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University of Louisiana, Monroe

Radiation Safety Manual
Revised August 2021

This Radiation Safety Manual is issued by:

The Radiation Safety Committee
And the University of Louisiana, Monroe

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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 5.7 0 G[0 0 1 216.05 235.25 Tm3 1 36 205.97 Tm0 g0 Gg0 G[ULM)-2( )-3(Po)-5(lic)3(e)8( )]TJETQq0.000 23

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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

$$>10eV\ photon^* \rightarrow H_2O \rightarrow H_2O^+ + e^-$$

Various types of ionizing radiation can have energies ranging from 10 eV (e.g. short wavelength UV) to 1×10^7 eV

Example of an Alpha Decay Series; Uranium to Radon

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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 <u>that alpha/beta particles are single ions that cause a</u>

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.

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.

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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

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).

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 consist

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

Exemption from Posting and

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.

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

SW

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/I00 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 pCipC

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 nalytical X

-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

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

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

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).

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 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.

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Approved by the Radiation Safety Officer for the RSC Date

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	[redacted] OF LABORATORY
1. BACKGROUND (blank)			
2.			

[redacted]

58an421 41.29 437.47 62.5 0.1O8 g 36.48 [(58297.29 437241 41mC g 2):9 12 Tf 1 0

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

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

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, b nBTd .74 ua0toccu i14.04 Tf1 0 0 1 179.18 677.74 Tm0.251 g0.251 G[ )]TJETQ* nB

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, , NCRP Report No. 116, Bethesda, MD, 1993.

Radiation Dose to the Embryo/Fetus ς Regulatory Guide

(Draft was issued as DG-8011)

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

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 assessmenta

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 5(t)-4(o)]TJETQ179.54 Tm0 g0 G[sto 5ETQqQq0.00eu 0 (p)-4(r)-6(u)-4(ivale)9(n)-4(t)5( )-3(t)5(o)-6(t)

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:

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

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., c* nBTnservativ

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.