RADIATION SAFETY MANUAL

MEDICAL COLLEGE OF OHIO
TOLEDO, OHIO 43699

RADIATION SAFETY OFFICE

REVISED MARCH 1985

MEDICAL COLLEGE OF OHIO

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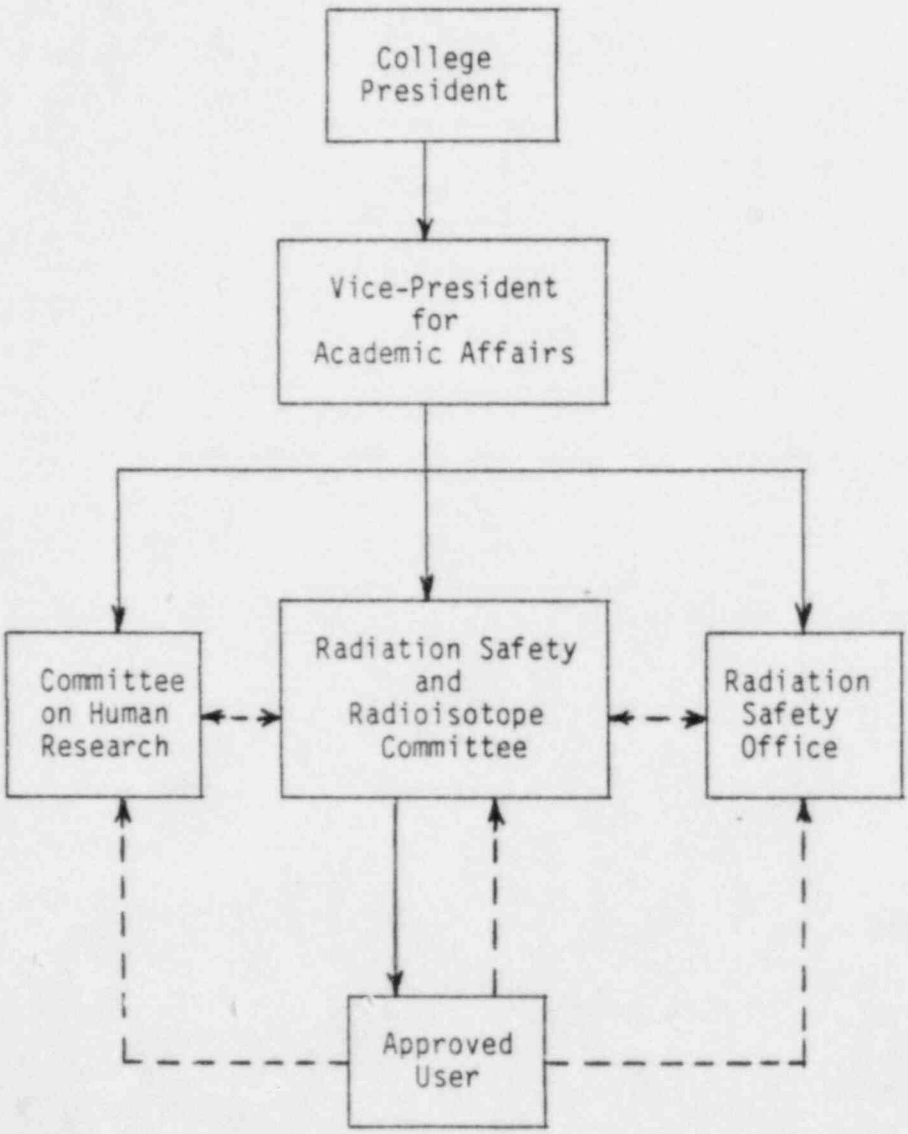
I. Administrative Controls

A. ORGANIZATION

The administrative control of the College's Radiation Safety Program is schematically represented by the chart below. There are two channels of administrative authority. The first channel is for appointments and executive responsibility, and the second, for review and approval of applications:



Appointments and Executive Responsibility _____

Application Review and Approval - - - - - - - - - -

B. RADIATION SAFETY AND RADIOISOTOPE COMMITTEE

1. Function

The Radiation Safety and Radioisotope Committee has the responsibility of establishing and enforcing the College's Radiation Safety Program to ensure the safety and welfare of College personnel and property as well as protecting the surrounding community from the potential hazards of all sources of ionizing radiation used at the College. The committee formulates and enforces such policies that are necessary to establish uniformly safe practice throughout the College for the procurement, use, storage and disposal of all sources of ionizing radiation.

2. Membership

The Chairman of the Committee is appointed by the Vice-President for Academic Affairs; members of the Committee are appointed upon the recommendation of the Radiation Safety Officer. The Committee shall consist of the Chairman and at least three representatives from the various departments at the College.

3. Meetings

The Committee shall meet regularly, at least once every quarter. Meetings, other than regular meetings, may be called by the Chairman or any three members of the Committee. Minutes of the proceedings shall be recorded and circulated by the secretary to the membership and to those personnel of the College having a specific interest in the proceedings.

4. Procedures

The meeting shall generally be conducted according to the principles of Robert's Rules of Order and the Chairman shall use them as a guide at the request of any individual member.

a. The Order of Business shall proceed as follows:
    1) Review of minutes of the previous meeting
    2) Old business
    3) New business
b. The voting procedures are:
    1) A simple majority of the entire membership shall constitute a quorum.

2) For revisions of the College's Radiation Safety Program, approval by two-thirds of the entire membership shall be required.

3) For all matters not concerning revisions of the Radiation Safety Program, approval by a simple majority of a quorum shall be required.

5. Duties

a. Review and act upon applications for the procurement and use of sources of ionizing radiation within the College. Applications shall be reviewed from the standpoint of radiation safety. Use of radioactive materials in humans shall be reviewed by the Radiation Safety and Radioisotope Committee before being acted upon by the Committee on Human Research.

b. Prescribe specific conditions that may be necessary for the safe handling of any source of ionizing radiation in connection with granting approval of an application.

c. Review and take appropriate action with regard to violation of the College's Radiation Safety Program.

6. Enforcement

In the event of a failure to observe the rules and regulations governing the safe use of sources of ionizing radiation, the Radiation Safety Officer shall inform the offending investigator(s): 1) of the violations and, 2) that an unfavorable report will be made to the Committee unless they are remedied. If a remedy has not been made within a reasonable period of time, the Radiation Safety Office shall bring the violation to the attention of the Committee at its next regular meeting, or he may call a special meeting to consider the violation. After consideration of such a report, the Committee may make recommendations for mandatory remedial action with failure to comply being just cause for withdrawal of the Committee's approval of the application. In enforcement cases, the Approved User may be present at the Committee hearing if he or she so desires.

C. RADIATION SAFETY OFFICE

1. Function

The Radiation Safety Office shall be responsible for the surveillance and maintenance of the Radiation Safety Program of the College on a daily basis and shall be responsible for notifying the Radiation Safety and Radioisotope Committee and the Vice-President for Academic Affairs as to the status of said program.

2. Organization

The Radiation Safety Office shall be composed of the Radiation Safety Officer plus a sufficient number of technical and secretarial personnel to carry out the functions and duties of the Radiation Safety Office.

3. Duties

The Radiation Safety Office shall:

a. Make checks for adherence to all regulations issued by the Radiation Safety and Radioisotope Committee in all areas and facilities where sources of ionizing radiation are employed as well as those surrounding areas where the effects of radiation may be a possibility.

b. Maintain personnel dosage records on all persons exposed to ionizing radiation resulting from materials or devices possessed by the College.

c. Maintain records of procurement of ionizing radiation sources.

d. Maintain records of radioisotope disposal.

e. Perform radiological surveys.

f. Perform leak tests on sealed sources requiring such tests.

g. Review all requests for radioisotopes to determine compliance with possession limits.

h. Provide assistance, advice and training on radiological safety procedures.

D. APPROVED USER

1. Definition

An Approved User is any person who has been granted permission to use some form(s) of ionizing radiation at the Medical College of Ohio and/or its affiliated institutions by the Radiation Safety and Radioisotope Committee.

2. Qualifications

In order to qualify as an Approved User, the applicant shall:

a. Be a member of the faculty of the Medical College of Ohio or its affiliated institutions, with the rank of Instructor or higher.

b. Be actively engaged in work, instruction, and/or research at the College or its affiliated institutions which requires the use of ionizing radiation.

c. Possess the minimum training and experience outlined in Appendix #1.

3. Function

The Approved User shall have the primary safety responsibility for those sources of ionizing radiation which he has been approved to use. He shall assure that their procurement, storage and usage complies with the rules and regulations in this manual.

4. Duties

The Approved User shall:

a. Confine his possession and use of sources of ionizing radiation to those limits, locations, and purposes authorized by the Committee.

b. Not transfer, abandon, or dispose of such sources except as authorized by the Committee.

c. Maintain records as specified in this manual.

d. Conduct or cause to have conducted the required surveys and leak tests.

e. Limit the use of sources of ionizing radiation under his control to those persons subject to his direct supervision.

f. Instruct the personnel under his supervision in the use of radiation safety procedures and equipment.

g. Assure that personnel under his supervision have become familiar with the College's Radiation Safety Program and that they comply with all regulations therein.

h. Plan his research and use of sources of ionizing radiation to assure that adequate safety precautions are taken.

i. Communicate to the Radiation Safety Officer pertinent information with respect to changes in operational procedures, new techniques and alterations in the physical facilities.

j. At all times comply with the Medical College of Ohio's Radiation Safety Program as described in this manual.

II. General Instructions

A. APPLICATION FOR USE OF SOURCES OF IONIZING RADIATION

1. General Requirements

In order to process or use any source of ionizing radiation at the College and its affiliated institutions, approval must be obtained from the Radiation Safety and Radioisotope Committee.

a. Considerations

Approval of any application shall be based upon its radiation safety aspects and the conditions of the various licenses held by the Medical College of Ohio at Toledo.

b. Applicant Rank

The minimum college rank required shall be that of Instructor.

c. Training and experience

The applicants training and experience must meet the requirements of the Radiation Safety and Radioisotope Committee.

2. Procedures

All applications for possession and use of sources of ionizing radiation shall be made on appropriate forms obtainable from the Radiation Safety Office. (See Appendix #2 or #3)

3. Approval of Application

After the Committee has received and acted upon an application, the applicant will be notified of its decision by the Chairman. Any revisions in the original application must be approved by the Committee.

B. PROCUREMENT PROCEDURES

All sources of ionizing radiation shall be procured under the direction of the Radiation Safety Office. See Appendix #4 or #5 for procurement instructions. Any questions concerning the procurement of sources of ionizing radiation shall be directed to the Radiation Safety Officer.

C. TRANSFER OF SOURCES OF IONIZING RADIATION

The transfer of any source of ionizing radiation for the Medical College of Ohio must be approved by the Radiation Safety Office.

D. RECORDS

Records relating to personnel exposure, radiation surveys, leak tests, inventories, waste disposals and calibrations must be maintained and available for inspection as directed by the Radiation Safety and Radioisotope Committee.

E. FACILITIES AND LABORATORY EQUIPMENT

All designs and plans for new facilities, or alterations to existing facilities in which sources of ionizing radiation will be stored and/or used, shall be reviewed and approved by the Radiation Safety Officer prior to the start of any construction or alteration operations.

1. Release of Facilities for Other Usage

Facilities in which radioactive material was either used or stored shall not be released for other purposes until the facility has been surveyed under the direction of the Radiation Safety Office.

2. Transfer of Facility Responsibility

The responsibility for the operation of a facility is placed in the hands of the Approved User by the Radiation Safety and Radioisotope Committee. Therefore, this responsibility shall not be transferred to another individual until an application for such has been approved by the Committee.

3. Laboratory Equipment

Laboratory equipment which has been used for radioisotope purposes or located within a radioisotope facility shall not be transferred until it has been monitored and determined to be free of radioactive contamination. The monitoring and/or decontamination shall be completed by the Approved User under the direction of the Radiation Safety Office.

III. Radiation Safety

A. GENERAL

1. Objectives

The following sections contain recommendations which are intended to accomplish the objectives of the College's Radiation Safety Program which are:

a. To maintain as low a level of radiation exposure as is reasonably achievable.

b. To reduce the possibility of entry of radioactive materials into the human body by ingestion, inhalation, absorption, or through open wounds.

c. To reduce to the lowest reasonably achievable limits the amounts of radioactive materials released to the general environment.

Since these recommendations are made to cover most of the general situations and cannot possibly cover all circumstances, there may be instances in which these recommendations do not apply. In such situations the Radiation Safety Office should be contacted for assistance or clarification. If the problem cannot then be rectified, it shall be presented to the Committee for resolution.

2. Permissible Dose Limits

Permissible dose limits and concentrations of radioisotopes in air and water have been established by both the Nuclear Regulatory Commission (NRC) and the Department of Health of the State of Ohio. It must be emphasized that although these limits have been established under the concept that no probable radiation damage will occur at these levels, all exposure should be kept as low as reasonably achievable.

B. EXPOSURE

Exposure to radioactivity can essentially be classed into two categories: External and Internal.

1. External

   For protection against external exposure, the basic protection factors of time, distance, and shielding shall be employed to reduce the exposure potential to a value below maximum permissible levels. In every situation these three factors must be considered jointly. While shielding is desirable in reducing the exposure, it must be remembered that doing the job at twice the distance is just as effective as adding two half-value thicknesses of shielding material or doing the job in one-fourth the time. Continuous use of monitoring equipment is the best method of evaluating the hazard and reducing the exposure.

