August 31, 2007

To Whom It May Concern:

This manual was developed with the assistance of the Occupational Health and Safety staff, the Radioisotope & Radiation Safety Committee, and appropriate legal counsel and is published as the official policy of the University of Alabama at Birmingham for radiation studies and the activities surrounding those studies. Adherence to the procedures, practices, and recommendations described herein is essential if the University is to meet its obligation of providing a safe and healthful environment for study, training, and investigative pursuits.

Many of our research and educational activities utilize ionizing radiation. Their success very much depends on the thoughtfulness and care exercised by every individual involved with the program. The UAB Department of Occupational Health and Safety is hereby charged with the responsibility of ensuring that the University of Alabama at Birmingham is in compliance with the provisions stated in this manual and other appropriate state, county, and federal radiation control regulations. All faculty, staff, employees, and students engaged in work involving radioactive materials or radiation-producing devices are expected to be familiar with and comply with the policies presented in this manual.

Sincerely,

Carol Z. Garrison
President

University of Alabama at Birmingham
Radiation Safety Procedures Manual
Ninth Edition
2007

TABLE OF CONTENTS

I.	Introduction.....	5
II.	ALARA – A Management Concept.....	6
III.	Radioisotope & Radiation Safety Committee.....	7
IV.	Radioactive Drug Research Committee.....	11
V.	Subcommittee of Laboratory Use on Electronic Product Radiation.....	14
VI.	Radiation Safety Program.....	21
VII.	Responsibilities of Department Chairmen, Deans, and Administrators.....	27
VIII.	Responsibilities of Licensee.....	27
IX.	Responsibilities of Individual User.....	30
X.	Liability Aspects of Working with Radioactivity and Radiation Equipment.....	31
XI.	Instrument Calibration.....	32
XII.	Surveys of Radioisotope and Radiation Use.....	32
XIII.	Personnel Monitoring.....	36
XIV.	Storage of Radioactive Material.....	42
XV.	Posting and Labeling.....	42
XVI.	Procurement of Radioactive Materials.....	43
XVII.	Procedures for Working with Radioactive Material and Radiation Equipment.....	45
XVIII.	Use of Radionuclides in Experimental Animals.....	46
XIX.	Emergency Procedures.....	47
XX.	Transfer of Radioactive Material.....	49
XXI.	Disposal of Radioactive Material.....	50
XXII.	Sources of Concern.....	52

APPENDICES

A. UAB Radiation Safety Committees..... 53
B. Criteria for Approval of Human Use Studies in Radioactive Drug Research..... 55
C. Instructions for Operators of Particle Accelerators..... 57
D. Guide for External Radioisotope Monitoring..... 58
E. Guide for Internal Radiochemical Monitoring..... 61
F. Liquid Collection Technique to Minimize Spills and Contamination..... 77
G. Area Warning Signs, DOT Shipping Labels, and Radioactive Waste Tags..... 78
H. Radioactive Waste Management..... 79
1. Radioactive Waste Minimization, A Mandatory Program (Supplement A)..... 84
2. Methods Utilized by Licensee in A Radioactive Waste Minimization Program (Supplement B)... 85
I. Criteria for Approval of Radioisotope Licensure and Use..... 86
1. Nonhuman Use Criteria..... 86
2. Human Use Criteria..... 87
3. Responsibilities & Supervision (Supplement A)..... 89
4. Handling Techniques (Supplement B)..... 91
J. Criteria for Ventilation Design..... 93
1. Criteria for Radiochemical Culture Work in Class II Type A Biosafety Cabinets (Supplement A)..... 99
K. Radiation Dose Disclosure Form..... 101
L. Quarterly Report Form on Human Use Radioactive Drug Research..... 103
M. Schedule of Deminimus Levels of Radioactivity... 104
N. UAB Policy Regarding Radiation Exposure During Pregnancy 115
Pregnancy Precautions in Nuclear Medicine 119
Pregnant Worker's Guide 120
Instructors Guide 123
Effects of Risk Factors on Pregnancy Outcome..... 125
Pregnancy Instruction Statement..... 127
O. Radiation Safety Audit Schedule and Escalated Enforcement Actions..... 128
P. Procedures for Therapy Treatment With Unsealed Radiopharmaceuticals..... 131
Q. Procedures for Therapy Treatment With Sealed Radiopharmaceuticals..... 139
R. Radiation Safety Terms and Definitions..... 143
S. Accepted Half-lives Of Commonly Used Radioisotopes..... 150

I. Introduction

In a comparatively short period of time, the University of Alabama at Birmingham has gained recognition as a center of excellence for teaching, medical services, and research programs. This is a highly commendable achievement and one that could not have been realized without the continued support and dedication of faculty, staff members, and employees. Similar unfailing cooperation and support is necessary for the institution to be equally successful in its development of a comprehensive occupational health and safety program for protection of university personnel, students, and the community. An important part of this program is concerned with safety in research studies and safe disposal of laboratory wastes, including radioisotopes and radiotoxic chemicals.

The Department of Public Health for the State of Alabama has granted UAB a broad radioactive materials license and other licenses authorizing the use of radioactive materials. A radioactive materials license of broad scope is issued to institutions that perform a variety of tasks with many different radionuclides. Prior to receiving such a license, an institution must have previously demonstrated that it has the knowledge, resources, and capability for using these materials safely.

The UAB Radioisotope and Radiation Safety Committee (RRSC), which is composed of individuals knowledgeable in the various applications of radiation, administers the activities conducted under this license. This committee must approve in advance the manner in which all radioactive materials are licensed, purchased, stored, used, transferred, and disposed. At UAB, there is one other committee which has responsibilities in radiation protection as it applies to human use research with radioactive drugs. This is the Subcommittee for Human Use (SCHU). In addition, the staff of the Radiation Safety Program provides advice and assistance in solving radiological safety problems. It also has the responsibility for evaluating the use of radioisotopes and other radiation sources throughout the University. Any findings and recommendations are discussed with the principal investigator and reported to the appropriate committee.

This manual is part of the broad radioactive materials license granted UAB by the State of Alabama, and, as such, cannot be changed without the approval of the UAB RRSC and the Office of Radiation Control, Alabama Department of Public Health. Its purpose is to describe the operation of the radiation safety program and to provide guidance for the safe operation of facilities which use radiation in experimental research or in diagnostic or therapeutic studies. This manual also defines the proper procedures for procuring and using radioactive materials. These procedures are based on the Alabama Radiation Protection Rules and must be followed if we are to continue to use radiation in our work. Unless other provisions are approved in writing by the RRSC or the UAB Radiation Safety Officer or his designate, the procedures set forth in this manual must be followed by all personnel at UAB. A copy of this manual must be made available on-line for each radioactive materials licensee, x-ray registrant, particle accelerator registrant, and affected department heads. Personnel working with radioisotopes or devices producing radiation must also be able to access this manual on-line.

II. ALARA – A MANAGEMENT CONCEPT

The ALARA concept is one involving every individual working around radiation and essentially means that each person must strive to maintain radiation exposures as low as reasonably achievable. This is to reduce unnecessary exposure to themselves and others. Those persons authorized by the University of Alabama at Birmingham to make its policies and direct its activities have the responsibility of seeing that the ALARA concept is applied to employees, visitors, students, and patients not under the medical supervision for the administration of radiopharmaceuticals for therapeutic and diagnostic purposes. This responsibility will be carried out through:

A. Encouragement of all employees to participate in the establishment, implementation and operation of the ALARA program as required by Alabama Radiation Protection Rules or required by the UAB Radioisotope and Radiation Safety Committee.

B. Employee briefings and safety training in radiation work-related activities which include ALARA concepts.

C. Appropriate planning to ensure that any new facilities or equipment (or modifications of old facilities or equipment) which may affect radiation protection will be performed in consultation with the Radiation Safety Officer (RSO) or his designate.

D. Delegation of sufficient authority to the Radiation Safety Officer to enforce regulations and administrative policies regarding radiation safety.

E. Continuing management evaluation of the radiation safety program through appropriate management reviews of personnel requirements, budget requirements, and operational efforts to maintain exposures ALARA.

III. RADIOISOTOPE & RADIATION SAFETY COMMITTEE (RRSC)

A. Organizational Structure

The President of UAB appoints members to serve on the UAB Radioisotope & Radiation Safety Committee (RRSC). The committee must hold a formal meeting once every quarter, usually on a Thursday of each of the following months: January, April, July, and October. A quorum of the membership constitutes more than fifty percent of its members, and a quorum is required during each of its formal meetings. Membership on the RRSC includes, but is not limited to, representatives of the following units:

Medical Staff expert in nuclear medicine, internal medicine, hematology, therapeutic radiology, diagnostic radiology, and/or pathology, which uses or directly supervises the use of radioisotopes and radiation in humans;
Hospital Administration
Nursing Service
Occupational Health and Safety
Business Office
Medical School
Dental School
University College
The Kirklin Clinic
UAB Highlands

Committee members may have designated alternates to serve on the RRSC and vote on action items in their absence.

The members of the committee can be found in APPENDIX A. A current list of committee members must be maintained and provided on request to all licensees, x-ray registrants, particle accelerator registrants, and affected department heads.

B. Responsibilities

The RRSC's main responsibility, through the Radiation Safety Officer or his designate, is to ensure that all individuals who work with or in the vicinity of radioactive material or radiation equipment have sufficient training and experience to enable them to perform their duties safely. In discharging this responsibility, the RRSC must ascertain that the work is performed in accordance with the following:

Alabama Radiation Control Rules (ARCR);
Jefferson County Regulations to Govern the Production and Use of X-ray Radiation;
UAB Broad Radioactive Materials License, the conditions noted therein and the UAB Radiation Safety Procedures Manual, which is also a part of the license as well as any other representations made therein;
Any radioactive material licenses issued to investigators by the Radiation Safety Program under the Broad Radioactive Materials License; conditions of any of these licenses; and representations made in the applications for these licenses;
Other pertinent radioactive materials licenses issued to UAB;
x-ray registrations, and particle accelerator registrations issued to UAB; conditions of any of these registrations; statements or representations made in the applications for registrations to use ionizing radiation-producing equipment.

The RRSC is also responsible for assuring that the receipt, possession, storage, use, transfer, and disposal of radioactive materials and radiation equipment are conducted in a safe manner.

III. RADIOISOTOPE & RADIATION SAFETY COMMITTEE (RRSC) (Continued)

C. Duties

The RRSC shall:

1. Enforce, at the University level, the radiation safety practices outlined in the UAB Radiation Safety Procedures Manual, the Alabama Radiation Control Rules, the Jefferson County Regulations to Govern the Production and Use of X-ray Radiation, the radioactive material licenses and radiation equipment registrations issued to UAB and the radioactive materials licenses issued to individuals working at UAB by the Radioisotope & Radiation Safety Committee (RRSC). All committee members will be encouraged to be familiar with those regulations governing the use of radioactive materials, sources, and devices.

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

3. Review the entire radiation safety program, at least on an annual basis, to determine that all activities utilizing radioisotopes are being conducted safely and in accordance with the ALARA (As Low As Reasonably Achievable) principle when considering radiation exposure.

4. Coordinate radiological safety matters with the UAB Biosafety Committee, the UAB Chemical Safety Committee, the UAB General Liability Committee, the UAB Investigational Review Board For Human Use, the UAB Subcommittee for Human Use, the UAB Institutional Animal Care and Use Committee, and the UAB Hospital Safety Committee.

5. Develop (and modify when necessary) criteria to evaluate the qualifications of all individuals applying for a license to use radioactive materials at UAB.

6. Review and maintain the standards for training and experience of individuals who use radioactive materials (including physicians, technologists, technicians, physicists, chemists, biologists, etc.).

7. Maintain a training program dedicated to teaching the fundamentals of radiation safety to all individuals actually involved in the use of radioactive materials and radiation equipment.

8. Establish and provide as part of the radiation safety training program refresher courses in radiation safety training and require the periodic attendance to these refresher courses by all radioactive materials licensees and their staff at an interval not to exceed five years, as established by the RRSC, or viewing equivalent on-line courses when these courses become available.

9. Establish a training program to ensure that all individuals whose duties require work near radioactive materials or radiation equipment (e.g., technicians, nurses, security personnel, maintenance personnel, and environmental services' personnel) are properly instructed as required by regulation.

<u>Non-Human Use</u>

The Subcommittee for Laboratory Use acts in an advisory capacity to the Radiation Safety Officer concerning licensure of proposals for non-human use and the radiation safety procedures specified in these proposals. These procedures may involve non-ionizing radiation (i.e., laser radiation, microwave, etc.) as well as ionizing radiation. The members of this Subcommittee may be called upon by the RSO from time to time for guidance concerning various aspects of a proposed study. Such studies must be completely described to subcommittee members and their responses documented. All information relating to the proposed study will be forwarded to members at their request.

Human Use

The Subcommittee for Human Use (SCHU) reviews and approves applicants for routine diagnostic and therapeutic human use (according to the new drug applications (NDAs) approved by the U.S. Food and Drug Administration). It also approves applications for uses of a new drug application (NDA approved) not specified on the package insert labeling or conducted under investigational new drug (IND) exemptions (to be filed with the FDA for final approval). In addition, it reviews proposals involving medical devices within which radioactive materials are used either as approved medical devices or those with premarket approval (with both FDA and NRC approval) or even investigational devices (IDs) with an investigational device exemption (IDE) – also having NRC or Agreement State approval. These proposals and any other proposals requiring approval by the Institutional Review Board for Human Use (IRBHU) require the following information to be submitted to the RSO:

Human Subjects Protocol and any changes thereto,
Information Naming the Radiopharmaceutical or the Radioisotope,
Name of the Routine or Investigational Study,
UAB Radioactive Materials Licensee(s) Performing or Participating in the Study
Patient Consent Form

A radioactive materials licensee for medical use may be approved to use radiopharmaceuticals by drug use categories (specified in Part 420-3-26-.07 of the Alabama Radiation Control Rules (ARCR) entitled "Use of Radionuclides in the Healing Arts," by the State of Alabama). Sufficient training and experience to meet regulatory requirements is a prerequisite for any approvals. A preceptor's statement to support training and experience must be submitted to the RSO along with the initial application for human use licensure if the training and experience information has not been previously submitted to the RSO. See Part 420-3-26-.07 of the ARCR regarding training and experience criteria. See APPENDIX I, as it pertains to human use in basic radioactive drug research.

As new NDA approved drugs are added to the drug use categories by the FDA, they are automatically approved for use under the license or group license for which the drug use category is authorized. A licensee’s possession of radiopharmaceuticals is limited to those authorized by the license. Diagnostic radiopharmaceuticals may be ordered by the licensee and kept in quantities needed for diagnostic use. All diagnostic radiopharmaceuticals may be received directly from the shipper by the UAB licensee. Therapeutic radiopharmaceuticals are limited to the maximum possession limits authorized by the radioactive materials license. Sealed diagnostic or therapeutic sources require specific approval by the SCHU and the conditional authority given in the broad medical license. Information concerning the manufacturer, model number, and activity of each sealed source and the maximum activity in a medical device must be submitted along with the application for medical device use. Sealed radionuclides (except Ir-192 ribbons) and unsealed quantities of therapeutic quantities of radioiodine should be received by the Hazardous Materials Facility (HMF); however, when timeliness of receipt is a prerequisite to enable proper patient care and provided that proper surveys are made upon the transfer of such shipments (and their associated transport containers), these may be received directly by UAB licensees. Orders may be placed by the licensee for therapeutic radionuclides provided that the licensee is licensed for these and notification is given to the Radiation Safety Program concerning each order. The RSP must check the specifications of ordered sealed and unsealed radiopharmaceuticals and/or radioisotopes for proper licensure. Orders must not be made until proper licensure has been established or approval for the order is given by the Radiation Safety Officer or his designate.

Human Use (Continued)

Only authorized physician users are allowed to prescribe the type of radiopharmaceutical/radioisotope to be used in a study, to prescribe the amount to be used, and to interpret the clinical results. See APPENDIX I, Supplement A for more information regarding the responsibilities of the licensed nuclear medicine physician and the supervision required for nuclear medicine studies. Misadministrations are defined in APPENDIX R of this manual and must be reported to the RSO or his designate. Reports of all misadministrations of radiopharmaceuticals must be forwarded to the RSP to be reported to the State of Alabama, as required by regulation. Licensees or authorized physician users utilizing NDA approved radiopharmaceuticals should follow the guidelines of the FDA and the package insert instructions of the labeled drug regarding dosage and use. For uses other than those specified in the labeling or other than those recently approved by the FDA, the dose and use should be as approved by the SCHU.

If an individual wishes to use radiopharmaceuticals at locations other than those authorized under a group license, the use and location must first be approved by the Radiation Safety Officer and the Chairman of the RRSC before an individual license is issued. All changes in personnel must be submitted to the Radiation Safety Program for approval by the RSO and the Chairman of the RRSC. Written quality assurance and radiation safety procedures for use in the licensee's work area must be approved by the RSO or his designate and maintained in the licensee's work area. Any changes in these procedures must have the prior approval of the RSO or his designate and must be submitted in written form within thirty days of the proposed change.

D. Issue and Revocation of Radioactive Materials License

New radioactive materials licenses are issued on a temporary basis for the first full year of active use of radioactive materials. Upon approval by the Radiation Safety Program, as demonstrated through a program of compliance with radiation safety requirements, a license of a more permanent nature will be issued, usually for five years. The RRSC may revoke a license (or user authorization by a license) for just cause, e.g., whenever individuals refuse to abide by the procedures and regulations or whenever individuals habitually create radiation hazards. An individual who has had a license revoked by the committee may not use radioisotopes even under the direction of a licensee for a period of twelve months. Following the twelve-month period, the individual may reapply for authorization to use radioactive materials and is then required to take the radiation safety training course given by the RSP.

E. Review and Approval of Special Studies Utilizing Radiation Equipment

The Subcommittee for Laboratory Use and/or the Subcommittee for Human Use may, upon the request of the RSO, review any special studies involving the use of ionizing radiation equipment. A joint session of the two subcommittees might be necessary when human use is involved. Any recommendations and/or decisions reached by either or both of these two committees are documented and reported at the next regularly scheduled meeting of the RRSC.

F. Review and Approval of Studies Involving Basic Metabolic Research with Radiopharmaceuticals in Humans

The Radioactive Drug Research Committee is an ad hoc UAB committee to the RRSC and reviews only those aspects of radiation safety dealing with the use of radiopharmaceutical drugs for research in humans involving basic metabolic studies. **The Radioactive Drug Research Committee is currently inactive, but can be reactivated by applying to the United States Food and Drug Administration (FDA) when needed.** It is not involved with IND studies nor with any studies involving monoclonal antibodies. Information regarding approval of research must be submitted quarterly to the RSP on questionnaires provided for this purpose.

III. RADIOISOTOPE & RADIATION SAFETY COMMITTEE (RRSC) (Continued)

Human Use (Continued)

F. Review and Approval of Studies Involving Basic Metabolic Research with Radiopharmaceuticals in Humans *cont.*

This committee meets quarterly and reviews applications involving this type of research. The Committee's decisions on these applications, along with the conditions for such approval, are accepted by the RRSC for licensure of the individual, since its membership is composed of the members of the SCHU. In addition to the application forms required by the RDRC, the following forms or reports required by the Institutional Review Board for Human Use (IRBHU) must also be sent to the RDRC:

Report of the Project Review Panel
Human Subjects Protocol
Patient Consent Form
any questionnaires or materials supplied to research subjects

Before radiopharmaceuticals may be used for research approved by the RDRC, final approval must be received from the IRBHU. Also, projects extending one year beyond the date of approval requires renewal approvals from the IRBHU. Copies of approvals and renewal approvals, if any, must be sent to the RSP. Projects failing to have renewal approvals must be discontinued until such approvals are obtained.

IV. RADIOACTIVE DRUG RESEARCH COMMITTEE

A. Organizational Structure

The Radioactive Drug Research Committee is currently inactive, but can be reactivated by applying to the United States Food and Drug Administration (FDA) when needed. The President of UAB appoints at least five persons to serve on the UAB Radioactive Drug Research Committee. The committee must hold a formal meeting as often as required but not less than once each quarter in which research activity has been authorized or conducted. A quorum consisting of more than half of the members must be present with appropriate representation of the required fields of specialization. The committee shall include the following specialties:

a physician recognized as a specialist in nuclear medicine;
a person qualified by training and experience to formulate radioactive drugs; and
a person with special competence in radiation safety and radiation dosimetry

The remainder of the committee shall consist of individuals qualified in various disciplines pertinent to the field of nuclear medicine (e.g., radiology, internal medicine, clinical pathology, hematology, endocrinology, radiation therapy, radiation physics, and radiopharmacy). The membership should be sufficiently diverse to permit expert review of the technical and scientific aspects of proposals submitted to the committee.

B. Responsibilities

1. Select a Chairman who shall sign all applications, minutes, and reports of the committee.

2. Keep minutes of the meeting and include the numerical results of votes on research protocols involving radioactive materials use in human subjects.

3. Require that members not be allowed to vote on research protocols with which they are involved.

IV. RADIOACTIVE DRUG RESEARCH COMMITTEE (Continued)

B. Responsibilities (Continued)

4. Submit an annual report on or before January 31 of each year to the Food and Drug Administration, Bureau of Drugs, HFD-150, 5600 Fishers Lane, Rockville, MD 20857. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, and for each study conducted during the preceding year, a summary of the information requested in Form 2915.

5. Immediately submit to the Food and Drug Administration a special summary of information, in the same format as the annual report, at any time a proposal is approved which involves radiation exposure of either of the following:

   a. more than 30 research subjects, or of
   b. any research subject under 18 years of age.

6. Provide for public disclosure of the contents of reports submitted to the FDA, unless confidentiality is requested by the investigator because the report constitutes a trade secret or confidential commercial information.

7. Submit changes in membership and applications for new members to the FDA as soon as, or before, vacancies occur on the committee.

8. Require that the responsible investigator be licensed to possess and use the specific radionuclides for research use.

9. Ensure that each investigator is qualified by training and experience to conduct the proposed research studies.

10. Require that the investigator utilize adequate and appropriate instrumentation for both the detection and the measurement of the specific radionuclides.

11. Ensure that the radioactive drug chosen for the study is evaluated as regards half-life, types of radiation, radiation energy, metabolism, chemical properties, etc., to ensure that those exposed receive the lowest dose to the whole body or specific organs necessary to conduct the study. The radiation dose must be limited according to the criteria specified in APPENDIX B.

12. Require that the investigator provide an acceptable method of radioassay of the radioactive drug prior to its use to ensure that the dose calculations actually reflect the administered dose.

13. Require that the investigator provide absorbed dose calculations based on biologic distribution data available from published literature or from other valid studies.

14. Require that the investigator provide pharmacological dose calculations based on data available from published literature or from other valid human studies.

B. Responsibilities (Continued)

15. Determine that the amount of active ingredients to be administered is known not to cause any clinically detectable pharmacological effect in human beings. If the same active ingredients (exclusive of the radionuclide) are to be administered simultaneously, e.g., under a "Notice of Claimed Investigation Exemption for a New Drug" or for a therapeutic use in accordance with labeling for a drug approved under Part 314, Chapter I, Title 21, Code of Federal Regulations, the total amount of active ingredients, including the radionuclide, shall be known not to exceed the dose limitations applicable to the separate administration of the active ingredients excluding the radionuclide.

16. Determine that radioactive materials for parental use are prepared in sterile and pyrogen-free form. Furthermore, any radioactive drug used in the research study shall meet appropriate chemical, pharmaceutical, radiochemical, and radionuclide standards of identity, strength, quality, and purity as needed for safety and be of such uniform and reproducible quality as to give significance to the research study conducted.

17. Immediately report to the FDA all adverse reactions probably attributable to the use of the radioactive drug in the research study. The word "drug" in this context means the entire formulation of the preparation being given to the subject.

C. Review and Approval of Research Studies on Human Subjects

No matter how small the amount of radioactivity, studies involving administration of a radioactive drug to research subjects shall not be permitted unless the Radioactive Drug Research Committee concludes that scientific knowledge and benefit is likely to result from the study. Studies involving subjects less than eighteen (18) years of age shall be supported with review by qualified pediatric consultants to the RDRC. The investigator must also obtain the review and approval of UAB's Institutional Review Board for Human Use before a study is initiated.

The research protocol must:

1. Be based upon a rationale derived from appropriate animal studies or published literature and be of sound design such that information of scientific value may result.

2. Show that the radiation dose is both sufficient and no greater than necessary to obtain a valid measurement.

3. Show that the projected number of subjects reflects that the study is intended to obtain basic research information and is not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).

4. Show that the pharmacological dose is within the limits known not to cause any clinical pharmacological effects in human beings.

5. Show that the radiation is within the limits set forth in APPENDIX B, Section I.

6. Show that the selection and consent of human subjects is consistent with the criteria given in APPENDIX B, Section II.

7. Show that the radiation exposure is justified by the quality of the study being undertaken and the importance of the information it seeks to obtain.

C. Review and Approval of Research Studies on Human Subjects (Continued)

8. Show that the requirements regarding the qualifications of the investigator, proper licensure for handling radioactive materials, selection and consent of research subjects, quality of radioactive drugs, research and protocol design, reporting of adverse reactions, and approval by the Review Board for Human Use have been met.

The investigator must:

1. Immediately report to the Radioactive Drug Research Committee all adverse effects associated with the use of the radioactive drug in the research study.

2. Report quarterly the activity of the approved research project to the Radioactive Drug Research Committee. Form RD (See APPENDIX L) must be completed and sent to the RSP no later than two weeks following each calendar quarter. Reports of inactivity of research studies that are not formally terminated must also be submitted. Reports of inactivity of studies that have not been initiated need not be filed with the RDRC quarterly.

3. Report annually the results of the approved research project to the Radioactive Drug Research Committee, which must forward the report to the FDA. Form FD 2915 (available on the FDA website at this address: http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2915.DOC) must be completed and sent to the RSP no later than two weeks after December 31 of each calendar year. Reports of inactivity of non-terminated or uninitiated research studies must also be submitted.

4. Immediately report to the Radioactive Drug Research Committee as soon as it is known that the project involves more than 30 research subjects or involves a research subject under 18 years of age. In either case, the investigator is required to immediately submit a special summary report to the FDA.

V. SUBCOMMITTEE FOR LABORATORY USE INVOLVING ELECTRONIC PRODUCT RADIATION

A. Responsibilities:

1. Advise the Radioisotope & Radiation Safety Committee on matters concerning the safety of electronic product radiation.

2. Review studies involving radiation equipment which pose a significant radiation safety hazard and forward written recommendations to the RRSC.

3. Formulate safety procedures that conform with the recommendations of Title 21, Chapter J, entitled "Radiological Health," of the Code of Federal Regulations, with the Jefferson County Regulations "To Govern the Production and Use of Radiation", with the Alabama Radiation Control Rules (involving particle accelerator equipment registration and use), and with the UAB Radiation Safety Manual.

4. Seek outside consultation as necessary in formulating safety procedures for electronic product radiation.

B. Review of Studies and Use of Electronic Product Radiation

Particle Accelerators

In reviewing applications for the use of a particle accelerator, the Radiation Safety Officer must give consideration to the following:

1. The applicant is qualified by reason of training and experience to safely use the particle acce1erator and any associated radioactive material,

2. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to the health and well-being of UAB personnel and of the public,

3. The application by the Radiation Safety Officer to the State of Alabama for a notice of registration must not be harmful to the health and well-being of UAB personnel and of the public,

4. The applicant has supplied all information requested by the Radiation Safety Officer in order to receive approval by the State Health Department for the issuance of a Notice of Registration,

5. Each installation shall be provided with such primary protective barriers and/or secondary protective barriers as are necessary to ensure compliance with ARCR. All protective barriers shall be fixed except for entrance doors or beam interceptors.

6. The applicant has established written operating and emergency procedures.

Approval, Training and Experience

7. In applying for human use of a particle accelerator in the practice of medicine, the registration will be issued only if:

   a. The applicant has access to adequate facilities for the clinical care of patients,

   b. Each physician designated on the application as an individual user has the prerequisite training and experience delineated in Section 420-3-26-.07(75) of the State of Alabama regulations dated December 18, 1996.

   c. The applicant has designated a teletherapy physicist on the application who has the training and experience delineated in 420-3-26-.07(76) of the State of Alabama regulations dated December 18, 1996.

   d. The teletherapy physicists must be certified in therapeutic radiological physics, or in Roentgen ray and gamma ray physics, or x-ray and radium physics; or in radiological physics; or hold a master’s or doctor’s degree in physics, biophysics, radiological physics, or health physics from an accredited program, and have completed 1 year of full time training in therapeutic radiological physics and also 1 year of full time work experience under the supervision of a teletherapy physicist at an authorized medical use licensee of the State of Alabama, U.S. Nuclear Regulatory Commission or an Agreement State. To meet this requirement, the individual shall have performed Full Calibration Measurements, Periodic Spot-Checks, Radiation Surveys for Teletherapy Facilities, and the Requirements for Possession of Sealed Sources and Brachytherapy sources, all under the supervision of a teletherapy physicist during the year of work experience and in accordance with the ARCR.

B. Review of Studies and Use of Electronic Product Radiation (Continued)

Particle Accelerators (Continued)

8. An applicant involved in research and development must also meet the following conditions:

   a. Have substantial experience in the use of particle accelerators for a variety of research and development uses.

   b. Have an adequate training program for particle accelerator operators consisting of:

      i. initial training in the subjects outlined in APPENDIX C;
      ii. periodic training;
      iii. on-the-job training; and,
      iv. means to be used by the applicant to determine the operator's knowledge and understanding of and ability to comply with, or use, the Alabama Regulations for Control of Radiation, the applicant's operating and emergency procedures, survey instruments as required by the UAB Radiation Safety Manual, and personnel monitoring equipment.

   c. Have an adequate training program for staff personnel other than particle accelerator operators.

   d. Provide for monitoring radiation levels in the particle accelerator room prior to room entry following equipment operation.

   e. Maintain logs of particle accelerator use.

   f. Request the approval for intended particle accelerator operators. This would include all personnel using the machine and also any physicians or physicists involved in the calibration of particle accelerator equipment or human use.

Personnel Monitoring

9. The applicant must ensure that all particle accelerator operators are monitored externally for radiation exposure and radiation dose. Personnel monitoring devices used shall be calibrated for the appropriate radiations and energies of radiation produced by the particle accelerator and shall be used by each individual who receives, or is likely to receive, a whole body dose in excess of 10 millirems per week and each individual who enters a high radiation area.

Controls and Safety Devices

10. Only the particle accelerator operator at the control panel located outside the shielded room shall be capable of turning on particle accelerator beams that are capable of producing exposure rates in excess of two (2) millirems per hour.

11. All entrances into a target room, treatment room, or other high radiation areas shall be provided with safety interlocks that shut down the machine under conditions of barrier penetration.

12. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

B. Review of Studies and Use of Electronic Product Radiation (Continued)

Controls and Safety Devices (Continued)

13. Whenever any safety interlock is interrupted, broken, or tripped, either the particle accelerator will shut off automatically or the radiation level within the room will be reduced to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any accessible portion of the particle accelerator system.

14. Interlocks shall not be used to routinely shut off the particle accelerator.

15. An emergency cut-off switch shall be located in all high radiation areas. This switch shall be readily identifiable. This switch shall be capable of automatically causing the particle accelerator to either shut off or reduce the radiation level to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any accessible portion of the particle accelerator system. Such a cut-off switch shall include a manual reset at each such switch which must be reset at the switch before the particle accelerator may be restarted by the operator at the control panel. Radiation levels produced by radioactive materials shall not be considered as the radiation levels to be reduced.

16. All locations designated as high radiation areas shall be equipped with easily observable flashing or rotating warnings lights and/or audible warning devices that operate when, and only when, radiation is being produced. Each entrance to such area shall have a visual warning device, which need not be flashing or rotating, that operates when and only when radiation is being produced.

17. Each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of a high radiation area. Such a warning device shall be clearly discernible in all high radiation areas.

18. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with the ARCR.

19. Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

20. The particle accelerator control panel shall be provided with a locking device to prevent unauthorized use. Such a locking device shall, when locked, make the particle accelerator incapable of producing any area in which the radiation exposure is in excess of two (2) millirems per hour.

21. There shall be available at each facility, appropriate portable radiation monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced by the facility. Such equipment shall be tested for proper operation daily and calibrated for the appropriate radiations at the correct interval and after each instrument servicing and repair.

22. There shall be present at the control panel a device which shall give a continuous indication of the radiation levels being produced in the target area or areas.

23. Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and on file at each accelerator facility.

B. Review of Studies and Use of Electronic Product Radiation (Continued)

Operation

24. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

25. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency, or to test interlocks.

26. Interlocks may be prevented from operating only to test, adjust, maintain, and/or rearrange equipment, provided a clear indication of such condition is made at the control panel. This subparagraph does not authorize the operation of a particle accelerator with the high radiation area warning devices incapable of proper operation.

B. Review of Studies and Use of Electronic Product Radiation

Particle Accelerators (Continued)

Operation (Continued)

27. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

    (i) authorized in writing by the RRSC or the Radiation Safety Officer;
    (ii) recorded in a permanent log and a notice posted at the accelerator control console; and
    (iii) terminated as soon as possible.

28. No individual shall be permitted to enter an area, the access to which is controlled by interlocks, while such interlocks are prevented from operation, to test, adjust, maintain, and/or rearrange equipment and/or parts of the particle accelerator unless such individual is utilizing appropriate personnel monitoring equipment which will give an audible indication when a dose-rate of 25 millirads per hour is exceeded. The personnel monitoring equipment referred to in this paragraph is in addition to that required elsewhere in these rules.

Operating and Emergency Procedures

29. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel. These operating and emergency procedures shall include instructions in at least the following:
    (a) The use of particle accelerators such that no person is likely to be exposed to radiation doses in excess of the limits established by the ARCR;
    (b) Methods and occasions for conducting radiation surveys;
    (c) Methods for controlling access to high radiation areas;
    (d) Methods and occasions for locking the control panel of the particle accelerators;
    (e) Personnel monitoring and the use of personnel monitoring equipment;
    (f) Minimizing exposure of persons in the event of an accident;
    (g) The procedures for notifying proper persons in the event of an accident; and
    (h) Maintenance of records.

Tests and Surveys

30. The applicant must ensure that all safety and warning devices, including interlocks, are checked for operation at intervals not to exceed 3 months.

31. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the State of Alabama, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

32. Any interlock which has been bypassed or otherwise prevented from operation shall be tested to determine that it is functioning properly immediately upon its return to normal use.

33. Records of the three tests above shall be maintained for inspection by the State of Alabama.

34. A survey shall be made of each radiation area upon the initial entry by personnel into these areas following the operation of the particle accelerator. A record is not required for the survey required here. Users of particle accelerators for treatment of humans are not required to perform the surveys here, provided all interlocks and warning lights are operational and functional.

V. SUBCOMMITTEE FOR LABORATORY USE INVOLVING ELECTRONIC PRODUCT RADIATION *cont.*

B. Review of Studies and Use of Electronic Product Radiation

Tests and Surveys (Continued)

35. Provide for the posting of emergency procedures and high radiation area warning signs at entrances of the particle accelerator rooms.

36. Provide for the particle accelerator control panel to have a locking device to prevent unauthorized use, and maintain control of keys to the locking device.

37. Provide for the keeping of up-to-date electrical circuit diagrams of the accelerator and the associated interlock systems on file near the control panel.

38. Provide written operating and emergency procedures that will meet the requirements of the ARCR. These procedures must include instructions in at least the following:

    a. the safe use of the particle accelerator;
    b. methods and occasions for conducting radiation surveys;
    c. methods for controlling access to high radiation areas;
    d. methods and occasions for locking the control panel of the particle accelerator;
    e. personnel monitoring and use of personnel monitoring equipment;
    f. minimizing exposure in the event of an accident;
    g. procedures for notifying proper persons in the event of an accident; and
    h. maintenance of records.

39. Provide operators of particle accelerators with a copy of the operating and emergency procedures at the control panel.

40. Provide for the clear indication of when safety interlocks are bypassed. <u>High radiation warning devices must not be bypassed!</u>

41. The applicant must not permit any person to act as an operator of a particle accelerator unless that person has been instructed in the subjects outlined in APPENDIX C and shall have demonstrated an understanding of this instruction. This person must also have demonstrated competence in the use of the particle accelerator, related equipment, and appropriate survey instruments.

