

FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS <i>Office of Regulatory Science</i>	Document Number: MAN-000065	Revision #: 03 Revised: 27 Jul 2022
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1. Radiation Safety

The purpose of this section is to ensure that everyone working in the laboratory environment is aware of the radiation sources which might be present in the laboratory. Common Radiation sources which might be present in the laboratory will be enumerated and in so doing, policies and procedures to ensure that any radiation exposures are kept as low as reasonably achievable will be discussed.

Laboratorians may be exposed to both ionizing (i.e., possessing enough energy to strip electrons from atoms) and non-ionizing radiations in the performance of their work. These radiations may be electromagnetic in nature (e.g., radiofrequency, optical, x-rays and gamma rays) or particulate (i.e., alpha and beta particles). The sources of the radiations may be radiation emitting electronic products or radioactive material. Many laboratory

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operations require the use radioactive material (e.g., Uranyl acetate as a microbiological stain) or radiation emitting electronic products (e.g., microwave digesters). The following section will provide information on the safe use of these products and additional training references.

This section pertains to all analysts, technicians, microbiologists, and engineers who work in a laboratory setting as well as their supervisors and managers. Radiation safety is everyone's responsibility.

Further information on radiation safety can be found on the ORA Safety SharePoint Site.

This section will first cover electronic products and provide guidance on their safe use; a similar pattern will be used in the discussion of the radioactive material. It should be noted that unlike radioactive material, electronic products such as x-rays or lasers do not pose a safety hazard when powered off.

For a detailed list of training requirements for materials or devices with radiation hazards, see *ORA Radiation Safety Manual (ORA.006)*.

1.1. Electronic Products

1.1.1. Microwave Digesters

Microwave Digesters use radiofrequency radiation to digest samples. They produce microwaves at a frequency of 2450 Megahertz. These units may resemble a typical microwave oven, however there is no federal performance standard for these units. The biological effects of microwave radiation are thermal in nature (i.e., erythema and cataractogenesis). To prevent exposure to microwaves, follow the user manual and ensure that the door gasket is clean and that the door is not loose prior to use. Interlocks should be checked in accordance with the user manual. Microwave leakage should be checked annually and should not exceed 5mW/cm². See *ORA Radiation Safety Manual (ORA.006)* for details.

1.1.2. LASERS

Lasers serve many purposes in the laboratory. They emit electromagnetic radiation ranging from far infrared region to the far ultraviolet region (1000 μm to 180 nm). A federal performance standard does exist for laser products and ANSI Standard Z136.1 address the safe use of lasers, which is the basis of ORA Safety Policy. Laser products are classified by the hazard they present. Class 1 laser products are inherently safe. Class 2 lasers emit visible light and depend on the eye's aversion reaction (~0.25 seconds) to restrict exposure.

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The maximum power for a Class 2 laser is 1 mW. Class 3 laser products have a maximum power output of 5 mW. Class 3B lasers have beams whose power ranges between 5 and 500 mW. Class 4 lasers have outputs more than 500 mW. When using Class 3B and Class 4 lasers the use of proper eyewear is mandatory. See *ORA Radiation Safety Manual (ORA.006)* for details.

It should be noted here that a Class 1 laser product may contain a Class 3B or 4 lasers. If an operation requires that the laser needs to be removed from its protective housing, proper signage and precautions must be taken. See *ORA Radiation Safety Manual (ORA.006)* for details.

The biological effects from laser exposure are dependent on the wavelength of the optical radiation emitted. The eye is the critical organ, skin can also be affected by the beam. In addition to beam hazards, collateral hazards also exist with the use of high-powered lasers. These include electrical hazards, collateral radiation hazards and laser generated air contaminants (LGAC).

Laser products in the laboratory commonly include:

- A. Laser cutters
- B. Laser ablation units
- C. Laser microscopes
- D. Raman mass spectrometers
- E. Positioning lasers

1.1.3. Analytical X-ray systems

Analytical X-ray systems include x-ray fluorescence units (XRF) and x-ray diffraction units (XRD). The radiation emitted by these devices is classified as ionizing. All users of these devices shall wear ring and whole-body dosimeters when working with the device. The ring badge should be worn on the dominant hand. Users of these systems should be familiar with the user manual and must check interlocks regularly as described in the manual. XRF and XRD units must be tested for leakage at regular intervals, the user manual describes the frequency at which these units must be monitored. Leakage radiation should be no greater than 0.25 mRem/hr at 5 cm from any accessible surface of the analytical x-ray unit. See *ORA Radiation Safety Manual (ORA.006)* for details.

1.1.4. Scanning Electron Microscopes

Scanning Electron Microscopes can produce x-rays and should be monitored on a regular basis – yearly and after maintenance. Additionally, the user should be familiar with the user manual and perform all checks and

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maintenance in accordance with the manual. Stray radiation from the electron microscope should not exceed 0.5 mRem/hr at 5 cm from any accessible surface of the unit. See *ORA Radiation Safety Manual (ORA.006)* for details.

