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1. Purpose and Scope

The purpose of this document is to describe the Research Safety program at Boston University (BU) and the Boston Medical Center (BMC), and to define the interactions, roles, and responsibilities of the Research Safety Division and other BU and BMC departments.

The Research Safety program ensures that institutional policies and procedures relating to the safe conduct of research activities are followed. These policies and procedures are used as a foundation for research safety and environmental health programs throughout schools and departments at BU and BMC. Research Safety is a division of Environmental Health and Safety (EHS).

2. References

The Research Safety program is responsible for ensuring BU/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. City Regulations

- BPHC Laboratory Regulation
- BPHC Disease Surveillance Reporting
- BPHC Recombinant DNA Ordinance
- BFD Boston Fire Prevention Code of 1979
- BFD Ordinance Regarding the Registration of Laboratories in the City of Boston

2.1.2. State Regulations

- Hazardous Chemical Waste, 310 CMR 30
- Medical/Biological Waste, 105 CMR 480
- Massachusetts Controlled Substances, 105 CMR 700

2.1.3. Federal Regulations

- NIH Guidelines for Work Involving Recombinant DNA Molecules
- HHS/CDC Select Agent Regulation, 42 CFR Part 73
- USDA/APHIS Select Agent Regulation, 9 CFR Part 121
- USDA/APHIS Select Agent Regulation, 7 CFR Part 331
- USA PATRIOT ACT (H.R. 3162) Section 817
- OSHA Bloodborne Pathogens, 29 CFR Part 1910.1030
- DHS CFATS, 6 CFR Part 27

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- OSHA Laboratory Standard, 29 CFR Part 1910.1450
 - OSHA Hazard Communication, 29 CFR Part 1910.1200
 - OSHA HAZWOPER, 29 CFR Part 1910,120
 - OSHA Personal Protective Equipment, 29 CFR Part 1910.132-139
 - OSHA Hazardous Materials, 29 CFR Part 101
 - DOT Hazardous Materials Transportation, 49 CFR Part 100-199
 - Hazardous Chemical Waste, 40 CFR 260
 - USDA/APHIS Agent Transfer Permit
 - CDC Etiologic Agent Import Permit
 - DOC Export Control
 - USDA/APHIS Import of Animal and Plant Pathogens
 - Controlled Substance Act, 21 CFR Part 1300
- 2.1.4. Guidelines and Standards
- CDC/NIH Biosafety in Biomedical and Microbiological Laboratories
 - IATA Dangerous Goods Regulation (DGR)
 - ANSI/AIHA Z9.5. 2003 Standard for Laboratory Ventilation
 - NFPA 45, Standard on Fire Protection for Laboratories Using Chemicals
 - NFPA 101 Life Safety Code
 - NSF 49, Class II Biosafety Cabinets
 - European Committee for Standardization (CEN) Laboratory Biorisk Management Standard (CWA 15793)
 - ASHRAE HVAC Laboratory Standards
 - CDC Primary Containment of Biological Hazards: Biological Safety Cabinets
- 2.2. Other SOP**
- 2.2.1. Comprehensive Laboratory Inspection
 - 2.2.2. Biological Use Authorization Site Assessment
 - 2.2.3. Strain Verification
 - 2.2.4. USDA Permit Registration
 - 2.2.5. Laboratory Shutdown and Decontamination
- 2.3. Supplementary Documents**
- 2.3.1. Biosafety Manual
 - 2.3.2. Chemical Hygiene Plan
 - 2.3.3. Exposure Control Plan
 - 2.3.4. Environmental Health and Safety Plan