VI. RADIATION SAFETY PROGRAM

The Radiation Safety Program (RSP) is directed by a Radiation Safety Officer who shall have the training and experience delineated in Section 420-3-26-.07(26) of the ARCR. The Radiation Safety Officer is responsible to the President of UAB and acts as a liaison between the users of ionizing radiation and the Radioisotope & Radiation Safety Committee and the Subcommittee for Human Use. He also keeps these and other committees informed of matters affecting or involving the use of ionizing radiation at UAB.

All Radiation Safety Program health physics personnel must be knowledgeable in handling alpha, beta, gamma, and neutron emitters. They must be familiar with the instruments used in the detection of various types of radiation, with radiological safety principles, and with the applicable regulations.

The primary responsibility of the personnel in the RSP is to advise and assist University personnel in matters concerning the use of ionizing radiation and radiation safety. Problems concerning the safe use of radiation are generally dealt with by the RSO or his designate in the following order until satisfactory corrections have been made: the individual, the licensee, the appropriate committee, then the appropriate Dean or Administrator. The Radiation Safety Officer or any of the Radiation Safety Program health physics personnel may stop any work that in their opinion may be a radiological hazard.

If the above corrective procedure does not resolve the problem or if the problem requires immediate corrective action, the Radiation Safety Officer may go directly to the President of UAB. Normally the Radiation Safety Officer will get the necessary support for corrective actions through channels within UAB Administration. Once an unsafe activity has been stopped, further work with radioisotopes by the person or persons involved may not continue without the approval of the Radiation Safety Officer and the Chairman of the RRSC. The work will be allowed to continue only if sufficient evidence is given to demonstrate that corrective measures have been instituted and are adequate to protect the safety of UAB personnel.

A. The functions of the Radiation Safety Officer or his designate are as follows:

1. Perform a licensing review of all applications for the use of radioactive materials and ascertain that applicants have adequate facilities and equipment for storing and using radioactive materials and adequate training and experience for themselves and for personnel using radioactive materials under their supervision. Applications are reviewed in accordance with the criteria established by the RRSC, as contained in APPENDICES I and J.

2. Review and approve applications for all nonhuman use of radioactive materials after determining the radiation safety of the proposal. Review and approve applications for radiopharmaceutical NDA or IND diagnostic studies or routine therapy studies enumerated in the NRC, Agreement State or Alabama Radiation Control Regulations. Register users of particle accelerators for human use provided they are also board certified by a group recognized by the State of Alabama.

3. Applications for human use by physician users of radiopharmaceuticals, or for human use of particle accelerators by physician users who are not board certified by a recognized group, require the approval of a majority of the members of the Subcommittee for Human Use.

4. Forward applications for non-routine human studies to the Subcommittee for Human Use with recommendations of any restrictions, if any, which should be placed on any approval or disapproval. Applications for non-routine human use involving basic metabolic research are forwarded to the Radioactive Drug Research Committee (RDRC) in a similar fashion, except for those studies covered by another RDRC outside of UAB reporting to the FDA, which are forwarded instead to the Subcommittee for Human Use.

A. The functions of the Radiation Safety Officer (or his designate) are as follows: (Continued)

5. Review the physical form, chemical form, and amounts of radiochemicals intended for use and storage. Ensure that radiation doses from the various types of radiations are considered safe and meet ALARA concepts. Check sealed sources against the approved specifications referenced in sealed source catalogs possessed and otherwise available from NRC or Agreement State Licensing Sections.

6. Prescribe necessary radiation safety restrictions and quality control/quality assurance procedures as conditions to be incorporated in human use radioactive materials licenses.

7. Prescribe special conditions that are required during a proposed use of radioactive material, such as requirements for bioassays, physical examination of users, and special monitoring procedures.

8. Issue, with the concurrence of the Chairman of the Radioisotope and Radiation Safety Committee, licenses to possess and use radioisotopes according to the conditions in the licensing document. These conditions address radiation safety restrictions and bind the licensee to any representations, statements, or written procedures submitted with or related to the license application.

9. Review radioactive materials licenses issued to UAB and by UAB to ensure that they are amended when necessary, generally prior to any change in facilities, equipment, policies, procedures, and personnel directing radiation safety programs.

10. Review plans for all new buildings and modifications of existing structures where radiation is to be used, giving due consideration to radiation safety needs and regulatory requirements.

11. Maintain written records of all RRSC meetings, actions, recommendations, and decisions.

12. Provide adequate dosimetry for persons working in areas where radioactive materials and radiation are used and maintain records of radiation exposure of all persons issued personal dosimetry devices.

13. Direct a prioritized system of scheduling radiation safety audits with an in-depth review of the individual radiation safety programs of UAB licensees. This is to ensure that radioisotopes are being used safely in the separate licensed programs. Each audit includes a survey of the laboratories and personnel under the direction of each licensee. It also includes a review of radioactive materials use, transfer, and disposal; observations on the wearing of personnel monitoring devices; maintenance of appropriate records; adequacy of surveys by the licensee or licensee's staff; adequacy of instructions given to licensee's staff; labeling of radioisotope containers; and posting of appropriate warning signs and notices. Perform “active use” medical Radioactive Drug Research audits quarterly, when necessary. The prioritized system of scheduling is discussed in Section II of Appendix O “Radiation Safety Audit Schedule and Escalated Enforcement Actions”.

A representative sample of all the radioactive materials licenses at UAB is randomly audited on an unannounced basis during regular inspection intervals. A representative sample may be considered to be as few as thirty audits every twelve months.

A. The functions of the Radiation Safety Officer (or his designate) are as follows: (Continued)

14. Perform and/or direct a program of spot checks of laboratories to observe use, handling, surveys, labeling and security of radioisotopes, use of personnel monitoring equipment, posting of appropriate area signage - thereby providing university-wide radiation safety coverage. Because of the in-depth coverage of routine audits, there is no requirement for a specified number nor frequency of spot checks; however, auditors can use some time during regular audits to spot check the safety programs of neighboring laboratories covering safety from all forms of radiation hazards and even hazards of a more general nature in areas where radioactive materials are used (i.e., chemical, physical and biological hazards).

15. Perform and/or direct surveys surrounding the therapeutic use of radioisotopes.

16. Ensure that surveys of patients are performed following the removal of sealed sources used during therapy and see that these surveys are documented.

17. Ensure that x-ray and particle accelerator equipment is periodically surveyed in such a manner that regulatory limits are not exceeded in restricted or unrestricted areas.

18. Ensure that interlocks at entrances to particle accelerator and medical radioisotope teletherapy rooms are checked at least every six months and that these checks are documented.

19. Ensure that full calibrations of medical teletherapy equipment using radioisotopes are performed at least annually (and when required by regulation) and that spot check measurements are performed monthly.

20. Perform leak tests of all nonexempt sealed sources as required by applicable regulations.

21. Maintain records of all radiation surveys and tests for removable contamination performed by Radiation Safety Program personnel and ensure that surveys by users of radioisotopes are also periodically documented.

22. Provide for the order, receipt, survey, and the safe transfer of all radioactive materials (except for those departments licensed to do so for radiopharmaceuticals necessary for the clinical care of patients). All purchase order numbers for any nonexempt radioactive materials (including generally licensed devices) are provided only through the RSP.

23. Ascertain that all orders for radioactive materials are in accordance with the individual's license and that possession limits are not exceeded.

24. Inform the Director of the group involved and the RRSC (during committee meetings) whenever an individual’s periodic exposure reading exceeds the investigational level and whenever uptakes from radioactive contamination or exposure to radiation exceed the amounts prescribed in this manual or in the applicable regulations. All radiation exposures of personnel in excess of regulatory limits must be reported to the appropriate governmental agency and to the individuals involved, as required by regulation.

25. Ensure that all radiation equipment is properly labeled.

26. Ensure that air and water releases do not exceed the Annual Limits of Intake (ALIs) in restricted and unrestricted areas.

VI. RADIATION SAFETY PROGRAM (Continued)

A. The functions of the Radiation Safety Officer (or his designate) are as follows: (Continued)

27. Investigate and report to the Radioisotope & Radiation Safety Committee any accident or loss involving nonexempt activities of radioactive materials.

28. Collect and ensure the proper disposal of radioactive waste. This includes ensuring that all radioactive waste shipments conform to applicable regulations.

29. Ensure that all shipments of radioactive materials from UAB follow the applicable regulations.

30. Calibrate all portable survey instruments on a routine basis (see Section XI), and maintain records of all calibrations of survey meters or other instruments.

31. Direct radiological safety training programs.

32. Maintain records of receipt, transfer, and disposal of radioactive materials.

33. Maintain a current set of DOT and NRC regulations concerning the transfer, packaging, and transport of low level radioactive waste.

34. Conduct an audit of UAB activities associated with the transfer, packaging, and transport of low-level radioactive waste. Records of these audits must be maintained.

35. Formulate emergency procedures and administrative controls as necessary.

B. Review and Approval of Studies Involving Radioisotopes

<u>All Studies</u>

All studies in which radioisotopes are used for non-human use must have the approval of the Radiation Safety Officer or his designate. Those studies involving human use of radiopharmaceuticals or radioisotope devices require the consent of a majority of the members of the Subcommittee for Human Use, of which the RSO is an ex officio member. The safety of any proposed study must be evaluated before it can be approved. The review process begins with the individual user. The individual user must have training and/or experience appropriate to the type, amount, and the manner in which the radioisotope is used (See Criteria for Radioisotope Licensure and Use in APPENDIX I). An individual who applies for a license to use radioisotopes must complete an application form and return it to the Radiation Safety Program of the Occupational Health and Safety Department. Application forms may be obtained from the Radiation Safety Program. <u>Applicants must be UAB employees</u>.

In general, the review process will focus on the following:

(1) qualifications of the investigator,
(2) the radioisotope, its chemical and physical form,
(3) risks presented by experimental procedures,
(4) adequacy of containment equipment and facilities (see ventilation requirements of APPENDIX J),
(5) training level and experience of persons directly associated with the work,
(6) need for health surveillance of laboratory personnel,
(7) survey and personnel monitoring equipment, and
(8) other factors relevant to the safe conduct of the study.

VI. RADIATION SAFETY PROGRAM (Continued)

B. Review and Approval of Studies Involving Radioisotopes (Continued)

All Studies (Continued)

The Radiation Safety Officer (RSO) or his designate must review the application and inspect the applicant's facilities and equipment to ensure their adequacy for the use specified in the application. If the application is disapproved, the applicant will be informed of the reasons for disapproval. If the application is approved, a license will be granted for the conditions specified in the application and for any additional conditions which the Radiation Safety Officer or the RRSC determine to be necessary.

No UAB employee may independently use radioactive materials within the University Complex nor on its premises, except for exempt quantities, without having a radioactive materials license. Authorized Users who work under the supervision of a licensee must have a current understanding of radiation safety as demonstrated by training and/or experience.

Evidence of formal radiation safety training not received at UAB must be submitted to the Radiation Safety Officer or his designate. Individuals who have had formal radiation safety training must at least attend a training session covering UAB Radiation Safety Procedures, or an equivalent UAB on-line course, when available. (Contact the Radiation Safety Program for course schedules.) Approval for licensure will be ordinarily granted only to those who have had formal training in radioisotope techniques and theory. A licensee may use (nonhuman use) radioisotopes under another licensee's program only if he or she is listed as an Authorized User on the other licensee's radioactive materials license, as indicated by the Authorized User records maintained by the Radiation Safety Program.

The Radiation Safety Officer may request comments from members of the Subcommittee for Laboratory Use concerning various aspects of written proposals for non-human use. The qualifications of applicants applying for human use studies of a routine (having a NDA number) or non-routine (not within the purview of RDRC) nature must be reviewed by the Subcommittee for Human Use (using the criteria established by the RRSC). The RSO will grant approval for these studies only if a majority of the members of the Subcommittee have reviewed and approved the study without reservations. A poll of the decision of each member must be taken by mail vote and/or by e-mail message. If one member disapproves the study, the concerns raised by the disapproving committee member must be discussed and resolved by a majority approval of the SCHU members. The RSO or his designate must send all pertinent material (completed application forms, personnel data forms, etc.) to subcommittee members who are either required or requested to comment on applications. The RDRC must meet to approve all nonroutine human use proposals involving basic metabolic research of radiopharmaceuticals that are not "biologicals", except for those studies covered by another RDRC outside of UAB reporting to the FDA.

Studies of a Limited Nature

These studies involve very small quantities (37 KBq or 1 microcurie) of only the well-established clinical procedures generally licensed by the Radiation Control Division, Bureau of Health Care Standards, State of Alabama. Approval for limited use involving in-vitro studies of radioisotopes may be obtained by a physician or clinical laboratory under a UAB general license (UAB-IV-GL). Evidence of some experience in radiation safety procedures and equipment is a prerequisite for approval. Only the approval of the RSO or his designate is required for this limited use. All licensees are encouraged to have these materials authorized by their specific radioactive materials licenses.

Approval for any studies, whether limited or otherwise, involving human use may only be obtained with the approval of the Subcommittee for Human Use or the Radioactive Drug Research Committee. Refer to the information given in the prior section entitled “All Studies” regarding any human use study or contact the RSP for more information.

C. Hazardous Materials Control Program

The center for receiving and shipping all of the radioactive materials to and from UAB is the Hazardous Materials Facility (HMF), a division within the Occupational Health and Safety Department. See APPENDIX H for more information. It is managed the Director of Hazardous and Regulated Materials (DHRM). The management of the receipt, transfer, and disposal of radioactive materials at UAB is the ultimate responsibility of the Radiation Safety Officer. The RSO or his designate must conduct an audit of these activities on at least an annual basis, particularly covering activities surrounding low level radioactive materials disposal. The RSO is assisted in carrying out these duties by both the Assistant Director for Radiation Safety and the DHRM.

Radioactive Materials are normally received at the Hazardous Materials Facility. Only in special cases, as allowed by a UAB radioactive materials license, this Manual or by the RSO or his designate, will a licensee be allowed to receive radioactive materials directly from a vendor. These special cases usually involve the clinical care of a patient (i.e., ordering, receipt, and transfer by a nuclear medicine laboratory is allowed by license). In rare instances, special approval may be granted by the RSO or his designate; however, special restrictions involving the safety in the receipt and transfer of this material will normally be imposed, as a condition for such approvals.

The DHRM must see that the day-to-day operations of radioactive waste disposal are conducted properly. He is assisted in these activities by the hazardous materials technicians. The duties of the DHRM include:

1. Be responsible for surveying the Radioactive Waste Materials Operations Site periodically for radiation exposure, air concentrations, and surface contamination.

2. Schedule, supervise, inspect, and coordinate the radioactive waste packing activities on the Operations Site.

3. Manage the distribution, transfer, and collection of radioactive materials, including radioactive waste.

4. Ensure that all radioactive packages that are received or collected are surveyed.

5. Ensure that the radioactive wastes received from the laboratory are packed and labeled according to the requirements of Section XXI and APPENDIX H.

6. Ensure that the information on each radioactive waste manifest submitted by a licensee is complete and has been signed by the licensee or alternate licensee.

7. Inspect the shipping manifests and containers of radioactive materials which are received by or shipped from UAB (including radioactive waste) to ensure that they are packed, labeled, and surveyed according to ARCR and U.S. Department of Transportation Regulations (DOT).

8. Notify the Radiation Safety Officer or his designate immediately concerning any radiation or suspected radiation exposure or contamination above the limits allowed by the ARCR and DOT Regulations and also for exposure exceeding the limits prescribed by this manual or other policies and procedures approved for the HMF by the State of Alabama and the RRSC.

9. Survey the rooms where therapeutic uses of unsealed sources have taken place after the patients have been released. Ensure decontamination where contamination is found and have these rooms resurveyed. Determine if a room can be released for normal use and notify both the charge nurse and environmental services. A room can be released only when the survey shows no contamination above background levels.

VII. RESPONSIBILITIES OF DEPARTMENT CHAIRMEN, DEANS, AND ADMINISTRATORS

A. The chief administrators of Departments, Research Institutes, or Centers are responsible for the general safety of faculty, staff, and students working with radiation in their overall area of jurisdiction. It should be emphasized that this responsibility is reduced in no way by activities of the Radioisotope & Radiation Safety Committee, the Institutional Biosafety Committee, or the Safety Officers.

B. The chief administrators shall ensure that the principal investigators in their areas of jurisdiction are provided with on-line access to copies of the UAB Radiation Safety Procedures Manual and should stress the importance of compliance with the guidelines described therein.

C. The chief administrators are mutually responsible, with the principal investigators, for informing the Radioisotope & Radiation Safety Committee of work involving radiation and reporting accidents or incidents involving radiation to the Radiation Safety Program.

D. The Department Chairmen and the faculty members who supervise teaching laboratories are mutually responsible for informing students of proper precautions to be taken when working with radiation.

VIII. RESPONSIBILITIES OF THE LICENSEE

The radioactive material license granted by the RRSC authorizes a principal investigator to conduct a radioactive materials use program. The license is valid provided that the investigator is a staff member of one of the departments, schools, or groups at UAB and has the approval of the appropriate department chairman, dean, or administrator to conduct such a program involving the receipt, possession, use, disposal, and transfer of radioactive materials.

The licensee is responsible for the following:

1. Complying with the UAB Radiation Safety Procedures Manual and applicable regulations, and license conditions.

2. Providing written laboratory safety procedures and instructions to supervised personnel and seeing that these are followed, and ensuring that any radioactive material being used under the conditions and terms of the license is used in accordance with all appropriate rules and regulations.

3. The training of personnel working with the radioactive material or radiation equipment. This includes the requirement for refresher training every five years. (UAB training courses are periodically available.) Every person working with radioactive materials must be familiar with these safety procedures. Formal UAB radiation safety training or its equivalent must be successfully completed by Authorized Users.

4. Adequate supervision of workers using radioactive materials. This supervision does not require the licensee to be physically present in the area during radioactive materials use provided that (a) the licensee has determined that these workers are competent in their ability to safely use these materials by themselves and (b) the licensee is available to respond and assist them in case of an emergency. Authorized Users who have not yet completed the UAB Radiation Safety Training Course or its equivalent must be closely supervised.

5. Making available properly operating radiation detection instruments, both bench and portable types, appropriate to the type of radiation being measured. This equipment must be calibrated periodically and be used for conducting laboratory surveys.

6. The procurement of all material and equipment needed for the safe use, storage, and transfer of radioactive material or radiation producing equipment. This includes use of proper warning signs, tags, and labels.

8. Maintaining up-to-date records showing the receipt, use, disposal, and transfer of all radioactive material. (Radioactive Material Transfer forms and Radioactive Material Record forms are available through the Radiation Safety Program.)

9. Ensuring that personnel wear laboratory coats and plastic gloves while handling radioisotopes.

10. Making sure that all personnel working with certain types and amounts of radioisotopes wear personnel monitoring equipment as specified by the Radiation Safety Officer or his designate, the License, or this manual. Personnel issued these personnel monitoring devices must wear them at all times while in areas where ionizing radiation is present. Personnel monitoring will also include measurement of biological samples as necessary (see Section XIII).

11. Written procedures (and subsequent changes to these) regarding the safe use of radiopharmaceuticals in nuclear medicine submitted for approval by the RRSC for each separate nuclear medicine license. Physician users are listed on the appropriate license. This applies to nuclear medicine licenses only.

12. Requesting, in writing, an amendment to the license concerning changes in personnel or location of radioisotope storage or use, in experimental protocol regarding radioisotope use, or in written laboratory safety procedures.

13. Making arrangements for an alternate licensee to agree by written consent to supervise the activities of the licensee's radioisotope program during the licensee's absence; otherwise, these activities must cease during such absence.

14. Notifying the Radiation Safety Program prior to an extended absence from the University if radioisotope activities will continue to be conducted under the license.

15. Notifying the Radiation Safety Program at least one month prior to terminating employment at UAB. This is to ensure that adequate arrangements are made for the transfer and/or disposal of all radioisotopes in the licensee's possession. Any ex-licensee returning to the University after failing to do so may be required to give explanation to the members of the RRSC before being allowed to reapply for a license.

16. Authorizing a requisition for a radioisotope only if it is of the type and chemical form authorized by license and only if receipt of the order does not cause possession limits to be exceeded.

17. The conduct of activities under another license only after accepting this responsibility in writing together with the written approval of the respective department chairman, dean, or administrator.

18. Develop adequate planning and procedures to ensure minimal radiation exposure.

19. Conducting inventories of nonexempt radioisotopes at times specified by the Radiation Safety Officer. (Those materials for which the licensee is exempt from this requirement are: (a) sealed sources in amounts less than 3.7 KBq (0.1 microcuries) for beta/gamma emitters and 370 Bq (0.01 microcuries) for alpha emitters and (b) fixed microscope slides in amounts less than 3.7 Bq (0.1 nanocuries) for beta/gamma emitters and 0.37 Bq (0.01 nanocuries) for alpha emitters, and (c) exempt quantities or exempt concentrations of radioisotopes, which are listed in APPENDIX M.)

20. Make initial determinations of the gaseous release of a radioisotope which may occur during an experimental procedure, documenting the extent of this release, and providing for its containment and/or use within a hood ventilating system. Significant releases must be brought to the attention of the Radiation Safety Program.

21. Keeping stocks of stored radioactive material to a minimum, and ensuring proper storage and security.

22. Ensuring proper posting of areas where radioisotopes are stored and used. This includes visible posting of areas where radioactive wastes are securely awaiting pickup by the RSP. See Appendix G for the proper sign to be used.

23. Ensuring proper labeling of all vials and containers of radioisotopes (see SECTION XV). Liquid scintillation or gamma-counting vials do not have to be labeled individually as to radioactive material and/or assay or assay date. A group of these vials must be labeled when held for storage, however.

24. Ensuring that all labeling, packaging, manifesting, and disposal of all radioactive wastes is in accordance with proper procedures (see SECTION XXI) and certifying the waste manifest by signature.

25. Ensuring that regular laboratory wastes are not stored near radioactive stock or waste materials.

26. Ensuring that all equipment released to non-radiation workers (maintenance, equipment moving personnel, etc.) or areas released for work by them has no radioactive materials nor radioactive contamination and the radiation levels there must not be above natural background. In addition, the shielded radiation levels in areas where radioactive work is conducted must not exceed 0.5 mR/hr. Prior to such release, the "Safety Release No Radiation" poster shown in Appendix G must be signed and dated either by the licensee or the laboratory worker performing the survey.

27. Establishing a mandatory radioactive waste volume reduction program for radioactive materials used by adopting those measures on Radioactive Waste Minimization, A Mandatory Program form (See Appendix H, Supplement B) that are reasonably achievable.

28. Being responsible for all packaging, labeling, manifesting and preparation of DOT shipping documents for all shipments of radioactive materials from UAB. The appropriate transfer and shipping document forms are available from the Radiation Safety Program, as well as instructions for their completion.

29. Getting licensed for equipment sometimes referred to as a “Generally Licensed Device” (i.e., liquid scintillation counter, gas chromatograph, etc.). Devices such as these have sealed radioisotopes within them. Normally, receiving these devices requires notification to the Alabama State Health Department within a ten-day period following their receipt. UAB has an exemption from such notification; however, the individual or department must:

    a. Get licensed prior to ordering and receiving any such device;
    b. Notify the Radiation Safety Program upon receiving or transferring one;
    c. Have the sealed source removed from such a device before it is transferred to the UAB warehouse for possible auction - normally performed by service personnel from a vendor. (The sealed source does not have to be removed when such a device is transferred from one licensee to another); and
    d. Must keep records of receipt and transfer of these devices.

    Note: A generally licensed device used by more than one UAB radioactive materials licensee is required to be listed on only one UAB specific radioactive materials license, usually the license of the primary person or department responsible for the possession and/or use of the generally licensed device.

30. Ensuring that Authorized Users successfully complete the UAB Radiation Safety Training Course or its equivalent within six months of being added to a UAB radioactive materials license as a closely supervised Authorized User of radioactive materials.

IX. RESPONSIBILITIES OF THE INDIVIDUAL USER

An INDIVIDUAL user is classified as any of the physicians, scientists, and other professional and technical workers engaged in patient care, clinical and laboratory research, and research support activities which involve actual use and handling of materials and devices producing ionizing radiation. These personnel usually work under the supervision (See Section VIII.4) of the licensee. The success of the radiological safety program at UAB depends on the individual's thoughtfulness and care in handling radioisotopes and devices producing potentially harmful radiation.

The INDIVIDUAL is responsible for:

1. Complying with the UAB Radiation Safety Procedures Manual, applicable regulations, license conditions, the safety procedures of the licensee, and any administrative controls that may apply to the work being done.

2. Using all appropriate protection and security measures for the safe use, storage, transfer, and disposal of radioactive materials, radiation-producing machines, and radiation-producing devices.

3. Providing accurate information on the radioactive waste manifest sent to the Radiation Safety Program prior to radioactive waste pickup.

4. Reporting any defective equipment or radiation survey instruments to the supervisor or the Radiation Safety Program.

5. Immediate notification of the Radiation Safety Program in the event of an emergency or of a situation which may create a radiological safety hazard (e.g., accidental inhalation, ingestion, or injury involving radioactive material) and carrying out recommended action and/or corrective measures.

6. Wearing of an applicable dosimeter in a location on the body that will give the most accurate measurement of radiation exposure and wearing it at all times while in the laboratory (see Section XIII). Keep radiation exposures as low as reasonably achievable.

7. Reporting immediately to the supervisor and to the Radiation Safety Program any lost or stolen radioactive material.

8. Wearing a laboratory coat and other appropriate clothing such as plastic gloves while handling radioisotopes and protective glasses while handling significant amounts of medium and high energy beta emitting radioisotopes.

9. Continuing to review the Radiation Safety Procedures Manual and continuing to improve personal standards regarding the job and radiation safety.

X. LIABILITY ASPECTS OF WORKING WITH RADIOACTIVITY AND RADIATION EQUIPMENT

All faculty members and investigators should be aware of personal liability possibilities which could result from the use of radiation or other hazardous agents. No rules specifically relating to liability in working with hazardous agents may be stated. However, the general rule of law that every INDIVIDUAL is liable to others for negligent acts which cause injury to other persons is applicable in this situation. The rule applies whether a faculty member is working with a hazardous agent or pursuing other routine duties of teaching, research, and administration, but the increased potential for personal injury in a laboratory where persons are working with hazardous agents is obvious. To avoid injury and liability for injury, an investigator should exercise due care in research activities. What constitutes due care, of course, will vary with the facts of a research situation. In everyday life activities, such as driving an automobile, the question to be asked in determining liability is whether a person acted as a reasonable person would have. In a laboratory, then, the question is whether the person in charge of research has behaved in a way that others with appropriate training and experience would have behaved. (One notable exception to the "reasonable man" standard is the principle of strict liability. Some activities have been judged to be so inherently dangerous that liability for injury attaches in absence of negligence. Research with some hazardous agents may fall into such a category.) Whenever there is a widely accepted procedure for handling materials or laboratory situations, that procedure usually will be the standard against which activities are measured. Departures from written policies of an institution may also be indications of failure to exercise requisite care. As injuries are most likely to involve employees, the most important responsibilities of a principal investigator are adequate procedural instructions for those working with hazardous agents and adequate supervision of those persons. The actual degree of instruction and supervision necessary will depend upon the project and the degree of education and sophistication of the individuals involved. The University of Alabama at Birmingham is an agent of the State of Alabama, and it may not be sued in most situations under discussion here. However, claims against UAB may be filed with the State Board of Adjustment, and UAB does administer a program of benefits for on-the-job injury. To promote efficient handling of claims or potential claims and to limit personal liability to the extent possible, all accidents or health problems related to work in a laboratory should be reported on an incident report form and forwarded to Occupational Health and Safety, which in turn would provide copies to UAB's Office of Risk Management and/or the Office of University Counsel.

XI. INSTRUMENT CALIBRATION

All portable radiation survey instruments used in monitoring areas where ionizing radiation is used must be calibrated at least annually. The Radiation Safety Program (RSP) generally provides meter calibration twice a year, once before May 15th, and once after August 15th, and gives UAB radioisotope licensees and x-ray or particle accelerator registrants prior notice of scheduled dates for access to survey meters for calibration. These meters will normally be scheduled for pickup by the RSP Staff or delivery by the licensee staff depending on the locale of a licensee's laboratory. All survey meters received by the RSP must be operable with batteries of sufficient strength to meet battery check indications on the meter. Scheduled calibrations occur over approximately a four to six-week period. If a licensee, registrant, or department does not provide proper access, pickup and/or delivery of survey meters (requiring calibration) during this period, their survey meters must be brought to the RSP (Room 445, Community Health Services Building, 933 South 19th Street) or other designated areas in order to be calibrated. Any survey meter that has been repaired must be recalibrated before it can be used for monitoring. All calibrations are performed using standard sealed sources (Cobalt-60, Cobalt-57, Cesium-137, Barium-133, or Iodine-129) appropriate to the type of survey meter and traceable to the National Institute of Standards and Technology (NIST). All instruments are calibrated using two points (approximately 1/3 and 2/3 full-scale readings) on each scale and are calibrated to an accuracy of within 20% of the determined exposure rate. The RSP is capable of calibrating survey meters in radiation fields up to 1,100 microcoulombs per kg air exposure per hour. Each licensee or registrant is notified when the survey meters have been calibrated and are expected to have these picked up promptly, if the meters are not delivered by the RSP. A record of calibration accompanies each meter and includes such data as date of calibration, accuracy at various radiation exposure levels, type of meter, model number, serial number, and the type of source with which it was calibrated. If the survey meter has a check source, its measurement also appears on the record. The check source readings are taken with the window in the open position and the maximum contact readings recorded. If, in checking the instrument, it does not respond as indicated on the record or label, check the batteries. If the batteries are not the cause of the incorrect reading, notify the RSP. The RSP checks the instrument in this case, and, if it cannot be recalibrated, the user will be notified that it will be in need of repair or replacement as soon as possible. Don't depend on one survey meter only for your laboratory work. The RSP staff must be given reasonable time to calibrate these meters. The RSP is not required to supply users with substitute meters during calibration. A very limited number of survey meters are, however, available on a first-come, first-serve basis for temporary use during meter calibration. The Radiation Safety Program maintains records of instrument calibrations for at least five years.

XII. SURVEYS OF RADIOISOTOPE AND RADIATION USE

Laboratory and personnel surveys are conducted to inform the user of radiological hazards. Surveys must be performed daily in any areas where radioisotopes are being used and also in areas suspected of having radiological hazards. These surveys must be documented no more than seven (7) days after each date of radioisotope use. This documentation must be maintained for at least five years.

Personnel monitoring is a special type of survey and is addressed in the following section (XIII). Complete surveys include measurements of radiation exposure or dose rates and any radioactive contamination that may accumulate on surfaces in the laboratory. The more frequent the surveys, the better informed the user is of the work environment. Frequent surveys are very important when the user is performing a new task or working with a new isotope or compound. Area and personnel monitoring surveys should be performed during use, when the work is completed, prior to break periods, and/or at the end of the day, and MUST be performed daily when radioisotopes are used. The Radiation Safety Program personnel perform surveys in the laboratories during its "Spot Check Program" to help ensure that each UAB licensee is maintaining an adequate radiation safety program.

Appropriate Instrumentation

All radioisotope users must have available or access to appropriate instrumentation with which to survey themselves and their work areas.

Portable radiation survey meters must be used (except for monitoring tritium) which are appropriate for the type and energy of the radiation as well as for its magnitude.

For high level beta/gamma radiation, portable ionization chambers or proportional counting meters are required. Radiation dose levels from gamma or bremmstrahlung x-rays in excess of ten millirems per hour are considered high level radiations for the purposes of these requirements. Radiation dose levels from beta radiation in excess of 15 millirem to the lens of the eye are considered high level radiations. Remember that Geiger Mueller (GM) counters may measure lower than actual radiation levels when they are used to survey levels greater than twenty millirems per hour. As radiation increases beyond these levels, the number of "lost counts" increases significantly because of the increasing "dead time" of these instruments in higher radiation fields. If their electronic circuitry is not corrected for “saturation effects”, they will read nearly zero measurements in rem per hour radiation fields. Care must be taken when the GM survey meters are used in the laboratory by first taking readings distant from suspected or known radiation sources and then moving the probe closer to the sources.

The GM surveys meters are calibrated for gamma and x-ray radiation. When these instruments are used to measure high energy beta radiation such as from ^{32}P, the reading on the meter will depart from the actual dose reading. For cylindrical probes, the beta dose rate will be approximately 25% higher than the reading (taken from the front of the probe) and for the pancake probes, the beta dose rate will be approximately 50% of the reading (also taken from the front of the probe.)

Low Energy Beta Sources

A thin window of approximately 1 milligram per square centimeter density thickness on a GM probe may be used to measure most ionizing particulate radiations encountered in the laboratory. However, there is no portable GM survey meter presently available for measuring tritium (^{3}H). The beta radiation from tritium is similar to alpha particle radiation in that it does not present an external radiation problem as long as the radiochemical is contained and is not allowed contact with even the natural intact barrier of the skin (i.e., skin with no cuts nor abrasions through its protein layer). Once it contaminates the air or skin, it does become a problem. In the form of tritiated vapor, it is easily absorbed through the skin. One can survey for tritium hazards by taking measurements of surface contamination through the use of wipe samples and liquid scintillation counting instrumentation.

Alpha Sources

The vast majority of the alpha particles are emitted from heavy radionuclides and they are emitted with energies that are always greater than 4 MeV. In addition, these alpha emitters are usually one or more of a series of radioactive progeny of daughter products. The end result is usually the presence of all three major types of radiation: alpha, beta and gamma radiation. Some of the gamma radiation may have relatively high energies. The hazard is multiplicative not only from having more radionuclides involved, but from higher energy radiations and from the much higher quality factors (20 for alpha particles and recoil atoms) of alphas that might diffuse into living tissue from contamination on the skin.

Although alpha particles are not penetrating even at their high energies, they give rise to energetic electrons known as delta rays which provide further penetration of ionizing radiation into the sensitive volume of a thin window GM probe. These GM probes cannot, however, distinguish between the alpha radiation and the beta/gamma radiation. It is therefore necessary for any investigative user or licensee who uses unsealed alpha

Alpha Sources (Continued)

sources (and has been approved for such use) to have a alpha proportional counter available to measure only the alpha radiation emitted by these sources. The GM survey maters are still a necessary part of the survey equipment that must be available. By using both types of survey equipment, the character of the radiation field can be more appropriately evaluated and the radiological risk from exposure better determined.

Measurement of Removable Contamination

In measurements of radioactive material contamination, wipe samples must be taken from surface areas of approximately 100 cm^2. These are counted to determine how much of the contamination is removable and poses a personnel contamination problem. Don't use one wipe to survey the entire laboratory; this would only spread the contamination problem if present. Any observation of removable contamination of more than 100 counts per minute (cpm) above background, as measured by a liquid scintillation counter (or a gamma counter or other detection instrument, when appropriate for the type of radioactive materials being measured) is considered significant and should be cleaned up soon after it occurs. Any observation of removable contamination of more than 1,000 cpm above background, measured as described in the previous sentence, must be cleaned up immediately; also, the Radiation Safety Program must be notified about the more than 1,000 cpm contamination immediately so that bioassays, which are required for all individuals working at or near the contaminated areas, can be performed in a timely manner. Higher removable radioactive material contamination limits may be permitted in procedures or license conditions approved by the Radiation Safety Officer or his designate.

