

<b>Unit:</b> Environmental Health and Safety	<b>SOP #:</b>
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## 1. Purpose and Scope

The purpose of this document is to describe the Medical Physics and Radiation Safety program at Boston University (BU) and the Boston Medical Center (BMC), and to define the interactions, roles, and responsibilities associated with the management of that program.

The Medical Physics and Radiation Safety program at BU and BMC includes the personnel, policies, and activities which ensure compliance, support exceptional patient care, and continuously improve the quality of services provided by BU/BMC relating to the use of radioactive materials. Medical Physics has the core responsibility of ensuring the safe and proper functioning of diagnostic imaging equipment with specific regard to radiation safety and image quality; Radiation Safety has the core responsibilities of establishing and maintaining programs for the use of clinical and research radiation sources, and ensuring compliance with all applicable federal, state, and local regulations. Together these two groups comprise the Medical Physics and Radiation Safety Division of Environmental Health and Safety (EHS).

## 2. References

The Medical Physics and Radiation Safety program is responsible for ensuring BU and BMC compliance with a number of regulations, standards, and best practices, including but not limited to those listed below.

### 2.1. Regulations

#### 2.1.1. Federal Regulations

- Code of Federal Regulations Title 21
- 21 CFR Part 1020 Performance Standard for Radiation Emitting Products
  - 1020.30 Diagnostic x-ray systems and their major components
  - 1020.31 Radiographic equipment
  - 1030.32 Fluoroscopic equipment
  - 1030.33 Computed tomography (CT) equipment
  - 1030.40 Cabinet x-ray system
- Food and Drug Administration
  - 21 CFR Part 900 – Mammography (Mammography Quality Standards Act Regulations)
- US Department of Transportation (DOT)

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- 49 CFR 170–179
- Nuclear Regulatory Commission (NRC)
  - 10 CFR Part 20 – Standards for Protection Against Radiation
  - 10 CFR Part 19 – Notices, Instructions, and Reports to Workers: Inspection and Investigations
  - 10 CFR Part 35 – Medical Use of Byproduct Material

#### 2.1.2. State Regulations

Radiation Control Program, Massachusetts Department of Public Health (MA DPH RCP):

- 105 CMR 121.000: Laser System
- 105 CMR 122.000: RF and Cellular Phone Tower
- 105 CMR 120.001: General Provisions
- 105 CMR 120.016: Enforcement
- 105 CMR 120.020: Registration of Radiation Machine Facilities and Services
- 105 CMR 120.100: Licensing of Radioactive Material
- 105 CMR 120.200: Standards for Protection Against Radiation (PDF)
- 105 CMR 120.300: Radiation Safety Requirements for Industrial Radiographic Operations (PDF)
- 105 CMR 120.400: X-Rays in the Healing Arts (PDF)
- 105 CMR 120.430: Therapeutic Radiation Machines (PDF)
- 105 CMR 120.500: Use of Radionuclides in the Healing Arts (PDF)
- 105 CMR 120.600: Radiation Safety Requirements for Analytical X-Ray Equipment (PDF)
- 105 CMR 120.620: Licensing and Radiation Safety Requirements for Irradiators (PDF)
- 105 CMR 120.700: Radiation Safety Requirements for Particle Accelerators (PDF)
- 105 CMR 120.750-1: Notice to Employees (PDF)
- 105 CMR 120.750: Notices, Instructions, and Reports to Workers; Inspections (PDF)
- 105 CMR 120.770: Transportation of Radioactive Material (PDF)
- 105 CMR 120.800: Licensing and Operational Requirements for Low-Level Radioactive Waste Facilities (PDF)
- 105 CMR 120.890: Low-Level Radioactive Waste Minimization Regulations (PDF) | RTF

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- Low-Level Radioactive Waste Regulations Table of Contents (PDF) | RTF
- 345 CMR 1.00: Low-Level Radioactive Waste Management Plan (PDF) | RTF
- 345 CMR 1.13: Maximum Average Concentrations in High Volume, Low Activity Waste (PDF) | RTF
- 345 CMR 2.00: Low Level Radioactive Waste Reserved for Future Use (PDF)
- 345 CMR 3.00: The Selection of Operators (PDF)
- 345 CMR 4.00: Low Level Radioactive Waste Management Fund (PDF)
- 105 CMR 127.000: Mammography Facilities Licensing (PDF)

#### 2.1.3. City Regulations

- City Of Boston Fire Prevention Code Section 20.08: Radioactive Materials

## 2.2. Other SOPs

2.2.1. American College of Radiology (designated by the Centers for Medicare & Medicaid Services as an accreditation body for the following imaging modalities):

- Mammography
- Computed Tomography
- Magnetic Resonance Imaging

2.2.2. Other accrediting bodies as required

## 3. Definitions

None.

