EXHIBIT A

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION 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	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
Indiana University - Indianapolis 1100 West Michigan St. Indianapolis, IN 46223 TELEPHONE NO.: AREA CODE ( ) ____ ____	See Attachment
2. PERSON TO CONTACT REGARDING THIS APPLICATION Mack L. Richard, M.S. Radiation Safety Office TELEPHONE NO.: AREA CODE (317) 264 2003	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ NEW LICENSE b. ☐ AMENDMENT TO LICENSE NO. c. ☒ RENEWAL OF LICENSE NO. 13-02752-03
4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* Individual users approved by Radionuclide Radiation Safety Committee (RRSC member list attached)	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.)* Mack L. Richard, M.S. (Curriculum Vitae Attached)

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	X	See 6.b.
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	6,000

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	As needed in Group IV
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	As needed in Group IV
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	As needed in Group IV
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	As needed in Group V
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	As needed in Group V
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	2,500

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 Attachment			

Applicant ... May 1 ...
Check No. ... EXEMPT 35
Amount Fee Category ...
Type Fee ... REN
Date Check Rec'd ... 3/12/85
Received By ...

FORM NRC-313M (8-78)

8707280068 870317
REG3 LIC30
13-02752-03 PDR

FEE EXEMPT - see 5/13/85 ltr & 5/15/85 ltr
170.11(a)(4)

CONTROL NO. 78792

A Colvin

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 seperate 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. 1* Date: October, 1980

7. MEDICAL ISOTOPES COMMITTEE	
X — Names and Specialties Attached; and	
— Duties as in Appendix B; or *(Check One)*	
X — Equivalent Duties Attached	
8. TRAINING AND EXPERIENCE	
na — Supplements A & B Attached for Each Individual User; and	
X — Supplement A Attached for RSO. Curriculum vita attached	
9. INSTRUMENTATION *(Check One)*	
— Appendix C Form Attached; or	
X — List by Name and Model Number	
10. CALIBRATION OF INSTRUMENTS	
— Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	
X — Equivalent Procedures Attached; and	
— Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	
X — Equivalent Procedures Attached	
11. FACILITIES AND EQUIPMENT	
X — Description and Diagram Attached	
12. PERSONNEL TRAINING PROGRAM	
X — Description of Training Attached	
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X — Detailed Information Attached	
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
— Appendix F Procedures Followed; or	
X — Equivalent Procedures Attached	
	15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*
	— Appendix G Rules Followed; or
	X — Equivalent Rules Attached
	16. EMERGENCY PROCEDURES *(Check One)*
	— Appendix H Procedures Followed; or
	X — Equivalent Procedures Attached
	17. AREA SURVEY PROCEDURES *(Check One)*
	— Appendix I Procedures Followed; or
	X — Equivalent Procedures Attached
	18. WASTE DISPOSAL *(Check One)*
	— Appendix J Form Attached; or
	X — Equivalent Information Attached
	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*
	— Appendix K Procedures Followed; or
	X — Equivalent Procedures Attached
	20. THERAPEUTIC USE OF SEALED SOURCES
	X — Detailed Information Attached; and
	— Appendix L Procedures Followed; or *(Check One)*
	X — Equivalent Procedures Attached
	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)
	X — Detailed Information Attached
	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
	X — Detailed Information Attached
	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b
	X — Detailed Information Attached

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. 1* Date: October, 1980

7. MEDICAL ISOTOPES COMMITTEE		**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*	
X	Names and Specialties Attached; and		Appendix G Rules Followed; or
	Duties as in Appendix B; or *(Check One)*	X	Equivalent Rules Attached
X	Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*	
8. TRAINING AND EXPERIENCE			Appendix H Procedures Followed; or
na	Supplements A & B Attached for Each Individual User; and	X	Equivalent Procedures Attached
X	Supplement A Attached for RSO. Curriculum vita attached	**17. AREA SURVEY PROCEDURES** *(Check One)*	
9. INSTRUMENTATION *(Check One)*			Appendix I Procedures Followed; or
	Appendix C Form Attached; or	X	Equivalent Procedures Attached
X	List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	X	Equivalent Information Attached
X	Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*	
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*		Appendix K Procedures Followed; or
X	Equivalent Procedures Attached	X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		**20. THERAPEUTIC USE OF SEALED SOURCES**	
X	Description and Diagram Attached	X	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached	X	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)**	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**	
		X	Detailed Information Attached
	Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**	
X	Equivalent Procedures Attached	X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr.	Monthly
	X	TLD	R.S. Landauer, Jr.	Quarterly
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr.	Monthly
		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
State Institution - exempt

(2) LICENSE FEE ENCLOSED: $ -0-

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
Glenn W. Irwin

(TYPED NAME (Type or Print)
Glenn W. Irwin, M.D.

(2) TITLE
Vice President

c. DATE
April 9, 1985

FORM NRC-313M (8-78)

CONTROL NO. 7 8 7 9 2

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.

BUILDING ADDRESSES FOR BYPRODUCT MATERIAL USE

The following is a list of the Indiana University - Indianapolis buildings in which byproduct material is (or is likely to be) used or stored. Any other buildings which may be used in the future will be evaluated by the Radionuclide Radiation Safety Committee.

Building	Address	Zip Code
Business/SPEA Building	801 W. Michigan St.	46223
Cavanaugh Hall	425 Agnes St.	46202
Clinical Building	541 Clinical Dr.	46223
Coleman Hall	1140 W. Michigan St.	46223
School of Dentistry	1121 W. Michigan St.	46202
Emerson Hall	545 Barnhill Dr.	46223
Eng. & Tech. Building	902 W. New York St.	46202
Fesler Hall	1120 South Dr.	46223
Krannert Inst. of Card.	1001 W. 10th St.	46202
Long Hospital	1100 W. Michigan St.	46223
Medical Science Building	635 Barnhill Dr.	46223
Med. Sci. Research Bldg.	1001 Walnut St.	46223
School of Nursing	610 Barnhill Dr.	46223
Oral Health Res. Institt.	415 Lansing St.	46202
Psychiatric Res. Building	791 Union Dr.	46223
Radiation Therapy Building	535 Barnhill Dr.	46223
Regenstrief Health Cntr.	1001 W. 10th St.	46202
Riley Hospital	702 Barnhill Dr.	46223
Riley Research	702 Barnhill Dr.	46223
Rotary Building	702 Rotary Circle	46223
University Hospital	926 W. Michigan St.	46223
Power Plant	1102 North Dr.	46223
Krannert Science Building	1125 E. 38th St.	46223
Wishard Memorial Hospital	1001 W. 10th St.	46202
Lilly Clinic for Research	1001 W. 10th St.	46202
Larue Carter Hospital	1315 W. 10th St.	46202
Indiana Masonic Home*	690 S. State St. Franklin, Indiana	46131

*I-125 source in bone mineral analyzer

CURRICULUM VITAE

MACK L. RICHARD

EDUCATION

1. Indiana State University, Terre Haute, Indiana - Environmental Health - B.S. degree awarded August, 1975.

2. Purdue University, West Lafayette, Indiana - Health Physics - M.S. degree awarded August, 1976.

PROFESSIONAL EXPERIENCE

1. Radiation Safety Officer - Indiana University Medical Center, Indianapolis, Indiana - February, 1979 to present.

2. Assistant Radiation Safety Officer - Indiana University Medical Center, Indianapolis, Indiana - November, 1978 through January, 1979.

3. Operational Health Physicist - Purdue University, West Lafayette, Indiana August, 1976 through October, 1978.

ACADEMIC APPOINTMENTS

Assistant Professor of Radiology (part time) - August, 1982 to present.

CERTIFICATIONS

1. Qualified Expert (State of Indiana) - X-ray Machine Physicist

2. Qualified Expert (State of Indiana) - Health Physicist

PROFESSIONAL ORGANIZATIONS

1. Health Physics Society - plenary member

2. Hoosier Chapter of Health Physics Society - Treasurer, 1979-1980; President-elect, 1985-1986.

PROFESSIONAL COMMITTEES

1. Indiana University Medical Center - Radiation Safety Committees

2. Ad Hoc Committee on the Disposal of Low Level Radioactive Waste

3. Indiana Radiation Emergency Response Committee

PUBLICATIONS

F.C. Cook, M.L. Richard, "Incineration of Low Level Radioactive Waste - A Planning Approach", "Proceedings of the 38th Annual Purdue Industrial Waste Conference", Purdue University, West Lafayette, Indiana, May 10-12, 1983, Ann Arbor Press, 1984.

Item 5
4/9/85

Element/mass #	Chem/Phys Form	Max mCis	Purpose of Use
Atomic #'s 3 thru 83	Any	1500 ea.	Medical research, diagnosis, and/or therapy; Research & development as defined in 10 CFR 30.4(q)
H-3	Any	10000	See above
I-125	Any	3000	See above
Am-241	Any	50	See above
Cs-137	Sealed sources	200	Calibration of instruments
Gd-153	Sealed sources	4000	For use with "Lunar" spine scanner or equiv.
Cs-137	Sealed sources	1440 Ci	Irradiation of blood & blood products
Depleted Uranium	Cadmium plated metal	34 kg	Shielding for therapy devices

CONTROL NO. 8792

Item 6b
4/9/85

DUTIES & RESPONSIBILITES OF THE RADIATION SAFETY COMMITTEES

I. Radiation Safety Council (RSC)

The RSC has the overall responsibility for the radiation safety program of Indiana University - Indianapolis (IU-I) and associated facilities. The RSC coordinates the activities of various radiation safety sub-committees and makes management decisions on those activities which involve all of the facilities affected by federal, state, and/or local regulations. The RSC meets periodically to review the activities of the various radiation safety sub-committees.

II. Radionuclide Radiation Safety Committee (RRSC)

The RRSC is the administrative body responsible for the safe handling of byproduct material within the IU-I complex. This committee is the equivalent to the Medical Isotopes Committee specified in NRC Regulatory Guide 10.8. The RRSC derives its authority from the RSC and has the following responsibilities:

A. To be familiar with all pertinent NRC regulations, the terms of the NRC license, and information submitted in support of the license renewal application and amendments.

B. To review the training and experience of Principal Investigators who utilize and/or supervise the use of byproduct material and determine that their qualifications meet the minimum qualifications set forth elsewhere within this renewal application.

C. To establish a program to ensure that all individuals whose duties may require them to work with or in the vicinity of byproduct material are adequately trained.

D. To review and approve (or disapprove) applications for new and/or continued usage of byproduct material within the IU-I complex and to issue Radionuclide Use Permits for said usage.

E. To prescribe special conditions that may be necessary for the safe handling of byproduct material such as additional training and/or special precautions in the use, storage, or disposal of such material.

F. To review reports by the Radiation Safety Office concerning personnel exposures, accidents involving byproduct materials, violations of regulations, et. al.

G. To take any necessary action in the case of unsafe procedures which could result in a significant radiation hazard and/or violate pertinent regulations. In addition,

the RRSC shall require adequate measures to assure that all radiation exposures associated with the use of byproduct material are maintained as low as reasonably acheivable (ALARA).

H. To review the entire radiation safety program at least annually to assure that all activities are being conducted in accordance with all pertinent regulations and within the ALARA philosophy.

I. To maintain written records of all committee meetings, actions, recommendations, and decisions.

J. To meet as often as is necessary to conduct business but not less than once each calendar quarter.

Attendance of at least 50% of the membership at an RRSC meeting is considered a quorum. In addition, the following conditions apply when establishing a quorum: 1) the Radiation Safety Officer (or his designee) shall be in attendance, 2) a Nuclear Medicine Physician shall be in attendance for a meeting in which applications for the human use of byproduct material are being considered. RRSC members are permitted to temporarily designate individuals to attend a meeting providing the designee maintains a faculty and/or staff position at IU-I and possesses an understanding of the precautions necessary for the safe use of byproduct material. The membership of the RRSC is reviewed and updated annually as necessary. A list of the names and specialties of the current RRSC members is attached.

III. Radioactive Drug Research Committee (RDRC)

The RDRC is established under the appropriate regulations of the Food and Drug Administration and is responsible for the review and approval of protocols in which radioactive drugs are administered to human research subjects for the purpose of obtaining basic information regarding the metabolism of that drug or regarding human physiology, pathophysiology, or biochemistry, but not intended for immediate therapeutic, diagnostic or similar purposes or to determine the safety and effectiveness of the drug in humans. Protocols which do not meet the aforementioned criteria or which have been submitted directly to the FDA under an IND/NDA are referred to the RRSC for appropriate action.

