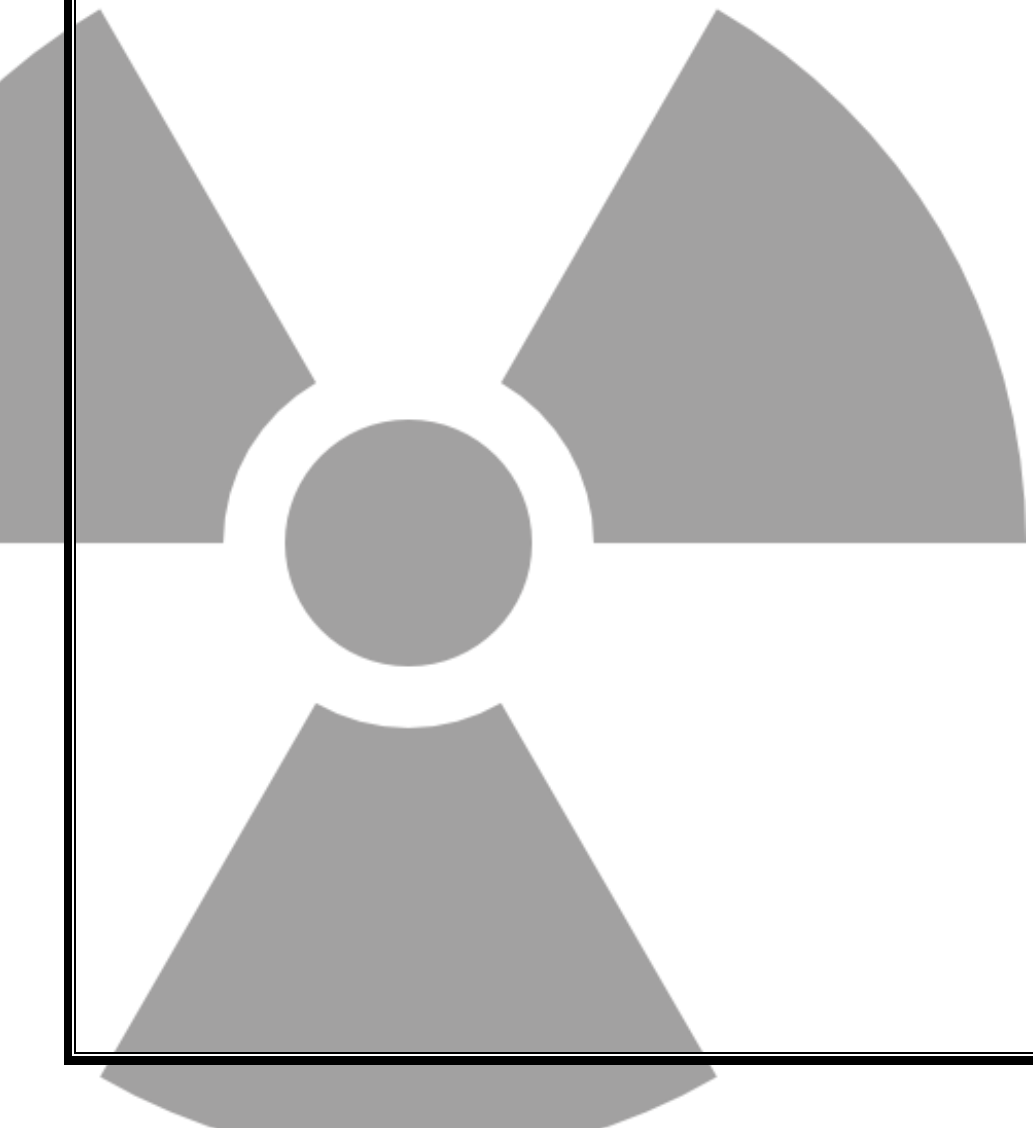
University of Louisiana Monroe

RADIATION SAFETY MANUAL



Page left intentionally blank

This Radiation Safety Manual is issued by:

The Radiation Safety Committee
And the University of Louisiana, Monroe

Originally Prepared by:
Catherine I. Whipple, R.Ph., B.C.N.P.
School of Pharmacy
College of Health Sciences

Revision by:
Shane Dykes
Radiation Safety Officer
Environmental Health & Safety Officer

EMERGENCY PHONE NUMBERS

In case of a radiation accident call:

Shane Dykes	318-342-5177 (office)
Radiation Safety Officer	318-557-1914 (mobile)
ULM Police	318-342-5350
DEQ Emergency Hotline	(225)765-0160

Table of Contents

I. ORGANIZATION AND RESPONSIBILITY 8
A. Administrative Organization of Radiation Safety 8
B. Responsibilities of the Radiation Safety Committee 8
C. Responsibilities of the Radiation Safety Officer 8
D. Responsibilities of the Authorized User 9
II. INSTRUCTIONS AND TRAINING FOR ULM PERSONNEL USING RADIOACTIVE MATERIALS AND/OR DEVICES 10
A. Students enrolled in Dental Hygiene and Radiologic Technology Programs 10
B. Authorized Users, Staff, Graduate and Undergraduate Students Using 10
Radionuclides or Ionizing Radiation in Research Projects. 10
C. Emergency Response Personnel 10
III. OVERVIEW OF PRINCIPLES OF IONIZING RADIATION 10
A. Ionizing Radiation, Radionuclides 10
B. Alpha and Beta Particles 11
C. Gamma and X-Ray Photons 13
D. Basic Safety Factors for External Ionizing Radiation 14
E. Biological Effects of Ionizing Radiation 16
F. Detection and Monitoring of ionizing Radiation 19
G. Radionuclide Calculations 20
IV. MANDATED ON-SITE POSTING IN LABORATORIES/FACILITIES WORKING WITH IONIZING RADIATION AND RADIOACTIVE MATERIALS 22
A. Louisiana Radiation Regulations and Notices 22
B. Caution Signs and Labels 23
C. General Laboratory Procedures and Cautions 24
D. Emergency Response to Radioactive Material Accidents and Spills. 25
V. WIPE TESTS AND CONTAMINATION MONITORING GUIDELINES FOR LABORATORIES AND EQUIPMENT 27
A. Routine Laboratory Wipe Tests to Monitor Beta Emitter Contamination 27
B. Survey Instruments for High Energy Beta (32P) and Gamma Emitting Radioactive Contamination 29
C. Contamination Guidelines for Containers and Apparatus 29
VI. PERSONNEL MONITORING FOR EXPOSURE TO IONIZING RADIATION 30
A. Routine Personnel Monitoring 30
B. Non-routine Bioassay 30
VII. AUTHORIZATION TO USE AND PURCHASE RADIOACTIVE MATERIALS 30
A. Authorized User of Radioactive Materials 30
B. Procurement of Radioactive Materials 31
C. Receipt and Use of Radioactive Materials 32

D. Inventory and Storage of Radioactive Materials and Devices 33
E. General Record Keeping Requirements for Radioactive Materials 33
VIII. RADIOACTIVE MATERIAL WASTE MANAGEMENT 33
A. Regulatory Definition of Radioactive Materials 33
B. Disposal of Specific Radioactive Materials: Carbon-14, Iodine-l31, and Tritium 33
C. Disposal of All Other Radionuclides and Specific Radionuclides (14C, 3H, 125I) 35
IX. OTHER RADIATION SOURCES 36
A. Policies and Procedures for X-Ray and Ionizing Radiation Producing Machines 36
B. Policy and Procedures for Gas Chromatograph Equipped with Electron Capture Detector (ECD) Cells 37
C. Policy and Procedures for 85Kr Aerosol Neutralizers 37
X. References 38
Appendix I 39
Short Course on Radiation Safety Verification Form 40
Authorized User Qualifications 41
REQUEST FOR PERSONNEL MONITORING 42
PRENATAL EXPOSURE TO RADIATION VERIFICATION FORM 43
RADIOACTIVE MATERIALS PROCUREMENT AND USE 44
RADIOISOTOPE ANNUAL INVENTORY RECORD 46
RADIOISOTOPE RECEIPT AND USE 47
WIPE TEST SURVEY 48
DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA SANITARY SEWER 49
DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA SOLVENT DILUTION 50
DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA BIOHAZARDOUS WASTE STREAM 51
DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA SOLID WASTE STREAM 52
Appendix II 53
REGULATORY GUIDE 8.13 53
INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE 53
A. INTRODUCTION 53
B. DISCUSSION 54
C. REGULATORY POSITION 54
D. IMPLEMENTATION 55
Radiation Dose to the Embryo/Fetus – Regulatory Guide 56
A. INTRODUCTION 56
B. DISCUSSION 56
C. REGULATORY POSITION 58
D. IMPLEMENTATION 65

FORWARD

This Manual is required reading for all users of radioactive materials.

The receipt, possession and use of radioactive material at the University of Louisiana, Monroe (ULM) is authorized by a Louisiana Department of Environmental Quality, Nuclear Division Broad Scope License (LA-2383-L01) as provided by the Environmental Regulatory Code, 2001, Title 33, Environmental Quality. The License is available for review in the Environmental, Health & Safety Office.

Guidelines and procedures for the use of radionuclides and radiation producing devices are set forth in the Manual. Following these guidelines and procedures will help ensure that radiation exposure to all personnel at ULM, the public, and the environment will be as low as reasonably achievable. This Manual is also intended to serve as an aid and reference by reviewing biological effects of ionizing radiation, calculations, the handling of radioactive material, and the prudent disposal of radioactive wastes.

I. ORGANIZATION AND RESPONSIBILITY

A. Administrative Organization of Radiation Safety

- President of University
- Vice-President for Academic Affairs
- Chair, Environmental Health and Safety Committee
- Radiation Safety Committee
- Radiation Safety Officer
- Authorized User

While the ultimate responsibility for radiation safety rests with Administration Officers of the University, the Radiation Safety Committee establishes policies, guidelines, and procedures for radiation safety and control of radiation sources and devices consistent with regulation and license requirements. The Radiation Safety Officer (RSO) is responsible for ensuring that all aspects of the use of radioactive materials and radiation devices comply with University policy and license requirements.

B. Responsibilities of the Radiation Safety Committee

The chair of the University Environmental Health and Safety Committee makes appointment to the Radiation Safety Committee with the approval of the Vice-President of Business Affairs. The Radiation Safety Committee consists of the RSO and at least one representative of each of the University Departments that are major users of radioactive materials or radiation devices; one member is elected as chairperson. Each member of the committee must have experience in the use of radioactive materials, sources or devices used within their department. By regulatory mandate, a representative of the administration must serve as member on the committee. The chair and members of the committee serve for an indefinite period of time.

The Committee meets once each spring and fall semester, or as necessary, at the request of the Chair or the RSO. A quorum consists of the Chair, the RSO and two other Committee members. The functions of the Radiation Safety Committee are as follows:

1. Establish policies, guidelines and procedures for radiation safety, control of radioactive materials and devices consistent with regulation and license requirements.
2. Act on all radioactive material use applications. This includes the qualifications of the Authorized User, proposed use of radioactive materials, adequacy of facilities, equipment, and written procedures to safely accomplish the experiment or instructional task.
3. Periodically review the overall use of all radioactive material, sources, and devices to assure University-wide radiation safety programs are operational.
4. Maintain minutes and records of Radiation Safety Committee Meetings.

C. Responsibilities of the Radiation Safety Officer

The Radiation Safety Officer (RSO) is appointed by the President of the University and reports directly to the Chair of the University Environmental Health and Safety Committee. The RSO should have several years of experience in handling radionuclides or radiation devices, a working knowledge of pertinent Louisiana and Federal radiation regulations, and as a minimum of formal training, have attended an 8-hour course of basic radiation safety. Duties of the RSO and assistant RSO include the following:

1. Represent the University as the direct contact and liaison with the Louisiana Department of Environmental Quality and to maintain a valid Radioactive Material License.
2. Receive, review, and make recommendations to the Radiation Safety Committee on all radioactive material use applications and Authorized User qualifications.
3. Review and approve all purchase requests for radioactive materials. Supervise the receipt, inspection, recording of receipt data, and delivery to the Authorized User for radioactive materials.
4. Ship all radioactive materials in accordance with U.S. DOT and DOE regulations.
5. Oversee a personnel radiation-monitoring program and bioassay testing as such is necessary.
6. Supervise or conduct a University-Wide radiation monitoring and survey program. Such surveys must be performed three times a year; One University-Wide inspection is conducted each fall, spring and either Summer Term.
7. Maintain records of personnel exposure, radioactive material receipt, use, transfer, inventory, laboratory monitoring and survey, leak test results, disposal, inspections, accidents and instrument calibration records.
8. Order and distribute health physics supplies and warning signs as required.
9. Conduct a radioactive waste disposal program.
10. Conduct a program for leak tests of sealed sources.
11. Supervise and assist with decontamination in case of accidents involving radioactive materials.
12. In the event of violation of safety procedures using-radiation sources, terminate the unsafe action immediately and inform the Authorized user, the Radiation Safety Committee Chair, and the Administration of the Violation and of the corrective actions taken.

D. Responsibilities of the Authorized User

1. Comply with the policies, guidelines and procedures of this manual.
2. Submit all order/requisitions for radioactive materials through the RSO or his designate.
3. Submit to the RSO all radioactive material use applications for projects utilizing radioactive materials. Applications include detailed procedures and methods, information on equipment and facilities, and all personnel involved in the project. Applications are to be updated or amended as necessary.
4. Establish that the Authorized User and all staff, graduate or undergraduate students using radioactive materials in the laboratory have completed the ULM radiation safety short course, and that all personnel have an adequate understanding of radioactive materials guidelines and procedures.
5. Perform weekly wipe test contamination surveys if radioactive materials are in use in the laboratory.
6. Maintain an inventory of all radioactive materials, sources and devices.
7. Keep radiation exposure to all project personnel as low as reasonably achievable (ALARA).

II. INSTRUCTIONS AND TRAINING FOR ULM PERSONNEL USING RADIOACTIVE MATERIALS AND/OR DEVICES

A. Students enrolled in Dental Hygiene and Radiologic Technology Programs

All students enrolled in the Dental Hygiene and Radiologic Technology Programs must complete formal courses outlined in their respective curriculums and receive specific instruction concerning prenatal exposure to ionizing radiation before they will be permitted to receive a personnel-monitoring device and allowed to operate x-ray equipment. Students in Dental Hygiene must complete DHYG 3027 (2 cr; Oral Radiology) to meet this requirement. Radiologic Technology students must complete RADT 2001 (3cr; INTRO TO IMAGING SCIENCES & HC to fulfill this requirement.)

B. Authorized Users, Staff, Graduate and Undergraduate Students Using Radionuclides or Ionizing Radiation in Research Projects.

All personnel engaged in research projects using radioactive materials and/or ionizing radiation devices must attend the ULM Radiation Safety Course to receive authorization and clearance to work on such projects. All new members of the Radiation Safety Committee are required to attend the course as an orientation to the ULM program. This short course in radiation safety is offered at ULM every September. The four-hour course is offered on a Saturday to lessen class-scheduling conflicts. The intent of the course is to familiarize the participant with the ULM radiation safety program and this Manual, Louisiana regulations concerning radioactive materials, proper procedures for performing a contamination survey, operation of a liquid scintillation counter, and emergency response procedures regarding radioactive material spills. A Radiation Safety Course Verification Form to which the participant acknowledges receiving training and instruction on the above topics will document participation.

