COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

OFFICE OF THE
EXECUTIVE VICE PRESIDENT FOR RESEARCH

RESEARCH ENVIRONMENTAL HEALTH AND SAFETY HANDBOOK

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I. INTRODUCTION

A. Purpose of Handbook

The use of hazardous materials, including chemicals, radioactive materials and potentially infectious biological materials, in research laboratories requires appropriate care and management to ensure the safety of all personnel and compliance with applicable federal, state and local laws and regulations. This Handbook has been created to give practical guidance to faculty, staff and students at Columbia University (the **University** or **Columbia**) conducting research using hazardous materials, to provide information on important environmental health and safety policies, procedures and regulations, and to introduce all faculty and staff to the services and programs offered by the University's Office of Environmental Health & Safety **(EH&S**). **This Handbook covers only research uses of hazardous materials or other research-related safety hazards and does not cover any hazards that may result from other activities associated with the operations of the University.**

Readers should be advised that changes in policies and regulations may be more current than the contents of this Handbook. While every attempt will be made to keep this Handbook up-to-date, ultimately the most current information will be found in government regulations and the University's numerous websites.

B. Resources

The University has websites and other resources that provide a wealth of information to research personnel. This section describes some of those resources.

1. Office of Executive Vice President for Research

The website of the Office of the Executive Vice President for Research (**EVPR**) https://research.columbia.edu provides quick links to other useful pages, including:

- Environmental Health and Safety: https://research.columbia.edu/environmental-health-safety
- Radiation Safety Program: https://research.columbia.edu/content/radiation-and-laser-safety
- Sponsored Projects Administration: http://spa.columbia.edu/
- Institute of Comparative Medicine: https://research.columbia.edu/content/institute-comparative-medicine
- Institutional Animal Care and Use Committee: https://research.columbia.edu/content/institutional-animal-care-and-use-committee
- Human Research Protection Office/Institutional Review Boards: https://research.columbia.edu/content/human-research-protection-office-and-irbs
- Clinical Trials Office: https://research.columbia.edu/content/clinical-trials-office
- Research Compliance and Training: https://research.columbia.edu/office-research-compliance-and-training

2. Handbooks

The Office of the EVPR has produced the following additional Handbooks to provide guidance to faculty, staff and students of the University in matters relating to research. The Handbooks are also available in pdf format on the EVPR website.

· Sponsored Projects Handbook:
https://research.columbia.edu/sites/default/files/private/EVPR/SponsoredProjectsHandbook.pdf
· Clinical Research Handbook:
https://research.columbia.edu/sites/default/files/private/EVPR/ClinicalResearchHandbook.pdf
· Animal Research Handbook:
https://research.columbia.edu/sites/default/files/private/EVPR/AnimalResearchHandbook.pdf
· Research Radiation Safety Handbook
https://research.columbia.edu/system/files/EVPR/ResearchRadiationSafetyHandbook.pdf

3. EH&S Resources

EH&S has a number of resources on the EH&S website that are more particularly described elsewhere in this Handbook. Such resources include the Biological Safety Manual, the Health and Safety Manual, the Laboratory Information Online Network, the Laboratory Assessment Tool and Chemical Hygiene Plan, the Radiation Safety Manual and the Laser Safety Manual.

4. Rascal

Rascal is a web-based suite of information technology modules that was developed internally at the University to house many of the University's research compliance processes. Rascal can be accessed at: https://www.rascal.columbia.edu.

Rascal houses training courses relating to research and tracks compliance with training requirements. Trainings relating to environmental health and safety will be described in more detail in later chapters of this Handbook.

Any faculty or staff member and student may use Rascal. In addition, non-Columbia personnel who are acting as collaborators on a research project may obtain a temporary UNI and be permitted access in Rascal if they have the proper credentials. A UNI can be obtained by the applicable Departmental or School Administrator.

5. Annexes

This Handbook contains a number of Annexes; an **Index of Annexes** can be found following the text of this Handbook immediately prior to the Annexes. See **Annex I-A** for a **Glossary of Acronyms and Abbreviations** used in this Handbook.