RADIONUCLIDE RADIATION SAFETY COMMITTEE

AS OF 15-JAN-85

NAME	DEPARTMENT/SPECIALTY
Robert M. Witt, Ph.D (Chairman)	V.A.M.C./Medical Physicist
Robert L. Baehner, M.D.	School of Med./Pediatrics
Robert E. George, Ph.D.	Rad. Oncology/Med. Physicist
Richard Kohlar, M.D.	School of Med./Infect. Dis.
Jon P. Lindemann, M.D.	School of Med./Cardiology
Nancy Martin, R.N.	Univ. Hospital/Nursing
Bruce H. Mock, Ph.D.	Nuclear Med./Radiopharmacist
T.O. Oei, M.D.	School of Med./Pathology
Bernard E. Oppenheim, M.D.	Nuclear Med./N.M. Physician
James L. Rice	Hospital Administration
Mack L. Richard, M.S.	Radiation Safety Officer
Peter Roach, Ph.D.	School of Med./Biochemistry
Raoul S. Rosenthal, Ph.D.	School of Med./Microbiology
Robert L. Wolen, Ph.D.	Lilly Clinic/Pharmacology
Kenneth Lipkowitz, Ph.D.	School of Sci./Chemistry

CONTROL NO. 1792

Item 7
4/9/85

ADMINISTRATIVE REVIEW FOR ISSUANCE OF

RADIONUCLIDE USE PERMITS

All uses of byproduct material for research, diagnosis, or therapy are reviewed by either the Radionuclide Radiation Safety Committee (RRSC) or the Radioactive Drug Research Committee (RDRC) as specified previously. Approval of applications for use of byproduct material is issued in the form of a Radionuclide Use Permit - Rad. Safety Form A-8. These Permits are initially issued for a period of one year. At the time of expiration, the Principal Investigator has the option of cancelling the Permit or renewing the Permit by the submission of a Progress Report - Rad. Safety Form A-6. Renewed Permits are reissued for a period of two years and may be renewed every two years thereafter. Issuance of a Radionuclide Use Permit for non-human uses of byproduct material is based upon information provided to the RRSC through the submission of the Application for Project Approval/Amendment for Radioactive Material - Rad. Safety Form A-1 or equivalent by the Principal Investigator. Issuance of a Radionuclide Use Permit for the use of byproduct material in humans for research is based upon information provided to the RRSC (for research performed under IND) or the RDRC (for research as specified above in item III) through the submission of the Request for Radioactive Research Protocol Review for Human Use - Rad. Safety Form A-1a or equivalent by the Principal Investigator.

Amendments to Radionuclide Use Permits are also reviewed and approved by the RRSC/RDRC. The amount of information required to amend a given Radionuclide Use Permit is based upon the magnitude of the amendment. For example, amendment requests to change a possession limit or to add a new chemical form may be submitted via a written memorandum from the Principal Investigator to the Radiation Safety Office. More extensive amendments may require the submission of either Rad. Safety Form - A-1 or Rad. Safety Form A-1a. Upon approval by the RRSC or the RDRC an Amendment is issued to the affected Radionuclide Use Permit on Rad. Safety Form - A-8a. Principal Investigators may also request minor changes to their Radionuclide Use Permits at the time of the renewal of a Permit, e.g. with the submission of the Progress Report - Rad. Safety Form - A-6. The Radiation Safety Officer reviews each Progress Report prior to renewal by the RRSC/RDRC to ascertain the necessity of acquiring more information from the Principal Investigator.

The Radiation Safety Officer or his designee may issue temporary approval for initial requests for usage or amendments to Permits involving non-human uses of byproduct material. Temporary approval for initial requests or amendments to Permits involving the use of byproduct material in humans may only be issued by the

Chairman of either the RRSC or the RDRC. In either case, this temporary approval allows the Principal Investigator to begin the proposed use until such time that the RRSC or the RDRC is able to meet, formally review and approve the proposed use, and issue the Radionuclide Use Permit or Amendment. Samples of the aforementioned Rad. Safety Forms are attached. The RRSC may modify these forms as necessary and appropriate.

Rad. Safet, Form A-1
(Revised Oct., 1983)

Date Rec'd:_____

INDIANA UNIVERSITY MEDICAL CENTER
RADIATION SAFETY OFFICE

APPLICATION FOR PROJECT APPROVAL/AMENDMENT
FOR RADIOACTIVE MATERIAL

Note: Please type or print.

Applicant:_____ Expected starting date:_____

Department:_____ Office (bldg/rm):_____

Telephone #'s - Office:_____ Home:_____ Lab:_____

Check one of the following:
___ This is an initial application.
___ This application is to amend a currently approved project (#:_____)

Nuclide(s)	Chemical and physical form(s)	Maximum mCi/experiment	Maximum Poss. Limit (mCi)

Building and room(s) where radioactive materials will be used and/or stored:

(Bldg-rm) _____

Rad. Safety Form A-4 "Application for Facility Approval for Radionuclide Usage" must be submitted for all facilities not previously approved for such use.

Applicant's Signature:_____ Date:_____

Do not write below this line.

Radionuclide Use Permit Number:_____ Amendment Number:_____

Temporarily Approved By:_____ Date:_____

Approved By Radionuclide Radiation Safety Committee Date:_____

Item 7
4/9/85

Attachment 1

[illegible] NO. [illegible]

PLEASE SUBMIT THE FOLLOWING INFORMATION ON ADDITIONAL PAPER.

The following item numbers should be keyed to your responses on attached pages. For amendments to currently approved Radionuclide Use Permits, some of these items may be omitted; however, incomplete information will delay the approval of this application. Consult the Radiation Safety Manual and/or the Radiation Safety Staff if you have questions regarding the completion of this application.

1. Summarize the purpose and method of your project or amendment. Discuss in detail your protocol for the physical handling of the radionuclide(s) (e.g. dilution techniques, labeling procedures, method of radioassay, etc.).

2. Discuss laboratory monitoring and survey procedures. Specific details should include the method and frequency of lab surveys, instrumentation used to evaluate such surveys, and the location of your survey records.

3. Indicate the types of radioactive waste (solids, aqueous liquid, organic liquids, scintillation vials, animal carcasses, etc.) which will be generated during the course of your procedure. Specify any extraordinary radwastes which will be generated and/or any special conditions (e.g. shielding) necessitated by the radwaste.

4. Specify the precautions, procedures, and equipment which will be utilized in conjunction with your protocol to minimize the possibility of contamination and/or external radiation hazards (e.g. absorbent paper, vinyl gloves, spill trays, shielding, remote handling devices, et.al.).

5. Indicate the storage conditions for the radioactive material including location and type of containment and precautions taken to prevent unauthorized removal of the material from storage and use areas.

6. If a radionuclide is to be used in animals (in-vivo), provide the following information:

   a. Type of animal(s) to be used.
   b. Average mass of each animal.
   c. Total number of animals to be used in the entire study.
   d. Activity (mCis) to be administered to each animal.
   e. Number of animals to be disposed of each week.
   f. Route of radionuclide administration.
   g. Provisions for any radioactivity which will be exhaled or excreted by the animal and methods to control contamination from such animals.
   h. Indicate where the animals will be housed for long-term studies.

7. Include all training and experience which qualifies you to use the radioactive material(s) in the proposed manner.

8. List all personnel involved in this project who will be handling any radioactive materials. Rad. Safety Form A-3, "Authorization to Use Radioactive Materials" should be completed and submitted to the Radiation Safety Office for each of these individuals.

Rad. Safety Form A-1a
(Revised Aug. , 1978)

Date Received: _____

INDIANA UNIVERSITY MEDICAL CENTER
RADIOACTIVE DRUG RESEARCH COMMITTEE

REQUEST FOR RESEARCH PROTOCOL REVIEW

Note: Please type or print. You will receive written authorization upon approval.

Application No. ___ _____ ___
(Do not write in this box)

Applicant: _____ Expected starting date: _____

Department: _____ Phone (office) _____ (home) _____

Title of research project: _____

_____

Brief description of the research project:

Has application been approved by the Protection of Human Subjects Committee? ☐ Yes ☐ No ☐ Pending

Applicant's Signature: _____ Date: _____

Temporary Approval: Chairman, Radioactive Drug Research Committee Date: _____

Approved: Radioactive Drug Research Committee Date: _____

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Radiation Safety Form A-1
Radioactive Drug Research Committee

PLEASE SUBMIT THE FOLLOWING INFORMATION ON ADDITIONAL PAPER

1. Pharmacological dose calculations based on data available from published literature or other valid human studies. (The amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings.)

2. Biological distribution data (i.e., percent uptake of administered dose by various organs and the biological half-life for those organs) available from published literature or from other valid studies.

3. An acceptable method of radioassay of the radioactive drug prior to its use to assure that the radiation absorbed dose calculations actually reflect the administered dose.

4. Statement that the radioactive material for parenteral use is prepared in sterile and pyrogen-free form.

5. Statement of training and experience which qualifies you to conduct the proposed research study.

6. Statement that a log of the following will be kept and submitted to the Radiation Safety Office (for annual reporting purposes to the FDA) when requested.

    a. Subject's approximate weight
    b. Age
    c. Sex
    d. Name of each radioactive drug administered, the radionuclide and active administered, number of times the radioactive drug was administered, and any x-ray procedures done in conjunction with the study.

7. Statement that all adverse reactions probably attributable to the use of the radioactive drug in the research study shall be immediately reported to the Radioactive Drug Research Committee.

CONTROL NO. 7 8 7 9 2

Rad. Safety Form A-6
(April, 1')

INDIANA UNIVERSITY MEDICAL CENTER
RADIATION SAFETY OFFICE

PROGRESS REPORT

Principal Investigator:_____ Authorization #:_____

A current copy of your Radionuclide Use Permit and associated Amendments is attached. This Permit has expired or is about to expire. If this project is to be continued, please review each section of the attached Permit and indicate any changes and/or discrepancies directly on the Permit if space is sufficient. If more space is required, attach supplemental pages as necessary and return this entire packet of information to the Radiation Safety Office by _____. The Progress Report will then be reviewed by the Radionuclide Radiation Safety Committee or the Radioactive Drug Research Committee at the next quarterly meeting which is scheduled for _____. The project may be continued under the existing Permit until review and approval by the appropriate Committee is attained. Failure to complete and return this Report will result in termination of the Radionuclide Use Permit.

Please check the appropriate box and sign below:

☐ This project is completed. (If this is the case, please list any radioactive materials and their activities that you intend to store; remaining inventory must be taken to the Radioactive Waste Disposal Facility.)

☐ I wish to renew this project with the changes indicated on the attached Radionuclide Use Permit and supplemental pages.

☐ I wish to renew this project exactly as stated on the attach Radionuclide Use Permit.

Investigator's Signature:_____ Date:_____

(Note: You may wish to retain a copy of the completed Progress Report Form until your new Radionuclide Use Permit is issued.)

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Rad. Safety Form A-8
(Revised Oct , 1984)

INDIANA UNIVERSITY MEDICAL CENTER
RADIONUCLIDE USE PERMIT

☐ Initial Permit
☐ Renewal

Authorization Number:_____ Issued to:_____

Date Issued:_____ Expiration Date:_____

In accordance with the statements and representations made in your Application for Project Approval and/or your Progress Report dated_____ an approval authorizing the below named individuals to order, possess and use the materials or items designated below in accordance with NRC regulations, state regulations, university regulations and such other conditions as are herein specified.

1. Authorized Users:

Name	Department

2. Locations of Use:

Building	Room	Comments

3. Authorized Items:

Nuclide or Item	Chemical Form	Max. Amt.(mCi)/Exprmt.	Poss. Limit (mCi)

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Attachment 4

(over)

4. Authorized Use:

5. Conditions of Authorization:

Approved: _____ Date _____
Chairman, Radionuclide Radiation Safety Committee

Rad. Safety Form A-8a
(June, 1979)

RADIONUCLIDE USE PERMIT
AMENDMENT

Authorization Number:_____ Issued to:_____

Amendment Number:_____ Amendment Date:_____

Date of Project Approval:_____ Expiration Date:_____

In accordance with the statements and representations made in your Application for Amendment dated_____, approval of the Amendment is hereby granted with specific conditions as are herein specified.

Approved:_____ Date:_____
Chairman, Radionuclide Radiation Safety Committee

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Attachment 5

CONTROL NO. 7 8 7 9 2

RADIONUCLIDE RADIATION SAFETY COMMITTEE

MINIMUM TRAINING REQUIREMENTS FOR USE OF BYPRODUCT MATERIAL

I. Human use - routine diagnosis and therapy

A. For Groups I, II, and III (as per 10-CFR-35) the user shall:

1. Be a licensed physician in the State of Indiana,

2. Be certified by one or more of the following:

a. American Board of Nuclear Medicine

b. American Board of Radiology with Special Competency in Nuclear Imaging

c. American Board of Radiology in General Radiology

3. In lieu of the certifications specified in item 2, the physician shall:

a. Have completed an AMA approved nuclear medi- residency, or

b. Have satisfied the training requirements as specified in NRC Reg. Guide 10.8, Appendix A for Groups I, II, and III.

4. Physicians who have been previously approved for Groups I, II, and III under another license (either NRC or Agreement State) are automatically approved under the IU-I license.

B. For Groups IV and V, the user shall:

1. Be a licensed physician in the State of Indiana,

2. Be certified by one or more of the following:

a. American Board of Radiology in General Radiology or Therapeutic Radiology

b. British Fellow of the Faculty of Radiology

c. Canadian Fellow of the Royal College of Radiology

d. Royal College of Physicians and Surgeons with certification in therapeutic radiology

3. In lieu of the qualifications specified in item 2, the physician shall:

a. Meet the minumum qualifications as specified in item A for Groups I, II, and III and have participated in clinical studies as outlined in NRC Reg. Guide 10.8, Appendix A, 4.b., or

b. Have completed an AMA approved residency program in either nuclear medicine or radiation therapy (oncology) which includes training for uses of radiopharmaceuticals listed under Groups IV and V, or

c. Have satisfied the training requirements as specified in NRC Reg. Guide 10.8, Appendix A, 4.a. and b.

4. Physicians who have been previously approved for Groups IV and V under another license (either NRC or Agreement State) are automatically approved under the IU-I license.

C. For Group VI sealed sources used for therapy, the user shall:

1. Be a licensed physician in the State of Indiana,

2. Meet the certification requirements as listed above in item B.2., or

3. Have completed an AMA approved residency program in radiation therapy, or

4. Have met the requirements set forth in NRC Reg. Guide 10.8, Appendix A, 5.a.,b., and c.

5. Physicians who have been approved for therapeutic uses of Group VI sources under another license (either NRC or Agreement State) are automatically approved under the IU-I license.