Note: analytical x-ray systems and electron microscopes produce low energy x-rays and special detectors are required to survey the units. The individual performing the surveys must be a qualified expert.

1.2. Radioactive Material

Safety regulations pertaining to radioactive material at ORA fall under distinct Nuclear Regulatory Commission (NRC) or Agreement State Licensure types. Each licensure type has unique regulations that specify safety procedures and possession requirements. Therefore, it is crucial for facilities to have an accurate inventory of radioactive material which includes licensure category. For more information, see *ORA Radiation Safety Manual (ORA.006)*.

Facilities may possess radioactive material under one of the following NRC licensure types: 1) NRC Specific License, 2) NRC General License, 3) Exempt Distribution License. Typically, ORA facilities possess radioactive material that fall under General or Exempt Distributed Licenses.

1.2.1. Specifically Licensed Radioactive Material

ORA holds an NRC Broad Scope Type A License that allows the Winchester Engineering and Analytical Center (WEAC) to use loose forms of alpha, beta, and gamma emitters. All ORA locations specifically listed under this license must follow all safety instructions stated in the license (e.g., authorized use, training, disposal). For requests to be added to the license, please contact ORA's Health Physicist whose contact information is available on the ORA Safety SharePoint Site.

In addition to the radioactive material authorized for use at WEAC, ORA's NRC License authorizes the use of tritium labeled Saxitoxin at the following laboratories:

- A. ORA Northeast Laboratory
- B. ORA Pacific Northwest Laboratory

For details on the Tritium in Saxitoxin Safety Procedures and training requirements see *Radiation Safety Manual – Saxitoxin (SOP-000350)*

1.2.2. Generally Licensed Radioactive Material

NRC Generally Licensed radioactive material typically includes radioactive material contained in a sealed source within a shielded device or capsule. These devices are designed with inherent radiation safety features, so they

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can be used by persons with limited or no radiation training or experience and are typically found in the following laboratory instruments or supplies:

- A. Electron Capture Detectors (ECD) in Gas Chromatographs (GC) containing Ni-63
- B. Ion Mobility Spectrometers (IMS) containing Ni-63
- C. Liquid Scintillation Counters containing a built-in source (i.e., Co-60, Cs-137, Eu-152)
- D. X-ray fluorescence units (XRF) containing a gamma emitter (i.e., Cd-109)
- E. Static eliminators containing Po-210
- F. In-vitro laboratory kits containing H-3 or C-14.
- G. Small quantities of Thorium or Uranium (see [10 CFR 40.22](#)) greater than 0.05% by weight but less than 1.5 kg.
- H. Radium in quantities less than 1 microCi (see [10 CFR 31.12](#))

End-users automatically become General Licensees when they purchase these instruments and are required to comply with NRC Regulations (See 10 CFR 31) regarding the registration, leak testing, transfer, reporting, and disposal of these Radioactive materials. In addition to NRC regulations, ORA radiation safety policies that include procuring, utilizing, labeling, storing, surveying, tracking, disposing as well as training and dosimetry requirements must be followed by lab personnel. See *ORA Radiation Safety Manual (ORA.006)* for details.

1.2.3. Exempt Distributed Licensed Radioactive Material

Some manufacturers hold an NRC Exempt Distribution License and produce radioactive materials that are exempted from licensing requirements. The NRC deems that using these products does not constitute an unreasonable risk to public health and safety and the environment. Radiation safety features are built into the sealed source or device or the amount of radioactive material that can initially be distributed in such a device is restricted. Typical Exempt Distribution radioactive materials in the laboratory include:

- A. Radioactive Check sources containing a gamma emitter (i.e., Cs-137)
- B. Liquid scintillation calibration and quality standards (i.e., H-3 and C-14)
- C. Some types of Ion Mobility Spectrometers containing Ni-63.
- D. Very small quantities of loose radioactive material

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Although, there are no formal regulatory requirements for exempt-distributed material, ORA radiation safety policies that include procuring, utilizing, labeling, storing, surveying, tracking, disposing as well as training and dosimetry requirements must be followed by lab personnel. See *ORA Radiation Safety Manual (ORA.006)* for details.

