Edward Hines, Jr. Hospital
Hines IL 60141

Veterans Administration

September 10, 1985

In Reply Refer To: 578/115
Control No. 17743

William J. Adam, Ph.D.
Materials Licensing Section
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Dr. Adam:

The enclosed information is submitted to you in response to your letters dated July 11, 1985 and August 1, 1985.

We wish to thank you for the extension which you granted us on August 1, 1985. It has enabled us to be more complete in our response and truly reexamine our license application.

Although we understand that you must retain all documents which you receive, we will perform the following changes in our copy of the license application:

1. Response to Item 1 - July 11, 1985

a. Please remove page (1-1, 6-12-84) and insert page (1-1, 9-10-85).

This should separate the diagnostic and therapeutic uses from research uses. It is felt that it is not necessary to change Item 7 (Medical Radioisotope Committee), Item 8 (Training and Experience), or rearrange equipment lists in Item 9 (Instrumentation). As you can see, we have adjusted the "broad scope" part of the application in Item 6.

b. Please remove page (6-1, 6-15-84) and insert page (6-1, 9-10-85).

2. Response to Item 2 - July 11, 1985

a. Please remove page (7-1, 6-15-84), (7-2, 6-15-84), and (7-3, 6-15-84) and insert pages (7-1, 9-10-85), (7-2, 9-10-85), and (7-3, 9-10-85).

Facilities always have been an important consideration in the authorization of radioactive material usage. We did not document that fact in the license application because it is incorporated in our internal procedures.

b. Please remove page (8-6, 6-15-84) and (8-7, 6-15-84) and insert page (8-6, 9-10-85) and (8-7, 9-10-85).

We agree that the insertion in our license will reinforce our own internal mechanism which accomplishes the same result.

William J. Adam, Ph.D.

3. Response to Item 3 - July 11, 1985

We have found that internal flexability and effective growth are predicated on the ability to change methods, controls, and procedures. The best guidelines to change, are audits. Since 1981 we have been performing quarterly and annual audits at our facility which encompasses management control of licensed activities, MRC/RDRC operations, and Hospital Radiation Safety Officer surveillance and compliance. If we were to be required to incorporate our lengthy internal documents and audit forms, it would make alteration and improvement a slow and extremely awkward task on both of our parts. It would seem prudent at this time to list for you some of the audits which we perform to demonstrate our knowledge of what is significant and our ability to regulate ourselves. They are as follows:

a. Annually - Management audit of MRC/RDRC activities
Management audit of hospital radiation policies and bulletins
Management audit of inspection results and corrections
MRC/RDRC audit authorized users for renewal
MRC/RDRC audit of MRC/RDRC minutes, records, policies
HRSO audit of user facilities
HRSO audit of inventories of sources, calibrations, wipe test results, etc.

b. Quarterly - MRC/RDRC, HRSO user facility inspection
MRC/RDRC, HRSO sewer, transfer, waste disposal
MRC/RDRC, HRSO ALARA action levels
MRC/RDRC, HRSO bioassay action levels
MRC/RDRC, HRSO training of personnel
HRSO "areas of concern"
HRSO issued citations/corrections
Misadministrations

We ask that you consider your inspection records of this facility, the longevity of our license, and our above mentioned annual and quarterly activities. We request that you allow us to determine the nature and frequency of audits with the understanding that problems discovered will be promptly corrected.

4. Response to Item 4 - July 11, 1985

Please remove page (14-1, 6-15-84) and insert page (14-1, 9-10-85)

a. We feel that our statement was adequate but have changed it to your wording.

b. If we excluded from wipe testing the final source container of RIA kits, beta emmitters, and sealed sources we would still have a horrendous job which must be performed prior to the beginning of a patient work day. We have little to no history of contamination of personnel or facilities from package opening procedures and request that you reconsider the impact on patient care and radiation safety man-hours.

c. See also above mentioned insert.

William J. Adam, Ph.D.