D. For Group VI sealed sources utilized for diagnostic procedures, the user shall:

1. Be a licensed physician in the State of Indiana,

2. Meet the qualifications specified above in items A.,B., or C.

3. In lieu of meeting the qualifications specified in item 2, the user shall either:

a. Have received a total of 8 hours of training

covering (but not limited to) the following topics:

1. Radiation physics and instrumentation

2. Radiation biology

3. Radiation protection

b. Or have actively participated in the use of sealed sources for diagnostic purposes for 20 patients over a period of one year under the supervision of a fully trained individual.

4. Physicians who have been approved for the diagnostic uses of Group VI sources under another license (either NRC or Agreement State) are automatically approved under the IU-I license.

E. For use of Sr-90 ophthalmic therapeutic applicators, the user shall:

1. Be a licensed physician in the State of Indiana,

2. Meet the qualifications specified in NRC Reg. Guide 10.8, Appendix A, 6.a. and b., or

3. Have actively participated in the use of Sr-90 eye applicators involving a minimum of 10 patients.

4. Physicians who have been approved for the use of Sr-90 eye applicators under another license (either NRC or Agreement State) are automatically approved under the IU-I license.

II. Human use - research

A. For human use research involving annual radiation dose equivalents to research subjects of 1 rem or less to the whole body and/or 3 rem or less to an individual organ, the user shall:

1. Be a licensed physician in the State of Indiana,

2. Meet the training requirements specified in the next section (III), and

3. Have actively participated in at least 5 studies involving the use of byproduct material in humans.

B. For human use research involving annual radiation dose equivalents to research subjects greater than those listed above in item A, the user shall meet the mini-

mum qualifications previously specified in section I., A.

III. For non-human use of byproduct material, the user (Principal Investigator) shall:

A. Be a faculty and/or professional staff member, and

B. Meet the training requirements specified in 10-CFR-33.15.

C. An individual who has completed one of the following combinations of training and experience is deemed to be adequately trained as specified in item B:

1. Either, 30 hours training/experience in handling byproduct material of the types and quantities for which approval is being requested and have attended a formal course including the following general topics (or equivalent):

a. Elementary radiation physics

b. Biological effects of radiation

c. Radiation protection

d. Regulations

2. Or, 40 hours training/experience in handling the types and quantities of byproduct material for which approval is being requested.

3. Other combinations of training/experience are considered adequate providing the total number of hours is not less than 40.

All physicians/Principal Investigators are required to provide documentation to the RRSC/RDRC to substantiate the extent of their training and experience. Documentation of training for physicians who wish to use byproduct materials in humans must include the information requested on Form NRC 313M - Supplement A. Documentation of training for individuals who wish to use byproduct materials for non-human use applications must provide said documentation on Rad. Safety Form A-3 (attached) or equivalent.

Rad. Safet Form A-3
(Revised Feb., 1982)

INDIANA UNIVERSITY MEDICAL CENTER
RADIATION SAFETY OFFICE

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

This form must be on file in the Radiation Safety Office (920 Clinical Bldg.) prior to beginning work with radioactive materials. Note: You are required to read and understand the "IUMC Radiation Safety Manual". In addition, the pertinent regulations of the U.S. Nuclear Regulatory Commission are available for review in the Radiation Safety Office.

Name:_____ Birth Date:_____ Sex: ○M ○F

Department:_____ Supervisor:_____

Laboratory Location:_____ Phone #:_____

○ I have taken a course in Radiation Safety at _____.
(Attach certificate if available.) (Institution)

○ I have received _____ of on-the-job training using the following isotopes: (# of years)

Nuclide	Chemical and Physical Form	Maximum Amount Utilized

○ I have taken no Radiation Safety Courses nor have I received any on-the-job training regarding radioisotope handling.

I certify that all of the above information is correct and that I have read and understand the "IUMC Radiation Safety Manual".

Signed:_____ Date:_____

(Do Not Write Below This Line)

Applicant Authorized to Work with Radioactive Materials by:

○ Completing the IUMC Radiation Safety Course on_____

○ Previous training and/or experience

Approved:_____ Date:_____
(Radiation Safety Officer)

Item 8
4/9/85

Attachment 1

INSTRUMENTATION FOR SURVEYING AND MONITORING

Type of Instrument	# Available	Max. Range	Use
Ludlum Model 3 Geiger Counter	2	200 mR/hr	Surveying
Ludlum Model 44-3 NaI Probe	1	n/a	Surveying
Eberline RO-1 Ion Chamber	1	500 R/hr	Surveying
Ludlum Model 177 Ratemeter/W.B. Johnson DIG-5 Scaler	1	200 mR/hr and 400000 cpm	Surveying and Monitoring
Packard Tri-Carb Model 3255 Liquid Scintillation Counter	1	n/a	Counting
Packard Tri-Carb Model 3003 Gamma Spectrometer	1	n/a	Counting
Canberra Series 80 MCA with GeLi/NaI Detectors	1	n/a	Counting
Canberra/Ortec 2030 SCA with thin NaI Detector	1	n/a	Thyroid Counting

The equipment listed above is a current inventory of instrumentation located in and utilized by the Radiation Safety Office. This inventory may be updated periodically with the purchase of new equipment and the replacement of old equipment.

The Radionuclide Radiation Safety Committee (RRSC) shall determine the necessity of the procurement and use of survey instrumentation during the review of initial applications, amendments, and renewals for the use of radioactive materials. A specific requirement for survey instrumentation shall be spelled out on the Principal Investigator's Radionuclide Use Permit(s).

CALIBRATION OF SURVEY INSTRUMENTATION

I. Instruments utilized for measuring exposure rates

Survey instruments utilized for measuring exposure rates from gamma or x-ray emitting sources of radiation are calibrated by comparing the calculated exposure rates from Cs-137 sources of which the accuracy is known. Copies of the Cs-137 source certificates of the sources utilized for this purpose are attached. The procedures utilized for the calibration procedure are as follows:

A. The output of each source utilized in the calibration is determined by decay correcting the values as indicated on the calibration certificate for the source.

B. Calibration is verified at 2 points on each scale with each point separated by at least 1/3 of the full scale reading.

C. The true exposure rates for the points identified in item 2 are calculated utilizing the inverse square law as well as any attenuation factors associated with the calibration device.

D. An instrument is considered to be in calibration if the measured exposure rate differs from the true exposure rate by no more than +/- 10%.

E. If the criteria specified in item 4 are not met, an attempt is made to adjust the calibration pot(s) on the instrument to meet said criteria (i.e. within +/- 10%).

F. If an instrument cannot be adjusted to meet the +/- 10% criteria but the measured exposure rate is within +/- 20% of the true exposure rate, the instrument will be considered in calibration provided a correction factor or graph is attached to the instrument which will allow the user to correct the measured reading accordingly.

G. If the measured exposure rates differ from the true exposure rates by more than +/- 20%, the instrument is not considered to be in calibration and is either repaired or replaced.

H. A calibration certificate (sample attached) is completed for each instrument calibrated.

I. A calibration label (sample attached) is affixed to the instrument upon completion of calibration.

J. If the instrument is equipped with a check source, the reading from the check source is recorded on both the calibration certificate and the calibration label.

K. All individuals performing these calibrations wear whole body personnel dosimeters during the calibration procedures.

L. Calibration procedures are carried out in restricted areas within the Radiation Safety Office and are posted as "Radiation Areas" during said procedures.

M. Calibration procedures are performed utilizing methods and areas which minimize scatter.

II. Calibration of survey instruments utilized for measurement of contamination levels

In many cases survey instruments are utilized to determine the presence or absence of contamination. These types of instruments do not require calibration; however, in some cases these instruments are utilized to provide a quantitative indication of the amount of radioactive contamination present. For those instruments, the following calibration procedures are utilized:

A. Counting rates from disk sources (either beta or gamma) of known radioactivity are measured on the appropriate scale of the instrument and recorded.

B. The efficiency of the instrument for that particular radionuclide (or energy) is then calculated and recorded on the calibration certificate and the calibration label (samples attached).

C. Unless otherwise noted, these efficiency measurements are taken at or near contact and the efficiency calculated is based upon 4 pi geometry.

Rad. Safety Form A-9
(December, 1978)

Date Calibrated: _____

INSTRUMENT CALIBRATION FOR GAMMA DETECTORS

INSTRUMENT DATA

Principal Investigator: _____

Manufacturer: _____

Model #: _____ Serial #: _____

Last Calibration Date: _____

SOURCE DATA

Source #: _____ Nuclide: _____ mR/hr at 1 meter: _____ date

Source #: _____ Nuclide: _____ mR/hr at 1 meter: _____ date

CALIBRATION DATA

Source #	True mR/hr	Distance	Scale	Observed mR/hr	mR/hr after Adjustment

---

Check source reading with window open: _____

Battery condition: _____ Speaker working: ☐ yes ☐ no ☐ na

Comments: _____

Calibrated by: _____ date

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4/9/85

Attachment 1

CONTROL NO. 78792

(December 78)

Date Calibrated: _____

INSTRUMENT CALIBRATION
FOR BETA DETECTORS

INSTRUMENT DATA

Principal Investinator: _____

Manufacturer: _____

Model #: _____ Serial #: _____

Last Calibration Date: _____

****

CALIBRATION DATA

Nuclide	E-max	Activity	Assay Date	Calculated DPM	Observed CPM	Detector Efficiency

****

Check source reading with window open: _____

Battery condition: _____ Speaker working: ☐ yes ☐ no ☐ na

Comments: _____

Calibrated by: _____
date

Item 10a
4/9/85

Attachment 2

CALIBRATION LABELS

RADIATION SAFETY OFFICE

Calibration Date: _____

Source: _____ *Scales:* _____

Calibrated By: _____

Calibration Due: _____

BETA EFFICIENCY CALIBRATION

Nuclide	Energy	% Eff.
C-14	0.156 MeV	_____
Tc-99	0.292 MeV	_____
Cl-36	0.714 MeV	_____
Bi-210	1.16 MeV	_____

By _____ Date _____

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4/9/85

Attachment 3

ICN Chemical & Radioisotope Division

A Division of International
Chemical & Nuclear Corporation

2727 Campus Drive
Irvine, California 92664
Telephone 714: 833-2500

CALIBRATION CERTIFICATE

Owner Indiana University

[illegible] West Michigan St

Indianapolis, Ind. [illegible]

Nuclide Cesium-137 Amount [illegible] Ci

Capsule type [illegible] Capsule number [illegible]

Calibration is made using an ionization chamber and electrometer. Standardization of chamber has been accomplished with ± 2% and ± 3% standards.

Source number [illegible] measured [illegible] mrhm

on February [illegible], 19[illegible]. Total error is within ± 5%.

H B Carter
Source Department

Item 10a
4/9/85

Attachment 4

ICN Chemical & Radioisotope Division

A Division of International Chemical & Nuclear Corporation

2727 Campus Drive
Irvine, California 92664
Telephone 714: 833-2500

CALIBRATION CERTIFICATE

Owner Indiana University Hospital
926 W. Michigan Street
Indianapolis, Indiana, 46202

Nuclide Cesium-137 Amount 10.5 mCi

Capsule type 375 Capsule number 1213

Calibration is made using an ionization chamber and electrometer. Standardization of chamber has been accomplished with ± 2% and ± 3% standards.

Source number 1213 measured 3.36 mrhm

on May 30,1978. Total error is within ± 5%.

Source Department

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4/9/85

Attachment 5

THIS SOURCE WAS TESTED FOR
EXTERNAL CONTAMINATION OR LEAKAGE
on 11-7-84 by RLK
and 11-7-84 by RLK

Ref 213

Standards Laboratory Report

Tech/Ops

Tech/Ops, Inc.

TECHNICAL OPERATIONS INC

Radiation Products Division
Burlington, Massachusetts 01803

GAMMA RAY SOURCE CALIBRATION

Isotope	Test No.	Date Measured
CS-137	30090	20 NOV 1984

Source Identification	Roentgens/Hr. at 1 Meter	Curies
S-509	0.0490	0.153

Source decay correction factors

Age in:	Cobalt-60 years	Cobalt-60 mos	Iridium-192 weeks	Iridium-192 days	Cesium-137 years
0	1.000	1.000	1.000	1.000	1.000
1	.877	.989	.937	.991	.977
2	.768	.978	.877	.981	.955
3	.674	.967	.821	.972	.933
4	.590	.957	.769	.963	.912
5	.518	.946	.721	.954	.892
6	.454	.936	.675	.945	.871
7	.398	.926	.632	.937	.852
8	.349	.916	.592		.832
9	.306	.905	.554		.813
10	.268	.895	.519		.795
11	.235	.886	.486		.777
12	.206	.877	.455		.759
$T_{\frac{1}{2}}$	5.26y		74.0d		30.2y
Rhm/ci	1.30		0.55		0.32

MODEL 773, S/N 199

The gamma-ray emission of the sealed source herein described was intercompared with the radiation from a reference standard cobalt-60 source whose intensity had been established relative to a National Bureau of Standards calibrated cobalt-60 source. Comparison was made either with an uncollimated plastic-lined ionization chamber encased in a 3-mm thick aluminum container sealed against atmospheric pressure, or with an NBS-calibrated Victoreen R-meter whose readings were compensated for atmospheric pressure and temperature. All readings were corrected for air scattering and absorption. The source was measured with its axis of symmetry parallel with/perpendicular to the line joining source and detector. The reported output is believed to be accurate within ± 3 percent, the stated uncertainty of the reference NBS sources. Precision is believed to be better than ± 1 percent.

