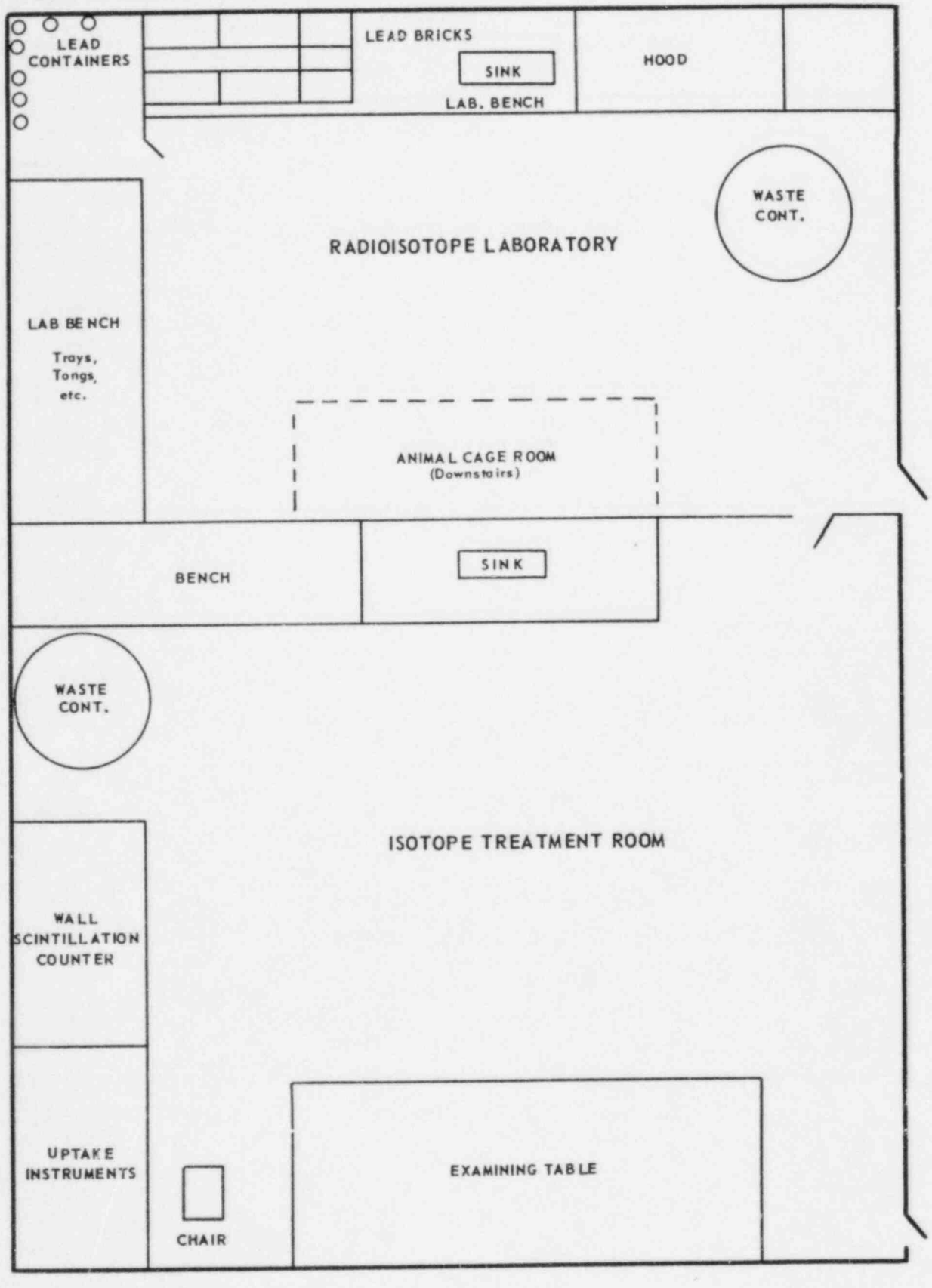
**SAMPLE**

**NURSING INSTRUCTIONS FOR PATIENTS RECEIVING COBALT 60**

Patient _____
mc of *cobalt 60* was inserted on _____

at_____p.m._____

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

_____
(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 coun' d.

*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

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 (Include ZIP Code)

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 | | |
| | Dilution studies | | |
| | Excretion studies | | |
| | Brain tumor localization | | |
| | Scanning studies | | |
| | Treatment of hyperthyroidism | | |
| | Treatment of cardiac conditions | | |
| | Treatment of thyroid carcinoma | | |
| 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 1958 to June 1971 1,000 hours +

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

John F. Smith

AT University Hospital, Durham, Missouri (Institution) Name and Address 01-00021-01 (Byproduct Material License Number)

John F. Smith, M.D.
Chairman, Isotope Committee
(Preceptor's Name and Title)

Page Two

TRAINING AND EXPERIE! OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use emental 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./cm.²) | 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 | 30 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 IN DUPLICATE**

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, 1972

By John A. D. Doe, M.D.
John A. D. Doe
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 : 1968 O—322-213

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 (Include ZIP Code)

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 hype-thyroidism | 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, 1971 to July 21, 1971 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

02-00034-01 (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, 1972

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

## 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.<br>502 Medical Plaza<br>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-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)

## 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 animals 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 by 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 rationale for using the dose selected.

C. 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.

Each report should include:

A. A statement of the purpose for conducting the study.

B. A summary of the clinical information provided by the diagnostic or therapeutic procedure which includes the following information:

(1.) The radioisotope administered, its chemical form, and route of administration.

(2.) The number of patients involved in the study, their ages, sex, and clinical diagnosis before administration of the radiopharmaceutical.

(3.) The dosage and frequency of administration.

(4.) Complementary drugs administered, if any.

(5.) The method of preparation of the radiopharmaceutical, if it was not obtained in a prepackaged, precalibrated, sterile and pyrogen-free form from a pharmaceutical supplier.

(6.) Special radiation detection instrumentation used.

(7.) A statement of organ distribution and an estimate of the respective biological half-life of the administered radioisotope as determined during the course of the study. State the rationale behind these estimates or methods used to make the determination.

(8.) A synopsis of the toxicity data obtained.

(9.) Brief clinical histories of all patients exhibiting any adverse reactions to any radiopharmaceutical administered. The investigator should describe the reaction and include his interpretation of the nature and cause of the reaction.

C. An evaluation by the investigator of the safety and efficacy of the diagnostic or therapeutic procedure. This evaluation should include a statement of side effects, toxicity, contraindications, and ineffectiveness. In the case of diagnostic procedures, the investigator should state whether or not the resultant diagnosis was confirmed by other methods.

## 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 | Mo 99/ to 99m generator | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Diag. | Ther. | Ther. | Ther. | Diag. | Ther. | Diag. | Diag. | 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 | X | GM survey meter. |
| 2. High level | — | X | — | X | — | X | — | — | — | — | — | X | Survey meter capable of measuring up to 1 roentgen per hour. |
| C. Personnel monitoring: | | | | | | | | | | | | | |
| 1. Film badge | — | X | — | X | — | X | — | — | — | — | — | X | |
| 2. Pocket meters | — | X | — | 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 should be submitted.

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. The 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, information about how the leak tests 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 microcurie 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 reciept, 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, 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 of 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 byproduct 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 areas, 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.

D. 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.

## 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

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*In preparation.

U.S. NUCLEAR REGULATORY COMMISSION

January 1979

# REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 10.8

## GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL PROGRAMS

### 1. INTRODUCTION

#### 1.1 Purpose of Guide

This guide describes the type and extent of information needed by the Nuclear Regulatory Commission (NRC) staff to evaluate an application for a specific license for the possession of byproduct material (reactor-produced radionuclides) and its use in or on human beings. This type of license is provided for under 10 CFR Part 35, "Human Uses of Byproduct Material."

The NRC will usually issue a single byproduct material license to cover an institution's entire radioisotope program other than teletherapy. Separate licenses, except for teletherapy, are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the hospital.

The applicant should carefully study the regulations (see Section 1.2 of this guide) and this guide and should submit all information requested. The NRC will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

#### 1.2 Applicable Regulations

In addition to 10 CFR Part 35, other regulations pertaining to this type of license are found in 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections;" 10 CFR Part 20, "Standards for Protection Against Radiation;" 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material;" and 10 CFR Part 170, "Fees for Facilities and Materials Licenses."

#### 1.3 Items Requiring Separate Applications

A separate application should be submitted for kilocurie sources used in teletherapy facilities. A specific licensing guide for teletherapy applications is available upon request from the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Source and Special Nuclear Materials. Except for depleted uranium used for shielding in linear accelerators or teletherapy devices, separate applications should be submitted for these materials in accordance with 10 CFR Part 40, "Domestic Licensing of Source Material," and Part 70, "Domestic Licensing of Special Nuclear Material." Source material is defined in paragraph 40.4(h) of 10 CFR Part 40 as (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores that contain by weight 1/20 of one percent (0.05%) or more of (a) uranium, (b) thorium, or (c) any combination thereof. Source material does not include special nuclear material.

Special nuclear material is defined in paragraph 70.4(m) of 10 CFR Part 70 and includes (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any one of the foregoing but does not include source material.

### 1.4 As Low As Is Reasonably Achievable (ALARA)

Paragraph 20.1(c) of 10 CFR Part 20 states that "...persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," provides the NRC staff position on this important subject. Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," provides ways of applying the ALARA philosophy in medical institutions. License applicants should give consideration to the ALARA philosophy, as described in Regulatory Guides 8.10 and 8.18, in the development of plans for work with radioactive materials. NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable," contains information and references useful in establishing radiation safety programs to maintain exposures ALARA in medical institutions.

### 1.5 Types of Materials Licenses

The general license provided in §35.31 of 10 CFR Part 35 authorizes the 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-58 and cobalt-60 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 and receive a registration number prior to receiving or using the diagnostic radiopharmaceuticals covered by the general license.