Any skin contamination should be washed immediately with soap and water. Care should be taken not to wash the contamination to another part of the body. If soap and water do not remove the contamination, contact the Radiation Safety Program for assistance. Dose estimates and further precautionary measures will be given by the Radiation Safety Officer or his designate in this case. Records for area surveys must include the following information:

Date
Radiation Exposure Rates Surrounding Usage and Storage Areas
Contamination Count Results
Location of Check Points in the Laboratory
Room Number
Name of Person Making Survey Record Entries

Leak tests of sealed sources are special types of surveys made by the Radiation Safety Program. These are checks for removable contamination from singly or doubly encapsulated radioisotopes. All sealed sources must be leak tested every six months unless otherwise exempted by licensure or regulation. Any sealed sources which are removed from storage must be leak tested before use if the six-month interval has been exceeded. Leak testing must be performed by methods capable of detecting 185 Becquerels (0.005 uCi) of activity of the radioisotope being tested, with the exception of Radium-226. Radium-226 sealed sources must be tested by checking for the presence of Radon-222 in the amount of 37 Becquerels (0.001 uCi) of activitiy over a 24-hour period. The Georgia Jar or activated carbon cannister technique may be used for the radon leakage measurements. Normally, the most sensitive methods available for detecting contamination will be used in leak tests (i.e., use of liquid scintillation counting). Since leaks test of tritium are not required and the majority of radioisotopes in use give nearly 100% yield or more in particle emissions, unless otherwise indicated, a conservative estimate of one Becquerel of activity will be assumed for each count per second registered with liquid scintillation. Then, unless otherwise indicated in the analysis, the count rate above background levels will be considered to represent Becquerel quantities of radioactivity. The person in charge of a sealed source showing any significant amounts of removable contamination must be notified of the findings. Any sealed source, other than a teletherapy source, having removable contamination in excess of the regulatory limits shall be transferred immediately to the Radiation Safety Program. The RSP shall store the source until arrangements have been completed to repair or dispose of the source. For the teletherapy sources, any test wipes (of the collimator or accessible ports to the

Measurement of Removable Contamination (Continued)

teletherapy head) which reveal the presence of 185 Becquerels (0.005 uCi) or more of removable contamination shall be considered as exceeding regulatory limits and the source shall not be used until repaired or replaced. The RSP shall file a report with the State of Alabama Health Department within five days of the test, describing the equipment involved, the test results, and the corrective action taken. The Radiation Safety Program shall maintain records of leak tests for a period of five years.

A variance from the daily requirement of surveys and use records is permitted by the Radiation Safety Officer and Chairman of the Radioisotope and Radiation Safety Committee when no more than Deminimus Levels (DL) of radioactive materials are used by a UAB radioactive materials licensee. Deminimus Levels (DL) of radioactive materials are, for the purposes outlined in this section, defined as limited amounts of radioactive materials which, if carefully used daily in the research laboratory, would not cause appreciable radiation exposure to the worker when compared to the natural background levels of radiation. Deminimus levels of radioactivity are restricted to the following:

1. The maximum amount of the radioisotope allowed in any container is the quantity given in the Schedule of Deminimus Levels of Radioactive Materials given in APPENDIX M. The total possession limit allowable under these terms for the radioisotope is ten times the quantity given in APPENDIX M.

2. The maximum concentration, after dilution of a transferred amount from a stock vial, in any container other than the stock vial is the concentration given in APPENDIX M.

3. The Deminimus quantities and Deminimus concentrations must not be used for the production, packaging or repackaging of radioactive materials for purposes of commercial distribution, or the incorporation of radioactive materials into products intended for commercial distribution.

Area survey, use, transfer, and waste disposal records are not required when Deminimus quantities or Deminimus concentrations of radioactive materials are used or possessed as described in items 1-3 above, unless an activity of radioactivity was initially above the Deminimus quantity or Deminimus concentration amount and in the possession of the radioactive materials licensee, and has decayed below the Deminimus quantity or Deminimus concentration amount. Also, if a person on UAB property uses or possesses only Deminimus quantities or Deminimus concentrations of radioactive materials as described in items 1-3 above, a radioactive materials license is not required for the possession of these radioactive materials.

A variance from the daily requirement of surveys and use records may also be granted by the Radiation Safety Officer and Chairman of the Radioisotope and Radiation Safety Committee for radioisotopes and amounts allowed for use in standard, generally licensed, diagnostic kits for "in vitro" medical studies. UAB Radioactive materials licensees must demonstrate good laboratory safety records for a period of at least six months, showing no significant contaminations when routinely checked by the Radiation Safety Program, in order to apply for and receive this variance. Furthermore, the variance allowed may be repealed from a license by the Radiation Safety Officer and the Chairman of the RRSC when significant contamination is discovered in a laboratory where radioactive materials work that caused the contamination was performed under that license. This variance may be allowed as described below:

1. The radioisotopes and amounts allowed for use in standard, generally licensed, diagnostic kits for "in vitro" medical studies only. These include Iodine-125, Iodine-131, Carbon-14, Cobalt-57, and Selenium-75 of an amount not greater than 0.37 MBq (10 microcuries) for each container. For Iron-59 this container limit is 0.74 MBq (20 microcuries), and for Hydrogen-3, it is 1.85 MBq (50 microcuries). Except for Carbon-14 and Hydrogen-3, the total possession limit for use is 7.4 MBq (200 microcuries).

If the variance is granted for a researcher or investigator using standard, generally licensed, diagnostic kits for "in vitro" medical studies as described above:

XII. SURVEYS OF RADIOISOTOPE AND RADIATION USE (Continued)

Measurement of Removable Contamination (Continued)

A. Area Surveys of radiation levels and/or contamination are required and must be documented no more than seven (7) days after each date of radioisotope use.

B. The only information required in the usage records is the type of kit, the radioisotope, its activity, when the use of a kit began, when completed, and when its activity is transferred in its entirety to radioactive waste.

XIII. PERSONNEL MONITORING

Personnel monitoring is required when it is likely that an individual may receive a total effective radiation dose in excess of ten percent of the annual limits, given in the following paragraphs. The total effective dose includes a summation of the separate exposures from internal exposure as well as external exposure. Normally, exposure from radiation sources external to the body is determined through the use of monitoring devices worn by the individual. These may be whole body monitors to measure several components of a radiation exposure. The deep dose reading, which results from the penetrating component of a radiation field, is the most important measurement. The shallow dose component reading is essentially a determination of the amount of exposure received by the skin of the whole body. If a monitor is worn close to the head of the body, the eye dose reading is a determination of the exposure received by the lens of the eye. Changes in external personnel monitoring do not take place without conferring with the licensee or registrant.

Exposures due to uptakes of radioisotopes into the body are determined from measurements of biological samples and/or partial body counting of radiations emitted from within the body. The need for the various types of monitoring is determined by the Radiation Safety Officer or his designate through a review of the situation and the applicable regulatory requirements.

The method of monitoring in each group, whether internal or external, is determined at the time applications for radiation use are reviewed; however, the monitoring requirements for an individual may be reviewed and, if necessary, changed at any time by the Radiation Safety Officer. If a licensee or registrant believes that a type of monitoring is necessary, then such monitoring will be provided initially and the results as to the need for further monitoring evaluated by the Radiation Safety Program. If such monitoring is completely unnecessary, it will be brought to the licensee's attention by the Radiation Safety Officer or his designate.

A. External Monitors

External monitoring is usually and adequately served by the use of a single monitor positioned appropriately for personnel working with ionizing radiation or working in its vicinity. The types and the conditions under which these are required are as follows:

Body Monitors for Whole Body and Skin of Whole Body Dose Measurement

1. Any person 18 years of age or more who may receive a 500 millirem deep dose or a shallow dose of 5000 millirem of whole body radiation in an annual period
2. Any person less than 18 years of age who may receive 50 millirem deep dose or a shallow dose of 500 millirem of whole body radiation in an annual period
3. Any person entering a high radiation area

Body Monitors for Eye Dose Radiation Measurement

1. Any person 18 years of age or more who may receive a 1500 millirem deep dose of whole body radiation in an annual period

XIII. PERSONNEL MONITORING (Continued)

A. External Monitors (Continued)

2. Any person less than 18 years of age who may receive 150 millirem deep dose of whole body radiation in an annual period
3. Any person entering a high radiation area

Finger, Hand, Wrist or Forearm Monitors for Extremity Dose Measurement*

1. Any person 18 years of age or more who may receive 5000 millirem to their arms beyond the elbows to their fingers in an annual period
2. Any person less than 18 years of age who may receive 500 millirems to the hands or forearms in an annual period
3. Any person who operates or services analytical x-ray equipment

* Extremity dose includes exposure to the feet, forelegs, hands and forearms

Monitors Over Pelvic Region for Embryo/Fetus Radiation Measurement**

1. Any Declared Pregnant Worker
2. Any Worker Suspected of Being Pregnant

** Usually required to be worn underneath the lead apron that is worn as an additional precaution.

The body monitors must be worn at or above the hip level in a position that most accurately reflects the highest exposure to the body. The position where monitors are worn must be documented by the licensee or registrant for every individual supervised. In cases where protective shielding is used and does not also provide protection for the head and eyes of individuals (i.e., when using a lead apron or a shadow shield), the body monitor must be worn at the collar outside of the protected region. Extremity monitors must be worn on the portion of the body likely to receive the greatest radiation exposure during the monitoring period. If necessary, extremity badges may be sterilized with the ethylene oxide gas commonly used for heat sensitive equipment.

Before wearing a lead apron while working with radioisotopes, consult the Radiation Safety Officer or his designate. The presence of this type of shield may actually increase one's exposure due to the nature of the radiation.

The necessity for wearing external monitors for individuals working with radioisotopes has been determined and is based on the type and quantity of radioisotope used and on the time working with and distance from the source. The general guide used by the Radiation Safety Program in determining the necessity for the use of external personnel monitors is given in APPENDIX D. When a licensed possession limit for a particular radioisotope of specified chemical form is equal to or greater than the amount of radioactivity listed in the guide, then personnel monitoring requirements are listed in the UAB specific radioactive materials license. In this guide, it has been assumed that an individual would work with one unshielded radioisotope at a time, which should be the case while working with stock materials.

Any radiation exposure just over the annual limits set by the State of Alabama and Jefferson County regulations is considered a technical overexposure and must be reported to the applicable agency and to the individual so exposed. Any overexposure shown by a personnel monitor of at least thirty percent of the annual limit must be investigated by the Radiation Safety Officer or his designate and by the Subcommittee for Radiation Exposure. During this investigation, the probable causes for the exposure and necessary corrective measures must be determined. Efforts must be made to keep individual radiation exposure and collective radiation exposure to personnel as low as reasonably achievable.

XIII. PERSONNEL MONITORING (Continued)

A. External Monitors (Continued)

UAB and other institutions are required to keep records of the total effective radiation dose to individuals entering restricted areas who may receive 10 percent or more of the maximum permissible annual limits allowed by State of Alabama and Jefferson County regulations. In order to keep an accurate accounting of an individual's total radiation exposure, the UAB Radioisotope & Radiation Safety Committee finds it necessary to require the following from each individual for which external monitoring is required:

1. Wear UAB issued personnel radiation monitors only at UAB owned or leased facilities, The Kirklin Clinic, and UAB Highlands (NOT including the Gamma Knife at UAB Highlands.)

2. Disclose to the Radiation Safety Program information regarding radiation work at other facilities and previously accumulated radiation exposure. This information must be submitted to the RSP on a Radiation Dose Disclosure form (see Appendix K) prior to first entry into a restricted area for which personnel monitoring is required. This information must be periodically updated by the individuals as changes occur in outside employment.

3. Provide information regarding radiation exposure received at other facilities to the Radiation Safety Program as soon as possible after occurrence. This involves workers at risk who receive radiation doses during the monitoring interval that are much higher than routinely recorded levels.

4. Notify the Radiation Safety Program if it is suspected that the dose to:

   a) any individual may exceed the annual dose limits allowed by this manual or the ARCR, or

   b) any individual may exceed the investigational level (thirty percent of the annual limit prorated for the fractional part of the monitoring interval to the annual period) in any monitoring interval (i.e., 125 millirem in a monthly period and 375 millirem in a quarterly interval for whole body exposure).

The maximum permissible annual limits cited in the applicable regulations are as follows:

Whole Body Radiation Dose

500 millirems for a person under 18 years of age

5,000 millirems for a person 18 years of age or older

Skin of Whole Body Radiation Exposure

5,000 millirems for a person under 18 years of age

50,000 millirems for a person 18 years of age or older

Extremity Radiation Exposure

5,000 millirems for a person under 18 years of age
50,000 millirems for a person 18 years of age or older

Exposure of Any Organ of the Body

5,000 millirems for a person under 18 years of age
50,000 millirems for a person 18 years of age or older

XIII. PERSONNEL MONITORING (Continued)

A. External Monitors (Continued)

Embryo/Fetus Radiation Exposure

500 millirems term limit and 50 millrem monthly limit

In order to maintain an adequate personnel radiation monitoring program for external exposure, it is necessary that the monitors be carefully distributed and collected in a timely manner. To accomplish this, it is necessary that each of the groups receiving monitors comply with the following requirements:

1. Assign an individual responsible for issuing and collecting monitors for each group.

2. Collect and return all radiation monitors to the Radiation Safety Program by the seventh day following the end of the monitoring period. Collect and return immediately for processing badges previously designated by the RSP radiation dosimetry technician.

3. Remove from radiation exposure those individuals specified by the Radiation Safety Officer or his designate as being near the annual limit or as having exceeded the annual limit. The Radiation Safety Program must inform the Director of the group when excessive exposures have occurred. In the event that badges designated for immediate processing have not been returned to the RSP in time to be sent in for immediate processing, they will be sent with the badges returned for normal service.

B. Internal Monitoring

Personnel working with unsealed radioisotopes are required to submit biological samples to the Radiation Safety Program Office. In most cases, these are urine samples when an individual is working with unsealed amounts of radiochemicals that exceed certain threshold use values. Some individuals are required to have external body counting conducted (e.g., those persons working with radioiodine). The Radiation Safety Program must schedule routine bioassays to determine internal radioisotope exposures according to the guidance given in APPENDIX E and at lower thresholds and at more frequent intervals when necessary. The frequency of this monitoring may be changed at any time by the Radiation Safety Officer and may be coordinated with radiation safety audits.

The threshold use levels, derived investigational levels and monitoring intervals given in the APPENDIX E guide reflect the bioassay technique normally used. These depend on expected routes of intake, uptake to the extracellular fluids in the body, organ and tissue distribution, routes of release from the body and the sensitivity of counting equipment. The most likely route of entry into the body is through inhalation. Consideration is also given to the type of radiochemical compound used, its metabolic breakdown and subsequent pathways in the body. The threshold use values are related to the Annual Limits of Intake (ALIs) given in the Alabama Rules For Control of Radiation (ARCR) and the monitoring intervals shown in the APPENDIX E guide. Any worker exposed to unsealed quantities of a radiochemical at monthly levels at or exceeding the threshold use levels in the APPENDIX E guide must be scheduled for routine radio-bioassays taken at the RSP.

Individuals who are performing radioiodinations or are working with unsealed alpha emitters (with radioactive daughters) are required to notify the RSP prior to use. Each individual worker must keep records of the quantities of radiochemicals used and the names of other workers who are in the immediate surroundings of this work. These exposures should be logged in as they occur. It is the responsibility of the licensee to ensure that monthly totals of such exposures are kept for each worker at risk and that workers keep up with their own exposures. This is to determine whether or not the amount of radiochemical to which they are exposed approaches the threshold use level given in the table of APPENDIX E.

XIII. PERSONNEL MONITORING (Continued)

B. Internal Monitoring (Continued)

Scheduling Baseline and Routine Bioassays

A baseline (preoperational) bioassay is required for workers prior to their beginning work with any unsealed radiochemicals at UAB. The licensee is required to notify the RSP of new workers who are anticipated to be either using these radiochemicals or be in the immediate vicinity of such work. These individuals are required to go to the RSP office and submit biological samples, usually urine, to the Radiation Safety Program (RSP). Some individuals are required to go to the RSP office for external baseline counting (i.e., those persons working with radioiodine).

In regards to routine monitoring, radiochemical workers are required to notify the RSP and schedule the necessary bioassays according to the use levels they have recorded in their laboratories. It is the responsibility of the RSP and UAB licensees, through periodic review, to ensure that personnel are adequately scheduled for monitoring and that periodic monitoring is maintained. Only the RSO shall determine whether such monitoring is no longer necessary. Appropriate information concerning changes in radiochemical use, worker exposure and containment must be submitted to the RSO or his designate for these determinations to be made. Individuals performing radioiodinations are required to notify the RSP prior to performing each radioiodination.

The monitoring interval represents the routine or base schedule whereby workers are assigned to report for in vivo measurements or submission of specimens for bioassay. At any time that the applicable threshold use levels are equaled or exceeded in a month, bioassays must be performed at the monitoring intervals specified in the guide. Licensees are responsible for notifying the RSP when the use of a particular radiochemical requiring bioassay monitoring has been halted, discontinued, or fallen below the monthly threshold use levels.

The threshold use levels given in the table in APPENDIX E (or otherwise determined by the particular chemical form utilized) may be modified by the RSO depending on material containment or precautionary measures taken in the use of the radiochemical. Licensees may apply for less restrictive bioassay requirements than those that appear in the guide. If the results of previous bioassay data and/or surveys for contamination show that even if any uptake has occurred, it has been negligible, then approval may be granted by the Radiation Safety Officer (RSO) but within a reasonable safety factor deemed appropriate; however, if surveys or circumstances warrant the return to the levels in the guide, these must be reinstituted. During general and simple laboratory procedures, contamination of workers is not expected to be more than 0.1 percent of the quantity of the radiochemical used in an interval of time, and this would occur to only a small fraction of laboratory workers. Rarely will processes using volatile materials be allowed in the open room without the use of a fume hood or glovebox (See Appendix J), and special conditions of licensure would then be necessary. Processes involving possible escape of volatile or dispersible materials and which are carried out within a fume hood of adequate design, face velocity, and performance reliability still require bioassay when used at the threshold use level. Those processes carried out within a glovebox, ordinarily closed, but with possible release of the volatile or dispersible materials from process containment and occasional exposure of the worker to contamination or glovebox leakage require bioassay when amounts used are at 10 times the threshold use level. With all of the factors considered, bioassays are absolutely necessary at the threshold use levels determined above unless licensees can demonstrate through repeated radiation safety audits, contamination checks by the RSP or through bioassay results, that no significant contamination or exposure from contamination has occurred in their laboratories.

Bioassays are required when contamination in laboratories is either discovered by, or reported to, the RSP. A contaminated laboratory area for bioassay purposes is defined as more than 1,000 counts per minute above background of radioactive contamination, as measured by a liquid scintillation counter (or a gamma counter or other detection instrument, when appropriate for the type of radioactive materials being measured.) When radioactive contamination of 1,000 counts per minute above background is measured by a UAB radioactive materials licensee or authorized user, the Radiation Safety Program must be notified immediately. In these circumstances, a bioassay is required for all individuals working at or near the contaminated areas in these laboratories. Also, an investigation of the operations involved should be carried out by the UAB radioactive

materials licensee to determine significant causes of the exposure and to evaluate the potential for further exposures.

Emergency bioassays are required immediately following any incident where contamination of workers is suspected. A series of diagnostic bioassays is required within a week or two following intake greater than an investigational level (causing an internal radioactivity exposure that is greater than five percent of the annual dose limit to the critical organ) to more accurately determine the committed dose equivalent from uptake of the radiochemical. As soon as possible, the cause of the exposure (once confirmed) should be referred for appropriate medical consultation and for recommendations regarding therapeutic procedures that may be carried out to accelerate the removal of the radiochemical from the body. Personnel monitoring by external counting of contaminated areas of the body and of wash or wipe samples taken from these areas are also utilized to determine the extent of exposure, particularly following spills of radiochemicals.

Documentation of Bioassay Results

Records of background count rates, control group count rates, the control group average, the standard deviations of these measurements, the minimum detectable activities, and bioassay results of studies performed shall all be maintained. Laboratory controls throughout UAB are used as a signal for any possible spread of contamination. Documentation of cumulative dose measurements is performed only for those bioassay results that are above the recording level (one-tenth the investigational level). Any bioassay result less than the recording level or less than three standard deviations above the average background control group measurement is considered as an insignificant or zero reading.

Corrective Actions

Whenever bioassay results show that radioactive materials intake is approaching a level greater than the recording level, then the monitoring frequency must be reviewed as to a need for an increase. When bioassay measurements, use of acceptable human models (such as ICRP reference man, woman, and child), and calculations show results greater than derived investigational levels, then more frequent monitoring shall be required. Also, an investigation of the operations involved should be carried out to determine significant causes of the exposure and to evaluate the potential for further exposures. Corrective actions that should eliminate or lower the potential for further exposures should be implemented. A worker may be removed from an operation when bioassay results show an uptake of a radiochemical at the intervention level. The intervention level at UAB is a level that is three times the investigational level. If the value of the uptake or rate of radiochemical uptake is predicted to give rise to an exposure above the annual limit, then such intervention is required.

XIV. STORAGE OF RADIOACTIVE MATERIAL

Each licensee must carefully designate specific locations for the storage of radioactive materials and, if possible, locate these away from the more traveled areas of the laboratory. These areas must be approved by the Radiation Safety Program prior to storage of radioactive materials. When the area of storage is located inside a laboratory or office, it must have adequate shielding to ensure that the radiation exposure rate at one foot from the surface (or plane describing the boundary) of the area of storage does not exceed 0.5 millirem per hour gamma ray and 1.5 millirem per hour beta radiation to the lens of the eyes. If the storage facility is located in an area that is open to the public, it must have adequate shielding to ensure that the radiation exposure rate at contact does not exceed 0.5 millirem per hour and the beta dose rate does not exceed 1.5 millirem per hour at contact. Storage facilities located in any area open to the public must also be kept locked at all times. Radioactive materials that are volatile or powdery or that might become airborne must be kept in a hood. All storage facilities must be labeled with the conventional radiation symbol and must bear the words "CAUTION RADIOACTIVE MATERIAL". The word "DANGER" may be used in lieu of "CAUTION" (see Appendix G).

Special Rooms set aside for radioactive waste storage that are infrequently occupied and secured from normal access by lock and key may have higher radiation levels within them. Whole body radiation levels must not exceed 5 millirems per hour and beta doses to the lens of the eyes must not exceed 15 millirem per hour at a distance of one meter from the surface of any container.

All storage containers must be labeled with a standard radiation symbol, and the identity, quantity, and assay date of the radioisotope must be on the container. No radioactive material will be allowed to be stored in a hallway -- not even temporarily awaiting authorized waste-pickup. This includes any equipment that contains radioactive materials (i.e., liquid scintillation counters). Radioactive waste must be stored in a secured area of the laboratory, well away from the more heavily traveled areas.

All radioactive materials should be stored on the side of the room away from hallways, offices and stairwells. Otherwise, sufficient shielding must be used to reduce radiation levels in these areas to 0.25 milliroentgens per hour (0.75 millirad per hour for beta radiation) for hallways and offices, and 0.5 millirem per hour for elevators and stairwells (1.50 millirad per hour beta radiation), when measured at a distance of one foot from the walls in these areas. Proper shielding must be maintained for radioactive waste in order to limit whole body exposure rates to 0.5 milliroentgen per hour at one foot from waste containers. In addition to the posting requirements cited above, all waste storage areas must be visibly posted as follows:

RADIOACTIVE WASTE
DO NOT EMPTY
TO BE PICKED UP
ONLY BY THE
RADIATION SAFETY PROGRAM

An inventory must be taken quarterly by the licensee for all sealed sources that are in storage and are either not being used or have not been used in six months.

XV. POSTING AND LABELING

UAB radioisotope licensees and registrants of x-ray and particle accelerator equipment are responsible for posting areas and labeling equipment as is necessary to comply with the applicable regulations. The Radiation Safety Program is responsible for ensuring that UAB licensees and registrants comply with these requirements. The appropriate labels and signs are available through the UAB Scientific Stores.

Signs and labels are required in the following situations.

1. Any radiation area where a major portion of the body, head, eyes, or gonads could receive in any one hour a dose in excess of 100 millirems shall be posted with a sign containing the conventional radiation symbol and the words "CAUTION HIGH RADIATION AREA." These signs shall be posted so that they can be

seen and read from any entrance to the high radiation area. Each entry to this area shall be equipped with an interlock so that upon entry by an individual, the radiation level will drop below 100 mR/hour. An audible or visible alarm shall be activated in such a manner that the individual and the supervisor shall be made aware of such entry.

2. Any radiation area where a major portion of the body, head, eyes, or gonads could receive in any one hour an exposure of five millirems is a “Radiation Area” and it shall be posted with a sign containing the conventional radiation symbol and the words "CAUTION RADIATION AREA". These signs must be posted so that they can be clearly seen by an individual near the radiation area (see Appendix G).

3. Each area or room in which radioactive material other than exempt quantities or concentrations are used or stored shall be labeled with a "CAUTION RADIOACTIVE MATERIAL" sign. This sign must also have the conventional radiation symbol (see Appendix G).

4. Each container of radioactive material in non-exempt quantities or concentrations shall be labeled with a "CAUTION RADIOACTIVE MATERIAL" label. If space permits, the radioisotope, quantity, and date of measurement shall be stated on the label or attached to the container.

5. Packages used to ship or transfer radioactive material shall be labeled according to the Radiation Safety Program's directions.

6. Each area or room containing analytical x-ray equipment shall be posted with a sign bearing the radiation symbol and the words "CAUTION X-RAY EQUIPMENT".

7. Freezers, refrigerators, or cold rooms which contain radioactive materials must be labeled "CAUTION -- NOT FOR STORAGE OF FOOD OR BEVERAGE" or with a message of similar intent.

8. Radioactive waste storage areas must be visibly posted with a sign bearing the radiation caution emblem and the words "RADIOACTIVE WASTE -- DO NOT EMPTY! – THIS WASTE IS TO BE DISPOSED OF ONLY BY HAZMAT PERSONNEL" or words of similar intent. This sign is shown in Appendix G.

9. "Radioactive material" caution labels must always be placed on containers of radioactive material in such a manner that these labels shall always be visible.

10. Radioactive stock or waste material must not be placed into any container until the container has been properly labeled.

11. Form X (notice to employees working in a restricted area) must be posted in laboratories where ionizing radiation is used.

12. UAB radioisotope licenses and radiation registrations must be posted or readily available in the laboratories where the use of ionizing radiation is authorized.

13. "Emergency Procedures in the Event of Radiation Incident" must be posted in all laboratories in which radioisotopes are used.

XVI. PROCUREMENT OF RADIOACTIVE MATERIALS

Only those persons licensed by the RRSC may receive radioactive material. To order radioactive materials, one must create a requisition in Oracle. All orders for radioactive materials at UAB MUST be processed through the Radiation Safety Office. **The laboratory must not phone in orders to the vendor.** Purchase order numbers must be acquired through Oracle and the Radiation Safety Office must place the orders. Please contact Sherri Price at 934-4751 with any questions or inquiries.

There are a few noteworthy items when entering a requisition in the Oracle system. If these items are not addressed properly, your order could be delayed. If all of the items are not filled out properly, your order could go through the wrong approval path and bypass the Radiation Safety Office.

When entering requisitions for radioactive materials in the **Requisition Header** screen:

- **Order Method: Phone** (*NOT* fax or mail). Radiation Safety phones in all radioactive material orders. If fax or mail is selected there is the possibility of duplication with the vendor.

Under the **Lines button** (at the bottom of the Requisition Header screen):

- **Category: Radioactive Material**
- **Hazard Class: RAD –** Click **Details Tab** to get to this
- **[ ]** symbol: Under this button is where you give the information of Licensee Name, Number, Quantity on Hand, etc.

Please be sure in the item description to include catalog number (example: BLU002H), description (example: P-32 dctp), and amount to order (1 x 250 uCi). Any special shipping instructions can be put in the ship to field (Fresh Lot, Ship a particular date, etc.)

Once the order is properly entered it is forwarded through the approval path (if you entered RAD in the Hazard Class section) to the Radiation Safety Office. All orders that are in our worklist by 1 p.m. are placed on that same business day. Any order after 1 p.m. is placed the following business day.

Licensees may not receive radioactive materials directly from a vendor unless given special approval by the RSO or his designate or is so approved by a condition on the UAB radioactive materials license issued to them. The total amount of the radioisotope on hand in the licensee's laboratory(ies) for the chemical form requested must be stated on the requisition. The Radiation Safety Program checks the information on the requisition to determine whether the licensee has been granted approval to receive the radioisotope in the chemical form desired and whether the amount ordered plus the amount on hand would exceed the amount stated on the license when received. If all specifications are fulfilled, the requisition is approved. Radioisotope orders are usually made via telephone by the Radiation Safety Program. In instances in which radioisotopes are needed for clinical study and care of patients, licensees may place their orders directly with the vendors in the same manner as the Radiation Safety Program, provided that prior approval concerning this has been granted by the RSO or his designate. A copy of the purchase requisition must be sent to the Radiation Safety Program regarding these orders. The Radiation Safety Program does not assume any responsibility for the material until it is delivered to the Radiation Safety Program Receiving Office.

The Radiation Safety Program personnel are available for assistance in ordering the material or equipment. Containers of radioactive material delivered to the Radiation Safety Program are wipe tested on the outside and inside of the external package and counted with an instrument capable of detecting alpha, beta, and gamma radiation. An exposure rate measurement is taken at the surface of the package on all sides and at one meter from the package on all sides. The maximum readings are recorded. Proper precautions indicated by this survey are given to the licensee when the material is delivered to licensee personnel. When licensees are approved to receive packages directly from vendors, they are required to make package surveys and maintain records as specified above.

The Radiation Safety Program maintains a log of all radioactive shipments, stating the radioisotope, the chemical form, the activity, the purchase order number, the vendor, the licensee, the date received, and the results of the wipe test and radiation survey.

As mentioned previously, some situations necessitate that radioactive materials be delivered directly to the licensee. Prior approval must be obtained from the Radiation Safety Program before the material is delivered

routinely. Before the material is used, a survey must be made to determine the radiation contamination and radiation level of the package. A log must also be kept containing the information regarding these shipments (as specified by the Radiation Safety Program), including the results of package surveys. The RSP must be notified when contamination levels of 10,000 cpm/100 cm^2 surface area of package or greater have been found.

XVII. PROCEDURES FOR WORKING WITH RADIOACTIVE MATERIAL AND RADIATION EQUIPMENT

Radioisotope Procedures

Work with radioactive material must be performed only in rooms that have been approved by the Radiation Safety Officer or his designate and the Chairman of the RRSC. Rooms that have been approved are listed on the investigator's license. Any work that may produce airborne contamination must be performed in a hood. The face velocity of hoods must range between 100 and 150 linear feet per minute. Filters may be necessary for hoods in which certain levels, chemical forms, and types of radioisotopes are used, e.g., radio-iodine or powdery radioactive material. The appropriate filters are specified by the Radiation Safety Officer or his designate. See APPENDIX J for further information regarding ventilation requirements. To reduce the probability of a costly clean-up operation, the work area should be lined with a protective covering. If liquids are involved, an absorbent material with a water-repellent backing should be used as a liner. Trays may be used in lieu of liners. When liquids are collected, the arrangement of the double flask technique shown in APPENDIX F helps minimize liquid spills and resulting contamination. If radiation gasses are known (or suspected) to be released from the liquids collected, then use of the vacuum utility lines in laboratories is prohibited. In these cases, independent vacuum lines must be used and must have prior approval by the RRSC. This is to ensure that proper ventilation is utilized in the protocol and that concentration limits are not exceeded. The particulate filter shown in the diagram in APPENDIX F must always be provided and assayed to determine the extent of any radioactive contamination released. Documentation of the results of these assays is required and must be reported to the RSP if contamination greater than 100 cpm appears on filters during daily collections. An instrument capable of detecting the radioactive material must be available to monitor the area and the hands at frequent intervals. The hands must be monitored before eating, smoking, or applying cosmetics. Eating, smoking, and applying cosmetics are not allowed in laboratories when radioactive materials are used. The laboratory area should be monitored when the work is finished or when leaving for the day, and must be monitored each day when radioisotopes are used in any areas where radioisotopes are used. These surveys must be documented no more than seven (7) days after each date of radioisotope use and when significant contamination or radiation levels are found. If the radioactive material and equipment are left unattended, a sign with the conventional radiation symbol must be posted to notify any one who may enter the area that there is work being conducted using radioactive material. All containers used to store radioactive material must be labeled with the radiation symbol; and, if the size of the container permits, the radioisotope, amount, and date should also be noted. Counting vials need not be labeled.

Pipetting of radioactive materials by mouth is prohibited. The individual must be aware of the potential hazard of internal deposition of radioisotopes from pipetting, eating, drinking, and smoking. Food containers are not permitted in the laboratory while working with radioactive materials. Refrigerators shall not be used for both foods and radioactive materials. Much of the job of preventing the spread of contamination is a matter of good housekeeping. Strive to keep the laboratory neat and clean. Also strive to keep the work area free of equipment and material not required for the immediate procedure. Fingernails should be kept short and clean. Minor skin breaks must be covered with waterproof bandages before handling any radioisotopes. Persons having deep cuts or large abrasions are not permitted to work with radioisotopes. Plastic or surgical gloves must be worn whenever working with any radioactive materials. Contaminated gloves should be washed before removal from the hands. The proper technique for removing gloves should be practiced by all radioisotope users. Double-layer plastic gloves can significantly reduce exposure to beta radiation. Laboratory coats must be worn at all times while personnel are in laboratories working with radioisotopes. Contaminated laboratory coats must be put in plastic bags and decontaminated.

XVIII. USE OF RADIONUCLIDES IN EXPERIMENTAL ANIMALS

The UAB Radiation Safety Officer or his designate and the Director of the Experimental Animal Resource Program (EAR) must be fully informed by the investigator before studies requiring the administration of radionuclides to experimental animals are undertaken. In addition, the investigator must also contact the UAB Biological Safety Officer when studies involve the use of infectious agents, chemical carcinogens, or other hazardous substances. These officials and the principal investigator must concur on aspects of containment conditions and practices essential for protection of personnel, other experimental animals, and the environment. It is imperative that no hazardous work be started until agreement is reached. Once radionuclide studies are underway, any emergency or accident involving radiation exposure or loss of containment must be reported immediately to the Radiation Safety Program, the Director of EAR, and the Biological Safety Officer. Persons performing experimental animal studies are expected to be thoroughly familiar with guidelines described in (1) the UAB Radiation Safety Procedures Manual, (2) the UAB Experimental Animal Resources Information Manual, and (3) the UAB Biosafety Manual. Research requiring the use of radionuclides (and any other hazardous agent that may be used during the course of the study) in animals must be carefully planned to minimize health risk to personnel and to prevent unwanted exposure of other experimental animals. All authorized personnel are to be given explicit instructions concerning the safety precautions and procedures to be followed. This responsibility shall rest with the investigator conducting the study. Personnel authorized to follow these procedures are expected to follow the explicit instructions given by the investigator and to conduct their work in accordance with the operating policies of Animal Services. Under certain circumstances involving high risk or technically difficult containment procedures, the investigator may also be required to assume responsibility for routine husbandry of the animals. Persons performing such husbandry must be provided with and are expected to wear protective devices (wrap-around garments, gloves, masks, etc.) as dictated by the particular hazard involved. Adequate utensils and instructions must be provided when radioactive materials are added to food or drinking water. Protection devices should also be worn during the handling of potentially hazardous materials such as necropsy material and excreta.

In studies involving radionuclides, standard animal cages, which can be readily cleaned by mechanical cage washing, are available. However, if decontamination is expected to be difficult, arrangements must be made for metabolic cages or other nonstandard caging requirements. Investigators requiring special caging not available from the University equipment pool are expected to provide appropriate caging. When high levels of radiation are anticipated, portable radiochemical glove boxes are available for housing small numbers of rodents for short periods of time. In most instances, it is preferred that animals given radioisotopes be housed in separate rooms by species and investigator. Special ventilation, surface preparation, drainage, or other room design requirements should be considered. To protect against undue radioactive contamination, all surfaces should be nonporous and easily washable. Cracks and crevices should be sealed. Rubber or vinyl tiles, or linoleum, applied over a floor provide adequate protection, since these materials are nonporous and easily removed.

Both animal rooms and cages containing radioactive animals are to be posted with "CAUTION RADIOACTIVE MATERIAL" signs, and the entrances to rooms restricted to authorized personnel. In addition, if the animals have been infected or treated with a carcinogen, the rooms and cages must be posted with "BIOHAZARD" signs. The use of volatile chemicals in Animal Resource Facilities is restricted. Investigators should check with the Director of EAR prior to bringing any volatile chemical into the Animal Resource area. Authorized animal care personnel must be provided with appropriate radiation survey equipment and personnel monitoring devices to assure their safety. Investigators must provide adequate instructions in the use of these devices. Periodic monitoring of radioactive animals and monitoring of their cages and rooms shall be conducted by investigative personnel instructed in the use of monitoring equipment. If the measured radiation exposure rate exceeds 2 mR/hour, the Radiation Safety Officer or his designate should be contacted. Routes and forms of excreted radiolabeled material must be taken into consideration in regards to safe handling of animal bedding, cages, room surfaces, and room air. Plastic-backed absorbent pads, plastic bags, and other items should be used in animal wards for containment of radioisotope spillage or waste. Animal carcasses, contaminated bedding, and equipment must be surveyed for radioactivity and provisions made for decontamination or disposal. Mechanical washing equipment used to decontaminate cage equipment should be of the type that facilitates decontamination but does not accumulate radioactive materials. For example, radioactive cages should not be washed in machines which recirculate the wash solution until after the radioactivity in the solution has decayed to an acceptable level.