Signed Robert L. Kelly

Calibration performed for: Nuclear Associates
Division of Victoreen, Inc.
100 Voice Road
Carle Place, NY 11514

Attachment 6

Item 10a
4/9/85

CONTROL NO. 78792

METHODS FOR CALIBRATION OF DOSE CALIBRATORS

All radiopharmaceutical doses must be assayed for amount of radioactivity with a dose calibrator to an accuracy of + or - 10%. To assure that all dose calibrators provide this degree of accuracy, the following calibration procedures are carried out:

I. Instrument constancy (daily) - a long-lived radioactive source is assayed on a daily basis prior to use of the dose calibrator on the appropriate instrument setting and recorded. Decay corrections shall be made as necessary. Variations from one day to the next of greater than + or - 5% indicate a need for instrument repair or adjustment.

II. Instrument accuracy (at installation and annually) - measurements of at least 3 NBS-traceable standards are made on the appropriate instrument settings and recorded. The measured activities are compared with the decay corrected standard values. Variations between the calculated and measured values of greater than + or - 5% indicate a need for repair or adjustment.

III. Instrument linearity (at installation and quarterly) - an aliquot of a short-lived radioactivity (typically 200 mCis of Tc-99m) is eluted and assayed at least 4 times over a 48 hour period. At the time of each assay, the amount of radioactivity remaining is calculated based on the elapsed time from the initial assay and recorded. The measured value is compared to the decay corrected value and recorded. Variations between the calculated and measured values of greater than + or - 5% indicate the need for repair or adjustment.

IV. Geometrical variation (at installation) - a properly calibrated, unopened vial containing a specific radiopharmaceutical is assayed at the setting recommended by the dose calibrator manufacturer. If, after accurate decay correction, the measured value differs by more than + or - 5% from the calculated value, the dose calibrator setting is adjusted to yield the calculated activity or a correction factor is calculated. A commonly used volume is then withdrawn from the vial into an appropriate syringe. Like volume of water or saline is placed into the vial to restore the original geometry. The vial is reassayed and the difference in the readings is assigned to the syringe. The syringe is assayed and an alternate setting or correction factor established if variations of greater than + or - 5% are noted. These procedures are used for all routinely encountered syringes, vials, tubes, etc. The specific settings or correction factors for each geometry are posted on or near the dose calibrator.

All of the aforementioned tests are performed following any extensive service or repair of the dose calibrator.

FACILITIES AND EQUIPMENT

Each Principal Investigator (P.I.) desiring to use byproduct material in previously unauthorized areas must complete and submit Rad. Safety Form A-4 or equivalent (see attached). The information provided on this form is evaluated along with the intended use of the facility by the Radiation Safety Staff. In areas where large quantities of byproduct material are to be utilized (e.g. > 100 mCis) or where particularly hazardous procedures (e.g. iodination procedures with I-125 or I-131) are to be carried out, the completed Rad. Safety Form A-4 will be submitted to the Radionuclide Radiation Safety Committee (RRSC) for review and subsequent approval. Such approvals shall be documented in the minutes of the RRSC meeting. The Radiation Safety Officer may issue temporary approval prior to action by the RRSC.

Authorization to use the proposed facility is granted provided the facility is adequate to carry out the specific use of the byproduct material safely. The RRSC may require modification of facilities and/or equipment or place restrictions on the use of byproduct material in order to maintain an adequate margin of safety and to maintain exposures ALARA. The Radiation Safety Staff shall verify that such modifications/restrictions have been implemented prior to the specific use.

An updated Rad. Safety Form A-4 or equivalent information is required in areas where extensive renovation has taken place since initial approval was granted.

Rad. Safety Form A-4
(Revised August, 1978)

Date Received: _____

INDIANA UNIVERSITY MEDICAL CENTER
RADIATION SAFETY OFFICE

APPLICATION FOR FACILITY APPROVAL FOR RADIONUCLIDE USAGE

Department _____ Building and Room _____

Sketch of Facility:

Type of Floor Covering: _____ Bench Top Materials: _____

Walls and Ceiling: (painting or coating) _____

Hood(s): Singly ducted? ☐ yes ☐ no; Flow rate with sash open: _____ fpm

Number of persons normally working in area: _____

Educational level of persons in area: ☐ undergrad; ☐ grad; ☐ technician;

☐ postdoct or faculty

Are other personnel working in this facility approved radioisotope workers? _____

Is this area also used for study/office area for research personnel? _____

List monitoring devices located in this facility: (Make, Model, Type, Range)

List special handling facilities: (shielding, glove boxes, etc.)

Staff member in charge of laboratory: _____

Individual submitting this request: _____ Date: _____

Approved: _____ Date: _____
(Radiation Safety Officer)

Item 11
4/9/85

Attachment 1

CONTROL NO. 7 8 7 9 2

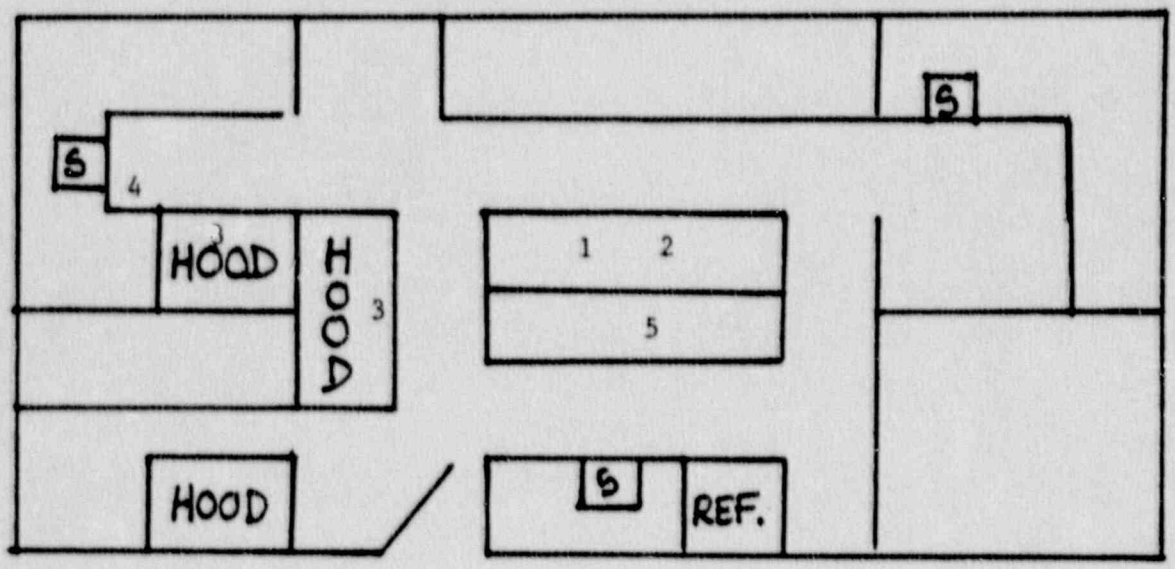
Principal Investigator: Henry Wellman

Building/Room: University Hospital Radiopharmacy

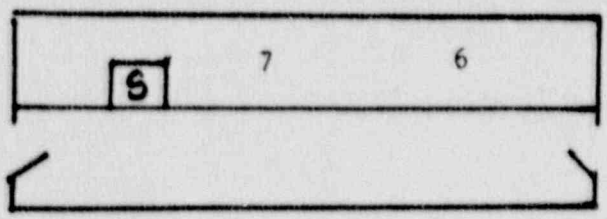
Date Updated/Activated: July, 1984

1. Dose calibrator
2. "L" shield
3. Radiopharmaceutical hoods
4. Shielded radwaste storage
5. Constant area monitor
6. Dose calibrator
7. "L" shield

RADIOPHARMACY/HOT LAB



DISPENSING AREA



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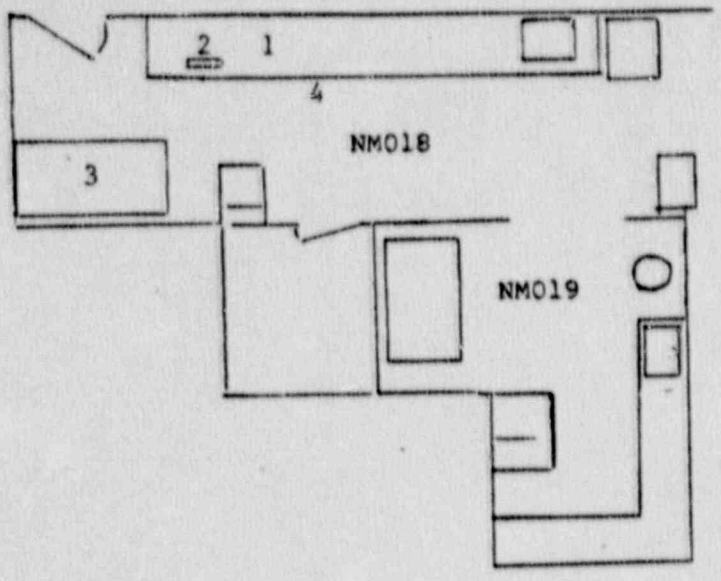
Attachment 2

W .IARD NUCLEAR MEDICINE

RADIOPHARMACY

Principal Investigator: Dr. Park



1. Dose calibrator
2. "L" shield
3. Radiopharmaceutical hood
4. Shielded radwaste storage

Item 11
4/9/85

Attachment 3

[redacted] NO. [redacted]

PERSONNEL TRAINING PROGRAM

I. Principal Investigators

Principal Investigators (P.I.) are those individuals who are issued Radionuclide Use Permits by the Radionuclide Radiation Safety Committee or the Radioactive Drug Research Committee and are responsible for the radiation safety aspects of all procedures carried out under those permits. The minimum training requirements for P.I.s are spelled out elsewhere in this renewal application (see Item 8). If a prospective P.I. does not meet the minimum qualifications as specified in Item 8, he/she may partially meet those requirements by attending the Radiation Safety Course provided by the Radiation Safety Department. This course consists of approximately 10 one hour lectures which include the following topics:

Atomic Structure & the Nature of Radiation
Interaction of Radiation with Matter
Radiation Quantities and Units
Sources of Radiation Exposure
Biological Effects of Radiation
Permissible Dose Limits
External Radiation Protection
Internal Radiation Protection
Radiation Monitoring Devices
Regulations/Handling Procedures

This Radiation Safety Course is offered a minimum of two times annually. Attendance records are maintained of all individuals who attend this course.

The P.I. is also required to possess practical experience in handling byproduct material. This practical experience may be received under the supervision of another fully authorized P.I. and should be of approximately 30 hours duration. All P.I.s are required to read the IUMC Radiation Safety Manual. Documentation of the training and experience of each P.I. is maintained via Rad. Safety Form A-3 (sample attached in Item 8) or equivalent for non-human uses of byproduct material or NRC 313M - Supplement A or equivalent for human uses of byproduct material.

If new or revised regulations, policies, and/or procedures mandate additional training for P.I.s, this additional training is typically accomplished via written directives from the Radiation Safety Office and/or the RRSC/RDRC. These directives may be specific to a given P.I. or may be general to all P.I.s. Additional training in a lecture format may be requested by the P.I. or may be required as necessary and appropriate. The P.I. has the responsibility to educate all individuals under his/her supervision regarding matters of radiation safety.

II. Authorized users

Authorized users are those individuals who are working on one or more Radionuclide Use Permits under the supervision of a P.I. Much of the training received by these individuals is provided by the P.I. These individuals are required to read the IUMC Radiation Safety Manual and to complete and submit Rad. Safety Form A-3. If these individuals independently perform tasks (e.g. iodinations) which carry a greater degree of risk and previous experience in these tasks is absent, the individual is required to attend the Radiation Safety Course. Changes in regulations, policies, and/or procedures which may directly affect these individuals are provided to the P.I. who in turn must inform those individuals working under his/her Radionuclide Use Permit(s). Additional training in a lecture format may be requested by the P.I. or may be required as necessary and appropriate. Documentation of formal lectures regarding radiation safety shall be maintained.

III. Other individuals considered occupational radiation workers

These individuals are those whose duties require that they work with byproduct materials under rigidly controlled guidelines (e.g. nurses attending brachytherapy or radiopharmaceutical therapy patients, animal handlers, et.al.). These individuals are provided specific written guidelines that are directed to their particular situation. Written revisions in these guidelines are submitted through the appropriate supervisor. In cases where personnel monitoring is required, female employees are required to review NRC Regulatory Guide 8.13 with documentation that they have done so. Additional training in the form of inservice lectures may be requested by the individuals or their supervisor. Additional training in the form of inservice lectures may by required as necessary and appropriate. Documentation of inservice lectures regarding radiation safety shall be maintained.

Written guidelines for the examples listed above are included in the appropriate sections of the renewal application.

IV. Other individuals who occasionally enter restricted areas

These individuals are those persons whose duties may require that they enter a restricted area for a brief period of time (e.g. secretaries, janitors, etc.). These types of employees attend some type of orientation program provided by the university or the hospitals. During this orientation program, a packet of information regarding employment at this institution is distributed to each employee. A copy of a document entitled "Instructions to Individuals Who Frequent Areas Containing Radioactive Materials" (sample attached) is included in the orientation packet. Additional information may be requested by any concerned individuals through the Radiation Safety Office. Additional training may be required as necessary and appropriate. Documentation of formal presentations regarding radiation safety shall be maintained.