5. Response to Item 5 - July 11, 1985

Please remove page (15-4, 6-15-84) and insert (15-4, 9-10-85).

We believe that all doses up to your misadministration criteria shall be acceptable.

6. Response to Item 6 - July 11, 1985

Please remove page (5-3, 6-15-84) and insert (5-3, 9-10-85).

The Hospital Radiation Safety Officer is authorized to carry out all responsibilities assigned to him.

If any of the enclosed sections do not meet with your approval, please inform us. We will make the necessary corrections for the insertions.

Sincerely yours,

JOHN R. FEARS
Director

Enclosures

NRC FORM 313M
(9-81)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

# APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB
3150-0041

**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

Veterans Administration
Edward Hines, Jr., Medical Center
Hines, Illinois 60141

TELEPHONE NO.: AREA CODE ( 312 ) 343 - 7200

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

(See Item 1.a.)

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Lawrence Case (HRSO)

TELEPHONE NO.: AREA CODE ( 312 ) 343-7200,X2678

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 12-01087-07

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

(See Item 4)

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.)*

Lawrence Case
Hospital Radiation Safety Officer
(See item 5)

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 | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP II | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP III | X | 10,000 |
| 10 CFR 35.100, SCHEDULE A, GROUP IV | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP V | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP VI | X | 2,100 |

| ADDITIONAL ITEMS: | MARK ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM | X | 100 |
| PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES | X | 50 |
| PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | X | 50 |
| GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | X | 300 |
| IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA | X | 300 |
| XENON 133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | X | 150 |

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 |
|---|---|---|---|
| | (See Item 6) | | |

Item 1-1
9-10-85

## ITEM 6

## RADIOACTIVE MATERIAL FOR MEDICAL USE
## RADIOACTIVE MATERIAL FOR RESEARCH, EDUCATION, AND CLINICAL LABORATORY

The responses in this section containing the statement "As Needed" should be construed to represent the broad license, 50 mCi maximum possession limit unless indicated here below.

| Byproduct material (element and mass no.) | Chemical and/or physical form | Maximum amount or radioactivity which licensee may possess at any one time |
|---|---|---|
| a. Any byproduct material between Atomic Nos. 1 and 83 inclusive | a. Any | a. 50 mCi of each byproduct material between Atomic Nos. 1 and 83, inclusive, except as provided below |
| b. Hydrogen - 3 | b. Any | b. 750 mCi |
| c. Carbon - 14 | c. Any | c. 750 mCi |
| d. Cobalt - 60 | d. Any | d. 100 mCi |
| e. Iodine - 125 | e. Any | e. 750 mCi |

The NRC Groups IV and V (radiopharmaceuticals) information is located in ITEM 19.

The NRC Group VI (sealed sources) information is located in ITEM 20.

A. COBALT - 57 FLOOD FIELDS

| MANUFACTURER | MODEL NUMBER | ACTIVITY AT PURCHASE | NUMBER THIS TYPE | TOTAL ACTIVITY 4-12-84 |
|---|---|---|---|---|
| NEN | NES-392 | 10.00mCi | 1 | 8.76mCi |
| NEN | NES-392 | 10.00mCi | 1 | 0.48mCi |

ITEM 7

## MEDICAL RADIOISOTOPE COMMITTEE/RADIOACTIVE DRUG RESEARCH COMMITTEE (MRC/RDRC)

A. RESPONSIBILITY: This committee (MRC/RDRC) shall:

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

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

3. Receive, review and authorize all protocols submitted by proposed users wishing to use radioisotopes and radioisotope techniques in their studies. This will include human studies, animal studies, and tracer use.

4. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, physicists, and pharmacists, etc.) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations, the conditions of the license, and FDA regulations.

5. Review the facilities and equipment of proposed authorized users for adequacy of floor plans, room ventilation, fume hoods, sinks, counter tops, remote handling equipment, source storage and use shielding.

6. 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.

7. 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 HRSO, results of NRC inspections, written safety procedures, and the adequacy of the institution's management control systems.