2. Internal

   The prevention of internal exposure is more exacting and less easily performed than that of external exposure. The maximum permissible levels of radioactive contamination in the air or on laboratory surfaces is of such a low level that they cannot be detected with ordinary survey instruments. If a low level contamination is suspected, the Approved User in charge of the area should be notified so that a survey can be made. The general policy in the use of radioisotopes is to use such equipment and procedures which will reduce the probability of ingestion and inhalation of radioisotopes into the body.

3. Additional Rules

   Outlined below are additional rules and procedures to be followed for protection against exposure to sources of ionizing radiation.

   a. The exposure potential shall be estimated before placing into operation any procedure in which personnel may become exposed to radiation.

   b. The use of sources of ionizing radiation shall be subjected to programs of continuous monitoring or regularly scheduled surveys as a means of evaluating the radiation hazards.

c. Special clothing which can be easily laundered or disposed of shall be worn and properly fastened when there is a possibility of contamination with radioisotopes. When necessary, impervious gloves, safety glasses, and shoe covers shall be worn. These items should not be worn outside the laboratory. Protective clothing should be monitored for contamination before sending to the laundry. Any protective clothing which has become contaminated should be handled as any other piece of contaminated material.

d. Before any work is undertaken with radioisotopes, attention shall be given to precautionary measures including the use of hoods, remote handling equipment, and glove boxes. The Radiation Safety Office should be consulted for recommendations on specific operations. Plan the procedure to be used, and, if possible, perform a dry run.

e. The situations which necessitate the wearing of impervious gloves are listed below:
   (1) Manipulation of any radioisotope.
   (2) The presence of an open wound on the hand.

f. Plastic-backed absorbent paper shall be used when working with radioactive materials.

g. Pipetting by mouth is prohibited. Use rubber bulbs, syringes or pipettors.

h. When transporting or transferring radioactive materials, double containers with absorbent material must be used.

i. Containers affording adequate protection and shielding shall be used to store radioactive materials.

j. Keep the laboratory neat and clean. Keep the work area free of equipment and material not required for the immediate procedure. Eating, storing or preparation of food (including candy and beverages), and smoking is not permitted in a laboratory or rooms where work with unsealed radioactive material is taking place or where contamination may exist. Refrigerators and freezers in

which radioactive material is stored shall not be used for the storage of food or beverages.

k. An area shall be set aside for the decontamination and cleaning of laboratory apparatus used with radioactive material. A sink in this area shall be designated for use with radioactive material. Do not use this area for any operation which does not involve radioactive material. Isolate all laboratory apparatus and equipment which are used in operations involving radioactive material.

l. Use of flammable liquids shall not be permitted in laboratories unless such flammables are (1) contained in U.L. approved safety cans with anti-flashback screens and (2) used in a properly vented enclosure. Pressure bottles or tanks containing counting or laboratory gas shall not be used or stored in the laboratory unless they are securely mounted to the wall, bench or floor.

m. Good personal hygiene practices, such as washing hands and arms thoroughly, using plenty of soap and water, before handling any object which goes to the mouth, nose, or eyes, will greatly reduce the possibility of internal exposure. Wash and monitor the hands whenever leaving the laboratory after handling radioactive material. Keep fingernails clean and short.

n. Do not apply cosmetics in a laboratory where unsealed sources of radioactive material are in use.

o. Monitor shoes and other clothing for contamination and remove all contamination before leaving work areas.

C. AREA CONTROLS

Areas in which sources of ionizing radiation are used or stored shall be controlled to prevent any unnecessary exposures to personnel. In order to assure good area controls, the methods listed below shall be employed:

1. Posting

Areas shall be classified for posting as follows:

a. High Radiation Area

b. Radiation Area

c. Airborne Radioactivity Area

d. Caution - Radioactive materials

Both the Nuclear Regulatory Commission (NRC) and the State of Ohio have regulations governing posting, control, and safety devices required for these areas:

N.R.C. 10CFR20 Section 20.203(6), (c), and (d).

State of Ohio HE-38-20, (B), (C), and (D).

In addition, rooms or areas in which radioactive materials are used or stored shall be posted according to:

N.R.C. 10CFR20 Section 20.203 (e-1) and (e-2) and Section 20.204. State of Ohio HE-38-20 (E).

The State of Ohio requires that all devices and equipment capable of producing radiation during operation shall be labelled in a manner which cautions individuals of such fact. Both the Nuclear Regulatory Commission and the State of Ohio have regulations governing the posting of "Notice to Employees" and other instructions to employees.

N.R.C. 10CFR19

State of Ohio HE-38-22

2. Restrictions

a. Those areas authorized by the Radiation Safety and Radioisotope Committee for use with sources of ionizing radiation are restricted to usage by the Approved User and those personnel under his immediate supervision. Therefore, caution shall be taken to prevent unauthorized admittance when authorized personnel are not present in the areas.

b. Sealed and unsealed sources of radioactive materials shall be kept in their storage containers when not in use. Generators of ionizing radiation shall have

control locks or mechanisms to prevent their unauthorized and accidental activation.

D. MONITORING AND SURVEYS

In order to ensure satisfactory radiation safety throughout the College complex, routine and periodic monitoring and surveying of personnel, equipment, and facilities are required. The frequency of surveys will depend upon the classification of the facilities employing sources of ionizing radiation. See Appendix #7.

1. Responsibilities

a. It is the responsibility of the radiation worker to see that his working environment is safe and well organized, safety devices are installed and properly working, appropriate records are maintained, and that contamination is not permitted to build up.

b. The Radiation Safety Office will periodically monitor and survey all controlled areas.

c. The Radiation Safety Office shall supply the Approved User with reports of findings in these investigations, along with recommendations for the elimination of all items of non-compliance to Federal, State, Local, and Medical College of Ohio regulations, and a specific time period for making the necessary corrections.

d. Experimental work shall be monitored throughout on a periodic basis to determine the occurrence, or possibility of occurrence, of new and increased radiation hazards.

2. Leak Tests and Special Surveys

The College's N.R.C. License has conditions regarding the testing of sealed sources for leakage and/or contamination. The State of Ohio has similar regulations governing the testing of sealed sources. It is the responsibility of the Approved User of such devices to see that each of his sealed sources, except those simultaneously exempt from same by both the N.R.C. and the State of Ohio, is tested in the manner and at the intervals required. Copies of

results of these tests shall be kept on file and made available to the Radiation Safety Office when necessary. These tests will be performed by the Radiation Safety Office upon request.

3. Personnel Monitoring

All personnel working with or around sources of ionizing radiation shall wear monitoring devices approved by the Radiation Safety Office.

a. Film Badges

Film badges shall be the general personnel monitoring device used throughout the Medical College. To initiate film badge service for any individual, contact the Radiation Safety Office. A supply of film badges will be available for temporary use upon request. Each individual assigned a film badge shall wear only the specific badge assigned to him or her.

In the event of a lost badge, notify the Radiation Safety Office. Personnel assigned badges shall wear them at all times that they are in their working areas. Film badges may be worn comfortably on the waist or chest. All film badges shall be kept in a controlled area when not in use and put back at the end of the work period. They should not be removed from the College. Assigned film badges shall not be used for any purpose other than personnel monitoring.

New film packets shall be distributed by the Radiation Safety Office within the first three working days of each month and used film packets shall be collected within the first three working days of each month. It is the responsibility of the Approved User to ensure the change of film packets. If certain operations require special badges for the wrist, fingers, etc., or special film packets, contact the Radiation Safety

Office. If a film badge is suspected of being contaminated, contact the Radiation Safety Office for replacement.

b. Pocket Dosimeters

Pocket dosimeters shall be worn by all personnel who enter a high radiation area. Pocket dosimeters may be obtained from the Radiation Safety Office upon request.

c. Bioassay

Special tests for determining the presence of radioactive material in the body are desirable for persons handling intermediate or high levels of unconfined radioactive material. All persons working with such radioactive material shall make themselves available for such tests when requested by the Radiation Safety Office. See Appendix #12.

d. Medical Examinations

When deemed necessary by the Radiation Safety Office, a medical examination may be required for individuals who will be working with materials or equipment producing ionizing radiation. The Radiation Safety Office shall notify those workers who are to receive an examination.

e. Survey Meters

Every facility utilizing sources of ionizing radiation shall have appropriate survey instruments available. These instruments shall be used by the laboratory personnel to measure possible radiation fields, check for contamination of hands, shoes, clothing, and work areas.

E. CALIBRATION OF EQUIPMENT

All instruments utilized as radiation monitors must be calibrated at appropriate intervals to assure the validity and integrity of results. It becomes the responsibility of each Approved User to see that his instruments are properly functioning and in calibration. All survey meters used to quantitate radiation exposure must be calibrated at least every six months or whenever such instruments have been repaired. Survey

instruments may be made available for short term loan as deemed necessary by the Radiation Safety Office.

F. CONTAMINATION

No amounts of radioactivity shall be released into unrestricted areas in any manner which will cause the limits specified in the following regulations to be exceeded:

Code of Federal Regulations, Title 10, Part 20, Sections 20.105 and 20.106.

Ohio Radiation Protection Standards, Part 1, Rules 3701-38-15 and 3701-38-16.

G. DECONTAMINATION

Successful decontamination calls for planned action. Decontamination shall be accomplished by the Approved User and/or his laboratory personnel under the direction of the Radiation Safety Office. Decontamination procedures depend upon source type, strength, chemical and physical properties, and total area contaminated.

1. Procedures

   a. Decontamination of any area shall be accomplished by working from the outside towards the center.

   b. Make full use of protective clothing, footwear, gloves, masks, etc., to reduce the possibilities of personnel contamination for those conducting the decontamination procedures.

   c. Do not wear protective clothing, etc. outside of a designated change area.

   d. Handle all equipment used in decontamination and all run-off solutions as ones which are potentially contaminated.

   e. Make provisions for the disposal of all used cleaning materials and equipment as well as other contaminated articles in the area. Therefore, always bring the necessary collection receptacles to the area in question, not vice versa.

f. Make full use of available instrumentation for monitoring, choosing the most effective for your purposes.

g. Make a complete record of the decontamination operations.

h. After decontamination has been completed, do not permit any work or occupancy within the area(s) until approval has been obtained from the Radiation Safety Office.

i. Monitor each step of the decontamination operations just as if it was a separate, unrelated incident.

j. Suggested agents for removal of contamination from various surfaces can be found in Appendix #10.

IV. Radioactive Waste

All radioactive waste shall be disposed of via procedures approved by the Radiation Safety Office. Accumulation and storage shall be in designated containers, kept either in central storage areas or within approved individual laboratories. Proper disposal or transfer of radioactive waste is the responsibility of the Approved User.

A. METHODS OF DISPOSAL

The following methods of disposal will be utilized at the Medical College of Ohio.

1. Storage for Decay

Waste contaminated with radionuclides having a half life of less than 30 days may be stored for decay. The material may be discharged into the sewer or through normal waste disposal when the activity is below the maximum permissible level. (Code of Federal Regulations, Title 10, Part 20, Appendix B, Table 1, Column 2) Prior to disposal of solid waste (excluding ash from incineration), it shall be monitored with a suitable instrument and there shall be no detectable radioactivity.

2. Disposal into the Municipal Sewer System

Radioactive waste which can be conveniently disposed of through the municipal sewer system shall be processed for same in accordance with Federal and State regulations.

3. Shipment to Commercial Disposal Facilities

Radioactive waste materials which cannot be disposed of by other designated means shall be disposed of through a licensed commercial facility. Radioactive materials shall be incinerated at the Medical College of Ohio at Toledo only under the direction of the Radiation Safety Office.

B. RESPONSIBILITIES

1. Approved User's Responsibilities

The proper storage and disposal of radioactive waste within the laboratory is the responsibility of the Approved User. He shall ensure compliance with applicable regulations and maintain positive control over all such waste in his area until it is removed. The Approved User shall ensure that

the following procedures are complied with in the proper storage of radioactive waste in his facilities:

a. Radioactive waste material shall be segregated per instruction from the Radiation Safety Office.

b. Radioactive waste shall be stored in a separate designated area within the individual laboratories. The waste shall be removed from the individual laboratories periodically and be placed in designated containers within the central storage area. The appropriate form on each container will be filled out with the required information: The isotope; the quantity of each isotope; the date on which the waste is placed in the container; the Approved User's name; and other pertinent information. The containers provided for the accumulation and storage of radioactive waste material shall not be used for any other purposes.

c. The Approved User shall use due care in the selection of containers for the transfer and storage of liquid waste. In case of organic solvents, containers of a capacity not exceeding five gallons shall be used for accumulation and storage purposes.

d. Acids and bases shall be neutralized to approximately pH7 before depositing them in waste containers.

e. Liquid waste shall be stored in such a manner that there will be no possibility of a chemical reaction which might cause an explosion or cause the release of radioactive or toxic gas or vapors.

f. The Approved User shall not dispose of radioactive waste into the sewer system without approval of the Radiation Safety Office. In addition, the release of gaseous waste to the air effluent shall be accomplished only through hoods designated for this purpose and with written approval from the Radiation Safety Office.

