NIH Policy Manual

1341 - Working with Radioactive Materials or Radiation Producing Machinery

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Transmittal Notice

1. **Explanation of Material Transmitted:** This chapter updates the National Institutes of Health (NIH) policy and procedures governing working with radioactive materials or radiation producing machinery required by the NIH Radiation Safety Program. This chapter is being revised to meet the requirements that NIH Manual Chapters be revised or reissued every five years. Links have been updated, definitions of radiation safety terms have been added, and the responsibilities of the NIH Management, the NIH Radiation Safety Committee (RSC), the Division of Radiation Safety (DRS) in the Office of Research Services (ORS), and individuals working with ionizing radiation have been delineated.
2. **Filing Instructions:**

   Remove: NIH Policy Manual, Chapter 1341, dated 06/17/2013

   Insert: NIH Policy Manual, Chapter 1341, dated 10/1/2018

   PLEASE NOTE: For information on:

   - Content of this chapter, contact the issuing office listed above.
   - NIH Policy Manual, contact the Division of Management Support, OMA on 301-496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx.

A. Purpose

This chapter establishes the NIH policy and procedures for working with radioactive materials or radiation producing equipment in the intramural research program as required by the NIH Radiation Safety Program.

B. Scope

The policies and procedures of the NIH Radiation Safety Program are described at http://drs.ors.od.nih.gov and apply to the NIH intramural research program where radioactive materials or radiation producing machinery such as x-ray devices and cyclotrons or other particle accelerators are used in the workplace. The NIH Radiation Safety Program has been established in accordance with the requirements of the U.S. Nuclear Regulatory Commission (NRC), U.S. Department of Labor (DOL), U.S. Department of Transportation (DOT), U.S. Food and Drug Administration (FDA) and U.S. Environmental Protection Agency (EPA).

C. Policy and Procedures

The NIH policy mandates that all individuals (i.e.; authorized individual users, clinical users, and/or any other designated users) working with radioactive materials or radiation producing equipment, and others who potentially risk exposure to ionizing radiation and thus receive an occupational radiation dose while performing their jobs, be informed of the policies, procedures, and protective measures required by the NIH Radiation Safety Program. Radioactive materials can be open form (e.g.; P-32, I-125, F-18, etc.) or sealed sources, including Cs-137 and Co-60 radionuclide irradiators; while radiation producing equipment include x-ray producing machines (e.g. fluoroscopy units and x-ray irradiators). Specific requirements from the NRC and DRS exist for the use of sealed source irradiators; and irradiator custodians are assigned to oversee the use of each irradiator. The DRS Irradiator Security Manager grants approval for unescorted or escorted access to the irradiators and monitors compliance with relevant policies and regulations. There are also clinical and non-clinical contracts in the form of human subject research and radiation safety protocols between the DRS and the research community. Compliance with the NIH Radiation Safety Program is mandatory. Employees must be properly trained in protective measures for their safety, the safety of patients and members of the general public, and employees must be assigned radiation dosimeters if required under applicable regulations.

1. **Requirements for Individuals Age 18 and Over:**

   Before an individual (age 18 and above) begins working with radioactive materials or radiation-producing equipment at NIH, he/she is required to register and complete radiation safety training. Registration for this training can be found in the following website: https://drsportal.ors.od.nih.gov/pls/onlinecourse/training/start_registration.html.

2. **Requirements for Minors:**

   Separate requirements exist for minors (ages 16-17). See the following website for more information: https://drs.ors.od.nih.gov/training/Pages/minor.aspx

3. **Dosimeters:**

Anyone intending to work with radioactive materials or radiation producing equipment at NIH must complete and submit a radiation dosimeter evaluation form (http://drsportal.ors.od.nih.gov/pls/onlinecourse/training/dosimetry_form.html) to DRS prior to beginning the work. The DRS reviews the form, and based on the employee's proposed use of ionizing radiation, issues none, one, or more dosimeters on a prescribed frequency (e.g., weekly, monthly, bi-monthly, quarterly, etc.) as appropriate. The individual returns the used dosimeters to DRS; and the DRS sends them to a vendor who determines and reports the amount of exposure to ionizing radiation the dosimeters received. Then, the DRS assigns doses to the individual and enters them in the Radiation Safety Comprehensive Database (RSCD).The DRS investigates unusual doses and reports them to the NRC or DOL if required under applicable regulations. . When necessary, and in response to unusual doses, the DRS also takes appropriate measures to ensure the safety of employees, patients, and the public.