8. Recommend remedial action to correct any deficiencies identified in the Radiation Safety Program, and promptly transmit pertinent information, as necessary to the Hospital Director; Director, Nuclear Medicine (10/115); the NRC; and other regulatory agencies.

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

10. Ensure that the by-product material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license with the following exception:

    The Director of Hines V.A. Hospital agrees to maintain the disciplines as required by Part 33.13, C., 1. and Part 35.11, b. of the NRC regulations, but requests the right to make changes in the membership without lengthy amendment procedures. The Director agrees to maintain records of all changes, qualifications and membership lists with indicators of "specialties represented" for all members.

C. MEETINGS

The MRC/RDRC will regularly meet on a quarterly basis; additional meetings will be called by the Chairman, as necessary. In these cases, notice of a minimum of one week will be given to the committee members.

D. NAME AND SPECIALTY OF EACH COMMITTEE MEMBER

Chairman: Ervin Kaplan, M.D.
Chief, Nuclear Medicine Service
**(internal medicine, specialist in nuclear medicine)**

Members:

**(therapeutic radiologist)**

Nirmala Bhoopalam, M.D.
Staff Physician, Hematology/Oncology Sec., Medical Service
**(hematologist)**

Randall Wade, Ph.D.
Chief, Radiation Physics Section
Therapeutic Radiology Service
**(radiation physicist)**

Lawrence Case, B.S.
Hospital Radiation Safety Officer
Health Physicist, Nuclear Medicine Service
**(radiation specialist)**

Harald Norgello
Coordinator for Radiation Safety, Nuclear Medicine Service
**(chemist)**

Members:

Lucia Droege, ACSW
Supervisory Social Worker, Social Work Service
**(representative of Human Studies Committee)**

Roland Mais, M.S.
Research Chemist
Research Service
**(radiochemist)**

Irene Held, Ph.D.
Chief, Neuroscience Research Section
**(representative of Research)**

John W. Cooper
Administrative Assistant, Chief of Staff
**(representative of management)**

Maynard L. Freeman, M.D.
Assistant Chief, Nuclear Medicine Service
**(Internal medicine, specialist in nuclear medicine)**

Susan Sandelli, R.N., B.S.
Supervisory Nurse, 11W, Nursing Service
**(representative of Nursing Service)**

c. Mathematics pertaining to the use and measurement of radioactivity ( 4 hours)

d. Radiation biology ( 8 hours)

This information may be submitted on Supplement A of Form NRC-313M. The hours listed next to each of the four subjects are suggested minimum values and should not be interpreted as specific requirements.

3. Evidence of active participation in the treatment of five patients (to be submitted on Supplement B (Preceptor Statement) of Form NRC-313M).

"Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be used, administration of the dose to the patient, and followup and study of patient case histories.

C. Additional - In addition, specific training of technical personnel, non-Nuclear Medicine or Therapeutic Radiology physicians, and all personnel who will handle radioisotopes and radioactive chemicals and biologicals must (1) have a degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering and (2) have at least 40 hours of training and experience in safe handling of radioactive materials, and characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material for which authorization is requested.

D. Training Purposes - Trainees such as residents, technologists in training, etc., will be under the protective supervision of a fully qualified individual in terms of their handling of radionuclides. However, when handling radionuclides, they must be supervised by a person present in the laboratory while the radioactive material is being used. In addition, they must either be receiving or have received a degree of training regarding radioactive materials commensurate with the tasks they will be required to perform.

E. Research - A researcher who wishes to be authorized for one or more specific procedures should have training in basic radionuclides handling techniques and procedures commensurate with the techniques to be performed and the quantities of radionuclide to be used.

The authorized user assumes the responsibility for the competency in handling radionuclides of all individuals under his supervision. This competency may be obtained by formal training or by preceptorship. This competency must be demonstrable to the HRSO and the MRC/RDRC. In whatever manner such competency is attained, the final responsibility for the training of personnel in radiation safety rests with the principal investigator of a project.