2. Radiation Safety Office's Responsibilities

The Radiation Safety Office has the responsibility for the ultimate disposal of radioactive materials. The Radiation Safety Office shall maintain central storage areas in those places where the use of radioactive materials warrant them. These storage areas shall be used for the accumulation and storage of radioactive material. Radioactive waste normally shall be removed periodically from the individual laboratories and be placed in appropriate containers within the central storage areas.

C. ANIMAL CARCASSES AND EXCRETA CONTAINING RADIOACTIVE MATERIAL

Instructions

Listed below are the instructions to be followed when working with animals containing radioactive materials:

1. All objects which can inflict a wound shall be removed from animal carcasses.
2. Animal carcasses shall be double packaged in plastic bags in a manner which will ensure against the leakage of body fluids.
3. Each package shall be labeled with the isotope, amount of isotope, date of injection or treatment, weight in kilograms and the Approved User's name.
4. Animal carcasses shall be stored only in freezers designated by the Radiation Safety Office.
5. All excreta shall be collected and placed in appropriate containers. Solids, including liquids mixed with sawdust, shavings, etc., shall be placed in plastic bags and then stored in 55 gallon metal drums. Liquids shall be placed in one gallon plastic containers.
6. An estimate of the activity that is expected to be eliminated by the animal shall be made and recorded.
7. The containers shall be labeled with the name of the Approved User, the isotope(s), the estimated activity, and the date of collection.

V. Classification of Facilities and Sources of Ionizing Radiation

A. LABARATORY AREAS

Type 3: Laboratories which are specifically designed for handling high levels or highly toxic radioactive materials. They incorporate special apparatus, equipment, materials of construction and construction designed to limit the spread of contamination and to assist in maintaining high standards of laboratory hygiene.

Type 2: Laboratories which handle intermediate levels of activity or radioactive material of intermediate toxicity. This type of laboratory incorporates many features of the Type 3 laboratory but with some of the more specialized features being omitted.

Type 1: Laboratories intended for use with only low levels of toxicity or activity. This type of laboratory is usually one which has a few special features to accommodate work with radioactive materials.

Type 0: Laboratories in which the use of radioactive materials is limited to small tracer amounts. Here the activity shall not exceed the limits specified for Type 0 laboratories as contained in Appendix #8. These laboratories shall not be used for regular isotope projects of studies.

B. GENERATOR AREAS

Class A: Those areas which contain high energy accelerators and radioisotopic teletherapy devices housed in specially designed facilities.

Class B: Those areas which contain generators rated below 250 KV that are housed in specially designed facilities.

Class C: Those areas which contain generator equipment such as mobile x-ray machines, mobile isotopic devices, fixed installations such as x-ray diffraction units and other analytical equipment utilizing ionizing radiation.

Class D: Those areas which contain devices not ordinarily considered as emitting ionizing radiation.

C. RADIOACTIVE MATERIALS

See Appendix #8.

VI. Emergencies

Any circumstances or events which have caused or threaten to cause abnormal exposure of persons to ionizing radiation, or a loss of radioactive materials, shall be termed a radiological emergency. Emergencies may arise from a variety of situations; therefore, procedures cannot be established to cover all situations. Lifesaving procedures shall be the primary concern in any emergency. Following this shall be the protection of all personnel from exposure to ionizing radiation and then the confinement of contamination to the local area of the accident if this is possible.

A. NOTIFICATION

All emergencies shall be reported to:

1. Radiation Safety Office
2. Approved User responsible for the source of ionizing radiation.

B. EMERGENCY PROCEDURES

1. Accidents involving Release of Radioactive Material

   a. Notify all persons in the area at once and isolate those involved. Simultaneously forestall further spillage and initiate isolation and decontamination procedures.
   b. Keep the number of persons dealing with the spill to a minimum.
   c. Notify the Radiation Safety Office.
   d. Monitor all persons involved in the spill and clean up operations, paying particular attention to the shoe soles.
   e. Decontamination of personnel and the area involved shall be undertaken only under the direction of the Radiation Safety Office
   f. Occupancy of, or work in, the area shall not be resumed until approved by the Radiation Safety Office.

2. Sealed Source Rupture (also, Accidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapor or Gases).
   a. Notify all persons to vacate the room immediately.
   b. If time permits, all windows should be closed, fans or air conditioners should be shut off, the door and all other openings should be sealed with wide masking or adhesive tape.
   c. Notify the Radiation Safety Office.
   d. Restrict the movement of potentially contaminated persons to a local zone just outside the spill area until the extent of contamination is ascertained.
   e. If no means are available for monitoring, it should be assumed that all personnel involved are contaminated.
   f. Decontamination of the area shall be done only under the direction of the Radiation Safety Office.
   g. Occupancy of, or work in, the area shall not be resumed until approved by the Radiation Safety Office.
3. Injuries to personnel Complicated by Radioactive Contamination.
   a. All life-saving procedures should be carried out immediately; contact a physician at once if needed.
   b. Report all radiation accidents involving personnel (contaminated wounds, ingestion, inhalation) to the Radiation Safety Office as soon as possible.
   c. Wash minor wounds under running water immediately, while spreading the edges of the wound.
   d. Permit no person who has sustained a radiation injury to return to work without the approval of the Radiation Safety Office and the attending physician.
   e. A report shall be prepared by the individual injured and the Approved User in charge.
4. Overexposure and/or Suspected Overexposure
   a. Contact the Radiation Safety Office at once.
   b. A report shall be prepared by the individual exposed and the Approved User in charge.

5. Emergencies Involving Fires in Approved Areas and Adjacent Locations.

   a. Notify, in order, all persons in the area: The Fire Department, Public Safety and the Radiation Safety Office immediately. The caller must relate his name, location, and degree of any radiation hazard involved.

6. Emergencies Involving Motor Vehicles Acting as Carriers of Radioactive Materials.

   Because of the nature of this kind of emergency, the following set of instructions shall be carried in every vehicle used while transporting radioactive substances. These instructions are to be read and followed by all personnel in the event of an emergency.

   a. Immediate notification is to be given by telephoning, in the following order: Local Police and/or Highway Patrol, Local Health Authorities, and the Radiation Safety Office at the Medical College of Ohio. Caller must state his or her name, location, what happened, when, where, who was involved, and what has been done to control or contain the radioactive materials. Someone must maintain the security of the vehicle and radioactive material and keep bystanders away while calls are being made.

   b. All traffic should be detoured around the scene of the accident. If this is not possible, vehicles should be moved the shortest distance necessary to clear the right of way. If radioactive material is spilled, passage through the area should be prevented unless absolutely necessary. If right of way must be cleared before radiological assistance has arrived, the spillage should be washed to shoulders with minimum dispersal of wash water, or cover with at least four inches of earth or sand.

c. The nearest Nuclear Regulatory Commission (NRC) Office should be notified as soon as possible.

d. If the accident involves wreckage and a person is believed to be alive and entrapped, every possible effort should be made to rescue him or her.

e. The area of the accident should be restricted. The public should be kept as far from the scene as practical. Local authorities should make only necessary entries and investigations in the accident area. No attempt should be made to clean up any debris or material involved in the accident prior to the arrival of an emergency monitoring team.

f. Persons who have had possible contact with the radioactive material should be segregated and confined until they can be examined further. The names and addresses of those involved should be obtained and recorded.

g. The injured should be removed from the area of the accident with as little contact as possible and held at a transfer point. All life-saving measures should be performed promptly, but elective first-aid and surgical procedures should be delayed until advice or help can be obtained from a physician familiar with radiation medicine. Except in extreme emergency, patients should not be moved to local hospitals or doctors offices before a radiological survey has been made.

h. If the accident involves fire, attempts to extinguish it should be made from as great a distance as possible. The fire should be treated as one involving toxic chemicals. Suspected material should not be handled until it has been monitored and released by monitoring personnel. Clothing and tools used at the fire should be segregated until they can be checked by emergency monitoring teams.

i. Eating, drinking or smoking in the area of the accident should be prohibited. Food or drinking water which may have been in contact with material from the accident should not be used.

j. Careful attention and consideration should be given in matters of public relations to:

(1) Transmission of information to the public by press, radio, and television.

(2) Tactful handling of volunteers and curious onlookers.

7. Lost Sources

a. If a source is lost, notify all personnel in the area, monitor each individual and evacuate the area.

b. Restrict movement of personnel involved to a known and controlled area.

c. Do not remove any articles such as waste containers, laundry bags, soiled linens, from the areas involved.

d. Notify the Radiation Safety Office.

8. Other Emergencies

If any questions exist, call the Radiation Safety Office.

VII Transporting of Radioactive Material

Transporting of radioactive material by personnel of the Medical College of Ohio at Toledo must be done in full compliance with State and Federal Regulations and specifications. All questions pertaining to transporting of radioactive material must be directed to the Radiation Safety Office. Proper labels and forms and some types of shipping containers may be obtained from the Radiation Safety Office. Prior written approval for transporting of radioactive material must be obtained from the Radiation Safety Office.

A. INSTRUCTIONS

1. Intra-Facility Transport

   a. Transport shall be in unbreakable, spillproof, double containers which are free from loose, external contamination.

   b. Gamma radiation, or equivalent, shall not exceed 100 mr/hr at one meter distance.

   c. Containers shall be labeled in accordance with Federal and State regulations.

2. Transport Via Motor Vehicle

   The transport of radioactive material from one facility to another within the College complex or to outside facilities via motor vehicle shall be performed under the following conditions:

   a. All radioactive material shall be packaged in Department of Transportation specification containers. All containers shall be free of loose contamination on the outside.

   b. The gamma radiation or equivalent shall not exceed 200 mr/hr at the surface of the container and shall not exceed 10 mr/hr at one meter.

   c. There must not be any loose radioactive material in the motor vehicle and all containers shall be securely blocked and braced to prevent leakage or shift of loading under conditions normally incident to transportation. There shall not be more than 40 units per vehicle (one unit equals 1 milliroentgen per hour at

one meter for hard gamma radiation or the amount of radiation which has the same effect on film as one mR/hr of hard gamma rays of radium filtered by one-half inch of lead).

d. All shipments must meet regulations and general packaging requirements of 49 CFR Parts 170-190.

e. The motor vehicle shall be placarded in conformity with Department of Transportation regulations, 49 CFR Part 177.

f. Shipping orders, bills of lading and other forms or shipping papers shall be prepared in conformity with transportation regulations.

g. The motor vehicle shall be attended at all times. For transportation of high levels of unsealed radioactive materials, two people shall accompany the shipment.

h. Emergency instructions and an appropriate survey instrument shall accompany the driver of the motor vehicle.

i. Cars, buildings, area, or equipment in which radioactive material has been spilled shall not be placed in service or occupied until decontaminated by qualified persons.

VIII Additional Procedures and Instructions

A. TESTING OF SEALED SOURCES

Before any sealed source is put into useful service for the first time, and at other intervals, the Approved User shall conduct or have the following tests conducted to determine its integrity.

1. Initial measurement of activity.
2. Dry wipe test.
3. Wet wipe test.
4. Immersion test when applicable.
5. Other applicable non-destructive procedures.

The presence of radioactive material which exceeds the limits set forth by the Radiation Safety and Radioisotope Committee in any of the above tests shall be cause for rejection of the source.

B. INSTRUCTION REGARDING THE USE OF ANIMALS EXPOSED TO RADIOACTIVE MATERIAL

1. Approved User's Responsibilities

The Approved User of radioisotopes in charge of a research project involving animals is responsible for the radioisotopes and radiation safety involved while the animals are confined in animal facilities.

a. Laboratory animal technicians must be notified of animals containing radioactive material and given specific information in regard to the care to and management of these animals, their biological waste, required equipment, and necessary radiation safety instructions.

b. All cages containing food or that contain radioactive material shall be tagged with the following information (using a "Caution-Radioactive Material" tag):

(1) Name of isotope.
(2) Activity of radioactive material injected per animal.
(3) Date of injection.
(4) Principal investigator's name and phone number.

c. Animals containing radioactive materials shall be kept in cages apart from other animals.

d. All procedures, including injection of radioisotopes and preservation of carcasses, carried on outside of cages shall be done on steel trays with absorbent paper. The investigator shall make any necessary surveys of the area to verify that there is no contamination of the facilities.

e. Animals which have been injected with radioactive material that may be volatilized and dispersed into the room shall be kept in an area with adequate ventilation and air cleaning facilities.

f. Exercise of animals containing radioactive material normally will be restricted to their cages or primary enclosure. If some type of activity outside the cage or primary enclosure is required, it will be carried out by the investigator or a person directly responsible to him. The investigator shall be responsible for any emergency or contamination which may arise.

g. Appropriate surveys, by the Approved User, during and at the end of a project, of the facilities used by an investigator shall be made and results of these surveys shall be recorded and kept on file. Any pertinent information arising from these surveys which imply a health hazard shall be given immediately to the Radiation Safety Officer.

h. No animals from outside the Medical College of Ohio and containing radioactive material shall be placed in animal quarters without prior written approval of the Radiation Safety Officer, and the Director of Laboratory Animal Medicine.

i. The cages will be monitored by the investigator with equipment and methods appropriate to the radioisotope involved to determine the level of contamination. If contamination is found, it shall be reported to the Radiation Safety Office and decontamination of the cages will be performed under the direction of the investigator.

C. SUPPORT PERSONNEL

Support personnel shall constitute the members of maintenance, housekeeping and public safety.