D. Responsibilities

1. Deputy Director for Intramural Research:

    a. Serves as the Institutional Official for interactions with the NRC
    b. Appoints the RSO for the intramural research program (with delegated authority from the NIH Director)
    c. Appoints a Chair for the RSC and a management representative for the RSC

2. NIH Radiation Safety Committee (RSC):

    a. Oversees the NIH Radiation Safety Program managed by the DRS, ORS
    b. Serves as one of the liaisons between the Radiation Safety Program and NIH Management, along with the DRS, ORS
    c. Meets at least quarterly
    d. Includes representatives of radiation workers (i.e.; physicians, researchers, Nuclear Medicine/PET staff, nurses, the RSO, and an NIH management representative

3. The DRS, ORS:

    a. Maintains the administrative/operational responsibility for the NIH Radiation Safety Program
    b. Maintains the license(s) issued to the NIH by the NRC
    c. Provides and documents radiation safety training to individuals and ancillary personnel who plan to work with sources of ionizing radiation

d. Provides comprehensive consultation and oversight to individuals using radioactive materials
e. Conducts environmental monitoring as needed
f. Issues dosimeter(s) as needed
g. Measures and evaluates potential internal exposures
h. Submits used dosimeter(s) to vendor for evaluation
i. Assigns dose(s) to individual and enters it in the RSCD
j. Reports assigned dose(s) to individual upon request
k. Investigates unusual doses and reports them to regulatory authority if required under applicable regulations
l. Receives, inspects, and delivers packages containing radioactive materials
m. Disposes of radioactive waste
n. Performs compliance inspections and contamination monitoring of areas where sources of ionizing radiation are used/stored
o. Maintains the historical record of radioactive material usage at NIH in the RSCD
p. Manages the Irradiator Security Program for NIH

4. An individual planning to work with a source of ionizing radiation:

a. Contacts DRS https://drs.ors.od.nih.gov/Pages/contact.aspx and completes the required training
b. Adheres to regulations and policies pertaining to use of ionizing radiation
c. Wears a dosimeter if required under applicable regulations.
d. Returns a dosimeter to DRS within five business days of receiving a new dosimeter
e. Monitors him/herself and his/her work area with the appropriate technique following work with open form radioactivity

E. Internal Controls

The RSC provides oversight of the Irradiator Security Program program, and serves as one of the liaisons between the program and NIH Management (along with DRS) by performing the following ongoing internal controls/assessment:

1. Frequency of Review (in years): Ongoing.
2. Method of Review: The DRS maintains oversight and ensures effective implementation and compliance with this policy through conducting inspections of laboratories in which radioactive materials are used; follows up on any items of non-compliance; tracks training data to ensure all individuals working with ionizing radiation have been trained; tracks doses received by radiation workers; and updates policies as needed in response to changes in requirements of the NRC, DOL, DOT, FDA, and the EPA. The DRS uses a comprehensive custom-designed database , the RSCD to demonstrate compliance with radiation safety requirements.

