SUMMARY: Employees who work in research laboratories need to be aware of the presence of chemicals or equipment that may present specific risks to their reproductive health. Both male and female employees, and students, can take prudent precautions to reduce these risks. Pregnant individuals, in particular, can remain productive and on-the-job for their full term. OSEH provides technical support regarding occupational risk, as well as workplace safety assessments, fetal radiation dose monitoring, and educational materials that focus on preventative and protective measures.

SCOPE: This Guideline applies to all employees and students at the University of Michigan who work in environments where hazardous materials are present. See California Proposition 65 for a list of reproductive toxins. This list may not be all-inclusive since many toxins still have not been tested for reproductive hazards.

REFERENCE REGULATIONS: Hazardous Work in Laboratories (MIOSHA Part 431)
Hazard Communication Standard (MIOSHA Part 430)
Standards For Protection Against Radiation (10 CFR 20.1003; 10 CFR 20.1208)
MDCIS Ionizing Radiation Rules (Rule 203 & 205)
NRC Regulatory Guide (8.13; 8.36)

DEFINITIONS: Authorized User of Radioactive Materials – an individual who has approval by the Radiation Policy Committee (RPC) to procure and use radioactive materials. Normally only members of the academic or research faculties will be approved as Authorized Users of radioactive materials.

The following definitions are from 10 CFR 20.1003:

Declared Pregnant Woman - a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.
Embryo/Fetus - the developing human organism from conception until the time of birth.

ALARA – acronym for “As Low As Reasonably Achievable”

Occupational Dose - the dose received by an individual in the course of employment in which the individual’s assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released in accordance with § 35.75, from voluntary participation in medical research programs, or as a member of the general public.

RESPONSIBILITY: Everyone working at the University of Michigan has the right to expect a safe and healthy work environment. They also have a responsibility to help assure a safe and healthy environment for themselves and others. These responsibilities are detailed in the University of Michigan Academic Laboratory and Research Safety Policy, issued jointly by the Department of Occupational Safety & Environmental Health (OSEH) and the Office of Research Ethics & Compliance (UMOR). Please click on the Policy link to view role specific responsibilities including but not limited to the following categories:

- All faculty, staff, other employees and students
- Graduate Student Research Assistants/Trainees
- Post-Doctoral Trainee/Fellow
- Laboratory Director (Faculty/Lab Manager/Supervisor
- Department Chair
- Facility Managers/Department Managers/Key Administrators/Chief Department Administrators
- Unit (School/College/Department) Safety Coordinators

Additional responsibilities specific to the implementation of this guideline follow.

Laboratory Director/Authorized User
Implement and document appropriate safety policies and procedures in accordance with the U-M Chemical Hygiene Plan.

Ensure that adequate facilities, ventilation, and equipment are provided for the safe use of Reproductive hazards.
Ensure employees are instructed on and follow proper procedures and utilize protective equipment provided during their work as detailed in written SOPs.

OSEH
Respond to reproductive health concerns of individual employees and students.

Provide a Reproductive Hazard Evaluation Form to be filled out by employees or students who may potentially be exposed to reproductive hazards in the workplace.

Evaluate workplace reproductive health hazards and recommend material/method options that may reduce or eliminate specific reproductive risks.

Provide instructional materials focusing on preventative and protective measures.

Provide a Pregnancy Declaration Form (RSS -105A) to women who may receive an occupational radiation dose and who are interested in voluntarily declaring their pregnancy to Radiation Safety Service (RSS).

Monitor dose to the fetus on a monthly basis and provide results to the Declared Pregnant Woman. RSS will assist the employee / student in ensuring the occupational radiation dose to the embryo/fetus does not exceed 500 millirem (mrem) per gestation period. If a dose greater than 55 millirem/month (mrem) is anticipated or received, an evaluation of procedures and laboratory practices will be conducted by RSS. Additional measures may be instituted based upon the evaluation to maintain ALARA conditions.

Employees / Students
Individuals are responsible for conducting activities in a safe manner. This includes utilizing all necessary engineering controls, safety equipment and procedures, and protective clothing while at work.

Individuals working with radioactive materials or radiation generating devices should be familiar with information supplied by the Nuclear Regulatory Commission (NRC), UM Radiation Policy Committee (RPC), Michigan Department of Licensing and Regulatory Affairs (LARA) and RSS regarding potential health effects from radiation to both the
employee/student and the embryo/fetus. RSS can assist employees and students seeking this information.

A declaration of pregnancy to RSS can be made using the standardized Pregnancy Declaration Form (RSS-105A) or a signed letter of declaration.

Employees and students are responsible for maintaining their occupationally related dose to the embryo/fetus in accordance with ALARA principles.

Employees and students should be aware of non-occupational exposures that may affect reproductive health such as alcohol, smoking, medications, non-prescription drugs, and household chemicals.

**PROCEDURES:**

I. **Laboratories Using Radioactive Materials or Radiation-Producing Devices**

Radiation Safety Service (RSS) may be contacted at any time during the pregnancy, preferably within the first trimester. Employees and students are informed of the Declared Pregnant Woman Policy during regularly scheduled RSS Orientation Courses. If a woman declares her pregnancy, she will be issued a dosimeter and receive reports of the results periodically. The reports summarize the dose to the fetus during the course of the woman’s pregnancy. A fetal monitor dosimeter will have a monthly wear period. The woman does not need to be employed by U-M to declare her pregnancy.

In addition, RSS may evaluate the workplace and procedures to assess anticipated occupational doses and make recommendations to reduce occupational doses in keeping with regulatory limits and ALARA if requested or determined necessary by RSS.

A. At any time during the pregnancy, the woman may revoke her declaration for any reason without explanation. A Pregnancy Declaration Revocation Form (RSS-105B) must be submitted to RSS to revoke the declaration.

B. Declaration ceases upon the end of pregnancy, termination of employment, or exposure to occupational radiation. Submission of Pregnancy Declaration Expiration Form (RSS-105C) can be sent to RSS.

C. RSS reserves the option to terminate a declaration:
   1. 60 days after estimated date of delivery, or
2. One year after the date of receipt of the declaration form at RSS offices.

II. Laboratories Using Chemicals That Present Potential Reproductive Hazards

Employees and students may contact OSEH Laboratory Safety to arrange a reproductive hazard assessment of the workplace. A **Reproductive Hazard Evaluation Form** will be provided to the individual and must be completed to supplement the OSEH risk assessment. After a comprehensive evaluation of the form by an OSEH representative a visit to the workplace may be scheduled.

Recommendations for control measures to reduce or eliminate any reproductive hazards and protect the health and safety of the individual will be provided by OSEH.

Upon request, information from the assessments can be made available to the supervisor and the individual’s personal physician. The personal physician is expected to counsel their patients on the implications of the workplace conditions.

**RELATED DOCUMENTS:**

- Pregnancy Declaration Form (RSS-105A)
- Pregnancy Declaration Revocation Form (RSS-105B)
- Pregnancy Declaration Expiration Form (RSS-105C)
- Reproductive Hazard Evaluation Form
- Reproductive Health at the University of Michigan: Know the Hazards

**TECHNICAL SUPPORT:**

All referenced guidelines, regulations, and other documents are available through OSEH (763-6973).