The investigator is responsible for the proper disposal of radioactive wastes, decontamination of equipment, and the final decontamination of containment areas after each set of experiments. Dead animals must be placed in leakproof double-wall plastic bags which are sealed prior to removal from the containment for disposal. Animal litter must be disposed of separately in a similar manner. Filter-top cages with solid bottoms and sides must be used for transfer of rodents between buildings. The Director of EAR should be consulted regarding appropriate transfer procedures for non-rodent species. The Radiation Safety Program must be notified of all transfers of radioactive animals between radioactive materials licensees. Completed Radioactive Material Transfer forms must be submitted to the Radiation Safety Officer or his designate for written approval. For animals infected with Class 3 etiologic agents or etiologic agents not yet classified as to hazard, the Biological Safety Officer must also be notified. Only investigative personnel who are experienced animal handlers should transfer, restrain, or handle non-human primates. Investigator personnel should wear face masks and protective clothing when working with non-human primates. Each housing area should provide the necessary masks and gowns or equivalent protective devices. All persons should thoroughly wash their hands and forearms after working with these animals.

XIX. EMERGENCY PROCEDURES

A. Who to Call

In the event of an emergency involving a radiation source, contact:

1. During normal working hours, the Radiation Safety Program - 934-4751

2. During off-duty hours and on holidays, UAB Paging - 934-3411 (ask to have the Health Physicist On-Call, the Radiation Safety Officer, or the Assistant Radiation Safety Officer paged)

B. Loss of Source

In the event of a lost source, notify all personnel in the area and contact the Radiation Safety Program - 934-4751.

C. Minor Spills

1. NOTIFY: All persons in the area in which the spill occurred.

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

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

4. SURVEY: With a GM survey meter, check the area around the spill, hands, clothing and shoes for contamination.

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

D. Major Spills

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

2. PREVENT THE SPREAD: Cover the spill with absorbent pads; do not attempt to clean up. Confine the movement of all personnel potentially contaminated to prevent the spread. Prevent entry into area.

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

4. VENTILATION SYSTEM: Switch off all fans, air conditioners and hoods and close air vents and hood sashes. In some locations, maintenance will have to be called to turn off the air conditioners.

5. CLOSE THE ROOM: Leave the room and lock all doors leading to it to prevent entry and to further prevent the spread of contamination beyond the confines of the immediate room.

6 CALL FOR HELP: Notify the Radiation Safety Program immediately.

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

E. Accidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors and Gases

1. Notify all other persons to vacate the room immediately.

2. Hold breath and close escape valves, switch off air circulating devices, etc., if time permits.

3. Vacate the room.

4. Notify the Radiation Safety Program at once.

5. Ascertain that all doors giving access to the room are closed, lock if possible, and post conspicuous warnings or guards to prevent accidental opening of doors.

6. Report at once all known or suspected inhalations of radioactive materials.

F. Accidents Involving Injuries to Personnel and a Radiation Hazard

1. Protect human life. At the present time, there is no radioactive source at UAB that should prevent one from retrieving an injured person from a dangerous situation. If there is a probability of airborne radionuclides, use something to cover the mouth and nose while retrieving an injured person.

2. Call the UAB Emergency Room, the UAB Police, then the Radiation Safety Program at once.

3. Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer or his designate. Check the survey meter before use to be sure it is working properly and is not contaminated.

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

5. Report all radiation accidents involving personnel (wounds, overexposures, ingestion, inhalation) to the Radiation Safety Officer or his designate as soon as possible.

6. Protect property. The risk involved will depend on the amount of damage that may occur, and the individual may have to make an immediate appraisal of the situation.

XIX. EMERGENCY PROCEDURES (continued)

7. Prevent the spread of contamination beyond the confines of the immediate room, area, or building by:

   a. Turning off all fans and air conditioners and closing air vents.

   b. Turning off all hoods and closing the hood sashes. Maintenance personnel may have to be called.

   c. Restricting the movement of all persons suspected of being contaminated and preventing entry into the area.

   d. Closing and locking all doors leading to the scene of the accident. Post conspicuous warnings or guards to prevent accidental opening of doors.

8. Decontamination of the area shall be supervised by the Radiation Safety Officer or his designate.

XX. TRANSFER OF RADIOACTIVE MATERIAL

UAB is licensed to use radioactive material only in UAB facilities, leased or owned, located in the University College or the Medical Center Complex. Any radioactive material leaving this area must be transferred to another facility licensed by the State of Alabama Health Department, the Nuclear Regulatory Commission, or an Agreement State such as Alabama. In some instances, it may be necessary to have the UAB broad license amended by the State of Alabama Health Department before a transfer of radioisotopes can take place. Information regarding these requirements may be obtained from the Radiation Safety Program.

The Record of Radioactive Material Transfer form must be completed prior to the transfer of radioactive material within UAB facilities. These forms are available from the Radiation Safety Program. If the transfers occur at such a frequency that completion of the forms creates an undue burden on the licensee, approval may be obtained from the Radiation Safety Officer for recording transfers from the licensee's authorized locations. In transferring radioactive materials, the following steps should be observed.

1. "Record of Radioactive Material Transfer" forms must be completed and sent to the Radiation Safety Program.

2. Containers must bear a radioactive material symbol. When the size of the container permits, it must bear information as to the type of radioisotope, its amount, and the date of assay.

3. Always transport radioisotopes in shielded containers appropriate to the type of radiations emitted. Exposure rates from the containers must not exceed 10 mR/hour at three feet from the surface of the container or 200 mR/hour at contact.

4. Liquids must be wrapped in material capable of absorbing twice the volume of liquid in the container.

5. Transfers must be made directly and care taken to plan the route taken so as to minimize radiation exposure to other individuals.

6. Material to be moved over the public highways or by commercial carrier must go through the Radiation Safety Program, which must ensure proper packaging and labeling. Nuclear Medicine Sections within the UAB Medical Complex are exempted from this requirement provided that they follow proper packaging and labeling requirements.

7. A Shipping Manifest must be completed and accompany the shipment of any radioisotopes over public highways.

XXI. DISPOSAL OF RADIOACTIVE MATERIAL

All radioactive waste must be disposed of according to applicable regulatory requirements. The licensee should be aware that only limited quantities can be disposed of without obtaining commercial assistance; therefore, if two different radioisotopes are equally suited for an experiment, the shorter-lived radioisotope should be used.

A. Methods of Disposal

For UAB licensees, the following methods have been approved by the RRSC.

1. Radioisotopes which have half lives less than or equal to 90 days may be allowed to decay to background levels of radiation exposure rates and disposed through regular trash, provided that they have also decayed through at least 10 half lives and are not otherwise toxic or fire hazards. Special approval is not required to dispose of radioactive wastes in this manner. Disposal records must be maintained by the licensee indicating the exposure rates at the time of disposal as well as information giving the type of radioisotope, the date of disposal, the chemical and physical form, and the name of the person making the entry.

2. Animal tissue containing 1.85 KBq (0.05 microcuries) or less of Hydrogen-3 or Carbon-14, per gram averaged over the weight of the entire animal, may also be disposed of by regular methods. Such material may not be disposed in a manner that would permit its use as food for humans or as animal feed. The licensee must have the prior approval of the Radiation Safety Officer or his designate before such disposal takes place. The disposal records must be properly documented to demonstrate that the regulatory limits have been met.

3. All other radioactive wastes must be transferred to the Hazardous Materials Facility (HMF) for disposal. All radioactive waste containers packaged for transfer to the HMF must be properly labeled (see APPENDIX H) identifying the waste as to physical and chemical form, type of radioisotope, its activity, date of assay, the pH (if an aqueous liquid), and the name of the person making the entry.

In addition to the first two options available for UAB licensees for radioactive waste disposal, the HMF may dispose of radioactive waste by the following methods:

1. Radioactive material in soluble or readily dispersible form may be disposed of into the sanitary sewerage system as long as the limits set by the Alabama Regulations for Control of Radiation are not exceeded. Records of such disposals must be maintained by the HMF.

2. Radioactive wastes may also be disposed by incineration at the HMF provided that this has special approval of the State of Alabama, Bureau of Radiological Health.

3. Radioactive wastes may also be disposed of by transfer to a licensed facility. The packaging of the waste may be performed by a person or company licensed by the State of Alabama Health Department.

B. Radiation Surveys of Waste Packages

All packages containing radioactive materials must be surveyed, including radioactive material waste packages. The radioactive waste packages that are disposed through regular waste channels must have no radiation exposure rates above background rates. The measurements must be taken with a radiation survey meter, such as a Geiger counter, sensitive enough to detect background levels of ionizing radiation and with the window of the probe in the open position. "Background levels" of radiations are those radiation rates normally measured in areas away from where radioactive materials are stored or used. Radioactive material labels must be removed from or defaced on packages disposed in the manner described above.

C. Radioactive Waste Generation

UAB licensees must make all reasonable efforts to minimize the amount of radioactive waste generated in the laboratories. This does not mean to decrease the amount of research or laboratory work performed, but rather to look at various ways that needless radioactive waste is being generated and to take measures to prevent this from occurring. This helps to decrease the burden on the country's low level radioactive waste disposal sites.

D. Transfer of Radioactive Waste to HMF

The UAB Radioactive Waste Management Policy regarding the collection, documentation, packaging, labeling, marking, transport, and control of radioactive waste generated in UAB laboratories has the approval of the RRSC. All licensees and users of radioisotopes are required to follow this policy as long as it meets the needs and safety requirements of the applicable regulations. This policy is given in APPENDIX H, and licensees and users will be notified in advance and given copies of changes when they become necessary.

E. Unauthorized Releases to Unrestricted Areas

Any release of radioactive material above exempt amounts to unrestricted areas constitutes an unauthorized release. All such releases must be reported to the Radiological Health Branch of the State Department of Health, State of Alabama. Unauthorized releases to the sanitary sewage system cannot be recovered; however, with proper notification, accidental releases to regular trash receptacles may be recoverable. Releases of this type have occurred and will occur, but UAB personnel must make every reasonable effort to minimize their occurrences and strive to retrieve them when they do occur. In order to minimize or otherwise prevent occurrences of unauthorized releases to regular trash, the RRSC has adopted a policy (given below) regarding unauthorized releases. In the opinion of the members of the RRSC, more should be expected of the personnel responsible for the unauthorized releases in the recovery operations conducted by the RSP.

1. In situations where licensees or individuals working under their license are responsible for the release, they should:

    a. Immediately notify the RSP of any suspected loss of radioactive material.

    b. Participate in the recovery operation, when asked to do so. This would include a search of the disposal route taken by the released material and even, possibly, a trip to the sanitary landfill for final recovery.

    c. Be informed that the RRSC strongly suggests that they participate in the search if they refuse to do so.

    d. Be requested to attend the next scheduled RRSC meeting to plead their cases if there is further refusal on their part.*

2. In situations where individuals who do not work under a radioactive materials license are responsible for the release, they should:

    a. Participate in the recovery operation.

    b. Be scheduled for consultation with the UAB Personnel Department.

    c. Receive proper instruction regarding radioactive materials control.

XXI. DISPOSAL OF RADIOACTIVE MATERIAL (continued)

E. Unauthorized Releases to Unrestricted Areas (continued)

* The individuals involved may have a legitimate reason for not actively participating in the recovery operation. If they do not otherwise show some willingness to participate, they may risk losing their right to work with radioactive materials or possess a radioactive materials license.

XXII. SOURCES OF CONCERN

Sources of Concern (**SofC**) have been defined by the United States Nuclear Regulatory Commission and the Alabama Department of Public Health, Office of Radiation Control, and these are sources of ionizing radiation from materials which are radioactive that require extra precautions. All of the **SofC** are contained within devices that are intended to prevent direct access to them. There is no primary beam of radiation directed from any of these devices, and the radiation levels exterior to these devices are nearly at natural background levels.

As required by regulations, **SofC** have extra security precautions intended to prevent unescorted access to them. Authorized users who desire unescorted access to **SofC** must pass a background check. For more information about **SofC**, including how to be approved for unescorted access to **SofC**, call the UAB Radiation Safety Program at 934-4751.

APPENDIX A

UAB RADIATION SAFETY COMMITTEES

Radioisotope and Radiation Safety Committee

Banks, Christi, RN	Heart & Vascular Ctr	JT N664	4-4522
Bernhard, Steve, R.Ph.	University Hospital Pharm	1728 JT	4-3488/2162
Bowman, Kathy W., R.N.	Nurse Manager/Rad Onc	WTI 6832	4-5671
Boyd, Katherine, M.S., CHP	BVAMC RSO	2C159 VA	12-6610
Brezovich, Ivan, Ph.D.	Radiation Oncology	WTI 119A	4-1758
Brinkley, Bradley M.S., MBA, RSO	Radiation Safety	CH19 445	4-7418
Daily, Sandra, RN	Nurse Mgr, Periop. Svcs.	NP	4-2252
Durboraw, Earle, CSP	Animal Resources Program	B10F VH	4-3538
Greenup, Patsy, E., Ph.D.	Clinical Lab Sciences	RMSB 432	4-5995
Henry, Marilyn, MSN, RN	Hospital Administration	MEB 300	5-0287
Kim, Robert Y., M.D.	Radiation Oncology	WTI 120	4-1788
Martin, James C., Ph.D.	Physics	CH 344	8090/4736
Nath, Hrudaya, M.D.	Radiology-Cardio	JT N370	4-5345
O'Malley, Janis, M.D.	Radiology/NucMed	QT 214C	4-1388
Richard, Max L., M.P.H.	Health & Safety	CH19 445	4-2487
Wills, Edward L., Ph.D.	Physics	CH 305	4-5347
Yester, Michael, Ph.D.	Radiology-Nuclear Med.	301F GSB	4-3213
Zinn, Kurt R., D.V.M., M.S., Ph.D., Chair	Hem Onc	BDB 802	5-6414

Subcommittee for Laboratory Use

Wills, Edward L., Ph.D., Chair	Physics	CH 305	4-5347
Brinkley, Bradley M.S., MBA, RSO	Radiation Safety	CH19 445	4-7418
Durboraw, Earle	Animal Resources Program	B10F VH	4-3538
Martin, James C., Ph.D.	Physics	CH 344	4-8090
Zinn, Kurt R., D.V.M., M.S., Ph.D.	Hem Onc	BDB 802	5-6414

Subcommittee for Human Use

Brinkley, Bradley M.S., MBA, RSO	Radiation Safety	CH19 445	4-7418
Bernhard, Steve, R.Ph.	University Hospital Pharm	1728 JT	4-3488
Brezovich, Ivan, Ph.D.	Radiation Oncology	WTI 119A	4-1758
Kim, Robert Y., M.D.	Radiation Oncology	WTI 120	4-1788
Nath, Hrudaya, M.D.	Radiology-Cardio	JT N370	4-5345
O'Malley, Janis, M.D.	Radiology/NucMed	QT 214C	4-1388
Yester, Michael, Ph.D.	Radiology-Nuclear Med.	301F GSB	4-3213
Zinn, Kurt R., D.V.M., M.S., Ph.D., Chair	Hem Onc	BDB 802	5-6414

APPENDIX A (Continued)

Radioactive Drug Research Committee (Inactive)

Brinkley, Bradley M.S., MBA, RSO	Radiation Safety	CH19 445	4-7418
Bernhard, Steve, R.Ph.	University Hospital Pharm	1728 JT	4-3488
Brezovich, Ivan, Ph.D.	Radiation Oncology	WTI 119A	4-1758
Kim, Robert Y., M.D.	Radiation Oncology	WTI 120	4-1788
Nath, Hrudaya, M.D.	Radiology-Cardio	JT N370	4-5345
O'Malley, Janis, M.D.	Radiology/NucMed	QT 214C	4-1388
Yester, Michael, Ph.D.	Radiology-Nuclear Med.	301F GSB	4-3213
Zinn, Kurt R., D.V.M., M.S., Ph.D., Chair	Hem Onc	BDB 802	5-6414

Radiochemical Bioassay Committee

Brinkley, Bradley M.S., MBA, RSO	Radiation Safety	CH19 445	4-7418
Martin, James C., Ph.D.	Physics	CH 344	4-8090
Wills, Edward L., Ph.D.	Physics	CH 305	4-5347

Subcommittee to Review Radiation Exposure

Yester, Michael, Ph.D.	Radiology-Nuclear Med.	301F GSB	4-3213
Brinkley, Bradley M.S., MBA, RSO	Radiation Safety	CH19 445	4-7418
Nath, Hrudaya, M.D.	Radiology-Cardio	JT N370	4-5345

APPENDIX B

CRITERIA FOR APPROVAL OF HUMAN USE STUDIES IN RADIOACTIVE DRUG RESEARCH

Section I. Criteria for Dose Limits of Radioactive Drugs in Humans

1. The subject shall receive the smallest radiation dose with which it is practical to perform the study without jeopardizing the benefits to be obtained from the study.

2. Under no circumstances may the radiation dose to an adult research subject from a single study or cumulatively from a number of studies conducted within one year be generally recognized as safe if such dose exceeds the following:

	Rems
Whole body, active blood-forming organs, lens of the eye, and gonads	
Single dose.	3
Annual dose and total dose commitment.	5
Other organs	
Single dose.	5
Annual dose and total dose commitment.	15

3. For research subjects under 18 years of age at their last birthday, the radiation dose shall not exceed 10 percent of the above limits.

4. All radioactive material included in the drug, either as essential material or as a significant contaminant or impurity, shall be included when determining the total radiation doses and dose commitments.

5. Radiation doses from x-ray procedures that are part of the research study (i.e., would not have occurred but for the study) shall also be included in determining the total radiation dose and dose commitments.

6. The possibility of follow-up studies shall be considered for inclusion in the dose calculations.

7. Numerical definitions of dose shall be based on an absorbed fraction method of radiation absorbed dose calculation, such as the system set forth by the Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine, or the system set forth by the International Commission on Radiological Protection.

Section II. Criteria for Selection and Consent of Human Subjects

1. The research subject shall be at least 18 years of age and legally competent. Exceptions are permitted only in those special situations when it can be demonstrated to the committee that the study presents a unique opportunity to gain information not presently available and requires the use of research subjects less than 18 years of age and is without significant risk to the subject.

2. Studies involving minors shall be supported with review by qualified pediatric consultants to the Radioactive Drug Research Committee.

3. Each female research subject of child-bearing potential shall, on the basis of a pregnancy test, be confirmed as not pregnant before she may participate in any study.

Section II. Criteria for Selection and Consent of Human Subjects (Continued)

4. Each investigator shall select appropriate human subjects and obtain the consent of the subjects or their representatives in accordance with 310.102 of Chapter I, Title 21 CFR.

Section III. Criteria for the Physician User

1. The physician user must have the specific approval of the Radioisotope and Radiation Safety Committee. This Committee reviews these requests on the basis of the specific criteria given in Appendix I.

APPENDIX C

TOPICS OF INSTRUCTION FOR OPERATORS OF PARTICLE ACCELERATORS

I. Fundamentals of Radiation Safety

- A. Characteristics of alpha, beta, gamma, neutrons, and X-radiation
- B. Units of radiation dose (millirems) and quantity of radioactivity (Becquerels or Curies)
- C. Biological effects of radiation
- D. Methods of controlling radiation dose
  1. Working time
  2. Working distance
  3. Shielding

II. Radiation Detection Instrumentation to be Used

- A. Use of radiation survey instruments
  1. Operation
  2. Calibration
  3. Limitations
- B. Survey Techniques
  1. Methods of surveys
  2. Records which must be made and retained
- C. Use of personnel monitoring equipment

III. Operation and Control of Particle Accelerators

IV. Requirements of State Regulations

V. Registrant's Written Operating and Emergency Procedures

APPENDIX D

GUIDE FOR EXTERNAL RADIOISOTOPE MONITORING

THRESHOLD QUANTITIES IN MILLICURIES

		EXTREMITY DOSE	EYE DOSE	WHOLE BODY DOSE	SKIN DOSE
Bromine-82	A	10	50	2.4	25
	B	2	50	2.4	25
Cadmium-109	A	No	No	No	No
	B	"	"	"	"
Calcium-45	A	No	No	No	No
	B	"	"	"	"
Carbon-14	A	No	No	No	No
	B	"	"	"	"
Cerium-139	A	No	No	No	No
	B	"	"	"	"
Cerium-141	A	320	1,440	80	800
	B	50	1,440	80	800
Chlorine-36	A	160	No	No	No
	B	16	No	No	No
Chromium-51	A	1,000	3,600	200	2,000
	B	160	3,600	200	2,000
Cobalt-57	A	160	600	200	325
	B	30	600	200	325
Cobalt-60	A	10	50	2.4	25
	B	2	50	2.4	25
Hydrogen-3	A	No	No	No	No
	B	"	"	"	"
Iodine-125	A	150	480	30	266
	B	25	480	30	266
Iodine-131	A	60	240	16	125
	B	10	240	16	125
Indium-114m	A	800	2,400	160	1,250
	B	125	2,400	160	1,250
Iron-55	A	No	No	No	No
	B	"	"	"	"
Iron-59	A	5.0	70	3.2	40
	B	0.5	15	3.2	40
Krypton-85	A	No	No	No	No
	B	"	"	"	"
Molybdenum-99	A	10	144	16	80
	B	1	144	16	80
Nickel-63	A	No	No	No	No
	B	"	"	"	"
Niobium-95	A	35	120	8	60
	B	5	120	8	60
Phosphorus-32	A	8	480	No	No
	B	1	480	"	"
Phosphorus-33	A	No	No	No	No
	B	"	"	"	"

GUIDE FOR EXTERNAL RADIOISOTOPE MONITORING

THRESHOLD QUANTITIES IN MILLICURIES

		EXTREMITY DOSE	EYE DOSE	WHOLE BODY DOSE	SKIN DOSE
Platinum-195m	A	No	No	No	No
	B	"	"	"	"
Potassium-42	A	1	4.8	16	2.5
	B	0.16	4.8	16	2.5
Radium-226	A	16	72	3.2	40
	B	3.2	72	3.2	40
Rubidium-86	A	5.0	360	64	200
	B	0.5	360	64	200
Ruthenium-103	A	No	No	No	No
	B	"	"	"	"
Scandium-46	A	10	48	2.4	25
	B	2	48	2.4	25
Sodium-22	A	10	48	2.4	25
	B	2	48	2.4	25
Sodium-24	A	5	24	0.8	13
	B	0.5	24	0.8	13
Strontium-85	A	50	190	8	100
	B	10	190	8	100
Sulfur-35	A	No	No	No	No
	B	"	"	"	"
Technetium-99	A	No	No	No	No
	B	No	No	No	No
Technetium-99m	A	190	500	40	250
	B	35	500	40	250
Tin-113	A	250	960	64	500
	B	50	960	64	500
Vanadium-48	A	10	10	2.4	25
	B	2	10	2.4	25
Xenon-133	A	No	No	No	No
	B	"	"	"	"
Ytterbium-169	A	100	360	16	200
	B	20	360	16	200
Yttrium-88	A	10	50	2.4	25
	B	20	50	2.4	25
Zinc-65	A	50	240	8	125
	B	10	240	8	125

A. Specified for general laboratory procedures when handling of stock solutions and mixing vials is not prolonged.
B. Specified for techniques such as sterile procedures which cause prolonged handling times.

The rationale used to determine the values to be used as guidelines for personnel monitoring are described below for the different types of monitoring involved. The values represent licensed amounts of radioisotopes which, if an individual were to use, would give approximately 10 percent of the maximum permissible limits of radiation exposure. Use is based on a scenario of times and distances from unshielded radioisotopes encountered in laboratories. Exposure from shielded radioisotopes kept at the limiting exposure rates allowed in the laboratories does not affect the calculated values.

Extremity and/or Skin Dose (or Shallow Dose)

These doses were calculated assuming actual hand contact with vials containing radioactive materials. (Hand contamination was not considered since plastic gloves are required to be worn and hands to be monitored after radioisotope use.) Two situations involving vial quantities of activity were considered: stock vials of millicuries (37 MBq) quantities and vials or containers of 10 microcurie (0.37 MBq) quantities. A uniform vial size of 2.6 cm in diameter and 2.6 cm in height and containing a liquid solution of 10 milliliters was used in the calculations. The dose to the fingers of the hand was calculated at a distance of 0.75 cm from the surface of the vial. Times of exposure were based on two situations. Normal handling time was estimated at 12 minutes a year for unshielded stock solutions and 120 minutes a year for vials containing 10 microcuries (0.37 MBq) or less of activity. Meticulous handling procedures involving longer handling time (such as sterile injections into research animals, etc.) were considered to take ten times longer than normal handling.

Skin dose equivalents were calculated for the maximum dose equivalent in the body from a depth of 0.07 mm to 10 mm depth. In most situations involving beta and low energy x-ray radiation, this will occur near the 0.07 mm depth in the skin. Allowances are made for self-absorption in the source medium, attenuation in container walls, air, and the epidermis (dead layer) of the skin. No considerations were given to dose averaging radiation scattering within the whole body.

Eye Dose Equivalents

Eye dose equivalents were calculated for the maximum dose equivalent to the lens of the eye from a tissue depth of 0.3 cm (300 mg/cm^2). In most situations involving beta and low energy x-ray radiation, this will occur near the 0.3 cm depth in the eye. Allowances are made for self-absorption in the source medium, attenuation in container walls, air, and the cornea of the eye.

Whole Body Doses

These doses were calculated based on the scenario that the researcher would take a stock solution out of its shielding container and place it on a counter at a distance of one foot from the body. Since the researcher may forget to quickly return stock vials to shielded storage, the estimated doses relate to the stock amounts (also all of the vials of smaller amounts will total to the amount taken from stock containers). Prolonged handling may be expected to give some additional dose (approximately 11 percent to the skin or whole body) at the one and two unit distances considered (distances in feet) but was not included in the dose estimates. The accumulative doses for the two handling times below were used to determine the values in the guide:

1. It is assumed that exposure would occur at a distance of one foot from the whole body for 20 hours during the year.
2. It is assumed that exposure would occur at a distance of two feet from the whole body for 200 hours during the year.

If the radiation is absorbed significantly beyond the 10 mm depth of the skin, it is considered a whole-body deep dose. No considerations were given to dose averaging radiation scattering within the whole body.

APPENDIX E

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Barium-133			
Ingestion Route			
All compounds	15	2.56 uCi whole body	Semiannually
Inhalation Route			
All compounds	5	2.87 uCi whole body (3.77 uCi lungs)	Semiannually (*3)
Bromine-82			
Ingestion Route			
All compounds	25	7.2	Biweekly
Inhalation Route			
All compounds			
Bromides, Class D	30	7.81 (96.2 uCi lungs)	Biweekly (*3)
Bromides, Class W	500	9.09 (206 uCi lungs)	Biweekly (Biannually)
Cadmium-109			
Ingestion Route			
All inorganic compounds	2.5	0.75 uCi kidneys	Quarterly
Inhalation Route			
Oxides and Hydroxides	0.8	1.35 uCi lungs (0.076 uCi kidneys)	Semiannually
Sulfides, halides and nitrates	0.8	0.96 uCi lungs	Semiannually
All other compounds	0.4	0.076 uCi kidneys	Semiannually
Calcium-45			
Ingestion Route			
All compounds	15	0.073	Monthly
Inhalation Route			
All compounds	5	0.060	Monthly

APPENDIX E (Continued)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Carbon-14			
Ingestion Route			
Organic compounds	15	0.025	Semiannually
Inhalation Route			
Organic Compounds	15	0.025	Semiannually
Carbon dioxide	1500	0.063 urine 125 exhaled air	Semiannually (*3)
Carbon monoxide	1500	6.46 exhaled air	(*3)
Cerium-139			
Ingestion Route			
All compounds	40	0.0013 uCi liver	Semiannually
Inhalation Route			
Oxides, hydroxides and fluorides	6	6.20 uCi lungs	Semiannually
All other compounds	6	43.9 uCi lungs	Semiannually
Cerium-141			
Ingestion Route			
All compounds	15	0.0043 uCi liver	Bimonthly
Inhalation Route			
Oxides, hydroxides and fluorides	5	6.19 uCi lungs	Semiannually
All other compounds	5	9.57 uCi lungs	Semiannually

APPENDIX E (cont'd)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Chlorine-36			
Ingestion Route			
All compounds	15	3.5	Quarterly
Inhalation Route			
Class D chlorides	15	3.5	Quarterly
Class W chlorides	15	0.087 (2.3 uCi lungs)	Bimonthly
Chromium-51			
Ingestion Route			
In trivalent state (i.e., CrC13 or Cr203)	300	0.12	Bimonthly
In hexavalent state (i.e., Cr04)	300	1.27	Quarterly
Inhalation Route			
Oxides and hydroxides	150	0.29 (199 uCi lungs)	Quarterly
Halides and nitrates	150	1.32 (277 uCi lungs)	Semiannually
All other compounds	400	19.4 (926 uCi lungs)	Semiannually (*3)
Cobalt-57			
Ingestion Route			
Oxides and hydroxides and other inorganics in tracer amounts	30	1.0	Semiannually

APPENDIX E (cont'd)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Cobalt-57			
Ingestion Route			
Other inorganics in presence of carrier amounts and complexed organically compounds	60	0.13	Quarterly
Inhalation Route			
Oxides, hydroxides, halides, and nitrates	5	6.19 uCi lungs (0.0051)	Semiannually (Biweekly)
Other compounds	25	25.7 uCi (0.12)	Semiannually (Quarterly)
Cobalt-60			
Ingestion Route			
Oxides and hydroxides and other inorganics in tracer amounts	1.0	0.036	Biweekly
Other inorganics in presence of carrier amounts and complexed organically compounds	2.0	0.049	Monthly
Inhalation Route			
Oxides, hydroxides, halides and nitrates	0.025	0.31 uCi lungs	Semiannually
Other compounds	0.25	2.91 uCi lungs (0.013)	Semiannually (Biweekly)
Gold-198			
Ingestion Route			
All compounds	15	0.26	Weekly

APPENDIX E (cont'd)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Gold-198			
Inhalation Route			
Oxides and hydroxides	50	0.37 (24.5 uCi lungs)	Biweekly
Halides and nitrates	50	1.40 (28.5 uCi lungs)	Biweekly
All other compounds	20	1.49 (6.82 uCi lungs)	Biweekly (*3)
Hydrogen-3			
Ingestion Route			
All compounds	100(*4)	90	Monthly
Inhalation Route			
All compounds	100(*4)	90	Monthly
Iodine-125			
Ingestion Route			
All compounds	0.3	0.36 uCi thyroid	Quarterly
Inhalation Route			
All compounds	0.5	0.55 uCi thyroid	Quarterly
Iodine-131			
Ingestion Route			
All compounds	0.25	0.25 uCi thyroid	Monthly
Inhalation Route			
All compounds	0.4	0.42 uCi thyroid	Monthly

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Indium-114m			
All other compounds	2	0.81 uCi whole body (0.30 uCi lungs)	Semiannually (*3)
Iron-55			
Ingestion Route			
All compounds	300	0.012 uCi solids	Annually
Inhalation Route			
Oxides, hydroxides, and halides	500	0.0095 uCi solids	Annually
All other compounds	300	0.0012 uCi solids	Annually
Iron-59			
Ingestion Route			
All compounds	6	0.19 uCi liver 2.4 uCi whole body	Semiannually
Inhalation Route			
Oxides, hydroxides and halides	2.5	7.54 uCi lungs 9.80 uCi whole body	Semiannually
All other compounds	4	12.0 uCi whole body	Semiannually (*3)
Krypton-85	(*5)	(*5)	(*5)

APPENDIX E (cont'd)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Lead-210			
Ingestion Route			
All compounds	.01 uCi	0.0037 uCi whole body	Biweekly
Inhalation Route			
All compounds	3 uCi	0.0038 uCi whole body	Weekly
Manganese-54			
Ingestion Route			
All compounds	15	7.1 uCi whole body	Semiannually
Inhalation Route			
Oxides, hydroxides, halides, and nitrates	6	15.7 uCi lungs	Semiannually
All other compounds	7.5	39.8 uCi whole body (14.7 uCi lungs)	Semiannually (*3)
Molybdenum-99			
Ingestion Route			
Sulfides	8	0.0033 0.22 uCi liver	Weekly
All other compounds	15	0.24 15.7 uCi liver	Biweekly
Inhalation Route			
Sulfides, oxides and hydroxides	8	19.2 uCi lungs	Biweekly
All other compounds	25	8.30 (39.5 uCi lungs)	Biweekly (*3)
Nickel-63			
Ingestion Route			
All compounds	75	0.00044 uCi solids	Annually
Inhalation Route			
Oxides, hydroxides, and carbide	15	0.0014 uCi solids	Annually
All other compounds	25	0.0062 uCi solids	Annually

APPENDIX E (cont'd)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Niobium-95			
Ingestion Route			
All compounds	15	0.012 0.51 uCi whole body	Biweekly
Inhalation Route			
Oxides and hydroxides	8	12.7 uCi lungs (0.035)	Semiannually (Biweekly)
All other compounds	8	19.2 uCi lungs (0.11)	Semiannually (Monthly)
Phosphorus-32			
Ingestion Route			
All compounds	5	0.048	Bimonthly
Inhalation Route			
Class W phosphates	3	0.023 (4.2 uCi lungs)	Bimonthly
All other compounds	7	0.048 (4.1 uCi lungs)	Bimonthly (*3)
Phosphorus-33			
Ingestion Route			
All compounds	50	0.76	Quarterly
Inhalation Route			
Class W phosphates	25	0.14	Bimonthly
All other compounds	65	0.77	Quarterly

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Platinum-195m			
Ingestion Route			
All compounds	15	0.028 uCi kidneys	Biweekly
Inhalation Route			
All compounds	30	6.45 uCi kidneys	Monthly
Polonium-210			
Ingestion Route			
All compounds	25 uCi	0.046 uCi mouth & hand surface	Weekly
Inhalation Route			
Oxides, hydroxides, and nitrates	5 uCi	0.016 uCi nasal passage	Weekly
All other compounds	5 uCi	0.0092 uCi nasal passage	Weekly
Potassium-42			
Ingestion Route	2.5	1.57	Weekly
Inhalation Route	3	0.81	Weekly
Radium-226			
Ingestion Route			
All compounds	15 uCi	0.012 uCi whole body	Quarterly
Inhalation Route			
All common compounds	5 uCi	0.54 uCi whole body (0.0068 uCi lungs)	Bimonthly

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Rubidium-86			
Ingestion Route			
All compounds	4	0.18	Quarterly
Inhalation Route			
All compounds	6	0.18 (10.9 uCi lungs)	Quarterly (*3)
Ruthenium-103			
Ingestion Route			
All commonly occurring compounds	15	0.33 uCi whole body	Semiannually
Inhalation Route			
Oxides and hydroxides	15	6.86 uCi whole body (6.59 uCi lungs)	Semiannually
Halides	8	13.1 uCi whole body (10.7 uCi lungs)	Semiannually
All other compounds	15	38.1 uCi whole body (34.3 uCi lungs)	Semiannually (*3)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Scandium-46			
Ingestion Route			
All compounds	7.5	0.0020 uCi whole body	Quarterly
Inhalation Route			
All commonly occurring compounds	1.5	2.29 uCi lungs	Semiannually
Sodium-22			
Ingestion Route			
All compounds	3	0.58 15.7 uCi whole body	Quarterly
Inhalation Route			
All compounds	5	0.58 25.0 uCi whole body (9.3 uCi lungs)	Quarterly (*3)
Sodium-24			
Ingestion Route			
All compounds	30	6.73 183 uCi whole body	Weekly
Inhalation Route			
All compounds	40	7.51 322 uCi whole body (119 uCi lungs)	Weekly (*3)
Strontium-85			
Ingestion Route			
All soluble salts	25	0.54 (18.0 uCi whole body)	Monthly (Quarterly)
SrTiO3	25	0.019 (0.62 uCi whole body)	Weekly (Monthly)
Inhalation Route			
All soluble salts	25	21.1 uCi whole body (0.64)	Seminannually (Bimonthly)
SrTi03	15	14.7 uCi lungs (0.0027)	Semiannually (*3)

APPENDIX E (cont'd)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Strontium-90			
Ingestion Route			
All soluble salts	50	0.061 uCi whole body	Quarterly
SrTi03	0.5	0.43 uCi whole body	Quarterly
Inhalation Route			
All soluble salts	50	0.088 uCi whole body	Quarterly
Sulfur-35			
Ingestion Route			
Elemental form	50	0.028	Bimonthly
All inorganic compounds	80	0.085	Quarterly
All organic compounds	(*6)	(*6)	(*6)
Inhalation Route			
Elemental form and all inorganic compounds	160	0.049	Quarterly
Organic compounds	(*6)	(*6)	(*6)
S02,COS,H2S, and CS2 gases	80	1.82	Semiannually
Technetium-99			
Ingestion Route			
All compounds	30	0.024	Quarterly
Inhalation Route			
Oxides, hydroxides, halides, and nitrates	5	0.0024	Monthly
All other compounds	50	0.024	Quarterly

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Technetium-99m			
Ingestion Route			
All compounds	600	225 uCi stomach	Weekly
Inhalation Route			
Oxides, hydroxides, halides, and nitrates	1500	3400 uCi lungs 267 uCi stomach	Weekly
All other compounds	1500	486 uCi stomach (3000 uCi lungs)	Weekly (*3)
Tin-113			
Ingestion Route			
All compounds	15	0.20 uCi whole body	Semiannually
Inhalation Route			
Sulfides, oxides, hydroxides, halides, nitrates and stannic phosphates	4	6.58 uCi whole body (5.86 uCi lungs)	Semiannually
Tin-113			
All other compounds	8	12.9 uCi whole body (10.0 uCi lungs)	Semiannually (*3)
Vanadium-48			
Ingestion Route			
All compounds	5	0.047 uCi whole body	Bimonthly
Inhalation Route			
Oxides, hydroxides, carbides, and halides	5	10.3 uCi whole body (9.6 uCi lungs)	Semiannually
All other commonly occurring compounds	8	4.3 uCi whole body	Semiannually
Xenon-133	(*5)	(*5)	(*5)

GUIDE FOR INTERNAL RADIOCHEMICAL MONITORING

Radiochemical*	Threshold Use Level (mCi)	Derived Investigational Level (uCi/l)**	Monitoring Interval
Ytterbium-169			
Ingestion Route			
All compounds	15	0.0046 uCi whole body	Bimonthly
Inhalation Route			
Oxides, hydroxides, and fluorides	6	7.54 uCi lungs	Semiannually
All other commonly occurring compounds	6	12.7 uCi whole body (11.3 uCi lungs)	Semiannually
Yttrium-88			
Ingestion Route			
All compounds	25	0.0020 uCi whole body	Bimonthly
Inhalation Route			
Oxides and hydroxides	5	7.7 uCi whole body (6.6 uCi lungs)	Semiannually
Yttrium-88			
All other compounds	10	3.0 uCi lungs	Semiannually
Zinc-65			
Ingestion Route			
All compounds	15	0.0040	Quarterly
Inhalation Route			
All commonly occurring compounds	10	6.86 uCi whole body (5.02 uCi lungs)	Semiannually

REFERENCE NOTES TO APPENDIX E

* The radiochemical forms or groupings given here are according to those recommended by the International Commission on Radiological Protection and for which committed dose equivalents were calculated based on reference man. Inhaled radiochemicals are considered to be in the form of aerosols unless specifically given as gasses. When a class designation (i.e., Class W) for aerosols appears, refer to Table 1 at the end of the guide.