3. Review Reports: The RSC reviews a report of significant incidents and doses received by NIH radiation workers on a quarterly basis. Also, the DRS prepares and presents to the RSC a comprehensive report of DRS activities on an annual basis. Review reports will indicate that controls are in place and working well. Issues of special concern will be brought immediately to the attention of the Chair, RSC and/or the Director, ORS

F. References

1. NIH Policy Manual, Chapter 1743 *Keeping and Destroying Records*, available at: https://policymanual.nih.gov/1743
2. The U.S. Department of Transportation: https://www.phmsa.dot.gov/standards-rulemaking/hazmat/hazardous-materials-regulations
3. The Division of Radiation Safety: http://drs.ors.od.nih.gov/
4. DRS Research Safety Protocols: https://drs.ors.od.nih.gov/policies/protocols/Pages/protocols.aspx
5. Clinical Protocols: https://drs.ors.od.nih.gov/rsc/CPI/Pages/protocol_index.aspx
6. The U.S. Nuclear Regulatory Commission Regulations: www.nrc.gov/reading-rm/doc-collections/cfr/
7. The U.S. Department of Labor: www.osha.gov/SLTC/radiationionizing/
8. The U.S. Food and Drug Administration: www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/
9. The U.S. Environmental Protection Agency: www.epa.gov/radiation/

G. Glossary

1. **AU** – Authorized User
2. **DOL** – U.S. Department of Labor
3. **DOT** – U.S. Department of Transportation
4. **DRS** – Division of Radiation Services, ORS
5. **DU** – Designated User
6. **EPA** – U.S. Environmental Protection Agency
7. **FDA** – U.S. Food and Drug Administration
8. **IU** – Individual User
9. **NIH** – National Institutes of Health
10. **NRC** – U.S. Nuclear Regulatory Commision
11. **OMA** – Office of Management Assessment
12. **ORS** – Office of Research Services
13. **OSHA** – Occupational Safety and Health Administration, DOL
14. **RSC** – NIH Radiation Safety Committee
15. **RSCD** – Radiation Safety Comprehensive Database
16. **RSO** – NIH Radiation Safety Officer

H. Definitions

Common Radiation Safety Terminology

1. **Authorized User (AU):** an individual authorized by the RSC to order or purchase radioactive material and responsible for the safe and proper use and final disposition of the material. The AU must ensure that an IU under their supervision is properly trained and complying with all radiation safety rules and procedures.
2. **Designated User (DU):** an individual authorized to use an NIH sealed source irradiator under the supervision of an irradiator custodian. A DU may have either escorted or unescorted access to an irradiator(s).
3. **Dose:** a measure of the energy deposited in an individual by ionizing radiation per unit mass.
4. **Exposure:** the amount of ionizing radiation traveling through the air.
5. **Individual User (IU):** an individual authorized to work under the supervision of an AU. An IU is not permitted to order or purchase radioactive material.
6. **Irradiator:** a machine that exposes products to gamma radiation to kill radiosensitive cells and for other purposes.
7. **Irradiator Custodian:** an individual authorized to manage the use of NIH irradiators. Irradiator Custodians ensure training and supervision of DUs with access to their irradiator and ensure the irradiator is functioning correctly.
8. **Irradiator Security Manager:** an individual within DRS who oversees the NIH Irradiator Security Program and ensures compliance with the NIH Irradiator License and pertinent NRC regulations.
9. **Radiation Dosimeter:** a measuring device used to detect, measure and record exposure to ionizing radiation such as x-rays, gamma rays, and beta particles.
10. **Radiation Producing Device:** a device capable of producing ionizing radiation as governed by the Maryland Department of the Environment and the DOL, OSHA, except those devices with radioactive material as the only source of radiation. Devices utilizing radioactive material as the source of x-rays or radiation are governed under additional regulations of the NRC.
11. **Radiation Safety Protocol:** a written contract between authorized users of radioactive material and the DRS. The DRS research safety protocols (https://drs.ors.od.nih.gov/policies/protocols/Pages/protocols.aspx) are required for lab uses of certain quantities or types of radionuclides. Standard protocol requirement documents or Standard Operating Procedures (SOPs) exist for various radionuclides and radionuclide use applications.
12. **Radioactive Material:** a substance that contains unstable radionuclides that give off radiation as they decay.
13. **Radionuclide:** a radioactive atom or nucleus characterized by a specific number of protons and neutrons.