1. Emergencies

If a question exists regarding a possible radiation hazard, the Radiation Safety Officer, as well as the staff member in charge of the facility shall be called. No attempt should be made to enter an area where a real or suspected radiation hazard exists.

2. Requested Maintenance and Custodial Service

Maintenance and custodial personnel shall request the Approved User to conduct a radiation survey of the area where the services are required. This survey shall be conducted prior to, or simultaneously with, the service being rendered.

3. Routine Maintenance and Custodial Service

Routine services shall be established in those areas where arrangements have been made with the Approved User. These arrangements shall be approved by the Radiation Safety Officer and may contain certain requirements and/or restrictions, depending upon the type of facility involved and the type of service desired.

4. Training Program for Support Personnel

Training programs for support personnel shall be conducted periodically by the Radiation Safety Office for purposes of familiarizing personnel with those aspects of radiation safety relevant in the discharge of their duties. Participation of support personnel in these programs shall be mandatory upon notification from the Radiation Safety Officer. In general, the topics covered in these programs shall consist of:

a. Types of ionizing radiation.
b. Description of posting placards, signs, labels.
c. Instructions regarding services in posted areas.
d. Special instructions regarding emergencies or suspected incidents.

IX. Medical Use of Radioactive Material

Applicants for routine medical use of byproduct material will complete the following forms:

1. Application Form for Approved Users (See Appendix #2)
2. NRC Form 313m (See Appendix #15)

If applicant is an Approved User, he need only complete the NRC Form 313m. If the applicant's Preceptor Statement, Supplement B of NRC Form 313m, is on file with the Radiation Safety Office, he need only provide new information.

Applicants for experimental or nonroutine medical uses of radioactive material must furnish additional information to the Radiation Safety and Radioisotope Committee in addition to the above forms. This supportive information may be completed in one of two methods.

1. Research Protocol which includes the information requested in the attached Appendix F, Non-Routine Medical Uses of Byproduct Material. (See Appendix #15)

2. H.H.S.'s Investigational New Drug Application (Form 1571)

It is the applicant's responsibility to provide the necessary supportive information in the above applications to the Radiation Safety and Radioisotope Committee. The committee's review of the application may be delayed if the appropriate information is not furnished.

If there are any questions pertaining to the application for Medical Use of Radioactive Material, please contact the Radiation Safety Office.

X. Training and Experience for Medical Uses of Byproduct Material

A. THE SIX MEDICAL GROUPS OF BYPRODUCT MATERIAL ARE DEFINED AS FOLLOWS (10 CFR 35.100)

1. Prepared radiopharmaceuticals used in diagnostic studies not involving imaging or tumor localization.
2. Prepared radiopharmaceuticals used in diagnostic studies for imaging and tumor localization.
3. Generators and reagent kits used for preparation of radiopharmaceuticals used in diagnostic studies.
4. Prepared radiopharmaceuticals used for therapy not normally requiring hospitalization for purposes of radiation safety.
5. Prepared radiopharmaceuticals used for therapy which normally requires hospitalization for purposes of radiation safety.
6. Sealed radioactive sources used for diagnosis and therapy.

For further information concerning specific radiopharmaceuticals or sources listed in the preceding six groups, consult the Radiation Safety Office, Extension 4301.

B. GENERAL TRAINING

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

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

a.	Radiation Physics and Instrumentation	(100 hours)
b.	Radiation Protection	(30 hours)
c.	Mathematics pertaining to the use and measurement of radioactivity	(20 hours)
d.	Radiation Biology	(20 hours)
e.	Radiopharmaceutical Chemistry	(30 hours)

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

2. Experience with the types and quantities of byproduct material for which the application is being made, or equivalent (500 hours).
3. Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and include:
   a. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.
   b. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of radiation dose, related measurement, and plotting data.
   c. Follow-up of patients when required.
   d. Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitations, contraindications, etc.

   Alternative:

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

C. Training Requirements for Therapy Procedures Involving Radiopharmaceuticals

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

1. Training in basic radioisotope handling techniques (200 hours) as described in Section X.B.1.

2. Clinical training in specific therapy procedures:

For Group IV

a. Iodine-131 for treatment of hyperthyroidism and/or cardiac conditions:
   --Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

b. Phosphorous-32 for treatment of polycythemia vera, leukemia, and/or bone metastases:
   --Treatment of three patients with any combination of these three conditions.

c. Colloidal phosphorous-32 intracavity treatment:
   --Active participation in the treatment of three patients.

For Group V

a. Iodine-131 for treatment of thyroid carcinoma:
   --Clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of three patients with thyroid carcinoma.

b. Colloidal Gold-198 for intracavity treatment:
   --Active participation in the treatment of three patients.

D. Training Requirements for Therapy Procedures Involving Sealed Sources

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

1. Training in basic radioisotope handling techniques (200 hours) as described in Section X.B.1.
2. Clinical training in specific therapy procedures:
   a. Radiation sources for intersitial, intracavity, or surface treatment of cancer:
      --Active practice in therapeutic radiology with a minimum of three years experience.

b. Beta ray applicators for the treatment of superficial eye disease:

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

(Evidence of certification by American Board of Radiology in Radiology or Therapeutic Radiology may be submitted in lieu of the information requested in Subsections D.1 and D.2, above.)

XI. Use of Brachytherapy Sources

A. RESPONSIBILITIES OF THE RADIATION ONCOLOGIST

1. The attending radiation oncologist shall be solely responsible for all aspects of prescription, use and return of sources of brachytherapy storage area at Medical College of Ohio Hospital.
2. Prior to insertion and following removal, brachytherapy sources shall be in possession of the radiation oncologist or locked in appropriately shielded designated areas for which he is responsible.
3. Sources shall be brought to the patient in the Operating Room or at the patient's bedside by the radiation oncologist or his designee. A physicist, dosimetrist or radiologic technologist qualified in brachytherapy source handling may aid the radiation oncologist and, in so doing, shall remain with the sources until the radiation oncologist takes charge of the sources.
4. When brachytherapy sources are removed from a patient, the radiation oncologist or his designee shall see that a source count and a radiation survey are performed before discharge. The radiation oncologist shall also see that the sources are returned to a designated safe storage area. His designee may assist the radiation oncologist by receiving the brachytherapy sources and returning them immediately to safe storage area.
5. The radiation oncologist shall maintain a current copy of standing orders for patients undergoing brachytherapy with the Radiation Safety Office for review by the Radiation Safety and Radioisotope Committee.

B. ADDITIONAL REQUIREMENTS

1. Use of Outside Sources

If radioactive sources other than those available at the Medical College of Ohio Hospital are brought to the MCO hospital, prior approval by the Radiation Safety and Radioisotope Committee shall be obtained. The Radiation Safety Office will provide the necessary forms for pre-

paring a protocol. Since human use is involved, the request for use should be prepared well in advance so that review by the Radiation Safety and Radioisotope Committee may be completed prior to the need for patient care. In case of an emergency, one should contact the Radiation Safety Office or a physician member of the Radiation Safety and Radioisotope Committee.

2. Accountability

   a. A log of each source shall be kept in the brachytherapy storage area so that the location of all sources can be determined. For sources removed from the safe, the log should indicate the type and strength of the sources, the patient's name, the date of removal, the date of return and the initials of the persons removing and returning the sources.

   b. The person preparing brachytherapy sources for implantation or applicator loading will do so as prescribed by the radiation oncologist on the Radiation Oncology Brachytherapy Source Record. He will then sign the Brachytherapy Source Record and Source Log. Before the sources leave the brachytherapy storage area, another qualified person will check the prepared loading, verify it with the prescription on the Brachytherapy Source Record and sign the source log.

3. Accident or Incident: Immediate Notification

   In the event of any type of accident, incident, or loss of a brachytherapy source, the radiation oncologist shall immediately notify the Radiation Safety Office.

C. GENERAL BRACHYTHERAPY PROCEDURES

1. Patients receiving brachytherapy shall be assigned to private rooms, either in a designated medical-surgical unit or an intensive care unit.

2. A radiation survey of the patient's room shall be performed as soon as possible after the insertion of the sources.

3. During the period of brachytherapy treatment, the patient's room shall be posted with appropriate signs indicating
   a. source type, strength, and site of application
   b. radiation exposure levels at bedside, and 1 meter and 6 feet from the source of radiation
   c. instructions to nursing personnel and visitors indicating any restrictions
4. The patient's chart will also be posted with a Radioactive Materials label and will contain physician's orders regarding radiation protection.
5. All nursing personnel and other staff at MCO Hospital who attend a patient while radioactive sources are in place shall be issued personal monitors (film badges) supplied by the Radiation Safety Office. Nurses should observe the time limits (maximum time for 100 millirems exposure) and enforce the prescribed limits for pregnant women, minors and visitors. Any nurse who is pregnant, or suspects herself to be pregnant, shall not attend the patient. Nurses and other assistants should employ the principles of minimum time, maximum distance and shielding as protection measures.

D. GUIDELINES FOR TEMPORARY BRACHYTHERAPY IMPLANTS

These procedures are in addition to the General Brachytherapy Procedures listed under XI. C. 1-5 of this manual.

1. Immediately preceding the insertion of radioactive sources in a patient, the radiation oncologist will visually check the radioactive source loading to insure that the sources loaded are exactly as prescribed. After inserting the brachytherapy sources in the patient, the radiation oncologist will sign the Radiation Oncology Brachytherapy Source Record under "Certificate of Receipt." This entry will include the number and type of sources and the time and date of insertion.

2. As an additional safety check, exposure rate levels measured at one (1) meter from the patient will be compared with expected levels. If the comparison is not within ± 20%, the safe will be rechecked to ensure that the appropriate sources have been removed from the safe. If the comparison is not within ± 50% of the expected levels, the sources will be removed from the applicator and checked.
3. The radiation survey after insertion will include the rooms above, below and adjacent to the patient's room. These exposure readings will be entered on the Brachytherapy Source Record. No room will remain occupied if an exposure rate greater than 2.0 mR/hr is measured.

E. GUIDELINES FOR PERMANENT BRACHYTHERAPY IMPLANTS

These procedures are in addition to the General Brachytherapy Procedures listed under XI. C. 1-5 of this manual:

1. Following implantation, a radiation survey shall be performed in the operating room before the room is cleaned. The survey will specifically include all suction fluids, sponges, trays and linens which might contain a source.
2. a. In cases where there is a possibility of brachytherapy sources being discharged through surgical wounds or body orifices, linens and appropriate waste materials will be kept in the room, e.g. urine, drainage, stool. The patient's room will be surveyed daily to check for the presence of dislodged sources. A radiation survey log will be posted on the door to the patient's room and a notation will be made daily indicating that waste materials and linens have been checked, are not contaminated with radioactive material and may be discarded in the normal manner.

   b. If after 15 days no dislodged sources have been found and, in the opinion of the radiation oncologist, there is negligible chance of a source becoming dislodged, the

Radiation Safety Officer may authorize the discontinuance of daily radiation contamination surveys.

3. A final radiation survey shall be performed after the patient is discharged, but before linens and waste have been removed and the room cleaned.
4. Upon discharge from the hospital, patients at risk of discharging a radioactive source (e.g. prostate, vaginal implants) will be given instructions for handling any sources that may be recovered.

XII. Guidelines for the Therapeutic Administration of Iodine-131 for Thyroid Cancer (doses greater than 30 millicuries)

A. ROOM SELECTION

1. The therapy room should be a corner room in a low traffic section of hallway.
2. No carpeting on floor.
3. Private toilet facilities must be available since urine and perspiration will be contaminated with iodine-131.
4. Adequate ventilation is necessary since iodine is volatile and levels of airborne iodine-131 can build up.
5. No patients in adjoining rooms shall be less than 18 years of age and should be over 45 years of age. No females of childbearing age are permitted in adjoining rooms unless approved by the Radiation Safety Officer.

B. ROOM PREPARATION

1. Determine if urine is to be stored in room. If so, select area and provide shielding if necessary.
2. Remove unnecessary furniture from room. Arrange coverings for floor, tabletops, telephone, television as necessary to aid in decontamination.
3. Arrange for meals to be brought on disposable trays.
4. Provide two labeled waste containers. All disposable items go in one; gowns and linens go in the other.
5. Central Service must be contacted to provide a cart to hold the following items:
   a. Two boxes each of small, medium and large gloves.
   b. Ten large plastic bags with ties.
   c. Three rolls of 2" masking tape.
   d. Isolation gowns--five each of small, medium and large.
   e. Foot coverings, ten pair each of small, medium and large.

   This cart, as loaded above, is to be kept in the hall immediately outside patient's room.

C. IODINE-131 DOSE PREPARATION AND ADMINISTRATION

1. The dose should be corrected for decay from the manufacturer's assay.
2. The dose must be assayed in the dose calibrator and compared to the manufacturer's assay. Values must agree within 10% in order to proceed with administration of the iodine-131.
3. The dose should be placed on a tray having absorbent coverings and appropriate shielding to reduce external radiation levels below 10 mR/hr at 12 inches from the container.
4. The dose must be administered to the patient in the patient's room (for iodine-131 cancer therapy).
5. After administration of the dose, the vial must be reassayed to determine the net quantity administered. This residual quantity may be used as a check on the response of the survey meter. See previous section.
6. The administration of the dose and the time period immediately thereafter represent the period of greatest radiation safety concern. Volatile iodine can represent an exposure to personnel, therefore only experienced personnel should handle the dose. The patient may regurgitate the iodine dose immediately after administration and cause elevated air concentrations as well as gamma levels. Decontamination supplies should be readily available during the time period following the administration of the iodine-131.
7. The usual safety procedures such as wearing a lab coat, ring dosimeter, whole body monitors, and gloves are absolutely necessary.