2. Radionuclides in Foods Program

2.1. Procedures in the Radionuclides in Foods Program

This section is to inform analysts of the various procedures in the Radionuclides in Foods Program. Procedures are conducted safely in accordance with the *WEAC Radiation Safety Manual (WEAC-LAB-RS.002)*. The food program may include, but is not limited to, the following training assignments:

A. Gamma Analysis

1. "Determination of Gamma-Emitting Radionuclides in Foods by High-Purity Germanium Spectrometry" (WEAC-RN-Method.3.0)
2. "Determination of γ -ray Emitting Radionuclides in Food Matrices Using Cerium Bromide γ -ray Spectrometry" (WEAC-AB-TM.005)
3. "Determination of Food-Specific Efficiency Calibrations for Gamma-Emitting Radionuclides in High Purity Germanium Spectrometry" (WEAC-AB-TM.003)

B. Sr-90 Analysis

1. "Determination of Strontium-90 in Foods by Internal Gas-Flow Proportional Counting" (WEAC-RN-Method.2.0)
2. "Analysis of Strontium-90 in Food by Liquid Scintillation Counting" (SOP-000450)
3. "Generation of Yttrium-90 Efficiency Attenuation Curve Using Sr Resin Extraction Chromatography" (WEAC-AB-TM.002)

C. Tritium Analysis

1. "Determination of Tritium in Foods" (WEAC-RN-Method.8.0)

D. Gross Alpha/Beta Analysis

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1. Analysis of 241Am, 238, 239, 240Pu, and 90Sr in Foods by Solid-Phase Extraction Liquid Scintillation Counting (WEAC-RN-Method.7.0)

E. Other Analytical Methods

1. "Analysis of Polonium-210 in Food Products by Isotope-Dilution Alpha Spectrometry" (WEAC-RN-Method.4.0)
2. "Analysis of Americium-241 in Food Products by Isotope-Dilution Alpha Spectrometry" (WEAC.RN.Method.5.0)
3. "Analysis of Plutonium-238 and-(239+240) in Food Products by Isotope-Dilution Alpha Spectrometry" (WEAC-RN-Method.6.0)

2.2. Training

Analysts must be trained and authorized to perform methods on WEAC's scope of accreditation and additional analyses as described in WEAC-QMS.5.2 and in accordance with the *WEAC Radiation Safety Manual (WEAC-LB-RS.002)*

Additionally, analysts performing in house calibrations must also be trained and authorized to perform the calibration procedures. Job specific training for individual analyses can be found in the references above for the specific work.

3. Radiation Detection Instrumentation

3.1. Radionuclide Laboratory Equipment

This section will familiarize the trainee with the radionuclide laboratory equipment. The equipment may include, but not limited to, the following instrumentation:

A. Gamma Detection

1. "The Canberra APEX Operated High-Purity Germanium Gamma-Ray Spectrometer" (WEAC-AB-RN.12.0)

B. Alpha/Beta Detection

1. "Gas-Flow Low-Level Alpha/Beta Proportional Counter" (WEAC-AB-RN.019)
2. "PerkinElmer Quantulus GCT 6220 Liquid Scintillation Counter" (SOP-000281)
3. "PerkinElmer Quantulus 1220 Liquid Scintillation Counter" (WEAC-AB-RN.15.0)

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4. "Integrated Alpha Spectrometric System" (WEAC-AB-RN.16.0)

C. Isotopic Determination

1. "Agilent 7700x Quadrupole Inductively Coupled Plasma Mass" (WEAC-AB-RN.018)

3.2. Training

Analysts must be trained and authorized to perform methods on WEAC's scope of accreditation and additional analyses as described in WEAC-QMS.5.2 and in accordance with the *WEAC Radiation Safety Manual (WEAC-LB-RS.002)*.

Additionally, analysts performing in house calibrations must also be trained and authorized to perform the calibration procedures. Job specific training for individual analyses can be found in the references above for the specific work.

4. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	02/06/2012	LMEB	LMEB
1.3	R	02/14/2013	LMEB	LMEB
02	R	06/30/2020	LMEB	LMEB
03	R	SEE QMIS	ELON MALKIN, HEALTH PHYSICIST, SRMS KATHRYN EMANUELE, KELLY GARNICK, & ANTHONY WETHERBY (CHEMISTS, OMPTSLO/WEAC/AB)	LMEB

* - D: Draft, I: Initial, R: Revision

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5. Change History

Revision #	Change
1.2	Table of Contents – deleted Quality Assurance/Quality Control; added Document History Section 12.1 Introduction – revised Section 12.2 C. – Questions 7. and 9. revised; added 10. and 11. Section 12.2 D. – References 1. and 2. updated; added WEAC Radiation Safety Manual SOP Section 12.3 B. – Bullets 1, 2., and 5. revised; added ICPMS Section 12.3 C. – deleted 2. Section 12.3 D. – updated 1. and 2.; added WEAC Radiation Safety Manual SOP Section 12.4 A. and B. – revised Section 12.4 C. - deleted 2. and 5. Section 12.4 D. – updated 9. Section 12.5 A. and B. – revised Section 12.5 C. – updated 9. Section 12.6 – deleted Section 12.7 Answer Key (now 12.6) – added 10. and 11. to 12.2; deleted 2. from 12.3; deleted 2. and 5. from 12.4; deleted 12.6
1.3	Header – Division of Field Science changed to Office of Regulatory Science
02	Section 1: expanded to include different categories of radiation producing devices and radioactive materials
03	Removed question and answer sections. Replaced with training and safety references.

6. Attachments

None