II. ENVIRONMENTAL HEALTH AND SAFETY

A. Introduction

EH&S provides environmental health and safety services across the University, including (1) the Morningside Heights campus (**Morningside)**, (2) the Manhattanville campus (**Manhattanville)**, Columbia University Irving Medical Center (**CUIMC**), (3) the Lamont-Dougherty Earth Observatory (**Lamont)** and (4) Nevis Laboratories (**Nevis).** EH&S also provides certain services to Barnard College (**Barnard),** NewYork-Presbyterian Hospital (**NYP) at CUIMC** and New York State Psychiatric Institute (**NYSPI)**. EH&S is responsible for ensuring compliance with federal, state and local laws and regulations and University policies relating to environmental health and safety.

EH&S is committed to establishing and maintaining a healthy and safe work environment for the University's faculty, staff, students, neighbors and surrounding communities. Through the identification, evaluation, and control of personal and environmental hazards, the University strives to eliminate individual risks and reduce the environmental impact of its activities. EH&S offers a broad range of services and actively develops partnerships with faculty and departmental personnel to ensure a safe work environment and compliance with University policies and applicable regulations in the most efficient manner possible. These endeavors are realized through programs such as personnel training, chemical hygiene plans, biological safety, environmental safety, fire safety and occupational safety.

B. EH&S Programs

EH&S serves as an umbrella organization for a number of separate but related programs relating to research, as follows. Each program will be described in more detail elsewhere in this Handbook.

Biological Safety

The Biological Safety Program provides guidance to anticipate, assess and control risks posed by the handling and use of biological materials in research, including bacteria, viruses, recombinant DNA, other microorganisms, biological toxins and other potentially infectious human and animal materials.

Controlled Substances

The Controlled Substances Program provides guidance to researchers planning to work with controlled substances to understand the requirements of federal, state and local laws and regulations relating to controlled substances.

Fire Safety

The Fire Safety Program provides guidance on training and certification and instructions for safe laboratory practices to prevent fires.

Hazardous Materials

The Hazardous Materials Program provides guidance in complying with applicable hazardous materials laws and regulations, promoting best practices and supporting waste minimization.

Laboratory and Research Safety

The Laboratory and Research Safety Program provides support in recognizing, evaluating and controlling all hazards associated with working in a research laboratory, including those relating to the use of biological, chemical and radiological materials, and the use of laboratory equipment. This program includes guidance on hazardous materials regulations, and the management and pick-up of hazardous waste.

Occupational Safety

The Occupational Safety Program provides guidance with respect to research health hazards, the control or minimization of potential exposures, medical surveillance and emergency procedures.

Radiation Safety

The Radiation Safety Program covers the safe use of ionizing radiation, radioactive materials and magnetic resonance imaging in research.

Laser Safety

The Laser Safety Program covers the safe use of lasers in research, including registration, purchase, design and training.

C. EH&S Office Locations

EH&S has a number of office locations that house personnel active at each of the campuses. However, most EH&S personnel work at multiple locations depending on where their expertise is needed.

- **Morningside, Lamont, Nevis and Barnard**

  Address: 419 West 119th Street
  Phone: (212) 854-8749

- **Manhattanville**

  Address: 612 West 120th Street, Jerome L. Greene Science Center; Mezzanine L1A-008
  Phone: (212) 854-8749

- **CUIMC, NYP and NYSPI**

  Address: 617 West 168th Street, Georgian Building 2nd Floor
  Phone: (212) 305-6780

III. LABORATORY AND RESEARCH SAFETY

A. Introduction

The EH&S Laboratory and Research Safety Program (the **Research Safety Program)** is responsible for recognizing, evaluating and controlling the hazards and risks associated with storing, handling and using chemical materials and/or equipment, including, but not limited to, flammable, corrosive, toxic or reactive materials, and heat- or pressure-generating equipment used in research conducted in laboratories at the University. Through the application of materials substitution, engineering controls, administrative controls and the use of Personal Protective Equipment (**PPE**), the Research Safety Program aims to minimize the incidence of laboratory-related injuries and to ensure a safe and productive working environment for research faculty, staff and students, and the wider University community.

Research Safety Program staff members work closely with members of the other EH&S programs. Research Safety Program staff are often the faces of EH&S, visiting researchers in their laboratories, teaching courses and being generally available as direct liaisons between the research staff and EH&S. Laboratory safety surveys are a core component of the Research Safety Program.