D. PERSONNEL SAFETY

1. Radiation Oncologist

The training of radiation oncologists includes the procedures to be carried out during an iodine-131 therapy administration. It is the responsibility of the radiation oncologist to insure that his staff reviews the applicable procedures just prior to any administration.

2. Personnel Present at the Administration

This group includes the radiation oncologist and may include any or all of the following: other physicians, physicist, dosimetrist, therapy technologist, nurse.

The administration of large quantities of iodine-131 presents a radiation safety problem not normally encountered. Namely, it is quite possible for a small thyroid uptake of iodine-131 by personnel to occur if standard safety practices are not followed. All doses must be opened only inside the hood. Once the dose has been administered, the next most likely site for a possible thyroid uptake is in the patient's room where elevated air concentration of iodine-131 might be found. Should the room be poorly ventilated, the limits of occupancy by visitors, nurses, and other staff may be limited by the air concentration, instead of the external gamma levels. This can be determined by the Radiation Safety Office through the use of air sampling. A 24-hour thyroid uptake measurement must be performed on all personnel present at the administration (a) if the dose administered was in a liquid form, or (b) if at the administration there was any regurgitation, spill or any other incident which would produce excessive exposures.

3. Nursing Personnel

As part of In-Service Education, seminars on radiation safety (including iodine-131 therapy) are routinely given. In addition, just prior to the administration of an iodine-131 therapy dose, Radiation Safety will review the program with the appropriate nursing personnel.

Personnel monitoring as required by Radiation Safety will be used. This may be either whole body film badges, or pocket dosimeters. Thyroid uptake counts may also be required at the discretion of the Radiation Safety Office.

4. Housekeeping

Housekeeping personnel are not to enter the patient's room without the permission of the Radiation Safety Office.

5. Visitors

No visitors less than 18 years of age are permitted. No female visitors of childbearing age are permitted. Visitors are limited to time periods as indicated by the Radiation Safety Office. (See Section H, Form 2)

E. ROOM SURVEY

1. The survey of the patient's room must be performed immediately after the dose has been administered to the patient and before any bedside nursing care is given or visitation is permitted.
2. A calibrated survey meter must be used to determine the radiation levels at bedside, at chairs where visitors may sit, in adjoining patient rooms, and in the hallway. (See Section H, Form 1) The form titled "Iodine-131 Therapy Administration Limits of Exposure" (Section H, Form 2) is to be posted at the entrance to the patient's room.
3. The frequency of surveys is to be determined by the Radiation Safety Office. Physical decay of iodine-131 and biological elimination from the patient may decrease radiation levels sufficiently to permit more lenient time limits for nurses and visitors.
4. Air sampling must be performed when a patient has received 100 millicuries or more, and urine is stored in room in unsealed containers. Sampling must be done with a low volume air sampler using charcoal activated filters. (See Section H, Form 3)

F. PATIENT DISCHARGE

The patient may not be discharged until the total remaining activity in the patient is less than 30 millicuries. Restrictions to members of the household will be necessary as follows:

If Remaining Activity is:	Restrictions
8 mCi to 30 mCi	No restriction if members are older than 45 years of age. Members under 45 years are limited to 0.1 Rem.
8 mCi or less	No restriction to members older than 21 years.

Restrictions for household members are given in the form titled "Instructions for Family of Released Patient" which should be given to the appropriate household members before the patient is discharged. (See Section H, Form 7)

G. ROOM DECONTAMINATION, WASTE DISPOSAL

The Radiation Safety Office must survey all areas likely to have been contaminated prior to their release for unrestricted use. Door signs and stickers must be removed. The room must be cleaned with the goal of removing all removable contamination. Standard procedures for decontamination are to be followed. Some items (e.g., telephone) may require removal for radioactive decay in storage.

Although the patient's urine will likely contain large quantities of radioactive iodine-131,. disposal of the material in the sanitary sewer system is permitted because of the large dilution factor. If space doesn't present a problem, the urine can be stored until the activity decays to background level. All other waste materials (such as food, trays, paper, plastic and bedding) must be stored for decay in plastic bags until background readings are obtained. These plastic bags must have the "Caution--Radioactive Materials" tag, identifying the date of collection and the radioisotope present. A record shall be kept showing that items were monitored prior to return for use or disposal. The treatment room cannot be released to nursing service without the approval of the Radiation Safety Office.

H. RECORD KEEPING REQUIREMENTS

The following seven forms are to be filled out for each iodine-131 therapy administration for cancer. The purpose of each form is discussed below.

1. Radiation Safety Survey Form

   This form is to be used to record the radiation levels in and around the patient's room. The measurements may be made by anyone experienced with the survey meter (physicist, dosimetrist, technologist, or physician). This form will be saved for possible NRC inspection. It will also be the source of the calculated values tc be placed on the "Limits of Exposure" form.

2. Limits of Exposure

   This form will provide the nursing personnel and visitors with specific limits of time of patient visit. This form is to be posted at the entrance to the patient's room.

3. Air Sampling Worksheet

   This form will be useful to the Radiation Safety Office when high air concentrations may exist.

4. Radioactivity Precautions for Nursing Personnel

   This is a list of precautions to be taken by all nursing personnel to provide exposures as low as reasonably achievable.

5. Patient In-Hospital Instructions

   This is a list of precautions to be taken by the patient to provide for minimum contamination and exposures as low as reasonably achievable.

6. Permanent Implant or Internal Dose

   This is a sticker to be attached to the outside of the patient's chart. This helps advertise the fact that the patient contains radioactive materials.

7. Instructions for Family of Released Patient

   This form is the set of written instructions given to patient's family. A copy of this should be maintained in Radiation Safety Office.

RECORD KEEPING REQUIREMENTS -- IODINE-131 CANCER THERAPY

Form Title	Kept During Rx in/on	Permanent Disposition
1. Radiation Safety Survey Form	Radiation Safety Files	Radiation Safety Files
2. Limits of Exposure	Patient's Room Entrance	Radiation Safety Files
3. Air Sampling Worksheet	Radiation Safety Files	Radiation Safety Files
4. Radioactivity Precautions for Nursing Personnel	In Patient's Chart	Discard
5. Patient In-Hospital Instructions	Patient's Room	Discard
6. Permanent Implant or Internal Dose	Cover of Patient's Chart	Discard
7. Instructions for Family of Released Patient	In Patient's Chart	Original to Family Copy to Radiation Safety

RADIATION SAFETY SURVEY FORM

Patient_____ Room_____Date_____

Administered Dose_____mCi

1. Sketch in room, include furniture and storage (urine).
2. Indicate with numbers those locations to be surveyed.
3. Record values below.
4. Limit nurses and visitors to 2.5 mR in any hour.
5. Limit other patients to 100 mRem total -- note time of scheduled discharge.
6. Make sure some diagnostic exam isn't interfering with the survey.
7. Rooms above, below and adjacent should be surveyed.

	Date_____	Date_____	Date_____
	Time_____	Time_____	Time_____
Location	mR/hr_____	mR/hr_____	mR/hr_____
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

IODINE-131 THERAPY ADMINISTRATION

LIMITS OF EXPOSURE

PATIENT_____Room_____ Date_____

Administered Dose_____mCi

NURSES

1. Not more than _____ minutes in any one hour at bedside.
2. Not more than _____ minutes in any one hour at six (6) feet.

VISITORS

1. Not more than _____ minutes in any one hour at bedside.
2. Not more than _____ minutes in any one hour at six (6) feet. (in chair)
3. Do not eat, smoke, drink, or apply cosmetics in patient's room.
4. Pregnant women or minors (under 18 years of age) should not visit a patient.
5. Visitors and neighboring patients should remain at a distance of more than six feet from patient.

IODINE-131 THERAPY ADMINISTRATION

AIR SAMPLING WORKSHEET

PATIENT_____ Room_____ Date_____

AIR SAMPLER_____

TIME OF SAMPLE START_____

TIME OF SAMPLE STOP_____

TIME OF SAMPLE COUNT START_____

TIME OF SAMPLE COUNT STOP_____

CFM X TOTAL MIN = TOTAL VOL (V)

$$\frac{\text{TOT, COUNT - BKG}}{C_{eff} \times F_{eff}} = \text{DPM} \times \frac{\text{uCi}}{2.22 \times 10^6 \text{ dpm}} = \text{uCi}$$

$$\frac{\text{uCi}}{\text{ml}} = \text{concentration} \times \text{time in room} = \text{mPCa - hrs}$$

Table I, Col 1 MPC_a (sol. restricted area) = 9×10^{-9} uCi/ml

Table II, Col 1, MPC_a (sol. unrestricted area) = 1×10^{-10} uCi/ml

RADIOACTIVITY PRECAUTIONS

FOR NURSING PERSONNEL

DURING IODINE-131 THERAPY APPLICATIONS

1. Permissible time limits at bedside and at six (6) feet for nurses (and visitors) will be posted at the entrance to the patient's room.

2. Gloves and gowns must be worn when entering the patient's room.
3. Visitors are limited as follows.
    1. No visitors under the age of 18
    2. No pregnant visitors.
    3. Visitors limited to times as posted at the entrance to the patient's room.
4. Utensils, bedding, and clothing of attendants and nurses, etc., that may be contaminated by the patient should be kept in the container provided to be checked by Radiation Safety.
5. Unless notified otherwise, all excreta can be disposed of in the normal manner. When other precautions are required, specific orders will be written in the patient's chart.
6. When permitted, urinals, bedpans, and urine collection bottles may be used by the patient. These will be "hot" and should be handled only by the patient or radiation safety, unless otherwise instructed.
7. Film badges or pocket dosimeters may be necessary for personnel monitoring when specified by Radiation Safety.
8. If any emergency should arise with regard to radiation safety, the Radiation Safety Office should be called.

PATIENT IN-HOSPITAL INSTRUCTIONS

1. You may eat three (3) hours after treatment and your diet need not be altered.
2. Prior to urination, place one ounce (two [2] tablespoonfuls) of Radioiodine Cleaning Solution in toilet bowl water. If you need assistance, call the nurse.
3. Urinate directly into the toilet taking care so that the area around the toilet is not soiled with urine.
4. Flush the toilet three (3) times.
5. Always wash hands thoroughly after urinating, then fill the sink basin with water and add one ounce of Radioiodine Cleaning Solution. Let it stand for two minutes, then drain and run tap water for 2 minutes.
6. Wash out bath tub or shower with soap or cleanser after use.

INSTRUCTIONS FOR FAMILY OF RELEASED PATIENT

Home precautions to be taken by patient after receiving a therapeutic dose of radioiodine (Iodine-131):

FOR TWO WEEKS

1. The patient should sleep alone and except for brief periods, other persons should remain at a distance greater than six (6) feet. This is especially important for children and other persons under 45 years of age.

2. Whenever possible, use separate toilet facilities, that is, a toilet not used by other members of the family.

3. Before urinating, always place one ounce (two [2] tablespoonfuls) of Radioiodine Cleaning Solution in toilet bowl water before flushing the toilet. Then flush the toilet three (3) times.

4. Use care so that the area around the toilet is not soiled with urine.

5. If you return to work within two weeks, take a 3 ounce bottle of Radioiodine Cleaning Solution with you and use as above each time.

6. Bed linen and clothing need no special precautions, <u>except</u> when there are young children in the family, in which case your linen and clothing should be washed separately with soap or detergent, after the other clothing has been washed. Then the tub or washing machine should be rinsed three (3) times.

7. Wash out bath tub or shower with soap or cleanser after use.

8. Use stringent contraceptive measures to avoid pregnancy during the three (3) months after treatment. Do not breast feed during this time.

9. If any questions arise regarding these instructions, please feel free to call 381-4301 or 381-5114 and ask to discuss them.

GLOSSARY

Activity: The number of nuclear transformations occurring in a given quantity of material per unit time. (See Curie)

Becquerel: The SI unit of activity. One becquerel equals 1 nuclear transformation per second.

Contamination, radioactive: Deposition of radioactive material in any place where it is not desired, and particularly in any place where its presence may be harmful.

Controlled Area: A defined area in which the occupational exposure of personnel to radiation or to radioactive material is under the supervision of an individual in charge of radiation protection. (This implies that a controlled area is one that requires control of access, occupancy, and working conditions for radiation protection purposes.)

Curie: A unit of activity. One curie equals 3.7×10^{10} nuclear transformations per second. (Abbreviated, Ci.) Several fractions of the curie are in common usage:
millicurie (mCi) = 10^{-3} curies
microcurie (uCi) = 10^{-6} curies

Decay, radioactive: Disintegration of the nucleus of an unstable nuclide by spontaneous emission of charged particles and/or photons.

Dose: A general form denoting the quantity of radiation or energy absorbed. For special purposes, it must be appropriately qualified. If unqualified, it refers to absorbed dose.

Dose, absorbed: The energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The unit of absorbed dose is the rad. One rad equals 100 ergs per gram. (See rad and gray)

Dose, cumulative: (Radiation) The total dose resulting from repeated exposures to radiation.

