1. **Purpose and Scope**

   The purpose of this document is to describe the scope of the Campus & Clinical Division (CCD) of Environmental Health and Safety (EHS) and to its roles and responsibilities.

   The CCD provides services to Boston University (BU) and Boston Medical Center (BMC) and the Charles River and Medical Campuses to promote safety and maintain compliance with safety regulations. CCD works closely with other divisions of EHS and BU and BMC departments.

2. **Definitions**

   - **ACES Plan**: Formally used at Boston University this procedure describes the steps employees and staff will implement upon discovery of smoke or fire no matter how small. The ACES fire plan: alert, confine, evacuate and special assistance. The RACE plan replaces ACES however; some placards may still exist on campus.

   - **Authorities Having Jurisdiction (AHJ)**: Those regulators, generally local authorities, that have jurisdiction in enforcing and interpreting regulations and standards.

   - **Boston University (BU)**: the Charles River Campus (CRC) and Medical Campus (MED).

   - **CCD**: Campus & Clinical Division of Environmental Health and Safety (EHS):
     - At BU, EHS reports to the Executive Director, Research Compliance (ORC).
     - At BMC, EHS reports to the Senior Director, Facilities and Support Services.

   - **Campus Incident Tracking System (CITS)**: This incident tracking system is a reporting system used by EHS to describe and track incidents and to identify corrective actions and root causes. CITS is accessible through the EHS website. Information about individual incidents is distributed via email through the system.

   - **Continuity of Operations Plan (COOP)**: This plan provides details on the physical space that will be utilized in the event of an emergency in which current office space is rendered inaccessible or otherwise unusable.

   - **Environment of Care (EC)**: A chapter within The Joint Commission (TJC) standards that addresses the work environment and safety and health practices and expectations. EHS is responsible for the administration of EC programs at BMC, as determined necessary or appropriate.

   - **Environmental Protection Agency (EPA)**: The branch of the federal government tasked with protection of the environment. The EPA promulgates and enforces environmental regulations on a national level.
• **Hazard Communication**: The communication of known hazards to employees who may be associated with them. Hazard Communication affords all employees the “right to know” about the hazards they may work with or around.

• **HAZWOPER**: Hazardous waste operations and emergency response standards as defined by OSHA. Specifically, 29 CFR (Code of Federal Regulations) 1910.120.

• **Higher Education Opportunity Act**: A federal law requiring the reporting of fire-related incidents, alarms, systems, and drills.

• **Industrial Hygiene (IH)**: Industrial hygiene is the art and science dedicated to the anticipation, recognition, evaluation, communication, and control of environmental stressors in, or arising from, the workplace that may result in injury, illness, impairment, or otherwise adversely affect the wellbeing of workers and members of the community.

• **The Joint Commission (TJC)**: An independent non-profit organization that accredits and certifies more than 17,000 health care organizations and programs in the United States. TJC accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards.

• **Massachusetts Department of Environmental Protection (DEP)**: The branch of the state government tasked with protection of the environment. The DEP promulgates and enforces environmental regulations on a state level. DEP regulations must be at least as strict as the national EPA regulations. In many circumstances—including in regards to hazardous waste, water emissions, air emissions, and underground storage tanks—DEP regulations overlap with and even exceed EPA regulations.

• **Massachusetts Division of Occupational Safety**: The branch of the state government that promulgates and enforces worker safety regulations.

• **Occupational Safety and Health Administration (OSHA)**: The branch of the federal government tasked with the protection of US workers. The OSHA promulgates and enforces safety and health regulations on a national level.

• **RACE Plan**: Used at the Boston University and Boston Medical Center, this procedure describes the steps employees and staff will implement upon discovery of smoke or fire no matter how small, the RACE fire plan incorporates the following: rescue, alert, confine, and extinguish.

• **Safety Information Management System (SIMS)**: is a web-based system used within EHS that is used to track inspection activities. It is mostly used to support inspection programs at BMC though can be used at BU as well. There are also modules for tracking training though those records are now maintained in RIMS.

• **USP 797 Environmental Assessments**: A procedure used by EHS staff that describes the required environmental monitoring performed in support of the U.S. Pharmacopeia's
3. **References**

The CCD is responsible for ensuring BU and BMC compliance with a number of regulations, standards, and best practices, including but not limited:

### 3.1. Regulations

#### 3.1.1. Federal Regulations
- Occupational Safety and Health Administration (OSHA)
- Environmental Protection Agency (EPA)
- Higher Education Opportunity Act

#### 3.1.2. State Regulations
- Code of Massachusetts Regulations (CMR) State Building Code
- Department of Public Health
- Massachusetts Division of Occupational Safety
- Department of Environmental Protection (DEP)

#### 3.1.3. Local Regulations
- Boston Fire Code
- Brookline Fire Department
- Boston Public Health Commission (BPHC)

#### 3.1.4. Guidelines and Standards
- The Joint Commission (TJC)
- National Fire Protection Association (NFPA)
- American National Standards Institute (ANSI)
- U.S. Pharmacopeia's (USP) Revised General Chapter <797>

### 3.2. Supplementary Documents

CCD maintains a comprehensive health and safety manual that includes policies, programs, SOPs, and guidance documents.