(October, 1979)

INSTRUCTIONS TO INDIVIDUALS WHO FREQUENT AREAS CONTAINING RADIOACTIVE MATERIALS

As part of your routine job duties, you may be required to enter an area of the university complex containing radioactive material. The areas in which this material is stored are located throughout the IUPUI complex. All of these areas are required to be posted with the radiation warning symbol. The actual containers holding radioactive material will also be labelled with this symbol (An illustration of this radiation symbol is found below). It is important that you do not touch any object with a radiation warning symbol on it or remove it from the area in which it is stored. Although the levels of radiation exposure expected in the restricted areas are low, good radiation safety measures should be taken. In order to minimize your exposure to radioactive materials, the safety principles of time and distance should be applied, that is:

1) Keep the time of exposure to radiation to a minimum while performing the appropriate duty.
2) Maintain a reasonable distance between the source of radiation and yourself.

If you observe any condition in a restricted area that appears to be unsafe, leave the area immediately and notify:

The Radiation Safety Office----264-4797 (8:00 AM to 5:00 PM)

The University Operator----0 (After Hours)

If you have further questions regarding radiation safety, please do not hesitate to call the Radiation Safety Office at the number listed above.

----Red symbol and lettering

----Yellow background

Item 12
4/9/85

Attachment 1

CONTROL NO. 78792

PROCEDURES FOR ORDERING AND RECEIVING BYPRODUCT MATERIAL

I. Ordering of byproduct material

A. In general, the Radiation Safety Officer (or his designee) places all orders for byproduct material.

B. In emergency situations, a Principal Investigator (P.I.) is permitted to call the byproduct material vendor directly providing the following actions are taken:

1. The Radiation Safety Office is notified by phone of such action within one working day, and

2. The byproduct material is shipped to a location designated below in item II, and

3. The P.I. shall submit any documentation deemed necessary by the Radiation Safety Office.

C. Prior to placing the order, the Radiation Safety Officer (or his designee) shall verify that the P.I. is authorized to procure the byproduct material.

D. In the event that a P.I. is not authorized for the byproduct material, the order may be placed with the stipulation that appropriate written information be submitted to the Radiation Safety Officer to obtain temporary authorization for said material. Upon receipt, the byproduct material will not be released to the P.I. until such written information is received and reviewed by either the Radiation Safety Officer, Assistant Radiation Safety Officer, or Health Physicist.

II. Receipt of byproduct material

A. Packages containing byproduct material are delivered to one of the following locations:

1. University Hospital - Emergency Admitting Ofc.
2. Wishard Hospital - General Supply Office
3. Wishard Hospital - Nuclear Medicine Dept.
4. Clinical Building - Radiation Safety Office

B. Procedures for University Hospital - Emergency Admitting Personnel

1. The package is examined as per attached procedures, logged in, and placed in a secure area.

2. During normal working hours, the Radiation Safety Office is notified via telephone of the arrival of the shipment.

3. Shipments received during non-working hours are automatically picked up during the next working day.

4. Shipments can only be picked up by Nuclear Medicine personnel, the Radiation Safety Officer (or his designee), or other individuals specifically authorized by the Radiation Safety Officer.

C. Procedures for Wishard Hospital - General Supply

1. The package is examined as per attached procedures and logged in.

2. At this point, the package is delivered to the Wishard Nuclear Medicine Department.

RADIATION SAFETY
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INDIANA UNIVERSITY

PROCEDURES FOR RECEIPT OF RADIOACTIVE PACKAGES

1. Verify that the number of packages to be signed for corresponds to the number of packages delivered.

2. Visually inspect the package(s) for damage and/or leakage.

3. If the package is in satisfactory condition, log package in as per current procedures and place in the designated storage area. All packages must be locked up to prevent unauthorized removal.

4. If the package is severely damaged and/or appears to be leaking, the following procedures should be implemented:

   a. If the package is leaking, you should request that the driver of the vehicle in which the package was delivered remain there until it can be ascertained that no significant radioactive contamination hazard is present.

   b. Avoid handling a leaking package until instructed otherwise by a member of the Radiation Safety Staff.

   c. Avoid external radiation exposure by remaining at least 15 feet away from the damaged package.

   d. If you would happen to get any liquid from the package on your hands or clothing, simply wash your hands thoroughly with soap and water (do not break the skin), remove any contaminated clothing and place it in a plastic bag.

   e. Notify a member of the Radiation Safety Staff as follows:

      1. Call extension 4797 (8:00 AM to 5:00 PM - weekdays), or

      2. Call the Campus Operator ("0") and request that the Radiation Safety Officer be paged (after hours & weekends).

Any further questions regarding the receipt or handling of radioactive packages should be directed to the Radiation Safety Office at extension 4797.

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4/9/85

Attachment 1

CONTROL NO. 78792

RADIATION SAFETY

INDIANA UNIVERSITY

PROCEDURES FOR RECEIPT OF RADIOACTIVE PACKAGES

1. Verify that the number of packages to be signed for corresponds to the number of packages delivered.

2. Visually inspect the package(s) for damage and/or leakage.

3. If the package is in satisfactory condition, log package in as per current procedures.

4. If the package is severely damaged and/or appears to be leaking, the following procedures should be implemented:

   a. If the package is leaking, you should request that the driver of the vehicle in which the package was delivered remain there until it can be ascertained that no significant radioactive contamination hazard is present.

   b. Avoid handling a leaking package until instructed otherwise by a member of the Radiation Safety Staff.

   c. Avoid external radiation exposure by remaining at least 15 feet away from the damaged package.

   d. If you would happen to get any liquid from the package on your hands or clothing, simply wash your hands thoroughly with soap and water (do not break the skin), remove any contaminated clothing and place it in a plastic bag.

   e. Notify a member of the Radiation Safety Staff as follows:

      1. Call extension 264-4797 (8:00 a.m. to 5:00 p.m. - weekdays), or

      2. Call the Campus Operator (0) and request that the Radiation Safety Officer be paged (after hours and weekends).

5. Deliver package directly to Wishard Nuclear Medicine.

Any further questions regarding the receipt or handling of radioactive packages should be directed to the Radiation Safety Office at extension 264-4797.

Item 13
4/9/85

Attachment 2

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

I. All packages are opened in accordance with 10 CFR 20.205.

II. In accordance with 10 CFR 20.205(d), the following procedures have been established:

A. Each package will be inspected and opened as soon as possible after receipt.

B. Disposable gloves shall be worn when opening packages containing unsealed sources of radioactivity of 0.1 mCi or greater.

C. Personnel opening packages shall observe and follow any instructions provided by the vendor regarding the opening of the package.

D. If the package appears to be damaged and is being opened by personnel other than a Radiation Safety Staff member, the Radiation Safety Office shall be notified immediately.

E. Verification shall be made to assure that the package received is in agreement with the material ordered.

F. The inner container of any package containing amounts of radioactivity in excess of those specified in 10 CFR 20.205(b)(1)(i through iv) shall be surveyed for removable contamination.

G. Contamination surveys of the inner lead (or equivalent) shield rather than the inner container shall be performed for packages containing 100 mCis or more of a gamma-emitting radionuclide.

H. Contamination surveys shall be performed on the inner container of any package which appears to be damaged.

I. Inner containers or lead shields found to be contaminated > 200 cpm/100 sq cm above background shall be either decontaminated such that contamination is reduced to < 200 cpm/100 sq cm or a notation shall be plainly visible on the outer container that the inner container (or lead shield) is contaminated.

J. Personnel opening packages shall utilize proper precautions and equipment (e.g. forceps, lead bricks) to maintain radiation exposures ALARA.

CONTROL NO. 7 8 7 9 2
Item 14
4/9/85

K. Documentation of all receipts and associated surveys shall be maintained.

RULES FOR SAFE USE OF RADIOACTIVE MATERIALS

I. General rules - these rules apply in general to all individuals handling radioactive materials. Some of these rules may be superceded in other sections. In addition, individuals may petition the Radionuclide Radiation Safety Committee (RRSC) for exemption from a specific rule. Such exemptions require justification by the individual with the review and approval or disapproval documented in the RRSC meeting minutes.

A. All areas where radionuclides are used or stored will be posted in accordance with 10 CFR 19.11 and 10 CFR 20.203, 20.204.

B. Before any work is undertaken with radionuclides, attention shall be given by the user for precautionary measures including (but not limited to) the use of fume hoods, remote handling equipment, and contamination control. The Radiation Safety Office shall be consulted for recommendations on initial or unusual operations.

C. Work shall be planned carefully in order to minimize the possibility of spills. Good housekeeping is encouraged at all times.

D. Laboratory coats should be worn at all times by individuals handling radioactivity. Personnel are encouraged to remove laboratory coats prior to leaving a restricted area.

E. Smoking, eating, drinking, storage of consumable items, and/or application of cosmetics is prohibited in immediate areas where radioactive materials are used or stored.

F. Personnel monitors (if required) are to be worn at all times when handling radioactive materials which may be measured by such devices.

G. Disposable gloves should be worn when handling > nCi quantities of radioactive materials.

H. Pipetting of radioactive material by mouth is prohibited.

I. Procedures which may result in contamination of work areas should be performed over non-permeable surfaces covered with absorbent paper.

J. Procedures which include a high probability of spillage of radioactive material should be performed in trays lined with absorbent paper.

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Item 15
4/9/85

K. Additional precautions may be required by the RRSC based upon review of the proposed uses of radioactive materials.

II. Special procedures requiring additional precautions

A. Labeling procedures utilizing radioiodines

1. It is always to be assumed that the lead pig and the vial containing the radioiodine is contaminated.

2. All radioiodine stock vials are to be stored in a fume hood which has been approved by the Radiation Safety Office.

3. All iodination procedures are to be carried out either in a closed system utilizing a charcoal trap or within a fume hood which is equipped with a charcoal filter and a linear flow rate of not less than 100 ft/min.

4. All personnel performing iodinations must frequently utilize an appropriate survey instrument (as a minimum, a thin end window GM survey meter) to monitor for potential contamination during the iodination procedure and to monitor for contamination after completion of the procedure.

5. All personnel involved in iodination procedures shall have their thyroid monitored at the frequencies established by the Radiation Safety Office (see Item 23).

6. All individuals utilizing 0.1 mCi or more of I-131 shall wear whole body and extremity personnel monitors.

7. Pregnant personnel shall not be allowed to perform nor assist in iodination procedures without specific approval from the RRSC.

B. Procedures utilizing mCi amounts of P-32 (e.g. phosphorylation procedures)

1. Whole body and extremity personnel monitoring is required for personnel performing these procedures.

2. An appropriate survey instrument (e.g. GM survey meter) is required to be used

frequently during the procedure and after the procedure to monitor for contamination.

3. Urine analysis may be required when several mCis are handled during a single procedure or when several procedures are performed within a short period of time (see Item 23).

4. The necessity for shielding shall be reviewed by the RRSC during the review of the procedure/protocol.

III. Specific precautions for nuclear medicine areas

A. Each dose of gamma emitting radiopharmaceuticals shall be assayed in a properly calibrated dose calibrator prior to administration. The dose shall not be used if the measured activity differs from the prescribed dose by more than +/- 10%.

B. Appropriate shielding (e.g. vial shields) shall be utilized when preparing radiopharmaceuticals for administration.

C. Syringe shields will be available and used for administration of radiopharmaceuticals except when, in the opinion of the person administering the patient dose, such use compromises the well-being of the patient.

D. Disposable gloves shall be used during the preparation of radiopharmaceuticals for administration.

E. Disposable gloves are not used during the administration of patient doses; however, the technologists perform frequent surveys of their hands to detect contamination.

EMERGENCY PROCEDURES

In the event of an emergency or suspected emergency (e.g. major spill, overexposure, etc.) the Radiation Safety Officer and the Principal Investigator shall be notified immediately without such action as to cause excessive spread of contamination or additional radiation exposure. If the Radiation Safety Officer cannot be reached (e.g. after normal working hours), the Campus Operator shall be contacted and will in turn page a member of the Radiation Safety Staff. The following are general guidelines to be implemented for radiation emergencies:

I. Minor spills involving no significant radiation hazard to personnel

A. Notify all persons in the area immediately.

B. Permit only the minimal number of persons necessary to deal with the spill into the area.

C. Confine the spill using the following precautions:

1. Liquid spills

a. Wear disposable gloves
b. Place absorbent material on the spill

2. Dry spills

a. Wear disposable gloves
b. Gently dampen area thoroughly and place absorbent material over area being careful not to spread contamination

D. Notify the Radiation Safety Officer and Principal Investigator as soon as possible.

E. Restrict the number of persons in the spill area until the extent of shoe and clothing contamination is ascertained.

F. Determine the area of contamination with proper instrumentation, mark with chalk or tape, and post warning signs.

G. Decontaminate the area by using procedures prescribed by the Radiation Safety Office.

H. Monitor all persons involved in the spill and decontamination procedure and decontaminate as necessary.

I. Permit no individuals to resume work in the area until contamination is reduced to acceptable levels and

approval of the Radiation Safety Officer or his designee is secured.

II. Major spills involving a radiation hazard to personnel

A. Notify all persons not involved in the spill to vacate the area immediately.

B. Make no immediate attempt to clean up the spill; however:

1. If the spill is liquid and the hands are protected, right the overturned container.

2. If the spill is on the skin, wash thoroughly with mild soap and water. Do not use harsh detergents or excessive scrubbing which could break the skin.