Section 31.11 of 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," establishes a general license authorizing physicians, clinical laboratories, and hospitals to possess certain small quantities of byproduct material (iodine-125, iodine-131, carbon-14, hydrogen-3, iron-59, selenium-75, and mock iodine-125 reference sources) for in vitro clinical or laboratory tests not involving the internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals. Section 31.11 explains the general license requirements and requires the applicant to register with the Commission and receive a registration number prior to receiving or using the byproduct material for in vitro testing.

Licenses issued to physicians for private practice specify the radioisotopes and the clinical uses that may be performed by the physician to whom the license is issued. Such licenses are issued to physicians who are located in private offices and not on hospital premises. It is not required that a medical isotopes* committee be formed. The private practice license does not permit other physicians to obtain clinical radioisotope training and experience under it. Section 35.12 of 10 CFR Part 35 outlines specific requirements for this type of license.

Specific licenses of limited scope issued to institutions specify the radioisotopes and the clinical uses that may be performed by physicians named on the institution's license. The regulations in paragraph 35.11(b) of 10 CFR Part 35 require an institutional licensee to have a medical isotopes committee (see Appendix B to this guide) 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 medical 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 that may enable them to qualify as individual users. Training and experience criteria for physicians are outlined in Appendix A to this guide.

Specific licenses of broad scope for medical use, i.e., licenses authorizing multiple quantities and types of byproduct material for unspecified uses, are issued to institutions that (1) have had previous experience operating under a specific institutional license of limited scope 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.

Individual users are not named on the license nor are radioisotopes limited to specified uses. Individual users and procedures are approved by the institution's medical isotopes committee. Physicians may obtain basic and clinical radioisotope training and experience in the use of radiopharmaceuticals in such programs. This type of license is not appropriate for most institutions using byproduct material in medical programs.

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*Alternative titles are "radioisotope" or "radiation safety" committee.

## 2. LICENSE FEES

An application fee is required for most types of licenses. The applicant should refer to §170.12, "Payment of Fees," and §170.31, "Schedule of Fees for Materials Licenses," of 10 CFR Part 170 to determine the amount of fee that must accompany the application. Review of the application will not begin until the proper fee is received by the NRC.

## 3. FILING AN APPLICATION

A license application for specific licenses for human use should be submitted on Form NRC-313M, "Application for Materials License--Medical" (see Exhibit A). The applicant should complete all items on the application form in sufficient detail for the NRC staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form NRC-313M is limited, the applicant should append separate sheets of paper for Items 7-23 listed in the form or may indicate by checking the appropriate box that specific procedures will be followed. Each separate sheet should contain the item number and the application date in the lower right corner.

One copy of the application, with all attachments, should be retained by the applicant, since the license will require as a condition that the licensee follow the statements and representations set forth in the application and any supplement to it. The original and one copy should be mailed to the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

## 4. CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form NRC-313M.

Item 1.a. Enter the name, mailing address, and telephone number of the applicant. If the request is for a private license, enter the name of the physician or partnership.

Item 1.b. List the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1.a. 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.

Item 2. Enter the name and telephone number (including area code) of the individual to be contacted.

Item 3. Indicate whether this is an application for a new license, an amendment, or a renewal.

Item 4. List the full names of all physicians who will use or directly supervise the use of byproduct material. These are the physicians who use the byproduct material directly or who are direct supervisors of physicians, technicians, technologists, or other paramedical personnel to whom specific activities are delegated.

Physicians under direct supervision of the named users may be delegated the following responsibilities:

a. The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources.

b. The prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered.

c. The determination of the route of administration.

d. The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

Properly trained technicians, technologists, or other paramedical personnel under a user's supervision may be delegated the following activities:

a. Preparation and quality control testing of radiopharmaceuticals and sources of radiation.

b. Measurement of radiopharmaceutical doses prior to administration.

c. Use of appropriate instrumentation for the collection of data to be used by the physician.

d. Administration of radiopharmaceuticals and radiation from radioisotope sources to patients, within limits otherwise permitted under applicable Federal, State, or local laws.

Item 5. State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program.

Item 6.a. For routine human use, the applicant may check the group numbers of Schedule A in §35.100 of 10 CFR Part 35 for which the license is requested. Groups I, II, and III consist of the more commonly used diagnostic procedures that involve radiopharmaceuticals; Groups IV and V consist of routine therapeutic procedures that involve radiopharmaceuticals; and Group VI consists of sealed sources used primarily for therapeutic procedures.

For Groups I, II, IV, and V, possession limits are not listed on the license.

For Group III, the possession limit will be two curies of each radioactive material listed unless a larger limit is requested in the application. State the requested possession limit for Group VI and any radioactive material listed separately from Groups I through V. The possession limit for each radionuclide includes material held as radioactive waste.

Item 6.b. For routine human use not listed in Groups I through VI and for nonhuman use, list each radionuclide to be used, the chemical and physical form, and the maximum quantity (in millicuries).

List the manufacturer's name, model number, and activity (in millicuries) for all sealed sources. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under paragraph 35.14(d) of 10 CFR Part 35 and should not be listed.)

A specific authorization must be obtained from the NRC to perform studies involving the use of radioactive material in animals.

Describe the intended use for each radionuclide and form listed in Item 6.b. If the radioactive material is for human use and has not been approved for routine human use by the Food and Drug Administration (FDA), submit evidence that procurement, preparation, and use of the material will be in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. If the study is conducted under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) sponsored by the physician or institution, state the radionuclide, chemical form, possession limit, and use, and submit a copy of the IND acceptance letter from the FDA.

Item 7 Medical Isotopes Committee. In accordance with paragraph 35.11(b) of 10 CFR Part 35, an institution applying for a byproduct material license for human use is required to establish a medical isotopes committee of at least three members. This committee evaluates all proposals for research, diagnosis, and therapeutic use of radioisotopes. Membership of the committee should include:

a. At least one physician specializing in nuclear medicine, internal medicine, hematology, therapeutic radiology, diagnostic radiology, or pathology, who will use or directly supervise the use of radioactive materials in humans.

b. A person with special competence in radiation safety.

c. A representative of the institution's management.

Submit the following information:

a. The responsibility and duties of the committee.

b. The meeting frequency of the committee (at least quarterly).

c. The name and specialty of each member of the committee.

Appendix B to this guide contains an example of typical responsibilities and duties for a medical isotopes committee. Indicate, by checking the appropriate box in Item 7, that the responsibilities, duties, and meeting frequency will be as described in Appendix B, or propose alternatives. If the responsibilities, duties, or meeting frequency will be different from those described, submit a complete description.

Item 8 Training and Experience

a. Authorized User(s). If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license number (if issued by the AEC or NRC) or a copy of the license (if issued by an Agreement State).

If the physician has not been previously authorized to use the radioactive material being requested, state where he is licensed to practice medicine, and submit a complete description of his training and experience. Use Supplements A and B to Form NRC-313M (see Exhibit A) for the description of the physician's training and experience. Criteria for acceptable training and experience are contained in Appendix A.

b. Radiation Safety Officer. If the radiation safety officer is not one of the physicians named in Item 4, submit a complete description of his training and experience. Supplement A to Form NRC-313M may be used for the description of the radiation safety officer's training and experience.

Item 9 Instrumentation. Instruments required in a typical nuclear medicine laboratory are:

a. Survey Instruments

(1) A low-level survey meter capable of detecting 0.1 milliroentgen per hour to perform contamination surveys.

(2) A high-level survey meter such as an ionization type capable of reading up to 1 roentgen per hour to measure radiation exposure rates that may exist in the vicinity of Mo-99/Tc-99m generators and therapeutic quantities of radioactive material.

b. Dose calibrators and other instruments to assay radiopharmaceuticals.

c. Diagnostic instruments for all procedures (e.g., gamma camera, well counter, thyroid probe).

d. Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

Appendix C to this guide contains a form that may be used to describe the instruments. Complete this form by listing the instruments to be used. If this form is not used, attach equivalent information. Check the appropriate box in Item 9 of Form NRC-313M.

Item 10 Calibration of Instruments

a. Survey Instruments. An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily constancy checks of survey instruments should be supplemented at least every 12 months with a battery check and two-point calibration on each scale of the instrument. One point should be in each half of the scale, and the two points should be separated by 35-50% of full scale. Survey instruments should also be calibrated after repair and after battery replacement.

A survey instrument may be considered properly calibrated at one po when the exposure rate measured by the instrument differs from the true exposure rate by less than 10% of full scale.

If you propose to calibrate your own radiation survey and monitoring instruments, submit a detailed description of your planned calibration procedures. Include in the description:

(1) The manufacturer's name and model number of the source(s) to be used.

(2) The nuclide and activity (in millicuries) of radioactive material contained in the source.

(3) The accuracy* of the source(s).

(4) The step-by-step procedures, including associated radiation safety procedures. These procedures should include a two-point calibration of each scale of each instrument with the points separated by 35-50% of full scale.

*The maximum deviation of the nominal value of the source from the true value. This information is normally provided by the manufacturer.

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, specify his name, address, and the license number. Contact the firm or consultant that will provide the calibration to determine if information concerning calibration services and procedures has been filed with the Commission. If this information has not been filed, submit it with your application.

Section 1 of Appendix D to this guide contains an acceptable procedure for calibrating survey instruments and a form that may be used to supply the information required in Item 10 of the application form. Indicate, by checking the appropriate box in Item 10 of Form NRC-313M, if the procedure described in Appendix D will be followed. If the procedure in Appendix D is not followed, submit equivalent procedures.

b. Dose Calibrator. All radiopharmaceuticals should be assayed for activity to an accuracy of 10% prior to being administered to patients. The usual method for performing assays is with a dose calibrator. Upon installation and periodically thereafter, dose calibrators should be tested for accuracy of response for the energies commonly used, for geometrical variation, for linearity of response over the entire range of activities to be used, and for day-to-day constancy of operation.