C. Emergency Response Personnel

In the event of a radioactive materials spill or accident, the RSO or his designate are to be immediately informed of the incident and will oversee decontamination and clean up. In the event the RSO is unavailable, the Authorized User will oversee containment of the radioactive materials, decontamination and clean up. ULM Campus police officers and the campus Safety Coordinator that may respond to a radioactive materials spill emergency must participate in the above short course. However, their role is limited to securing the area to prevent personnel from entering the contaminated area. See Section IV, Part D for emergency response procedures.

III. OVERVIEW OF PRINCIPLES OF IONIZING RADIATION

A. Ionizing Radiation, Radionuclides

Ionizing radiation comprises the upper end of the electromagnetic spectrum and is best described as particles or photons of energy. Any form of energy with an electron volt (eV) potential greater than 10 eV that strikes a neutral molecule is capable of ionizing that neutral molecule by displacement of an electron.

>10eV photon* → H_2O → $H_2O^+ + e^-$

Various types of ionizing radiation can have energies ranging from 10 eV (e.g. short wavelength UV) to 1 x 10^7 eV (e.g. Cosmic rays). The greater the quanta of energy transferred to an object, the greater the impact on the object by the energy absorbed.

Radioactive elements, also known as radionuclides, are unstable isotopes of an element that produce ionizing radiation as they transform (i.e. Decay) to a more stable isotope of that element or another element. Radioactive isotopes spontaneously disintegrate with the emission of radiation while achieving a more equal ratio of protons and neutrons in the nucleus of the atom. This transformation of matter into energy, and vice versa, is quantified by Einstein's mass-energy equation ($E = mc^2$). An atom consists of a nucleus of protons (+ charge) and neutrons (no charge) surrounded by an extended cloud or negatively charged electrons.

The atomic number (Z) of an element states the number of protons in the nucleus. The **atomic mass number (A)** of an element is the sum of protons and neutrons in the atom's nucleus. Atoms that have the same Z value are isotopes of an element and have chemical properties identical to other isotopes of that element.

Examples of Isotopes

Carbon	Hydrogen
Atomic mass (A) → $^{12}C_6$ $^{13}C_6$ $^{14}C_6$	$^1H_1$ $^2H_1$ $^3H_1$ ← atomic number (Z)

Among these elemental isotopes, 14C is radioactive carbon and 3H (tritium) is radioactive hydrogen; the other isotopes of the elements are stable.

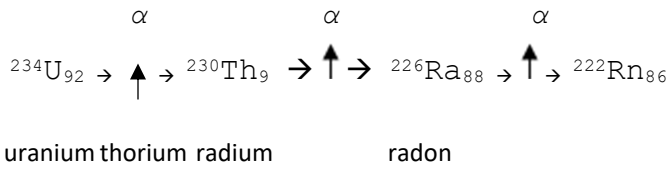
There are many forms of radiation emitted by radioactive elements, but for the majority of radionuclides used biochemical tracer studies, the major types of emitted energy are alpha, beta and gamma radiation. X-Rays, which are machine-generated forms of radiation with properties similar to gamma radiation, are discussed along with gamma rays in Section C of this chapter.

B. Alpha and Beta Particles

Alpha (a) particles originate in the nuclei of radioactive heavy elements, and alpha emission is generally the rule for radioactive elements heavier than ^{206}Pb (lead). Alpha particles are a cluster of two protons and two neutrons, the same mass as the nucleus of helium but being doubly charged. Alpha particles possess very high (>4MeV) kinetic energy transfer potential, but because of their mass and relatively slow velocities in air, alpha particle energy is rapidly dissipated in atmospheric molecular collisions.

Alpha particles travel only about 4 cm through air and cannot penetrate a sheet of paper or the stratum corneum layer of the epithelium of the skin. However, alpha-emitting radionuclides are considered internal radiation hazards and are dangerous if inhaled or ingested.

Example of an Alpha Decay Series; Uranium to Radon

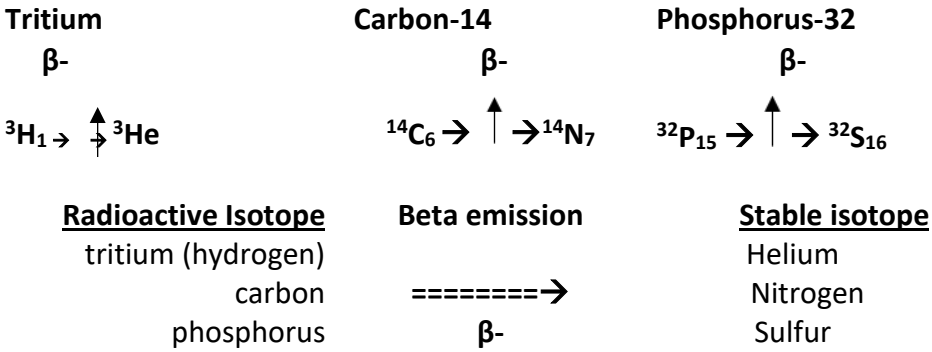


The atomic mass (A) decreases by four and the atomic number (Z) decreases by two for each alpha emission in the radionuclide decay series.

Beta (β) particles are an important class of ionizing radiation as many of the common isotopes used in biological research such as tritium, carbon-14, phosphorus-32, sulfur-35 and calcium-45 emit only beta particles. Beta radiation is the emission of high velocity negative charged electrons having the mass and charge of an electron. However, beta particles are emitted from within the nuclei of atoms in a radioactive decay process during the transformation of a neutron into a proton. Unlike alpha emitters that show a decrease in the "Z" number of the decay product, the transformation of a neutron to a proton within the nucleus of a beta emitter results in an increase in the atomic number of the decay product.

Radionuclides that emit beta particles can be a hazardous external source of ionizing radiation. The ability of beta particles to penetrate a material is dependent upon the energy of the particle. The kinetic energy potential for beta particles ranges from 0.02 MeV for tritium (^{3}H) to 1.7 MeV for beta particles emitted from phosphorus-32.

Examples of Pure Beta Decay Radionuclides



The atomic mass (A) is constant and the atomic number (Z) increases by one for the pure beta emitter radionuclide.

Among the pure beta emitters, phosphorus-32 beta particles have enough energy to travel through 20 feet of air or 8 mm of water before they are stopped. Thus, such beta particles can penetrate the body to a depth of 8 mm. On the other hand, only 6 mm of air or a 5-micron film of water stops low energy beta particles from a tritium source. Tritium beta particles do not have enough energy to penetrate a single layer of dead skin cells and are not an external radiation hazard.

The average energy potential of carbon-14 beta particles is about 5% that of phosphorus-32, so the beta emitter carbon-14 is also of negligible risk as an external radiation hazard. Carbon-14 beta particles can travel through up to 1 foot of air or through 0.2 mm water before they are stopped. All beta emitter radionuclides do pose some risk as an internal radiation hazard if inhaled or ingested. The probability and severity of risk of beta emitter deposition is related to the kinetic energy of the beta particle, the physical half-life of the radionuclide and the biological half-life of the radioisotope.

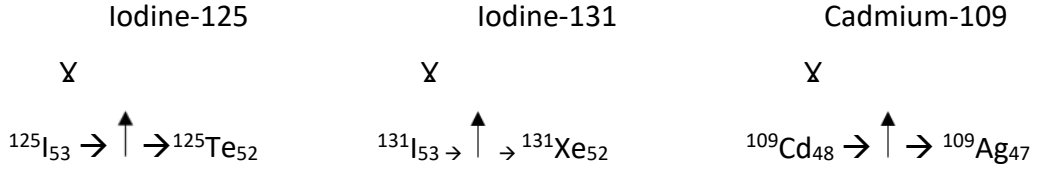
C. Gamma and X-Ray Photons

Gamma (y) radiation or gamma rays exhibit properties that are better described in terms of waveforms rather than particles because these electromagnetic radiations are emitted by radioactive nuclei as photons, or quanta of light. Gamma ray emission may accompany the emission of beta particles from certain radionuclides. While gamma rays have MeV kinetic energy potentials over the same range as beta particles, gamma rays differ from the charged and direct ionizing alpha and beta particles in two important ways.

First, unlike beta particles that quickly slow down as they lose their energy from molecular collisions and finally become attached to an atom as an electron, **gamma rays of all energies always travel at the speed of light.** Gamma rays lose energy by chance molecular collision with atoms resulting in the ejection of an electron from the struck object. A gamma ray may lose only part of its energy by atomic collision and continue to travel through space at the speed of light but as a lower energy photon. The second major difference between gamma radiation and alpha/beta particles is **that alpha/beta particles are single ions that cause a short path ionization events while gamma rays indirectly generate ionization events over a relatively long path.** When a gamma ray collides with an atom, that atom is ionized. The electron ejected from this impact is a high-energy electron that could strike adjacent atoms in the target medium and cause thousands of ionization events before the ejected electron's energy is dissipated.

Gamma rays are emitted from gamma radiation sources at discrete energies dependent upon the radionuclide. The penetration of such photons is dependent upon their energies. The photons from a low energy gamma emitter such as Iodine-125 lose about half of their energy after penetrating 2.5 cm of water; high-energy gamma emitters such as Cobalt-60 can penetrate 10 cm of water before losing half of their energy.

Examples of Radionuclide decay by Gamma Radiation Emission



The atomic mass (A) is constant while the atomic number (Z) decreases by J for gamma emitting radionuclides.

X-Rays are photons generated when high-speed electrons strike the tungsten surface within the electron tube. Thus, such radiation generated by a machine is identical to gamma rays of equivalent energies except that processes that take place outside the atomic nucleus produce X-Rays. Electrons accelerated in an electron tube by a high voltage potential near the highly charged heavy element target may lose all or most of their energy through the emission of photons. The violent acceleration of the electron instantaneously followed by a braking action (and deflection) as the accelerating electron interacts with the electrical field around the target results in photon emission termed **"Bremsstrahlung"**, a German word for "braking radiation". Because ^{32}P beta particles can produce Bremsstrahlung X-Rays when they strike density shielding such as lead, ^{32}P radionuclides should be shielded with low-density materials such as polycarbonate plastics.

X-Rays may be generated by machine in discrete energies ranging from 0.01 to more than 10 MeV potentials. X-Rays are also emitted from certain radionuclides by processes involving transitions of electrons from an atomic outer orbital shell to an inner orbital shell (electron capture). However, the topic of radionuclide X-Ray production is beyond the scope of this overview of ionizing radiation: It is important to remember is that X-Rays and gamma rays are of the same nature and differ only in their origin.

Half-Lives of Radionuclides

The emission of radiation by a radionuclide results from the transformation or decay of an atom of the source to that of another element. The rate of radiation emitted from the source is directly proportional to the number of atoms of radioactive material present. As the number of radioactive atoms in the source decreases because of transformations the rate of emission of radiation decreases.

When one-half of the source atoms have decayed, the rate of radiation emitted will be one-half of the original rate of emitted radiation. Thus, the half-life of a radionuclide is the amount of time elapsed for one-half of the atoms of the source to decay by radioactive emission.

The half-life of ^{14}C is 5730 years; the disintegration rate (i.e. Activity) of this source would essentially be unchanged for many years. On the other hand, ^{32}P has a half-life of 14.3 days. A source of this radionuclide would have negligible activity, i.e. <0.1 % of original activity, after 10 half-lives which would be 143 days for this radionuclide.

D. Basic Safety Factors for External Ionizing Radiation

Three key safety factors are emphasized in procedures for working with ionizing radiation: **time, distance and shielding.** The safety parameter of **Exposure Time** is the basic factor that limits the amount of exposure time to no longer than necessary to safely work around radioactive sources. Obviously, the longer one is exposed to the source, the greater the exposure dose from the radioactive source.

Distance is very effective in reducing the intensity of ionizing radiation incident upon the body from small radiation sources. It is desirable to have as much distance as possible between the user and the source. As with all forms of energy, the radiation flux rate from a source varies inversely with the square of the distance from the source:

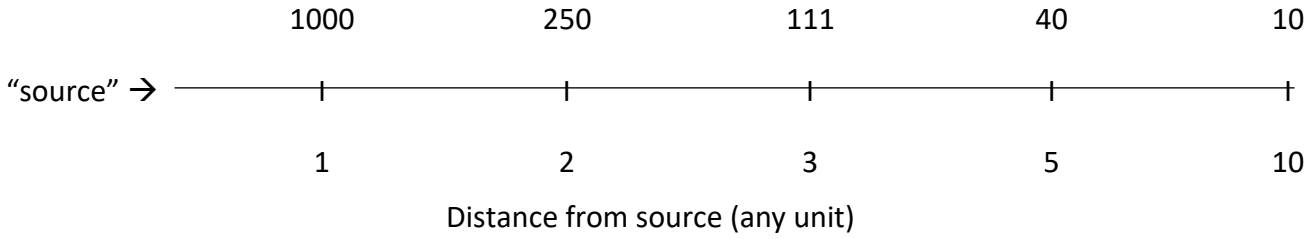
$I_1 (d_1)^2 = I_2 (d_2)^2$

The Inverse Square Law

Where I represents radiation intensity and D represents distance from the source for any two points from the source.

The Relationship of Radiation Intensity to Distance

Radiation Intensity from source (any unit)



Distance from source (any unit)

This graphic illustrates that if one is handling high activity radionuclides, the extra distance provided by the use of tongs or tweezers gives a tremendous reduction in exposure compared to holding the source in one's hands.

Shielding is often used to protect or guard against incident radiation from radioactive sources or devices. The effectiveness of shielding material to prevent penetration of ionizing radiation is dependent upon the energy of the radiation particles or photons and their electrical charge. Alpha and beta particles have finite penetration ranges through mass as they slow down because of the loss of kinetic energy during collisions with the shielding material. As stated previously, alpha particles cannot penetrate a sheet of paper because of their relative slow velocities and double ion charge. Because gamma rays are photons with no electrical charge and travel at the speed of light, such energy forms have a probability of passing through shielding materials. Therefore, gamma and X-Ray shielding requires materials that are quite dense and have great mass.

The thickness of a shielding material that will reduce radiation intensity by 50% is called a **half-value layer.** If the thickness of the shielding material is doubled (two half-value layers), the radiation penetrating the shield and reaching the object will be reduced to 25% of the radiation intensity received by a non-shielded object.

The table below summarizes the radionuclide properties for some commonly used radioisotopes in the physical and life sciences. For each radionuclide listed, its half-life, type of ionizing radiation emitted, the relative strength and range of emitted particles, and effective half-value layer of water and lead needed to stop 50% of the emitted energy are given.