** The values given in this column are the expected warning levels for hypothetical bioassays of a reference male immediately following a contaminating event (an investigational level of intake that would cause an internal dose at one-twentieth of the annual limit) for each radiochemical. The numbers that appear without units represent daily warning levels shown either by urine assays or assays of exhaled air from a reference man. It is reasonable not to allow any higher values in women (and children) for these warning levels since the radiation doses are measured in specific quantities (absorbed energy per gram tissue). Those values given in specific quantities such as microcurie (37 KBq) whole body, kidneys, lungs, or liver represent activity warning levels in those portions of the reference man body. Differences should be taken into account when body weights are significantly different from reference man. Reference women and children values should be determined when applicable in cases of exposure immediately below these levels. Those values given as microcurie (37 KBq) solids represent the only practical type of assay available for non-transportable radiochemicals and are the warning levels of activity for a one-day, solid elimination from the body.

*3 Special urine assays should be conducted only at times immediately following suspected exposures.

*4 This is a requirement of the Radiation Control Division of the Bureau of Health Care Standards, State of Alabama. For this radiochemical no higher threshold use level is allowable by them above which internal monitoring begins and below which it is not required routinely.

*5 Internal monitoring is unnecessary since very little krypton-85, xenon-133, or other radioactive noble gasses (except for daughter products of Radon-222 and Radon-220) are absorbed within the human body. Personnel monitoring is performed externally only.

*6 Most organic compounds with sulfur are tenaciously retained by the body. The need for any special bioassays would be reviewed by the Subcommittee for Laboratory Use of the UAB Radioisotope and Radiation Safety Committee as necessary.

Table 1 Pulmonary clearance classification of inorganic compounds

Class Y-Avid retention: cleared slowly (years)
- Carbides-actinides, lanthanides, Zr, Y, Mn
- Sulfides-none
- Sulfates-none
- Carbonates-none
- Phosphates-none
- Oxides and hydroxides, lanthanides, actinides Groups 8 (V and VI), lb, 2b (IV and V), 3b except Sc+3, and 6b
- Halides-lanthanide fluorides
- Nitrates-none

Class W-Moderate retention: intermediate clearance rates (weeks)
- Carbides-Cations of all Class W hydroxides except those listed as Class Y carbides
- Sulfides-Groups 2a (V + VI), 4a (IV-VI), 5a (IV-VI), lb, 2b and 6b (V + VI) Sulfates-Groups 2a (IV-VII) and 5a (IV-VI)
- Carbonates-lanthanides, Bi and Group 2a (IV-VII)
- Phosphates-Zn^{2+}, Sn^{3+}, Mg^{2+}, Fe^{3+}, Bi^{3+}, and lanthanides
- Oxides and hydroxides-Groups 2a (II-VII), 3a (III-VI), 4a (III-VI), 5a (IV-VI), 6a (IV-VI), 8, 2b (VI), 4b, 5b, and 7b Sc
- Halides-lanthanides (except fluorides), Groups 2a, 3a (III-VI), 4a (IV-VI), 5a (IV-VI), 8, lb, 2b, 3b (IV-V), 4b, 5b, 6b and 7b
- Nitrates-all cations whose hydroxides are Class Y and W

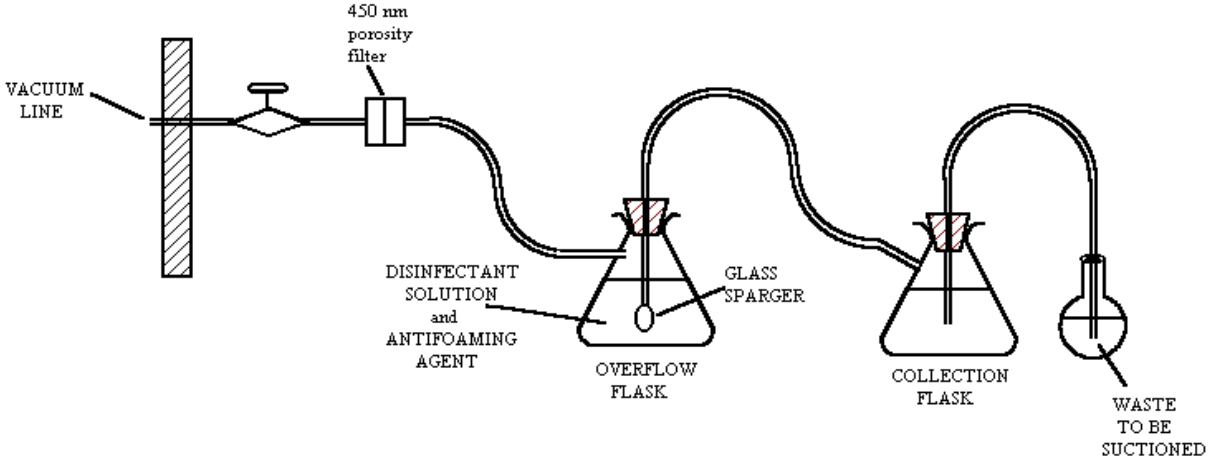
Class D-Minimal retention: rapid clearance (days)
- Carbides-see hydroxides
- Sulfides-all except Class W
- Sulfates-all except Class W
- Carbonates-all except Class W
- Phosphates-all except Class W
- Oxides and Hydroxides-Groups 1a, 3a (II), 4a (II), 5a (II, III), 6a (III) Halides-Groups 1a and 7a
- Nitrates-all except Class W

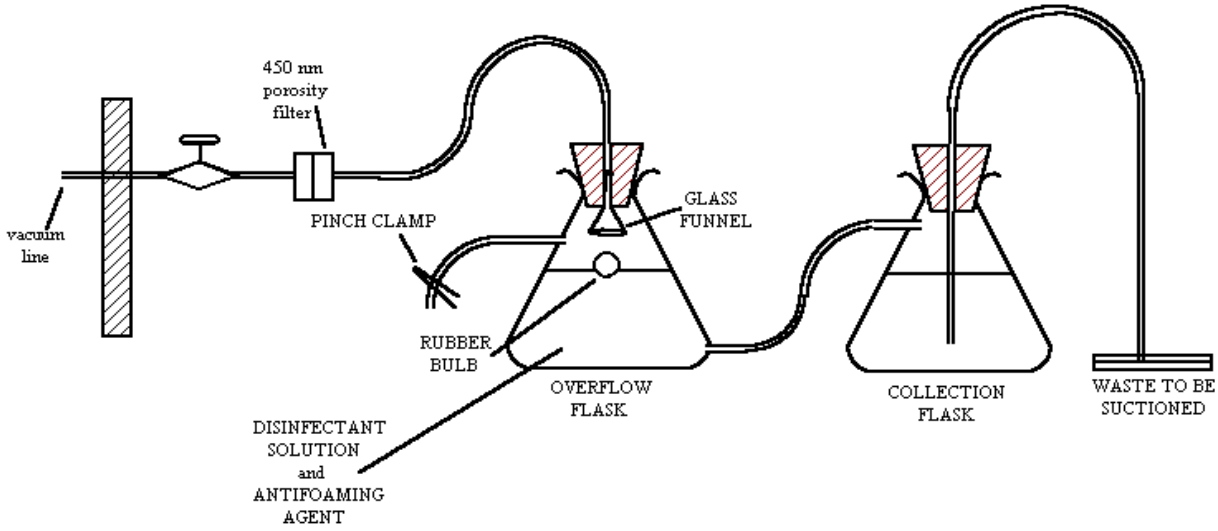
Noble Gases-Group 0

Note: Where reference is made from one chemical form to another, it implies that an in vivo conversion occurs, e.g. hydrolysis reaction.

APPENDIX F

LIQUID COLLECTION TECHNIQUE TO MINIMIZE SPILLS AND CONTAMINATION

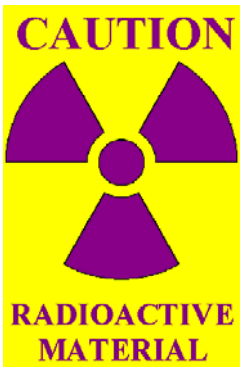


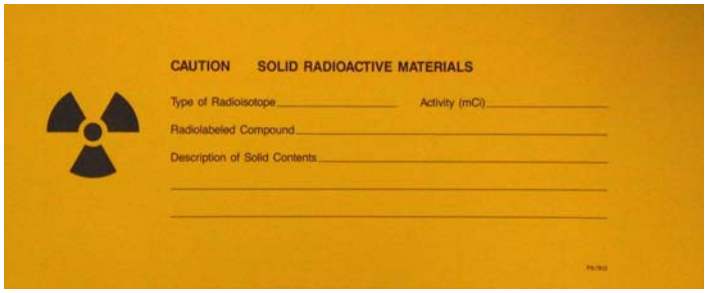


TWO TECHNIQUES FOR PROTECTING VACUUM SYSTEM FROM CONTAMINATION

APPENDIX G

AREA WARNING SIGNS, DOT SHIPPING LABELS, AND RADIOACTIVE WASTE AREA SIGNS





APPENDIX H

RADIOACTIVE WASTE MANAGEMENT AT UAB

Due to requirements of such Agencies as the U.S. Department of Transportation, the U.S. Environmental Protection Agency, and the Alabama Department of Public Health, a number of changes have occurred in the UAB Radioactive Waste Management Policy. In addition, there have been increasing concerns surrounding the transport of radioactive wastes over public roads and highways. There is also an increasing awareness that, in many instances, the chemical hazards of some of these shipments are much greater than the radiation hazards. For the majority of radioactive shipments, the concentrations of those constituents that are potentially hazardous are very low. For each waste package transported, those chemicals that are hazardous must be identified and their weight percents must be documented; all other chemicals present in amounts greater than 0.5% must also be documented; and the radioisotopes must be identified and documented. Regardless of how the two types of hazards compare, both have to be identified, documented, and the materials handled properly during their transfer. The process of determining whether a chemical constituent in a packaged shipment significantly adds to the total hazard involves comparing such chemical traits as reactivity, flammability, corrosivity, and toxicity.

The process of identifying the contents of a shipment of hazardous materials through specific lists is known as the manifesting of hazardous materials. For radioactive waste shipments, the specific document used is known as the radioactive waste transport manifest. This document serves multiple purposes, it: (1) identifies the radioactive materials, (2) identifies the chemical constituents by weight and (3) certifies that the radioactive wastes have been packaged according to the requirements of the UAB Radioisotope and Radiation Safety Committee as set forth herein. A copy of the form to be utilized in completing this manifest is shown in Appendix G of this manual. Also shown are the instructions for completing the manifest; these instructions appear on the back of each of these forms as well. It should be noted that this policy applies only to radioactive solids, chemicals or biologicals. For non-radioactive chemicals or biologicals, refer to either the UAB Chemical or Biosafety Manuals.

THE PROCEDURE FOR WASTE MANAGEMENT CONTROL:

A radioactive waste transport manifest must be filled out and signed by the licensee or alternate licensee. The completed manifest must be mailed or delivered to the Radiation Safety Program to initiate the waste pick-up procedures. The Hazardous Materials Manager or his/her assistant must call the licensee and issue the radioactive waste control number(s) which apply to each manifest. Note that there is a control number for each package and this control number must be placed on the package label and the copies (yellow and pink) of the manifest. This call also serves to notify the licensee that his/her radioactive wastes have been scheduled in a timely manner for pick-up. To be picked up, radioactive waste must be manifested, packaged and marked. Failure to comply with these procedures results in a delay in pick-up and, if habitual, could be considered an act of noncompliance with the license agreement.

PHYSICAL FORMS OF RADIOACTIVE WASTE: Different forms of radioactive wastes must be collected and packaged according to the procedures described for each form. The different physical forms specified are solid wastes, liquid wastes and animal tissue wastes. No radioactive waste gases are collected for disposal other than those radioisotopes that might adhere to activated charcoal filters in significant quantities with long half-lives.

SEPARATION OF RADIOISOTOPES: Radioisotopes must be collected in separate containers to enable the more effective management and reduction of the volume of waste that is shipped to low-level radioactive waste disposal sites. There is an exception to this requirement for radiochemicals if they fall into the special categories given below:

i) Different radioisotopes with half lives less than 19 days may be grouped within the same collection containers.

ii) Carbon-14 and hydrogen-3 may be grouped together within the same collection containers.

iii) The experimental protocol or laboratory test requires a dual or multiple labeling procedure that makes separation impossible. Special approval through licensure must first be obtained in this case.

APPENDIX H (Continued)

VOLUME ACCUMULATION IN THE LABORATORIES:

The volume of radioactive waste packages allowed to accumulate within UAB laboratories should be kept to reasonable amounts. There are many good reasons for making periodic requests for waste pickups as the number of radioactive waste packages begins to increase. Radiation levels are kept to a minimum at lower volumes of accumulation. There is an attendant reduction in the concentrations of radioactivity in the air from unsealed containers of volatile radiochemicals (i.e., from vapors of radioiodine and tritium). Many of the scintillation fluids used to count the radiochemicals are themselves chemically volatile, toxic, and flammable. Keeping the numbers of packages containing these to minimum levels significantly reduces the health hazard.

Requesting radioactive waste pickups on a periodic basis more evenly distributes the collection workload. This reduces the delay in daily pickups caused by large-volume requests. If radioactive waste is picked up and taken to regular trash disposal by mistake, it is better to have fewer numbers of these packages involved.

RADIOACTIVE WASTE SECURITY: Make certain that the waste storage area is properly posted and segregated to prevent inadvertent disposal by housekeeping personnel.

If total segregation is difficult to achieve in the laboratory all containers or packages of radioactive waste must be clearly marked. A copy of the warning poster is shown in Appendix G. Warning posters are available in the UAB Scientific Stores.

OTHER HAZARDOUS AGENTS IN WASTES: All biological hazards must be killed or otherwise inactivated as described in the UAB Biosafety Manual. All chemical constituents must be evaluated for potential hazard - e.g., toxicity, corrosivity, flammability. In general, compounds that are present at levels greater than 0.5 percent (by weight) must be identified on the manifest. Corrosive or reactive compounds must be neutralized and rendered non-reactive. Solutions must be adjusted for pH to the 5 to 9 range. In special cases, particularly hazardous chemicals must be reported even when they are present below the 0.5 percent level. The Chemical Safety Manual (or Officer) is available for additional information concerning the degree of chemical hazards.

SPECIAL DOT TRANSPORT REQUIREMENTS: The package must be labeled by the Hazardous Materials Facility personnel with the appropriate transport labels required by the U.S. Department of Transportation. These are the DOT White I, Yellow & White II, or Yellow & White III labels. There must be at least two of these and they are placed on opposite surfaces of the container - preferably the sides. The maximum radiation level at one meter from the surface of the packing container cannot exceed 10 millirem per hour. The radiation level at the surface of the package cannot exceed 200 millirem per hour. Survey these waste packages and enter the package survey information on the manifest before you submit your request for a waste pick-up. The information is used to determine whether shielding materials are needed to meet the DOT radiation exposure limits during transport. The radioactive waste control number must be visibly marked on the waste package.

LIQUID RADIOACTIVE MATERIALS

The liquids must be reasonably separated or otherwise filtered from solid residues. The containers for liquids must be completely devoid of any solid radioactive waste.

WASTE COLLECTION: Type of Container. The container must be made of a durable material of substantial thickness to prevent breakage or cracking and subsequent leakage. Milk jugs are no longer allowed for use due to their leakage problems. Use the smallest container size to match the volume of radioactive waste routinely generated. The container should have a reasonably broad base in relation to its height, making it less likely to tip over during collection. If the smallest possible container would be unstable, it may be tightly packed in a fiberboard or other container which then may be placed in the packing container (see below). Liquid radioactive wastes that are aqueous and contain 2.5% (or less) chemicals may be collected in regular polyethylene and/or polypropylene containers. Other radioactive liquid wastes, especially those containing organic solvents, should be collected in high-density polyethylene (similar to nalgene), fluorocarbon treated plastic, acetal plastic, or durable glass containers.

Filling, Neutralizing and Capping the Container. Fill the collection container to within one inch of the neck. Make sure that it is tightly capped. This is to prevent the leakage of chemical vapors during storage and both liquids and vapors during the handling of these wastes. Additionally, all compounds must be neutralized and treated to make them nonreactive (with respect to reactions with water or other chemicals or biological constituents of the waste solutions). Biological agents must be killed. Additional information is referenced earlier in this document (Section - Other Hazardous Agents).

Labeling of Containers. All of the chemical constituents in the radioactive wastes that are present in proportions greater than 0.5 percent (by weight) must be identified. Any compounds judged to be highly hazardous must be identified regardless of concentration. The contents of each container must be identified by a "stick-on" label (available from Scientific Stores) giving the following information:

CAUTION LIQUID RADIOACTIVE MATERIALS

Type of Radioisotope _____ Activity (mCi) _____
Container: Plastic ____ Glass ____ LSV ____ Vial ____ Bottle ____
Labeled Compound(s) _____
_____

Chemical Constituents _____	Proportion _____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Note: The label must include the percent (by weight) of water and of radioisotopically labeled compounds

Liquid Scintillation Vials. The best method of collection is in the trays in which some of the vials are packed, usually 100 vials per tray, when purchased. If these are not supplied with your purchases, then empty trays may be available at the Hazardous Materials Facility. If they are not collected in trays, then they must be placed within a plastic liner of at least four mil thickness. (Two plastic liners of two mil minimum thickness may also be used). They are to be collected in packaged amounts not weighing over 50 pounds. Both the trays or bags of vials must be placed in fiberboard boxes for disposal and subsequent transport to the Hazardous Materials Facility. The trays must be sealed within a two-mil thick plastic liner inside the fiberboard package.

WASTE PACKAGING:

Type of Package. These packages must be constructed of a durable fiberboard material no larger than twenty-four (24) inches on a side and when filled should weigh no more than 50 pounds. An inner plastic liner shall be placed within each package to contain any leakage that might otherwise occur during handling. The inner liner must surround and seal its contents. The top of the package should be closed firmly. If glass jugs are used as collection containers, then there must be a shock absorbing partition (i.e. fiberboard) between collection containers within the package to prevent breakage. The partitions must be at least the same height as the glass containers. Some packing material must be added to prevent the physical movement of the glass containers within the boxes. No liquid absorbent material is required within the boxes of liquid collection containers since this is placed within the transport carts. All of the packages should be filled to capacity.

SOLID RADIOACTIVE WASTES

It is required that liquids be separated from solid wastes to the extent that there is no more than 0.5% (by weight) free standing liquids.

WASTE COLLECTION AND PACKAGING

Collection. Radioactive contaminated solid waste such as paper, plastic, glassware, gloves, bench paper, animal bedding, etc., must be collected in fiberboard boxes lined with a plastic liner of at least two mil thickness. Sharp material such as thin pasteur pipettes or needles must be placed in rigid collection containers such as small plastic (bag) lined fiberboard boxes which are firmly closed. Use string or tape (not radioactive materials identification tape) to secure the exteriors of these packages.

Type of Package. These packages must be constructed of a durable fiberboard material no larger than 24 inches on a side and when filled should weigh no more than 50 pounds. The plastic bag in which the waste is collected must be sealed and placed within this package. The top of the package must be firmly shut.

Labeling. Each container must be identified by a "stick-on" label (available from Scientific Stores) giving the following information:

CAUTION SOLID RADIOACTIVE MATERIALS
Type of Radioisotope _____ Activity (mCi) _____
Radiolabeled Compound _____
Description of Solid Contents _____
_____
_____

ANIMAL TISSUE CONTAINING RADIOACTIVE MATERIALS

Any animal or animal tissue that is included for waste disposal must be kept in a freezer prior to pickup. In its frozen state, it must be able to fit within a 30-gallon drum for shipment to a low-level radioactive waste burial site.

Type of Package: Fiberboard boxes containing animals or animal tissue may be used only if their heights are not greater than 30 inches and the diagonal dimensions of their ends do not exceed 18 inches. It is preferable to have the large animals placed inside a 30-gallon fiberboard or metal drum, having inside dimensions of at most 18 inches in diameter and 30 inches in height. The thirty-gallon metal drums can be provided by the Radiation Safety Program for the large animals upon request.

WASTE COLLECTION

The biological wastes are collected within plastic bags of at least four mil thickness and serve as liners on the inside of the packages. Seal these plastic bags (liners) tightly when full. Two plastic bags of two mil thickness may be used in lieu of a four mil thick bag. No animal excreta are allowed to be packaged within the biological waste.

Labeling of Container. These plastic bags must be identified by a "stick-on" label giving the following information:

CAUTION RADIOACTIVE ANIMAL/ANIMAL TISSUE
Type of Radioisotope _____ Activity (mCi)_____
Labeled Compound Used _____
Animal Species _____
Total Weight in Collection Container (lb) _____

APPENDIX H (Continued)

SUPPLEMENT A

RADIOACTIVE WASTE MINIMIZATION, A MANDATORY PROGRAM

Legislation and Rules approved by the State of Alabama has now made it a requirement for an institution using radioactive materials to have and maintain a Radioactive Waste Minimization Policy. Monetary penalties can be levied by the State of Alabama against those facilities that do not abide by these requirements.

In order to have a radioactive waste minimization program, it is first necessary for licensees to identify both the major and minor contributors to the increases in the cost of radioactive waste disposal. For radioactive material users within a medical research facility such as UAB, it is the volume of the radioactive waste generated that causes the majority of this expense. The amount of radioactivity used in research and clinical laboratories generally gives rise to greater volumes of waste generated. A third major contribution to waste costs is from the unnecessary contamination of solid non-radioactive materials used in this work. Finally, the failure of many licensees to take reasonable measures to reduce the volumes of radioactive wastes disposed contributes to the volumes of radioactive wastes packed and manifested for shipment to low-level radioactive waste burial sites. These reasonable methods would include the decay of radioactive materials to background levels with subsequent disposal to regular trash, the use of short-lived radioactive materials when economically feasible, etc. If proper and reasonable measures are taken to segregate radioactive wastes and not intermix high and low-level materials, the volumes generated can be significantly reduced and dealt with using further disposal methods.

If any of the Waste Minimization Methods outlined on the following page are, in your opinion, <u>unreasonable and cannot be applicable</u> to your radioactive materials use program, write “N/A” (not applicable) in the appropriate space and explain why the particular effort would not be helpful towards minimizing the volume or the cost of the radioactive waste generated from your laboratory areas of use.

APPENDIX H (Continued)

SUPPLEMENT B

METHODS UTILIZED BY LICENSEE IN
A RADIOACTIVE WASTE MINIMIZATION PROGRAM

1. _____ To order only those quantities of radioactive materials that are necessary in a series of clinical tests or experiments, keeping in mind the normal expiration periods of the chemical forms used.
2. To guard against unnecessary contamination of solid nonradioactive materials by:
   _____ Preventing unnecessary dripping or seepage of radioactive liquids from containers or needles used to inject these liquids.
   _____ Restricting the size of the radioactive material use area thereby reducing the amount of bench paper used.
   _____ Taking care not to spill liquids from their containers during their transfer from one work area to another.
   _____ Sealing liquid containers prior to their transfer over considerable distances.
   _____ Monitoring and separating non-contaminated materials from contaminated materials (i.e., disposable protective gloves that are not contaminated can be thrown into regular trash).
3. _____ Disallow the intermixing of large specific activity liquids with small specific activity liquids.
4. _____ Disallow the intermixing of highly contaminated solid radioactive waste with low-activity radioactive waste.
5. _____ Allowing the evaporation of nonvolatile liquids within fume hoods.
6. _____ Use trapping media such as solid Dowex beads and/or 0.22 micron filters to filter radioactive materials and thereby minimize the amount of activity collected in waste liquids.
7. _____ Make use of a core facility to perform radioiodinations and thereby minimize releases of radioiodine to the environment and to liquid waste.
8. _____ Use, safe placement, and identification of special collection containers when using or handling anything which might produce a cut.
9. _____ Disallow the use of autoclaves for neutralizing infectious volatile radioactive waste.
10. _____ Make use of properly filtered ovens as a measure to neutralize infectious volatile radioactive wastes.

COMMENTS:

_____
Radioactive Material Licensee (Date)

APPENDIX I

CRITERIA FOR APPROVAL OF RADIOISOTOPE LICENSURE AND USE

Nonhuman Use Criteria

Individuals who are granted a license to use radioactive materials at UAB must have appropriate training and/or experience in handling* the radioactive materials for which they are licensed. In addition, they and any persons using radioisotopes under their supervision must be familiar with the applicable sections of the Alabama Regulations for Control of Radiation, the UAB Radiation Safety Procedures Manual, and any written laboratory safety requirements submitted to the Radiation Safety Officer or his designate for approval.

Listed below are the training and/or experience requirements adopted by the Radioisotope and Radiation Safety Committee. They are to be utilized in evaluating training and experience qualifications of all persons applying for UAB radioactive material licensure, as well as the training and experience qualifications of all persons to be listed on a license as a UAB alternate radioactive materials licensee, and/or as a UAB authorized user of radioactive materials under the supervision of a UAB radioactive materials licensee. Documentation of training and experience of UAB radioactive materials licensees, UAB alternate radioactive materials licensees, and UAB authorized users of radioactive materials should be maintained in the licensees' files.

UAB Radioactive Materials Licensees

Satisfactory completion of the UAB Radioactive Materials Licensure & Management Course and the UAB Radiation Safety Training Course, and the possession of a graduate degree (a doctorate degree is preferred, but a master's degree is acceptable.) Training and experience must be completed to the satisfaction of the Radiation Safety Officer or his designate. A Licensee can take and pass the Challenge Examination instead of successfully completing the UAB Radiation Safety Training Course, or can have previous training and experience certified (documentation of at least one year of experience as a radioactive materials licensee or an authorized user at an institution outside of UAB, and the successful completion of a formal radiation safety course taken at an institution outside of UAB.) Also, if UAB radiation safety training is more than five years old, successful completion of the UAB Radiation Safety Refresher Course or attending a one-day session of instruction in UAB radiation safety procedures given by the Radiation Safety Program.

UAB Alternate Radioactive Materials Licensees

Same as above for UAB radioactive materials licensees, except that UAB alternate radioactive materials licensees are required to possess at least a bachelor's degree (a graduate degree is preferred, but a bachelor's degree is acceptable.)

UAB Authorized Users of Radioactive Materials

Satisfactory completion of the UAB Radiation Safety Training Course. A UAB authorized user must successfully complete the UAB Radiation Safety Training Course or its equivalent within six months of being added to a UAB radioactive materials license as a closely-supervised authorized user of radioactive materials. Training and experience must be completed to the satisfaction of the Radiation Safety Officer or his designate. A UAB authorized user can take and pass the Challenge Examination instead of successfully completing the UAB Radiation Safety Training Course, or can have previous training and experience certified (documentation of one year of experience as a radioactive materials licensee or an authorized user at an institution outside of UAB, and the successful completion of a formal radiation safety training course taken at an institution outside of UAB.) In order to have previous training and experience certified, a UAB authorized user must also attend a one-day session of instruction in UAB radiation safety procedures given by the Radiation Safety Program, or successfully complete the UAB Radiation Safety Refresher Course or the UAB Radioactive Materials Licensure & Management Course. Also, if UAB radiation safety training is more than five years old, successful completion of the UAB Radiation Safety Refresher Course, attending a one-day session of instruction in UAB radiation safety procedures given by the Radiation Safety Program, or successful completion of the UAB Radioactive Materials Licensure & Management Course.

* Specific techniques in the handling of radioisotopes are given in Supplement B of this Appendix.

NOTE: If an individual makes a score of 76—79 on the Challenge Examination, the UAB Radiation Safety Training Course (RSTC) must be taken by the individual, but not the test for the RSTC, in order for the individual to complete training deemed equivalent to the successful completion of the RSTC. The UAB Radiation Safety Training Course, the UAB Radiation Safety Refresher Course, and the UAB Radioactive Materials Licensure & Management Course may be partially or completely replaced by on-line versions of these courses in the near future as on-line versions become available. Less training may be required in special circumstances, such as using only a generally-licensed device or using radioactive materials only in a classroom setting, with the specific approval of the Radiation Safety Officer or his designate.

Human Use Criteria

A licensee for medical use may be approved to use radiopharmaceuticals by drug use categories (specified in Part 420-3-26-.07 of the Radiation Control Regulations entitled "Use of Radionuclides in the Healing Arts," by the State of Alabama). Sufficient training and experience to meet regulatory requirements is a prerequisite for any approvals. A preceptor's statement to support training and experience must be submitted along with the initial application for human use licensure. See Part 420-3-26-.07 of the Alabama Radiation Control Regulations regarding training and experience criteria. Once physicians are approved for the types of radiopharmaceutical uses specified by the Radioisotope and Radiation Safety Committee, they have certain responsibilities involving the patient and the supervision of workers helping to conduct these studies. These are given in Supplement A of this Appendix. The following section addresses the approval of researchers who may become involved in radioactive drug research which would lead to human use.

ACCEPTABLE TRAINING AND EXPERIENCE FOR INDIVIDUALS TO BE APPROVED FOR HUMAN USE STUDIES IN BASIC RADIOACTIVE DRUG RESEARCH

The Code of Federal Regulations (CFR) provides for the use of radioactive drugs or chemicals in "basic research" in man, as defined in CFR section 21 CFR 361.1. These studies must be fully reviewed as specified by the CFR and approved by the UAB Radioactive Drug Research Committee (RDRC), unless a Radioactive Drug Research Committee at another institution fully reviews the study and makes quarterly and annual reports about the study to the FDA. (See the CFR Section cited and also Section IV of the Manual.) These studies may not have immediate diagnostic or therapeutic intent or be a clinical trial done to evaluate diagnostic or therapeutic uses, although it is understood that basic information obtained might properly and ultimately have bearing on such uses. It is not required that physician users of radioactive drugs for such human basic research (e.g., metabolic or pharmacologic research, as distinct from diagnosis or therapy) be fully trained in nuclear medicine. They must, however, submit documentation of sufficient training and experience to satisfy the Radioisotope and Radiation Safety Committee of their competence to perform the proposed study in a radiologically safe and scientifically valid manner. The physician user must be a UAB radioactive materials licensee, a UAB alternate radioactive materials licensee, or a fully-trained radioisotope worker listed as an authorized user working under the supervision of a UAB radioactive materials licensee.

Physician users may be deemed to have had adequate training in radiopharmaceutical use and clinical experience for a specific research project if the proposal is approved by the RDRC, or the SCHU if a Radioactive Drug Research Committee at another institution fully reviews the study and makes quarterly and annual reports about the study to the FDA, and it is shown that the physician has completed forty (40) hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals and twenty (20) hours of supervised clinical experience.

1. To satisfy the basic instruction requirement, the forty hours of classroom* and laboratory instruction shall include:

   (i) Radiation physics and instrumentation,
   (ii) Radiation protection
   (iii) Mathematics pertaining to the use and measurement of radioactivity,
   (iv) Radiation biology, and
   (v) Radiopharmaceutical chemistry

2. To satisfy the requirement for twenty hours of supervised clinical experience, this must be conducted under the supervision of an authorized physician user at a medical institution and shall include:

   (i) Examining patients and reviewing their case histories to determine their suitability for radioactive drug research, limitations, or contraindications,

   (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages,

   (iii) Administering dosages to patients and using syringe radiation shields,

   (iv) Collaborating with the authorized user in the interpretation of radioisotope test results, and

   (v) Patient follow-up.

Physicians must then produce a preceptor statement signed by an approved physician user of the same or similar radionuclide(s) used showing evidence in the fulfillment of the items above, unless previously submitted to the Radiation Safety Officer or his designate.

Should the training/experience requirements of the State of Alabama be changed, then these criteria must be changed to meet those requirements.

* A challenge examination taken by an individual deemed equivalent by the RDRC (or the SCHU) may be utilized.

SUPPLEMENT A

RESPONSIBILITIES AND SUPERVISION IN MEDICAL RADIOPHARMACEUTICAL USE

The purpose of this section is to clarify the requirements of the Radiation Control Regulations in (1) the responsibilities of the licensed nuclear medicine physicians in the medical use of radiopharmaceuticals, (2) the limitations of the occupational activities allowed for technologists or technicians working under their supervision, and (3) the training criteria for an on-site physician present within the hospital at the time a nuclear medicine study is conducted.

The responsibility for authorizing in vivo nuclear medicine procedures must be exercised only by licensed nuclear medicine physicians. In all cases, this approval is required prior to the conduct of the nuclear medicine procedures.

Approval of the conduct of nuclear medicine procedures must be based on a licensed nuclear medicine physician's taking one or more of the following actions:

(a) Examining the patient,

(b) Reviewing the patient's clinical history, or

(c) Discussing the patient's clinical condition with the referring physician.