Dose, equivalent (DE): A quantity used in radiation protection. It expresses all radiations on a common scale for calculating the effective absorbed dose. It is defined as the product of the absorbed dose in rads and certain modifying factors. (The unit of dose equivalent is the rem)

Dosimeter: Instrument used to detect and measure an accumulated dosage of radiation; in common usage it is a pencil-size ionization chamber with a built-in, self-reading electrometer used for personnel monitoring.

Exposure, external: Exposure to ionizing radiation when the radiation source is located outside the body and the body and the radiation must then penetrate into the deeper tissues.

Exposure, internal: Exposure to ionizing radiation when the radiation source is within the body as a result of deposition of radionuclides in the body tissue.

Film Badge: A pack of photographic film used for approximate measurement of radiation exposure for personnel monitoring purposes. The badge may contain two or three films of differing sensitivity, and it may contain a filter which shields part of the film from certain types of radiation.

General population: All persons who are not designated as being specifically engaged in a field of endeavor which subjects them to exposures of ionizing radiation. Further, by law, this population is limited to dosages of ionizing radiation of only one-tenth that allowed for the occupational population.

Gray: The unit of absorbed dose equal to 1 J/kg in any medium. 1 gray = 100 rad

Half-life, biological: The time required for the body to eliminate one-half of an administered dosage of any substance by regular processes of elimination. Approximately the same for both stable and radioactive isotopes of a particular element.

Half-life, effective: Time required for a radioactive element in an animal body to be diminished 50 percent as a result of the combined action of radioactive decay and biological elimination.

$$\frac{\text{Biological half-life} \times \text{Radioactive half-life}}{\text{Biological half-life} + \text{Radioactive half-life}}$$

Half-life, radioactive: Time required for a radioactive substance to lose 50 percent of its activity by decay. Each radionuclide has a unique half-life.

Ionization: The process by which a neutral atom or molecule acquires a positive or negative charge.

Maximum Permissible Dose (MPD): The maximum RBE dose that the body of a person or specific parts thereof shall be permitted to receive in a stated period of time.

Nuclide: Any individual nuclear species such as ^{14}C, ^{32}P, ^{131}I, etc., irrespective of whether or not the nuclide has other isotopes. The term isotope is frequently misused for nuclide, but the strict meaning of the former as originally defined by Soddy (1914) is of the same place, i.e. in the same position in the periodic table. Thus, one may say that the nuclide phosphorus-32 is an isotope of phosphorus, or even more specifically of, say, phosphorus-33. A radioactive nuclide is often referred to as a radionuclide.

Occupationally Exposed Population: All persons who are designated as being specifically engaged in a task which subjects them to possible exposures of ionizing radiation.

Rad: The unit of absorbed dose equal to 0.01 J/kg in any medium. 1 rad = 0.01 gray

Rem: A special unit of dose equivalent. The dose equivalent in rems is numerically equal to the absorbed dose in rads multiplied by the quality factor, the distribution factor, and any other necessary modifying factors.

Roentgen: An exposure dose of x- or gamma radiation such that the associated corpuscular emission per .001293 gm. of air produces, in air, ions carrying 1 electricity of either sign.

Sealed Source: A radioactive source sealed in an impervious container which has sufficient mechanical strength to prevent contact with a dispersion of the radioactive material under the conditions of use and wear for which it was designed.

Shall: Denotes that the ensuing recommendation is necessary or essential to meet the currently accepted standards of protection.

Should: Indicates advisory recommendations that are to be applied when practicable.

Survey, radiological: Evaluation of the radiation hazards incident to the production, use, or existence of radioactive materials or other sources of radiation under a specific set of conditions. Such evaluation customarily includes a physical survey of the disposition of materials and equipment, measurements or estimates of the levels of radiation that may be involved, and a sufficient knowledge of processes using or affecting these materials to predict hazards resulting from expected or possible changes in materials or equipment.

APPENDIX #1

Minimum Training and Experience Required for Authorized Users

(Non-Human)

The minimum training and experience required for approval of authorized users is thirty (30) hours of training in basic radioisotope technique.

The training may be obtained in a formal course or incorporated in a program using byproduct materials. The training should include general training in basic radioisotope handling technique including:

a) A working knowledge of principles and practice of radiological health safety; radioactivity measurements; standardization of monitoring techniques and instruments; mathematics and calculations basic to the use and measurements of radioactivity; and biological effects of radiation.

b) Experience in the use of byproduct material for the type and quantities for which the application is being made or equivalent experience.

APPENDIX #2

MEDICAL COLLEGE OF OHIO

APPLICATION FOR USE OF RADIATION SOURCE(S)

APPLICANT _____
Last Name First Name Initial

Department _____ Academic Rank _____

Business Address: Home Address:

_____ _____

List and Identify each Lab you wish to use:

Bldg.	Room	Phone	Lockable? (Yes or No)	Radioactive Sink? (Yes or No)	Type* of Lab

Persons who will routinely use sources:

Name	Date of Birth	Social Security Number

In the event of an emergency in your area, who can be contacted?

Name _____ Office Phone _____

Address _____ Home Phone _____

Name _____ Office Phone _____

Address _____ Home Phone _____

*See Appendix #8 of MCO Radiation Safety Manual

1. UNSEALED SOURCES--RADIONUCLIDES

A_X *	SOLID LIQUID, OR GAS	CHEMICAL FORM	SOLUBLE OR NONSOLUBLE IN WATER?	VOLATILE OR TOXIC OR COMBUSTIBLE?	MAXIMUM AMOUNT IN MILLICURIES PER YOUR ORDER	MAXIMUM AMOUNT IN MILLICURIES PER YOUR LAB

* e.g., ^{3}H, ^{14}C, ^{32}P, etc.

2. SEALED SOURCES

RADIONUCLIDE	MANUFACTURER	ACTIVITY/DATE	SERIAL NUMBER

3. OTHER SOURCES

DESCRIPTION	MANUFACTURER	MODEL NUMBER	SERIAL NUMBER

RADIOLOGICAL HAZARDS EVALUATION

A. Will you need a survey meter?_____

_____

(Only two Approved Users may share a meter.)

B. Will you need film badge service?_____

_____

C. Is your staff familiar with routine radiation safety procedures in the lab? _____

_____

(Safety course offered by Radiation Safety Office--mandatory attendance for those with no prior instruction.)

D. What type and how much radioactive waste will you generate? _____

_____

_____

(If animals, indicate the radionuclide.)

E. Will you dispose of radioactive waste via the sewer (a sink)?

_____

_____

F. Do you need "Caution" signs? _____

FORMAL COURSES TAKEN AND/OR EXPERIENCE IN USE OF RADIOACTIVE MATERIAL(S) BY THE APPLICANT

1. COURSES IN RADIATION SAFETY

Course Title	Place Where Taken	When (Month & Year)	Number of hours

2. EXPERIENCE WITH RADIONUCLIDES (RADIATION SAFETY)

Type	Place of Experience	When (Month & Year)

PROJECT DESCRIPTION:

PROJECT DESCRIPTION (Continued):

*IMPORTANT! READ AND SIGN THE FOLLOWING STATEMENT:

I, the undersigned, have read and understand the applicable N.R.C., State of Ohio, and Medical College of Ohio at Toledo Radiation Safety regulations, and agree to comply with same in the handling and using of all sources of ionizing radiation.

SIGNATURE_____ DATE_____

APPENDIX #3

MEDICAL COLLEGE OF OHIO

AMENDMENT TO CERTIFICATE OF USE FOR RADIATION SOURCE(S)

APPLICANT _____
Last Name First Name Initial

Department _____ Academic Rank _____

List and Identify each Lab you wish to use:

Bldg.	Room	Phone	Lockable? (Yes or No)	Radioactive Sink? (Yes or No)	Type of Lab

Persons who will routinely use sources:

Name	Date of Birth	Social Security Number

RADIOLOGICAL HAZARDS EVALUATION

A. Will you need a survey meter? _____
(Only two Approved Users may share a meter.)

B. Will you need film badge service? _____

C. Is your staff familiar with routine radiation safety procedures in the lab? _____
(Safety course offered by Radiation Safety Office--mandatory attendance for those with no prior instruction.)

D. What type and how much radioactive waste will you generate? _____

_____
(If animals, indicate the radionuclide.)

E. Will you dispose of radioactive waste via the sewer (a sink)?

_____

F. Do you need "Caution" signs? _____

1. UNSEALED SOURCES--RADIONUCLIDES

A_X*	SOLID, LIQUID, OR GAS	CHEMICAL FORM	SOLUBLE OR NONSOLUBLE IN WATER?	VOLATILE OR TOXIC OR COMBUSTIBLE?	MAXIMUM AMOUNT IN MILLICURIES: PER YOUR ORDER	MAXIMUM AMOUNT IN MILLICURIES: TOTAL IN YOUR LAB

2. SEALED SOURCES

RADIONUCLIDE	MANUFACTURER	ACTIVITY/DATE	SERIAL NUMBER

3. OTHER SOURCES

DESCRIPTION	MANUFACTURER	MODEL NUMBER	SERIAL NUMBER

* e.g., ^{3}H, ^{14}C, ^{32}P, etc.

PROJECT DESCRIPTION:

*IMPORTANT! READ AND SIGN THE FOLLOWING STATEMENT:

I, the undersigned, have read and understand the applicable N.R.C., State of Ohio, and Medical College of Ohio at Toledo Radiation Safety regulations, and agree to comply with same in the handling and using of all sources of ionizing radiation.

SIGNATURE_____ DATE_____

APPENDIX #4

Procurement of Radioisotopes

The Purchasing Department will not honor a requisition for radioisotopes unless it is approved by the Radiation Safety Office.

A. Procedure for Routine Requisitions

1. Fill out a standard purchase requisition. Mark it "RADIOACTIVE MATERIAL."
2. On Purchase Requisitions, spell out clearly whether quantities are MILLICURIES or MICROCURIES.
3. The Purchase Requisition must be signed by the Approved User.
4. Forward the requisition to the Radiation Safety Office for approval. After approval, the Radiation Safety Office will forward the requisition to the Accounting Department. The Accounting Department will then forward the purchase requisition to the Purchasing Department.
5. The Receiving Department will automatically forward all shipments of radioactive material that are received to the Radiation Safety Office, unless prior arrangements are made and approved.
6. The Radiation Safety Office will notify the Approved User of the arrival of a shipment. The Approved User will pick up the shipment and sign a copy of the packing slip to indicate that it has been received. This copy remains on file in the Radiation Safety Office.
7. Packages containing radioactive material should be opened according to rules given in Appendix #6. The radioisotope disposition form provides an area for this documentation.

B. Procedure for Standing Orders

1. Follow steps 1, 2 and 3 in Section A.
2. Each isotope on a Standing Order must be specified individually and the requisition must be approved by the Radiation Safety Office.
3. All persons permitted to call in orders must be specified on the Purchase Order.
4. Only persons with specific knowledge of radioisotopes will be approved to call in orders, e.g., physicians, physicists, technologists.
5. The Radiation Safety Office must be notified prior to calling in an order. Notification shall include the anticipated date of arrival of the shipment, the isotope expected, and the amount of the isotope in millicuries or microcuries.

C. Procedure for Blanket Orders

1. Follow steps 1, 2 and 3 in Section A.
2. Each isotope on a Blanket Order must be specified individually and the requisition must be approved by the Radiation Safety Office.
3. The Purchase Requisition for a Blanket Order must include an attachment listing each radionuclide, the chemical form, maximum activity per order and estimate of total activity.
4. Individual releases against Blanket Orders do not require the approval of the Radiation Safety Office.

D. Procedure for No-Charge Shipments

1. All no-charge shipments must have the prior approval of the Radiation Safety Office. Written notification shall include the anticipated date of arrival of isotope, and the amount in millicuries or microcuries.
2. All shipments must be delivered through the Radiation Safety Office.

APPENDIX #5

Procurement of Sources of Ionizing Radiation Other than Radioisotopes

The Purchasing Department will not honor a routine requisition for sources of ionizing radiation such as x-ray generators, linear accelerators, electron microscopes, etc., without approval of the Radiation Safety Office. The procedure for ordering sources of ionizing radiation other than radioisotopes will be as follows:

1. Fill out a standard purchase requisition. Forward the requisition to the Radiation Safety Office for approval. After approval, the Radiation Safety Office will forward the requisition to the Purchasing Department via the Accounting Department.
2. The Radiation Safety Office will send a copy of the State of Ohio Registration form to the Approved User requesting the source.
3. Upon receipt of the source, the Approved User will complete the form and return it to the Radiation Safety Office.

APPENDIX #6

Procedure for Opening Packages Containing Radioactive Materials

1. Wear gloves while handling package(s).
2. Place package in a restricted area for inspection.
3. Visually inspect the package for breakage or wetness. If any questionable conditions exist, go directly to Step 8.
4. For shipments labeled with a radioactive diamond II or III, survey the maximum exposure level on the outside of package, using an appropriate and calibrated meter. If the reading is 10% greater than the level indicated by the Transport Index, go directly to Step 8.
5. Wipe test the outside of the package and count in an appropriate counter for contamination. Document on Receipt and Disposition Log. If contaminated, go directly to Step 8.
6. If no contamination is found, open package and observe for internal damage or wetness. If none exists, log the receipt and place the material in the proper storage area. If damage or wetness is present, go directly to Step 8.
7. Check packing material for contamination after opening the package and before discarding. Completely deface or destroy all radioactive labels before discarding the package.
8. DO NOT CONTINUE OPENING THE PACKAGE. AVOID CONTAMINATION. ISOLATE THE PACKAGE, AND CALL THE RADIATION SAFETY OFFICE.