Table of Properties for Some Radionuclides

PROPERTY	^{3}H	^{14}C	^{32}P	^{60}C	^{125}I
Emitter	beta	Beta	beta	gamma	Gamma
Half-life[a]	12.3y	5730y	14.3d	5.3y	60d
Maximum MeV	0.018	0.156	1.71	1.17	0.088
Range[b], air (cm)	0.06	30.5	610	∞	∞
Range[b], H_2O (cm)	0.0005	0.003	0.8	∞	∞
H_2O , d[c]= 1.0	--	0.002	0.1	11.0	2.3
Lead, d[c]= 11.1	--	--	0.009	1.1	0.004

a- radionuclide half-life expressed in days (d), years (y)
b- range of gamma particles in air, water is very large (∞)
c- density as grams per cubic cm of material

E. Biological Effects of Ionizing Radiation

Humans are continuously to low levels of radiation from many natural sources. These include cosmic radiation bombardment from outer space, naturally radionuclides such as uranium, radium, and radon in geologic formations, soils and waters and, a relative distribution of the chemical elements that make our bodies. Additional synthetic non-occupational exposures to radiation include dental and medical X-Ray, consumer products such as ionizing-type smoke materials such as brick and gypsum board and radioactive fallout from thermonuclear weapons tests conducted over the past 55 years.

Contribution of Radiation Sources to the Effective Dose of the U.S. Population

Source	Percentage	Natural	Man-made
RADON	**55**	**X**	
INTERNAL	**11**	**X**	
MEDICAL X-RAYS	**11**		**X**
TERRESTRIAL	**8**	**X**	
COSMIC	**8**	**X**	
NUCLEAR	**4**		**X**
CONSUMER PRODUCTS	**3**		**X**
OCCUPATIONAL	**0.3**		**X**
NUCLEAR FALLOUT	**0.3**		**X**
	100%	**= 82%**	**+ 18%**

This “background radiation” is part of our environment. If prudent practices are followed, external exposure to common life science research radioisotopes and exposure to incident radiation such as sealed sources and X-Ray machines pose a negligible risk to the user.

However, handling or using radioactive materials cannot be taken lightly and extreme caution is in line with the known biological effects of ionizing radiation and the mandated exposure limits that have been established for users of materials and devices.

Quantifying Exposure to Ionizing Radiation

When high-energy radiation passes through a material, it transfers energy to the material ionization of the material. To radiation is assessed by the recorded number of the ionization events within a time. The unit used to express **exposure** to ionizing radiation is the **Roentgen I,** particularly for of exposure to gamma and X radiation.

In turn, the amount of energy absorbed by the target material following exposure to gamma and X radiation (i.e. Radiation absorbed does) is expressed in units of rads or grays (I gray = 100 rads).

While the injury to living systems produced by a given type of ionizing radiation depends on the amount of energy imparted to the matter, some forms or particles of energy produce greater effects than others for the same amount of energy imparted do. For example, for equally absorbed doses alpha particles produce more injury than beta amount of energy imparted. For particles. The effectiveness of one the biological material irradiated, the exposure particles because alpha more energy in a shorter travel distance within the material than do beta relative to another may also vary considerably depending upon the of the appearance of the adverse effect and the ability of the body to repair the injury.

The **linear energy transfer (LET)** imparted by a radiation particle is the best indicator for estimating the relative effectiveness of the absorbed dose. The LET of radiation particles is expressed as a **Quality Factory (QF).** By using the Quality Factor for each the of ionizing radiation, a **dose equivalent** can be expressed to standardize the unit of absorbed dose, the RAD. Quality factors can range from 1, for beta, X-ray, and most gamma sources, to as high as 20 for alpha, neutron and proton radiation particles.

Dose equivalents are expressed in rems or Sieverts. The acronym, REM stands for “Radiation Equivalent Man” and is based on the rad unit. A sievert has the same to a gray in the SI units:

Rems = rads x QF
Seivert = grays x QF

Dose equivalent units such as the rem allow for the calculation of the internal dose of radiation received based on the external exposure to radiation. Such units are more relevant to evaluating the adverse biological effects of radiation than the external dose one receives. For highly penetrating gamma and X-Rays and internal sources of beta

1 R = 1 rad and 1 rem = 1000 mrem

The annual rem dose one receives form non-occupational exposure to background radiation is dependent upon location on earth, the altitude above sea body elemental make-up, and exposure to naturally and man-made radionuclides. Natural radioactivity in the body is predominantly from potassium-40 and carbon-14 based on relative abundance of radioactive to non-radioactive source accounts for approximately a 20-mrem exposure each year.

Natural background radiation, which varies by location and altitude, accounts for an annual radiation exposure to an individual of about 88 mrem for the average U.S. population. A chest X-Ray is equivalent to 5-15 mrem; a dental X-ray is about 240-350 mrem. A person such as a pilot flying high altitude airplanes receives an additional annual dose of as much as 4,400 mrem from cosmic radiation. The adverse and lethal effects of exposure to very levels of radiation are well established. There is more uncertainty about the adverse effects of exposures to relatively lower levels of ionizing radiation.

Exposures to high levels of ionizing radiation result in dire consequences because of the disruption of biochemical processes necessary to sustain life. The direct ionization of tissues and the in vivo production of free radicals by radiation can result in cell-denatured proteins, disruption of cell membranes and to DNA. Cell most sensitive to radiation are those with a high mitotic index (i.e. Turnover) and low differentiation stem Radiation sensitive tissues include intestinal epithelium and most other epithelial the testes and ovary germ cells, and the fetus.

Whole body radiation doses above 200 R are often lethal to the victim within 60 after exposure. Any survivors to such exposures would be burdened with shortened lifetimes, high rates of leukemia and persistent with infections. Acute radiation doses at 50-100 R induce radiation sickness and symptoms such as intestinal loss of and pulmonary fibrosis.

Adverse Effects of exposure to High Levels of Radiation

Exposure	**Significance**
650 R, single dose whole body	LD50 (lethal dose) to humans
100 R, single dose whole body	Mild radiation sickness
10R, whole body dose	Elevated chromosomes aberrations in circulating lymphocytes

Exposure to lower levels of ionizing radiation can damage DNA at several levels of organization through mechanisms including mutagenesis (gene locus mutation), clastogenesis (chromosomal breaks) or aneuploidy (gain or loss of intact chromosomes). In adult somatic cells, these adverse genetic events may be expressed as disease, cancer, or result in a shortened lifespan.

Genetic damage to germ cells such as sperm or ovary can result in heritable mutations that could be expressed by fetal death, teratogenesis (birth defects), physical or mental retardation of the fetus or an increased risk to a newborn contracting cancer such as leukemia in their childhood or adulthood.

The fetus is very sensitive to ionizing radiation and any woman who is pregnant or of childbearing age should be fully aware of the risks to an unborn child being exposed to radiation. Evidence suggests that the end of the first trimester and the beginning of the third trimester of the pregnancy are the more sensitive times in the gestation period. Occupational exposure of women who have declared they are pregnant should not exceed 0.5 R (500 mrem) during the entire nine-month period of gestation.

With the exception of the above circumstances where protection of an unborn child from the effects of radiation is the issue, **Permissible Exposure Limits (PEL)** to radiation for adults are established by Federal statute through the Nuclear Regulatory Commission and the Department of Energy. Louisiana, as an

Agreement State, follows the same established guidelines but in accordance with Environmental Regulatory Code, 2002, (ERC) Pat1 XV Radiation Protection issued by the Department of Environmental Quality. See Chapter 4, Sections 401-414; 453, 455, and Chapter 10, section 1012, 1013 or ERC for detailed information regarding special circumstances, exclusions, and reporting excessive occupational exposure to radiation.

As stated in the Forward of this Manual, ULM supports the concept of limiting exposure to ionizing radiation to "As Low as Reasonably Achievable (A LARA). The ULM Radiation Safety Committee and RSO have established" ALARA: goals for limiting occupational exposure to ionizing radiation to one-tenth the established PEL.

The RSO will review the quarterly reports of personnel monitoring exposure records for all personnel and will notify the supervisor of any person whose exposure record indicates radiation exposure exceeding the calculated ALARA value. More than one exposure in excess of the ALARA will result in a formal inquiry before the Radiation Safety Committee. Any occupational exposure that is in excess of the ionizing radiation PEL will be immediately reported to the Radiation Safety Committee and the Department of Environmental Quality.

Occupational Exposure to ionizing Radiation for Adult Individuals in Restricted Areas

mREMs per Calendar Year		
	ULM target	**ERC mandated**
Body Exposure	ALARA	PEL
Whole body; head and trunk; or sensitive target tissues of gonads, bone marrow, lens of eye	500	5,000
Hands, forearms, feet, and ankles	7,500	75,000
Skin, whole body	3,000	30,000

Under Federal and Louisiana radiation regulations, whole body exposure (PEL) cannot exceed 5,000 mREM (5 R) in one calendar year. The ULM Radiation Safety Committee has the stated goal of limiting occupational exposure to ionizing radiation to less than 500 mREMs per year.

F. Detection and Monitoring of ionizing Radiation

Liquid scintillation counting is the only means of quantitating ^{3}H radionuclides and the appropriate analytical approach for quantifying beta emitter radionuclides such as $^{3}\mathrm{H}$, $^{14}\mathrm{C}$, $^{32}\mathrm{P}$, and $^{35}\mathrm{S}$. An aliquot of a sample or a swabbing of the area surveyed is placed in a vial or mixed with a solvent/fluor medium. In the scintillation counter, the emitted beta particle energy causes excitation of the fluor dye resulting in the emission of photons from the sample vial. This emitted light is detected by a photomultiplier tube and, based on the efficiency of the conversion of the beta particle energy to measured light, one can determine the radioactivity of the sample analyzed. Consult the professor-in-charge of the liquid scintillation counter or the Operator's Manual for the particular machines for more information about this analytical instrumentation.

In area surveys for gamma-emitting radionuclide contamination (e.g. IO'Cd, 131 1), many beta emitters, and for measuring incident radiation emitted from X-Ray devices, a hand-held **Geiger-Mueller Counter** survey meter is the appropriate instrument for such surveys. The detector is a gas-filled tube a thin wire insulated from the outside of the tube and connected to a high voltage source. As X-Ray, gamma or high-energy beta particles pass through the gas-tilled tube, gas molecules are ionized and the free electrons generate an electronic current in the wire.

This current is amplified to produce a counting signal for radiation striking the tube. The type of probe fitted to the G-M survey meter will greatly determine the sensitivity and use of the instrument. A window "pancake" probe is used for general-purpose surveys and will detect beta particle emission from 14C radionuclides if held close to the surface being monitored as well as higher energy radiation. "Side window" probes have a thicker window and will only detect high-energy 12p beta particles and gamma radiation. **All G-M survey meters must be calibrated at intervals not to exceed one year.** Contact the RSO for additional information about the availability of survey meters or their use.

G. Radionuclide Calculations

Health physics calculations for estimating and quantifying exposure to radiation were given in previous sections of this Manual. The following involved calculations for using and handling radionuclides for tracer studies. The basic event that characterizes a radionuclide is the transformation or decay of its nucleus to that of another elemental species. The number of decays or disintegrations that occur per unit time is called activity and each disintegration emits one or more types of radiation. Units of activity are expressed in terms of **Becquerels (Bq) or Curies (Ci).**

1 Becquerel	**=**	**1 disintegration per second (dps)**
1 Curie	**=** **=**	**3.7×10^{10} dps** **2.22×10^{12} disintegrations per min (dpm)**
1 millicurie (mCi)	**=**	**2.22×10^{9} dpm**
1 microcurie (µCi)	**=**	**2.22×10^{6} dpm**
1 picurie (pCi)	**=**	**2.22 dpm**
1 becquerel	**=**	**27pCi**

Specific Activity of a material refers to the quantity of radioactivity per mass of the material and is usually expressed in grams or Moles; e.g.: 32 mCi/mM (32 millicuries per millimole).

Total Activity is the total amount of radioactivity originally present in the prepared radionuclide calculated on the day the material was prepared; e.g. I 00 ~Ci or five mCi.

Example:

A carbon-14 radioisotope was ordered for metabolism or fate studies with the N-methylcarbanate insecticide carbaryl. A typical label would state:

1. Total activity, e.g. 100 µCi: 100 x 2.22 x 10^6 dpm/µCi = 2.22 x 10^8dpm

2. Description of the radiochemical and position(s) of the radionuclide within the molecule. The position of the radiocarbon may be of critical importance in metabolites of tile material.

Naphthyl-1-1-14c	UL-J4C carbaryl	carbonyJ-14C carbaryl
O	**O**	**O**
O-C-$NHCH_3$	O-C-$NHCH_3$	O-C-$NHCH_3$

3. Specific activity, e.g. 10.2 mCi/mM. Carbaryl has a molecular weight of 201.4; 201.4 ug = one mMole of carbardryl.

   10.2 mCi/mM x 2.22 x 10· dpm/mCi = 1.1243 x 108 dpm/ug carbaryl 201.4 ug/mM

   dpm/ug carbaryl = 1.12 x 10^8 dpm/ug =0.504 ug carbaryl
   Total activity 2.22 x 10^8 dpm

One can see that the received material consists of about 0.5 ug radio labeled carbaryl in form or in a small (0.2ml) volume.

Exercise great care in handling and diluting purchased stocks of radioactive chemicals. There is the potential for loss of radioactivity through mishap and/or the potential for errors in calculations when preparing solutions. Remember that once high specific activity stocks have been diluted with non-labeled chemicals to a lower specific activity, there is no way to enrich that working solution to a higher specific activity.

WHEN HANDLING OR MAKING TRANSFERS OF RADIOLABELED MATERIALS ALWAYS WORK OVER ABSORBBENT PAPER TO CONTAIN ANY SPILLED MATERIAL TO PREVENT CONTAMINATION AND TO ENHANCE CHANCES OF RECOVERING THESE EXPENSIVE CHEMICAL STOCKS.

Purchased radio labeled chemicals should be diluted with a relatively non-volatile solvent in a volumetric flask, sealed and labeled regarding specific activity, solvent, volume, etc. and stored at 0-5°C. Anytime portions of the stock solution are used to prepare different working solutions, record this transfer and make sure that the working solutions are appropriately labeled as above.

Determination of Activity Loss from Radionuclide Half-Life

While some radionuclides such as carbon-14 have extremely long half-lives, others such as ^{32}P, ^{35}S, ^{51}Cr ^{109}Cd and possibly ^{3}H (for old stocks) have relatively short half-lives and the specific activity of the stock solutions will change because of radioactive decay. Given the known specific activity on a certain date, the specific activity of a radionuclide material can be calculated for any other date after the material was prepared.

A	**=**	$A_0\ e^{-0.693(t/T\ 1/2)}$
A	**=**	Activity remaining after time, t
A_0	**=**	Activity of sample at time = 0
t	**=**	Elapsed time
$T_{\frac{1}{2}}$	**=**	Radionuclide half-life; both t and T ½ must in the same units as hours, days, years

Example:

What is the remaining activity of 1.5 mCi 32p sample 45 days after the date of assay?

(T1/2 of phosphorus-32 is 14.3 days.)

A = 1.5 e^-0.693(45/14.3)
= 1.5 e^-2.181
= (1.5) (0.113)
=0.169 mCi

The stock material of ^{32}P has only 11.3% of the initial activity 45 days after the material was prepared.

IV. MANDATED ON-SITE POSTING IN LABORATORIES/FACILITIES WORKING WITH IONIZING RADIATION AND RADIOACTIVE MATERIALS

A. Louisiana Radiation Regulations and Notices

The broad scope Radioactive Material License LA-23 83-LO I that governs the use of radioactive materials at ULM and the ERC Regulations are available for review in the Environmental Health and Safety Office, Strauss Hall Suite 255.