## 4. Roles and Responsibilities

The Medical Physics and Radiation Safety Division maintains close working relations with the Radiation Safety Committee, Institutional Review Board, Physician Credentialing Committee, Institutional Animal Care and Use Committee, Laboratory Safety Committee, and clinical and academic departments which use radiation-emitting devices. Lasers, radiation-generating devices, and radioisotopes fall under the purview of the Radiation Safety Committee.

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Medical Physics is responsible for:

- Ensuring the safe and proper functioning of diagnostic imaging equipment, with specific regard to image quality and radiation safety, including:
  - Computed tomography (CT)
  - Magnetic resonance imaging (MRI)
  - Radiography, fluoroscopy, and dental x-ray
  - Ultrasound
  - Mammography
  - Gamma cameras
  - Positron emission tomography (PET)
- Assisting in the implementation of as low as reasonably achievable (ALARA) exposure levels to patients, staff, and the public. Diagnostic imaging equipment includes, but is not limited to, all radiography, fluoroscopy, mammography, and dental x-ray machines, computed tomography, positron emission tomography, and magnetic resonance imaging scanners, ultrasound imaging devices, and nuclear medicine gamma cameras;
- Assisting in the improvement of diagnostic image quality as needed;
- Assisting the institution in the purchase of new diagnostic imaging equipment;
- Performing x-ray equipment testing of the x-ray imaging equipment which includes radiography, fluoroscopy, interventional, computed tomography, mammography, and dental x-ray systems, as well as CR readers, film processors, and protective apparel such as lead aprons, gloves, and shields (performance standards are based upon federal and state regulations, as well as standards recommended by professional organizations);
- Evaluating radiation safety and image quality performance of each imaging system. Testing is carried out:
  - At least annually for each x-ray unit (routine quality control)
  - Whenever new equipment is installed or existing equipment relocated
  - After repairs or adjustments which significantly affect image quality or radiation safety
  - When requested by hospital staff
- Evaluating radiation dose monitoring
  - For each x-ray unit, typical radiographic and/or fluoroscopic patient skin entrance exposures and technique factors are posted near the control panel based on x-ray tube output measurements carried out for that unit. These are reviewed annually by Medical Physics and

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compared with similar units within the institution as well as with published reference values or standards. For high dose fluoroscopically guided interventional procedures, skin entrance radiation doses are monitored for each individual patient. For cases where the peak skin entrance dose exceeds 1Gy (100 rad), the case is referred to the hospital Radiation Safety Committee for review and when necessary, further patient follow-up; and

- Providing training and in-service lectures to hospital staff, and making available the professional expertise of Medical Physics staff. Medical Physics personnel are available for in-service lectures and/or hands-on “labs” on subjects relating to radiation safety, image quality, and/or technology issues for diagnostic imaging equipment. These are offered either upon request or on as-needed basis. The Medical Physics Fluoroscopy Radiation Safety Training program for physicians who operate fluoroscopy equipment at BMC is a requirement to obtain fluoro privileges at the hospital and to meet Massachusetts DPH regulations.

Radiation Safety is responsible for:

- Ensuring that all clinical and research uses of radioactive materials and ionizing and non-ionizing radiation-generating devices throughout BU/BMC are safe for workers, patients, the general public, and the environment, and are in compliance with all applicable regulations (these responsibilities are carried out by implementing a program for authorizing and controlling the purchase, use, and disposal of these materials and devices; and by providing relevant faculty and staff with guidance on how these materials and devices are to be managed);
- Conducting the Radiation Safety Program, which contains multiple components implemented across numerous functioning areas of the campus;
- Acting as subject matter experts for individuals who work with, or around, radioactive materials and sources of radiation;
- Performing risk assessments of all proposed activities involving radioactive materials and radiation, in order to ensure that such activities are performed in accordance with the ALARA (As Low As Reasonably Achievable) philosophy. It is a primary objective of the Radiation Safety to ensure that radiation exposures to workers, patients, and the public, as well as any releases of radioactivity to the environment, are maintained below regulatory limits and that efforts are made to further reduce any such potential exposures and releases;