I. The responsibilities of the nuclear medicine physician are to include:

(a) Approving patients for radiopharmaceutical administration,

(b) Prescribing the type of radionuclide and dosage to be administered to patients,

(c) Interpreting the results of the diagnosis or treatment of patients, and

(d) Adequate supervision of technicians or technologists using radioactive materials and patients receiving the radiopharmaceuticals.

The supervision required above does not require the licensee to be physically present within the hospital during radiopharmaceutical use provided that (a) the licensee has determined that these technologists or technicians are trained and competent in their ability to safely use the radiopharmaceuticals themselves, (b) the licensee is available to respond and assist them in cases of emergency, and (c) there is an on-site physician meeting the training criteria given in Section III below. The responsibilities for authorizing nuclear medicine procedures may not be delegated to technologists or technicians.

II. Trained technologists or technicians are permitted to:

(a) Standardize the radiopharmaceutical dosage prior to administration,

(b) Administer the radiopharmaceuticals to the patient, and

(c) Calibrate and use counting equipment or other radiation measuring instruments to obtain necessary data for the responsible nuclear medicine physician.

III. A physician shall be on-site at the time radiopharmaceuticals are administered to patients in order to handle any reactions from the drug.

(a) Training criteria for diagnostic studies only.

The on-site physician is not required to have specialized training in nuclear medicine.

(b) Training criteria for therapeutic studies only.

The on-site physician must have a minimum of thirty (30) hours of training and experience in nuclear medicine. The term on-site, as it is used above, means to be within the hospital.

APPENDIX I (Continued)

SUPPLEMENT B

RADIOISOTOPE HANDLING TECHNIQUES

The following precautions usually refer to work with unsealed forms of radiochemicals, which generally require more care to prevent the spread of contamination.

1. Segregate work with radioactive materials from other chemical work.

2. All work must be conducted over surfaces covered and protected from radioactive contamination utilizing a layer of disposable material. For liquids, a spill tray should be utilized and the disposable layer on its surface should consist of a material resistant to diffusion.

3. Amounts of activity emitting radiation at levels where an individual may receive whole body dose rates of 0.5 millirads per hour or less may be handled on laboratory benchtops without the use of shielding. However, the sample must be in a chemically stable, bound form or nonvolatile form. Greater caution is to be exercised for more dispersible materials (that is, powders). These should be handled in a ventilated enclosure (See Appendix J).

4. Greater caution is also to be exercised when utilizing radioactive materials with biologically toxic materials (See UAB Biohazard Safety Manual).

5. When a fumehood or other type of hood is required for the type of work being performed, extreme care must be exercised to ensure that your face is not beyond the vertical plane of the sash and within the hood.

6. Open ampoules likely to contain volatile radioactive compounds only in a well-ventilated fume hood.

7. Do not eat, drink, smoke, or apply cosmetics in an area where unsealed radioactive substances are handled.

8. Use the minimum quantity of radioactivity needed for an investigation.

9. In addition to a laboratory coat, protective gloves (i.e., vinyl, rubber or latex) must be worn. Increased protection, due to increased resistance to permeability, is afforded when wearing cotton glove liners (dermal gloves) beneath the vinyl or latex gloves. This is especially beneficial when working with radioiodine. Dermal gloves, when used, should be surveyed when the outer gloves are removed. They should also be periodically washed in cold water with a mild detergent and allowed to dry before reuse. Be aware that static charges may develop on gloves when handling fine powders.

10. Never pipette radioactive solutions by mouth.

11. Segregate apparatus used for high-activity work from that used for low-level work.

12. Use only clean apparatus. Do not leave contaminated apparatus lying around the laboratory-someone else may use or handle it.

13. Except for containers of radioactive materials in process and under the direct supervision of laboratory personnel, and cases where exempted by the UAB Radiation Safety Procedures Manual, label clearly all containers of radioactive material indicating nuclide, compound, specific activity, total activity, date and name of use. In all cases, sufficient labeling should be placed on the container whereby the above information can be easily ascertained. Containers should be properly sealed.

14. Do not use "old" material, suspected of being impure, in a tracer investigation without first checking its radiochemical purity.

15. Always store compounds under the conditions recommended on a batch analysis or product specification sheet for the radiochemical.

16. In the event of a spill of radioactivity it is most important to minimize the possible spread of contamination. The extent of the spread should be determined by suitable monitoring techniques. The affected area should be cordoned off and restricted from traffic. If a volatile radioactive material is involved, a plastic-backed absorbent material must be quickly placed over the spill and the Radiation Safety Program called immediately (breathing protection is indicated for time spent in the vicinity of the spill and particularly during the cleanup of a spill of this nature). If the radioactive material is not volatile, any persons in the area of the spill should not leave until they have been monitored. If the spill is volatile they should remove themselves to a safe area beyond the spill for monitoring. (In situations involving nonvolatile materials, the Radiation Safety Program must still be notified as soon as possible). In any clean-up procedure, one begins from the outer edges of the spill. Proceed to the center only after determining through the use of wipe samples that each of the outer areas is clean (has been decontaminated).

CRITERIA FOR VENTILATION DESIGN

Hoods are required for radioisotopes which when used or stored produce effluents that contaminate the workplace and the environment. Within the laboratories, they should be located in minimum traffic areas (away from doorways). The general airflow pattern should be from the unrestricted and more heavily-traveled areas towards the hoods. This can be accomplished by establishing negative pressures (within laboratories) in relation to non-laboratory areas or corridors. Care must be exercised in the selection and placement of room air supply diffusion devices to avoid creating air currents that would adversely affect hood performance.

Due consideration must be given to the manner in which auxiliary air supplied to hoods might affect the total air flow pattern. The rates of airflow into hoods depend on the pressure differentials occurring throughout the entire hood ventilation system. Adequate allowances should be made for pressure losses occurring along ducts, in filters, and during hood entry. Design allowances for static pressures in hoods should take into account the required face velocities as specified below. If a fume hood is designed for low-level radioisotope work, the face velocities across the hood may be less than for higher-level radioisotope work; however, provision should be made for higher face velocities should higher level work ever become necessary.

All air exhausted from hoods containing radioisotopes is considered to be contaminated and must not be allowed to re-enter any part of a building normally occupied by personnel directly or indirectly without substantial dilution. Special situations involving re-circulated air will necessitate careful control measures for safety. In any case, there must be adequate room makeup air provided so as not to impede hood face velocities and prevent hoods from maintaining required flow rates.

Modifications affecting the ventilation system either directly or indirectly must be performed according to the specifications in this document and to current and pertinent local and state codes. The term "modifications" includes any structural changes in the vicinity of the ventilation system that would affect its performance or the manner in which it is maintained and tested.

The general specifications for hood use involving any type of radioisotope are given below. Additional requirements are given for different types of hoods or containment and for the level of radiation hazard involved. It should be noted that separate specifications for "Biological Safety Cabinets" and for “Chemical Hoods" deemed necessary by the biohazard safety officer and fire safety officer are also required in addition to those given herein.

General Specifications for Hoods Surrounding Radioisotope Work

1. Sashes or viewing panels must be provided and counterbalanced to maintain safe operating conditions; clear safety glass must be used in their construction.

2. The average light intensity at the work surfaces of the underlying cabinet shall be within the range of 90 to 120 foot candles; at no point over this surface shall the light intensity be below 60 or above 150 foot candles.

3. Lamps, ballasts, and starters must be installed away from contaminated work zones, must be accessible, and must be located so that reflected light does not interfere with visibility through the sash or view panel and so that the operator's eyes are shielded from direct visible radiation.

4. All controls for electrical, gas, air, water, and vacuum services must be located outside of the hood.

5. Structural reinforcements under the nonporous work surfaces are required to support loads up to 250 pounds per square foot (for radiation shielding purposes).

6. Hood entrance surfaces should provide for streaming airflow wherever economically feasible.

7. Hoods must contain baffles to direct radiochemical effluents properly with respect to their buoyancy in air; the baffles and the interior hood lining must be constructed of stainless steel, type 304.

8. Edges and corners of the hood must be covered.

9. Wood cabinet understructures are prohibited.

10. Cabinet work-surfaces must be of polished, stainless steel of type 304. It must be dished to a depth of at least ½-inch and be provided with a fitted drain outlet. When drainage is otherwise provided or required, it must be installed in such a manner as to facilitate removal of drain pans, and it should minimize or otherwise prevent splashing of drained liquids.

11. There must be no cracks or crevices on the cabinet working surface.

12. The average air flow rate may be set at a lower rate during storage but must not be less than 25 cfm. The hood must not be opened greater than one inch and this opening must be located under the airfoil *.

13. Auxiliary air system entering hoods must be designed to prevent or minimize spillover of forced air into the laboratory under any circumstances *.

14. Monitoring of hood airflow is required through the use of differential pressure sensors such as magnehelix gauges or other reliable devices.

15. Visual and audio warning devices are required to indicate when hood airflow fails to meet minimum requirements. There should be a silencing feature on the audible alarm.

* These specifications are not required for biosafety cabinets.

Fume Hoods Without Filters. This pertains to the regular chemical fume hoods which can be used for low-level radioisotope work involving some contaminated air effluent generation.

Restrictions on Use:

1. No radioiodinations may be performed in these fume hoods.
2. No alpha particle or neutron-emitting radioisotopes may be used in these hoods.
3. Beta and/or gamma-emitting radioisotopes are limited to activities prescribed as follows:

   50 millicuries (1.85 GBq) - radionuclides* with Kerma constants greater than 10 Rads/hour per millicurie at one centimeter

   500 millicuries (18.5 GBq) radionuclides with Kerma constants less than 10 Rads/hour per millicurie (37 MBq) at one centimeter, and pure beta emitters

   1 Curie (37 GBq) - Hydrogen-3

Additional Specifications

1. Provision must be made for filter boxes of standard size during the design of any facility. The boxes are not required to have filters until the need arises. This requirement is to provide for later installation of filters as the need arises for more hazardous types and quantities of radioisotopes.

2. The average face velocity of air flowing across these hoods must be 100 cfm per square foot of area used. Face velocities measured at any point in the plane of the sash must not be less than 80 linear feet per minute nor greater than 150 linear feet per minute.

Fume Hoods with Filters. These fume hoods are required when using radioisotopes which produce contaminated air effluents, either directly or indirectly, and which are used in amounts, forms, and types which exclude them from being used in fume hoods without filters.

Restrictions on Use:

1. More restrictive containment or control measures are necessary when radiochemicals exceed the limits of activities prescribed as follows:

   a. 10 millicuries (37 MBq) for alpha and neutron-emitting radiochemicals

   b. 500 millicuries (18.5 GBq) for radiochemicals* with Kerma constants greater than 10 rads per hour per millicurie at one centimeter

   c. 1 Curie (37 GBq) for radiochemicals with Kerma constants less than 10 rads per hour per millicurie at one centimeter

   d. 5 Curies (185 GBq) for Hydrogen-3

* These include: Antimony-124, Arsenic-72, Barium-140, Bromine-82, Cobalt-60, Cobalt-56, Gallium-72, Manganese-52, Iodine-130, Lanthenum-140, Magnesium-28, Scandium-46, Silver-ll0m, Sodium-22, Sodium-24, Vanadium-48, Yttrium-88.

Additional Specifications

1. Two types of filters must be used in these fume hoods at all times. There must be a roughing (prefilter) filter, across which the exhaust air must first flow and then a high-efficiency particulate air (HEPA) filter across which exhaust air must flow before entering the duct system. Prefilters are not required for biosafety cabinets.

2. When volatile forms of radioiodine are used (such as during radioiodination procedures), carbon activated filters must be used and may be placed within the HEPA filter box often provided - the HEPA filter being unnecessary.

3. The HEPA filters shall be corrosion, shock, and fire resistant.

4. HEPA filters shall be mounted in such a manner that there is no air bypassing the filters.

5. The hoods shall be designed to provide accessibility in order to expedite filter installation, testing, and sealing.

6. The average face velocity of air flowing across these hoods must be 125 cfm per square foot of area used. Face velocities measured at any point in the plane of the sash must not be less than 100 linear feet per minute nor greater than 150 linear feet per minute.

7. In exceptional cases, where the work may require large quantities of water when using high-level radioactive materials, provision must be made to handle any condensate which might result.

8. The filter box should be of standard size (24" x 24" x 11.5") and need not be constructed of steel.

APPENDIX J (Continued)

9. The fume hood must be labeled to indicate the make and model of the HEPA or charcoal filter that will fit the filter box.

Biosafety Cabinets. These are allowed for radiochemical work only if they do not contaminate laboratory air. They should be designed in such a manner that air re-circulated from them back into the laboratory is not contaminated and meets the licensing criteria established by the RRSC (See Appendix J, Supplement A). Otherwise, the exhaust air must be vented to the outside of the building through an approved ventilation exhaust system.

Restrictions

1. Those restrictions which apply for "Fume Hoods with Filters" also apply for these biosafety cabinets. (Except Class IIA).

2. No radioiodinations are allowed in biosafety cabinets without carbon-activated charcoal filters.

3. See Appendix J, Supplement A for restrictions on Class IIA Biosafety Cabinets.

Exemptions

1. Those specifications described in Items 12 and 13 under "General Hood Specifications for Radioisotope Use" do not apply for biological safety cabinets.

2. Prefilters are not required in biosafety cabinets.

3. None of these restrictions apply for Class IIA Biosafety Cabinets.

Additional Specifications

1. The specifications which apply for "Fume Hoods with Filters", with the exception of Item 6, also apply for biosafety cabinets.

2. The front access opening below the view panel shall be 8 inches wide and provide an average air intake velocity of not less than 90 linear feet per minute.

Glove Boxes. These are types of radioactive materials containment that is necessary only in a few exceptional cases, and are necessary when both of the restrictions below apply.

Restrictions

1. When the levels of alpha, neutron, beta, or gamma-emitting nuclides exceed the limits specified for "Fume Hoods with Filters."

2. When no specific control and handling procedures are adequate to ensure proper containment of the radionuclide. This decision for this type of container is made by the Radiation Safety Officer.

Specifications

1. The inner surface of glove boxes must be constructed of type 304 stainless steel.

2. The glove boxes must have a filtered Inlet air supply as an added measure to prevent contaminants from reaching the laboratory environment.

3. They must be provided with exhaust filters, as described previously for "Fume Hoods with Filters".

4. They must have air locks through which samples and handling equipment can be inserted and removed.

5. The glove boxes must be well-sealed from the outside environment to prevent spread of contamination.

6. The nonporous work surface must be reinforced to support up to 300 pounds per square foot of shielding material.

7. In some instances involving gamma emitters, dry boxes may be required with special manipulators to handle the radiation from a distance and thereby prevent sizable radiation exposures to the hands of personnel.

Ductwork Connecting Hoods, Glove Boxes or Dry Boxes

The design of the duct-work is very important for the proper operation of the containment devices to which it is connected.

Restrictions

1. Access to ductwork is allowed only after the forced airflow through the ducts has been turned off.

2. Controlled access would otherwise be required only in circumstances considered exceptional by either the Radiation Safety Officer or the Radiation Safety Committee. Situations which could possibly pose health and safety problems would be evaluated initially by the Radiation Safety Officer or his designate and thereafter during periodic surveys, as deemed appropriate for the circumstances involved.

Specifications

1. Ductwork connecting containment devices such as hoods and glove boxes must be streamlined and have long-radius turns.

2. Branch angles must be 30 to 40 degrees from major ducts.

3. The duct system must be balanced with respect to air flow.

4. The velocity of airflow within the ductwork must be within the range of 3500 to 4500 fpm.

5. The ductwork must exhaust directly to the environment outside of the building without recirculation into the building.

6. Only metal may be used in the construction of the ductwork and the ductwork downstream from the filter box need not be constructed of stainless steel.

Restrictions

1. For maintenance performed on exhaust blower motors or exhaust stacks where personnel would be directly exposed to exhaust emissions, the blower motors must be turned off.

2. Laboratory personnel must be given prior notice by the maintenance department when their hoods or biosafety cabinets utilize exhaust systems scheduled for "cutoff" and maintenance.

3. Controlled access to the rooftops of buildings is required for those which have exhaust stacks less than a seven-foot height above the rooftop.

4. Controlled access by maintenance personnel is limited to only those properly trained in "Notification and Cutoff Procedures."

5. Periodic evaluations of the radiation hazards for work conducted in areas surrounding exhaust stacks are required to be performed by the Radiation Safety Officer or his designate. These surveys are not necessary for each and every access to these areas.

Specifications

1. The radioactive exhaust stacks of a building must be straight vertical stacks of elevation not less than seven feet high and of lossless design. (Height allowed lower than this would require strict control measures concerning access to building rooftops.)

2. Exhaust stacks must be located well away from the air intakes of a building or from nearby buildings, and be designed in such a manner as to minimize or otherwise prevent the mixing of exhaust and intake air.

3. The exhaust air blowers must be located on the rooftop of a building directly forcing air into the vertical stacks.

SUPPLEMENT A

CRITERIA FOR RADIOCHEMICAL CULTURE WORK IN CLASS II TYPE A BIOSAFETY CABINETS

The UAB Radiation Safety Procedures Manual gives "Criteria for Ventilation Design" (Appendix J). In Appendix J, there is a special section on Biosafety Cabinets, and it states that the only allowable biosafety cabinets which can be utilized for radioisotope work are those from which the exhaust air is vented to the outside of the building through an approved ventilation exhaust system. Recirculation of air into the laboratory air is normally prohibited. Due to the needs of investigators in biological research, it has become necessary to set criteria for the use of Class II Type A Biosafety Cabinets for radiochemical use. In these types of Biosafety Cabinets, recirculation of room air does occur, but the criteria herein would allow such use but only according to the specifications and restrictions given below.

1. The primary purpose of use is product protection by maintaining sterility and preventing contamination of culture media and of radiochemicals during metabolic labeling procedures and cell (or tissue) culture work.

2. A general criterion for hazard and safety evaluation herein is as follows: if the radio-labeling or a radiochemical use can be conducted safely on a bench top without the use of additional ventilation equipment, then such may be approved for a Class II Type A Biosafety Cabinet.

3. The use of volatile, dry powdery, or flammable forms of radiochemicals is prohibited. Vapors or gases hazardous from a toxic, radioactivity, or flammability standpoint are also prohibited. The biosafety cabinet must have easily visible labeling warning "Do Not Use Volatile Toxic, Explosive or Flammable Substances in This Cabinet". Use of equivalent wording is allowed.

4. Volatile forms of unincorporated radiochemicals that might occur in radiochemical stock or working solutions (or during labeling and use) must be captured on absorbing mediums-i.e., pipettes or columns using activated carbon or using calcium chloride depending on the radiochemical.

5. The makes and models of the Class II Type A Biosafety Cabinets used must have met the leak tightness specification that does not allow 1 x 10-4 cubic centimeters per second or greater of air leakage at a gauge pressure of 2 inches of water.

6. If the biological agents used in the research are classified as biohazards (as determined by the Biosafety Officer), then such use will not generally be approved.*

7. Periodic surveys must be conducted by the licensee, especially during the first six months of use, to establish that no radiochemical contamination occurs on the inner surfaces of the Biosafety Cabinet.

8. The maximum amount of radioactivity that is allowed within a Biosafety Cabinet at any one time (excluding the original stock vial of material) must not exceed 100 microcuries (3.7 MBq). This includes the working radiochemical stock vials and the culture products. Stock vials containing more than 100 microcuries (3.7 MBq) are allowed within a Type A Biosafety Cabinet to make quick transfers when making up working stock solutions. The original stock vials should not be stored within these biosafety cabinets.

9. The maximum amount given in Item 8 above may be increased (ten-fold to one-hundred fold) if the original stock vials of radiochemicals are opened within a fumehood and allowed to vent for at least a minute before being transferred to the Biosafety Cabinet **. Amounts which would exceed one-hundred fold of the amount specified in Item 8 require special approval by the Subcommittee for Laboratory Use.

10. The vessels containing the labeled culture media and the radiochemicals are to be kept closed except during transfers between them within the Biosafety Cabinet. The transfers are to be accomplished in as little time as is necessary, safe, and reasonably achievable. No pipetting by mouth.

11. A High Efficiency Particulate Filter (HEPA) must be utilized and have an efficiency of 99.97 percent for 0.3 micron particles. It must also be periodically changed out when necessary-when air flow measurements show face velocities less than 75 linear feet per minute.

12. The licensee is to discontinue use and notify the Radiation Safety Officer (RSO) or his designate when a problem with proper airflow is suspected. Before scheduling maintenance activities, the RSO or his designate must receive from the licensee a written statement certifying that no biohazardous (infectious) agents have been used in the research activities conducted within the biosafety cabinet. The RSO or his designate is then responsible for surveying for contamination and releasing the biosafety cabinet to the Laboratory Ventilation Specialist (LVS).

13. If the Biosafety Cabinet is determined to be contaminated, it is the responsibility of the licensee to ensure its decontamination.***

14. The use of absorbent pads with plastic backing is required on the secured to work surfaces within the cabinet.

15. Loose materials such as chemwipes and paper towels are prohibited. These tend to be drawn into the ventilation slots and clog the air handling system.

16. Written safety procedures in the use of radioactive materials within Biosafety Cabinets must be provided for users to receive instruction in and to follow.

17. Exposure to an ultraviolet irradiation source within a Biosafety Cabinet, even for a short period of time, should be avoided because of danger of burns to the eyes and the skin.

18. Ensure compliance with respect to the "Responsibilities of the Licensee" and "Responsibilities of the Individual User" as specified in Sections VIII and IX, respectively, of the UAB Radiation Safety Procedures Manual.

19. Restrictions not specifically addressed in the UAB Radiation Safety Procedures Manual may be added as conditions for licensure of Biosafety Cabinets.

* Approval in these cases requires written safety procedures addressing the additional care that is to be exercised in the handling of the biohazards and toxic chemicals involved. In addition, the Biosafety Cabinet must have demonstrated compliance with the minimum allowed air flow face velocity and leak tightness specified herein (NSF Standard 49). Certification is required (1) before a newly installed cabinet is used, (2) after a cabinet is moved, relocated or partially dismantled for cleaning or repair, and (3) at least annually. Also, at the discretion of the Radiation Safety Officer, specialized training of Radiation Safety Program personnel may be necessary to certify these Biosafety Cabinets. Until trained personnel are available for in-house certification of these safety cabinets (if deemed necessary by the Radiation Safety Officer), it is necessary for the laboratory supervisor to employ the services of a reputable outside organization. The Radiation Safety Program should be informed every time a Biosafety cabinet is certified by an outside party.

** While it is unlikely that aerosols of a radiochemical will escape a leaktight biosafety cabinet, these special requirements are necessary in consideration of the possible buildup of radiochemical contamination that might occur in inaccessible areas within the biosafety cabinet, and subsequently cause undue problems during maintenance or repair. In case of gross spillage, regardless of the amount of radiochemical involved, the cabinet must be shut down immediately.

*** Should the Biosafety Cabinet also be licensed for biohazardous (infectious) agents, the removal or destruction of these agents is also necessary.

APPENDIX K

RADIATION DOSE DISCLOSURE FORM

Date:_____

Series:_____

Section 420-3-26-.03(5b) of the Alabama Regulations for Control of Radiation requires that institutions limit exposure from ionizing radiation from radiation sources. This includes any occupational exposure received at other facilities. Please fill out this form completely, where applicable.

1. NAME_____
   Last First Middle Initial

2. SS NO._____ 3. Birth Date_____ 4. Sex_____
   Mo day year

5. DEPARTMENT_____ 6. TELEPHONE NO._____

7. I, the undersigned, (have, have not) had prior occupational exposure to ionizing radiation while working at a facility other than any part of the University of Alabama at Birmingham (UAB). I also (have, have not) worn personnel monitoring equipment at another facility; and, (have, have not) had internal monitoring (whole or partial body counting, or bioassays) performed at another facility. I (am, am not) currently receiving occupational radiation exposure at another facility. If any occupational radiation exposure has recently occurred or is now occurring at other facilities, the amount of that exposure is as specified below.

8. If internal monitoring at any other facilities has indicated that you received a significant (i.e., equal to or greater than 10 percent of the annual limit) uptake of radioactive materials, you must contact the Radiation Safety Officer (RSO) at each facility at which this has occurred and arrange to have this information sent to UAB's RSO or his designate.

9. I (have, have not) filed all previous occupational radiation exposures with the last facility. I (have, have not) received occupational radiation exposure within the last three months.

_____
Signature (Full Legal Name) Date

10. If you have had radiation exposure within the last three months at other facilities give the amount of exposure in millirem. If personnel monitoring data is unavailable for this period, provide an estimate of your radiation dose. You should consult the Radiation Safety Officer of each facility concerning these estimates. Doses should be clearly indicated as "measured" or "estimated".

_____millirem

check one	measured	
	estimated	

11. Information concerning exposure at other facilities.

    Please print the information requested below for each facility where your radiation exposure has been documented.

A. Facility_____

   Address_____

   Department_____

   Telephone No._____

   Exposure Period:

   From_____ To_____
   Month, Year Month, Year

   From_____ To_____
   Month, Year Month, Year

B. Facility_____

   Address_____

   Department_____

   Telephone No._____

   Exposure Period:

   From_____ To_____
   Month, Year Month, Year
   From_____ To_____
   Month, Year Month, Year

---

12. I AUTHORIZE THE RELEASE OF MY RADIATION EXPOSURE RECORDS TO THE RADIATION SAFETY PROGRAM, OCCUPATIONAL HEALTH AND SAFETY DEPARTMENT, UNIVERSITY OF ALABAMA AT BIRMINGHAM.

Signature (Full Legal Name)

APPENDIX L

QUARTERLY REPORT
HUMAN USE RADIOACTIVE DRUG RESEARCH

CALENDAR YEAR_____

QUARTERLY PERIOD ENDING MARCH JUNE SEPTEMBER DECEMBER

PROTOCOL TITLE _____

DATE OF APPLICATION_____

DATE OF APPROVAL _____

PHYSICIAN LICENSED TO USE RADIOPHARMACEUTICAL IN THE STUDY

PHYSICIANS OTHER THAN LICENSEE PARTICIPATING IN THE STUDY

1. Are currently approved studies on-going? _____ If not, when were they discontinued?
2. Is supervision of radiopharmaceutical use maintained by Licensee?
3. Is there any plan to discontinue current studies?
4. When will the current study be completed?
5. What is the duration of subject involvement?
6. Is there any plan to renew studies that were inactive during the previous quarter?
7. Where are the subjects dosed with radiopharmaceutical(s)?
8. What is the maximum radioactive dose given each subject?
9. Are there any minors or pregnant women involved? _____ If so, describe the nature of their involvement.
10. How many patients were involved in the study this quarter?
11. Were there any subjects discontinued in the study? _____ If so, why?
12. Were there any adverse reactions in the study?
13. Are consent documents being obtained from each subject?
14. Provide a list giving for each subject their age and sex and for each type of radiopharmaceutical administered during this quarter the following information: amount administered, activity dose per single administration, and accumulative activity dose administered.

_____

Signature of Licensee Date

APPENDIX M

SCHEDULE OF DEMINIMUM LEVELS OF RADIOACTIVITY
(EXEMPT QUANTITIES**)**

Radioactive Material	**Microcuries**
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115 (Cd 115)	100
Cadmium-115m (Cd 115m)	10
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100

Radioactive Material	**Microcuries**
Erbium-171 (Er 171)	100
Europium- 152 (Eu 152)9.2h	100
Europium- 152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1
Europium- 155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113 m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10

Radioactive Material	Microcuries
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100

Radioactive Material	**Microcuries**
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100

SCHEDULE OF DEMINIMUS LEVELS OF RADIOACTIVITY (Continued)

Radioactive Material	**Microcuries**
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

SCHEDULE OF DIMINIMUM LEVELS OF RADIOACTIVITY
(EXEMPT CONCENTRATIONS)

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml*	Column II Liquid and solid concentration μCi/ml**
Antimony (51)	Sb-122		$3x10^{-4}$
	Sb-124		$2x10^{-4}$
	Sb-125		$1x10^{-3}$
Argon (18)	Ar-37	$1x10^{-3}$	
	Ar-41	$4x10^{-7}$	
Arsenic (33)	As-73		$5x10^{-3}$
	As-74		$5x10^{-4}$
	As-76		$2x10^{-4}$
	As-77		$8x10^{-4}$
Barium (56)	Ba-131		$2x10^{-3}$
	Ba-140		$3x10^{-4}$
Beryllium (4)	Be-7		$2x10^{-2}$
Bismuth (83)	Bi-206		$4x10^{-4}$
Bromine (35)	Br-82	$4x10^{-7}$	$3x10^{-3}$
Cadmium (48)	Cd-109		$2x10^{-3}$
	Cd-115m		$3x10^{-4}$
	Cd-115		$3x10^{-4}$
Calcium (20)	Ca-45		$9x10^{-5}$
	Ca-47		$5x10^{-4}$
Carbon (6)	C-14	$1x10^{-6}$	$8x10^{-3}$
Cerium (58)	Ce-141		$9x10^{-4}$
	Ce-143		$4x10^{-4}$
	Ce-144		$1x10^{-4}$
Cesium (55)	Cs-131		$2x10^{-2}$
	Cs-134m		$6x10^{-2}$
	Cs-134		$9x10^{-5}$
Chlorine (17)	Cl-38	$9x10^{-7}$	$4x10^{-3}$
Chromium (24)	Cr-51		$2x10^{-2}$
Cobalt (27)	Co-57		$5x10^{-3}$
	Co-58		$1x10^{-3}$
	Co-60		$5x10^{-4}$
Copper (29)	Cu-64		$3x10^{-3}$
Dysprosium (66)	Dy-165		$4x10^{-3}$
	Dy-166		$4x10^{-4}$

*Values are given in Column I only for those materials normally used as gases.
**μCi/g for solids.

APPENDIX M (Continued)

SCHEDULE OF DIMINIMUM LEVELS OF RADIOACTIVITY
(EXEMPT CONCENTRATIONS)

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml*	Column II Liquid and solid concentration μci/ml**
Erbium (68)	Er-169		$9x10^{-4}$
	Er-171		$1x10^{-3}$
Europium (63)	Eu-152 (.2h)		$6x10^{-4}$
	Eu-155		$2x10^{-3}$
Fluorine (9)	F-18	$2x10^{-6}$	$8x10^{-3}$
Gadolinium (64)	Gd-153		$2x10^{-3}$
	Gd-159		$8x10^{-4}$
Gallium (31)	Ga-72		$4x10^{-4}$
Germanium (32)	Ge-71		$2x10^{-2}$
Gold (79)	Au-196		$2x10^{-3}$
	Au-198		$5x10^{-4}$
	Au-199		$2x10^{-3}$
Hafnium (72)	Hf-181		$7x10^{-4}$
Hydrogen (1)	H-3	$5x10^{-6}$	$3x10^{-2}$
Indium (49)	In-113m		$1x10^{-2}$
	In-114m		$2x10^{-4}$
Iodine (53)	I-126	$3x10^{-9}$	$2x10^{-5}$
	I-131	$3x10^{-9}$	$2x10^{-5}$
	I-132	$8x10^{-8}$	$6x10^{-4}$
	I-133	$1x10^{-8}$	$7x10^{-5}$
	I-134	$2x10^{-7}$	$1x10^{-3}$
Iridium (77)	Ir-190		$2x10^{-3}$
	Ir-192		$4x10^{-4}$
	Ir-194		$3x10^{-4}$
Iron (26)	Fe-55		$8x10^{-3}$
	Fe-59		$6x10^{-4}$
Krypton (36)	Kr-85m	$1x10^{-6}$	
	Kr-85	$3x10^{-6}$	
Lanthanum (57)	La-140		$2x10^{-4}$
Lead (82)	Pb-203		$4x10^{-3}$
Lutetium (71)	Lu-177		$1x10^{-3}$
Manganese (25)	Mn-52		$3x10^{-4}$
	Mn-54		$1x10^{-3}$
	Mn-56		$1x10^{-3}$

APPENDIX M (Continued)
SCHEDULE OF DIMINIMUM LEVELS OF RADIOACTIVITY
(EXEMPT CONCENTRATIONS)

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml*	Column II Liquid and solid concentration μci/ml**
Mercury (80)	Hg-197m		$2x10^{-3}$
	Hg-197		$3x10^{-3}$
	Hg-203		$2x10^{-4}$
Molybdenum (42)	Mo-99		$2x10^{-3}$
Neodymium (60)	Nd-147		$6x10^{-4}$
	Nd-149		$3x10^{-3}$
Nickel (28)	Ni-65		$1x10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1x10^{-3}$
	Nb-97		$9x10^{-3}$
Osmium (76)	Os-185		$7x10^{-4}$
	Os-191m		$3x10^{-2}$
	Os-191		$2x10^{-3}$
	Os-193		$6x10^{-4}$
Palladium (46)	Pd-103		$3x10^{-3}$
	Pd-109		$9x10^{-4}$
Phosphorus (15)	P-32		$2x10^{-4}$
Platinum (78)	Pt-191		$1x10^{-3}$
	Pt-193m		$1x10^{-2}$
	Pt-197m		$1x10^{-2}$
	Pt-197		$1x10^{-3}$
Potassium (19)	K-42		$3x10^{-3}$
Praseodymium (59)	Pr-142		$3x10^{-4}$
	Pr-143		$5x10^{-4}$
Promethium (61)	Pm-147		$2x10^{-3}$
	Pm-149		$4x10^{-4}$
Rhenium (75)	Re-183		$6x10^{-3}$
	Re-186		$9x10^{-4}$
	Re-188		$6x10^{-4}$
Rhodium (45)	Rh-103m		$1x10^{-1}$
	Rh-105		$1x10^{-3}$
Rubidium (37)	Rb-86		$7x10^{-4}$
Ruthenium (44)	Ru-97		$4x10^{-3}$
	Ru-103		$8x10^{-4}$

APPENDIX M (Continued)
SCHEDULE OF DIMINIMUM LEVELS OF RADIOACTIVITY
(EXEMPT CONCENTRATIONS)

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml*	Column II Liquid and solid concentration μci/ml**
	Ru-105		$1x10^{-3}$
	Ru-106		$1x10^{-4}$
Samarium (62)	Sm-153		$8x10^{-4}$
Scandium (21)	Sc-46		$4x10^{-4}$
	Sc-47		$9x10^{-4}$
	Sc-48		$3x10^{-4}$
Selenium (34)	Se-75		$3x10^{-3}$
Silicon (14)	Si-31		$9x10^{-3}$
Silver (47)	Ag-105		$1x10^{-3}$
	Ag-110m		$3x10^{-4}$
	Ag-111		$4x10^{-4}$
Sodium (11)	Na-24		$2x10^{-3}$
Strontium (38)	Sr-85		$1x10^{-3}$
	Sr-89		$1x10^{-4}$
	Sr-91		$7x10^{-4}$
	Sr-92		$7x10^{-4}$
Sulfur (16)	S-35	$9x10^{-8}$	$6x10^{-4}$
Tantalum (73)	Ta-182		$4x10^{-4}$
Technetium (43)	Tc-96m		$1x10^{-1}$
	Tc-96		$1x10^{-3}$
Tellurium (52)	Te-125m		$2x10^{-3}$
	Te-127m		$6x10^{-4}$
	Te-127		$3x10^{-3}$
	Te-129m		$3x10^{-4}$
	Te-131m		$6x10^{-4}$
	Te-132		$3x10^{-4}$
Terbium (65)	Tb-160		$4x10^{-4}$
Thallium (81)	Tl-200		$4x10^{-3}$
	Tl-201		$3x10^{-3}$
	Tl-202		$1x10^{-3}$
	Tl-204		$1x10^{-3}$
Thulium (69)	Tm-170		$5x10^{-4}$
	Tm-171		$5x10^{-3}$
Tin (50)	Sn-113		$9x10^{-4}$
	Sn-125		$2x10^{-4}$

APPENDIX M (Continued)
SCHEDULE OF DIMINIMUM LEVELS OF RADIOACTIVITY
(EXEMPT CONCENTRATIONS)

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml*	Column II Liquid and solid concentration μci/ml**
Tungsten (Wolfram) (74)	W-181		$4x10^{-3}$
	W-187		$7x10^{-4}$
Vanadium (23)	V-48		$3x10^{-4}$
Xenon (54)	Xe-131m	$4x10^{-6}$	
	Xe-133	$3x10^{-6}$	
	Xe-135	$1x10^{-6}$	
Ytterbium (70)	Yb-175		$1x10^{-3}$
Yttrium (39)	Y-90		$2x10^{-4}$
	Y-91m		$3x10^{-2}$
	Y-91		$3x10^{-4}$
	Y-92		$6x10^{-4}$
	Y-93		$3x10^{-4}$
Zinc (30)	Zn-65		$1x10^{-3}$
	Zn-69m		$7x10^{-4}$
	Zn-69		$2x10^{-2}$
Zirconium (40)	Zr-95		$6x10^{-4}$
	Zr-97		$2x10^{-4}$
Beta-and/or gamma emitting radioactive material not listed above with half-life of less than 3 years.		$1x10^{-10}$	$1x10^{-6}$

*Values are given only for those materials normally used as gases.
**uCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes that are also radioactive. In expressing the concentrations in Schedule C, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 420-3-26-.02(4) where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentrations present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = 1$$

UAB POLICY REGARDING RADIATION EXPOSURE DURING PREGNANCY

Policy Statement

Any female worker planning to have children should seek the information and advice that is available concerning her work and risks involved. Due to the fact that the embryo/fetus is more at risk than others when exposed to a radiation environment and that this radiation exposure is entirely involuntary for the fetus, substantial protection is hereby provided for it. Furthermore, it is the general consensus of the Radioisotope & Radiation Safety Committee that department policies be adopted within the framework of these requirements to make it easier for workers to render decisions regarding work-related functions that would involve radiation exposure to the fertile worker and her embryo/fetus.