All Departments, Divisions, and laboratories at ULM that use radionuclides, sealed radioactive sources or devices that emit ionizing radiation shall post the following documents in prominent view:

DRC-3 "NOTICE TO EMPLOYEES"

Louisiana Radiation Regulations, Chapter 10; "Notices, instructions and Reports to Workers; Inspections"

"Certificate of Registration" for X-Ray Devices

Any notice of violation involving working conditions, proposed imposition of penalty or order issued by DEQ and any response from the Licensee.

All Departments, Divisions and laboratories at ULM that use radionuclides, sealed radioactive sources or devices that emit ionizing radiation shall make the documents available to their students and staff:

- Louisiana Radiation Regulations, Chapter 4; "Standards for Protection against Radiation"
- A copy of the ULM Radiation Safety Manual, Latest revision.
- Radiation exposure data for an individual and the results of any measurements, analyses and calculation of radioactive materials or retained in the body.

B. Caution Signs and Labels

Conspicuously post the following caution signs and labeling in designated areas. All required signs and labels shall bear the conventional 3-blade radiation caution symbol and colors (magenta or purple on yellow background).

Analytical X-Ray Equipment:

Analytical X-Ray devices should display **"CAUTION - HICH INTENSITY X-RAY BEAM"** on the X-Ray source housing and "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" near the switch that energizes the X-Ray tube if the radiation source is an X-Ray tube, or **"CAUTION - RADIOACTIVE MATERIAL"** if the radiation source is a radionuclide.

Medical X-Ray Equipment:

As stated in ERC 4: Section 422 G "all radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated".

Laboratories using or storing radioactive materials:

Each area or room in which radioactive materials is used or stored shall be conspicuously posted with a sign bearing the caution symbol and the words: **"CAUTION - RAOIOACTIVE MATERIAL"**. Each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents

Animal and metabolism changes should be labeled with the radionuclide and total amount of radioactivity used in the experiment. Activity can be on a per animal basis or, in feeding as activity per unit of food or water. At the end of the experiment, cages must be decontaminated prior to transport to the cage washer.

Laboratory containers such as flasks, beakers and test tubes used in laboratory procedures with radioactive materials do not require labels when the user is Labels are required if the user leaves the immediate area where the radioactive materials are being used.

Prior to the disposal of empty, uncontaminated containers or packing materials, laboratory shall remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.

Exemption from Posting and Labeling Requirements:

A room or area is not required to be posted with a caution because of the presence of a radioactive sealed source, provided that the radiation level 12 inches from the surface of the source container or housing does not exceed 5 mrem/hr. This exemption includes, among certain devices, all gas chromatograph equipped with ^{63}Ni electron capture detectors and all ^{85}Kl aerosol neutralizers.

C. General Laboratory Procedures and Cautions

THESE GENERAL PROCEDURES AND CAUTIONS ARE TO BE POSTED IN ALL LABORATORIES WHERE RADIOACTIVE MATERIALS ARE USED OR STORED

- No smoking, eating or drinking in the immediate area where radioactive material is being used.
- The storage of food in refrigerators/freezers where radioactive materials are stored is prohibited.
- Children are prohibited in laboratories where radioactive materials are in use.
- Laboratories are to be kept clean, orderly and free of excess equipment, supplies and printed materials.
- All radioactive solutions are to be pipetted using pipette filling devices; pipetting by mouth is prohibited.
- Plastic backed absorbent paper shall be used to cover work surfaces where radioactive materials are transferred or placed.
- All procedures using radioactive solutions are to be carried out over trays or work surfaces that can accommodate the experimental volume in case of an accident.
- Volatile radionuclides or radionuclides dissolved in volatile solvents should be transferred and handled in a fume hood.
- Protective clothing including gloves, lab coats, and safety glasses are to be worn in the laboratory. Other personal protective items such as respirators are to be available upon request to workers.
- Gloves that may be contaminated are to be removed before leaving the work area or laboratory.
- All personnel handling P-32 or gamma emitting radionuclides shall wear a personal monitoring device for radiation exposure.
- Work areas should be surveyed for radioactive contamination at the end of the procedure and before leaving the work area. Survey instruments and/or materials for conducting wipe tests are to be available at all times.
- All laboratories using radionuclides shall post and prominently display these procedures, emergency procedures and **Environmental Regulatory Code**, Chapter 10 and DRC-3 "Notice to Employees".

D. Emergency Response to Radioactive Material Accidents and Spills.

THESE EMERGENCY RESPONSE PROCEDURES ARE TO BE POSTED IN ALL LABORATORIES WHERE RADIOACTIVE MATERIALS ARE USED OR STORED.

Radiation Safety Officer: Shane Dykes Office 342-5177

Authorized User: _____ Office _____ Home _____

ULM Campus Police 342-5350

Spills of Radioactive Material; No Contamination of Personnel

1. PROTECT YOURSELF AND OTHERS IN THE AREA FROM BECOMING CONTAMINATED BY THE RADIOACTIVE MATERIAL.

Vacate the immediate area of the spill, notify others of the accident and prevent all personnel from entering the area. The person responsible for a liquid spill may prevent the spread of contamination by applying absorbent material.

2. NOTIFY THE RSO AND THE PRINCIPAL INVESTICATOR.

Be available and prepared to answer questions concerning the radionuclide and the amount of material spilled.

3. DO NOT BEGIN DECONTAMINATION PROCEDURES UNTIL THE AREA HAS BEEN CLEARED OF NON-ESSENTIAL PERSONNEL, SECURED, AND THE RSO HAS ARRIVED TO SUPERVISE CLEAN UP.

An impulsive clean up may do more harm than good.

4. CLEAN-UP PROCEDURE.

Persons responsible for the spill, unless physically incapable, shall decontaminate the area under the supervision and assistance of the RSO. All laboratories will have cleaning materials on hand including sponges, absorbent paper, containers and a detergent or a product recommended for radioactive decontamination.

THE FOLLOWING PROCEDURES DESCRIBE THE DECONTAMINATION PROCESS.

a. Prevent the spread of contamination.

b. Allow no one to leave the adjacent area until the person has been checked for contamination.

c. Make full use of monitoring instruments and available assistance. One person shall remain uncontaminated to operate instruments and do other monitoring.

d. The RSO shall provide protective clothing, footwear, and respiratory equipment to be used as needed.

e**.** Effective decontamination of radioactive material spills will be considered complete when surface contamination levels are less than 220 dpm per wipe test (<100 pCi/100 cm2).

Contamination of Personnel by Radioactive Materials

Personnel Decontamination

Under no circumstances should organic solvents be used in personnel decontamination procedures because of the increased probability of dermal penetration of the radionuclide. Except in rare circumstances, the same procedures used for personal cleanliness will remove radioactive contaminants from the skin. Soap and water should remove more than 99% of the contamination.

If personnel are contaminated during a radioactive spill or during the decontamination process, the following general procedures are to be undertaken:

1. PROMPTLY REMOVE ANY CLOTHING KNOWN OR CONSIDERED TO BE CONTAMINATED.

Wash the skin thoroughly with a mild soap and warm water, paying special attention to areas between the fingers and toes and around and under the nails of the digits. Repeat 3 times.

Perform a wipe test of the afflicted area to determine if removable contamination remains on the skin.

If further action is necessary apply a wetted mixture of 50% laundry detergent powder (e.g. TIDE), and 50% corn meal. Repeat if results are encouraging.

2. DECONTAMINATE AREAS OF THE BODY FOUND TO BE SIGNIFICANTLY CONTAMINATED BEFORE SHOWERING.

Spot cleaning is necessary to prevent spread of contamination to clean areas of the body that might occur in showering. If the contamination is widespread over the body surfaces, a very thorough shower using a body brush is necessary. Special attention should be paid to such areas as the hair and scalp, the hands, and fingernails. In the School of Pharmacy, there is a shower stall in the restroom on the fourth floor (vivarium).

After showering and monitoring, residual contamination can be removed by spot cleaning. If it is necessary to remove more of the contaminant, chemicals (e.g. Citric acid, sodium bisulfate, potassium permanganate) may be applied to the skin but only under direct medical supervision.

Written Reports Following Radioactive Material Accidents

Person Responsible for the Accident

A written report describing the accident and decontamination methods used will be submitted within 3 days after the accident to the RSO and Radiation Safety committee by the individual responsible for the accident.

Principal Investigator (Authorized User)

The RSO will meet with the Principal Investigator (Authorized User) responsible for the area where the accident occurred to discuss the cause of the accident and what measures are required to prevent reoccurrence. The Principal Investigator will submit a report to the Radiation Safety Committee within 14 days outlining remedial action taken to reduce the risk of a reoccurrence of a similar accident.

V. WIPE TESTS AND CONTAMINATION MONITORING GUIDELINES FOR LABORATORIES AND EQUIPMENT

A. Routine Laboratory Wipe Tests to Monitor Beta Emitter Contamination

To lessen the possibility of radioactive contamination workers are encouraged to use the fume hood when handling any radionuclide. Chemical fume hoods shall be used when handling a volatile radionuclide or a radionuclide dissolved in volatile solvents.

As a matter of good technique in the safe use of radionuclides, users should always perform a wipe test of the immediate work area after transferring high activity radionuclide stocks or at the end of involving manipulations or radioactive materials. Such checks for contamination of the work area should be incorporated into all experiments that use of the liquid scintillation counter to radioactivity.

All laboratories that use radionuclides <u>MUST</u> perform routine tests surveys of the laboratory on at least a <u>WEEKLY</u> basis if radionuclides have been used at any time during the past 7 days.

The RSO may reduce or increase the frequency of tests for an individual investigator or laboratory depending upon the radionuclide used, history or and procedure/assay used in the lab.

All laboratories will conduct wipe tests and maintain a historic the ULM-RS -03 form eight "Wipe Test". A diagram of the laboratory shall be sketched on the form to indicate the areas surveyed when the wipe tests are performed.

PROCEDURE: PERFORMING WIPE TESTS OF WORK AREAS AND SPECIFIED LOCATIONS IN THE LABORATORY (BETA EMITTERS; ^{3}H ^{14}C, ^{32}P, ^{35}S)

Materials:

Cotton-tipped wooden applicator swabs
20 ml scintillation vials
Methanol
ULM-RS 03 form 8 "Wipe Test Survey"

Liquid Scintillation counter with:
1. Counting program set for appropriate radionuclide energy window
2. Counter efficiency established for radionuclide

Procedure:

1. All wipe test locations are labeled by number and recorded on the wipe test form laboratory sketch. For each wipe test location, two wooden cotton-tipped swabs are moistened with alcohol and rubbed over the area no less than 100 cm^2 (4x4 inches).

2. The cotton-tipped portion of the swabs are inserted into a labeled empty scintillation vial and the wooden sticks are broken over the lip of the vial so that the cotton tips of the swab remain in the vial. The wooden sticks are discarded. This process is repeated for every area that is to be wipe tested.

3. A negative control (vial with unused swabs) is as a reference test vial to determine a background reading in the scintillation counter.

4. All vials are filled with 15 ml of water-soluble scintillation medium and capped. The series of test vials are analyzed using the scintillation counter to quantify radioactivity. Radionuclide counter programs are used to the data for wipe test.

5. Results of the wipe tests are to be recorded and reported in dpm, NOT cpm, and data calculations should reflect the counting efficiency for the radioisotope by liquid scintillation counting technique.

6. All survey wipe tests are to be and records maintained that demonstrate a laboratory is this routing safety procedure.

ANALYSIS AND FOLLOW-UP OF WIPE TEST DATA

Contaminated Areas:

1. Any wipe test that shows beta emitter radioactive material contamination above 220 dpm (<1OO pCi/l00 cm^2) is to be considered positive and indicative or radioactive material contamination of that surface area

2. The RSO is to be notified if a test shows radioactive material contamination exceeds 2,200 dpm (<1000 pCi/l00 cm^2)

3. The contaminated area will be scrubbed with a decontaminating solution to remove radioactive materials with precautions taken to ensure that the contamination is not spread during the clean-up effort.

4. A second wipe test shall be following the decontamination procedure and the results recorded along with the wipe test. Clean-up efforts shall continue until the affected area shows wipe tests that are negative (<1000 pCi/l00 cm^2).

5. Persistent or tests for a particular laboratory shall be immediately reported to the RSO.

B. Survey Instruments for High Energy Beta (32P) and Gamma Emitting Radioactive Contamination

Portable survey meters may be obtained from the RSO. Survey meters will be calibrated annually and a record of calibration will be maintained by the RSO. Laboratories using 32p and/or gamma radionuclides are monitored with survey instruments and after experiments that may contaminate the area.

Records shall be maintained that demonstrate that such surveys are being conducted; radiation shall be recorded in mrems/hr.

Survey meters are also available to individuals to monitor incident radiation emitted the operation of such equipment or for performing health physics calculations.

C. Contamination Guidelines for Containers and Apparatus

As a general practice, when laboratory apparatus or equipment is no longer required for radioactive materials it is to be removed from the lab or no longer a reasonable effort will be made to reduce residual contamination to less than 500 dpm/100 cm2 for beta or gamma emitting radionuclides.

VI. PERSONNEL MONITORING FOR EXPOSURE TO IONIZING RADIATION

A. Routine Personnel Monitoring

Prior to starting any work using high energy beta emitting radionuclides, gamma emitting radionuclides, neutron sources or the use of medical or analytical X-Ray devices, all personnel who will be exposed to such ionizing radiation must request personnel monitoring service. Clip-on personnel monitoring badges are issued and exchanged on a quarterly basis to record exposure to penetrating radiation, See Appendix i, Form 3 ULM-RS "Request for Personnel Monitoring Service", Quarterly radiation exposure reports will be issued as received from the vendor of this service.

B. Non-routine Bioassay

Biological monitoring of personnel for deposition of radionuclides is not offered at this time by the ULM Radiation Safety Program. Because of the need of this monitoring technique for assessing internal deposition (thyroid) in workers using 125^I and 131^I radionuclides in volatile forms or in amounts other than license exempted radioimmunoassay (RIA) kits, no work with these radionuclides will be permitted without prior approval by the RSO and the Louisiana Department of Environmental Quality.

VII. AUTHORIZATION TO USE AND PURCHASE RADIOACTIVE MATERIALS

A. Authorized User of Radioactive Materials

An Authorized User is the Principal Investigator on research projects involving the use of radioactive materials or radiation producing devices and carries the responsibilities outlined in Section I Part D of this Manual. An Authorized User of radioactive materials, specifically, the use of radioisotopes in pharmaceutical, toxicological,

biological or biochemical studies or use of radiation sources or X-Ray emitting devices for research purposes, must be approved by the RSO acting for the Radiation Safety Committee.

To gain approval, Authorized Users must satisfy the following conditions:

1. Completed at least one formal course or its equivalent in the theory and practice of the use of radioactive materials. Equivalency is defined as at least 6 months of practical experience and "on-the-job" training in a university or industrial research setting using radioactive materials.