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- Maintaining occupational exposure records for all employees who require monitoring to assure compliance with ALARA standards and all applicable laws;
- Ensuring the proper posting of information and protocols, monitoring of warning signs, and procedural enforcements in order to mitigate any risk to employees and the general public arising from working with or being exposed to radiation;
- Supervising all radiological waste disposals (decay in storage, release into sanitary sewerage, etc.);
- Controlling radioactive material through comprehensive ordering, receiving, delivery, and inventory of all incoming and outgoing RAM shipments;
- Maintaining an accurate inventory of radioactive materials at BU/BMC;
- Providing comprehensive oversight of all activities involving work with and/or the use of radioactive materials;
- Issuing, in consultation with the Radiation Safety Committee and other management, internal notices of violations and recommending corrective actions, and also responding to notices of violations issued by government agencies;
- Performs comprehensive inspection of all areas where radioactive material is used or stored according to license condition;
- Calibrating all radiation-detection and quantifying and qualifying instruments, in accordance with the appropriate regulations;
- Maintaining inventory and performing leak tests for all sealed sources on both campuses and clinical settings;
- Maintaining records of its activities in accordance with regulatory and institutional record retention policies;
- Overseeing all work and activities involving the use of radioisotopes;
- Overseeing all work and activities involving the use of lasers throughout BU/BMC;
- Overseeing all work and activities involving the use of analytical x-ray equipment;
- Overseeing all work and activities involving the use of radioisotopes and radiation safety practices.
- Conducting training sessions for various groups, as specified by appropriate regulations in addition to training sessions for clinicians, faculty members, students, and other groups. .

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- Maintaining and monitoring license conditions, filing amendments, license renewals and working closely with regulatory agencies to ensure uninterrupted radiological permitting process;
- Providing 24-hour coverage of guidance and emergency responses to situations involving radioactive materials;
- Maintaining and providing access to research irradiators, and providing guidance as needed to ensure compliance with IACUC;
- Providing technical guidance support during clinical treatments and procedures;
- Performing direct and indirect internal bioassay measurements and
- Overseeing the institution's pregnancy policy for radiation workers.

## 5. Special Requirements

### 5.1. Training

All personnel employed by the Medical Physics and Radiation Safety program must be approved by the Chief Medical Physicist and/or Chief Health Physicist and Radiation Safety Officer(RSO) prior to independently performing tasks associated with the required work. Task competency procedures are in place for all aspects of the program.

### 5.2. Monitoring Requirements

The program is subject to an annual internal audit and to external audits by the Massachusetts Department of Public Health and the United States Food and Drug Administration.

### 5.3. Personnel Protective Equipment (PPE)

Depending on the risk assessment, appropriate PPE, such as protective lead aprons, or other safety measures including area shielding, syringe shields, and shielded containers may be issued.

### 5.4. Medical Surveillance

Based on risk assessments, periodic bioassays (e.g., thyroid monitoring, urine analysis) or other surveillance may be required.

## 6. Other Prerequisites

None.

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## 7. Applicable Locations

The jurisdiction of Medical Physics and Radiation Safety Division activities covers all BU/BMC locations, and is specified in the broad scope license 44-0062, Boston Medical Center documents, and other appropriate documents.

## 8. Procedures and Instructions

In general, the Medical Physics and Radiation Safety program provides guidance, oversight, and training to help physicians, medical professionals, and researchers using radioactive materials and equipment.

The Radiation Safety program can only be administered through cooperation between Radiation Safety and the various other departments at BU/BMC which work with radioactive materials.

Procedures for specific programs are described in detail in the BU Environmental Health and Safety Policy Manual.

## 9. Forms

Forms and signage exist for a variety of Medical Physics and Radiation Safety processes. The attached Medical Physics and Radiation Safety functional chart further illustrates the disciplines within the division.

Forms also exist for radiation processes including inspections, equipment testing and maintenance, and use of Dosimetry badges.

## 10. Records Management

Each aspect of the program described above is explained in more detail in the appropriate policies and procedures, which are subject to continued review and to revision as appropriate. The Medical Physics and Radiation Safety program maintains printed and/or electronic records of its activities in accordance with regulatory and institutional record retention policies.