### 4. Roles and Responsibilities

Campus & Clinical Division (CCD) is responsible for developing, implementing, monitoring, and improving programs, including:

- **Health and Safety:**
  - Accident investigation
  - Job hazard analysis
  - Blood borne pathogens
  - EHS On-Call program
  - Ergonomics
  - Exposure monitoring
  - Anesthetic gas monitoring
  - USP 797 Environmental Assessment
• **Fire Safety:**
  o Fire prevention and response
  o RACE fire plans
  o Fire drill and critique plans

• **Worker Safety and Equipment Programs:**
  o Confined space
  o Control of hazardous energy (Lock-Out Tag-Out)
  o Emergency eyewash and safety showers
  o Fall protection
  o Fork lift and industrial truck safety
  o Fume hood management
  o Hazard communication
  o Hearing conservation
  o Personnel protective equipment (PPE)
  o Respiratory protection program (e.g. fit testing)
  o Roadside worker safety

• **Construction Safety Programs:**
  o Preconstruction Risk Assessment
  o Interim Life Safety Management Plan (BMC-specific)
  o Infection Control Risk Assessment (BMC-specific)
  o Asbestos management
  o Lead management

• **Hospital Safety and Environment of Care Programs:**
  Many of the programs listed in this document apply to BMC. Programs specific to BMC include the Interim Life Safety Management Plan and the Infection Control Risk Assessment program. Other policies and procedures are vetted and approved through BMC’s Policies and Procedures Committee and are posted on the BMC Intranet in section 6 of the Policies and Procedures Manual.

• **Regulatory Relationships:**
  CCD serves as a liaison between regulators and the university. Some of the regulators include:
  o OSHA
  o Massachusetts Division of Occupational Safety (on issues relating to asbestos, safety, etc.)
  o Massachusetts Department of Public Safety (DOS) (e.g., building permits, egress inspections, etc.)
  o Department of Environmental Protection (asbestos and lead programs)
  o City of Boston Inspectional Services Division (ISD)

• Obtaining egress inspections as required through the Boston Fire Department (BFD), ISD, and DOS.
• Inspecting facilities, generating corrective actions, and working with responsible departments to ensure that items are corrected.
• Responding to incidents, including site management, communication, and remediation.
• Providing training as appropriate and as required by the programs listed above.

Facilities Management & Planning (FMP) and Facilities Support Services (FSS):
• Allotting time for staff to attend all required safety training programs.
• Allowing access to fire safety systems maintenance and testing records and other fire safety-related maintenance items for EHS review.
• Responding to incidents involving environmental health and safety issues.
• Ensuring that workers and staff carry out their job functions in accordance with EHS policies.
• Identifying project managers, as necessary, to assist in the smooth integration of safety measures required by the plans, policies, and agencies listed above.

Office of General Counsel:
• Providing advice and legal counsel on incidents or complaints to regulatory authorities.
• Negotiating, as necessary, with regulatory authorities if enforcement actions are taken against BU/BMC.

Academic and other University Departments:
• Immediately reporting unsafe conditions to EHS.
• Participating in fire drills and other exercises when requested or required.
• Correcting deficiencies in a timely manner.

5. Special Requirements
The special requirements are as follows:

5.1. Equipment and Supplies
CCD maintains industrial hygiene (IH) equipment to monitor the environment that it serves, and also keeps up-to-date IH equipment lists. These lists identify each piece of equipment, its intended purpose, calibration and maintenance requirements, and estimated annual maintenance cost.

5.2. Safety
Safety requirements are plan-specific and are described in the programs list in Section 4: Roles and Responsibilities, above.

5.3. Training
All CCD staff members are trained to provide a comprehensive response to occupational safety and health concerns. Staff members are required to renew competencies as necessary and to attend local professional development meetings and seminars in order to remain current with changing regulations, standards, and best practices.
CCD staff members also participate in an annual Hazardous Waste Operations and Emergency Response (HAZWOPER) training session to be prepared to respond to incidents involving hazardous materials.

Training records are maintained within CCD and EHS offices.

5.4. Monitoring
Program performance within CCD is evaluated regularly and performance improvement is developed as needed.

IH monitoring is described in each of the IH-related programs. Results of monitoring are forwarded to the appropriate department managers and leadership within the Office of Research Compliance.

CCD also looks for systematic problems by monitoring fire alarm activity and other trending issues in order to identify root causes and take appropriate action.