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3. Definitions

- Occupational Safety and Health Administration (OSHA): federal agency in the U.S. Department of Labor charged with overseeing workplace health and safety.
- Boston Public Health Commission (BPHC): an independent public agency comprised of a variety of preventive health services. The BPHC Biosafety Program oversees the City's regulations on recombinant DNA and laboratories.
- Centers for Disease Control and Prevention (CDC): a government agency in the Department of Health and Human Services that focuses on public health.
- National Institutes of Health (NIH): a government agency in the Department of Health and Human Services whose mission is to improve human health through the promotion of research studies which aim to discover and develop drugs and therapeutics to cure diseases.
- United States Department of Agriculture (USDA): federal agency in charge of administering programs that affect animals and plants.
- Animal and Plant Health Inspection Service (APHIS): federal agency responsible for responding to animal and plant diseases and pest emergencies.
- Department of Homeland Security (DHS): federal department that administers all matters relating to homeland security.
- Environmental Protection Agency (EPA): branch of the federal government tasked with protection of the environment. The EPA promulgates and enforces environmental regulations on a national level.
- Massachusetts Department of Environmental Protection (DEP): state agency tasked with protection of the environment. 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 hazardous waste, water emissions, air emissions, underground storage tanks) DEP regulations overlap with and exceed EPA regulations.
- Massachusetts Department of Public Health: state agency which promulgates and enforces biological waste regulations.

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- Hazardous Waste: refers to chemical wastes which are governed under federal or state regulations due to their hazardous characteristics. In Massachusetts, waste oil is considered a hazardous waste.
- Medical/Biological Waste: human and animal tissues and fluids, infectious organisms, contaminated items, and sharp medical/research implements.
- Institutional Biosafety Committee (IBC): safety committee, internal to BU/BMC, in charge of reviewing biological research involving recombinant DNA, infectious agents and other potentially infectious materials, human materials, and select biological agents, to ensure the health and safety of both workers and the environment.
- Institutional Animal care and Use Committee (IACUC): safety committee, internal to BU/BMC, in charge of reviewing research involving vertebrate animals.
- Laboratory Safety Committee (LSC): technical safety committee, internal to BU/BMC, in charge of reviewing the overall safety and hazards of the lab workers, support staff, and the environment.
- Recombinant DNA: molecules that are constructed outside living cells by joining natural or synthetic DNA to DNA molecules that can replicate in a living cell. Also, molecules that result from the replication of the molecules described above.

4. Roles and Responsibilities

Individual School, College, and Department responsibilities include:

- Providing a safe workplace environment to promote and conduct academic research and teaching;
- Instituting health and safety programs for the health and well-being of the academic research and teaching community and staff.
- Working with faculty, researchers, and staff to promote a culture of safety in the workplace; and
- Identifying, reporting, and correcting unsafe conditions.

Principal Investigator (PI) responsibilities include:

- Implementing health and safety policies, programs, and procedures;
- Ensuring that the laboratory workplace is in compliance with all applicable regulations and policies;

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- Ensuring the safe maintenance of the workplace and equipment;
- Ensuring that all personnel complete their required trainings, job-specific work practices training, and agent-specific training;
- Reporting unsafe conditions;
- Reporting spills, accidents, and exposures;
- Ensuring that research is reviewed and approved as necessary by the appropriate safety and technical committees prior to start of research work;
- Providing appropriate personal protective equipment to lab workers; and
- Reporting employee absences to the Research Occupational Health Program for those who work with high-risk agents under the BPHC Disease Surveillance.

Laboratory Safety Coordinator responsibilities include:

- Assisting the PI with his or her responsibilities, as assigned and implement lab safety with the Research Safety Division and other EHS personnel as necessary.
- Taking positive action to determine and reduce, to as low as reasonably achievable, the potential for accidents and incidents associated with laboratory operations.
- Working with EHS and inform all laboratory personnel of the safety hazards associated with their work.
- Instructing all laboratory personnel in safe work methods.
- Keeping all individuals performing specific tasks apprised of the most recent procedures and trained in implementation.
- Ensuring that all work is performed in a safe manner and in accordance with regulatory and institutional requirements.
- Working with EHS to determine best safe practices and procedures.
- Working with EHS to ensure that all members of the laboratory complete their required training in a timely manner.
- Ensuring that all deficiencies identified by EHS or other regulatory inspectors are addressed and corrected within the time required.
- Ensuring that the Standard Operating Procedures (SOPs) for all laboratory procedures are approved and are current; that SOPs include appropriate safety instructions related to the use of personal protective equipment, special precautions for any infectious agents or highly hazardous chemicals are implemented, and instructions to perform procedures with appropriate safety equipment such as a fume hood, biological safety cabinet or sealed centrifuge as followed.