3. If the spill is on clothing, discard contaminated clothing in a plastic bag for evaluation and survey underlying skin for evidence of skin contamination.

C. Switch off all fans and air conditioners.

D. Vacate the room and prohibit unauthorized entrance to the contaminated area.

E. Notify the Radiation Safety Officer and Principal Investigator as soon as possible.

F. Restrict the movement of potentially contaminated persons to a local zone just outside the spill area until the extent of shoe and clothing contamination is ascertained.

G. Any potentially contaminated individual should be monitored for radioactivity and if contaminated should discard any contaminated clothing and be decontaminated. If instrumentation is not readily available for monitoring, it should be assumed that involved individuals are contaminated until proven otherwise.

H. Immediately initiate necessary steps to decontaminate personnel. Under no circumstances should an untrained individual attempt to examine or clean up the radioactive material.

I. The area shall be decontaminated under the supervision of the Radiation Safety Staff and no work shall be resumed in the area without specific permission from the Radiation Safety Officer or his designee.

J. A written report of major spills shall be compiled within 14 days.

K. The NRC shall be informed if required in accordance with 10 CFR 20.403.

III. Releases of airborne radioactivity

A. Notify all individuals to vacate the room immediately.

B. Hold breath and close any escape valves. Switch off air circulating devices if possible and if time permits.

C. Notify the Radiation Safety Officer and Principal Investigator as soon as possible.

D. Ascertain that all doors providing access to the room are closed and sealed by the use of wide masking tape or equivalent.

E. Post conspicuous warning signs or guards to prevent accidental opening of doors.

F. Immediately report all known of suspected inhalations of radioactive materials.

G. Decontamination shall only be performed under the direct supervision of a member of the Radiation Safety Staff.

H. All individuals in the area during the release shall be monitored for contamination.

I. A written report shall be prepared within 14 days.

J. The NRC shall be notified if required in accordance with 10 CFR 20.403 and/or 20.405.

IV. Injuries to personnel involving radiation hazards

A. Wash minor wounds immediately under running water while spreading the edges of the wound.

B. Report all injuries involving radioactive material to the Radiation Safety Office as soon as possible. If necessary, outside consultants experienced in such radiation hazards will be contacted.

C. Call a physician qualified to treat radiation injuries immediately (e.g. Radiation Oncology or Nuclear Medicine).

D. Permit no individual involved in a radiation related

injury to return to work without the approval of the Radiation Safety Officer and the attending physician.

E. Have appropriate bioassays performed as specified by the Radiation Safety Officer.

F. A written report shall be prepared within 14 days of the incident.

G. The NRC shall be notified if required in accordance with 10 CFR 20.405.

V. Fires or other major emergencies

A. Notify all individuals in the room and building at once.

B. Notify the campus switchboard operator that there is an emergency involving radioactive material and instruct the operator to notify the fire department and the Radiation Safety Officer.

C. Attempt to put out minor fires if a radiation hazard is not immediately present.

D. After the emergency is under control, any decontamination shall be performed under the supervision of the Radiation Safety Officer.

E. All persons involved in the emergency (e.g. fire personnel) should be monitored for contamination.

F. No work in the affected areas shall be resumed without the approval of the Radiation Safety Officer.

G. A written report of such emergencies shall be compiled within 14 days.

H. The NRC shall be informed if required in accordance with 10 CFR 20.403.

VI. Sealed source rupture

A. Notify all individuals to vacate the room immediately.

B. No immediate attempt should be made to clean up the spill source material.

C. If powdered or gaseous sources are involved:

1. All windows should be closed and air circulation devices (e.g. fans or air conditioners) should be shut off if possible.

2. All doors should be closed and sealed with wide masking tape or equivalent.

D. The Radiation Safety Office should be notified as soon as possible.

E. Restrict the movements of potentially contaminated individuals to a local zone just outside the accident area until the extent of personnel contamination can be ascertained.

F. All potentially contaminated individuals should be monitored for radioactivity and contaminated clothing removed and placed in a plastic bag for evaluation. If no instrumentation is readily available for monitoring, all involved personnel should be considered contaminated until proven otherwise.

G. If skin contamination is known or suspected, decontamination should be performed as previously mentioned.

H. A written report shall be prepared with 14 days.

The Radionuclide Radiation Safety Committee shall review all significant accidents and/or emergencies involving radioactive material. Such reviews shall be documented in the meeting minutes. The RRSC may update these emergency procedures as necessary.

AREA SURVEY PROCEDURES

I. Surveys performed by the Radiation Safety Office

A. All laboratories except nuclear medicine shall be surveyed on a quarterly basis.

B. These surveys include but are not limited to:

1. Contamination (swipe) surveys performed in representative areas within the laboratory. The Principal Investigator (P.I.) shall be notified of any areas in which the level of contamination is > 200 cpm/100 sq cm.

2. A comparison of inventory records (if required) maintained by the P.I. with the inventory records of the Radiation Safety Office for that P.I.

3. A direct radiation survey (if applicable) utilizing the P.I.'s survey instrument (if required).

4. A review of any surveys which are required to be performed by the P.I.

5. Verification that all procedures are being carried out within applicable federal, state, and university regulations as well as within specific restrictions spelled out on the P.I.'s Radionuclide Use Permit.

6. Documentation is maintained of all such surveys and the specific Principal Investigator is notified of any violations associated with activities under his/her supervision.

7. The Radionuclide Radiation Safety Committee (RRSC) may require more frequent surveys of a specific area by the Radiation Safety Office at its discretion.

C. All nuclear medicine areas are surveyed by the Radiation Safety Office on a monthly basis.

D. Surveys by the Radiation Safety Staff of the nuclear medicine areas include (but are not limited to):

1. Contamination surveys of representative areas within the nuclear medicine

laboratories. The Director of Nuclear Medicine is notified of levels of contamination in excess of 2000 cpm/100 sq cm for radiopharmaceuticals with half-lives of < 8 days and 200 cpm/100 sq cm for radiopharmaceuticals with half-lives of 8 days or more.

2. A direct radiation survey of representative areas within the nuclear medicine laboratories.

3. A review of all surveys which are required to be performed by nuclear medicine personnel (see next section).

4. A review of dose calibrator records including constancy checks and Mo-99 breakthrough tests.

5. A review of package receipt documentation.

6. Observance of procedures to verify compliance with federal, state, and university requirements.

7. The Director of Nuclear Medicine is notified of any violations noted during the survey by the Radiation Safety Office.

E. The Radiation Safety Office also performs specific surveys associated with patients undergoing radiopharmaceutical therapy or brachytherapy. These surveys are spelled out in Items 19 and 20.

II. Required surveys for Principal Investigators

A. Various surveys are required to be performed by the P.I. based on the review of the proposed use by the RRSC. The following is a general description of those requirements (except nuclear medicine):

1. P.I.s are generally required to perform contamination (swipe) surveys on a monthly basis. Areas requiring decontamination and resurvey are those exhibiting counting rates in excess of 200 cpm/100 sq cm. Records of all surveys are maintained by the P.I. and examined by the Radiation Safety Office during their compliance survey.

2. Direct radiation surveys and/or more frequent contamination surveys may be required at the discretion of the RRSC based upon the

particular procedure. These requirements are spelled out as "conditions of authorization" of the P.I.'s Radionuclide Use Permit.

3. P.I.s are not required to perform monthly surveys during months when no radioactive material is utilized.

4. P.I.s may petition the RRSC for specific exemptions from the aforementioned survey requirements. Such petitions shall include justification for said exemptions with the review, approval, or disapproval documented in the RRSC minutes.

B. The nuclear medicine departments are required to perform the following surveys:

1. Nuclear medicine personnel are instructed to survey their hands and clothing frequently and specifically when they exit the department. Documentation of such surveys is impractical; however, elevated extremity dosimeter readings may alert the Radiation Safety Office and the nuclear medicine personnel of hand contamination.

2. Contamination (swipe) surveys with appropriate documentation are required to be performed weekly with decontamination action levels as indicated above in II.,A.,1.

3. Detailed direct radiation surveys with appropriate documentation are required on a weekly basis.

4. General direct radiation surveys are required in elution/radiopharmacy areas on a daily basis to ascertain elevated levels of contamination. Should these surveys indicate exposure rates associated with contamination in excess of 2 mR/hr, the following actions will be carried out:

a. The chief nuclear medicine technologist or the radiopharmacist shall be notified,

b. A contamination (swipe) survey shall be performed and documented with appropriate decontamination should levels of contamination exist as previously indicated,

c. Documentation of these actions shall be maintained for review by the Radiation Safety Office.

5. In-vitro laboratories shall be surveyed for contamination on a monthly basis.

INDIANA UNIVERSITY
MEDICAL CENTER

RADIATION SAFETY OFFICE
Clinical Building 920
1100 West Michigan Street
Indianapolis, Indiana 46223
(317) 264-4797

April 18, 1985

Mr. Dave Jordan
Indianapolis Air Pollution Control Division
Department of Public Works
2700 South Belmont Avenue
Indianapolis, IN 46221

Dear Mr. Jordan:

As you are aware, this institution performs a considerable amount of medical research utilizing animals. Upon sacrifice, these animals are typically cremated in a crematory located in the Medical Sciences Building. It is my understanding that this crematory has been tested and found to be in compliance with all pertinent regulations.

Over the past five years, sacrificed animals containing small amounts of radioactivity have also been cremated in the aforementioned crematory. This practice has been under the direct control of the Radiation Safety Office. Measurements and calculations have been made and are kept on file to assure that the appropriate regulations promulgated by the Nuclear Regulatory Commission (NRC) regarding the airborne release of radioactivity have been met. No problems regarding this practice have been noted by representatives of the NRC during past inspections of our activities.

We are now in the process of renewing our NRC license to possess and use byproduct (radioactive) material. As a portion of this license renewal we are required to submit specific information regarding the incineration (or in this case cremation) of any radioactive waste to verify compliance with all applicable regulations. As part of that information, the NRC now requires that any local regulatory agencies also be notified of this practice; hence, the reason for this correspondence. Based on my discussions with representatives of the NRC licensing section, you need not respond; however, it is possible that the NRC may contact you to verify that this correspondence has been received by your office.

Item 18
4/9/85

Attachment 2

CONTROL NO. 78792

Should you have any questions regarding this matter, please do not hesitate to contact me. Thank you.

Sincerely,

Mack L. Richard

Mack L. Richard, M.S.
Radiation Safety Officer

cc: U.S.N.R.C. - Region III
Hal S. Stocks - Rad. Control Section, I.S.B.H.
Robert Welty - School of Medicine

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

I. When adminstration of a radiopharmaceutical for which admission to the hospital is required for radiation safety purposes (e.g. I-131 for treatment of thyroid carcinoma) is necessary, the following procedures shall be performed:

A. The patient shall be assigned to a private room equipped with a private toilet.

B. The patient room will be prepared by the Radiation Safety Staff or nuclear medicine personnel to minimize contamination problems.

C. Nursing instructions are provided (attached).

D. A summary of the radiation safety precautions associated with these patients is posted on the door of the patient's room (attached).

E. The patient will be provided disposable eating and drinking utensils.

F. Immediately after administration, a radiation exposure measurement is taken at approximately 1 meter from the patient and recorded. This measurement corresponds to the initial amount of radioactivity administered.

G. Additional radiation exposure measurements are made at the side of the bed and in the doorway and recorded.

H. Radiation precaution signs are posted on the door of the patient's room and on the patient's chart in accordance with 10 CFR 20.203.

I. In accordance with 10 CFR 20.105(a), we are requesting a relaxation of the permissible levels of exposure in unrestricted areas from those specified in 10 CFR 20.105(b). We propose an upper limit of 5 mR/hr at a distance of one foot beyond any barrier. This would coincide with areas which could be occupied by other non-radioactive patients or individuals. It is not likely that any individual would receive a whole body exposure in excess of 0.5 rem in a calendar year based on the following information:

1. There were only 17 I-131 carcinoma patients treated in 1984 which corresponds to an average of 1.5 patients per month.

2. The average length of stay for these

patients is usually between 24 and 30 hours during which time the exposure rate is constantly decreasing due to the excretion of the radioactivity by the patient.

J. If the exposure rate in an adjacent room exceeds 5 mR/hr at a location specified above in item H., the adjacent room shall be vacated and posted as a restricted area.

K. If the exposure rate at 1 foot from the outside of the patient room door (e.g. in the hallway) exceeds 5 mR/hr, a portable sign shall be posted at the point where the exposure rate is less than or equal to 5 mR/hr; thereby, restricting the area.

L. A member of the Radiation Safety Staff or the Nuclear Medicine Staff shall take periodic measurements with a survey meter at the same location specified in item F which will serve to estimate the level of radioactivity remaining in the patient's body. When the corresponding level of radioactivity is calculated to be less than or equal to 30 mCis, hospitalization will no longer be required for radiation safety purposes.

M. When the patient has been discharged (i.e. when the level of radioactivity is = or < 30 mCis) the Radiation Safety Staff or the Nuclear Medicine Staff shall remove all contaminated items (e.g. linen, paper, etc.) which will be stored for decay prior to final disposition (see Item 18 for decay-in-storage procedures).

N. 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.

O. The recommendations of NCRP Report #37 will be followed in the event of emergency surgery or death of a radioactive patient.