Submit a description of your calibration procedures. These should include as a minimum:

(1) The manufacturer's name and model number of any sealed sources to be used (unless authorized by paragraph 35.14(d) of 10 CFR Part 35).

(2) The nuclide and activity (in millicuries) of radioactive material in the standards.

(3) The accuracy of the standard.

(4) The step-by-step procedures used for calibration.

If an instrument other than a dose calibrator is used to assay patient doses, submit a complete description of:

(1) The assay method.

(2) The method of calibration.

(3) The frequency of calibration.

(4) The standards to be used for calibration (radionuclide, activity, accuracy).

Section 2 of Appendix D contains a description of an acceptable procedure for calibrating dose calibrators and a form that may be used to

supply the information required in Item 10 of this application form. Indicate, by checking the appropriate box in Item 10 of Form NRC-313M, if the procedure in Appendix D for calibrating dose calibrators will be followed. If Appendix D is not followed, submit equivalent procedures.

c. Diagnostic Instruments. The manufacturer's directions should be followed for calibration and maintenance of diagnostic instrumentation.

Item 11 Facilities and Equipment. Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation, and measurement of radioactive material.

Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Indicate any wall shielding, special storage area shielding, or movable shielding around storage areas, generators, kit preparation areas, etc.

For facilities in which radioactive material may become airborne, include schematic descriptions of the ventilation system in the diagrams with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Draw diagrams to a specified scale, or indicate dimensions.

Figures 1 and 2 contain examples of acceptable facility and equipment descriptions.

Item 12 Personnel Training Program. Describe the training required for all personnel who work with or in the vicinity of radioactive materials. Include the form of training (e.g., formal course work, lectures), frequency of training, duration of training, and subject matter. The training program should be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel, receive proper instruction in the items specified in §19.12 of 10 CFR Part 19, including:

a. Areas where radioactive material is used or stored.

b. Potential hazards associated with radioactive material.

c. Radiological safety procedures appropriate to their respective duties.

d. Pertinent NRC regulations.

e. Rules and regulations of the licensee.

f. Pertinent terms of the license.

g. Their obligation to report unsafe conditions.

h. Appropriate response to emergencies or unsafe conditions.

i. Their right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Verify that personnel will be properly instructed:

a. Before assuming duties with or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regulations, or the terms of the license.

Item 13 Procedures for Ordering and Receiving Radioactive Material. Describe procedures for ordering radioactive materials, for receiving materials during off-duty hours, and for notifying responsible persons upon receipt of radioactive materials. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive materials are secured at all times against unauthorized removal, and that radiation levels in unrestricted areas do not exceed the limits specified in §20.105 of 10 CFR Part 20.

Security personnel, nursing personnel, or anyone else who receives packages during off-duty hours should be issued written instructions as to procedures to be followed for receiving, examining, and securing the package; for notification procedures if the package is found or suspected to be leaking; and the immediate steps to be taken to prevent spread of contamination.

Appendix E to this guide contains sample procedures and instructions for ordering and receiving packages containing radioactive material. Attach a copy of your procedures.

Item 14 Procedures for Safely Opening Packages Containing Radioactive Materials. Describe your procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages in accordance with §20.205 of 10 CFR Part 20. Perform the monitoring as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but should, at a minimum, include instructions for surveying packages, wearing gloves while

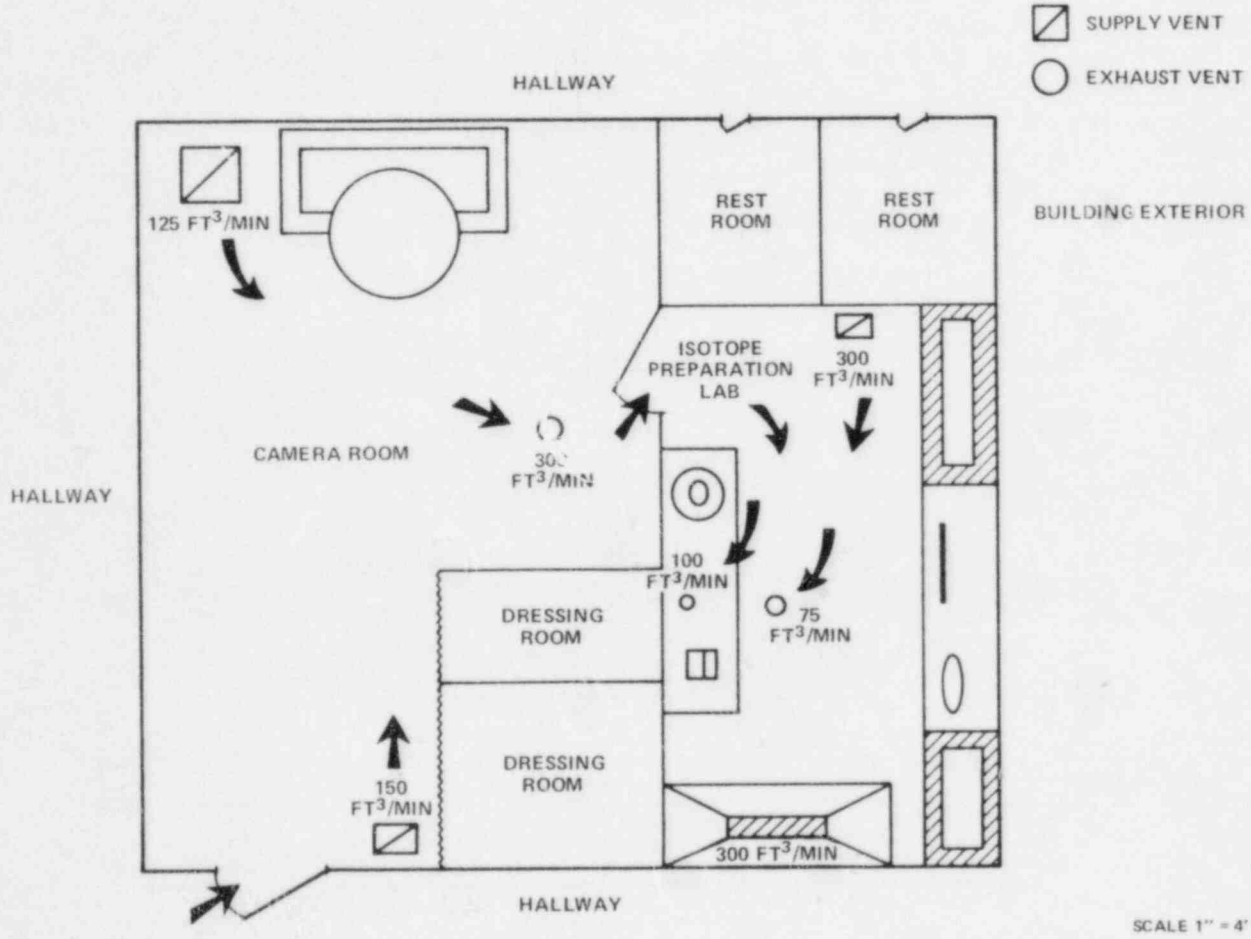


FIGURE 1.
EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR
A FACILITY DESCRIPTION INCLUDING VENTILATION FLOW RATES

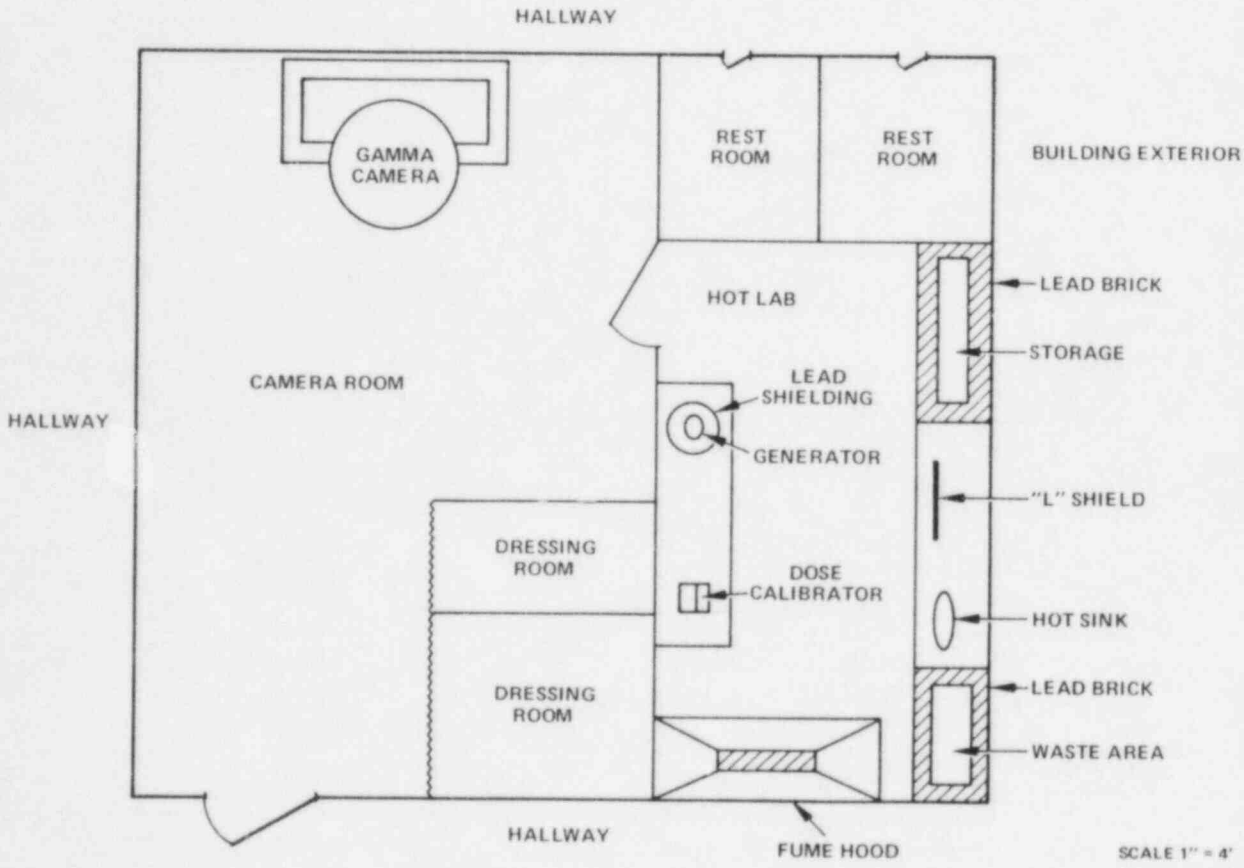


FIGURE 2.
EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR
A FACILITY DESCRIPTION INCLUDING SHIELDING PROVISIONS

opening packages, and checking packing material for contamination after opening. Even though §20.205 exempts certain packages from immediate monitoring, it is necessary that procedures be established for safely opening all packages containing radioactive material.