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Research Staff and Employee responsibilities include:

- Completing and updating all required trainings in a timely manner, including Laboratory Safety training provided by EHS;
- Completing job-specific training and agent-specific training provided by the PI or the Supervisor before working with hazardous materials;
- Seeking medical attention immediately after an injury, exposure, or undefined illness; and informing health care providers of the work in the lab and the agent used;
- Reporting injuries or exposure to the PI and the Research Occupational Health Program;
- Reporting unsafe conditions to the PI and EHS;
- Ensuring compliance with policies and procedures; and
- Reporting absences to the PI or supervisor.

Research Occupational Health Program responsibilities include:

- Reviewing and conducting medical clearances to employees requiring such clearances; and offering vaccines, PPD skin testing, etc., as necessary;
- Preparing follow-up reports of incidents and exposures;
- Providing reports in a timely manner to BPHC as required;
- Reporting employee absences as required under the BPHC Disease Surveillance;
- Conducting medical follow-up clearances for employees returning to work after recovering from sickness;
- Conducting employment termination clearances as necessary; and
- Providing consultations and agent-specific trainings as requested.

Institutional Biosafety Committee responsibilities include:

- Reviewing each biological research proposal and recommending appropriate containment level, personal protective equipment use, other applicable practices and procedures, and medical surveillance;
- Reviewing unsafe conduct in research and specifying necessary actions to be taken to ensure such conduct is abated and not repeated;
- Creating policies and procedures for the safe conduct of biological research;
- Reporting exposures to appropriate regulatory agencies; and
- Conducting follow-up investigations on exposures and accidents, as necessary.

Laboratory Safety Committee responsibilities include:

- Reviewing and approving the University's Chemical Hygiene Plan

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- Reviewing the use of hazardous chemicals and other similar materials for research protocols and recommending appropriate laboratory containment, personal protective equipment use, other applicable practices and procedures, and medical surveillance;
- Developing Standard Operating Procedures (SOPs) for high hazard chemicals;
- Reviewing unsafe conduct in research and identifying necessary actions to be taken to ensure such conduct is abated and not repeated;
- Creating policies and procedures for the safe conduct of research; and
- Conducting follow-up investigations on exposures and accidents, as necessary.

EHS Research Safety Division responsibilities include:

- Supporting the BU/BMC core academic mission of teaching and research through the implementation of comprehensive research safety programs, including program involving:
 - Recombinant DNA
 - Infectious Agents and Potentially Infectious Materials
 - CDC/USDA Select Agents and Biological Toxins
 - OSHA Bloodborne Pathogens
 - BPHC BSL3/BSL4
 - Agent and Material Transfer
 - Biological Use Authorization Risk Assessment
 - Chemical Inventory
 - High Hazard Chemicals
 - Homeland Security Chemical of Interests
 - Gas Management
 - General Laboratory Safety
 - Laboratory Fire and Life Safety
 - Laboratory Emergency Response
 - Use of Controlled Substances in Research
 - Diver Safety
- Serving as the technical and subject matter expert by consulting with faculties, research personnel, and staffs to provide guidance and recommendations on experimental designs, laboratory containment, and other issues related to working with hazardous materials or performing processes that may cause hazardous situations, including:
 - *Laboratory design and construction.* Provide input to engineers, architects, project managers, users, and other stakeholders on appropriate laboratory containment design criteria.