2. Attend the ULM short course in radiation safety.

Principal Investigators must complete and submit ULM-RS 03 Form 1 "Authorized User Qualifications" to the RSO for review and approval before such personnel will be allowed to use or supervise use of radioactive materials.

It is the responsibility of the Authorized User to oversee the overall use and possession of radioactive materials in his or her laboratory, to give instruction to personnel regarding the prudent hand ling of radionuclides and/or use of radiation producing devices, and to judge the competency of personnel performing such experiments. Students or staff assigned to such research projects will work under the direction of the Authorized User.

All staff, undergraduate and graduate students that will be working with radioactive materials in research projects **must attend** an ULM short course on radiation safety before they will be allowed to participate in such projects.

****

The health and safety of personnel working with or inadvertently exposed to radioactive materials is of the highest priority and supersedes any notion of "academic freedom" regarding use of radioactive materials for research purposes.

The broad scope radioactive materials license held by ULM can be jeopardized by a single Authorized User or his subordinates. Therefore, the Radiation Safety Officer (RSO) has the authority to suspend, revoke or prohibit the use of radioactive materials or radiation producing devices by any individual(s) at ULM.

Authorized Users (and by proxy their subordinates) who repeatedly deviate from the guidelines of this manual or are found in serious violation of the Environmental Regulatory Code may lose their privilege to engage in research requiring the use of radioactive materials or radiation producing devices.

The suspension of privileges of an Authorized User or his subordinates to purchase and use radioactive materials or radiation-producing devices for research purposes may be appealed to the Radiation Safety Committee.

****

B. Procurement of Radioactive Materials

Authorized Users may order, purchase, and use radioactive materials and/or radiation producing devices, but only after certain conditions established by the RSO and Radiation Safety Committee have been met. To order a radionuclide, sealed source or radiation device, an Authorized User must complete ULM-RS 03 Form 5 "Radioactive Materials Procurement and Use." The intent of this form is to notify the RSO and Radiation Safety Committee as to the type of experiments and projects that are being attempted and to ensure that the investigator has adequate resources and expertise to safely carry out the scope of work. The following information is requested and must be satisfactorily addressed before radioactive materials can be ordered or used:

-Description of the type of experiment or procedure
-Protocol or experimental design to be used
-Radioisotope or sealed source to be used or purchased
-Storage area for the material
-Duration of experiment, timetable or extended projects

-Description of chemical and biological wastes to be generated
-Details of handling and use of the procured material
-Names, training, and qualifications of project personnel

This form must also be completed for every research project that will entail the use of radionuclide or radioactive device that is on-hand, or if the radioactive material is to be used in a research project that substantially differs from the original protocol submitted.

All procurement and uses of radioactivity must be approved by the RSO and Radiation Safety Committee before a project can begin. Therefore, the Authorized Users should include a 3-4 week approval period from the time the Procurement/Use form is completed until approval for the project can be given.

After the plan of use has been approved by the RSO and Radiation Safety Committee, the Authorized User may order the radioactive materials through standard University channels.

The following procedure is used by the RSO or his designate to receive and inspect the radioactive material before the Authorized User can take delivery of the material:

1. The Pharmacy mailroom will accept delivery of radioactive materials and contact the RSO or his designate as soon as possible, but no later than 3 hours after receipt of the materials.

2. The external surfaces of the package are monitored for radioactive contamination. External surface monitoring is not required on packages containing less than I mCi beta and/or gamma emitting material or packages containing no more than 10 mCi ^{3}H, ^{14}C, ^{35}S and/or ^{125}I.

3. The RSO or Authorized User will open the package, inspect for damage, record any readings of the contents, and verify the contents compared to the purchase order.

4. The mailroom charge person will assign an ULM inventory number to the radioactive material received. A chain-of-custody form, ULM-RS 03 Form 7 "Radionuclide Receipt and Use", is filled out for the Authorized User's receipt and use of the radioactive material. The RSO or his designate will inform the user of special precautions or radiological hazards associated with the isotope.

C. Receipt and Use of Radioactive Materials

The Authorized User will sign for radioactive material on the "Radionuclide Receipt and Use" form and receive a copy for the laboratory's records. The intent of this form is to determine the amount of activity of a particular radionuclide on hand at any time after purchase of the material, either through use or by radioactive decay.

When the initial stock solution is depleted, the form is returned to the Pharmacy mailroom as a permanent record or receipt and use of this radioactive material.

D. Inventory and Storage of Radioactive Materials and Devices

All Authorized Users are required to submit an annual inventory of all radioisotopes and sealed sources in the possession of the Authorized User to the RSO. An inventory list, ULM-RS 03 Form 6 "Radioactive Material Inventory Record", will be sent to Authorized Users for update September 1 of each year and must be returned to the RSO by September 15.

Security measures must be taken by Authorized Users to restrict access to radioactive materials by unauthorized personnel. Laboratories that store or use radioactive materials must be secured and locked after regular working hours and on weekends. Authorized Users are requested to restrict access to laboratories whenever feasible.

E. General Record Keeping Requirements for Radioactive Materials

Every Authorized User of radioactive materials is obligated to keep records that document and track all radioactive materials in his or her possession. Each laboratory should develop a notebook or other means of record keeping that would allow one to follow a radionuclide from purchase through use to disposal of the radioactive material...a "cradle-to-grave" record of the radioactive material on hand. Such records are subject to inspection by the RSO, Radiation Safety Committee or the DEQ at any time during normal working hours.

VIII. RADIOACTIVE MATERIAL WASTE MANAGEMENT

A. Regulatory Definition of Radioactive Materials

Both Federal and Louisiana authorities recognize that disposal of very low concentrations of certain radioactive materials pose minimal hazards to humans and the environment. The disposal of three radionuclides, limited to tritium, carbon-14, and iodine-125 radioisotopes commonly used in life sciences research, has been given special consideration and regulatory exemptions are recognized for de minimis concentrations of these three radionuclides.

In accordance with both the Federal and Louisiana definitions of radioactive materials, the presence of ^{3}H, ^{14}C and ^{125}I at 0.05 microcurie or less per gram material (110,000 dpm/g) is by definition not radioactive.

B. Disposal of Specific Radioactive Materials: Carbon-14, Iodine-l31, and Tritium

Any hazards of chemicals, solvents or wastes contaminated with low-level radioactivity by these three radionuclides are limited to the physical or chemical properties of such wastes. Therefore, such non-radioactive wastes will be disposed of in accordance with prudent practices for such generated wastes. Because of these de minimis regulatory exemptions for **^{3}H, ^{14}C, and ^{125}I**, it is expected that ULM should generate little radioactive waste that will require removal off site by a contractor. While such wastes may be disposed of without regard to their low radioactivity, records must be kept to track disposal of all radioactive materials.

Guidelines for the disposal of these radionuclides, in accordance with ERC Chapter 4, Sections 462, 464 are given below.

Disposal via Sanitary Sewer:

Limited quantities of ^{3}H, ^{14}C, and ^{125}I and other radionuclides may be disposed by release into the sanitary sewer system (ERC, Section 462). Given the small amounts of radioactive materials used on campus and the fact that the University discharges on average 7,000,000 gallons of water into the sanitary sewer every month, this is the preferred method for disposing of water soluble or dispensable radioisotopes of these three radionuclides.

The following limitations on sanitary sewer disposal of these radionuclides apply to ULM as the License holder.

Maximum Quantity Released via Sanitary Sewer:
All materials released via sanitary sewer must be readily soluble or dispensable in water.

Annually: Tritium 5 Ci per year (Curies)
Carbon-14 I Ci per year
All others I Ci per year

Monthly: Quantities released if diluted by sanitary sewer outfall and averaged will not exceed:

Tritium 0.1 uCi/ml (microcurie/per ml water)
Carbon-14 0.02 uCi/ml
Iodine-125 0.0004 uCi/ml

Daily: Tritium 10 mCi (millicuries)
Carbon-14 I mCi
Iodine-125 10 uCi (microcurie)

All Authorized Users are requested to use water soluble, biodegradable scintillation media whenever possible to take advantage of the ease of disposal of such materials. All laboratories disposing of low-level radionuclide wastes via the sanitary sewer will select one sink per laboratory and record such disposal using ULMRS -03 Form 9A "Radioactive Material Sewer Disposal".

Disposal via Solvent Dilution:

Waste radioactive materials that are insoluble in water can be disposed of by dilution with waste solvents. Such materials would include scintillation fluids or stocks of such as PCBs, aromatic hydrocarbons, etc.

Laboratories with such wastes should use a polyethylene or Nalgener container to store such wastes in the laboratory to be picked up by the RSO or his designate when the container is full. This material will be diluted with waste solvents held in 55-gallon drums. Such mixtures will be treated as waste solvent without to radioactivity. These drums of chemical/solvent waste will be removed off-site by hazardous waste contractors,

To track the disposal of low-level radioactive wastes dilution with waste solvents, laboratories will record such using ULM-RS 03 Form 98 "Radioactive Material Solvent/Scintillation Fluid ". It is important to record both the activity of the waste and the total volume of disposed material so that one can calculate the proper dilution of such radioactive wastes to ensure that the waste solvent drums do not exceed the de minimis regulatory for radionuclide disposal.

C. Disposal of All Other Radionuclides and Specific Radionuclides (14C, 3H, 125I)

Disposal via Biohazard Waste Stream

Disposal material must meet the usual definitions of biohazard waste and must therefore be collected in the manner necessary for such material. Any radioactive biohazard waste must be collected in appropriate biohazard containers lined with a disposable plastic bag. The container must then be sealed and properly shielded to avoid unnecessary exposure to others. The approximate amount of radioactivity is recorded on ULM-RS 03 Form 9C. If possible, store the shielded radioactive biohazard waste until the total activity is below the definition of radioactive (less than 110,000 dpm/g or 0.05 µCi/g). Once the level of the material is considered that of background level then it may be removed through the contracted **biohazard waste stream**.

Disposal of biohazard radioactive waste grossly contaminated with radioactive materials through normal use or because of accidents are to be placed in an approved biohazard container lined with a disposable plastic bag. These contaminated materials should be sealed and stored with adequate shielding to prevent unnecessary exposure.

The approximate amount of is recorded on ULM-RS 03 Form 9C. When levels of radioactive biohazard waste are such that shielding is not to allow for decay in storage, contact the RSO or Assistant RSO in to disposal of radioactive biohazard waste.

Disposal via Solid Waste Stream

Disposal of solid radioactive waste such as gloves, disposable pads, and other expendable items that are contaminated with radioactive materials (excludes biohazard waste contamination) through normal use or because of accidents are to be placed in an approved container lined with a disposable plastic bag. Do not place such materials in ordinary trash containers. These contaminated materials should be sealed and stored with adequate shielding to prevent unnecessary exposure to laboratory personnel. The approximate amount of radioactivity is to be recorded on ULM-RS 03 Form 9D. If possible, this solid waste can be shielded and stored for decay until activity levels are below the definition of radioactive. When a sufficient quantity of such material accumulates to warrant disposal, contact the RSO or Assistant RSO in writing to **solid waste** disposal.

Heavily contaminated solid radioactive waste usually resulting from a spill shall be collected in separate and appropriate containers. The approximate amount of radioactivity is to be recorded on ULM-RS 03 Form 9D. The container is then sealed and temporarily stored with adequate shielding. However, if activity levels are such that adequate shielding is not possible to allow for decay in storage, contact the RSO or Assistant RSO in writing to request disposal of **radioactive solid waste.**

IX. OTHER RADIATION SOURCES

A. Policies and Procedures for X-Ray and Ionizing Radiation Producing Machines

X-Ray machines suitable for the medical arts are located within several Departments/Divisions on the ULM Campus. The Dental Hygiene Program (Caldwell Hall) has four dental X-Ray machines used for diagnostic purposes for the teeth and jaws for teaching and instruction of students. The Radiologic Technology Program (Nursing Building) has X-Ray equipment suitable for instruction and teaching students medical diagnostic imaging techniques. The Physics and Geology Departments (Hanna Hall) have analytical X-Ray devices for materials analyses and general research capabilities.

The following policies are applicable to operation of all X-Ray and radiation emitting devices or machines at ULM:

1. All women of childbearing age shall be required to read Appendix II of this Manual, US NRC "Instruction Concerning Prenatal Radiation Exposure" and be informed of the risks of ionizing radiation to the developing embryo and fetus. All informed personnel shall acknowledge receiving such instruction by signing ULM-RS form four "Acknowledgement of Prenatal Exposure Risks to Radiation" prior to using X-Ray or ionizing radiation emitting devices.

2. All X-Ray machines and ionizing radiation emitting devices shall be assigned to an Authorized User who has the responsibility for the operation and use of the instrument as the primary operator. All students and staff using such equipment for research purposes must attend the ULM radiation safety short course prior to operating such equipment.

3. All personnel who operate X-Ray machines shall wear a personnel-monitoring badge to monitor personal exposure to incident radiation. Personnel monitoring badges will be exchanged on a quarterly basis.

4. All X-Ray machines and devices must be registered with DEQ and a copy of the registration prominently displayed adjacent to the device. Appropriate warnings and labels as described in Section IV Parts A and B of this Manual must be posted in areas where these devices are housed or used.

5. All X-Ray machines and ionizing radiation emitting devices shall have either: I. For medical and dental units, a technique chart as described in ERC Chapter 6, Section 603; or 2. For analytical X-Ray devices or ionizing radiation emission devices, a set of written instructions or standard operating procedures for the use of the device.

B. Policy and Procedures for Gas Chromatograph Equipped with Electron Capture Detector (ECD) Cells

The use of sealed sources such as 63Ni in electron capture detectors used with gas chromatograph are common analytical instrumentation employed by several departments on campus. These sealed devices do not emit ionizing radiation as long as they are not opened and are operated within their designed thermal limits. Laboratories that utilize only this type of radioactive sealed source are not required to post radiation warning signs or notices.

The following are policies and procedures are applicable to all electron capture detectors in use on the ULM Campus.

1. The RSO will authorize shipment and/or receipt of all ECD that are being replaced, exchanged or repaired by the manufacturer.
2. Each ECD cell will be registered with the RSO and a file describing the cell, type of source, serial number, and its location will be maintained by the RSO.
3. ECD cells shall not be opened or radioactive foils removed except as specifically approved by the RSO upon amendment of the Radioactive Material License.
4. The RSO or his designate shall leak test detector cells at 6-month intervals to assure the integrity of the cell as required by the conditions of the License.
5. Gas chromatograph equipped with ECD that are not in use or ECD cells that are in storage do not have to be leak tested at 6 month intervals. However, the gas chromatograph must be de-energized, and the machine and/or stored ECD cells must be labeled with the following statement:

   "This (machine/cell) is officially in storage and is not to be energized or tampered with without authorization from the RSO."

6. Records will be maintained on site for each gas chromatograph with ECD. Such historical records will document leak tests performed on the instrument and contain a detector cell temperature program run that demonstrates that the detector cell-heating unit will de-energize and the detector will not exceed 400°C regardless of the detector temperature entered into the instrument operational parameters.