Appendix F to this guide contains a description of an acceptable procedure for safely opening packages. Indicate, by checking the appropriate box in Item 14 of Form NRC-313M, that the procedure in Appendix F will be followed, or attach equivalent procedures.

Item 15 General Rules for the Safe Use of Radioactive Material. Describe the general instructions to be followed by physicians and technologists while working with radioactive materials. The instructions should:

a. Outline control procedures for obtaining permission to use radioactive material at the institution.

b. Explain what laboratory apparel to wear and what equipment to use, e.g., wearing of laboratory coats and use of disposable gloves and trays.

c. Prescribe limitations and conditions for handling liquid or loose radioactive materials and the laboratory equipment to use in working with them. For example, specify which materials and operations should be confined to radiochemical fume hoods or gloveboxes.

d. Specify the shielding or remote handling equipment to be used when hard beta- and/or gamma-emitting materials are handled. Preparation of radiopharmaceuticals from reagent kits should be done behind shielding. Syringe shields should be used for the preparation and administration of patient doses.

e. Give instructions for preparation and assay of patient doses.

f. Give instructions concerning movement of material between rooms, in halls, or in corridors, if applicable.

g. Explain requirements for storage of materials, labeling of containers, and identification of areas where radioactive materials are used. Describe the shielding used for areas where large amounts of byproduct material are stored.

h. Specify personnel monitoring devices to be used, where to obtain them, and instructions for recording exposure results or properly turning in personnel monitoring devices for processing at appropriate intervals.

i. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived).

j. Describe contamination control procedures, including prohibitions against smoking, eating, drinking, or applying cosmetics in restricted areas and instructions for individuals who prepare doses and radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

For smaller programs, Appendix G to this guide contains an acceptable set of laboratory rules for the safe use of radioactive material. Indicate, by checking the appropriate box in Item 15 of Form NRC-313M, if Appendix G rules will be followed, or attach equivalent procedures.

Item 16 Emergency Procedures. Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should (a) describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, evacuation of the area, containment of the spill), (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency, and (c) instruct personnel on appropriate methods for re-entering, decontaminating, and recovering facilities that may have been accidentally contaminated.

An acceptable set of emergency procedures is contained in Appendix H to this guide. Indicate, by checking the appropriate box in Item 16 of Form NRC-313M, that you will follow the emergency procedures in Appendix H, or submit a copy of equivalent procedures.

Item 17 Area Survey Procedures. Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provisions for maintaining records of surveys. (A regulatory guide on radiation safety surveys at medical institutions is now under development.)

If the application is to cover multiple users and areas of use, the individual user should perform surveys of his own work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in Appendix I to this guide. Indicate, by checking the appropriate box in Item 17 of Form NRC-313M, that you will follow survey procedures in Appendix I, or submit equivalent procedures.

Item 18 Waste Disposal. Describe specific methods used for disposal of waste byproduct material. A licensee may dispose of waste by:

a. Transfer to a person properly licensed to receive such waste, e.g., commercial waste disposal firms. (See §20.301 of 10 CFR Part 20.) Submit the name and the NRC or Agreement State license number of the commercial firm selected.

b. Release into a sanitary sewer in conformance with §20.303 of 10 CFR Part 20. Describe your methods for controlling the sewage disposals of radioactive wastes in order to ensure that disposals do not exceed the limits specified in §20.303 of 10 CFR Part 20.

c. Burial in soil in conformance with §20.304 of 10 CFR Part 20.

d. Release into the air in conformance with §20.106 of 10 CFR Part 20.

e. Other methods specifically approved by the Commission pursuant to §20.302 of 10 CFR Part 20.

Note: No licensee may dispose of byproduct material waste by incineration unless specifically approved by the Commission. (See §20.305 of 10 CFR Part 20.)

Appendix J to this guide contains a form that may be used to supply the information requested in Item 18 of the application form. Indicate, by checking the appropriate box in Item 18 of Form NRC-313M, that you will dispose of wastes as specified on the form in Appendix J, or attach equivalent information.

Item 19 Therapeutic Use of Radiopharmaceuticals. Describe special precautions for patients treated with byproduct material listed in Groups IV and V, Schedule A, §35.100 of 10 CFR Part 35. Although Group IV procedures are often performed on an outpatient basis, hospitalization is sometimes required.

Establish appropriate procedures for all patients treated with byproduct material and include:

a. Method for preparation and administration of therapeutic doses of iodine-131. Instruct personnel to wear gloves and to open containers of iodine-131 in a fume hood with adequate airflow or to take other precautionary measures to prevent contamination of themselves and surrounding areas.

b. Methods for contamination control

(1) Assignment to private room.

(2) Use of disposable items (e.g., dishes, utensils).

c. Procedures for surveys of

(1) Unrestricted areas.

(2) Linens and other items removed from patient's room.

(3) Patient's room before it is reassigned to another patient.

[Licensees should also perform surveys (e.g., measurement of iodine-131 in air; measurement of iodine-131 in the thyroid gland of laboratory personnel; contamination surveys of personnel, equipment, and facilities) to determine compliance with §§20.103 and 20.106 of 10 CFR Part 20.]

d. Instructions to nursing staff.

e. Procedures for disposal of waste.

(1) Patient excreta.

(2) Surgical dressings.

(3) Disposable items.

f. Procedures to be followed in case of emergency surgery or death.

g. Procedures for release of patients.

(1) Criteria for release of patients.

(2) Instructions to patients and families.

h. Procedures for bioassay of personnel. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of iodine-131 for therapeutic doses. Guidance on situations requiring bioassay for iodine-131 and appropriate action levels may be found in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

Guidance for the management of therapy patients can be found in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."* Other pertinent references are given in Regulatory Guide 8.18 and NUREG-0267.

Appendix K to this guide contains a description of precautions to be followed for patients treated with iodine-131, gold-198, and phosphorus-32. Indicate, by checking the appropriate box in Item 19 of Form NRC-313M, that you will follow Appendix K procedures, or submit equivalent procedures. In either case, attach a separate description of facilities and detailed procedures for preparation and administration of therapeutic doses of iodine-131, phosphorus-32, and gold-198.

Item 20 Therapeutic Use of Sealed Sources. Describe special procedures for patients treated with byproduct materials listed in Group VI on Schedule A, §35.100 of 10 CFR

*NCRP reports are available from NCRP Publications, P.O. Box 30175, Washington, D.C. 20014.

Part 35. These procedures* should include descriptions of:

a. The areas where sealed sources will be stored, including (1) placement and thickness of shielding and (2) proximity of the storage area to unrestricted areas.

b. Special precautions to be used while handling sealed sources.

c. Special instructions for nursing care of patients who are treated with sealed sources. (Appendix L to this guide contains a description of procedures to be followed for patients treated with sealed sources.)

d. Your method for determining the radiation doses to the extremities of personnel handling sealed sources.

e. The equipment and shielding available for transporting sources from storage sites to the place of use.

f. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory, and the method for determining that all sources are accounted for and returned to storage following treatment.

g. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument after the end of treatment and before dismissal. Your dismissal survey should include a source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.

Submit detailed responses to Item Nos. 20.a, 20.b, 20.d, 20.e, 20.f, and 20.g. In response to Item 20.c, indicate that the procedures described in Appendix L will be followed, or submit equivalent procedures.

Item 21 Procedures and Precautions for Use of Radioactive Gases (e.g., Xenon-133). The use of radioactive gases (e.g., xenon-133 gas or gas in saline) requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas in restricted and unrestricted areas. The NRC requires that each applicant make such determinations for his own unique situation and submit sufficient evidence to the Commission in support of his request.

Appendix M to this guide contains instructions for submitting an application to use xenon-133. The information requested in Appendix M should be submitted.

Item 22 Procedures and Precautions for Use of Radioactive Material in Animals. Describe procedures to be followed if radioisotopes will be used in animals including (a) a description of the animal housing facilities, (b) a copy of instructions provided to animal caretakers for the handling of animals, animal waste, and carcasses, (c) instructions for cleaning and decontaminating animal cages, and (d) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

Item 23 Procedures and Precautions for Use of Radioactive Materials Specified in Item 6.b. Clearly state any additional radiation safety procedures to be followed while individuals are using the materials listed in Item 6.b, e.g., air sampling, other special surveys, bioassays.