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- *Drafting of safety SOPs.* Prepare safety SOPs to assist laboratories conduct work safely in the laboratory.
- *Agent and material transfer.* Work with the lab and appropriate departments and agencies to provide guidance and assistance on transfer of agents and materials including:
 - USDA/APHIS transfer permit of animal and plant pathogens
 - CDC Import of Etiologic Agents
 - DOC Export Control
 - IATA Shipment of Dangerous Goods
 - CDC/USDA Select Agent Transfer
- Working with the IBC, LSC, IACUC, and other safety and technical committees to develop and implement policies and procedures for BU/BMC designed to ensure compliance with research-related regulations, standards, and guidelines;
- Conducting risk assessments to identify hazards in the workplace, and providing recommendations on appropriate control measures to eliminate or reduce occupational injuries or exposures through the use of:
 - *Biological Use Authorization site assessments.* Review research projects submitted to IBC and perform an on-site review and risk assessment in order to verify that the work will be performed in an appropriate laboratory facility, and with the use of appropriate safety equipment and personal protective equipment. Also ensure that SOPs are in place, and lab personnel have completed appropriate training and medical clearance/surveillance as necessary.
 - *High Hazard Chemical Use site assessments.* Review research projects involving high hazard chemicals and perform an on-site review and risk assessment to verify that appropriate administrative and engineering controls and personal protective equipment are in place.
 - *Review of laboratory processes.* Assist labs in developing SOPs for safe operations, as needed.
- Monitoring the overall health and safety programs of BU/BMC laboratories and personnel by conducting:
 - *Comprehensive laboratory inspections.* In conjunction with the IBC, LSC, and other safety and technical committees; verifying lab compliance through inspections of laboratory conditions and the use of appropriate laboratory containment, fire and general safety, and work practices and procedures for research that involves biological agents, chemicals, controlled substances, etc. Verifying certification and maintenance of safety equipment including

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Biosafety Cabinets, fume hoods, safety showers, eyewashes, fire extinguishers, etc. Verifying decontamination and validation process, including biological waste treatment and autoclave validations used for wastes.

- *Unannounced follow up visits.* Conducting unannounced follow up visits to verify the lab's completion of corrective actions and adherence to ensure compliance.
- Reviewing the results of the inspections and recommend any programmatic corrective actions and modifications necessary to prevent the reoccurrences of such non-compliances.
- Developing content and providing training for research personnel as required by external regulations and internal BU/BMC policies to ensure safe operations:
 - Laboratory Safety Training
 - Emergency response
 - Fire and general safety
 - Safety equipment
 - Biological safety
 - OSHA Bloodborne Pathogen
 - Hazard Communication
 - The Chemical Hygiene Plan
 - Laboratory waste management
 - Shipping of Biological Agents
 - Shipping of Chemicals
 - Select Agent Training
 - BSL3 Training
 - BSL4 Training
- Serving as a liaison between regulatory agencies and working collaboratively for the implementation of applicable regulations and standards.
- Coordinating inspections, visits, and walkthroughs with the following regulatory agencies to ensure compliance with regulations and standards:
 - BPHC
 - BFD
 - DEP
 - Massachusetts DPH
 - OSHA
 - CDC
 - USDA
 - NIH
 - FAA

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- FBI
- Others, as appropriate
- Working with BU/BMC schools, departments, administration, and laboratories to secure required permits, certificates, and licenses for the operation of labs;
- Responding to emergency situations, including spills of hazardous materials; and assisting the labs in mitigation measures;
- Conducting follow-up investigations on exposures and accidents, as necessary; identifying root causes and recommending changes to prevent such events from reoccurring;
- Acting as a liaison between regulatory agencies and BU/BMC during their routine inspections, response to emergencies and accidents, and any follow-up investigations;
- Working with BU/BMC schools and departments to ensure that research facilities are operated safely to protect students, staffs, university property, the community, and the environment;
- Developing and preparing tools—such as plans, manuals, informational factsheets, and so on—that will assist labs, departments, and schools in maintaining compliance with all appropriate requirements and standards. Specific tools include:
 - Biosafety Manual
 - Chemical Hygiene Plan
 - Exposure Control Plan
 - Laboratory Research Animal Care Safety Plan
 - Agent Information Sheet
 - Chemical Use SOP
- Monitoring changing and emerging regulations and standards, and assessing the impact to the institution; and
- Working with BU/BMC administration to ensure adequate staffing and resources for the delivery of services.