Fertile individuals who may have occasion to be placed in a radiation field above background levels are strongly encouraged to report any confirmed pregnancy to their supervisor and the Radiation Safety Officer or his designate. Departments must be sensitive to the rights of personal privacy of the declared pregnant worker with regard to the results obtained from the monitoring of the dose to the embryo/fetus.

Declared pregnant workers with confirmed pregnancies must make decisions regarding continued work in their jobs once their options are explained to them. The work-related duties shall be described to these workers and their decisions and comments also documented with signature. Regardless of the worker's choice of her work-related activities, the following restrictions are necessary in the development of specific procedures to ensure that proper safety precautions and measures are taken at UAB:

1. The primary objective of the precautions taken is to prevent the embryo/fetus from being placed in a radiation environment such that any part of its body will receive more than a 50 millirem dose of radiation in any monthly period of time, and no more than 500 millirems for the entire gestation period.

2. Substantial variations above a uniform monthly exposure rate must be avoided.

3. In keeping with the ALARA concept adopted by UAB administrative officials, every effort must be made to keep the radiation dose to the embryo/fetus as low as reasonable achievable.

4. Intakes by a declared pregnant worker of inhaled or ingested radionuclides or via absorption through the skin must be evaluated and the subsequent effective committed dose equivalent to the embryo/fetus determined.

5. The recorded dose to the embryo/fetus will be the sum of (1) the deep-dose-equivalent to the pelvic region of the declared pregnant worker and (2) the effective committed dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant worker.

6. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure.

7. Arrangements must be made with the Radiation Safety Program for appropriate personnel monitoring.

It is the pregnant worker's obligation to immediately report any embryo/fetus exposure that is suspected to be significantly higher than the requirements prescribed herein. The suspect dose levels must then be investigated, detailed and corrective actions taken.

The following precautions apply to work performed by declared pregnant workers in areas using unsealed forms of radionuclides and are considered general guidelines:

1. Pregnant workers should not allow themselves to be exposed to radionuclides that are in volatile forms and easily absorbed through the skin or otherwise yield a dose equivalent of more than 50 millirems per month. This includes work in areas using radioiodine in unsealed volatile forms, except for exempt quantities listed in the Alabama Radiation Control Rules (ARCR).

2. Pregnant workers must wear appropriate protective clothing when handling radioactive material and there is a possibility of spills.

3. Pregnant workers must be directly supervised either by the persons licensed to possess and use the radioactive materials involved or their appropriately qualified designees.

4. Pregnant workers must not be allowed to clean up any radioactive spills, but should report them immediately to their supervisors.

5. When conducting any surveys for contamination, pregnant workers must utilize only dry filter samples and appropriate hand protection (i.e., a pair of vinyl or latex gloves).

6. Pregnant workers should not smoke, eat, drink, or apply cosmetics around radioactive material.

7. Pregnant workers should not pipette solutions by mouth.

8. Pregnant workers should monitor their hands for radioactive contamination after handling unsealed forms of radionuclides.

9. Pregnant workers should wash hands after working around radioactive material.

10. Any specific procedures, additional to those outlined herein, utilized by a department for the protection of the embryo/fetus must be filed with the Radiation Safety Program.

The following recommendations apply to work performed within an area utilizing significantly high levels of radiation exposure:

1. Pregnant workers must never be placed in situations where they may have to make a decision to enter a high radiation area under emergency conditions.

2. Decisions to utilize lead aprons or gonadal shields to be worn for the protection of the embryo/fetus must be discussed first with the Radiation Safety Officer or his designate.

3. For high energy radiation sources, additional efforts must be made to keep the average monthly doses to fertile women to no more than 50 millirems per month.

4. Pregnant workers must not involve themselves in situations or events requiring planned special exposures.

With regards to the exposure of fertile workers to ionizing radiation, the National Council on Radiation Protection and Measurements has determined that no observable effects have been demonstrated to any of the children, the embryo/fetus of whom was exposed in the period prior to the fifteenth week following conception.

PREGNANCY POLICY REGARDING IONIZING RADIATION (Continued)

Declaration of Pregnancy

When a radiation worker learns that she is pregnant or believes that she may be pregnant, she is strongly urged to notify her supervisor in writing of her pregnancy and the estimated month and year of conception. The Radiology Department must be sensitive to the rights of personal privacy of the declared pregnant worker with regard to the embryo/fetus dose. This documentation is kept confidential at the request of the worker. It is kept on file in the Personnel Department. UAB cannot guarantee that any exposure to the embryo/fetus will be within legal limits unless properly notified. With notification, proper steps can be taken to minimize further exposure.

At this point, the following steps must be taken:

1. Preliminary estimates of the radiation exposure already received since the date of conception must be ascertained.

2. Sufficient information and literature concerning the hazards of pregnancy and the safety precautions necessary in an ionizing-radiation environment must be given to her.

3. A counseling session must be scheduled with her, at which time she would be counseled by her supervisor or the Radiation Safety Officer (RSO) or his designate.

4. The pregnant worker shall be given the option of taking a leave of absence, or remaining at work and accepting the risks to the unborn associated with a potential radiation exposure within allowed limits.

5. The pregnant worker may receive additional counseling by the Chief Technologist and advised on specific safety measures that must be followed.

    a. A Whole Body Radiation Dosimeter (WBRD) must be worn at the collar level for x-ray technologists who are wearing lead aprons when exposed to x-rays.

    b. A second Whole Body Radiation Dosimeter (WBRD) must also be worn in the fetal area beneath the lead apron[1] for x-ray technologists who are wearing lead aprons when exposed to x-rays.

    c. More dosimetry may be used upon request or in special circumstances with the approval of the Radiation Safety Officer or his designate.

    d. During the gestation period, the maximum dose to the embryo/fetus shall not exceed 50 millirems for any one month and 500 millirems as a cumulative dose[2] to the embryo/fetus.

    e. ALARA efforts must be made to keep the individual away from areas of radiation exposure that are considered significantly high; however, due to work demands and staffing, complete removal from these areas cannot be guaranteed.

    f. The pregnant technologist must not hold any patients who have been recently dosed with gamma-emitting radiopharmaceuticals used for therapeutic procedures in amounts greater than 10 millicuries (370 MBq).

[1] It is recommended that a wrap-around lead apron be utilized should the worker be required to be actively working in the otherwise unshielded vicinity of an x-ray unit.

Declaration of Pregnancy (Continued)

[2] If the cumulative dose is likely to exceed 500 millirem at any point during the gestational period, the employee will be advised to take a leave of absence from that point until after the child is born and has her physician's permission to return to work. If the dose to the embryo/fetus exceeds this level, the individual, the Jefferson County Department of Health and/or the State of Alabama Radiological Health Branch shall be notified in writing of the overexposure in accordance with regulatory requirements.

Documentation of Embryo/Fetus Dose

The documentation of the radiation dose to the embryo/fetus for the entire gestation period must be recorded, but such documentation is not required on Form 4 or on Form 5 for the Bureau of Health Care Standards, Department of Public Health, State of Alabama (See Attachment N).

PREGNANCY PRECAUTIONS IN NUCLEAR MEDICINE

Methods to Reduce Exposure from External Radiation

1. For some radionuclides shielding apparel can be utilized to reduce the radiation exposure of the embryo/fetus.

2. If the pregnant worker in nuclear medicine decides to utilize a lead apron to reduce the dose to the embryo/fetus, she should still strive to minimize her time during the handling of radionuclides.

3. Lead aprons may not provide any significant measure of protection for some radionuclides used.

4. Syringe and vial shields can be used very effectively to decrease radiation exposure by a factor of twenty-fold or more in some cases.

5. The only other primary measures which can be taken by a pregnant nuclear medicine worker are those involving time and distance.

6. Radiation exposure to nuclear medicine technologists is reduced through the use of nuclear pharmacies.

7. The majority of the exposure comes from radiation exposure from the patients who have been dosed. By maintaining a minimum distance of one meter from the patient, the dose rate can be significantly reduced.

8. Plans could be made each day to reduce the pregnant worker's exposure by arranging her activity work load to involve the use of less radioactivity. The exposure received during quality assurance checks such as the constancy checks of the dose calibrator is insignificant.

9. Considering the various routes of intake (i.e., absorption through intact skin, ingestion and inhalation), the probabilities of uptakes causing internal exposure can be dramatically reduced by performing frequent personnel monitoring (i.e., checking the hands, arms and face for radioactive contamination; nasal swabs). These personnel surveys should be well documented.

Pregnant Worker's Guide

Possible Health Risks to Children of Women Who Are Exposed to Radiation During Pregnancy

During pregnancy, you should be aware of things in your surroundings or in your style of life that could affect your unborn child. For those of you who work in or visit areas designated as Restricted Areas (where access is controlled to protect individuals from being exposed to radiation and radioactive materials), it is desirable that you understand the biological risks of radiation to your unborn child.

Everyone is exposed daily to various kinds of radiation: heat, light, ultraviolet, microwave, ionizing, and so on. For the purposes of this guide, only ionizing radiation (such as x-rays, gamma rays, neutrons, and other high-speed atomic particles) is considered. The natural environment is radioactive and all human activities involve exposure to radiation. People are exposed to different amounts of natural "background" ionizing radiation depending on where they live. Radon gas in homes is a problem of growing concern. Background radiation comes from four sources (including radon), and the average annual dose equivalent is given as follows:

	Average Annual Dose
Terrestrial-radiation from soil and rocks	28 millirems
Cosmic-radiation from outer space	27 millirems
Radon	200 millirems
Radioactivity normally found within the human body	39 millirems
Total natural	300 millirems*

The first two of these sources expose the body from the outside, and the last two expose it from the inside. The average person is thus exposed to a total dose of about 300 millirems per year from natural background radiation. There are essentially no differences in the exposure of different tissues of the body from terrestrial and cosmic radiation.

* Radiation doses in this document are described in two different units. The rad is a measure of the amount of energy absorbed in a certain amount of material (100 ergs per gram). Equal amounts of energy absorbed from different types of radiation may lead to different biological effects.

Naturally occurring radon and its progeny cause an average dose equivalent to the bronchial epithelium of the lung in the amount of 2,500 mrems per year. A log-normal distribution of dosages (geographic and other factors) is encountered here. It ranges from levels close to the 2,500 mrems average to as high as 12,000 mrems, for one percent of the U. S. population.

In addition to exposure from natural background radiation, medical procedures may contribute to the dose people receive. The following table lists the average effective dose equivalents received by members of the U.S. population from different medical applications:

	Average Dose** (millirems)
Normal chest examination	8 millirems
Skull	220 millirems
CT (head and body)	111 millirems
Cervical Spine	200 millirems
Biliary	189 millirems
Lumbar Spine	127 millirems
Upper Gastrointestinal	244 millirems
Abdomen (KUB) examination	560 millirems
Barium enema examination	4,060 millirems
Pelvis examination	440 millirems
Hip	83 millirems
Extremities	1 millirem
Other	50 millirems

NRC/ALABAMA Position

NRC/ALABAMA regulations and guidance are based on the conservative assumption that any amount of radiation, no matter how small, can have a harmful effect on an adult, child, or unborn child. This assumption is said to be conservative because there are no data showing ill effects from small doses; the National Academy of Sciences expressed "uncertainty as to whether a dose of, say, 1 rad would have any effect at all". Since it is known that the unborn child is more sensitive to radiation than adults, particularly during certain stages of development, the NRC/ALABAMA has established a special dose limit for protection of the unborn child. Such a limit might unknowingly result in job discrimination for women of child-bearing age and perhaps in the invasion of privacy (if pregnancy tests were required). These regulatory limits make special protection of the unborn child mandatory. Decisions made by workers concerning job activities around ionizing radiation must consider the hazards and risks involved. Only after being properly informed of these risks can prudent decisions be made.

It is important that both the employee and the employer understand the risk to the unborn child from radiation received as a result of the occupational exposure of the mother. This document tries to explain the risk as clearly as possible and to compare it with other risks to the unborn child during pregnancy. It is hoped this will help pregnant employees balance the risk to the unborn child against the benefits of employment to decide if the risk is worth taking. This document also discusses methods of keeping the dose, and therefore the risk, to the unborn child as low as is reasonably achievable.

Like a working minor (one under 18), the embryo/fetus is limited to a dose equal to one-tenth that of adults, 500 millirems per year; however, there is an additional limit to the embryo/fetus of 50 millirems per month during the gestation period.

** The units used here are effective dose equivalents using the ICRP methodology of using weighting factors. The rem is a unit that reflects the biological damage done to the body. The millirad and millirem refer to 1/1000 of a rad and a rem, respectively.

This is due to the sensitivity of the unborn child to ionizing radiation and was based on the previous recommendations of the National Council on Radiation Protection and Measurements (NCRP) for the entire pregnancy. There are also recommendations that substantial variations in the rate of exposure be avoided.

Advice for Employee and Employer

Although the risks to the unborn child are small under normal working conditions, it is still advisable to limit the radiation dose from occupational exposure to no more than 50 millirems per month and 500 millirems for the total pregnancy. By keeping the dose level to no more than 50 millirems per month, the total dose during the pregnancy should not exceed 500 millirems. Employee and employer should work together to decide the best methods for accomplishing these goals. Some methods that might be used include reducing the time spent in radiation areas, wearing some shielding over the abdominal area, and keeping extra distance away from radiation sources when possible. The employer or health physicist is generally able to estimate the dose to the unborn child during the normal nine-month pregnancy period and to inform the employee of the amount. If the predicted dose exceeds 50 millirems per month, the employee and employer should work out schedules or procedures to limit the dose to no more than the monthly 50 millirem limit.

It is important that the employee inform the employer of her condition as soon as she realizes she is pregnant if the dose to the unborn child is to be minimized.

Internal Hazards

This document has been directed primarily toward a discussion of radiation doses received from sources outside the body. Workers should also be aware that there is a risk of radioactive material entering the body in the workplace where unsealed radioactive materials are used. Nuclear medicine clinics, laboratories, and certain manufacturers use radioactive materials in bulk form, often as a liquid or a gas.

A list of the commonly used materials and safety precautions for each is beyond the scope of this document, but certain general precautions include the following:

1. Do not smoke, eat, drink, or apply cosmetics in the vicinity of radioactive materials.

2. Do not pipette solutions by mouth.

3. Use disposable gloves while handling radioactive materials when feasible.

4. Wash hands after using radioactive materials.

5. Wear lab coats or other protective clothing whenever there is a possibility of spills.

Remember that the employer is required to have demonstrated that it has safe procedures and practices before the Radiological Health Branch, State of Alabama allows it to work under a license to use radioactive materials. Workers are urged to follow established procedures and consult the employer's radiation safety officer or health physicist whenever problems or questions arise.

Instructor's Guide

Effects on the Embryo/Fetus of Exposure to Radiation
and Other Environmental Hazards

In order to decide whether to continue working while exposed to ionizing radiation during her pregnancy, a worker must understand the potential effects on an embryo/fetus from different sources of risks. This would include those effects that may be produced by occupational, non-occupational, medical procedures, and various environmental risks such as smoking and drinking. This allows her to compare these risks with those produced by exposure to occupational ionizing radiation. She must understand, however, that the benefits from medical exposure to ionizing radiation, in most instances, far outweigh the risks involved.

Table 1 provides information on the potential effects resulting from exposure of an embryo/fetus to radiation and non-radiation risks. The second column gives the rate at which the effect is produced by natural causes in terms of the number per thousand cases. The fourth column gives the number of additional effects per thousand cases believed to be produced by exposure to the specified amount of the risk factor.

The following section discusses the studies from which the information in Table 1 was derived. The results of exposure of the embryo/fetus to the risk factors and the dependence on the amount of the exposure are explained.

1.0 RADIATION RISKS

1.1 Childhood Cancer

Numerous studies of radiation-induced childhood cancer have been performed, but a number of them are controversial. The National Academy of Science (NAS) BEIR report reevaluated the data from these studies and reanalyzed the results. Some of the strongest support for a causal relationship is provided by twin data from the Oxford survey. For maternal radiation doses of 1,000 millirems, the excess number of deaths (above those occurring from natural causes) was found to be 0.6 deaths per thousand children.

1.2 Mental Retardation and Abnormal Smallness of the Head (Microcephaly)

Studies of Japanese children who were exposed while in the womb to the atomic bomb radiation at Hiroshima and Nagasaki have shown evidence of both small head size and mental retardation. Most of the children were exposed to radiation doses in the range of 1 to 50 rads. The importance of the most recent study lies in the fact that investigators were able to show that the gestation age (age of the embryo/fetus after conception) at the time the children were exposed was a critical factor. The approximate risk of a small head size as a function of gestation age is shown in Table 1. For a radiation dose of 1,000 millirems at 4 to 7 weeks after conception, the excess cases of small head size was 5 per thousand; at 8 to 11 weeks, it was 9 per thousand.

In another study, the highest risk of mental retardation occurred during the 8 to 15 week period after conception. An EPA study has calculated that excess cases of mental retardation per live birth lie between 0.5 and 4 per thousand per rad.

1.3 Genetic Effects

Radiation-induced genetic effects have not been observed to date in humans. The largest source of material for genetic studies involves the survivors of Hiroshima and Nagasaki, but the 77,000 births that occurred among the survivors showed no evidence of genetic effects. For doses received by the pregnant worker in the course of employment considered in this guide, the dose received by the embryo/fetus apparently would have a negligible effect on descendants.

2. NONRADIATION RISKS

2.1 Occupation

A study involving the birth records of 130,000 children in the State of Washington indicates that the risk of death to the unborn child is related to the occupation of the mother. Workers in the metal industry, the chemical industry, medical technology, the wood industry, the textile industry, and farms exhibited stillbirths or spontaneous abortions at a rate of 90 per thousand above that of workers in the control group, which consisted of workers in several other industries.

2.2 Alcohol

It has been recognized since ancient times that alcohol consumption had an effect on the unborn child. Studies have indicated that small amounts of alcohol consumption have only the minor effect of reducing the birth weight slightly, but when consumption increases to 2 to 4 drinks per day, a pattern of abnormalities called the fetal alcohol syndrome (FAS) begins to appear. This syndrome consists of reduced growth in the unborn child, faulty brain function, and abnormal facial features. There is a syndrome that has the same symptoms as full-blown FAS that occurs in children born to mothers who have not consumed alcohol. This naturally occurring syndrome occurs in about 1 to 2 cases per thousand.

For mothers who consumed 2 to 4 drinks per day, the excess occurrences number about 100 per thousand; and for those who consume more than 4 drinks per day, excess occurrences number 200 per thousand. The most sensitive period for this effect of alcohol appears to be the first few weeks after conception, before the mother-to-be realizes she is pregnant. Also, 17% or 170 per thousand of the embryo/fetuses of chronic alcoholics develop FAS and die before birth. FAS was first identified in 1973 in the United States where less than full-blown effects of the syndrome are now referred to as fetal alcohol effects (FAE).

2.3 Smoking

Smoking during pregnancy causes reduced birth weights in babies amounting to 5 to 9 ounces on the average. In addition, there is an increased risk of 5 infant deaths per thousand for mothers who smoke less than one pack per day and 10 infant deaths per thousand for mothers who smoke one or more packs per day.

2.4 Miscellaneous

Numerous other risks affect the embryo/fetus, only a few of which are touched upon here. Most people are familiar with the drug thalidomide (a sedative given to some pregnant women), which causes children to be born with missing limbs. The use of the drug diethylstilbestrol (DES), a synthetic estrogen given to some women to treat menstrual disorders, has produced vaginal cancers in the daughters born to women who took the drug. Living at high altitudes also gives rise to an increase in the number of low-birth-weight children born, while an increase in Down's Syndrome (mongolism) occurs in children born of mothers who are over 35 years of age. The rapid growth in the use of ultrasound has sparked an ongoing investigation into the risks of using ultrasound for diagnostic procedures.

APPENDIX N (Continued)

Table 1

EFFECTS OF RISK FACTORS ON PREGNANCY OUTCOME

Effect	Number Occurring from Natural Causes	Risk Factor	Number of Additional Effects Per Thousand Cases
Cancer death in children	1.4 per thousand	Radiation dose of 100 millirems received before birth	0.6 per thousand
		Abnormalities	
		Radiation dose of 1000 millirads received during specific periods after conception:	
Small head size	40 per thousand	4-7 weeks after conception	5 per thousand
Small head size	40 per thousand	8-11 weeks after conception	9 per thousand
Mental retardation	4 per thousand	Radiation dose of 1000 millirads received 8 to 15 weeks after conception	4 per thousand

NONRADIATION RISKS

Effect	Number Occurring from Natural Causes	Occupation	Number of Additional Effects Per Thousand Cases
Still birth or spontaneous abortion	200 per thousand	Work in high-risk occupations	90 per thousand
		Alcohol Consumption (see text)	
Fetal alcohol syndrome	1 to 2 per thousand	2-4 drinks per day	100 per thousand
Fetal alcohol syndrome	1 to 2 per thousand	More than 4 drinks per day	200 per thousand
Fetal alcohol syndrome	1 to 2 per thousand	Chronic alcoholic (more than 10 drinks per day)	350 per thousand
Prenatal infant death	23 per thousand	Chronic alcoholic (more than 10 drinks per day)	170 per thousand (around the time of birth)
Perinatal infant death	23 per thousand	Less than 1 pack per day	5 per thousand

APPENDIX N (Continued)

Table 1

EFFECTS OF RISK FACTORS ON PREGNANCY OUTCOME

NONRADIATION RISKS (Continued)

Effect	Number Occurring from Natural Causes	Occupation	Number of Additional Effects Per Thousand Cases
Perinatal infant death	23 per thousand	One pack or more per day	10 per thousand

APPENDIX N (Continued)

PREGNANCY INSTRUCTION STATEMENT

I, _____ (print full name) declared my pregnancy on _____ (give the date) and was given the opportunity to receive and did review the following information regarding the hazards of ionizing radiation and prenatal exposure and clinical radiation safety precautions:

1. Instruction Regarding Prenatal Radiation Exposure _____ (date & initial)
2. Radiation Safety Procedures for Radiation Work
   Involving _____ _____ (date & initial)
3. Other Information Regarding Prenatal Radiation Exposure

   (Specify) _____ _____ (date & initial)

I understand the information given above and have made a decision to continue, not to continue (circle one) working at the same tasks required of me before my pregnancy. I further agree to notify my supervisor immediately if and when I suspect that I have been contaminated with radioactive materials.

If you have circled "not to continue" certain work within the department, please identify these specific tasks and then describe below, in the space provided, the tasks that you have agreed to perform in their place.

_____ Initial here if you have decided not to work, to work (circle one) around radioactive materials (if applicable) or radiation levels that are classified as "some risk".

_____ Initial here if you have decided to work in an area remote from radioactive materials (if applicable) or radiation levels that are classified as "some risk".

COMMENTS (Use the other side of this document if you need more space):

_____
Worker's Signature (Date)

_____
Supervisor's Signature (Date)

APPENDIX O

RADIATION SAFETY AUDIT SCHEDULE AND ESCALATED ENFORCEMENT ACTIONS

I. Rationale

Compliance with radiation safety requirements can be achieved through proper instruction and training of personnel, periodic radiation safety audits and spot checks of laboratory operations, and proper enforcement actions to correct deficiencies noted during these safety checks.

The frequency with which radiation safety audits are conducted should be tied in a reasonable manner to the degree of compliance achieved by UAB radioactive materials licensees. Deserving radioactive material licensees, who are safety conscious and who repeatedly demonstrate that their licensed operations are being conducted in a safe manner, may not be audited as often as those whose programs do not meet these requirements. On the other hand, they should not be extended to lengthy audit intervals that would lead to an atmosphere of regulatory relaxation, particularly in areas where there are high personnel turnover rates.

The overall goal is to gain complete compliance with the UAB Radiation Safety Procedures Manual, with the conditions of the radioactive materials licenses issued, and with the Alabama Rules for Control of Radiation. This is a difficult goal to achieve, particularly with the large number of licenses that have been issued by the Radioisotope and Radiation Safety Committee (RRSC) and with a significant turnover in personnel which periodically occurs at UAB.

The enforcement of radiation safety measures instituted within a licensee's radioactive materials program initially rests with the licensee. The results documented by the radiation safety audit demonstrate whether licensees are successful in their attempts to do so. It is recognized that there may be a situation where an individual working for a licensee may use radioactive materials in a manner contrary to the measures instituted deliberately. In a situation such as this, more frequent spot checks by the Radiation Safety Program of the individual acting in this manner may be performed. The licensee would not be penalized in these situations, if the licensee demonstrates measures taken in efforts to gain more appropriate responses and regulatory compliance from the individual.

II. Frequency of Radiation Safety Audits

Audits of UAB radioactive materials licensees must be conducted at least annually by the Radiation Safety Program. The interval between radiation safety audits conducted of radioactive materials licensees by the UAB Radiation Safety Program is generally either a six-month interval, a nine-month interval, or a twelve-month interval, as determined by the Radiation Safety Officer or his designate.

Those licensees who are in noncompliance may be audited for radiation safety compliance more frequently. The RRSC has left the decision for the length of the interval between scheduled audits up to the discretion of the Radiation Safety Program, as directed by the Radiation Safety Officer. That decision depends on many factors, such as how often the deficiencies have occurred, the severity of the noncompliance items, whether licensees appear to be sincere in their efforts to correct these noncompliance items, the health and welfare of the licensees and other individuals present in their surroundings, etc.

For those situations when licensees have more than just a few noncompliance items or the noncompliance items themselves are of a nature as to create situations causing or leading to a significant radiation exposure of personnel, then the RSO or his designate might direct the safety audits to be conducted much more frequently – perhaps at less than one-half the regular interval. When a decision is made by the RSO or his designate to conduct inspections of a UAB radioactive materials license much more frequently, the change in the licensee’s inspection frequency must be reported by the RSO or his designate during the next regularly scheduled quarterly meeting of the RRSC, along with the reasons for the change in inspection frequency. Repeated infractions may lead to escalated enforcement actions, as described in the next section.

II. Frequency of Radiation Safety Audits (Continued)

NOTE: In the future, UAB Occupational Health & Safety auditors may perform comprehensive audits of the laboratories of UAB radioactive materials licensees which include biosafety, chemical safety, and general safety audits, as well as radiation safety audits.

III. Escalated Enforcement Actions

UAB Radioactive Materials Licensees Who Do Not Respond To Citation Letters

In order to meet regulatory requirements of the Alabama Department of Public Health, Office of Radiation Control, the Radioisotope and Radiation Safety Committee (RRSC) has adopted the following policy for all UAB radioactive materials licensees who do not respond to citation letters, including citation letters for inadequate radioactive materials inventories. If a citation letter is issued to a UAB radioactive materials licensee and there is no response within 30 days of receipt of the letter, a second citation letter is issued and the licensee cannot order radioactive materials until an acceptable citation response has been received in writing by the Radiation Safety Program.

If there is still no response to the second citation letter within 30 days of receipt of the second letter, a notice will be sent by the Chairman of the RRSC and the Radiation Safety Officer stating that the individual's UAB radioactive materials license will be revoked unless the licensee appears before the RRSC during its next regularly scheduled meeting to offer some explanation for why the license should not be revoked and to offer corrective measures to prevent a recurrence. After hearing the licensee's explanations and corrective measures, the RRSC will vote on whether to revoke his/her radioactive materials license.

UAB Radioactive Materials Licensees Who Receive Repeat Citations

The Radioisotope and Radiation Safety Committee (RRSC) has adopted the following policy for all UAB radioactive materials licensees who receive repeat citations (for example, receiving a citation for Records of Area Surveys for consecutive audits, or receiving a citation for Inadequate Radioactive Materials Inventories for consecutive quarters.) If a UAB radioactive materials licensee receives a repeat citation, a repeat citation letter will be issued stating that if the licensee receives a third consecutive citation for the same item (for example, receiving a citation for Records of Area Surveys for three consecutive audits, or receiving a citation for Inadequate Radioactive Materials Inventories for three consecutive quarters), the radioactive materials license is in danger of being revoked.

If a UAB radioactive materials licensee receives a third consecutive citation for the same item, a notice will be sent by the Chairman of the RRSC and the Radiation Safety Officer stating that the individual's UAB radioactive materials license will be revoked unless the licensee appears before the RRSC during its next regularly scheduled meeting to offer some explanation for why the license should not be revoked and to offer corrective measures to prevent a recurrence. After hearing the licensee's explanations and corrective measures, the RRSC will vote on whether to revoke his/her radioactive materials license.

Other Reasons For Which A UAB Radioactive Materials License May Be Revoked Or Suspended

Radioactive Materials Licensees may be given notice by the Chairman of the RRSC that their radioactive material licenses are in danger of being suspended or revoked when the following occurs:

(1) Repeated occurrences of noncompliance and safety deficiencies persist, as shown by documented citations,

(2) Measures taken by licensees have been insufficient and appear to be due to lack of proper attitude of safety, and

III. Escalated Enforcement Actions (Continued)

Other Reasons For Which A UAB Radioactive Materials License May Be Revoked Or Suspended (Continued)

(3) The licensee has not demonstrated any measure of intent to correct reoccurring deficiencies.

The notice would direct them to appear before the RRSC during its next regularly scheduled meeting to offer some explanation and response on their behalf. (The Chairman of the RRSC and the RSO may jointly decide to hold a special meeting or to temporarily suspend a licensee's operations in matters involving timely compliance.) Failure in attending this meeting would mean an automatic revocation of their licenses. After hearing the licensees' explanations and corrective measures, if allowed to continue work under their licenses, the RRSC will vote on a decision whether to suspend or revoke the licensed activities.

Consequences Of Revoking Or Suspending A UAB Radioactive Materials License

A licensee whose radioactive materials license has been revoked loses the privilege to work with radioactive materials for a period of time not less than one year, and the individual would have to reapply for future work as a radioactive materials licensee. A licensee's privileges may be suspended for periods less than one year, but not for intervals shorter than one quarter. The period of the suspension is decided upon by the Radioisotope and Radiation Safety Committee.

Should the efforts of the Radioisotope and Radiation Safety Committee fail to gain compliance from radioactive materials licensees or individuals working under their licenses, the Office of the President of UAB will take positive measures to correct the situation.

APPENDIX P

PROCEDURES FOR THERAPY TREATMENT
WITH UNSEALED RADIOPHARMACEUTICALS

A. Rationale

The purpose for written nursing procedures in the care of patients undergoing the therapeutic use of radiopharmaceuticals can be explained in many ways and is not limited to the following:

Ensuring the optimal and safe care of patients receiving therapeutic amounts of radioactive material.

Ensuring that the radiation exposure to any individual does not exceed safety guidelines and regulatory requirements, and is kept to the lowest and most reasonably achievable level.

Obtaining the cooperation of patients, visitors and personnel by instilling in them the necessity for precautionary measures.

Preventing patients from feeling isolated and/or rejected by hospital personnel.

Preventing unreasonable fear by personnel caring for the patient.

Enabling nursing personnel to perform proper actions according to the use of these written precautions, the Radioactivity Precautions Notice in the patient's medical record, posted warning signs, and the standard nursing procedures.

Enabling nursing personnel to accept the nurse's station, the corridors and the rooms adjacent to radiation therapy rooms as safe areas.

Minimizing the potential spread of radioactive contamination.

Addressing annual instruction of nurses in radiation safety.

B. Facility and Equipment Requirements

Private rooms are required for patients receiving therapeutic quantities of radioactive materials. A corner room is preferable.

Arrangement of the furniture, lead shielding, radiation safety receptacles and other radiation safety equipment must be maintained according to the instructions of the Radiation Safety Program personnel and as indicated on the Radioactivity Precautions Notice.

Private bath and toilet facilities must be provided for patients receiving quantities of radioactive materials by mouth or intravenously (i.e., Iodine-131).

A copy of the "Procedures for Therapy Treatment with Unsealed Radiopharmaceuticals" must be available at all Nurses Stations where this type of radiation therapy occurs.

C. Assignment of Nursing Personnel

All nursing personnel assigned to care for patients who have received therapeutic quantities of radioactive materials shall be considered to be individuals who are occupationally exposed to ionizing radiation. Steps must be taken to ensure that personnel radiation monitors are issued to them, as needed (See Appendix D).

C. Assignment of Nursing Personnel (Continued)

Monthly personnel radiation dosimeters must be worn by all nursing personnel who are attending to the care of thyroid cancer patients treated with more than 30 millicuries (1.11 GBq) of iodine-131. The dosimeters must not be worn by nursing personnel while receiving medical or dental diagnostic x-rays or therapeutic x-rays.

Appropriate training shall include areas relevant to radiation protection. The amount of training depends on the potential for radiation exposure, the complexity of the task, and the role and responsibility of the individual.

Nursing personnel are limited to 25 millirems per 24-hour period of whole body exposure to radiation during routine care of patients being treated with iodine-131 for thyroid cancer. The "time limits for nursing personnel" are determined based on this limit. However, nurses are allowed a minimum 20 minutes per shift for routine care of patients being treated with iodine-131 for thyroid cancer regardless of the exposure levels.

Reports of radiation exposure must be posted in an area where assigned nursing personnel frequent.

The nurse-in-charge shall be responsible for ensuring that nurses on duty in these areas are familiar with the written precautions for radioactive materials treatment and for information and instructions given to the next shift.

Spare dosimeters must be made available for assignment and use by new nursing personnel giving care to patients undergoing treatment for thyroid cancer.

Nursing personnel with open wounds must have them properly dressed and covered prior to working in the rooms of patients receiving therapeutic amounts of radioisotopes.

Pregnant nurses must not be assigned to the routine care of these patients. In the event that it becomes known that there was a pregnancy during such care, the Radiation Safety Officer or his designate must be notified.

The nursing staff should observe the "Controlled Areas" (corridors, stairwells and perhaps other patient rooms adjacent to the patient's room) and attempt to limit unnecessary traffic through these areas and thus reduce occupancy in these areas as much as reasonably achievable.

An employee or student under eighteen years of age shall not be permitted to take care of these patients.

In the event that a special duty nurse is required, the Radiation Safety Officer or his designate must be notified.

Care for patients receiving radiotherapy should be rotated among the staff as much as reasonably achievable.

In the event of an iodine-131 spill (i.e., vomitus, urine spills, etc.), nursing personnel attending the patient must arrange for thyroid monitoring with the Radiation Safety Program.

D. Responsibilities of the Radiation Safety Program

The Radiation Safety Officer or his designate is responsible for evaluation and approval of rooms to be used for patients receiving therapeutically large amounts of radiopharmaceuticals.

Ensuring proper room preparation, availability of proper radiation safety supplies, caution signs (i.e., Caution Controlled Area No Loitering signs, etc.) and initiation of control procedures for isolating the patient's room.

Arranging the furniture in the patient's room, including any special portable lead shielding around the patient's bed (when required), for the safety of nursing personnel, visitors and other workers.

D. Responsibilities of the Radiation Safety Program (Continued)

Providing special, timely and **annual** radiation safety instructions to all personnel charged with the care of patients undergoing radioactive therapy.

Posting of the Radioactivity Precautions Notice in the patient's medical record and warning signs and instructions on the patient's door.