5.5. Personnel Protective Equipment (PPE)
The CCD staff maintains basic PPE as required for routine tasks. Among the equipment maintained at all times are hard hats, flashlights, respiratory protection, and other emergency response equipment.

5.6. Medical Surveillance
EHS staff members are expected to participate in a rotating on-call schedule to respond to various emergencies on campus, including hazardous materials incidents. To this end, CCD staff also participate in a medical surveillance program through the Research Occupational Health Program (ROHP).

5.7. Other Prerequisites
None.

6. Applicable Locations
All BU and BMC affiliated locations.

7. Procedures and Instructions
In general, the CCD provides guidance, oversight, and training to help a number of departments on both campuses and the hospital carry out their operations. See appendix 1 for more detail on programs CCD is responsible for.

Safety primarily remains the responsibility of each individual. The Campus and Clinical Division Safety Program can only be administered through cooperation between the individuals involved, CCD staff, and the relevant departments at BU and BMC, in order to develop and implement appropriate and effective health and safety programs. Building operation and maintenance, housing, and many other campus activities require input and direction from the CCD in order to ensure compliance with the various health and safety regulations that may apply.
CCD staff will carry out their responsibilities in a professional manner and will continue to promote safety awareness through safety program development and implementation, training of employees and staff, and monitoring of the environment to create and maintain a culture of safety.

8. Forms
Forms and signage exist for a variety of Campus and Clinical Division safety processes. Several attached functional charts further illustrate the disciplines within CCD, including the following:

- BMC/BU-wide and EOC
- Fire Safety
- Worker Safety
- Industrial Hygiene

CITS reports are generated for incidents and maintained through the EHS website and associated servers.

Forms are used by CCD programs and are defined in the programs listed within this plan. They are vital to the ongoing implementation of the programs.

9. Records Management
CCD maintains records in various forms. These records relate to policies, programs, SOPs, training programs, exposure and ergonomic assessments, and job hazard analysis. Additional reports are also maintained by the department.

CCD provides fit-testing of respirators. Records of fit-testing for BMC are forwarded to Occupational and Environmental Medicine. BU records are maintained in hard copy form in binders and on excel on the departmental drive, “Y Drive”.

Training records of sessions provided by CCD staff are also maintained in the online database. Hard copies of the training rosters are kept for three years.

The BMC Safety Committee minutes and associated records are maintained in both paper and electronic form for three years. Current records and working documents are posted on the committees SharePoint site for member use.

CCD staff members conduct many different types of inspections and assessments throughout BU and BMC. Records of these inspections are maintained in the online database.
### 10. SOP Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Section / Paragraph Changed</th>
<th>Changes Made</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>V.1</td>
<td>N/A</td>
<td>None, Original Version</td>
<td>2.3.10</td>
</tr>
<tr>
<td>V.2</td>
<td>See Track Changes</td>
<td></td>
<td>5.27.10</td>
</tr>
<tr>
<td>V.3</td>
<td>Throughout</td>
<td>Reformatted, made changes to program section</td>
<td>11.28.11</td>
</tr>
<tr>
<td>V.4</td>
<td>Throughout</td>
<td>Edited</td>
<td>03.01.12</td>
</tr>
<tr>
<td>V.5</td>
<td>Throughout</td>
<td>Updated based on review of CCD policy manual</td>
<td>10/01/13</td>
</tr>
<tr>
<td>V.6</td>
<td>Throughout and section 2.</td>
<td>Minor edits. Also added SIMS to definitions,</td>
<td>3/1/14</td>
</tr>
<tr>
<td>V.7</td>
<td>Throughout</td>
<td>Reformatted. Added detail to procedure section with campus and clinical tasks</td>
<td>12/19/15</td>
</tr>
</tbody>
</table>
Appendix 1

Worker Safety
Monthly trainings covering all shifts.
Assessments.

Fire Safety Support

12 fire drills each quarter. 6 annual for business use
Compliance round inspections, total units inspected every six months.
Construction inspections weekly, hours spent 1 construction tour/week. 3 to 4 hours/week
Average PCRA reviews each week. 6-10/week

Clinic Inspections
BFD quarterly clinic inspections, ISD annual, DPS inspections every two years.