Facilities Management and Planning responsibilities include:

- Conducting routine operation, maintenance, testing, and general management of laboratory facility structures (e.g., maintenance of negative pressure in lab space) and equipment to ensure for safe operations;
- Providing notification prior to the addition of or significant alterations to any significant laboratory installation;
- Involving EHS in the review of laboratory construction and renovation projects; and
- Providing adequate space and facilities to store and manage regulated wastes including chemical, biological, and radioactive wastes.

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Office of General Counsel responsibilities include:

- Providing advice and counsel in the event of a research-related incident; and
- Negotiating with regulators in the event of an enforcement action taken against BU/BMC in response to a research-related incident.

5. Special Requirements

5.1. Equipment and Supplies Required

- Chemical spill kits and materials
- Biological spill kits
- Chemical disinfectants
- Emergency response personal protective equipment,
- Air monitoring equipment and supplies

5.2. Safety Requirements

Research Safety program operations require compliance with all applicable BU/BMC safety policies and procedures implemented through Environmental Health and Safety.

5.3. Training

The Research Safety staffs are trained and maintain competencies to provide subject matter services for research laboratories. These competencies are maintained through continued professional developments, trainings, seminars and conferences. Areas and field of competencies include but not limited to regulatory, best practices, new or emerging technology.

These competencies allow the Research Safety staffs to develop and provide trainings for our lab community. The Research Safety Division provides training on:

- Laboratory Safety Training
 - OSHA Bloodborne Pathogen
 - Hazard Communication
 - Hazardous Waste
 - General Laboratory Safety
- Shipping of Biological Agents
- Shipping of Chemicals
- Select Agent Training
- BSL3 Training
- BSL4 Training

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5.4. Monitoring Requirements

Programs, manuals, SOPs, procedures, training and other critical program components are routinely reviewed to ensure that they meet regulatory requirements and BU policies and procedures.

5.5. Personnel Protective Equipment (PPE)

The Research Safety Division routinely visits laboratories with various hazards across BU/BMC. During these visits, staff members select an appropriate level of PPE based on laboratory-specific hazards and other requirements. Additionally, staff members may respond to emergency situations in BU/BMC laboratories, which may require additional levels of personal protective equipment. Staff members select an appropriate level of PPE based on the hazards or potential hazards present at the time of the response.

5.6. Medical Surveillance

Staff members in the Research Safety Division receive annual physical examinations and medical surveillance through the Research Occupational Health Program (ROHP).

5.7. Other Prerequisites

Staff members are required to have a thorough understanding of health and safety requirements in a diverse research-intensive institution.

6. Applicable Locations

All BU and BMC campus locations.

7. Procedures and Instructions

Procedures and instructions for the Research Safety Program are provided on the Environmental Health and Safety website, Standard Operating Procedures (SOPs), guidelines, and Safety Manuals.

8. Forms

Forms and signage exist for a variety of Research safety processes. Several attached functional charts further illustrate the disciplines within Research Safety, including the following:

- Laboratory Safety Equipment Functional Chart
- Controlled Substances Functional Chart

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- Chemical Safety Functional Chart
- Biosafety Functional Chart

There are several other forms used to implement the Research Safety Program. They include various inspections forms, risk assessment forms, space and equipment decontamination forms, and so on. These forms are located on Environmental Health and Safety website and also in the Safety Logbooks provided to all BU/BMC laboratories.