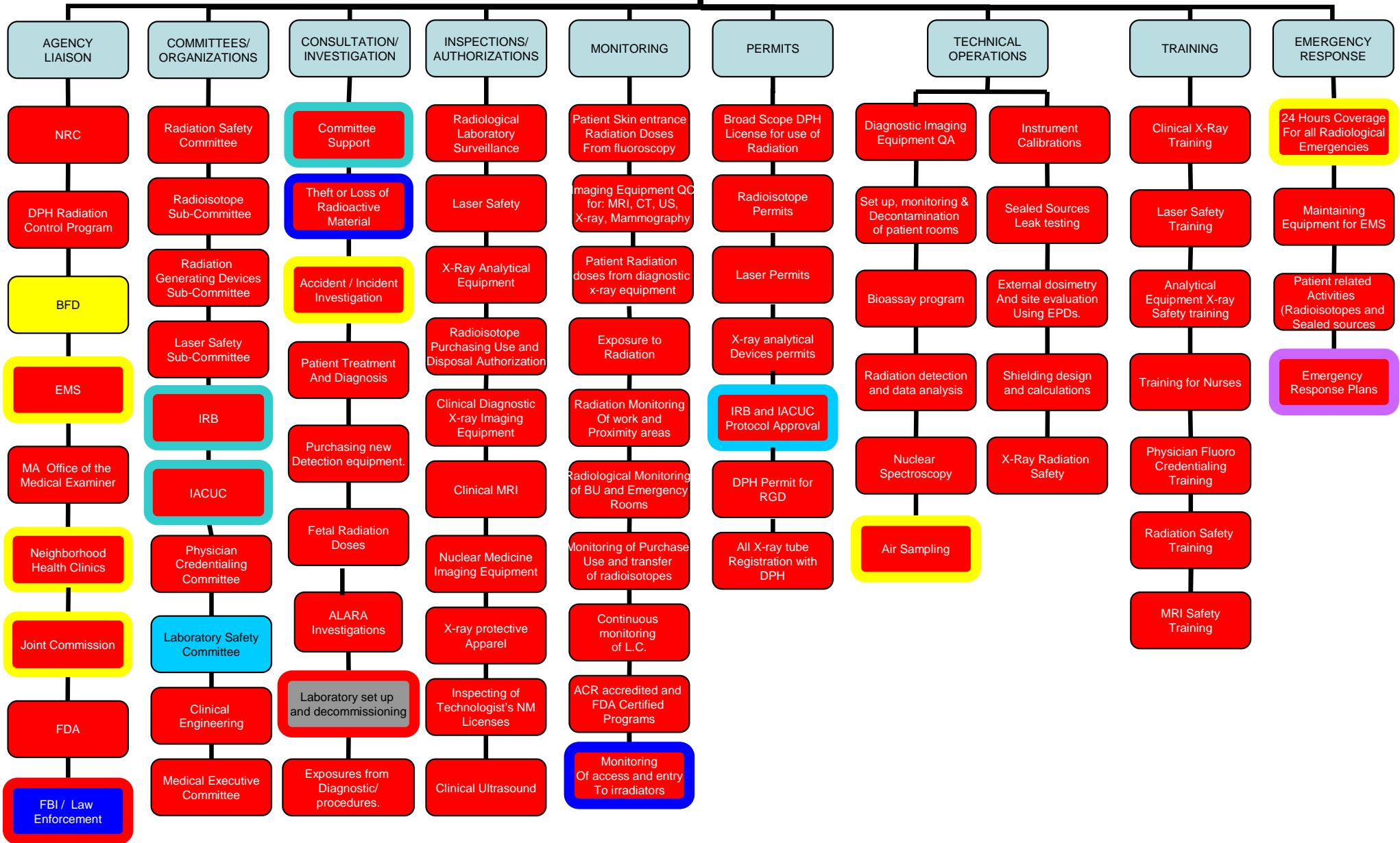
## 11. SOP Revision History



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Version	Section / Paragraph Changed	Changes Made	Effective Date
V.1	N/A	None, Original Version	
V.2	See Track Changes		
V.3	Final Edits	Final edits for posting	08/01/2010

# Medical Physics & Radiation Safety



- Research
- Clinical
- Facilities Management
- Research Occ. Health
- Radiation
- Emergency Mgmt
- Lab Animal Services
- Department / Division Responsible
- Campus
- Environmental
- Public Safety