Bioassays may be required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Show in the application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material. Guidance on bioassay programs for iodine-125 and iodine-131 is provided in Regulatory Guide 8.20. Guidance for bioassay programs for tritium and other radionuclides is available as staff criteria from the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Item 24 Personnel Monitoring Devices. State the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service. Specify the frequency with which the badges are changed and evaluated, and give a description of the type, e.g., whole-body, wrist, or finger badge. Where wrist badges are worn to monitor extremity exposures and exposures to fingertips are likely to be greater than the wrist exposures, describe how fingertip exposures will be estimated from the wrist badge data in lieu of fingertip monitors, and provide any backup data used to perform or verify these estimates.

Item 25 (For Private Practice Applicants Only).

Item 25.a. State the name and address of the hospital that has agreed to admit patients containing radioactive material.

*Guidance on facilities, equipment, and procedures is available in NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Is Reasonably Achievable," Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, December 1977. Guidance on brachytherapy procedures is given on pp. 3-16 to 3-19 of this report.

Item 25.b. Submit a copy of the letter of authorization, signed by the administrator, from the hospital that has agreed to admit patients containing radioactive material.

Item 25.c. If patients treated with therapeutic quantities under this license are admitted to the hospital, (1) describe the radiation detection instruments available at the hospital and (2) submit a copy of radiation safety procedures to be followed.

Item 26.a. Licensee Fee Category and Licensee Fee Enclosed may be selected from information pertaining to medical institutions in §170.31 of 10 CFR Part 170.

Items 26.b and c. Provide the signature of an individual authorized by management to represent an applicant institution or the signature of an individual physician, in the case of Category 7C of §170.31, with the date of signature.

## 5. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users or radiation safety officer, or byproduct material to be used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. A fee must accompany amendment applications as indicated in Item 26.a. An original and two copies of the application for amendment should be prepared, the original and one copy should be submitted, as in the cases for new or renewal applications. See Appendix N for commonly requested amendments.

## 6. RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the NRC as provided for in paragraph 30.37(b) of 10 CFR Part 30.

Renewal applications should be filed on Form NRC-313M appropriately supplemented, should contain complete and up-to-date information about the applicant's current program, and should meet all licensing and regulatory requirements in effect at the time of renewal. Renewal applications should also include the user physicians' training and experience (Supplements A and B of Exhibit A) or make a clear and specific reference to previous applications on which individual users received approval.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users). If such references cannot be avoided, they are acceptable provided:

a. The reference is made in response to a particular item of required information (e.g., bioassay procedures).

b. The reference is clear and specific (e.g., title of document, date of submission, page, and paragraph).

c. The referenced document contains all information required for a particular item at the time of renewal.

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original and one copy to the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. A fee must also accompany renewal applications, as indicated in Item 26.a.

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## APPENDIX A

## ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF BYPRODUCT MATERIAL

Paragraph 35.11(d) of 10 CFR Part 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 (1) basic radioisotope handling techniques and (2) the clinical use of byproduct material proposed in the application. Similar criteria are established in paragraph 35.12(c) of 10 CFR Part 35 for the approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the Commission, with the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI), 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 these will be reviewed by the Commission with the assistance of the ACMUI.

### I. General Training

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups I, II, and/or III in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques consisting of lectures, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory in the following areas: (200 hours)

   (1) Radiation physics and instrumentation (100 hours)

   (2) Radiation protection (30 hours)

   (3) Mathematics pertaining to the use and measurement of radioactivity (20 hours)

   (4) Radiation biology (20 hours)

   (5) Radiopharmaceutical chemistry (30 hours)

   (The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.)

b. Experience with the types and quantities of byproduct material for which the application is being made, or equivalent (500 hours).

c. Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

   (1) Supervised examination of patients to determine the suitability for radioisotope diagnosis 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 measurement, and plotting data.

   (3) Followup of patients when required.

   (4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

Note A:

The requirements specified in Sections 1.a, b, and c may be satisfied concurrently in a 3-month training program IF all three areas are integrated into the program.

Note B:

For each physician named in Item 4 of Form NRC-313M, complete Supplements A and B of Form NRC-313M (Preceptor Statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training (e.g., lectures, laboratory sessions).

Alternatives:

Certification by the American Board of Nuclear Medicine will be accepted as evidence that a physician has had adequate training and experience to use Groups I, II, and III.

Certification by the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology will be accepted as evidence that a physician has had adequate training in basic radioisotope handling techniques and has had adequate clinical experience to use Groups II and III.

**2. Training Requirements for Specific Diagnostic Procedures**

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of byproduct material being requested. Such requests will be examined on a case-by-case basis by the Commission with the assistance of the ACMUI.

**3. Training Requirements for Therapy Procedures Involving Radiopharmaceuticals**

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups IV and/or V in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques (80 hours) including:

(1) Radiation physics and instrumentation (25 hours)

(2) Radiation protection (25 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (10 hours)

(4) Radiation biology (20 hours)

(These requirements are in lieu of, not in addition to, those specified in Section 1.a, above.)

b. Clinical training in specific therapy procedures:

For Group IV

(1) Iodine-131 for treatment of hyperthyroidism and/or cardiac conditions:

Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

(2) Phosphorus-32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Treatment of three patients with any combination of these three conditions.

(3) Colloidal phosphorus-32 intracavitary treatment:

Active participation in the treatment of three patients.

For Group V

(1) Iodine-131 for 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.

(2) Colloidal gold-198 for intracavitary treatment:

Active participation in the treatment of three patients.

**4. Training Requirements for Therapy Procedures Involving Sealed Sources**

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Group VI in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques (200 hours) consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas:

(1) Radiation physics and instrumentation (110 hours)

(2) Radiation protection (40 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (25 hours)

(4) Radiation biology (25 hours)

(The hours listed next to each of the four subjects above are suggested values and should not be interpreted as specific requirements.)

b. Clinical training in specific therapy procedures:

(1) Radiation sources for interstitial, intracavitary, or surface treatment of cancer:

Active practice in therapeutic radiology with a minimum of 3 years experience.

(2) Beta ray applicators for the treatment of superficial eye disease:

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

Note:

Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR), or a Canadian certification from the Royal College of Physicians and Surgeons (RCPS) may be submitted in lieu of the information requested in Sections 4.a and b above.

## APPENDIX B

## MEDICAL ISOTOPES* COMMITTEE

Responsibility

The committee is responsible for

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by §19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Meeting Frequency

The medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

*Alternative titles are "radioisotope" or "radiation safety" committee.

## APPENDIX C

## INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: _____

      Manufacturer's model number: _____

      Number of instruments available: _____

      Minimum range: _____ mr/hr to _____ mr/hr

      Maximum range: _____ mr/hr to _____ mr/hr

   b. Manufacturer's name: _____

      Manufacturer's model number: _____

      Number of instruments available: _____

      Minimum range _____ mr/hr to _____ mr/hr

      Maximum range _____ mr/hr to _____ mr/hr

2. Dose calibrator

   Manufacturer's name: _____

   Manufacturer's model number: _____

   Number of instruments available: _____

3. Diagnostic instruments

| Type of Instrument | Manufacturer's Name | Model No. |
|---|---|---|

4. Other

## APPENDIX D

## CALIBRATION OF INSTRUMENTS*

### Section 1

### METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.

2. The source activities shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

3. The frequency shall be at least annually and after servicing.

4. Each scale of the instrument shall be calibrated at least at two points such that (a) one point is in each half of the scale and (b) the two points are separated by 35-50% of full scale.

5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10% of full scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ±20% will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

Note:

Sources of Cs-137, Ra-226, or Co-60 are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1 R/hr on the higher-range instruments. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation.

B. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, shall also be read at the time of the above calibration. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

1. Before each use and also after each survey to ensure that the instrument was operational during the survey.

2. After each maintenance and/or battery change.

3. At least quarterly.

If any reading with the same geometry is not within ±20% of the reading measured immediately after calibration, the instrument should be recalibrated (see item A).

C. The instrument must be calibrated at lower energies if its response is energy dependent and it is to be used to measure in the Xe-133 or Tc-99m energy ranges.

This calibration may be done either

1. As in item A above with calibrated standards of radionuclides at or near the desired energies or

2. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.

D. Records of the above items A, B-2, B-3, and C must be maintained.

E. Use of Inverse Square Law and Radioactive Decay Law

1. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specified date by the manufacturer or NBS.

   a. The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

   b. The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

*See ANSI N42.1.3, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

2. Inverse Square Law

S $(R_1)$ $(R_2)$

* - - $P_1$

- - - - - - - $P_2$

Exposure rate at $P_2$:

$$R_2 = \frac{(P_1)^2}{(P_2)^2} (R_1)$$

where

S is the point source

$R_1$ and $R_2$ are in the same units (mR/hr or R/hr)

$P_1$ and $P_2$ are in the same units (centimeters, meters, feet, etc.)

3. Radioactive Decay Law

Exposure rate t units of time after specified calibration date

$$R_t = R_o \times e^{-[\frac{0.693}{T_{1/2}} \times t]}$$

where

$R_o$ and $R_t$ are in the units mR/hr or R/hr

$R_o$ is exposure rate on specified calibration date

$R_t$ is exposure rate t units of time later

$T_{1/2}$ and t are in the same units (years, months, days, etc.)

$T_{1/2}$ is radionuclide half-life

t is number of units of time elapsed between calibration and present time

4. Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1975. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1977 (2.0 years)?

a. Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}}$$

$= 100 \times 0.77 = 77$ mR/hr at 1 foot on March 10, 1977.

b. Output at 3 feet, 2.0 years after calibration date:

$$R_3 \text{ feet} = \frac{(1 \text{ foot})^2}{(3 \text{ feet})^2} \times 77 \text{ mR/hr}$$

$= \frac{1}{9} \times 77 = 8.6$ mR/hr at 3 feet, 2.0 years after calibration.

## CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

_____ 1. Survey instruments will be calibrated at least annually and following repair.

_____ 2. Calibration will be performed at two points on each scale.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used

or

_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

_____ c. By a consultant or outside firm

(1) Name _____

(2) Location _____

(3) Procedures and sources

_____ have been approved by NRC and are on file in License No. _____

_____ are attached

Section 2

## METHODS FOR CALIBRATION OF DOSE CALIBRATOR

All radiopharmaceuticals must be assayed for activity to an accuracy of 10%. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument linearity (at installation and quarterly thereafter)

2. Geometrical variation (at installation)

3. Instrument accuracy (at installation and annually thereafter).

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Daily or before each use of the instrument:

1. Measure and record the activity of at least one reference source (e.g., 1-2 mCi of Co-57). This check should be repeated during the day whenever sample readings are not within 10% of the anticipated assay. Variation greater than 5% in this test will indicate the need for instrument repair, adjustment, or recalibration.

2. Measure and record the apparent activity of a long-lived standard radionuclide such as Cs-137 or Ra-226 at all the commonly used radionuclide settings (when the unit was first calibrated against NBS-traceable standards). Choose a source with activity in the 100 μCi range.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.

2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

| Assay Time (hr) | Correction Factor |
|---|---|
| 0 | 32 |
| 6 | 16 |
| 24 | 2 |
| 30 | 1 |
| 48 | 0.125 |

Example: If the net activity measured at 30 hours was 15.625 mCi, the predicted activity for 6 and 48 hours would be 15.625 mCi x 16 = 250 mCi and 15.625 mCi x 0.125 = 1.95 mCi, respectively.

4. Plot the measured net activity for each time interval versus the predicted activity on log-log graph paper.

5. The activities plotted should be within ±5% of the predicted curve if the instrument is linear and functioning properly. Errors greater than ±5% indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to either assay an aliquot of the eluate that can be accurately measured or to use the graph constructed in step 4 to relate measured activities to true activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant,

i.e., greater than ±2% (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1.

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

   Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected,

   $$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

   True Activity = Measured Activity x Correction Factor

   where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial and a correction factor may be calculated.

7. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125. Hence, adequate correction factors must be established for this type of syringe.

   An alternate to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test For Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides such as Cs-137, Co-57, and Ba-133 using appropriate reference standards whose activity is traceable to NBS. The activity levels of the reference sources used should approximate those levels normally encountered, giving adequate attention to source configuration. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ±5% after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ±5% indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated with the NBS-traceable standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more NBS-traceable standards. Keep a log of these initial and subsequent readings.

H. Test for Instrument Constancy

Assay two reference sources such as Cs-137 and Co-57 using a reproducible geometry before each daily use of the instrument.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).

2. Measure background level at same instrument setting.

3. Calculate net activity of each source subtracting out background level.

4. For each source, plot net activity versus the day of the year on semi-log graph paper.

5. Log the background levels.

6. Indicate the predicted activity of each source based on decay calculations and the ±5% limits on the graph as illustrated.

7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

8. Variations greater than ±5% from the predicted activity indicate the need for instrument repair or adjustment.

9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

## CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

_____ First elution from new Mo-99/Tc-99m generator

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

| Radionuclide | Activity (mCi) | Accuracy |
|---|---|---|
| Co-57 | _____ | _____ |
| Ba-133 | _____ | _____ |
| Cs-137 | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

C. _____ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

_____ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

## APPENDIX E

## PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine Technologist must place all orders for radioactive material and must ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers must be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

3. During off-duty hours, security personnel must accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

### SAMPLE MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: John Jones, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 p.m. and 7 a.m. or on Sundays shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

## RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. # _____ Survey Date _____ Time _____

   Surveyor _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ Punctured _____ Status _____ Wet

   _____ Crushed _____ Other

3. RADIATION UNITS OF LABEL: _____ Units (mRem/hr)

4. MEASURED RADIATION LEVELS:

   a. Package surface _____ mRem/hr

   b. 3 feet or 1 meter from surface _____ mRem/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE?

   a. Radionuclide _____ yes _____ no, difference _____

   b. Amount _____ yes _____ no, difference _____

   c. Chem Form _____ yes _____ no, difference _____

6. WIPE RESULTS FROM:

   a. Outer _____ CPM = _____ DPM

   eff = ( )

   b. Final source container _____ CPM = _____ DPM

   eff = ( )

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mRem/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION _____

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

_____ _____

Signature Date

## APPENDIX F

## PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

2. Measure exposure rate at 3 feet from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.

3. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

4. Put on gloves.

5. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that shipment does not exceed possession limits.

6. Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps; assay and record.

7. Monitor the packing material and packages for contamination before discarding.

   a. If contaminated, treat as radioactive waste.

   b. If not contaminated, obliterate radiation labels before discarding in regular trash.

In all the above procedures, take wipe tests with a paper towel, check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

## APPENDIX G

## GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well-being.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielding containers.

## APPENDIX H

## EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: _____
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

_____
_____
_____

## APPENDIX I

## AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with a low-range thin-window G-M survey meter and decontaminated if necessary.

2. Laboratory areas where only small quantities of radioactive material are used (less than 100 μCi) will be surveyed monthly.

3. All other laboratory areas will be surveyed weekly.

4. The weekly and monthly survey will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 $cm^2$ for the contaminant involved.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and type of equipment used.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 100 dpm/100 $cm^2$.

Note:

For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey reports will be recorded.

## APPENDIX J

## WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

_____ By commercial waste disposal service (see also item 4 below).

_____ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

_____ Other (specify): _____

_____

2. Mo-99/Tc-99m generators will be (check as appropriate)

_____ Returned to the manufacturer for disposal.

_____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

_____ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

_____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be

_____

(Name) (City, State)

NRC/Agreement State License No. _____

## APPENDIX K

## THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with iodine-131 or gold-198 will be placed in a private room with a toilet. The room and toilet areas more likely to be contaminated will be covered with protective material as appropriate to the amounts of contamination to be expected. Particular attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate.

2. The patient's room will be properly posted in accordance with §20.203 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, 3 feet (or 1 meter) away, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131, will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

9. Urine and vomitus from iodine-131 therapy patients will be stored for decay in the radioactive waste storage area. When it has reached background levels, as measured with a low-level survey meter, it may be released to the sanitary sewer system.

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

11. Nursing Instructions

    a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department with any questions about the care of these patients.

    b. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet from the patient.

    d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

    e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

    f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers

having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound will stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For iodine-131 patients:

(1) Urine from iodine-131 patients will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterwards, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

(3) Disposable plates, cups, and eating utensils will be used by patients who are treated with iodine-131.

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. _____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) All vomitus must also be kept in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times).

l. Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or his designee.

m. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

n. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

o. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department, and request that the room be surveyed for contamination before remaking the room.

Date: _____

## NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mRem/hr

| Date | 3 feet from bed | 10 feet from bed |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

(Comply with all checked items.)

____ 1. Visiting time permitted: _____

____ 2. Visitors must remain _____ from patient.

____ 3. Patient may not leave room.

____ 4. Visitors under 18 are not permitted.

____ 5. Pregnant visitors are not permitted.

____ 6. Film badges must be worn.

____ 7. Tag the following objects and fill out the tag:

____door

____bed

____chart

____wrist

____ 8. Gloves must be worn while attending patient.

____ 9. Patient must use disposable utensils.

____10. All items must remain in room until approved by the Radiation Safety Officer or his designee.

____11. Smoking is not permitted.

____12. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

____13. Other instructions.

In case of an emergency contact:

RSO _____ _____ / _____

Name On-duty/Off-duty Telephone Nos.

## APPENDIX L

## THERAPEUTIC USE OR SEALED SOURCES

1. All patients treated with brachytherapy sources will be placed in a private room with toilet.

2. The patient's room will be properly posted in accordance with §20.203 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, 3 feet (or 1 meter) from the patient, 3 feet (or 1 meter) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet (or 1 meter) from the patient on the patient's chart.

4. Immediately after sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" will be completed and placed on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

6. Nurses caring for brachytherapy patients will be assigned film badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient.

7. At the conclusion of treatment, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed and all film and TLD badges assigned to nurses will be collected.

8. Instructions to Nurses

   a. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. Call the Radiation Safety Office or his designee with any questions about the care of these patients in regard to radiation safety precautions.

   b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film badge.

   c. When a nurse receives an assignment to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.

   d. Pregnant nurses should not be assigned to the personal care of these patients.

   e. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.

   f. Bed bath given by the nurse should be omitted while the sources are in place.

   g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.

   h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee.

      Special orders will be written for oral hygiene for patients with oral implants.

   i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into these items.

   j. All bed linens must be checked with a radiation survey meter before being

removed from the patient's room to ensure that no dislodged sources are inadvertently removed.

k. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.

l. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet on the patient's chart.

m. Visitors should sit at least 3 feet (or 1 meter) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on his chart.

n. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

o. Emergency Procedures

(1) If an implanted source becomes loose or separated from the patient, or

(2) If the patient dies, or

(3) If the patient requires emergency surgery, immediately call _____

_____

Telephone No. (days)_____
(nights) _____

p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room and (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient.

## NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope Activity: _____

Date and Time of Administration: _____

Date and Time Sources Are To Be Removed: _____ Isotope: _____

Exposure Rates in mR/hr

| Bedside | 3 feet from bed | 10 feet from bed |
|---|---|---|
| | | |
| | | |
| | | |

(Comply with all checked items.)

_____ 1. Wear film badge.

_____ 2. Wear rubber gloves.

_____ 3. Place laundry in linen bag and save.

_____ 4. Housekeeping may not enter the room.

_____ 5. Patient may not have visitors.

_____ 6. Patient may not have pregnant visitors.

_____ 7. Patient may not have visitors under 18 years of age.

_____ 8. A dismissal survey must be performed before patient is discharged.

_____ 9. Patient must have a private room.

_____10. Other instructions.

RSO _____, _____ / _____

Name On-duty/Off-duty/Telephone Numbers

## APPENDIX M

## PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., XENON-133)

The following information should be submitted in support of requests to use xenon-133:

1. Quantities to be used

   a. Patient information

      (1) Number of studies expected per week

      (2) Average activity per patient

   b. State the desired possession limit. This should be sufficient to provide for shipments whose calibration dates are several days after receipt.