B. Regulatory Framework

Researchers should be familiar with the regulatory framework governing laboratory safety. Federal and New York State regulations apply to all campuses of the University. Local New York City regulations apply to Morningside, Manhattanville and CUIMC. This Handbook will frequently reference the relevant agencies and their jurisdictions as they apply to laboratory safety requirements.

1. Occupational Safety and Health Administration (OSHA)

Laboratory Standard

The Occupational Safety and Health Administration (**OSHA**) Occupational Exposure to Hazardous Chemicals in Laboratories (Standard) (29 CFR 1910.1450) (the **OSHA Laboratory Standard)** establishes general requirements for the laboratory use of hazardous chemicals. More detailed requirements can be found in the University's Chemical Hygiene Plan. See **Elements of the Columbia Research Safety Program: Chemical Hygiene Plan (CHP)** (**Section D(1))** below.

Hazard Communication Standard

The OSHA Hazard Communication Standard (29 CFR 1910.1200) (the **OSHA Hazard Communication Standard)** establishes requirements for manufacturers of hazardous chemicals to provide Safety Data Sheets (**SDSs**) to users following the UN Globally Harmonized System (**GHS**) of Classification and Labeling of Chemicals. Effective hazard communication includes

maintenance of current chemical inventories, provision of ready access to SDSs for hazardous chemicals, proper labeling of chemical containers, posting of hazard signs and training of laboratory personnel.

For more information about SDSs and chemical inventory at the University, see **Elements of the Columbia Research Safety Program: Hazard Communication—Safety Data Sheets (SDSs)** and **–Chemical Inventory Management—ChemTracker (Sections D(3)** and **(4))** below**.**

OSHA broadly defines a **hazardous chemical** as any chemical that is classified as a health hazard or simple asphyxiant in accordance with the OSHA Laboratory Standard. A chemical classified as a health hazard poses one or more of the following hazardous effects:

- Acute toxicity;
- Skin corrosion or irritation;
- Serious eye damage or eye irritation;
- Respiratory or skin sensitization;
- Germ cell mutagenicity;
- Carcinogenicity;
- Reproductive toxicity;
- Specific target organ toxicity; and
- Aspiration hazard.

The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A of the OSHA Hazard Communication Standard.

2. Fire Department of the City of New York (FDNY)

The FDNY is the "Authority Having Jurisdiction" over fire safety on the New York City campuses. Under the NYC Fire Code, Columbia laboratories are considered "non-production chemical laboratories" and laboratory spaces must meet a set of minimum requirements to use and store chemicals. For more information about FDNY regulations and fire safety at the University, see **Fire Safety (Chapter VIII)**.

3. Resource Conservation and Recovery Act (RCRA) and the Environmental Protection Agency (EPA)

RCRA governs the management of hazardous waste and several categories of non-hazardous and specialty waste. These requirements are enforced by the EPA and the New York State Department of Environmental Conservation (**NYS DEC)**; both agencies inspect the University for compliance with RCRA hazardous and non-hazardous waste management. For more information about RCRA regulations and laboratory waste management at the University, see **Hazardous Waste Management and Disposal (Chapter IV).**

4. The Community Right to Know Act and the NYC Department of Environmental Protection (NYC DEP)

The NYC DEP enforces the NYC Community Right-to-Know Law (Local Law 26) (the **NYC Right to Know Law),** which regulates the use and storage of hazardous chemicals. The NYC Right to Know Law is based on the EPA's Emergency Planning and Community Right-to-Know Act (Superfund Amendments and Reauthorization Act, Title III, Section 313) and sets thresholds for the quantities of hazardous materials that may pose a public health risk and therefore must be reported by an institution. Laboratory chemical inventories are used to prepare these reports.

5. The U.S. Department of Transportation (US DOT) and International Air Transport Association (IATA) Regulations for Shipping Hazardous Materials

The US DOT and IATA regulations cover the movement of hazardous materials between locations by ground and air transportation, respectively. When research materials are being moved from site to site, whether between campuses, domestically or internationally for research collaborations, it is mandatory to use a certified shipper, which is often FedEx or another commercial carrier. It is also strictly required that packages of most chemical material be prepared by certified personnel—typically EH&S staff. For more information about shipping hazardous materials, see **Transport and Shipment of Hazardous Materials (Section I)** below. See also the US DOT Hazardous Materials Regulations.