P. Records of all surveys associated with these patients shall be maintained in the Radiation Safety Office.

II. For patients admitted to the hospital for treatment of malignant effusions with radioactive colloids (e.g. P-32 or Au-198) the following precautions are implemented:

A. The patient shall be assigned to a private room.

B. Nursing instructions (attached) shall be provided.

C. The patient's room door and chart shall be posted in

accordance with 10 CFR 20.203.

D. A container for any radioactive waste (e.g. dressings) shall be provided and removed by the Radiation Safety Staff upon discharge of the patient.

E. A survey is performed and documented to serve as an indication of any leakage from the insertion site.

CONTROL NO. 7892

Item 19
4/9/85

(Revised April, 1985)

INSTRUCTION FOR NURSING PERSONNEL CARING FOR PATIENTS REQUIRING HOSPITALIZATION WHO HAVE RECEIVED THERAPEUTIC AMOUNTS OF RADIOIODINE (I-131)

I-131 is administered as the iodide salt in aqueous solution for treatment of thyroid carcinoma. Special precautions shall be observed with patients receiving this radioiodine therapy. If more than 30 mCis are to be administered, arrangements shall be made for the patient to be assigned to a private room and toilet until the retained radioactivity is below 30 mCis at which time the patient can be released from the hospital. Immediately following the administration of the radioiodine, the maximum exposure rate at a distance of approximately 1 meter from the patient is measured and recorded on the patient's chart. This measurement provides a basis for the determination of the residual radioactivity in the patient's body over the course of the treatment. Radiation exposure measurements are also made in other areas of the patient's room to ascertain the level of radiation exposure to persons either attending or visiting the patient. These initial radiation levels decrease over the course of the treatment due to the excretion of the radioiodine by the patient. In order to alert personnel that special precautions are required for dealing with the patient, both the door of the patient's room and the cover of the patient's chart shall be posted with radiation precaution signs as well as a set of general instructions for caring for this type of patient. These signs, measurements, and appropriate instructions are provided by the Radiation Safety Office.

In treatment with radioiodine, duration of exposure time is important due to the existence of a radiation field around the patient. In the past, maximum radiation exposures to nursing personnel and visitors has been well below the permissible limits; however, it is desirable to maintain all radiation exposures as low as reasonably achievable (ALARA). In keeping with the ALARA philosophy the following precautions should be followed:

1. Only the immediate next of kin should be allowed to visit the patient during the first 24 hours of treatment and no visitors under 18 years of age should visit the patient without specific approval from the Radiation Safety Office.

2. No pregnant visitors should be allowed to visit the patient nor should pregnant (or potentially pregnant) nursing personnel provide care for the patient. Female visitors should be asked whether they are pregnant.

3. Visitors should remain at least 6 feet from the patient during their visit and it is recommended that visitors under the age of 45 years limit their

visitation time to 30 minutes per day with the exception of the husband or wife who may be present during the entire visiting period.

4. In general, nursing personnel should limit their time with the patient to approximately 30 minutes per day (or shift). In cases where a patient requires extensive nursing care, the Radiation Safety Office should be notified in order to evaluate the necessity of additional precautions.

Due to the fact that the radioiodine is administered to the patient as an unsealed radiopharmaceutical, there is a potential for radioactive contamination of objects or persons who physically touch the patient. The Radiation Safety Staff takes specific measures to minimize the spread of contamination by covering objects and surfaces (e.g. floor, telephone, toilet, etc.) which are most likely contaminated by the patient. Greater than 90% of the excess radioiodine is excreted by the patient through urination; however, all excreta (e.g. saliva, perspiration, etc.) is potentially contaminated and should be treated as contaminated until proven otherwise. To minimize the possibility of personal contamination and/or the spread of contamination outside the patient's room, the following precautions should be followed:

1. If it is necessary for nursing personnel to assist the patient during urination, both the patient and the nurse should wear disposable gloves. If the urine is to be collected, it may be necessary to assist the patient with the transfer of the urine from the urine receptacle to the shielded container.

2. Nursing personnel should wear disposable gloves if it is necessary to touch the patient while providing care.

3. Bed baths should not be provided to the patient during the course of the treatment.

4. The patient should be provided with disposable eating utensils, trays, cups, etc. during the course of the treatment.

5. The patient's arm may be covered by a thin protective material (e.g. Saran Wrap) prior to the measurement of blood pressure to minimize the contamination of the blood pressure cuff.

6. No materials (e.g. food trays, linens, trash, etc.) should be removed from the room until it has been checked by a member of the Radiation Safety Staff and is determined to be free from radioactive contamination. Specific containers are provided by the Radiation Safety

Office for these items.

Should the patient become incontinent, vomit, or in the case of a spill of the patient's urine, the following procedures should be implemented:

1. Put on disposable gloves and cover the spilled liquid with absorbent material (e.g. "chucks") if it is practical to do so.

2. Examine your shoes and clothing visually for any evidence that you may be contaminated. If contamination of shoes is suspected, go to the doorway of the patient's room and remove the shoes, leaving them in the room to be checked by a member of the Radiation Safety Staff. If contamination of clothing is suspected, remove said clothing, place it in a plastic bag and set aside for evaluation by the Radiation Safety Staff.

3. If skin contamination is suspected, wash the area(s) with soap and water, being careful not to break the skin surface.

4. Contact the Radiation Safety Office (phone numbers below).

The Nuclear Medicine Department will be informed by the Radiation Safety Staff when the level of radioactivity in the patient's body is determined to be below 30 mCis. After the patient is discharged from the hospital, the Radiation Safety Staff will survey the patient's room. Once the room is determined to be free of contamination, the nurses station will be informed by a member of the Radiation Safety Staff and the room can then be released to the housekeeping staff. Further questions should be addressed to the Radiation Safety Office at the extension listed below.

Radiation Safety Office (8:00 AM to 5:00 PM) - ext. 4797

After hours and on weekends - contact the Campus Operator (0) and request that the Radiation Safety Officer be paged.

PRECAUTIONS IN THE MANAGEMENT OF PATIENTS WHO HAVE RECEIVED GREATER THAN 30 MCIS OF I-131

Patient Name:_____ Bldg/rm #:_____

Quantity Administered:_____(mCis) Date:_____

EXPOSURE RATE AT ONE METER AND ESTIMATE OF RESIDUAL ACTIVITY

DATE	TIME	mR/hr @ 1 M	APPROX.MCIS REMAINING
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SPECIAL INFORMATION AND INSTRUCTIONS

1. If vomiting or incontinence occurs within the first 48 hours, contact the Nuclear Medicine Department and the Radiation Safety Department immediately.

2. Only immediate next of kin permitted to visit during the first 24 hours. Pregnant visitors or visitors under the age of 18 years shall not be permitted to visit the patient.

3. All visitors should remain six (6) feet or more from the patient. Visitors under the age of 45 years should be limited to 30 minutes per day with the exception of the patient's spouse who may be present during the entire visiting period.

4. Pregnant nursing personnel shall not attend this patient.

5. Nursing attendants should limit their time with the patient to thirty (30) minutes per day if possible.

6. Attendants should wear disposable gloves when handling food utensils, linens, urine specimens, and bedpans. Soiled linen should be placed in a plastic bag provided by the Radiation Safety Staff and stored in the patient's bath tub. Plastic gloves and other disposable items should be placed in a separate container designated for radioactive waste.

7. Patients should wear disposable gloves when urinating. Nursing personnel assisting patients during urination shall also wear disposable gloves.

8. Nursing personnel shall be notified if urine is to be collected and when such collection is to be discontinued.

CONTROL NO. 7 8 7 9 2

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USES OF SEALED SOURCES

I. Administrative procedures

A. All patients treated with brachytherapy sources will be placed in a private room that has a toilet or in a semi-private room with another brachytherapy patient.

B. The patient's room will be properly posted or attended in accordance with 10 CFR 20.203 or 20.204. The patient's chart will also be posted to indicate the presence of radioactivity within that specific patient.

C. All nurses attending brachytherapy patients shall be properly instructed (nursing instructions attached).

D. The Radiation Safety Office shall be notified by the Radiation Oncology Staff when sources have been placed in a brachytherapy patient and the patient has been transported to the assigned room.

II. Surveys and monitoring

A. Once the patient has returned to the assigned room, direct radiation surveys will be taken at the following locations:

1. Approximately 1 meter from the patient.

2. The bedside of the patient.

3. The doorway of the patient room.

4. Surveys in adjacent rooms will be performed when a patient is loaded with > 80 mg-equivalent of Ra-226. This is based upon previous phantom and patient measurements which have been made and recorded and have shcwn that the exposure rates in adjacent unrestricted areas could potentially exceed 5 mR/hr when a patient is loaded with that > 80 mg-equivalent of Ra-226.

B. Upon removal of the brachytherapy sources, a radiation survey shall be performed and recorded to verify that all sources are accounted for. A visual source count will also be performed whenever possible.

C. All nurses who routinely attend brachytherapy patients s ıall be provided with a whole body personnel monitor (e.g. film badge).

III. Acceptable exposure limits for unrestricted areas

A. In accordance with 10 CFR 20.105(a) we are requesting a relaxation of the permissible levels of exposure in unrestricted areas from those specified in 10 CFR 20.105(b). We propose an upper limit of 5 mR/hr at a distance of one foot beyond any barrier. This would coincide with areas which could be occupied by other non-radioactive patients or individuals. It is not likely that any individual would receive a whole body exposure in excess of 0.5 rem in a calendar year based on the following information:

1. The total number of patients treated with brachytherapy sources in 1984 was 86 which corresponds to 1.7 patients per week. Some of these patients occupied the same semi-private room concurrently; therefore, only 64 individual room surveys were performed in 1984 for an average of 1.2 per week and rarely is an individual room used consecutively (e.g. a patient treated on Tuesday for 36 hours and then a patient treated in the same room on the following Thursday for 36 hours).

2. The average treatment time for brachytherapy patients is approximately 36 hours.

3. Our past measurements have shown that the locations of exposure rates in excess of 2 mR/hr in unrestricted areas are usually those which cannot be occupied by individuals (e.g. 7 feet above the floor) or are occupied infrequently (e.g. the hallway outside the door).

4. To verify compliance with 10 CFR 20.105(a), the exposure rate which has been measured (either at the time of the survey or from previous measurements) will be multiplied by the total treatment time to obtain the total integrated exposure in the unrestricted location.

(Revised April, 1985)

INSTRUCTIONS FOR NURSING PERSONNEL ATTENDING PATIENTS UNDERGOING BRACHYTHERAPY

Brachytherapy is a radiation treatment modality whereby sealed radioactive sources are placed within a patient's body, either temporarily or permanently, for treatment of different types of cancers. Due to the fact that the radioactivity itself is either sealed within some type of metal capsule or is supplied as a solid, the potential for contamination is negligible; however, the external radiation levels associated with these sources are significant. Through surveys and personnel monitoring over several years, it has been shown that the radiation exposures to nursing personnel, other patients, visitors, and the general public are typically minimal; however, it is the responsibility of all individuals attending these patients to maintain both their own exposures and the exposures of others as low as reasonably acheivable (ALARA). In keeping with the ALARA philosophy, the following guidelines have been established:

1. Brachytherapy patients shall be assigned to a private room or a semi-private room with another brachytherapy patient. When only one patient is assigned to a room with two beds, that patient should be placed in the bed farthest from the door to minimize the radiation exposure in the doorway.

2. Nursing personnel who routinely attend brachytherapy patients shall wear a whole body personnel monitor (e.g. film badge) at all times when working with these patients.

3. No pregnant visitors should be allowed to visit the patient during the time in which the radioactive sources are implanted in the patient nor should pregnant (or potentially pregnant) nursing personnel care for the patient. Female visitors should be asked whether they are pregnant.

4. Nurses should spend only the minimum time necessary near a patient for routine nursing care.

5. Needles, capsules, or applicators containing brachytherapy sources should never be handled directly. Should a source become dislodged, use long forceps and place it in the corner of the room and call either the Radiation Safety Office or the Radiation Oncology Department at the telephone numbers listed at the end of these instructions.

6. Bed baths should not be given the patients while brachytherapy sources are in place.

CONTROL NO. " 8792

7. Perineal care is not given during gynecological treatment; however, the perineal pad may be changed when necessary unless orders to the contrary have been issued.

8. Surgical dressing and bandages used to cover the area of needle insertion may be changed only by the attending physician and should not be discarded until all sources are accounted for by the individual removing the sources and a radiation survey is made.

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

10. All bed linens which are changed during treatment should remain in the patient's room until all sources are accounted for by the individual removing the sources and a radiation survey is made.

11. Gynecological brachytherapy patients are usually required to remain in bed. Other types of brachytherapy patients shall remain in their assigned rooms during the treatment period.

12. Visitors shall be limited to those 18 years and older. Any visitation by individuals under the age of 18 years must receive specific approval from the Radiation Safety Officer.

13. Visitors should remain at least six (6) feet from the patient and visitors under the age of 45 years with the exception of the spouse should limit their visitation time to 30 minutes per day.

14. For further information regarding the radiation safety procedures associated with brachytherapy patients, contact either the Radiation Safety Office or the Department of Radiation Oncology at the numbers listed below:

Radiation Safety Office - extension 4797 (8:00 AM to 5:00 PM); during non-working hours contact the Campus Operator (0) and request that the Radiation Safety Officer be paged.

Department of Radiation Oncology - extension 2524 (8:00 AM to 5:00 PM); during non-working hours contact the Radiation Oncology Resident on call.

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

I. Xenon-133 administration system

A. Xe-133 is purchased in unit dose vials specifically designed to be utilized in an injection device manufactured specifically for this purpose.