2. Use and Storage Areas

   a. Describe the area(s) in which you plan to use and store xenon-133. Include a diagram indicating the availability of shielding materials and the proximity to unrestricted areas.

   b. Describe the ventilation in all areas where xenon-133 is used and stored. The location of supply and exhaust vents, the measured airflow rates for each vent, and the fraction of air that is recirculated by the system should be indicated.

   c. All areas where xenon is used should be under negative pressure. State how you will ensure that all airflow rates are maintained as specified in this application.

3. Procedures for Routine Use

   a. Describe the procedures to be followed for routine use of xenon-133, giving particular attention to radiological safety factors.

   b. If you plan to use a special apparatus for administration and collection of xenon-133, specify the manufacturer's name and model number and include a description of its design characteristics. (Inclusion of a brochure would be helpful.)

   c. Describe any special procedures that you plan to employ to reduce leakage, e.g., use of nose clamps or special enclosures.

4. Emergency Procedures

   Describe the emergency procedures to be used in case of an accidental release of xenon-133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the area.

5. Air Concentrations of Xenon-133 in Restricted Areas

   No licensee shall permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity that would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material of $1 \times 10^{-5}$ μCi/ml.

   You may evaluate your situation by making actual measurements of xenon-133 concentrations or by means of calculations. If you choose the latter approach, you may make simplifying assumptions, PROVIDING they are reasonable, conservative, and stated explicitly in your request.

   In actual use and storage, some xenon-133 will be released into the room from the storage and administration devices, rebreathing apparatus, collection systems, and escape from the patient. All sources of loss must be considered when estimating the fraction of xenon-133 that is lost.

   The following procedures may be used to calculate the air concentration of xenon-133 in restricted areas:

   a. Estimate the maximum amount of activity to be used per week (A).

   b. Estimate the fraction of xenon-133 that is lost during use and storage (f). This fractional loss must include ALL sources of loss, e.g., during patient administration, storage, and disposal.

   c. Determine the measured airflow rate in the area(s) of interest, and calculate the volume of air available per week for dilution of the xenon-133 (V).

   d. For restricted areas, §20.103 of 10 CFR Part 20 requires that

$$\frac{A}{V} \times f \leq 1 \times 10^{-5} \text{ μCi/ml.}$$

e. Sample Problem

A nuclear medicine laboratory plans to use 10 mCi xenon-133 per patient and will perform a maximum of 10 studies per week. What ventilation rate is required to ensure compliance with §20.103 of 10 CFR Part 20?

Maximum activity used per week

$$A = \frac{10\ \text{mCi}}{\text{patient}} \times \frac{10\ \text{patients}}{\text{week}} \times 1 \times 10^{3}\ \frac{\mu\text{Ci}}{\text{mCi}}$$

$$= 1 \times 10^{5}\ \frac{\mu\text{Ci}}{\text{week}}$$

Assume a loss rate of 20% (f)

$$V = \frac{A \times f}{1 \times 10^{-5}\ \mu\text{Ci/ml}}$$

$$= \frac{1 \times 10^{5}\ \mu\text{Ci/week} \times 0.20}{1 \times 10^{-5}\ \mu\text{Ci/ml}}$$

$$= 2.0 \times 10^{9}\ \text{ml/week}.$$

The required ventilation rate is

$$\frac{2.0 \times 10^{9}\ \text{ml/week}}{40\ \text{hr/week}} \div \frac{1.7 \times 10^{6}\ \text{ml/hr}}{\text{ft}^3\text{/min}} = 30\ \text{ft}^3\text{/min}$$

The answer shows that, in order to meet the requirements of §20.103 of 10 CFR Part 20, the imaging room (RESTRICTED AREA) must have a ventilation rate of at least 30 $ft^3$/min with no recirculation of air. Where practical, the ventilation rate should be greater than that shown necessary by the calculations. Consider every alternative in order to maintain the air concentration of xenon-133 as low as reasonably achievable in accordance with paragraph 20.1(c) of 10 CFR Part 20.

If the ventilation rate is inadequate to meet the requirements of §20.103 of 10 CFR Part 20, consider methods of increasing ventilation or reducing the patient load.

The following table gives the amount of xenon-133 that can be released per week without exceeding the permissible levels for xenon-133 in restricted areas.

| Ventilation Rate ($ft^3$/min) | Maximum Xenon-133 Released per 40-Hour Week (mCi) |
|---|---|
| 100 | 67.9 |
| 500 | 339.7 |
| 1,000 | 679.4 |

6. Methods of Xenon-133 Disposal

a. Dilution through Exhaust Systems (less desirable).

One method for disposal of xenon-133 is by release to the atmosphere through an air exhaust system. Licensees are required to perform surveys (measurements or calculations) to ensure that they are in compliance with paragraph 20.1(c) and §20.106 of 10 CFR Part 20. Paragraph 20.1(c) requires that the concentrations of xenon-133 in effluents to unrestricted areas be as low as is reasonably achievable by the current state of technology, and §20.106 requires that the concentrations, averaged over a period of 1 year, shall not exceed $3 \times 10^{7}$ µCi/ml.

Many facilities do not have sufficient airflow to achieve the necessary dilution. The following procedure may be used to estimate the concentrations of xenon-133 in effluents to unrestricted areas.

(1) Estimate the maximum amount of xenon-133 to be released per year (A). This should include all anticipated losses during administration, storage, and disposal.

(2) Determine the flow rate of the exhaust system, and describe the methods and equipment used for measuring the airflow rates.

(3) Calculate the airflow per year (V).

(4) Calculate the average concentrations for unrestricted areas. Section 20.106 of 10 CFR Part 20 requires that

$$C = \frac{A}{V} \leq 3 \times 10^{-7}\ \mu\text{Ci/ml}.$$

(5) Sample Problem

A nuclear medicine laboratory plans to use 10 mCi per patient

and will perform a maximum of 10 studies per week. A fume hood is available for disposal of xenon-133 and has a measured airflow of 168 ft/min with an opening of 8 $ft^2$. What is the average concentration of xenon-133 at the point of release from the fume hood exhaust? (NOTE: All xenon that has been released, e.g., collection bags, filters, must be considered.)

$$A = \frac{10 \text{ patients}}{\text{week}} \times \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10^3 \ \mu\text{Ci}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{yr}}$$

$$A = 5.2 \times 10^6 \ \mu\text{Ci/yr}$$

$$V = 168 \frac{\text{ft}}{\text{min}} \times 8 \ \text{ft}^2 \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 1344 \frac{\text{ft}}{\text{min}} \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 2.01 \times 10^{13} \ \text{ml/yr}$$

$$C = \frac{5.2 \times 10^6 \ \mu\text{Ci/yr}}{2.01 \times 10^{13} \ \text{ml/yr}}$$

$$C = 2.6 \times 10^{-7} \ \mu\text{Ci/ml}$$

The following table gives the amount of xenon-133 that can be released per week without exceeding an average concentration of $3 \times 10^{-7}$ µCi/ml.

| Exhaust rate ($ft^3$/min) | Average Release of Xenon-133 per Week (mCi) |
|---|---|
| 100 | 8.6 |
| 500 | 42.8 |
| 1,000 | 85.6 |
| 1,500 | 128.4 |

If the exhaust is released to a restricted area, e.g., a roof to which access is controlled, or from a tall stack, Sutton's equation (Refs. 1 and 2) may be used to calculate the concentrations at the nearest unrestricted area. If this approach is used, describe the location of the exhaust system outlet, including proximity to unrestricted areas, air intakes, and open windows. Methods for controlling access to the area where the exhaust is located should also be described.

b. Adsorption onto Charcoal Traps

This is the disposal method of choice. The advantage of this disposal method is that xenon-133 is trapped onto charcoal or other adsorbing medium. Filters containing xenon-133 are then stored for decay.

One difficulty with this approach is that charcoal is not 100% efficient for trapping xenon-133. If this is your method of disposal, you should consider the following points.

(1) Describe how you will handle the problem of leakage from such trapping devices. If the exhaust is vented to the outdoors (UNRESTRICTED AREA), show that air concentrations of xenon-133, averaged over 1 year, do not exceed $3 \times 10^{-7}$ µCi/ml. (See example in item 6.a.)

(2) Describe how you will ensure that collection and trapping devices are performing according to specifications, both initially and on a continuing basis. Include in your description how you will monitor traps to determine when saturation occurs and filter must be replaced.

(3) Describe your procedures for handling saturated filters. Your discussion should include a description of the area (a diagram would be useful), available shielding, proximity to restricted areas, ventilation, and an evaluation of average concentrations of xenon-133 in air. (See example in item 5.e.)