C. General Roles and Responsibilities

1. Institutional Health and Safety Council (IHSC)

The IHSC reflects the executive-level commitment of the University to ensure that each health and safety program receives the appropriate support necessary for its success; it also delineates the responsibilities for meeting health and safety goals. The IHSC meets on a quarterly basis to review program quality through a variety of measures designed to assess compliance with regulatory obligations and University initiatives.

The IHSC:

- Proposes and approves health and safety policies and policy changes;
- Reviews reports from other University committees (e.g., Institutional Biological Safety Committee, Radiation Safety Committee, Laser Safety Committee, etc.) regarding the status of new and on-going programs and offers critical evaluations of such programs to ensure compliance and continued improvement;
- Discusses changes to regulations and their impact on current and future activities on each campus, and determines specific actions needed to address such changes; and
- Designates responsible departments or individuals to address new or outstanding health and safety issues

2. Research Safety Program

The Research Safety Program within EH&S assists University laboratories using hazardous materials with compliance with applicable federal, state and local regulations across multiple programs in EH&S: Research Safety, Biological Safety, Radiation Safety, Fire Safety, Occupational Safety and Hazardous Materials.

The EH&S professionals in the Research Safety Program:

- Perform periodic safety surveys of laboratories working with chemicals and hazardous materials in order to ensure the protection of human health and the environment;
- Escort external inspectors from regulatory agencies, including the EPA, NYS DEC, NYC DEP and FDNY, through laboratories to observe and record findings made by such agencies;
- Provide general safety training to the University research community;
- Advise laboratory personnel on chemical waste management practices;
- Manage chemical waste pick-up services;
- Assist in the preparation of shipments of chemicals;
- Consult on laboratory design and construction;
- Certify chemical fume hoods in laboratories annually;
- Respond to laboratory fires, spills and exposures;
- Provide EH&S clearance for laboratory equipment changing ownership and/or exiting the University;
- Provide or arrange for technical guidance on safety enhancements to experimental procedures;
- Conduct quarterly radioactive materials audits in laboratories working with radioactive isotopes; and
- Review hazardous materials protocols for experiments involving research animals.

3. Principal Investigators (PIs)

PIs are responsible for performing activity- and chemical-specific risk assessments for work with hazardous materials and chemical hazards.

PIs must:

- Complete a Laboratory Assessment Tool and Chemical Hygiene Plan to document a laboratory-specific Chemical Hygiene Plan, and update it annually;
- Perform a hazard assessment for the research activities in occupied space(s) and develop standard operating procedures (**SOPs)** to address hazards or operations in the laboratory. EH&S may be consulted to determine which operations warrant a SOP;
- Ensure that current and new laboratory personnel receive adequate laboratory process- and/or equipment-specific safety training;

- Ensure that all laboratory workers have fulfilled the University training requirements for the hazards in their research;
- Purchase PPE and distribute it to all researchers;
- Ensure that a laboratory member is flushing eyewashes weekly;
- Maintain aisles in the laboratory and clear access to emergency equipment such as fire extinguishers, eye washes and safety showers; and
- Report to EH&S any research-related injuries, accidents or incidents in the laboratory.

D. Elements of the Columbia Research Safety Program

1. Chemical Hygiene Plan (CHP)

The University is required to have a CHP by the OSHA Laboratory Standard and University policy. The CHP applies to faculty, staff and students on all campuses engaged in the laboratory use of hazardous chemicals. The CHP consists of two parts. The first part outlines the University policy for chemical hygiene and management in research laboratories by providing guidance on the safe use of chemicals, their health hazards and routes of exposure, the control of potential exposure, medical surveillance, training, waste disposal and emergency procedures.

The second part of the CHP is the web-based Laboratory Assessment Tool and Chemical Hygiene Plan (**LATCH).** Developed by EH&S, LATCH is designed to help individual laboratories prepare a laboratory-specific CHP, as required by OSHA. LATCH identifies laboratory tasks and indicates the corresponding appropriate administrative and engineering controls, safety training, and PPE needed to reduce potential exposures.