C. Policy and Procedures for 85Kr Aerosol Neutralizers

These devices are used to neutralize static charges generated when aerosols are formed to lessen aggregation of aerosol droplets to maintain a uniform aerosol droplet size necessary for conducting inhalation toxicology studies. As sealed sources that emit no ionizing radiation, no radiation warning labels or signs need to be posted where such devices are the sole radioactive material present.

The following policies are applicable to ^{85}Kr sealed sources:

1. The RSO will authorize shipment and/or receipt of all ^{85}K sources used on campus.
2. Each ^{85}Kr aerosol neutralizer will be registered with the RSO and a file describing the device and its location will be maintained by the RSO.

3. The RSO will inspect ^{85}Kr aerosol neutralizers on an annual basis.

X. References

1. Environmental Regulatory Code. 1987. Department of Environmental Quality, Office of Air Quality and Nuclear Energy, Nuclear Energy Div., Baton Rouge, LA.

2. Shapiro, 1. 1981. Radiation Protection: A guide for scientists and Physicians. 2nd Edition, Harvard University Press, Cambridge, MA.

3. Young, A.L. and G.P. Dix. 1988. The federal Approach to Radiation Issues. Environmental Science and Technology 22: 733-747.

4. Fundamentals of Industrial Hygiene, 3rd Edition. 1988. National Safety Council, Chicago, IL.

5. Radiation Safety Manual. 1986. U.S. EPA Environmental Research Center. Research Park Triangle, NC.

Appendix I

Standard Radiation Safety Forms and Documents

:
:
:
:
:
:
:
:

Form 1 ULM-RS 03

University of Louisiana, Monroe

Short Course on Radiation Safety Verification Form

This is to verify that today I have been given instruction and training in radiation safety as stated in the ULM Radiation Safety Manual. This instruction has included:

1. Overview of principles of radiation
2. Biological effects on ionizing radiation
3. Instruction concerning risk of prenatal radiation exposure
3. Safety with X-Ray devices
4. Standards for occupational exposure to ionizing radiation
5. Monitoring and measuring radiation
6. Performing radiation contamination surveys
7. ULM Radiation Safety Manual and Program
8. Emergency response to radioactive spills
9. Proper disposal of radioactive materials wastes

I have been given an opportunity to ask questions about radiation safety and the ULM Radiation Safety Program and to have those questions answered.

I have read and understood the above statements.

DATE _____

NAME _____

SIGNATURE _____

Form 2 ULM-RS 03

Authorized User Qualifications **- Training and Experience**

Name: _____ Date: _____

Department/Campus Address: _____

For the types of training listed, state where trained, duration of training (hours, days, other), 011 the job, formal course, or both.

TYPE OF TRAINING

1. PRINCIPLES AND PRACTICES OF RADIATION PROTECTION:
   Where_____When_____ Duration_____
   Job _____Course_____

2. RADIACTIVITY MEASUREMENTS, MONITORING TECHNIQUES, INSTRUMENTS, AND STANDARDIZATION:
   Where_____When_____ Duration_____
   Job _____Course_____

3. MATHEMATICS AND CALCULATIONS BASED TO THE USE AND MEASUREMENT OF RADIOACTIVITY:
   Where_____When_____ Duration_____
   Job _____Course_____

4. BIOLOGICAL EFFECTS OF RADIATION:
   Where_____When_____ Duration_____
   Job _____Course_____

5. ULM SHORT COURSE IN RADIATION SAFETY:
   YES_____ NO_____ (DATE: _____)

EXPERIENCE WITH RADIATION: Give a summary of your actual use of radionuclides, radiation sources, etc. List radionuclides handled, maximum activity at any one time, and techniques employed.

Approved by the Radiation Safety Officer for the RSC Date

Form 3 ULM-RS 03

REQUEST FOR PERSONNEL MONITORING **BADGE SERVICE, CHANGES, ADDITIONS, AND DELETIONS**

Department/Division: _____ Date _____

Departmental Contact: _____ Phone NO. _____

Request (X)

Add	Delete	Other	Badge No.	Last Name, F.I.	Sex	Birth Date	Social Security

Comments:

_____

_____

_____

_____

Form 4 ULM-RS 03

ULM INSTRUCTION CONCERNING RISK OF PRENATAL EXPOSURE TO RADIATION VERIFICATION FORM

This is to verify that today I have been given health risks associated with exposure to ionizing radiation and that special attention was to prenatal radiation exposure hazards to the developing embryo and fetus.

I received a copy of the US NRC Regulatory Guide 8.13 "Instructions Concerning Prenatal Radiation Exposure" as part of my instruction and was an opportunity to ask questions, and have such questions answered about prenatal radiation exposure and recommended occupational exposure limits to the expectant mother during pregnancy.

I understand it is my responsibility to inform my supervisor and Safety Officer if I become pregnant. Such information will be treated in confidence and will not affect my status as a student or employee of the University of Louisiana, Monroe.

I have read and understand the above statements.

DATE: _____

NAME: _____

SIGNATURE: _____

CWID: _____

Form 5 ULM-RS 03

RADIOACTIVE MATERIALS PROCUREMENT AND USE

DATE _____ RSO INITIALS: _____

_____ APPROVED BY RSO FOR THE RSC AS SUBMITTED
_____ NOT APPROVED AS SUBMITTED TO RSO

Principal Investigator: _____ Date: _____

Department/Division: _____ Telephone: _____

1. Description of Experiment. Provide a brief description of the study.

2. List the names, training and qualifications of ALL project personnel.

3. Radioisotope or source to be used or purchased: Specify the radionuclide, chemical form, label position, amount of material, and the specific activity. Submit stockroom requisition form with this document for purchase.

4. Work Areas: where work involving the radionuclide will be performed. Comment on equipment, facilities and other work currently performed in the same laboratory.

5. Storage Areas: (room no., refrigerator, hood, cabinet, etc.) and in what form and amounts the radioactive materials will be stored.

Form 5 ULM-RS 03

RADIOACTIVE MATERIALS PROCUREMENT AND USE – *Continued*

6. Duration of Experiment: An estimate of the time to complete the proposed experiment(s). Break out phases of work if this is an extended project.

7. Description of all and biological wastes from the project: Detail the type and amounts waste to be generated; Are any wastes considered extremely hazardous/toxic?

8. Specify Handling Procedures: Include the use of absorbent paper, gloves, shielding, and as necessary.

9. Radioisotope Tracer Use: Give a systematic procedural outline of flowchart that illustrates the various methods employed in the work. Describe preparation of solutions from the primary radioisotope material. State the activities or DPMs per tube for all in vitro reaction or binding studies. For animal studies, detail the number of animals and Doses to be administered and approach for collecting metabolites.

Form 6 ULM-RS 03

RADIOISOTOPE ANNUAL INVENTORY RECORD

An annual radioisotope inventory is required. An inventory list for update will be sent on September 1 and returned to the RSO on or before September 15.

Complete for ALL radioactive materials stored in the area.

Principal Investigator: _____ Year: _____

Laboratory/Room: _____ Date Submitted: _____

Isotope	Inventory No.	Activity (µCi)	Compound/ Sealed Source / Standard

Total Radioactivity On-Hand -mCi

^{3}H _____

^{14}C _____

^{125}I _____

Other Isotopes _____

_____

_____

Form 7 ULM-RS 03

_____ Inventory No.

_____ Radioisotope

RADIOISOTOPE RECEIPT AND USE

Principle Investigator: _____ Lab/ Room: _____

Compound: _____P.O. No.: _____

Supplier: _____Lot/Batch No.: _____

Condition of Package: _____

Wipe Test Results: _____Date Received by RSO: _____

Film Badge MUST ___/ NEED NOT ___ be worn when using this isotope.

Date/received by: _____ Activity upon receipt: _____

USAGE RECORD

Activity - µCi				**Volume - µl, ml**		
Date	Decayed to	Used	Remaining	Used	Remaining	Usage comments

Return this form to the EHS Office in Strauss Hall when the radioisotope is expended.

Form 8 ULM-RS 03

WIPE TEST SURVEY **for RADIOACTIVE MATERIAL CONTAMINATION / DECONTAMINATION**

Principle Investigator: _____ Year: _____

Laboratory/Room: _____ Fiscal Quarter: _____

Performed by: _____ Date: _____

Type of Survey: ___ Routine (at least weekly when using Radioactive Materials)
___ Non-Routine: Reason _____

Isotopes Used: _____ LS Counter Efficiency: _____

Gamma Counter Efficiency: _____

Wipe Area	CPM	DPM	DIAGRAM OF LABORATORY
1. BACKGROUND (blank)			
2. DOORKNOB			
3. FLOOR, DOOR , THRESHHOLD			
4. FLOOR, FRONT OF THRESHOLD			
5. FRONT LIP OF HOOD			
6. OUTSIDE WALLOF HOOD			
7. REFRIDGERATOR/ STORAGE INSIDE			
8. REFRIDGERATOR/ STORAE OUTSIDE			
9. SINK			
10. BENCHTOP			
11. BENCHTOP			
12. BENCHTOP			
13.			
14.			

Form 9A ULM-RS 03

DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA SANITARY SEWER **(SINK)**

Principle Investigator: _____ Year: _____

Laboratory / Room: _____Fiscal Quarter: _____

1. Radioactive material **MUST** be readily soluble or disposable in water. No toluene/xylene/dioxane based scintillation counting mediums shall be discarded into the sanitary sewer. Use one designated sink per lab.

2. Discarded radioactive material can **ONLY** be ^{14}C, ^{3}H, ^{125}I, and **MUST** be at concentrations of 0.05 microcuries (µCi) per gram (ml) or less. (0.05 µCi = 111,000 DPM) Consult RSO for sanitary sewer disposal restrictions for higher concentrations of other radioisotopes.

3. Record amounts of radioactive materials disposal to ± 0.01 microcurie.

4. Flush discarded material from the sink basin with a steady stream of COLD water for 2 minutes.

DATE	ISOTOPE	COMPOUND	No. OF µCi DISCARDED	INITIALS

Total µCi_____

Form 9B ULM-RS 03

DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA SOLVENT DILUTION

Principle Investigator: _____ Year: _____

Laboratory / Room: _____ Fiscal Quarter: _____

1. Discarded radioactive material can ONLY be 14C, 3H, 1251, and soluble or miscible in hydrocarbon solvents (e.g. benzene hexane, petroleum other, toluene, and xylene). Consult RSO for disposal of other waste sol vent mixtures of radioisotopes.

2. Pour xylene/toluene based scintillation vial fluids and solvents containing radioactive materials into the supplied polyethylene container with a screw top. Rinse high activity glassware with small volumes of solvent several times to remove residues of the radionuclide.

3. Record both TOTAL ACTIVITY (±0.0I microcurie) and TOTAL VOLUME (ml) of discarded material placed in the polyethylene container

4. Discard emptied glass/plastic vials in glass disposal box.

5. Contact RSO for pick up and disposal of accumulated radioactive solvent. Do not accumulate more than 15 liters contaminated waste solvent prior to pick up.

6. Empty scintillation vials into the polyethylene container on a regular basis. NEVER ACCUMULATE MORE THAN 500 20ml VIALS REQUIRING DISPOSAL.

Form 9C ULM-RS 03

DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA BIOHAZARDOUS WASTE STREAM

Principle Investigator: _____ Year: _____

Laboratory / Room: _____ Fiscal Quarter: _____

1. Our biohazardous waste contract presently does not provide for removal of radioactive materials. Thus, the amount of radioactivity MUST be such that the radiation emission from the bulk waste meets the definition of "not radioactive" essentially that of background counts. The radiation level in the bulk material must be less than 110,000 dpm/g (0.05 µCi/g) to meet the definition of "not radioactive".

2. The disposal material must meet the usual definitions for biohazardous waste, and collected in the according manner. See safety notebooks present in each lab, or the safety section of the School of Pharmacy "Intranet" site.

3. Record amounts of radioactive materials disposed to ± 0.1 µCi.

DATE	ISOTOPE	COMPOUND	NO. µCI DISCARDED	INITIALS
		Total µCi		

Form 9D ULM-RS 03

DISPOSAL RECORD OF RADIOACTIVE MATERIALS VIA SOLID WASTE STREAM

Principle Investigator: _____ Year: _____

Laboratory/Room: _____ Fiscal Quarter: _____

1. Any solid waste that includes normal solid material must be collected separately from the normal solid waste stream ("trash"). Such materials will contain only very low levels of radioactivity such as may be acquired by incidental contact (gloves, wipes, bench pads that have not absorbed a spill). It will be difficult to estimate levels of radioactivity in such materials and you need not use this form for them.

2. It may be possible, with written approval, to arrange for disposal of containers of such materials that contain low levels of radioactivity by verifying that the radiation emission from the bulk waste is such that the waste meets the definition of "not radioactive", essentially that of background counts. The radiation level in the bulk material must be less than 110,000 dpm/g (0.05 µCi/g) to meet the definition of "not radioactive". Submit written requests to the Chair of the School Hazardous Materials Committee, who will forward a copy of approvals to Radiation Safety Officer (RSO) and the pharmacy stockroom archives.

3. More heavily contaminated materials (usually resulting from spills) must be recorded on this form, with the amounts of radioactivity estimated to ± 0.1 µCi. Such materials must be collected separately from the routine solid waste described above (1.) and appropriately shielded. When removal becomes necessary, submit a written request to the ULM RSO, and a copy of this request to the Chair of the School of Pharmacy Hazardous Materials Committee. Please allow 6 to 8 weeks for removal of such materials, unless the amount of radioactivity is large enough to preclude the appropriate shielding and therefore necessitate immediate removal.

DATE	ISOTOPE	COMPOUND	No. OF µCi DISCARDED	INITIALS
____	_____	_____	_____	_____
____	_____	_____	_____	_____
____	_____	_____	_____	_____
____	_____	_____	_____	_____

TOTAL µCi _____ _____

Appendix II

REGULATORY GUIDE 8.13
(Draft was issued as DG-8014)

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

The Code of Federal Regulations in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," in Section 19.12, "Instructions to Workers," requires instruction in "the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed." The instructions must be "commensurate with potential radiological health protection problems present in the work place."

The Nuclear Regulatory Commission's (NRC's) regulations on radiation protection are specified in 10 CFR Part 20, "Standards for Protection Against Radiation"; and 10 CFR 20.1208,"Dose to an Embryo/Fetus," requires licensees to "ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv)." Section 20.1208 also requires licensees to "make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." A declared pregnant woman is defined in 10 CFR 20.1003 as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

This regulatory guide is intended to provide information to pregnant women, and other personnel, to help them make decisions regarding radiation exposure during pregnancy. This Regulatory Guide 8.13 supplements Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure" (Ref. 1), which contains a broad discussion of the risks from exposure to ionizing radiation.

Other sections of the NRC's regulations also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. In 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," licensees are required to monitor the occupational dose to a declared pregnant woman, using an individual monitoring device, if it is likely that the declared pregnant woman will receive, from external sources, a deep dose equivalent in excess of 0.1 rem (1 mSv). According to Paragraph (e) of 10 CFR 20.2106, "Records of Individual Monitoring Results," the licensee must maintain 8.13-8.13-2 records of dose to an embryo/fetus if monitoring was required, and the records of dose to the embryo/fetus must be kept with the records of dose to the declared pregnant woman. The declaration of pregnancy must be kept on file, but may be maintained separately from the dose records. The licensee must retain the required form or record until the Commission terminates each pertinent license requiring the record.