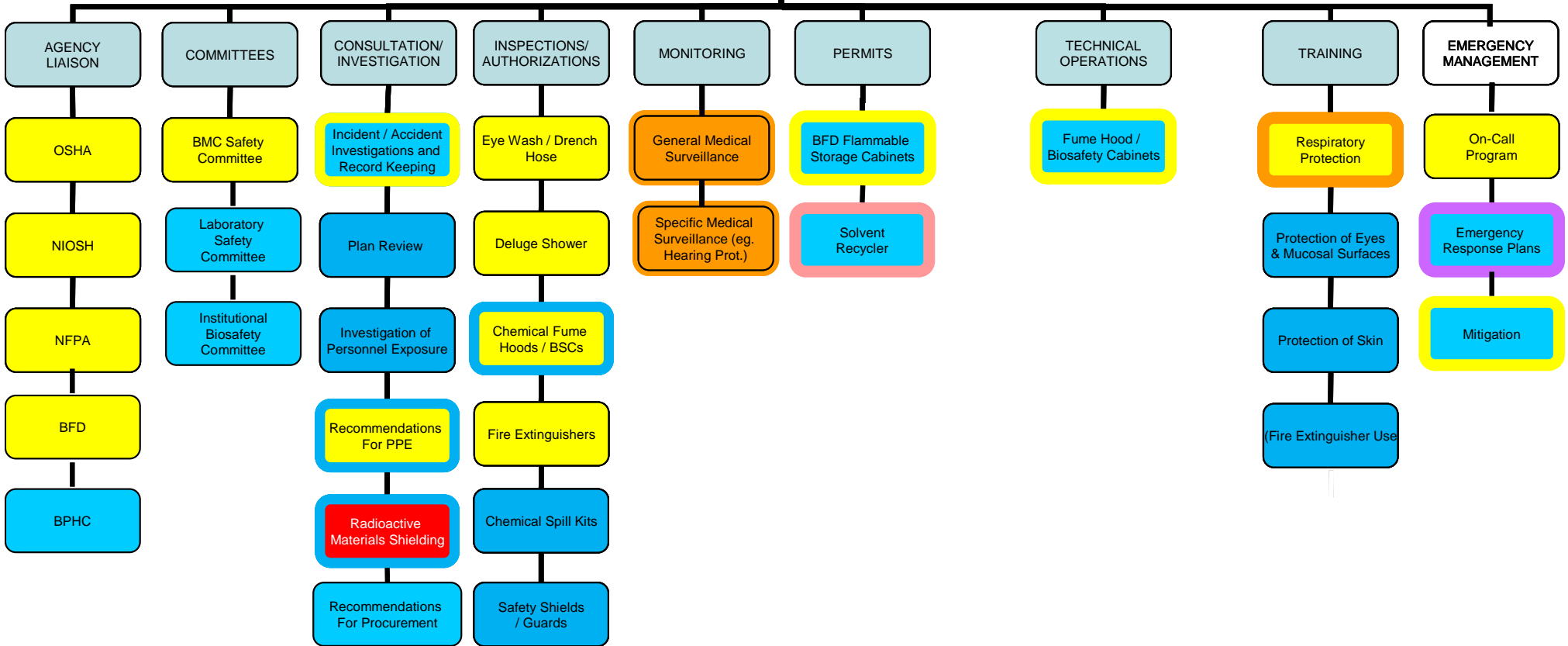
9. Records Management

Records are maintained through the Research Safety Division and EHS. These records include dates, names, and other important information pertaining to inspections and training sessions.