Having Onsite Radiation Safety Program personnel to survey areas around the patient's room during the day shift to ensure that the safety of workers is not being compromised during patient treatment.

Monitoring the radiation exposure rates in the controlled areas around the patient's room during the day shift and making adjustments in the position of the bedside shield or the patient in relation to the bedside shield when necessary.

Performing radiation surveys in and about patient’s rooms to evaluate the potential radiation hazards within and outside of restricted areas and in controlled areas. This would include determining the time limits for nursing personnel and visitors. Documentation of surveys must be provided for placement in the patient's medical record.

Maintaining file copies of radiation surveys for radiotherapy patients.

Responsibility in determining when the patient may be removed from isolation.

Completing the patient release log when it is determined that a patient may be released from the hospital. If the release is authorized via telephone, ensure that instruction is given to nursing personnel to document that release authorization was given.

E. Responsibilities of Nuclear Medicine Personnel*

Only a physician authorized by a Nuclear Medicine License may prescribe the kind and amount of radiopharmaceutical given to the patient. The physician user must specify by written directive the dose to the patient and information specified by the quality management program in Nuclear Medicine must be given to the patient.

Either a nuclear medicine physician or an intern physician with at least 30 hours of training in nuclear medicine therapy must be physically present while the patient is being dosed with therapeutic amounts of a radiopharmaceutical.

Preparation and administration of the radiotherapy dose to the patient.

Complete the Patient Report Form and Patient Consent Form and attach these to the patient's medical record. A copy of these will be maintained in the Nuclear Medicine office.

Provide assistance to the Radiation Safety Program, if required.

Provide consultation, when necessary, regarding the handling of patients.

Notify the Radiation Safety Program, the Clinical Laboratory, the nurse-in-charge on the Nursing Unit and Environmental Services of scheduled Iodine-131 therapy. Give the patient's name, type of therapy, the room number, extent of room preparation and time schedule. The Clinical Laboratory must be reminded to take blood tests before the dosing of the patient.

Transport the radioactive dose from the Nuclear Medicine Division to the patient's room using direct routes and taking care to maintain a safe distance from others.

E. Responsibilities of Nuclear Medicine Personnel* (Continued)

Nuclear Medicine Personnel attending a patient should ensure that the door to the patient's room is (1) either closed during dosing with radioactive iodine or (2) if open, the corridor is restricted from travel during the dosing of the patient.

Nuclear Medicine Personnel attending a patient should instruct the patient in the proper procedure in taking Iodine-131 doses orally so as to minimize exposure to the patient's lungs.

Nuclear Medicine Personnel attending a patient must wear suitable clothing (including shoe covers) to guard against Iodine-131 spills when entering a patient's room and during dosing of the patient.

* This would be the Nuclear Medicine Division of Diagnostic Radiology or Oncology Nuclear Medicine of the Radiation Oncology Department.

Nuclear medicine personnel attending a patient must carefully remove plastic gloves and shoe covers upon exiting a patient room, taking care not to spread contamination.

Nuclear medicine personnel attending a patient must monitor hands, clothing, and shoes after exiting the patient's room at an appropriate distance from the patient's room.

Determine the amount of residual Iodine-131 in the patient prior to performing clinical nuclear medicine studies which utilize Iodine-131 peaks. The prior survey information provided by the Radiation Safety Program may be used in these determinations.

F. Instructions for Nursing Personnel

Any of the nurses who care for radiation therapy patients are required to attend the radiation safety presentations given by the Radiation Safety Program. Nurses must familiarize themselves with the content and instructions given on the Radioactivity Precautions Notice in the medical record of these patients. For instance, the bedside "time limit for nursing personnel" must be observed.

Urgent actions to deal with accident situations arising from fire, explosion, or mechanical damage, or from the need to rescue or treat injured persons, must not be delayed because of the presence of radioactivity in the therapy patient.

The lead shields, when placed beside a patient's bed, must be utilized whenever possible for attendant care within two feet of the patient.

As any exposure may involve some degree of risk, any unnecessary exposure should be avoided and any exposure received by personnel kept as low as reasonably achievable (ALARA).

Good procedures are essential. All techniques must be well thought out and understood before work is undertaken. A balance should be struck between hurried manipulations, which may cause accidents, and prolonged operations, which may lead to excessive exposures.

The Radiation Safety Officer or his designate must be notified when any of the patients containing therapeutic quantities of radioactive materials expires, is transferred to another hospital or clinic, fails to observe isolation requirements during treatment or leaves the hospital against medical advice.

Nursing personnel should learn to identify and check for appropriate "warning” signs on patients' doors, and ensure that posting is maintained as required by the Radiation Safety Program.

F. Instructions for Nursing Personnel (Continued)

Nursing personnel should record routine care given to patients on the patients' medical records, including patients' comments. Nursing personnel should also record any visits made by visitors.

Attendant nurses should be familiar with the time limit and minimum distance restrictions placed on the visitors of patients undergoing radiotherapy treatments. Furthermore, visitors should be advised accordingly and the Radiation Safety Program notified if these instructions are disregarded or otherwise violated.

All non-radioactive laboratory work for these patients (i.e., involving the taking of blood or urine samples) should be done prior to dosing them with therapeutic amounts of radiopharmaceuticals. Laboratory work which becomes necessary during the radioactive treatments should be delayed at least 48 hours following the time patients received the dose, if possible.

Unless required, nurses must not be in the patients' rooms during their dosing with therapeutic amounts of radiopharmaceuticals. At any other time, nursing personnel may enter their patients' rooms to perform their normal duties; however, they should not spend excessive time visiting with them nor performing non-vital personal services such as shaving or hairdressing.

Patients should be encouraged to care for themselves and to be as self-sufficient as possible, thus reducing the need for close contact with hospital personnel.

When lead shields are required in the proximity of the bed during treatment, the position of the patient with respect to these shields should be periodically viewed to ensure effective use of the shields. Inform on-site Radiation Safety Program personnel at times when required bedside shields do not appear to be providing effective shielding of patient-emitted radiations.

When required, the hazard from collection or elimination of excreta can often be reduced by asking the patients to take charge of the operation themselves.

Bedding and utensils must be placed in special receptacles with the patients' rooms. These can be returned to the normal hospital flow pattern after being released by the Radiation Safety Program.

Questions regarding the handling or disposal of contaminated clothing or instruments should be directed to the Radiation Safety Officer or to other Radiation Safety Program health physics personnel.

The taking of blood samples for tests should be delayed at least 48 hours after the dosing of patients. Hands should be washed thoroughly. Care must be taken to prevent urine or other patient excreta from being spilled on the floor. If a spill is suspected, the Radiation Safety Program must be notified.

Gowns and suitable plastic or surgical gloves must be worn when handling the patients' bedpans, soiled bed linen or clothes or any containers of radioactive material (i.e., urine, vomitus or excreta from incontinent patients) from the patient. Gloves must be worn whenever and wherever contamination is likely. Once the gloves are removed and properly disposed, hands are washed thoroughly after giving care to therapy patients. One's hands must be monitored, using Geiger Counters that are kept at the Nurse's Station, to make certain that no contamination remains thereon. The spread of contamination from these gloves to other surfaces should be avoided. Handling should be kept to a minimum.

Shoe covers must be donned before entering patients' rooms, worn while in the patients' rooms, and taken off properly while stepping off the papered thresholds to their rooms. Care should be taken to prevent contamination of the shoes and to properly discard shoe covers into receptacles provided at room entrances. For additional details regarding entry and exit to and from patient's rooms, refer to Sections J and K.

F. Instructions for Nursing Personnel (Continued)

Disposable dietary plates and utensils should be provided and used by the patient.

The door to any of these patients' rooms should be kept closed except during room entry or exit.

For any work carried out by nursing personnel during the first 48 hours of radiotherapy treatment, the number of persons in the room should be limited to those essential for the work; however, if only one individual is involved, it is generally advisable that some other person is also available to give assistance if required, but not necessarily be inside of the patient's room.

The warning signs and notices posted on the door to any patient's room by the Radiation Safety Program should remain so until the patient's room has been decontaminated and patient isolation restrictions are released by the Radiation Safety Program.

Monitoring equipment should be periodically checked to ensure satisfactory operation. Care should be taken not to contaminate radiation detectors.

Decontamination of body surfaces should be carried out by washing the affected part, using toilet soap or a mild detergent and swabbing with cotton swab or a brush. Washing should be continued for at least 5 minutes, with continuous running water, after which the area should be checked for remaining contamination. Washing may be repeated if necessary but should not be continued to the point of skin irritation or abrasion. For persistent contamination, other procedures may be attempted but only under medical supervision.

Any contaminated tissue paper may be flushed down the toilet; other disposable and contaminated articles are to be saved in the bagged waste receptacles.

Decontamination of the eyes, nose or mouth requires special care under medical attention. As an immediate action, the eyes should be irrigated with water or saline only, the mouth rinsed and the nose swabbed, efforts being made to minimize ingestion or inhalation during this procedure and to avoid introducing further activity from surrounding contaminated areas of skin. It is difficult to estimate the amount of residual contamination in these circumstances and the advice of a specialist may be needed.

If any therapy patient is incontinent, the Radiation Safety Program must be notified of this prior to treatment because special precautions are warranted (i.e., paper double-layering in some locations, requiring the wearing of nonabsorbent shoe covers, very careful observation and monitoring upon room entry and exit).

The Radiation Safety Officer or his designate must be notified in the event any of these patients expire or emergency surgery is needed for a patient who has received therapeutic quantities of radiopharmaceuticals.

Nurses should refer to the Patient Release Log to determine whether a patient has been authorized for release by the Radiation Safety Program. This is particularly important once a shift has changed.

GCRC Nurses are responsible for retrieving radioactive blood samples contained in lead containers from the Hematology/Oncology laboratory and ensuring the proper disposal of blood specimens.

For additional information regarding patients or visitors, contact the Radiation Safety Program (4-4751) for clarification.

G. Patient Instructions

Patients are instructed to flush the toilet at least three times after using it. Patients must sit on the toilet when using it.

G. Patient Instructions (Continued)

Patients are encouraged and instructed to remain in bed as much as is reasonably achievable.

Patients are encouraged to bathe themselves as much as possible. The use of the shower is encouraged but the time spent showering must be as brief as is reasonable.

When bedside portable shielding is required, patients are instructed not to raise the head of the bed above the maximum inclined setting allowed by the Radiation Safety Program, because the effectiveness of any required bedside shielding would be compromised.

Unless otherwise allowed by the Radiation Safety Program, patients must restrict travel about their rooms to the papered portions of the floor and to refrain from sitting in or touching any chairs to be used by visitors when such visits are allowed. Patients may not leave their rooms until so notified by Nursing Personnel.

When allowed by the Radiation Safety Program, patients leaving their rooms must wear shoe covers. These are donned at the threshold exit from the room. After the patient's room and clothing have been monitored and/or decontaminated by the Radiation Safety Program, shoe covers will no longer be necessary.

Patient instructions regarding release from the UAB Medical Center must be given by the Authorized Physician User by both verbal and written communications.

H. Visitor Instructions

Patients may have visitors after the time they have received their therapy dose provided that they stay in areas designated by the Radiation Safety Program and follow the prescribed time limits.

Visitors are instructed not to eat, drink or smoke while in the patient's room.

Visitors are instructed to wash their hands and/or arms thoroughly if contamination is suspected. Their hands should be washed first.

Visiting time is limited to the maximum time given in the notice to visitors posted on the door to the patient's room.

Children (under 18 years of age) and pregnant women are not allowed to visit near the patient except in emergency situations. In restricted cases involving exposure to these individuals, the visits must be very brief and the distance between them and the patient should be kept to a minimum of six feet.

I. Procedures for Decontamination of Radioactive Spills in Area

Any spills or releases from a radioactive patient (i.e., vomitus, urine, sputum, etc.) are to be considered to be radioactive and necessitate decontamination. These spills generally occur in the patient's room. Until a plan has been worked out for decontamination after major spills, only minimum emergency actions should be taken. Proceed as follows:

1. Stop all operations, which, if continued, would add to the contamination, and shut off room ventilation (call hospital maintenance, if necessary).
2. Remove affected clothing and leave it in the contaminated area.
3. Evacuate all non-essential staff, ensuring that no persons proceed far into clean areas until after they have been monitored and found free from significant contamination; however, treatment of serious injuries shall take precedence over decontamination of an individual.

I. Procedures for Decontamination of Radioactive Spills in Area (Continued)

4. Control entry into the area by posting warning notices or other means.

5. Notify the Radiation Safety Officer or his designate and the nurse-in-charge.

6. While awaiting response from the Radiation Safety Program, mark off the entire region of potential contamination.

7. If there is appreciable liquid on a nonabsorbent surface, then any linen immediately available should be dropped on top of it and left there. Covering the spill completely with towels saturated with water reduces the levels of radioiodine in the air.

8. Essential personnel remaining in the room should remain at least six feet from the affected area.

9. Before the contaminated area can be used again by nursing personnel, a complete radiation survey must be made by the Radiation Safety Program and the safety of such entry determined.

J. Room Entry and Exit Procedures for Radiotherapy Rooms

How to Enter Room:

1. Put on two pairs of shoe covers.
2. Put on one disposable isolation gown.
3. Put on two pairs of disposable gloves.
4. Put on one surgical mask.

How to Exit Room:

1. Remove one outer shoe cover and place foot on exterior pad just outside door.
2. Remove the other outer shoe cover of the other foot and place on the exterior pad just outside door.
3. Remove isolation gown.
4. Remove outer pair of gloves.
5. Remove surgical mask.
6. Remove one shoe cover and place foot on bare floor.
7. Remove final shoe cover and place foot on bare floor.
8. Remove final pair of gloves.
9. Return to nurse's station and check yourself for contamination with a Geiger Counter.

K. Procedures for Operating Geiger Mueller Counters

Operation of Geiger Counter:

1. Turn switch to battery check position, "Battery"; the needle should be in the area marked "Battery OK".
2. Turn switch to the most sensitive scale position, "X.01".
3. Turn response knob all the way to the right (clockwise).
4. Check yourself for contamination with the probe about ½ inch away from the surface. If the needle goes past "2" on the upper portion of the scale, wash contaminated surface and recheck.
5. Turn switch to "Off" position.

APPENDIX Q

PROCEDURES FOR THERAPY TREATMENT
WITH SEALED RADIOPHARMACEUTICALS

(Radioactive Sources Used by the Radiation Oncology Department)

A. Rationale

The purpose for written nursing procedures in the care of patients undergoing the therapeutic use of radioactive materials can be explained in many ways and is not limited to the following: ensuring the optimal and safe care of patients receiving therapeutic amounts of radioactive materials; ensuring that the radiation exposure to any individual does not exceed safety guidelines and regulatory requirements, and is kept to the lowest and most reasonably achievable level; obtaining the cooperation of patients, visitors, and personnel by instilling in them the necessity for precautionary measures; preventing patients from feeling isolated and/or rejected by hospital personnel; preventing unreasonable fears by personnel caring for the patient; enabling nursing personnel to perform proper actions according to the use of these written precautions, the Radioactivity Precautions Notice, in the patient's medical record, posted warning signs, and the standard nursing procedures; enabling nursing personnel to accept the nurse's station, the corridors, and the rooms adjacent to radiation therapy rooms as safe areas; minimizing the potential spread of radioactive contamination; and **addressing annual instruction of nurses in radiation safety**.

B. Facility Requirements

Private rooms are required for patients receiving therapeutic quantities of radioactive materials. A corner room is preferable. Only rooms approved by the Radiation Safety Officer or his designate may be used for patients undergoing therapy treatments with radioactive materials of the following types and in amounts greater than those specified below:

Radium-226 30 millicuries (1.11 GBq)
Cesium-137 90 millicuries (3.33 GBq)
Iridium-192 100 millicuries (3.70 GBq)
Cobalt-60 20 millicuries (0.74 GBq)

Arrangement of the furniture, lead shielding, radiation safety receptacles, and other radiation safety equipment must be maintained according to the instructions of the Radiation Safety Program personnel and as indicated on the Radioactivity Precautions Notice. A copy of the "Precautions for Radioactive Materials Therapy Patient Treatment" must be available at all nurse’s stations where this type of radiation therapy occurs.

C. Assignment of Nursing Personnel

Any of the nurses who care for radiation therapy patients are required to attend the radiation safety presentations given by the Radiation Safety Program. All nursing personnel assigned to care for patients who have received therapeutic quantities of radioactive materials shall be considered to be individuals who are occupationally exposed to ionizing radiation. Steps must be taken to ensure that personnel radiation monitors are issued to them, as needed (see Appendix D). Monthly personnel radiation dosimeters, when required, must be worn by all nursing personnel who are attending to the care of radiotherapy patients. The dosimeters must not be worn while receiving medical or dental diagnostic x-rays or therapeutic x-rays. Appropriate training shall include areas relevant to radiation protection. The amount of training depends on the potential for radiation exposure, the complexity of the task, and the role and responsibility of the individual. Nursing personnel are limited to 50 millirems per 24-hour period of whole body exposure to radiation during routine care of these patients. The "time limits for nursing personnel" are determined based on this limit. Reports of radiation exposure must be posted in an area where assigned nursing personnel frequent. The nurse-in-charge shall be responsible for ensuring that nurses on duty in these areas are familiar with the written precautions for radioactive materials treatment and for information and instructions given to the next shift.

C. Assignment of Nursing Personnel (Continued)

In the event of a cardiac arrest or similar emergency situation which would necessitate working in close proximity to the patient, a nurse is authorized to remove the sources in the event that Radiation Oncology personnel or a physician on the floor is not immediately available. The criteria to be used by the registered nurse in charge is a need for extended patient care under these circumstances. In such an event, the Radiation Oncology Technician on-call must be immediately notified following source removal. At this time the technician must respond, carefully observe the situation, and perform a source count and radiation survey. The Radiation Safety Officer or his designate must also be notified at once. The registered nurse-in-charge should note the time the sources are removed from the patient. Spare dosimeters must be made available for assignment and used by new nursing personnel giving care to patients undergoing treatment. (See Appendix D). Pregnant nurses must not be assigned to the routine care of these patients. In the event that it becomes known that there was a pregnancy during such care, the Radiation Safety Officer must be notified. An employee or student under eighteen years of age shall not be permitted to take care of these patients. In the event that a special duty nurse is required, the Radiation Safety Officer or his designate must be notified. Care for patients receiving radiotherapy should be rotated among the staff as much as reasonably achievable. If the packing or dressing appears disturbed, the radiation oncology technician in charge shall be notified immediately. In this situation, nothing should be removed from the room until it has been checked for the presence of possible dislodged sealed sources. The Radiation Safety Officer or his designate must be notified immediately if there is any suspicion that a radiation source has been lost or if the source container or applicator has been opened.

D. Responsibilities of the Radiation Safety Officer

The Radiation Safety Officer or his designate is responsible for: evaluation and approval of rooms to be used for radioactive patients; ensuring proper room preparation and arrangement of furniture and lead shielding (when necessary) within the patient's room for the optimal safety of the patient, personnel, and visitors; providing special and timely **annual** radiation safety instructions to all personnel charged with the care of patients undergoing radioactive therapy; posting of the Radioactivity Precautions Notice in the patient's medical record and warning signs and instructions on the patient's door; notifying appropriate administrative and regulatory authorities in a timely manner in the event a radioactive source is lost or damaged; conducting a prompt and thorough search for a radioactive source reported lost or missing as a result of a source inventory; providing for the appropriate and timely disposal of therapeutic radioactive sources (i.e., seeds, wire, etc.) and maintaining records of the transfer and disposal of these sources; performing radiation surveys in and about patients' rooms to evaluate the potential radiation hazards within and outside of restricted areas (this includes determining the time limits for nursing personnel and visitors); for patients being treated with Iodine-125 seed implants of the prostate, surveying the catheter bag for the presence of dislodged seeds shortly after the patient has arrived at the recovery room; providing documentation of surveys for placement in the patient's medical record; maintaining file copies of radiation surveys for radiotherapy patients; and, alerting Environmental Services not to empty waste receptacles during treatment in the therapy patient's room unless given special approval by the RSP.

E. Responsibilities of Radiation Oncology Department

Only a physician authorized by the Radiation Oncology License (UAB License Number 314) may prescribe the type and the amount of radioactive materials given to the patient. **The Authorized Physician User must specify by written directive the dose to the patient and the information specified by the quality management program in Nuclear Medicine.** The Radiation Oncology Department is responsible for: the preparation and administration of the radiotherapy dose to the patient; completing the Patient Report Form and the Patient Consent Form and attaching these to the patient's medical record (a copy of these must be maintained in the Radiation Oncology Department); providing assistance to the Radiation Safety Program, if required; providing consultation, when necessary, regarding the handling of a patient; notifying the Radiation Safety Program and the nurse-in-charge on the Nursing Unit of scheduled radiotherapy, giving the patient's name, type of therapy, the room number, and time schedule (timely notification of changes in treatment schedules should also be given); and, transporting the radioactive therapy source from the Radiation Oncology Department to the patient's room using direct routes and taking care to maintain a safe distance from others. The transport container must provide adequate shielding. Tools used to handle the radioactive sources must be left either near the sources or in a designated area where they are readily available. Any transport of radiotherapy sources away from UAB

E. Responsibilities of Radiation Oncology Department (Continued)

premises must be conducted by the Radiation Safety Program. Radiation Oncology personnel attending a patient should ensure that the door to the patient's room is closed during the insertion and the removal of sealed sources.

The Radiation Oncology Department is responsible for notifying the Radiation Safety Program in the event a radioactive source is lost or damaged, and surveying the patient and the patient's room with an appropriate radiation survey meter to ensure that all sources have been accounted for following their removal from the patient, unless this survey is performed by personnel from the Radiation Safety Program. This includes the survey and release of any waste container within the patient's room. The Radiation Oncology Department is also responsible for removing radiation warning signs and labels from a patient's room after radioactive therapy sources have been removed from the patient, unless these warning signs and labels are removed by personnel from the Radiation Safety Program.

F. Instructions for Nursing Personnel

Any of the nurses who care for radiation therapy patients are required to attend the radiation safety presentations given by the Radiation Safety Program. Nurses must familiarize themselves with the content and instructions given on the Radioactivity Precautions Notice in the medical records of these patients. For instance, the bedside "time limit for nursing personnel" must be observed. Urgent actions to deal with accident situations arising from fire, explosion, or mechanical damage, or from the need to rescue or treat injured persons, should not be delayed because of the presence of radioactivity in a therapy patient. The lead shields, when placed beside a patient's bed, must be utilized whenever possible for attendant care within two feet of the patient. As any exposure may involve some degree of risk, any unnecessary exposure should be avoided and all doses kept as low as reasonably achievable (ALARA). Good procedures are essential. All techniques must be well thought out and understood before work is undertaken. A balance should be struck between hurried manipulations, which may cause accidents, and prolonged operations, which may lead to excessive exposures.

The Radiation Safety Officer or his designate and the Radiation Oncology Department must be notified when any of the patients containing therapeutic quantities of radioactive materials expires, requires emergency surgery, is unmanageable, fails to observe isolation requirements during treatment, or leaves the hospital against medical advice. Nursing personnel should learn to identify and check for appropriate "warning" signs on patients' doors, and ensure that posting is maintained as required by the Radiation Safety Program. Nursing personnel should record routine care given to patients on the patients' medical records, including patients' comments. Record any visits made by visitors. Bed baths performed by nursing personnel should be extremely limited while the sealed sources are in place within patients. Attendant nurses should be familiar with the time limits and minimum distance restrictions placed on the visitors of patients undergoing treatments. Furthermore, visitors should be advised accordingly and the Radiation Safety Program notified if these instructions are disregarded or otherwise violated. All non-radioactive laboratory work for these patients (i.e., involving the taking of blood or urine samples) should be done prior to the insertion of sealed sources. When such work is necessary during the treatment, specimens should be collected as rapidly as possible (i.e., within 5 minutes) and radiation shields utilized as much as possible. Unless required, nurses should not be in the patients' rooms during the insertion of sealed sources. At any other time, nursing personnel may enter their patients' rooms to perform any and all normal duties; however, they should not spend excessive time visiting the patients nor perform nonvital personal services such as shaving or hairdressing. Any dressings or bandages used to cover an area of insertion with colloidal gold (Au-198) or chromic phosphate (P-32) shall be changed only by the attending physician.

F. Instructions for Nursing Personnel (Continued)

The dressings are to be kept in a receptacle within the patient's room awaiting disposal. It may be disposed only by the Radiation Oncology Technician. For sealed sources, no contamination hazard exists; however, care should be exercised to avoid the loss of radioactive sources. For example, the source may become dislodged from its location in the patient. No special precautions for sealed sources are needed for vomitus, sputum, urine, feces, or for eating utensils, since no radioactive contamination is expected to be present. Linen, clothing, and bed pans should be examined visually on a regular basis to make sure that no radioactive tube or needle has fallen out of the patient. If a metal object which might be a sealed source is seen, it must not be touched. A moist towel should be placed over it and the Radiation Oncology Technician on-call and the Radiation Safety Program called at once. A forceps or hemostat or some other long-handled instrument should be used if it is necessary to pick it up. It should then be put into the shielded transport cart. This cart should be placed in the patient's room before picking up the source. Patients should be encouraged to care for themselves and to be as self-sufficient as possible, thus reducing the need for close contact with hospital personnel. The door to any of these patient's rooms must be kept closed except during room entry or exit.

For patients being treated with Iodine-125 seed implants of the prostate, call the Radiation Safety Program to survey the catheter bag for the presence of dislodged seeds shortly after the patient has arrived at the recovery room and before discarding the voided urine (4-4751). The warning signs and notices posted on the door to any patient's room by the Radiation Safety Program should remain posted until patient isolation restrictions are released by the Radiation Oncology Department or the Radiation Safety Program. For any additional information regarding patients or visitors, contact the Radiation Safety Program (4-4751) for clarification.

G. Patient Instructions

Patients must stay in bed and not sit up. Patients must remain in their rooms during radiotherapy treatments. Patients must try not to disturb or otherwise dislodge therapy sources. **Instructions for patients with permanent implants who are released from the UAB Medical Center must be given by the authorized physician user by verbal and written communications.**

H. Visitor Instructions

Visitors are instructed to not smoke while in the patient's room. Visiting time is limited to the maximum time given in the notice to visitors posted on the door to the patient's room. Children (under 18 years of age) and pregnant women are not allowed to visit a patient, except in emergency situations. In emergency situations, the visits must be very brief and the distance between the visitor and the patient should be at least six feet.

APPENDIX R

RADIATION SAFETY TERMS & DEFINITIONS

(a) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the Gray (Gy).

(b) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(c) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(i) In excess of the derived air concentrations (DACs) in the Alabama Radiation Control Rules (ARCR).

(ii) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 % of the annual limit on intake (ALI) or 12 DAC-hours.

(d) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rems) or a committed dose equivalent of 0.5 Sv (50 rems) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2 of Appendix B of the ARCR.

(e) "Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, preparing, or storing radioactive material.

(f) "ALARA" means as low as reasonable achievable and means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

1. Consistent with the purpose for which the licensed or registered activity is undertaken,

2. Taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

3. In relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

(g) "Authorized User" means persons authorized to use radioactive materials. The authorization to use these radioactive materials is given to UAB radioactive materials licensees or to individuals working under their supervision.

(h) "Authorized Physician User" means a practitioner of the healing arts who is identified as an authorized user on a State of Alabama license or particle accelerator registration, or on a permit issued by a State of Alabama specific license or particle accelerator registration of broad scope, that authorizes the medical use of radioactive material or a particle accelerator.

(i) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from licensed or registered sources regulated by the State of Alabama or Jefferson County, Alabama.

(j) "Becquerel" (Bq) means the SI unit of activity. One Becquerel is equal to 1 disintegration or transformation per second (dps or tps).

RADIATION SAFETY TERMS & DEFINITIONS (Continued)

(k) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, quantities of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. "Radiobioassay" is an equivalent term.

(l) "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(m) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. "Lung class" and "inhalation class" are equivalent terms.

(n) "Clean area" means an area free from all sources of radiation except naturally occurring radioactivity - synonymous with the concept of background as used within these procedures.

(o) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(p) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that is received from an intake of radioactive material by an individual during the 50-year period following the intake.

(q) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the UAB radioactive materials licensee or particle accelerator registrant for any reason.

(r) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(s) "Dedicated check source" means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

(t) "Deminimus Level" means a quantity of radioactivity that falls within those amounts established in the Schedule of Deminimus Levels of Radioactivity given in Appendix M. This term is used to describe those amounts of radioactivity for which area survey, use, transfer, and waste disposal records are not required, in accordance with the restrictions given on page 35 of this manual.

(u) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(v) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. The condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B of the ARCR.

(w) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A UAB radioactive materials licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(x) "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the Sievert (Sv) and rem.

RADIATION SAFETY TERMS & DEFINITIONS (Continued)

(y) "Editorial Changes in the Procedures" means changes in the procedures (including the radioactive materials application) that do not affect the management of this radiation safety program and the radiation safety surrounding the use, transfer, and disposition of radioactive materials possessed at this facility (i.e., approved providers of film badge service, of instrument calibration service and of radioactive waste disposal service, changes in appropriate instrumentation, the inclusion of clarifying definitions not covered by the Alabama Radiation Control Regulations, etc.)

(z) "Effective dose equivalent" (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma\, w_T H_T$).

(aa) "Enhanced Radioactivity" means radioactivity at levels above background (naturally occurring) levels.

(ab) "Exempt Concentration" is a special type of Deminimus Level. It is that concentration for a type of radioactive material that falls within those concentrations established in the Schedule of Deminimus Levels of Radioactivity given in Appendix M. See page 35 of this manual for more information regarding exempt concentrations.

(ac) "Exempt Quantity" is a special type of Deminimus Level. It is that quantity of a type of radioactive material that falls within those amounts established in the Schedule of Deminimus Levels of Radioactivity given in Appendix M. See page 35 of this manual for more information regarding exempt quantities.

(ad) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

(ae) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

(af) "Full-scale reading" means the reading of highest demarcation on a scale.

(ag) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

(ah) "High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

(ai) "Individual monitoring" means the assessment of:

(i) Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

(ii) Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

(aj) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body. An "intake" is the amount entering the body, an "uptake" is the amount absorbed into extracellular fluid, and a "deposition" is the amount which has entered and is present in the organ of reference.

(ak) "Licensees" means either departments, divisions or individuals licensed by the UAB Radioisotope and Radiation Safety Committee to possess and use the radioactive materials listed on the licensing documents issued to them.

(al) "Member of the public" means an individual in a controlled or unrestricted area; however, an individual is not a member of the public during any period in which the individual receives an occupational dose.

(am) "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

(an) "Misadministration" means the administration of:

Radioactive material or radiation from radioactive material:

(a) Other than events that result from intervention by a patient or human research subject, any event which results in:

1. A dose that differs from the prescribed dose by more than 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin; and either

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.05 sieverts (5 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) Any event resulting from intervention of a patient or human research subject which results, or is anticipated to result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

A Therapeutic Particle Accelerator Dose:

1. Involving the wrong patient or wrong treatment site;

2. When the treatment consists of 3 or fewer fractions and the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 10 percent of the total prescribed dose;

RADIATION SAFETY TERMS & DEFINITIONS (Continued)

(an) "Misadministration" means the administration of: (Continued)

A Therapeutic Particle Accelerator Dose: (Continued)

3. When the calculated weekly administered dose is 30 percent or more greater than the weekly prescribed dose; or

4. When the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 20 percent of the total prescribed dose.

(ao) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. "Radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(ap) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. "Deterministic effect" is an equivalent term.

(aq) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(ar) "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released, from voluntary participation in medical research programs, or as a member of the public.

(as) "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

(at) "Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received form background radiation, dose received as a patient from medical practices, from exposure to individuals administered radioactive material and released, or dose from voluntary participation in medical research programs.

(au) "Quality factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. The quality factor is 20 for alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge. The quality factor is 10 for neutrons of unknown energy and high-energy protons. The quality factor is 1 for X, gamma, or beta radiation and high-speed electrons.

(av) "Quarter" means one of the four following periods of time: January 1st—March 31st, April 1st—June 30th, July 1st—September 30th, and October 1st—December 31st.

(aw) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(ax) "Restricted area" means an area to which access is limited by the UAB licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

RADIATION SAFETY TERMS & DEFINITIONS (Continued)

(ay) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

(az) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in Sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(ba) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. "Probabilistic effect" is an equivalent term.

(bb) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive materials present.

(bc) "Total effective dose equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(bd) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose.

(be) "Unrestricted area" means an area, access to which is neither limited nor controlled by the UAB licensee or registrant. "Uncontrolled Area" is an equivalent term.

(bf) "Visiting authorized user" means an authorized user for medical use (appearing, by name, on a license or particle accelerator registration issued by the State of Alabama Health Department or on a permit issued by a State of Alabama Health Department specific license or particle accelerator registration of broad scope) who is not identified on the UAB license or particle accelerator registration of the UAB licensee or particle accelerator registrant being visited.

(bg) "Week" means 7 consecutive days starting on Sunday.

(bh) "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For gonads, $w_T = 0.25$; for breast, $w_T = 0.15$; for red bone marrow, $w_T = 0.12$; for lung, $w_T = 0.12$; for thyroid, $w_T = 0.03$; for bone surfaces, $w_T = 0.03$; and for remainder, $w_T = 0.30$. 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses. For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.00$, is specified.

(bi) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(bj) "Willful Violation" means acting in a manner contrary to the written requirements of radiation safety regulations with full knowledge that such acts are in noncompliance and present a hazard to the health and welfare of the individual and others.

(bk) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that results in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

RADIATION SAFETY TERMS & DEFINITIONS (Continued)

(bl) "Working level month" (WLM) means an exposure to 1 working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

(bm) "Written directive" means an order in writing for a specific patient or human research subject, dated and signed by a UAB authorized physician user prior to the administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 microcuries), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material, except as specified in 6(ii) of this definition, containing the following:

1. The name of the UAB patient or human research subject;

2. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

3. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

4. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

5. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

6. For all other brachytherapy including LDR, MDR, and PDR:

   (i) Prior to implantation: treatment site, the radionuclide, and dose; and

   (ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).

(bn) "Year" means the period of time beginning on January 1st and ending on December 31st.

Accepted Half-Lives of Commonly Used Radioisotopes

All UAB radioactive materials licensees are required to submit inventories to the Radiation Safety Program quarterly, even if they do not possess any radioactive materials. When decaying radioisotopes for inventory purposes, please use the accepted half-lives listed below.

Isotope	Half-Life	Isotope	Half-Life
Americium-241	432.2 years	Lutetium-177	6.71 days
Barium-133	10.74 years	Molybdenum-99	66 hours
Bismuth-212	60.55 minutes	Nickel-63	96 years
Cadmium-109	464 days	Phosphorus-32	14.29 days
Calcium-45	163 days	Phosphorus-33	25.4 days
Carbon-14	5730 years	Plutonium-239	24,065 years
Cesium-137	30 years	Polonium-210	138.38 days
Chlorine-36	301,000 years	Radium-226	1600 years
Chromium-51	27.704 days	Radon-222	3.8235 days
Cobalt-57	270.9 days	Rhenium-188	16.98 hours
Cobalt-58	70.8 days	Rubidium-81	4.58 hours
Cobalt-60	5.271 years	Selenium-75	119.8 days
Copper-62	9.74 minutes	Sodium-22	2.602 years
Copper-64	12.701 hours	Sodium-24	15 hours
Copper-67	61.86 hours	Strontium-85	64.84 days
Gallium-67	78.26 hours	Strontium-89	50.5 days
Gallium-68	68 minutes	Strontium-90	29.12 years
Gold-195	183 days	Sulfur-35	87.44 days
Hydrogen-3	12.35 years	Technetium-99	213,000 years
Indium-111	2.83 days	Technetium-99m	6.02 hours
Indium-113m	1.658 hours	Tin-113	115.1 days
Iodine-123	13.2 hours	Tungsten-188	69.4 days
Iodine-125	60.14 days	Uranium-235	703,800,000 years
Iodine-129	15,700,000 years	Uranium-238	4,468,000,000 years
Iodine-131	8.04 days	Xenon-127	36.41 days
Iron-55	2.7 years	Xenon-133	5.245 days
Iron-59	44.529 days	Yttrium-90	64 hours
Krypton-81m	13 seconds	Ytterbium-169	32.01 days
Krypton-85	10.72 years		