B. Xe-133 is administered to the patient by direct injection of the gas into the inhalation hose of an anesthesia breathing circuit.

C. At the completion of the study, the patient is taken off of the system and breathes in room air while exhaling into an exhaust hose which is connected to the room exhaust system which is in turn released at the roof of the hospital.

II. Precautions taken during administration to prevent leakage

A. Nose clamps or full face masks are used on all patients.

B. The system described above is utilized.

C. The exhaust hose is routinely kept near the patient's face during the study.

D. Patients are carefully instructed as to what is expected of them during the study.

III. Precautions taken during an actual release of Xe-133

A. The exhaust hose is placed as close as possible to the area of release (e.g. broken vial).

B. All personnel are evacuated from the room and the doors of the room are closed.

C. Personnel remain outside of the room for at least 5 total air exchanges within the room (calculation method attached).

IV. Storage of Xe-133

A. Xe-133 vials are stored within a constantly operating fume hood prior to use.

B. Xe-133 vials are stored in lead containers to maintain radiation exposure levels ALARA.

V. Compliance with regulatory limits - see attached sample calculation

MPC COMPLIANCE CALCULATIONS
INDIANA UNIVERSITY HOSPITAL

University Hospital Nuclear Medicine Facility Description

Imaging Room P-15 room size = 25'3" x 25'2" x 8'6"
Imaging Room P-09 room size = 20'1" x 25'2" x 8'6"

Total air exhaust = 2100 cfm
Total air supply = 1710 cfm
Net negative pressure = 390 cfm

1. Calculation of compliance with restricted area MPC:

$C = (A/V) \times f$

C = Concentration of Xe-133
A = Maximum activity in uCi
V = Air flow volume
f = Escape fraction (20% assumed)

V = 2100 cfm x 6.797E07 ml/40 hr week-cfm
= 1.43E11 ml/wk

Maximum studies that may be performed per week within restricted area:

$A = (V \times C)/f$

V = 1.43E11 ml/wk
C = Restricted MPC = 1E-05 uCi/ml
f = 20%

= 7.15E06 uCi/wk
= 7150 mCi/wk
= 358 studies/wk @ 20 mCi/study

2. Calculation of compliance with unrestricted are MPC for disposal of Xe-133 via exhaust system averaged over one year:

$A = (V \times C)/f$

C = Unrestricted MPC = 3E-07 uCi/ml
f = 1
V = 2100 cfm x 1.484E10 ml/yr-cfm
= 3.12E13 ml/yr

= 9.36E06 uCi/yr
= 9360 mCi/yr
= 468 studies/yr @ 20 mCi/study

3. Air volume turnover within imaging rooms:

Total volume in rooms = 9698 cubic ft

Time required for one air exchange = 9698 cu ft/2100 cfm
= 4.61 minutes

Time required for 5 air exchanges = 5 x 4.61 minutes
= 23.05 minutes

Item 21
4/9/85

Any facility utilizing a radioactive gas is evaluated in a similar manner. Records of all such evaluations shall be maintained in the Radiation Safety Office.

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIALS IN ANIMALS

I. Administrative procedures

A. The Radionuclide Radiation Safety Committee (RRSC) reviews all protocols involving the utilization of radioactivity in animals.

B. During the review, the RRSC considers the following:

1. The potential for contamination due to excretion of the radioactivity.

2. The external radiation exposure to individuals handling the animal.

3. Any special problems anticipated from the protocol.

C. Animals which are not sacrificed shortly after adminstration of the radioactivity are housed in the Laboratory Animal Research Center (LARC) facilities.

D. A copy of the approved protocol and any special conditions pertinent to the LARC staff is forwarded to the director of the LARC facility.

E. Based on the review by the RRSC and the Radiation Safety Staff, specific instructions are posted on the door of the room in which the radioactive animal is housed.

F. All animal rooms will be locked or otherwise secured unless attended by authorized personnel.

II. Surveys

A. Direct radiation surveys shall be performed and documented of areas housing animals containing radionuclides which emit high energy beta radiation or gamma radiation.

B. If radioactivity is excreted by the animal, a contamination (swipe) survey shall be performed after the animal is removed from the facility. Areas contaminated in excess of 200 cpm/100 square cm shall be decontaminated until they are below that level. All such surveys shall be documented.

The RRSC will formally review and approve any changes in the aforementioned procedures. Such reviews and approvals shall be documented in the minutes of the RRSC meetings.

ADDITIONAL PROCEDURES AND PRECAUTIONS

I. The necessity for urine bioassays is determined at the time the protocol is reviewed by the Radionuclide Radiation Safety Committee (RRSC). The RRSC considers such information as potential for spillage, volatility of radionuclide, etc. when determining the necessity for urine bioassay.

A. General guidelines for urine bioassays

1. A monthly urine bioassay is required for all individuals handling the following quantities in a single procedure:

a. H-3 - 30 mCis
b. Other radionuclides - 10 mCis

2. A monthly urine bioassay is required for all individuals handling 10 times the quantities specified above in any one week.

3. If the body burden is less than 10% of the maximum permissible limit (e.g. < 10% of maximum MPC-hours) after a period of three months, a quarterly urine bioassay schedule will be implemented for that individual.

4. If the body burden is greater than 50% of the maximum permissible limit, the individual will be restricted from further use of that particular radionuclide until the cause of the uptake can be investigated by the Radiation Safety Staff and until the body burden falls below 50% of the maximum permissible limit.

B. Urine bioassays are typically performed by counting an aliquot of urine from the individual in an instrument which has be efficiency calibrated for the radionuclide energy in question. The total body (or organ) burden and dose equivalent is then calculated utilizing acceptable metabolic data and dosimetry calculations (e.g. ICRP 2, MIRD, etc.).

II. Thyroid bioassays are performed (instead of or in addition to urine bioassays) for individuals utilizing potentially volatile iodine compounds (most commonly I-125 and/or I-131).

A. General guidelines for thyroid bioassay

1. Personnel using 1 mCi or more of I-125 or I-131 per procedure in a volatile form shall have their thyroid monitored at monthly intervals.

2. Thyroid monitoring will not be required during months in which an individual does not handle volatile radioiodine compounds.

3. If the thyroid burden is less than 0.12 uCi of I-125 or less than 0.04 uCi of I-131 after 3 months of thyroid monitoring, a quarterly monitoring schedule shall then be initiated and will not be required during quarters in which an individual does not handle volatile radioiodine compounds.

4. If at any time, thyroid burdens greater than those listed above in A.3. are encountered, monthly monitoring will be resumed and appropriate investigation taken to determine the cause of the elevated thyroid burden.

5. In the case of mixed thyroid burdens (i.e. both I-125 and I-131 are present), the level used to determine monthly or quarterly intervals will be calculated utilizing the formula from NRC Regulatory Guide 8.20, Appendix B.

6. Personnel using 10 mCis or more of I-125 or I-131 per procedure (except sealed sources) in a non-volatile form shall be monitored as specified above in items A.2.,3.,4., and 5.

B. Thyroid monitoring is performed by placing a detector which has been efficiency calibrated for the appropriate type of radioiodine over an individual's thyroid and obtaining counts over a specified period of time. The thyroid burden and dose equivalent is then calculated based on currently acceptable models (e.g. ICRP 2, MIRD).

III. A copy of an application for license amendment is attached for the procurement and use of a gamma irradiator for irradiation of blood and blood components. This amendment application was in process at the time of this license renewal. Any additions or corrections to this amendment application will also be referenced to this renewal application.

IV. Our program for maintaining exposures ALARA is attached.

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 13-02752-03
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Indiana University - Indianapolis
1100 West Michigan St.
Indianapolis, IN 46223
Attn: Radiation Safety Office

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Indiana University Hospital
926 West Michigan St.
Indianapolis, IN 46223

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mack L. Richard, M.S. - Radiation Safety Officer

TELEPHONE NUMBER: (317) 264-2003

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY: Exempt
AMOUNT ENCLOSED $: -0-

13. CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Glenn W Irwin	Glenn W. Irwin, M.D.	Vice President	4/9/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] < $250K
- [ ] $250K - 500K
- [ ] $500K - 750K
- [ ] $750K - 1M
- [ ] $1M - 3.5M
- [ ] $3.5M - 7M
- [ ] $7M - 10M
- [ ] > $10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial-proprietary-information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

PRIVACY ACT STATEMENT ON THE REVERSE

Item 23
4/9/85

Attachment 1

CONTROL NO. 7879 2

RADIOACTIVE MATERIAL

A. Radionuclide: Cs-137

B. Manufacturer and Model Number: AECL Gammacell 1000 - Model B

C. Chemical/Physical Form: 2 sealed sources

D. Maximum Activity: 1440 Ci

PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

The AECL Gammacell 1000 will be utilized for the irradiation of blood and blood components.

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

The individuals responsible for the Radiation Safety Program are those individuals which make up the Radionuclide Radiation Safety Committee (RRSC). Those individuals and their areas of expertise are listed below:

Robert M. Witt, Ph.D., (Chrmn)	Medical Physicist
Robert L. Baehner, M.D.	Pediatrics
Robert E. George, Ph.D.	Therapy Physicist
Richard Kohler, M.D.	Infectious Disease
Jon P. Lindemann, M.D.	Cardiology
Nancy Martin, R.N.	Nursing
Bruce H. Mock, Ph.D.	Radiopharmacy
T.O. Oei, M.D.	Pathology
Bernard E. Oppenheim, M.D.	Nuclear Medicine
James L. Rice	Hospital Administration
Mack L. Richard, M.S.	Radiation Safety Officer
Peter Roach, Ph.D.	Biochemistry
Robert L. Wolen, Ph.D.	Pharmacology
Kenneth Lipkowitz, Ph.D.	Chemistry

RRSC member appointments are reviewed and updated annually.

TRAINING

The Radionuclide Radiation Safety Committee (RRSC) reviews the training and experience of each Principal Investigator using or supervising the use of byproduct material in accordance with criteria set forth in our broad scope license application and supporting documentation. For the use of the gamma irradiator, the RRSC will review the training and experience of those individuals responsible to assure that said individuals are adequately trained to operate the gamma irradiator and maintain radiation exposures ALARA. The responsible individual(s) will be required to meet the same criteria as all Principal Investigators at this institution. In addition, those individuals will be required to review the gamma irradiator operation manual and the emergency procedures with appropriate documentation that they have done so. Members of the Radiation Safety Staff will verify that only properly trained personnel operate the gamma irradiator.

FACILITIES & EQUIPMENT

I. Irradiator location

The irradiator shall be located in a room which is either constantly occupied or which can be secured when not occupied.

II. Radiation detection instruments

The Radiation Safety Office is equipped with various types of survey instruments (both G.M. survey meters and ion chambers) which have the capability of monitoring levels of radiation up to several R/hr. These instruments are calibrated annually utilizing the procedures set forth in our broad scope license application (Item 11 - Appendix D).

III. Personnel monitoring equipment

Based upon the typical exposure rates around the irradiator (as provided by the manufacturer), it does not appear that routine personnel monitoring is required; however, individuals utilizing the irradiator for the first three months after the device is received shall be monitored to establish what levels of exposure are to be expected and the results recorded. If this initial monitoring period indicates radiation exposures in excess of 10% of the quarterly limits (i.e. > 125 mrem/qtr), routine monitoring shall be maintained. This monitoring will be in the form of either film badges utilizing a monthly change frequency or TLD badges utilizing a quarterly change frequency.

RADIATION SAFETY PROGRAM

I. Operating and emergency procedures - each individual who will use and operate the irradiator shall be provided with a set of operating and emergency instructions which include the following:

A. A step-by-step procedure for operation of the irradiator.

B. An instruction to wear appropriate personnel monitoring if applicable (see Item 9).

C. A requirement that the irradiator either be constantly attended or the irradiator room locked.

D. A requirement that in the event of an emergency situation, personnel evacuate the irradiator room, lock the door, and contact the Radiation Safety Office for instructions.

E. A requirement that no service shall be performed on the irradiator without prior approval from the Radiation Safety Office.

II. Leak testing

Leak testing of the irradiator shall be performed at six month intervals. Leak tests shall consist of a swipe test of the nearest accessible surface to the source (e.g. the sample chamber). The swipe test will then be counted in a gamma counter which has been efficiency calibrated in order to quantitate the total amount of radioactivity on the swipe test. The counting system shall be sufficient to detect 0.05 uCis. Should the source be found to be leaking in excess of 0.05 uCis, the irradiator will be immediately taken out of service, the NRC notified, and the source repaired or replaced by individuals specifically licensed to do so. This is the same basic procedure utilized for leak testing all other sources under our broad scope license.

PROGRAM FOR MAINTAINING RADIATION EXPOSURES AS LOW AS REASONABLY ACHIEVABLE (ALARA)

Investigational levels and the basic procedures for maintaining the ALARA concept are as follows:

Table 1

	Investigational Levels - (mRems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body	750	2250

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 1 values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational I. He will report the results of his reviews at the first Radionuclide Radiation Safety Committee (RRSC) meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel

exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RRSC at the first quarterly meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the chairman of the Radiation Safety Council for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of inspection.

d. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table 1.

In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RRSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c. above will be followed.

File

May 22, 1985

Indiana University
ATTN: Mack L. Richard, M.S.
Radiation Safety Officer
1100 West Michigan Street
Indianapolis, IN 46223

License No. 13-02752-03
Control No. 78792

SUBJECT: LICENSE RENEWAL APPLICATION

Gentlemen:

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Bruce S. Mallett

Material Licensing Section
Region III

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5/30/85-