APPENDIX #7

Area Survey Procedures

The following frequency for radiation surveys in radionuclide laboratories shall be followed and is the responsibility of the Approved User.

In all laboratories, consideration should be given to the possibility of cross-contamination. Therefore, it may be necessary to monitor before and after each procedure for experimental accuracy.

1. All elution, preparation, and injection areas will be surveyed daily with a low-range thin-window G-M survey meter and decontaminated if necessary.
2. Laboratories classified as Type 3 shall be surveyed after each procedure.*
3. Laboratories classified as Type 2 shall be surveyed weekly.*
4. Laboratories classified as Type 1 and 0 shall be surveyed monthly.*
5. The laboratory (2, 3, and 4) survey will consist of:
   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem/hr.
   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 cm^2 for the contaminant involved.

* For classification of laboratory, see Appendix #8.

6. A permanent record will be kept of all survey results, including negative results. The record will include:
   a. Location, date, and type of equipment used.
   b. Name of person conducting the survey.
   c. Drawing of area surveys, identifying relevant features such as active storage areas, active waste areas, etc.
   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
   e. Detected contamination levels, keyed to locations on drawing.
   f. Corrective action taken in the case of contamination or excessive exposure rates; reduced contamination levels or exposure rates after corrective action; and any appropriate comments.
7. Area will be cleaned if the contamination level exceeds 100 dpm/100 cm^2.

APPENDIX #8

Classification of Laboratories for Handling Radionuclides

Group of Radionuclide[1]	Type of Laboratory			
	Type 3	Type 2	Type 1	Type 0
1	1 mCi	10 uCi to 1 mCi	0.1 uCi to 10 uCi	0.1 uCi*
2	100 mCi	100 uCi to	1 uCi to	1 uCi
3	1 Ci	10 mCi to	10 uCi to	10 uCi
4	100 Ci	1 Ci 100 Ci	100 uCi to 1 Ci	100 uCi

1. See Table I

* Excluding any alpha emitters.

Modifying factors for activities in above classification:

Procedure	Factor
Storage (Stock solution)	100
Very Simple Wet Operations	10
Normal Chemical Operations	1
Complex Wet Operations with Risk of Spill	0.1
Simple Dry Operations and Work with Volatile Radioactive Compounds	0.1
Dry and Dusty Operations	0.01

TABLE I

RELATIVE HAZARDS OF VARIOUS NUCLIDES

GROUP 1. Very High Hazard

10 Ci	100 Ci	1 mCi	10 mCi	100 mCi	1 Ci	10 Ci
Low Level		Medium Level		High Level		

^{210}Pb*, ^{210}Po, ^{222}Rn*, ^{226}Ra*, ^{228}Ra*, ^{227}Ac, ^{228}Th, ^{230}Th, ^{237}Np, ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Pu, ^{242}Pu, ^{241}Am*, ^{242}Cm

GROUP 2. High Hazard

10 Ci	100 Ci	1 mCi	10 mCi	100 mCi	1 Ci	10 Ci
Low Level		Medium Level		High Level		

^{22}Na*, ^{45}Ca, ^{46}Sc*, ^{60}Co*, ^{90}Sr, ^{106}Ru*, ^{129}I, ^{131}I*, ^{137}Cs*, ^{144}Ce*, ^{154}Eu*, ^{182}Ta*, ^{210}Bi, ^{211}At, ^{224}Ra, ^{233}U

GROUP 3. Medium Hazard

10 Ci	100 Ci	1 mCi	10 mCi	100 mCi	1 Ci	10 Ci
Low Level			Medium Level		High Level	

^{24}Na*, ^{31}Si, ^{32}P, ^{35}S, ^{36}Cl, ^{42}K*, ^{47}Sc, ^{48}V*, ^{51}Cr*, ^{54}Mn*, ^{56}Mn*, ^{55}Fe, ^{59}Fe*, ^{64}Cu*, ^{65}Zn*, ^{72}Ga*, ^{76}As*, ^{86}Rb*, ^{89}Sr, ^{90}Y, ^{91}Y, ^{95}Zr*, ^{95}Nb*, ^{99}Mo*, ^{103}Ru*, ^{105}Rh*, ^{103}Pd, ^{105}Ag, ^{111}Ag, ^{109}Cd*, ^{113}Sn*, ^{127}Te*, ^{129m}Te*, ^{140}Ba*, ^{140}La*, ^{143}Pr, ^{147}Pm, ^{151}Sm, ^{166}Ho*, ^{170}Tm*, ^{177}Lu*, ^{183}Re*, ^{190}Ir*, ^{125}I, ^{192}Ir*, ^{191}Pt*, ^{193}Pt*, ^{196}Au*, ^{198}Au*, ^{199}Au*, ^{200}Tl*, ^{202}Tl*, ^{204}Tl, ^{203}Pb*, ^{220}Rn, ^{235}U,

GROUP 4. Low Hazard

10 Ci	100 Ci	1 mCi	10 mCi	100 mCi	1 Ci	10 Ci
Low Level				Medium Level		High Level

^{3}H, ^{7}Be*, ^{14}C, ^{18}F, ^{59}Ni, ^{69}Zn, ^{71}Ge, ^{238}U, Natural Thorium, Natural Uranium Noble Gases.

*Emits gamma radiation in significant amounts.

+Organic Materials.

APPENDIX #9

Contamination Levels in Controlled Area

Loose Contamination on surfaces:

Beta and Gamma Emitters	10^{-4} uCi/cm^2
Alpha Emitters	10^{-6} uCi/cm^2

In general, loose contamination is not acceptable and should be removed as soon as possible.

Fixed Contamination on Surfaces:

Radiation levels such that anyone present for a 40-hour work week will not receive an exposure in excess of 1/120th of the maximum permissible dose specified per calendar quarter in 10 CFR 20.101.

APPENDIX #10

Suggested Agents for Removal of Contamination

Contaminated Area	Decontaminating Agent	Remarks
Skin and Hands	Mild soap and water	Wash 2 to 3 minutes and monitor. Do not wash over 3 to 4 times.
	If necessary, follow by soft brush, heavy lather, and tepid water.	Use light pressure with heavy lather. Wash for 2 minutes, 3 times. Rinse and monitor. Use care not to scratch or erode skin. Apply lanolin or hand cream to prevent chapping.
	Other Procedures: A mixture of 50% Tide and 50% corn meal.	Make into a paste. Use with additional water with a mild scrubbing action. Use care not to scratch or erode the skin.
	A 5% water solution of a mixture of 30% Tide, 65% Calgon, and 5% Carbose (Carboxymethyl Cellulose).	Use with water. Rub for a minute and rinse.
	CHEMICAL PROCEDURES	(AS A LAST RESORT)
	Titanium Dioxide paste. Prepare paste by mixing precipitated titanium dioxide with a small amount of lanolin.	Work the paste into affected area for 2 minutes. Rinse and wash with soap, brush, and warm water. Monitor.
	Mix equal volumes of a saturated solution of potassium permanganate and 0.2 N sulfuric acid.	Pour over wet hands, rubbing the surface and using hand brush for not more than 2 minutes.

Contaminated Area	Decontaminating Agent	Remarks
Skin and Hands (continued)	Continue with the next step also. (Saturated solution $KMnO_4$ is 6.4 gms per 100 ml of water.) Apply a freshly prepared 5% solution of sodium acid sulfite ($NaHSO_3$).	(Note: Will remove a layer of skin if in contact with the skin for more than 2 minutes.) Rinse with water. Apply in the same manner as above. Apply for not more than 2 minutes. The above procedure may be repeated. Apply lanolin or hand cream when completed.
Hair	Liquid soap and rinse water.	Make repeated applications of liquid soap with water rinses, using towels to keep water from running onto the face and shoulders. Acid goggles can be used to protect the eyes. Thoroughly dry the hair before surveying. Apply lanolin or cream conditioner.
Wounds (cuts and breaks in the skin)	Running tap water. Report to Medical Officer and Radiation Safety Officer as soon as possible.	Wash the wound with large volumes of running water immediately (within 15 seconds). Spread the edges of wound to permit flushing action by the water.
Ingestion by swallowing.	Report to Medical Officer and Radiation Safety Officer as soon as possible.	Urine and fecal analysis will be necessary to determine amount of radionuclides in the body.
Clothing	Wash, if levels permit.	Use standard laundering procedures. Three percent versene or citric acid may be added to wash water. Wash water must be below the MPL for sewer disposal.

Contaminated Area	Decontaminating Agent	Remarks
Glassware	Soap or detergent and water. Chromic acid cleaning solution or conc. nitric acid.	Monitor wash water and plan disposal of it.
	Suggested Agents:	Elements Removed:
	Oxalic acid 5% (Caution-poison)	Zr, Nb, Hf.
	Versene (EDTA) 5% conc. NH_4OH 3%	Alkaline Earth Metals: Be, Mg, Ca, Sr, Ba, Ra, P as PO_4.
	To make, dissolve in order: (1) Versene (EDTA) 5% (2) Conc. NH_4OH, 3% by volume (3) Glacial acetic acid 5% by volume.	Trivalent metals, Al, Sc, Y, La, Ce, Pr, Nd, Pm, Sa, Eu. Rare Earths, Ac, Ga, In, Ti, B. Transition metals, Cu, Zn, Fe, Co, Ni, Cd, Sn, Hg, Pb, Th, U, Ag. (Always consider the radioactivity of the cleaning solution when disposing of it).
Laboratory Tools	Detergents and water, steam cleaning.	Use mechanical scrubbing action.
Metal Tools	Dilute nitric acid, 10% solution of sodium citrate or ammonium bifluoride.	As a last resort, use HCl on stainless steel.
	Metal polish, sand-blasting, other abrasives.	Such as brass polish on brass. Use caution as these procedures may spread contamination.
Plastic Items	Ammonium citrates, dilute acids, organic solvents.	

Contaminated Area	Decontaminating Agent	Remarks
Walls, Floors, Benches	Vacuum cleaning.	The exhause of the cleaner must be filtered to prevent escape of contamination with a pore size of 0.2 microns. Central vacuum systems shall not be used.
	Detergents and water with mechanical action.	
	Water from high pressure source. Steam cleaning.	This may spread contamination.
Specific Materials:		
Rubber	Washing or dilute HNO_3.	
Leather	Very difficult to decontaminate.	
Linoleum	CCl_4, kerosene, Ammonium citrate, dilute mineral acids.	
Ceramic Tile	Mineral acids, Ammonium citrate, trisodium phosphate.	Scrub hot 10% solution into surface and flush thoroughly with hot water.
Paint	CCl_4, 10% HCl	If this is not successful, any underlying concrete must be removed.
Wood	Hot citric acid, remove the wood with a plane or floor chippers and grinders.	
Traps and Drains	(1) Flush with water (2) Scour with rust remover. (3) Soak in a solution of citric acid. (4) Flush again.	Follow all four steps.

APPENDIX #11

Disposal of Liquid Waste to Sewage System

Liquid waste may be disposed via the sanitary sewer system at MCO provided that the following conditions are met:

1. Each Approved User of radionuclides must use only one sink for the disposal of liquid waste, unless an exception is given by the Radiation Safety Office.
2. Each sink must be identified as being a radioactive sink with the appropriate caution sign displayed.
3. The daily limits of radioactive material released must not be exceeded. These limits must be posted on each sink by the Radiation Safety Office.
4. All releases of radioactive material must be followed by flushing the sink with copious amounts of water.
5. The liquid waste must be readily soluble or dispersible in water.
6. Flammable solvents that are not miscible with water should not be flushed down the drain.
7. Radioactive material that can be conveniently decayed in storage must not be disposed via the sewer.
8. High concentrations of radioactive material that can be disposed of as liquid waste in the waste room should not be disposed of via the sewer system.

APPENDIX #12

Bioassay

The intent of bioassay is to monitor the radiation worker from the standpoint of possible INTERNAL exposure (as the film badge monitors possible EXTERNAL exposure). Inherently, however, bioassay is fraught with assumptions and unknowns and is relatively expensive. Therefore, it is unrealistic to use as a routine tool for those radiation workers using relatively low biohazard radionuclides.

For work with low levels of radiation, the control of possible internal radiation exposure is best accomplished by the education and enforcement of the standard laboratory rules.

There are occasions, however, when the quantity of radionuclides are such that, should an ingestion or inhalation occur, it is likely that the bioassay procedure would determine that internal dose with some degree of accuracy.

The first column in the following table is a "threshold" quantity of radionuclide which, if exceeded, mandates the use of the bioassay schedule as presented.

Other forms of bioassay (whole body counts) could become necessary should this examination be performed and some activity be found.