USEFUL CONVERSIONS

1 mCi = $10^3$ µCi

1 $ft^3$ = $2.832 \times 10^{-2}$ $m^3$ = $2.832 \times 10^4$ ml

1 $ft^3$/min = $1.699 \times 10^6$ ml/hr

= $6.797 \times 10^7$ ml/40-hr week

= $1.484 \times 10^{10}$ ml/yr

1 week = 168 hr

REFERENCES


1. Blatz, Hanson, Radiation Hygiene Handbook, McGraw-Hill (New York, 1959), pp. 22-7.

2. Cember, Herman, Introduction to Health Physics, Pergamon Press (New York, 1969), pp. 334-9.

## APPENDIX N

## GUIDANCE ON REQUESTS FOR LICENSE AMENDMENTS AND LICENSE TERMINATIONS

1. License Amendment Requests

   a. To add a new user

      (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or

      (2) Give Agreement State license number (preferably including a copy of the license), if applicable; or

      (3) Send letter of request, attaching Supplements A and/or B (see Item 8 of this guide) if new user has not been previously approved for this type of license.

   b. To add a user for Groups I-III*

      (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or

      (2) Give evidence of certification by the American Board of Nuclear Medicine, or other certifications as specified in Section 4 of Appendix A to this guide, and year of certification; or

      (3) Give information requested in Section 1 of Appendix A (i.e., 200 hours training in basic radioisotope handling techniques; 500 hours training and experience in handling the types and quantities of material requested; and 500 hours clinical experience).

   c. To add a user for Groups IV-V*

      (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or

      (2) Give evidence of certification by the American Board of Nuclear Medicine, or other certifications as specified in Section 4 of Appendix A to this guide, and year of certification; or

      (3) Give information requested in Section 3 of Appendix A to this guide (i.e., 80 hours training in basic radioisotope handling techniques and clinical experience as described in Section 3 of Appendix A).

   d. To add a user for Group VI*

      (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or

      (2) Give evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, or other applicable certifications in radiation oncology as specified in Section 4 of Appendix A to this guide; or

      (3) Give evidence of three years active experience in therapeutic radiology (see Section 4 of Appendix A to this guide).

   e. To add Group III

      The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

      (1) Calibration frequency, procedures, and standards for high-level survey meter capable of reading up to 1 R/hr.

      (2) Room diagram showing location of generator, kit preparation, patient dose preparation areas, etc., with special attention paid to shielding.

      (3) Use of syringe shields.

      (4) Method for assaying patient doses prior to administration.

      (5) Use of ring badges for personnel who elute generators, prepare radiopharmaceuticals from reagent kits, and prepare patient doses.

*See §35.100 of 10 CFR Part 35.

(6) Daily survey of areas used for generator elution, preparation of radiopharmaceuticals from reagent kits, and preparation of patient doses.

(7) Rules for personnel who elute generators or prepare radiopharmaceuticals from reagent kits to monitor hands and clothing after each procedure or before leaving these areas.

f. To add Groups IV and V*

The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

(1) Room assignment.

(2) Instructions to nurses.

(3) Procedures for handling contaminated linen and other contaminated items.

(4) Use of disposable items, primarily for iodine-131 patients.

(5) Survey procedures, including dismissal survey.

(6) Procedures for preparing oral iodine-131 doses, including procedures for controlling and monitoring airborne iodine-131 and thyroid uptake by personnel.**

g. To add Group VI***

The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

(1) Diagram of storage area with special attention paid to shielding and security.

(2) Procedures for handling sealed sources.

(3) Instructions for nurses.

(4) Use of ring badges by personnel handling sealed sources.

(5) Procedures for transporting sources from storage area to area of use and return.

(6) Inventory procedures to ensure that all sources are accounted for after treatment.

(7) Survey procedures. Dismissal survey, including radiation survey of patient and room after removal of sources, must ensure that all permanent sources are removed from patient and from those areas the patient occupied.

h. To add xenon-133

(1) Follow xenon-133 licensing guidance carefully (see Appendix M to this guide).

(2) Other concerns not expressed specifically in guidance.

(a) Area in which xenon-133 is used and stored should be under negative pressure.

(b) Air in these areas should not be recirculated.

(c) All losses of xenon-133 to restricted area should also be assumed to go to unrestricted areas. Concentrations in unrestricted areas must not exceed levels specified in §20.106.

i. To move Nuclear Medicine Department

(1) Provide diagram of new areas (see Item 11 of this guide).

(2) Provide survey showing all previously occupied areas are free of contamination and all sources have been removed. A decontamination guide is available from the License Management Branch.†

j. To terminate a License

a. Submit a signed Form NRC-314 indicating the disposition of the radioactive material.

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*Additional guidance on planning an acceptable radiation safety program for these uses is provided in NCRP Report 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides;" Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable;" and NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable."

**See Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

***Guidance on facility, equipment, and procedures for brachytherapy is provided in Regulatory Guide 8.18 and in NUREG-0267.

†A regulatory guide on radiation safety surveys at medical institutions is now under development.

b. Submit survey showing all previously occupied areas are free of contamination and all sources have been removed.

2. Actions Not Requiring Amendments

a. To add naturally occurring or accelerator-produced radionuclides (e.g., radium-226, cobalt-57, gallium-67, thallium-201). NRC has no authority over these materials.

b. To add use of particular radiopharmaceutical for participation in manufacturer-sponsored IND. This use is already covered in §35.100 of 10 CFR Part 35, provided the licensee obtains the radiopharmaceutical from a company authorized by NRC or an Agreement State to distribute the radioactive drug to NRC's group medical licensees.

c. To add sealed sources of less than 3 mCi for calibration or reference purposes. These sources are authorized by §35.14(d) provided the licensee obtains them from a company authorized by NRC or an Agreement State to distribute them to NRC's group medical licensees.

# EXHIBIT A

| FORM NRC-313M (8-78) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION<br>**APPLICATION FOR MATERIALS LICENSE – MEDICAL** | Approved: GAO R0557 |
|---|---|---|

**INSTRUCTIONS** – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to : Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials 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, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

| 1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE<br><br>TELEPHONE NO.: AREA CODE( ) _____ _____ | 1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE |
|---|---|
| 2. PERSON TO CONTACT REGARDING THIS APPLICATION<br><br>TELEPHONE NO.: AREA CODE( ) _____ _____ | 3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*<br>a. ☐ NEW LICENSE<br>b. ☐ AMENDMENT TO LICENSE NO. _____<br>c. ☐ RENEWAL OF LICENSE NO. _____ |
| 4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* | 5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)* |

**6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE**

| RADIOACTIVE MATERIAL LISTED IN: | ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| 10 CFR 31.11 FOR IN VITRO STUDIES | | |
| 10 CFR 35.100, SCHEDULE A, GROUP I | | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP II | | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP III | | |
| 10 CFR 35.100,SCHEDULE A, GROUP IV | | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP V | | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP VI | | |

| ADDITIONAL ITEMS: | MARK ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM | | |
| PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES | | |
| PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA | | |
| XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES. | | |

**6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a.** *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35 , and NEED NOT BE LISTED.)*

| ELEMENT AND MASS NUMBER | CHEMICAL AND/OR PHYSICAL FORM | MAXIMUM NUMBER OF MILLICURIES OF EACH FORM | DESCRIBE PURPOSE OF USE |
|---|---|---|---|
| | | | |

## INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

**7. MEDICAL ISOTOPES COMMITTEE**

- ☐ Names and Specialties Attached; and
- ☐ Duties as in Appendix B; or *(Check One)*
- ☐ Equivalent Duties Attached

**8. TRAINING AND EXPERIENCE**

- ☐ Supplements A & B Attached for Each Individual User; and
- ☐ Supplement A Attached for RSO.

**9. INSTRUMENTATION** *(Check One)*

- ☐ Appendix C Form Attached; or
- ☐ List by Name and Model Number

**10. CALIBRATION OF INSTRUMENTS**

- ☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
- ☐ Equivalent Procedures Attached; and
- ☐ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
- ☐ Equivalent Procedures Attached

**11. FACILITIES AND EQUIPMENT**

- ☐ Description and Diagram Attached

**12. PERSONNEL TRAINING PROGRAM**

- ☐ Description of Training Attached

**13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL**

- ☐ Detailed Information Attached

**14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS** *(Check One)*

- ☐ Appendix F Procedures Followed; or
- ☐ Equivalent Procedures Attached

**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*

- ☐ Appendix G Rules Followed; or
- ☐ Equivalent Rules Attached

**16. EMERGENCY PROCEDURES** *(Check One)*

- ☐ Appendix H Procedures Followed; or
- ☐ Equivalent Procedures Attached

**17. AREA SURVEY PROCEDURES** *(Check One)*

- ☐ Appendix I Procedures Followed; or
- ☐ Equivalent Procedures Attached

**18. WASTE DISPOSAL** *(Check One)*

- ☐ Appendix J Form Attached; or
- ☐ Equivalent Information Attached

**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*

- ☐ Appendix K Procedures Followed; or
- ☐ Equivalent Procedures Attached

**20. THERAPEUTIC USE OF SEALED SOURCES**

- ☐ Detailed Information Attached; and
- ☐ Appendix L Procedures Followed; or *(Check One)*
- ☐ Equivalent Procedures Attached

**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)**

- ☐ Detailed Information Attached

**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**

- ☐ Detailed Information Attached

**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**

- ☐ Detailed Information Attached

## 24. PERSONNEL MONITORING DEVICES

| TYPE (Check appropriate box) | | | SUPPLIER | EXCHANGE FREQUENCY |
|---|---|---|---|---|
| a. WHOLE BODY | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |
| c. WRIST | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |

d. OTHER (Specify)

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

## 26. CERTIFICATE

*(This item must be completed by applicant)*

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
*(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type of Print)*

(2) TITLE

c. DATE

FORM NRC-313M (8-78)

## PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
# AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| | |

## 3. CERTIFICATION

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| | | |

## 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING | |
|---|---|---|---|
| | | LECTURE/ LABORATORY COURSES *(Hours)*<br>C | SUPERVISED LABORATORY EXPERIENCE *(Hours)*<br>D |
| a. RADIATION PHYSICS AND INSTRUMENTATION | | | |
| b. RADIATION PROTECTION | | | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | | | |
| d. RADIATION BIOLOGY | | | |
| e. RADIOPHARMACEUTICAL CHEMISTRY | | | |

## 5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP CODE

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

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

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

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

## 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-131 or I-125 | DIAGNOSIS OF THYROID FUNCTION | | |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | | | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*

8. DATE

FORM NRC-313M-SUPPLEMENT B
(8-78)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555