The information collections in this regulatory guide are covered by the requirements of 10 CFR Parts 19 or 20, which were approved by the Office of Management and Budget, approval numbers 3150-0044 and 3150-0014, respectively. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

As discussed in Regulatory Guide 8.29 (Ref. 1), exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the relationship between low dose exposure and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects and that the likelihood of these effects increase as the dose increases. At the occupational dose limit for the whole body of five rem (50 mSv) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following in utero exposure is uncertain in that both negative and positive studies have been reported. The data from these studies "are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult" (NCRP Report No. 116, Ref. 2). The NRC has reviewed the available scientific literature and has concluded that the 0.5 rem (5 mSv) limit specified in 10 CFR 20.1208 provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions specified in 10 CFR Part 20, the woman must declare her pregnancy in writing to the licensee. A form letter for declaring pregnancy is provided in this guide or the licensee may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy.

C. REGULATORY POSITION

1) Who Should Receive Instruction

Female workers who require training under 10 CFR 19.12 should be provided with the information contained in this guide. In addition to the information contained in Regulatory Guide 8.29 (Ref. 1), this information may be included as part of the training required under 10 CFR 19.12.

2) Providing Instruction

The occupational worker may be given a copy of this guide with its Appendix, an explanation of the 8.13-8.13-3 contents of the guide, and an opportunity to ask questions and request additional information. The information in this guide and Appendix should also be provided to any who may be affected by or who may have to take some response to such a declaration.

Classroom instruction may supplement the written information. If the licensee provides classroom instruction, the instructor should have some knowledge of the biological effects of radiation to be able to answer questions that may go beyond the information provided in this guide. Videotaped presentations may be used for classroom instruction. Regardless of whether the licensee provides classroom training, the licensee should give workers the opportunity to ask questions about information contained in this Regulatory Guide 8.13. The licensee may take credit for instruction that the worker has received within the past year at other licensed facilities or in other courses or training.

3) Licensee's Policy on Declared Pregnant Women

The instruction provided should describe the licensee's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's policies, if any, that may affect the declared woman's work situation after a written declaration of pregnancy with 10 CFR 20.1208.

The instruction should also identify whom to contact for additional information as well as identify who should receive the written declaration of pregnancy. The recipient the woman's declaration may be identified by name (e.g., John Smith), position (e.g., immediate supervisor, the radiation safety officer), or department (e.g., the personnel department).

4) Duration Limits for the Embryo/Fetus

The lower dose limit for the embryo/fetus should remain in effect until the woman withdraws the declaration in writing or the woman is no longer pregnant. If a declaration of pregnancy were withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time the declaration is withdrawn. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

5) Substantial Variations Above a Uniform Monthly Dose

According to 10 CFR 20.1208(b), "The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section," that is, 0.5 rem (5 mSv) to the embryo/fetus. The National Council on Radiation Protection and Measurements (NCRP) recommends a monthly equivalent dose limit of 0.05 rem (0.5 mSv) to the embryo/fetus once pregnancy is known (Ref.2). In view of the NCRP recommendation, any monthly dose of less than 0.1 rem (1 mSv) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee justification. However, a monthly dose greater than 0.1 rem (l mSv) Should be justified by the licensee.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this regulatory guide. Unless a licensee or an applicant proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods described in this guide will be used by the NRC staff in the evaluation of instructions to workers on the radiation exposure of pregnant women.

REFERENCES

1. USNRC, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Revision 1, February 1996.

2. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.

Radiation Dose to the Embryo/Fetus – Regulatory Guide

(Draft was issued as DG-8011)

A. INTRODUCTION

Section 20.1208 of 10 CFR Part 20, Radiation, "Standards for Protection Against Radiation," requires that each licensee ensure that the dose to an embryo/fetus during the entire pregnancy, from occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). Paragraph 20.1208(b) requires the licensee to make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared woman that would satisfy the 0.5 rem (5 mSv) limit. The dose to the embryo/fetus is to be the sum of (1) the deep-dose equivalent to the declared pregnant woman (10 CFR 20.l208(c) (l)) and (2) the dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman (10 CFR 20.1208(c)(2)).

This guide is being developed to provide guidance on calculating the radiation dose to the embryo/fetus. Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," provides instructions concerning the risks associated with prenatal radiation exposure.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 20, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR 20 have been cleared under OMB Clearance No. 3150-0014.

B. DISCUSSION

Calculating the radiation dose to the embryo/fetus from internally deposited radionuclides requires quantitative information about maternal radionuclide intake, placental transfer and kinetics, and resulting embryo/fetus radionuclide concentrations. Intakes of radioactive material occurring prior to the pregnancy may also be important if these materials remain in the pregnant woman during all or part of the gestation period. Transfer kinetics from the mother to the embryo/fetus are modeled as a function of stage of pregnancy, route of intake by the pregnant woman, and time after intake. The stage of gestation (or fetal development) is an important parameter in estimating radionuclide concentrations in the embryo/fetus. The geometry of the embryo/fetus (i.e., size and weight) affects the radionuclide dosimetry.

It is recognized that calculation of prenatal radiation doses from internally deposited radionuclides has many associated difficulties, including a lack of quantitative information about prenatal radionuclide concentrations and transfer across the placenta. The International Commission on Radiological Protection (ICRP) in Publication 56 (Ref. 1) states that, for most radionuclides, preliminary estimates from dosimetric and biokinetic models indicate that the dose to the embryo can be approximated by the dose to the uterus. The dose to the fetus is dependent upon the activity present in both fetal and maternal tissues. ICRP Publication 56 (Ref. 1) also states that, for most radiol1uclides, the dose to fetal tissue will be similar to or less than the dose to the corresponding maternal tissues.

The current methods available for assessing the radiation dose to the human embryo/fetus from internally deposited radioactive materials in the pregnant woman are subject to a number of uncertainties. Revision 1 to NUREG/CR-5631, "Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses--

Interim Recommendations"(Ref. 2), provides recommendations and methods for estimating the radiation doses to the embryo/fetus from internal radionuclides.

In Revision 1 to NUREG/CR-5631, a number of radionuclides were evaluated. To expedite efforts, the initial evaluation was directed to those radionuclides that were expected to be of greatest significance for prenatal exposure in the work environment. The radionuclides that were identified and included were 3H, 14C, 57Co, 58Co, 60Co, 89Sr, 90Sr, 106Ru, 125I, 131I, 132I, 133I,134I,135I, 134Cs, 137Cs, 233U, 234U, 235U, 238U, 238Pu, 239Pu, and 241Am. The methods of Revision 1 to NUREG/CR-5631 are considered interim as efforts continue to further develop the bases and calculation methods for estimating prenatal radiation doses. Revision 1 to NUREG/CR-5631 provides details of the data and bases for the dosimetric features that were used for the radionuclides listed above.

It is expected that the embryo/fetus dose assessment methods will evolve over the next several years as more research is conducted in this area. As additional research is conducted, better estimates of actual embryo/fetus doses resulting from the exposure of the declared pregnant woman will be possible. For internal doses, research that categorizes the degree of placental transfer, the resulting embryo/fetus/placenta concentrations, and the potential radiation exposures of the embryo/fetus from radionuclides in their more usual chemical forms should simplify assessment of the dose to the embryo/fetus based on the maternal exposure. The ICRP is considering the formulation of dose assessment methods specific for the embryo/fetus.

This regulatory guide provides acceptable methods that may be used in determining the dose to the embryo/fetus. For internal exposure, a simplified approach and a more detailed methodology are presented for conducting dose evaluations. The regulatory position specified in Section 1 provides guidance on the threshold criteria for use in determining when the dose to the embryo/fetus needs to be evaluated. The regulatory position specified in Section 2 presents a simplified approach for estimating the dose to the embryo/fetus from intakes by the declared pregnant woman. The regulatory position specified in Section 3 provides an alternative, more detailed methodology for a limited number of radionuclides, using the gestation-time dependent dosimetric data from Revision 1 to NUREG/CR-5631 (Ref. 2).

A graded approach for determining when to evaluate, with both a simple and more detailed dose assessment methodology, is provided. Both methods are acceptable for evaluating the dose to the embryo/fetus. It is recognized that some licensees will only need to demonstrate that the dose to the embryo/fetus is not likely to exceed the 0.05 rem (0.5 mSv) monitoring threshold of 10 CFR 20.1502, while other licensees may need to determine an embryo/fetus dose for demonstrating compliance with the dose limit of 10 CFR 20.1208 and the recordkeeping requirements of 10 CFR 20.2106e.

Appendix A provides information on and a table of dose equivalent factors for use in approximating the embryo/fetus dose from radionuclides in maternal blood. Appendix B is a table of blood uptake fractions for ingested activity. Appendix C contains tables of gestation-time dependent doses to the embryo/fetus following introduction of specified radionuclides and chemical forms into maternal blood. Examples of the use of dose assessment methods are provided in Appendix D.

The total radiation dose to the embryo/fetus is the sum of the deep-dose equivalent to the declared pregnant worker and the dose to the embryo/fetus from intakes of the declared pregnant worker. If multiple

dosimetric devices are used to measure the deep-dose equivalent to the declared pregnant worker, the results of monitoring that are most representative of the deep dose to the embryo/fetus may be used. The licensee need not use the deep dose to the maximally exposed portion of the whole body of the mother as the deep dose to the embryo/fetus. The licensee may employee temporary or permanent shielding to reduce the deep dose to the embryo/fetus. Alternatively, deep dose to the embryo/fetus may be limited by placing restrictions that are more stringent on the exposure of the declared pregnant woman than on other members of the occupational work force.

As specified in 10 CFRR 20.1208(a), the dose to the embryo/fetus from occupational exposure of the declared pregnant woman during the entire gestation period is not to exceed 0.5 rem (5 mSv). In addition, the licensee is required to make efforts to avoid substantial variation in the monthly exposure throughout the period. If the dose to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv) or is within 0.05 rem (0.5 mSv) of this dose by the time the woman declares the pregnancy to the licensee, the licensee is required to limit the additional dose to the embryo/fetus to 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

The tables in the appendices to this guide were prepared directly from the computer outputs, which led to the values generally being expresses to three significant figures. This indicates greater accuracy than is warranted by the dosimetry model, but the results are presented in this form to avoid round off errors results should be rounded to in calculations. In general, results should be rounded to the nearest thousandth of a rem.

C. REGULATORY POSITION

1) CRITERIA FOR DETERMINIG DOSE TO THE EMBRYO/FETUS

1.1 Monitoring

The dose equivalent to the embryo/fetus should be determined based on the monitoring of the declared pregnant woman as required by 10 CFR 20.1502. Specifically, 10 CFR 20. 1502(a)2) requires monitoring of a declared pregnant woman when the dose to the embryo/fetus is likely to exceed, in 1 year, a dose from external sources in excess of 10% of the limit of 10 CFR 20.1208 (i.e., 0.05 rem). According to 10 CFR 20.1502(b)(2), the licensee must monitor the occupational intakes of radioactive material for the declared pregnant woman if her intake is likely to exceed, in 1 year, a committed effective dose equivalent in excess of 0.05 rem 0.5 mSv). Based on this 0.05 rem (0.5 mSv) threshold, the dose to the embryo/fetus should be determined if the intake is likely to exceed 1% of ALI (stochastic) during the entire period of gestation.

These monitoring thresholds will ensure that any potentially significant exposures to the embryo/fetus are evaluated and, as appropriate, doses are determined. The conditions specified in 10 CFR 20.1502(a) and (b) are based on a 1-year period. Prior to declaration of pregnancy, the woman may not have been subject to monitoring based on conditions specified in 10 CFR 20.1502(a)(1) and 10 CFR 20.1502(b)(1). In this case, the licensee should estimate the exposure during the period monitoring was not provided, using any combination of surveys or other available data (for example, air monitoring, area monitoring, and bioassay).

The monitoring criteria contained in 10 CFR 20.1502 do not establish required levels of detection sensitivity. For some radionuclides, it may not be feasible to actually confirm by bioassay measurements an intake of 1% of their stochastic ALI. Workplace monitoring, occupancy factors, and access control should be considered as appropriate in evaluating potential exposures and monitoring requirements.

1.2 Evaluation of Dose to the Embryo/Fetus

The appropriate dose to be evaluated for the embryo/fetus is the dose equivalent for the duration of the pregnancy. An assessment of the 50-year committed dose is not appropriate. In addition, it is not appropriate to use effective dose equivalent or committed effective dose equivalent. (Note: the committed dose equivalent to the uterus may be applied to the embryo/fetus under certain conditions as a simplified approach as described in the regulatory position specified in Section 2.)

1.3 External Dose to the Embryo/Fetus

According to 10 CFR 20.1208(c) (1), the deep-dose equivalent to the declared pregnant woman will be taken as the external dose component to the embryo/fetus. The determination of external dose should consider all occupational exposures of the declared pregnant woman since the estimated date of conception. The deep-dose equivalent that should be assigned is that dose that would be most representative of the exposure of the embryo/fetus (i.e., in the mother's lower torso region). If multiple measurements have been made, assignment of the highest deep-dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose is also the most representative deep-dose equivalent for the region of the embryo/fetus.

1.4 Internal Dose to the Embryo/Fetus

The internal dose to the embryo/fetus should consider the exposure to the embryo/fetus from radionuclides in the declared pregnant woman and in the embryo/fetus. The dose to the embryo/fetus should include the contribution from any radionuclides in the declared pregnant woman (body burden) from occupational intakes occurring prior to conception. The intake for the declared pregnant woman should be determined using air sample data, bioassay data, or a combination of the two. Guidance on bioassay measurements used to quantify intake is being developed and has been issued for public comment as Draft Regulatory Guide DG-8009, "Interpretation of Bioassay Measurements." Specific guidance on workplace air sampling is in Revision 1 to Regulatory Guide 8.25, "Air Sampling in the Workplace."

1.5 Evaluating Continuous Exposure

For continuous exposure to radioactive material that may be inhaled or ingested, the cumulative intake should be quantified and the dose determined at least every 30 days. If significant variation in the exposure levels have occurred, the time interval for quantifying the intake should be reduced. Evaluations that are more frequent should be considered as the potential dose to the embryo/fetus approaches the limit.

1.6 Existing Maternal Body Burdens

Maternal body burdens resulting from internal occupational exposures prior to conception should be included in determining the embryo/fetus dose. The contribution to the embryo/fetus dose from a maternal burden at the time of conception should be evaluated if the maternal burden at pregnancy exceeds 1% of the radionuclides for the appropriate intake and class (for inhalation intakes). Stochastic ALI value for the appropriate mode of intake and class (for inhalation intakes). For multiple radionuclide burdens, the dose should evaluated if the sum of the quotients of each burden divided by its stochastic ALI exceeds 0.01. Only body burdens existing at the time of conception need to be considered in this threshold; radioactive material already eliminated from the body should not be included.

This threshold of 1% ALI provides a simplified approach when pre-existing body burdens should be evaluated. At this threshold, it is unlikely that any resultant dose to the embryo/fetus would be significant (i.e., greater than 10% rem (5 mSv) limit). As an alternative, the dose assessment methods presented in the regulatory position specified in Section 3 of this guide may be used for determining whether a pre-existing body burden represents a potentially significant dose (i.e., greater than 0.05 rem mSv)).