Quantity/Use Necessitating Bioassay	Type of Bioassay	Frequency of Exam
Single use of:		
1 Ci Tc-99m	Thyroid	Immediate
100 mCi Tl-201	Urine	Immediate
100 mCi S-35	Urine	Within 14 days
100 mCi P-32	Urine	Within 14 days
100 mCi Cr-51	Urine	Within 14 days
10 mCi I-125	Thyroid	Within 24-48 hours
1 mCi I-131 liquid	Thyroid	Within 18-30 hours
100 mCi Co-57	Urine	Within 14 days
100 mCi Hg-203	Urine	Within 14 days
100 mCi H-3	Urine	Within 14 days
100 mCi C-14	Urine	Within 14 days
Continuous use of:		
10 mCi H-3 organic	Urine	Weekly
10 mCi C-14 organic	Urine	Weekly
100 mCi H-3	Urine	Weekly
100 mCi C-14	Urine	Weekly

APPENDIX 13

GUIDELINES FOR THE HANDLING OF RADIOACTIVE CADAVERS

All uses of radiation are carried out under the direction of the Radiation Safety and Radioisotope Committee which has the administrative responsibility of insuring the safe use of ionizing radiation within the hospital. The radioactive patient who expires and presents a radiation safety problem is a rare one, since therapeutic quantities of radioactive materials are seldom administered and then not to the moribund patient. It is possible for a radiation safety problem to occur in this manner, however. In radiation safety, any reduction in personnel exposure that can be effected should be used, and to this end this policy is presented.

The following table lists all sources of use of ionizing radiation within the hospital and whether or not safety procedures are needed.

Sources of Ionizing Radiation Within the Hospital	In Case of Death Are Safety Procedures Needed?	
Diagnostic Sources		
X-Rays	No	
Nuclear Medicine Scans	No	
Therapeutic Sources		
External Beam Therapy	No	
Temporary Implant or Application of Sealed Sources That Do Not Decay Away and Must be Removed	No,	Once the Sources are Removed
Permanent Implant of Sealed Sources that Decay Away and Need Not be Removed	Yes	
Liquid or Capsule Dose(s) or Therapeutic Amounts of Radioactive Material	Yes	

General Procedures

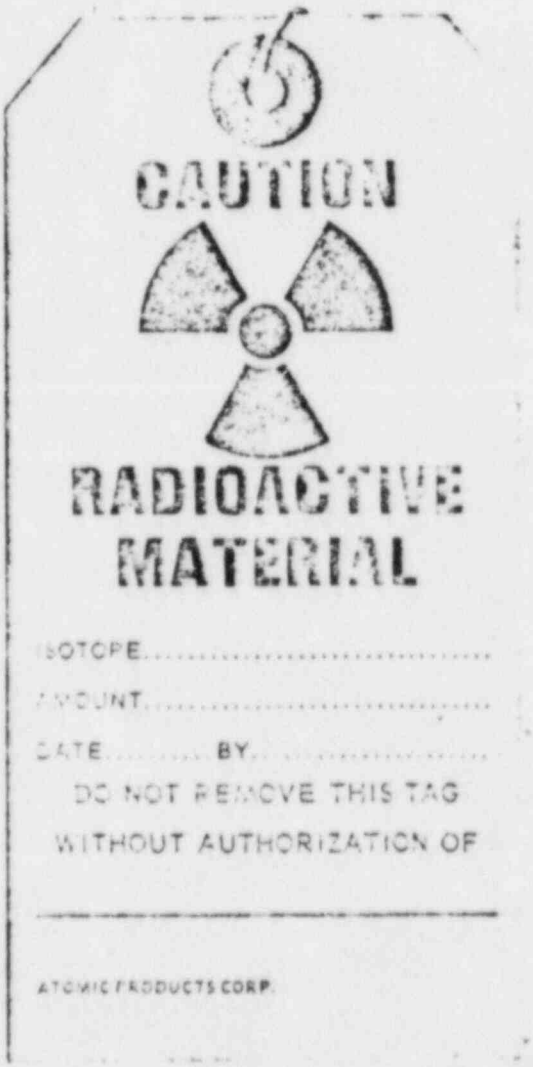
1. Patients who had received diagnostic quantities of radioactive material need no special procedures.
2. Patients who had received external beam therapy are not radioactive and no procedures are needed.
3. Patients who expire during a temporary intercavitary or interstitial implant present no safety problem once all the sources are removed! If during autopsy a small piece of metal is found, this may be a missing sealed source. Stand away from this source a minimum distance of ten feet. Call the Radiation Safety Officer.
4. Expired patients who had received either permanent implants or liquid or capsule doses of radioactive material do require special handling. The range of doses a patient might receive is large. The patient may have received a very small amount of radioactivity and the procedure may simply be to treat the expired patient in normal fashion. On the other hand, the dose and type of radiation may be such that the Radiation Safety Officer may have to monitor the pathologist during the entire procedure.
5. If a patient who is known to contain radioactive material dies outside of the hospital, the Radiation Safety Office should be contacted. Knowing the radionuclide present, the initial activity and chronology of application, specific instructions can be given to reduce personnel exposure during autopsy or preparation for burial or cremation.
6. The physician who pronounces the patient dead is responsible for notifying the Radiation Safety Office so that a radioactivity tag may be attached to the body (See Addendum #1). The physician in charge must also be notified at once.
7. If an autopsy is not performed, the Radiation Safety Office will fill out the radioactivity report to be attached to the death certificate and forwarded to the funeral director (See Addendum #2).
8. If an autopsy is to be performed, the Radiation Safety Office will provide specific instructions to reduce personnel exposure during autopsy (See Addenda #3 and #4).

9. Cremation of an expired radioactive patient cannot occur without the written permission of the Radiation Safety Office.
10. Nothing in these procedures is to be taken as the proper procedure to follow in the event of a death due to radiation accident at a radiation facility. In this case, the prevention of contamination is the overriding concern.

ADDENDUM #1

Radioactivity Tag

(To be filled out by the Radiation Safety Office
after being contacted by the physician
who pronounced the patient as dead.)



ADDENDUM #2

Specific Instructions to Reduce Radiation Exposure During Embalmment

Follow procedure A or B below during the embalming of _____.

A. This body does not contain significant amounts of radioactive material. No special precautions are necessary if standard embalming procedures are employed.

B. This body contains radioactive material. The following procedures should be observed:

A closed system should be used to drain fluids. Use suction if necessary. Fluid can be disposed of via sewer, flush with copious amounts of water.

Blood and urine should be removed via closed systems. Dispose via sewer with copious amounts of water.

Other_____

_____

_____

Signed _____
Radiation Safety Officer

Date: _____

A copy of this report is maintained in Radiation Safety Office files.

ADDENDUM #3

Radiation Hazard Evaluation Form

(To be filled out by Radiation Safety Officer for his use)

Name_____ Date and _____
Time _____
of Death

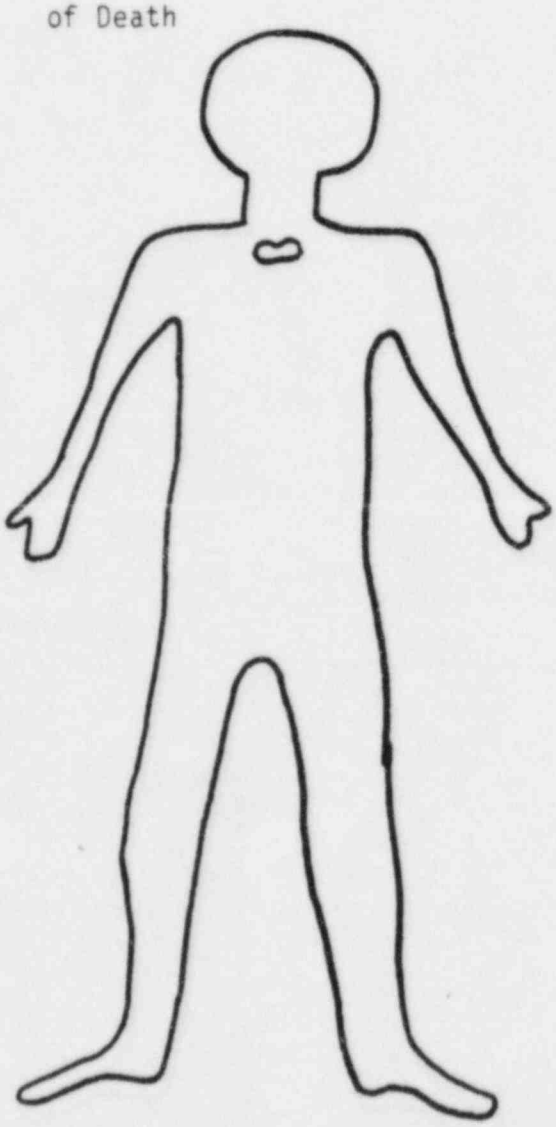
Radioisotope_____
Amount Administered_____
Route of Administration_____
Amount Present _____
Distribution
within Body _____

_____

_____

_____

Indicate Distances _____



Suggest ring badges if exposure
>0.25 R/hr @ 25 cm
See NCRP #37 p. 27.

Limit Hand Exposure to 1.5 Rems

Date of Survey_____
Instrument Used_____

Signed_____
Radiation Safety Officer
Date: _____

ADDENDUM #4

Specific Instructions for Autopsy

(To be filled out by Radiation Safety Officer)

The following procedures should be followed if so indicated:

- ☐ Wear Safety Glasses.
- ☐ Wear Plastic (non absorbant) Gown.
- ☐ Cover Floor with Bench Liner.
- ☐ Wear Double Thickness Autopsy Gloves.
- ☐ Wear Whole Body Film Badge.
- ☐ Wear Ring Badge.
- ☐ Remove the _____ area or tissue first before proceeding further. Identify it as radioactive.
- ☐ Leave the _____ area or tissue untouched until last.
- ☐ Cover the _____ area or tissue with shielding as provided.
- ☐ Use only long instruments--8" or greater.
- ☐ Fluids, Blood, Urine should be removed via closed system. Flush with copious amounts of water.
- ☐ Small specimens need--need not-- be handled with special precautions.
- ☐ Waste Container needs to be provided for contaminated sponges, gowns, and instruments.
- ☐ Organs are to be kept in storage for _____ days before processing for disposal.

Autopsy Performed by _____ Patient Name_____

Whole Body or Ring Badge No._____ Exposure _____

Signed _____
Radiation Safety Officer

Date: _____

THIS REPORT MUST BE FILED IN THE RADIATION SAFETY OFFICE

APPENDIX #14

Radiation Exposure to Individuals Less than Eighteen Years of Age

The exposure of individuals less than eighteen years of age must be limited in all instances to the applicable federal and state regulations. These regulations can be considered to be met if all of the guidelines below are followed.

1. Each Approved User is responsible for the immediate supervision of individuals less than eighteen years of age working in their laboratory.
2. Under no circumstances may such individuals work with radiation sources without approval of the Radiation Safety Office.
3. Individuals less than eighteen years of age must be denied access to laboratories or experiments or environments which could result in their receiving one-tenth of the maximum permissible dose for a radiation worker. See Table I.
4. Individuals less than eighteen years of age must be denied access to laboratories or areas or experiments which have a bioassay, film badge, or TLD immediate history greater than the Radiation Safety Office action levels. See Table I.
5. Individuals less than eighteen years of age must be instructed in basic laboratory safety rules as required by Medical College of Ohio regulations.
6. Individuals less than eighteen years of age must be provided with appropriate dosimeters as necessary to evaluate any possible exposure.
7. Individuals less than eighteen years of age must have explained to them the extent of any radiation hazards associated with the work intended.
8. The Radiation Safety Office must be notified of the intent on the part of the Approved User to permit individuals less than eighteen years of age to engage with radiation or radioactive materials under their supervision. Requests must be made prior to any actual work done by individuals less than eighteen years of age. The purpose of this request is to permit the Radiation

Safety Office to evaluate the conditions of intended work in light of the above guidelines and to grant approval for such individuals to work in a radiation laboratory.

ALL APPROVED USERS MUST RECEIVE APPROVAL FROM THE RADIATION SAFETY OFFICE PRIOR TO PERMITTING INDIVIDUALS LESS THAN EIGHTEEN YEARS OF AGE TO ENTER RADIATION AREAS.

TABLE I

Critical Organ	Max. Permissible Monthly Dose	Radiation Safety Office Action Level*
Whole Body**		
(External)	400 mRem	200 mRem
(Internal	400 mRem	20 mRem
Hands and Forearms		
Feet and Ankles	6250 mRem	3125 mRem
Thyroid	2500 mRem	750 mRem
Skin	1250 mRem	625 mRem
All other Organs	1250 mRem	625 mRem

* Radiation Safety Action Level is the dose which exceeded will necessitate an investigation.

** Whole Body includes any portion of major bone marrow, gonads, and lens of eye.

APPENDIX F

NON-ROUTINE MEDICAL USES OF BYPRODUCT MATERIAL

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

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

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

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

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

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

1. Title of study.

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

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

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

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

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

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

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

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

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

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

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

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

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

A. The expected half-life in various organs.

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

C. The rationale for using the dose selected.

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

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

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

B. Availability of clinical material.

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

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

13. Estimated time needed to complete the study.

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

FORM NRC 313M SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

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

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

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

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

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

FORM NRC-313M Supplement A
(8-78)

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

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

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

PRECEPTOR STATEMENT *(Continued)*

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

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

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

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

a. NAME OF SUPERVISOR

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

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

8. DATE

NRC FORM 313A SUPPLEMENT B
(8-79)

NOTE TO: License Fee Management Branch, ADM

FROM: Region III

SUBJECT: VOIDED APPLICATION

Control Number 378624

Applicant Med. Col. of Ohio

Date Voided 6/19/85

Reason for Void "-05" license was combined with "34-13011-04 license under Contol No. 316630.

Signature W. J. Olson (R5)

Attachment:
Application

OLPMD

ET 34 78624