The authorized user will have to be qualified; the laboratory supervisor, if different from the authorized user, will have to be qualified; and the qualified laboratory supervisor must be responsible for the competent radionuclide handling techniques of those under his supervision.

This qualified user should be listed in a research proposal as that person qualified to be responsible for radioactive materials and radioactive procedures. For example, if a researcher is not qualified to handle isotopes but his laboratory supervisor is so qualified, then the laboratory supervisor should be the authorized user.

ITEM 14

## PROCEDURES FOR THE SAFE OPENING OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

A. **WEAR DISPOSABLE GLOVES WHILE CONDUCTING THE PROCEDURE AND ASSUME THE PACKAGE IS TOTALLY CONTAMINATED.**

B. All packages should be opened in an operating fume hood.

C. Visually examine the package for the Department of Transportation hazardous material label and use precautions appropriate to the "White I, Yellow II, Yellow III or radiation symbol."

D. If additional hazardous material labels (i.e., biohazard, caustic, corrosive, flammable, etc.) appear on the package, take the appropriate measures which the situation demands.

E. Visually interest the package for any sign of damage (i.e., wet, crushed, punctured, etc.), and proceed using decontamination techniques.

F. Open outer package (following the manufacturers directions (if supplied) and remove the packing slip. Open the inner package and verify that the packing slip, order form and bottle or container label agree.

G. Check integrity of final source container (i.e., breakage of seals, vials, loss of liquid, loose screw caps, discoloration of packing materials).

H. Check all shipping and packaging material with the area survey meter for contamination.

1. If the packing materials are found to be uncontaminated, dispose of them in the normal waste.

2. If either positive or negative results are found on packaging materials the results will be recorded on the inventory sheet for that shipment.

3. If the packing materials are found to be contaminated, dispose of them as radioactive waste and notify the HRSO of the final radiation survey readings found in counts/minute.

4. If externally contaminated or leaking packages are discovered, the HRSO will notify the NRC as required.

b. Records of radioactive material discarded of into the laboratory sink.

c. Reports of ingestion, inhalation, or injury involving radioactive material.

B. **GENERATOR ELUTION AND RADIOPHARMACOLOGY**

1. Generator installation, elution, and pharmacological preparation shall be done according to manufacturers' directions maintaining a sterile technique.

2. **LABORATORY COATS OR PROTECTIVE CLOTHING SHALL BE WORN WITHOUT EXCEPTION.**

3. TLD rings badges shall be worn without exception during installation of generators, elution of generators, assay of elution from generators, pharmacological procedures, and transportation of radioactive material to patient administration areas.

4. All personnel performing the above operations shall be required to use all mechanical handling devices, body shields, lead caves, and shielding as prescribed by the HRSO.

5. During the assay procedure, the operator shall be a maximum reasonable distance from the instrument.

6. All generator elution products shall be transported with sufficient lead shielding and in such a manner as to minimize the exposure of personnel and the general public.

7. The generator elution area shall be surveyed and wipe tested daily for contamination and records of results will be maintained.

8. Decontamination shall be implemented if surface contamination exceeds 200 dpm/100 $cm^2$.

C. **PATIENT INJECTION AND IMAGING**

1. All radioactive material not being injected is to be stored in lead or lead glas "pigs" behind body shields or in lead lined refrigerators designated for such use.

2. All doses of radioactive material to be administered (i.e., oral, IV, IC) shall be assayed and will be rejected if diagnostic doses exceed 50% error or therapeutic doses exceed 10% error.

3. Syringe shields shall be used for the preparation and administration of patient doses except in circumstances where their use would compromise the patient's well-being.

(21) Be responsible for assuring the calibration of monitoring and survey instruments.

(22) Verify and report to appropriate authorities any radiation incident which may have resulted or may have been likely to have resulted in injury to or contamination of personnel, damage to property, or significant release of radioactive material into the environment.

(23) Terminate immediately any activity he judges to be a threat to health safety, property the environment or a violation of the regulations or the conditions of this license.