10. SOP Revision History

Version	Section / Paragraph Changed	Changes Made	Effective Date
V.1	N/A	None, Original Version	

Laboratory Safety Equipment

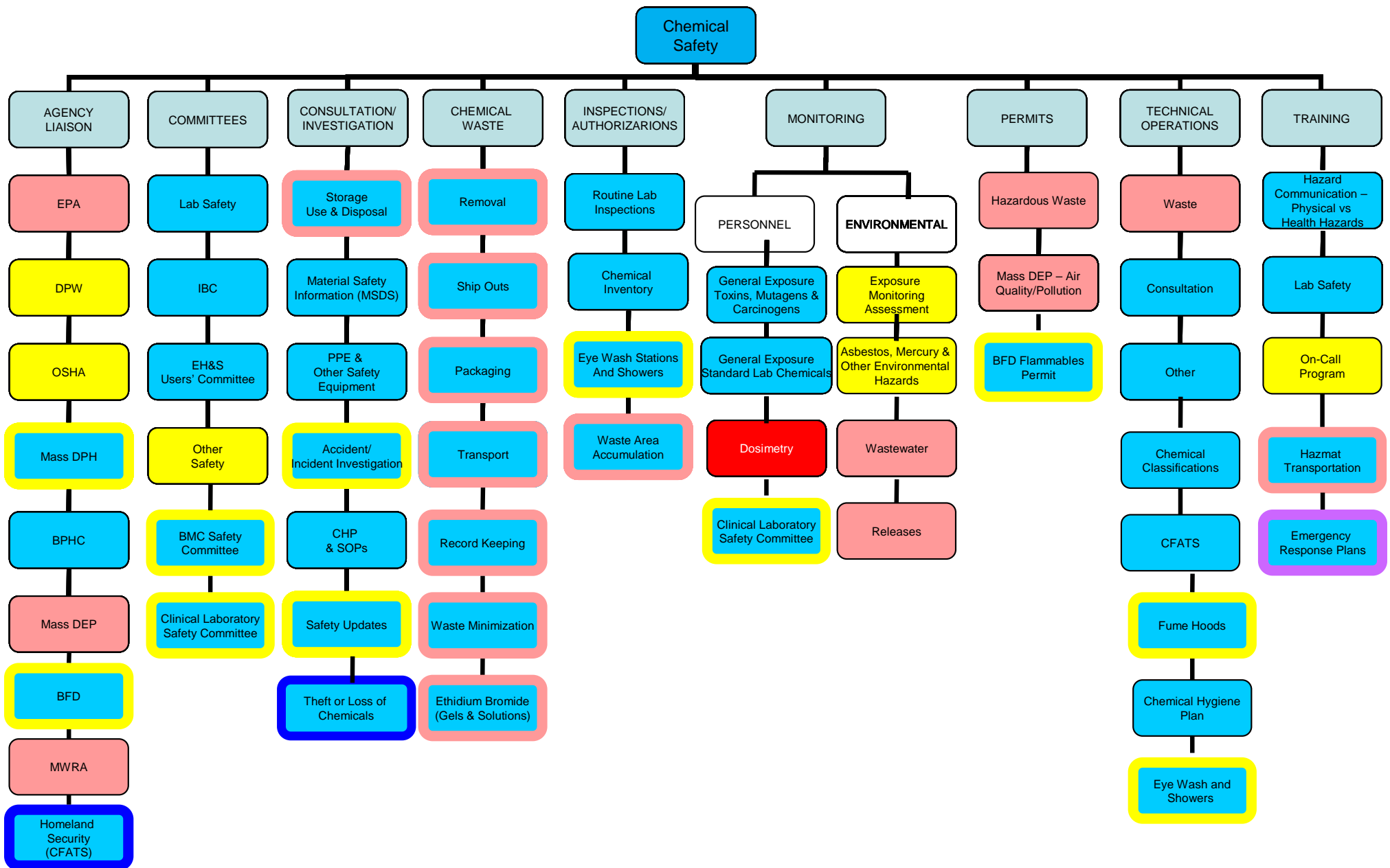


█ Research
█ Radiation
█ Campus

█ Clinical
█ Emergency Mgmt
█ Environmental

█ Facilities Management
█ Lab Animal Services
█ Public Safety

█ Research Occ. Health
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