2) SIMPLIFIED METHOD FOR DETERMINING EMBRYO/FETUS DOSE FROM MATERNAL INTAKES

The determination of the dose to the embryo/fetus from the intake of radioactive material by the pregnant woman should be based on the best available scientific data. At present, the NRC staff considers Revision 1 to NUREG/CR-5631(Ref. 2) to provide such data. For most radionuclides, the dose to the embryo/fetus will be similar to or less than the dose to the maternal uterus (Ref. 1). However, the data in Revision 1 to NUREG/CR-5631 indicate that for some radionuclides the embryo/fetus may be significantly different, either greater than or less than the dose to the uterus.

Based on premises (uterus dose similar to fetal dose and data in Revision 1 to NUREG/CR-5631 (Ref. 2)), a set of dose factors has been developed for use in calculating an embryo/fetus dose. Except for those radionuclides addressed in Revision 1 to NUREG/CR-5631 (Ref. 2), the dose factors presented in Appendix A to this guide represent the committed dose equivalent to the uterus per introduction of unit activity into the first transfer compartment (i.e., blood) of the woman.

For the radionuclides in Revision 1 to NUREG/CR-5631, the dose factors in Appendix A represent the maximum dose equivalent to the embryo/fetus for the gestation period from the introduction of unit activity into the first transfer compartment of the woman at any time during the gestation period.

The dose limit for the embryo/fetus is expressed as a 9-month gestation dose equivalent. Particularly radionuclides with both long radiological half-lives and long-term biological retention, the committed dose equivalent to the uterus may be significantly different from a 9-month gestation dose equivalent to the embryo/fetus. Several radionuclides of this type have been evaluated in Revision 1 to NUREG/CR-5631 (Ref. 2), and data have been developed for calculating an embryo/fetus gestation dose instead of using the committed dose equivalent to the uterus.

For demonstrating compliance with the dose limits of 10 CFR 20.1208, the dose factors in Appendix A may be used for approximating the embryo/fetus dose equivalent for the entire gestation period.

The steps for determining the embryo/fetus dose, using the simplified method, are as follows:

2.1 Include all the intakes by the declared pregnant woman at any time during the gestation period in the calculation of the embryo/fetus dose.

2.2 For ingested radionuclides, determine the activity uptake by the first transfer compartment (blood) by multiplying the intake (1) by the appropriate uptake factor (f1) from Appendix B (adapted from Federal Guidance Report No. 11, Table 3 (Ref. 4)). The uptake factor, f1, is the fraction of an ingested compound of a radionuclide that is transferred into the first transfer compartment (i.e., blood uptake fraction).

2.3 For inhaled radionuclides, determining the fraction of initial intake that is transferred to the blood involves an evaluation of the deposition in the three compartments of the lung and the subsequent time-dependent transfer to the body fluids and to the GI tract. Unless it is known otherwise, it should be assumed that the transfer from the lung to body fluids and from lung to GI tract to body fluids follows the ICRP 30 (Ref. 3) modeling (which is the basis for this guide).

2.4 For simplicity and conservatism in the modeling, the total uptake into the blood from the maternal intake is assumed instantaneous. However, for radionuclides with lung clearance class of W (10- to 100-day half-life clearance) or Y (greater than 1OO-day half-life clearance), the actual translocation from the lung and uptake in the blood may occur over a period that exceeds the gestation period. Clearance from the lung may take up to several years. Not all of the initially deposited material is immediately available for uptake by the first transfer compartment (blood). However, an incremental transfer from the lung to the blood may be assessed based on the lung model as described in ICRP Publications 30 and 19 (Refs. 3 and 5). 2

Table 1, adapted from the data in Figure 5.2 of ICRP 30 (Ref. 3), may be used for determining the total transfer from the lung to the first transfer compartment (i.e., blood), where fl is the blood uptake fraction from Appendix B. 3 The lung clearance class (D, W, or Y) for a particular chemical form of a particular radionuclide may be obtained from Appendix B to 10 CFR 20.1001-20.2401.

Table 1

Transfer Fraction of Inhaled Activity to First Transfer Compartment

Class	Transfer Fraction (TF)
D	**0.46 + 0.15 f1**
W	**0.12 + 0.51 fl**
Y	**0.05 + 0.58 f1**

2.5 Based on the determination of the maternal intake, the dose to the embryo/fetus for the entire gestation period should be calculated using the following equations:

For ingestion intakes:

$DE = \sum Ii \times f\ 1,ix\ DFI$ (Equation 1)

For inhalation intakes:

$DE = \sum Ii \times TFi \times DF1$ (Equation 2)

Where:

DE = dose equivalent to the embryo/fetus for the entire gestation period from the acute intakes of all radionuclides during the gestation period (rem)

Ii = intake of radionuclide i by the declared pregnant woman at any time during the gestation period (µCi)

Dfi = dose factor for use in approximating the dose equivalent to the embryo/fetus for the entire gestation period from the introduction of unit activity (l µCi) into the maternal blood at any time during the gestation period, from tabular data presented in Appendix A to this guide (rem/µCi in maternal blood)

f1,I = the fraction of radionuclide i reaching the body fluids following ingestion (i.e., the fraction of ingested activity of radionuclide i that enters the blood), from data presented in Appendix B to this guide

TFi = transfer fraction of inhaled activity to the first transfer compartment (i.e., the fraction of inhaled activity of radionuclide i that enters the blood, see Table 1 of this guide)

2.6 For pre-existing body burdens, the total burden determined to exist at time of pregnancy should be assumed available for uptake in the blood of the woman. The dose should be assigned to the embryo/fetus as if the maternal blood uptake occurs within the first month of pregnancy. The embryo/fetus dose is calculated by multiplying the maternal burden of the radionuclide by its dose factor from Appendix A using the equation:

$$DE = \sum Ai \times DF1 \quad \text{(Equation 3)}$$

Where:

DE = dose equivalent to the embryo/fetus

Ai = maternal burden existing at time of pregnancy (μCi)

DFi = dose conversion factor (Appendix A)

This method provides a simplified and conservative approach for evaluating the significance of pre-existing conditions. If the embryo/fetus is likely to receive a dose in excess of 25% of the limit from pre-existing burdens (i.e., greater than 0.125 rem (1.25 mSv)), more detailed modeling should be considered. 4

2.7 Doses from multiple nuclides or multiple intakes should be evaluated on a frequency corresponding to the determination of the intake. Multiple dose determinations should be added to determine the total dose. Doses may need to be re-evaluated if better estimates of intakes are provided by follow-up bioassay measurements.

3) DETERMINING GESTATION-TIME DEPENDENT DOSE TO THE EMBRYO/FETUS USING REVISION 1 TO NUREG/CR-5631 METHODS

As an alternative to the simplified methods presented above, a gestation-time dependent dose to the embryo/fetus may be calculated for the radionuclides addressed in Revision 1 to NUREG/CR-5631 (Ref. 2). Revision 1 to NUREG/CR-5631 presents dosimetric methods for calculating the dose to the embryo/fetus following the instantaneous introduction of unit activity into the first transfer compartment (blood) of the pregnant woman at successive stages of gestation. These methods include the contribution to the embryo/fetus dose from the resultant body burdens of the declared pregnant woman and from activity in the embryo/fetus resulting from transfer across the placenta. Refer to Revision 1 to NUREG/CR-5631 (Ref. 2) for a detailed description of the modeling.

The methods and data of Revision 1 to NUREG/CR-5631 (Ref. 2) may be used for determining the dose to the embryo/fetus from maternal intakes at successive stages of gestation for the radionuclides 3H, 14C, 57Co, 58Co, 60Co, 89Sr, 90Sr, 106Ru, 125I, l31I, 132I, 133I, l34I, l35I, 134Cs, 137Cs, 233U, 234U, 235U, 238Pu, 239Pu, and 241Am.

The steps for determining the embryo/fetus dose using the Revision 1 to NUREG/CR-5631 (Ref. 2) methods are as follows:

3.1 The methods presented in the regulatory position in Sections 2.1 through 2.4 should be used for determining the uptake in the first transfer compartment (blood) of the declared pregnant woman.

3.2 Equations 1 and 2 of the regulatory position specified in Section 2.5 may be used for determining the embryo/fetus dose with following clarifications:

3.2.1 For Equations 1 and 2, in place of the dose factor parameter, DF, the dose values should be taken from Appendix C to this guide for the period representing the time of intake relative to stage of gestation. The data in Appendix C to this guide are for an absorbed dose (in rads) from the introduction of 1 µCi of the radionuclide into the first transfer compartment (blood) of the woman at beginning of the specified month of gestation. To convert from an absorbed dose (rad) to a dose equivalent (rem), data in Appendix C should be multiplied by the appropriate quality from Table 1004(b).1 of 10 CFR Part 20. For 3H, 14C, 57Co, 58Co, 60Co, 89Sr, 90Sr, 106Ru, 125I, 131I, 132I, 133I, 134I, 135I, 134Cs, a quality factor of 1 should be applied. For 233U, 234U, 235U, 238U, 238Pu, 239Pu, and 241 Am, a quality factor of 20 should be applied, recognizing that most of the embryo/fetus dose results from alpha decay.

For some radionuclides (e.g., 235U), a blood uptake at the beginning of the gestation period results in a negligible dose contribution to the embryo/fetus. These radionuclides are identified in the tables in Appendix C to this guide by an "N" entry in the row for the 0-day of gestation at radionuclide introduction (i.e., the first row of dose factor data). For an intake of these radionuclides within the first month of gestation, a time-weighted dose factor using the second month data (31-day row) should be used. The 31-day dose factor should be multiplied by the quotient of the days-to-date in the first

gestation month at time of intake divided by 30 days. For example, assuming a maternal intake of 14C resulting in a l-µCi blood uptake on the 20th day of the pregnancy, the embryo/fetus dose should be determined by multiplying the cumulated dose from an intake at day 31 (i.e., Table C3, Cumulated Dose column, 1.89E-04 rads) by the ratio of 20 days to 30 days (i.e., 20 divided by 30).

3.2.2 For using the tabular dose data in calculating the embryo/fetus dose, it may be assumed that all intakes occurring within any of the 30-day periods of gestation occur at the beginning of that period. 5 The cumulated dose column should be used in order to determine the total dose for the remainder of the gestation period.

3.2.3 3.2.3 For pre-existing body burdens from occupational exposure, the total burden determined to exist at time of pregnancy should be assumed available for uptake in the blood of the woman. The dose should be assigned to the embryo/fetus as if the maternal blood uptake occurs within month of pregnancy. The embryo/fetus dose is calculated by multiplying the maternal burden of the radionuclide by its dose factor (Equation 3). The dose factor to be used from the Appendix C tables is that factor corresponding to the cumulated dose for an O-day of gestation at radionuclide introduction (i.e., right-most column, first data entry). However, for those radionuclides with an "N" for this O-day entry, the entry for the second gestation month should be used (i.e., the right-most column, second data entry). Alternatively, time-dependent release kinetics may be used for calculating that fraction of the body burden that is translocated to the blood through the duration of the pregnancy. The time-dependent release

is described in ICRP Publications 30 and 54 (Refs. 3 and 6). This approach is complex, involving interlinking differential equations, and is considered outside the scope of a routine health physics program.

3.3 Doses from multiple nuclides and multiple intakes should be evaluated with a frequency corresponding to the intake (i.e., at least once every 30 days). Multiple dose determinations should be added to determine the total dose. Doses may need to be reevaluated if better estimates of intakes are provided by follow-up bioassay measurements.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant proposes an acceptable alternative method of complying with specified portions of the Commission's regulations, the methods described in this guide will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with 10 CFR 20.1001-20.2401.

Appendix A	Dose Equivalent Factors for Use in Approximating the Embryo/fetus Dose from Radionuclides in Maternal Blood
Appendix B	Blood Uptake Fractions for Ingested Activity
Appendix C	Radiation Absorbed Dose to the Embryo/fetus Following Introduction of Specified Radionuclides and Chemical Forms into the Maternal Transfer Compartment (Blood)
Appendix D	Examples of Embryo/Fetus Dose Calculations

REFERENCES

1. International Commission on Radiological Protection, "Age-Dependent Doses to Members of the Public from Intake of Radionuclides: Part 1," ICRP No. 56, Pergamon Press Inc., 1989.
2. M. R. Sikov et al., "Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses--Interim Recommendations," NUREG/CR-5631, Revision 1 (PNL-7445), U.S. Nuclear Regulatory Commission, March 1992.
3. International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP No. 30, Parts 1 through 4, including supplements, Annals of the ICRP, Volume 2, No. 3/4, Pergamon Press Inc., 1979.
4. K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Environmental Protection Agency, Federal Guidance Report No. 11 (EPA-520/1-88-020), September 1988.
5. International Commission on Radiological Protection, "The Metabolism of Compounds of Plutonium and Other Actinides," ICRP No. 19, Pergamon Press Inc., May 1972.
6. International Commission on Radiological Protection, "Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation," ICRP No. 54, Annals of the ICRP, Volume 19, No. 1-3, Pergamon Press Inc., 1988.

Footnotes

1. The committed dose equivalent factors for the uterus presented in Appendix A were calculated based on the modeling employed during the development of the ICRP 30 (Ref. 3) data. It is recognized that the metabolism of the pregnant woman may not be adequately represented by the standard metabolic model. However, partly because of the lack of more definitive data, this modeling has been used for determining the dose commitment factors for the uterus that may be used for evaluating compliance with the embryo/fetus dose limit.

2. As modeled in ICRP Publications 19 and 30, the clearance from the different lung Compartments is assumed to follow first-order kinetics. This approach is complex, involving interlinking differential equations, and is considered outside the scope of a routine operational health physics program.

3. The coefficients for the transfer fraction equations in Table 1 are applicable to particles with a 1-micrometer activity median aerodynamic diameter (AMAD). As a default, these equations may be used for all particle sizes. However, if the actual particle size distribution is known, transfer fractions for other AMAD particle sizes may be derived from data in Figure 5.2 of ICRP 30 (Ref. 3).

4. This approach for evaluating pre-existing body burdens does not specifically address time-dependent releases as could occur for certain radionuclides with both a long biological retention and radiological half-life. However, the assumption of blood uptake of the total burden in the first month of the gestation period provides a simple method with reasonable assurance that any actual dose to the embryo/fetus will not be significantly underestimated. More detailed evaluations may be needed for unusual circumstances in which a pre-existing body burden could present a significant source of exposure to the embryo/fetus. An evaluation of this nature should be conducted by individuals

knowledgeable in the area of internal dosimetry. Such a detailed evaluation could consider the element retention functions as presented in ICRP Publications 30 and 54 (Refs. 3 and 6). In addition, the modeling presented in Revision 1 to NUREG/CR-5631 (Ref. 2) could be applied. The details of this type of an evaluation are beyond the types of analyses that are considered routinely required and, as such, are outside the scope of this guide.

5. The correlation of intake to actual stage of gestation can only be roughly estimated. For this reason, it is believed that the correlation should be limited to the best estimate of the month of gestation.