For the full text of the CHP, see
https://research.columbia.edu/sites/default/files/content/EHS/Manuals/ChemicalHygienePlan.pdf

The LATCH is managed and maintained by each PI or his/her designee. EH&S has developed a comprehensive electronic database, the Laboratory Information Online Network to manage the creation and maintenance of the LATCH. LATCH also includes information on staff training, emergency equipment and other laboratory assets and spaces under the management of the PI.

2. Laboratory Information Online Network (LION)

The LION is a cloud-based laboratory safety dashboard that permits researchers and staff to access and view records unique to their laboratories. LION serves as a communication tool between EH&S and the research community. Operating through the University's UNI-authentication credentials, researchers are required to use this network to manage, or designate a laboratory manager to manage:

- An up-to-date laboratory personnel roster by UNI;
- A minimum of two 24-hour emergency contact phone numbers for the laboratory;
- Room number(s) associated with the laboratory space(s);

- LATCH for their laboratory; and
- Response to survey findings and corrective action plans, as needed.

LION allows the faculty and laboratory staff to:

- Track training records for research staff and students in their group, including FDNY C-14 status;
- Review and correct safety survey findings; and
- If applicable, manage radioactive materials inventory and waste.

To log in to LION, use the URL: http://research.columbia.edu/LION and enter your UNI and password. Software training guides are available within LION, and EH&S provides one-on-one tutorials by request at labsafety@columbia.edu.

3. Hazard Communication

Hazard communication is a critical part of an academic research enterprise where projects are diverse, scientific disciplines overlap and experiments are evolving on the frontiers of science. Research laboratories can include faculty, staff, students and visitors, often at different educational and career levels. Communication should be managed by the PI so that information is regularly reaching all members of the laboratory group.

A researcher overseeing a research laboratory is required to:

- Ensure that each member of his/her research group have taken the necessary safety training courses provided by the University. See **Training (Section E)** below;
- Provide and document hands-on training that is protocol specific;
- Ensure that all equipment is labeled and marked with appropriate hazard symbols;
- Maintain easy-to-access copies of SDSs for materials used in their procedures;
- Keep an up to date laboratory door sign, including emergency contact information; and
- Complete and annually review the laboratory's LATCH.

EH&S is available to assist with the identification, evaluation and control of laboratory hazards and has created a **Laboratory Hazard Assessment Questionnaire** to help evaluate possible hazards in a laboratory. See **Annex III-A** for a sample Questionnaire. Upon receipt of the Questionnaire, EH&S will arrange a visit to your laboratory to collect additional detailed information and develop a work plan to produce the appropriate recommendations, SOPs or other information.

Signs

Each laboratory must have on its entrance door a sign identifying the room number, name and phone number of the PI overseeing the space, the appropriate hazard symbols describing the research inside, and emergency contact information.

The PI is responsible for updating the emergency contact information for his/her space as personnel change. This information is updated on the physical door sign and in the LION database below the laboratory roster. All emergency contact numbers must be 24-hour accessible, such as a cell phone number, and cannot be a daytime only or office line. It is recommended that the primary emergency contact be the PI; however, this is not required. The emergency contact selected should be knowledgeable about the research materials and equipment inside the space, and ideally live near to campus to facilitate liaising with emergency response staff. Emergency contacts can differ from room to room depending on the research conducted inside.

Samples of **laboratory door signs** utilized at CUIMC and the non-CUIMC campuses are attached hereto as **Annexes III-B and III-C,** respectively.

Examples of **Hazard Symbols** are attached hereto as **Annex III-D.**

Labels

By adopting the GHS, OSHA now requires that hazard communication labels contain the following features: product identifier, supplier information, precautionary statements, hazard pictograms, signal word, hazard statements and supplemental information. For a comprehensive list of label components and descriptions, see http://www.osha.gov/Publications/OSHA3636.pdf. See also the **GHS Information Sheet** attached hereto as **Annex III-E.**

Commercial suppliers of chemicals must label chemical containers with the chemical name, hazard information and safe storage conditions. These labels must never be defaced or obstructed unless an emptied and rinsed container is to be used for another purpose. Chemicals produced within laboratories must be labeled in English to meet these requirements.