New employee orientations: 4x/month
Construction Safety Orientations: 1x/week

Health and Safety
Worker injury investigations
OSHA 300 log
BLS annual report

Industrial Hygiene Program Support (approximate time effort)
Eyewash and Safety Showers flow tests: 145 units; 48 hours biannually, 96 hours annually
Fume Hood Certifications: 90 units; 25 hours annually
Isolation room validations: 65 units; 16 hours monthly = 192 hours annually
Procedures room pressure validations – 10 spaces; 2.5 hrs weekly/monthly = 80 hrs annually
Fit testing 3000 people; 500 hrs annually, (2015 4500 staff fit tested) 750 hours annually
Asbestos consultation (inspections, sampling and coordinating) – 400 hrs annually
Pharmacy QC (USP) support – 200 hrs annually
Trades & Lab Med Training = 85 hrs annually
Industrial Hygiene Sampling – 96 hrs annually
IAQ, odor, water, mold, particulate, etc – 600 hrs annually
Central Processing Department (CPD) sampling – 40 hrs annually
Ergonomic assessments – 120 hrs annually
Website (Intranet) maintenance – 200 hrs annually

IH Detail – Pharmacy and CPD Effort
2016 anticipated regulatory changes resulting in an increase in the frequency and costs of environmental sampling conducted by us for all 4 of the BMC compounding pharmacies. Asked by the Pharmacy Manager to provide the proposed environmental sampling services when regulations are finalized.
CPD has also identified EHS as the group that will perform endoscope validation sampling beginning September 2015. More information on each of these events is identified below.

The most impactful change is the Compounding Pharmacy regs proposed by DPH in response to the Framingham NECC contamination and associated fatalities. The Manager expressed concern that the DPH reg could go into effect at any time. I’m not certain that it will be as soon as she is expecting it as I don’t believe comments have been received/reviewed and the current draft is in need of polishing. Also, given the impact that it would have on operations, I would hope they would give sites some time to implement the new requirements. Below, I’ve summarized what we currently do to meet the US Pharmacopeia Standard 797, which is enforced by Joint Commission, (and costs associated) vs. what is currently proposed by DPH in their draft regulation 247 CMR 17.00.

**Current USP Pharmacy Services for 4 BMC Pharmacies:**
- Nonviable sampling 2 times a year in each compounding Pharmacy (labor and equipment only, no lab associated fees)
- Viable sampling 2 times a year in each compounding Pharmacy (labor and equipment and lab fees for bacteria sampling – approx. $350/pharmacy/event = $3,000/yr)
- Each sampling event takes approximately 4-8 hrs in total, sometimes more time and lab fees to retest when the pharmacies fail. We offset the timing of these sampling events so that we are in each pharmacy every quarter. Time includes prep, sample, and report – with nonviable being the less intensive sampling.
- We’ve had the equipment for this task for a few years now. We’ve replaced the Balometer and 1 SKC pump within the past 2 yrs. Never replaced the particle counter – during my time anyway.

**Proposed DPH Pharmacy Services and Costs for 4 BMC Pharmacies:**
- Nonviable & Viable sampling 12 times a year in each compound Pharmacy. Viable sampling includes bacteria and fungal samples. Need to collect both using separate pumps.
- Additional time and costs:
  - 4-8 hrs/quarter/pharmacy now becomes 4-8 hrs/month/pharmacy. May be 2 people actually doing the sampling given all the equipment and samples to be collected, but we’ll figure that out over time.
  - Equipment needs: will need 2 more pumps and should purchase a new particle meter given that the old one is going to get quite a work out. Estimate $6,000 one-time cost.
  - Lab costs: approx. $550/pharmacy/month = $27,000/yr. New requirement to test potable water for microorganisms in pharmacies quarterly. Est. $2,000 in lab fees.
  - May require 3rd party outside assessment of sampling techniques every quarter (draft reg is a little unclear at this time). Estimate 4-6 hrs of consultant’s time quarterly at $100/hr.
In addition to DPH, the US Pharmacopeia has another draft standard (0800) that will result in a new type of sampling to be conducted twice a year, but only for hazardous drug compounding (Moakley only at this time). The laboratory analytical fees for chemo drugs are expensive ($110 - $185 per wipe sample), as so few labs have the capabilities to do it. Given what’s currently written in the draft, I’d estimate a dozen samples biannually. So approx. $3500/year. I would anticipate this one being approved sooner rather than later, as it has already gone through a public review and comment period. It appears that the labor will be inconsequential (a few hrs/event).

And lastly, CPD has requested our assistance with sampling endoscopes to validate their disinfection process to meet new FDA requirements. This is a result of reports throughout the US of superbug contamination/fatalities after bio-matter was left in scopes. EH&E did this for them earlier this year and charged $10,000 for 1 sampling event (5K in labor and 5K for lab analysis). Approximately 12 samples/sampling event will be collected over a 4 hour period – you have to sample and then wait for them to disinfect the scope and then resample to validate the disinfection process. It is described to me as a 2 person job (EH&E also considers it a 2 person job) given the number of bottles of water collected and the length of the endoscopes and the need for sterility. The estimated laboratory costs will be $5,000/quarter ($20,000 over the next 12 months). This is quarterly sampling that they state needs to start next month, although if no contamination is found after 4 sampling events, the frequency moves to semiannually and then to annually.