When chemicals are transferred from primary, labeled containers to portable, secondary containers, the NYC Fire Code requires labeling of such containers with a chemical name. OSHA may also require labeling in certain instances. It is good chemical hygiene practice to label all laboratory containers with a chemical name.

Safety Data Sheets (SDSs)

Columbia uses a subscription-based software platform, **ChemWatch**, to quickly obtain reliable hazardous material safety information and SDSs. All manufacturers are legally required to include a copy of an up to date SDS with any sale of chemicals, and ChemWatch is intended to supplement and provide easy access to this information. SDSs provide useful information about emergency aid/response measures and a chemical's constituents, hazards, exposure and controls. A hazardous chemical's SDS will identify likely routes of exposure (i.e., inhalation, skin (or eye) absorption, ingestion, and injection). In addition, other important information about the chemical manufacturer, fire-fighting procedures, PPE requirements, and spill clean-up procedures is provided.

PIs are required to maintain SDSs for all hazardous chemicals in their laboratories. This information must be readily accessible to all research staff and students. The PI must ensure that when a new product or chemical is brought into the laboratory, laboratory members are provided with the information from the SDS and are trained on the hazards of the new chemical.
To access ChemWatch, a computer must be connected to Columbia University ethernet or WiFi internet connection at this URL: https://jr.chemwatch.net/chemwatch.web/account/autologinbyip

From there, ChemWatch is fast and easy to use:

- Open the above link;
- Enter the identifying information into one of the search boxes; for example, the chemical name, the chemical's Chemical Abstract Service number **(CAS#)** or supplier/vendor name;
- Select the applicable entry from the list provided; and
- Review, print, save or send the SDS using the available icons on the screen.

4. Chemical Inventory Management – ChemTracker

PIs are required to maintain an accurate chemical inventory for their laboratories pursuant to the NYC Right to Know Law. Laboratories at Morningside, Manhattanville and CUIMC are audited annually by the City to confirm that this regulatory requirement has been met. The inventory should include relevant information about each hazardous chemical, including where it is normally used or stored. The inventory should be updated as needed, but not less than annually.

Each of the Morningside and Manhattanville campuses has a chemical inventory management program to aid with compliance and reduce the burden on laboratory staff to maintain an accurate chemical inventory on their own. By using a specified delivery address for chemicals, detailed below, hazardous chemicals entering the campus are tagged with a radio-frequency identifier (**RFID)** barcode and entered in an available online inventory system called **ChemTracker**, which PIs and laboratory groups can access. Once a package is received at the proper delivery address, EH&S manages the incoming and outgoing records. Laboratory staff are notified when chemical orders are received so that they can pick them up at the loading dock.

At this time, CUIMC, Lamont and Nevis are not supported with incoming and outgoing record updates by EH&S. Access to the ChemTracker chemical inventory software tool is freely available; however, there is no central support for record creation. PIs at these campuses are welcome to create an account and manage their records individually. Laboratories at CUIMC, Lamont and Nevis are still required to maintain their chemical inventories in a spreadsheet or other sharable method and be able to provide them to EH&S if requested. At Lamont, the LDEO Chemical Hazardous Materials Database is used and is accessible at https://www.ldeo.columbia.edu/campus-services/facilities-management/safety/chemical-inventory.

ChemTracker is accessible with Columbia UNI credentials at: https://columbia.bioraft.com/. An account is created after a PI is on-boarded by EH&S or by sending an email to chemtracker@columbia.edu.

Please visit https://research.columbia.edu/chemical-tracking-system-chemtracker for Frequently Asked Questions and a link to a ChemTracker software training guide. Any specific questions or additional training to use the ChemTracker system are available from EH&S by request.

Chemical Ordering and Delivery Addresses

For Morningside and the Jerome L. Greene Science Center **(JLGSC**) at Manhattanville**,** hazardous chemicals must be shipped to an EH&S Chemical Inventory Station at one of the campus loading docks, where EH&S will receive the chemicals, RFID tag them and enter them into ChemTracker. Chemicals and other supplies that do not meet the definition of a hazardous chemical under the OSHA regulations may be delivered directly to a laboratory and should not be sent to EH&S.

Delivery addresses for Morningside:

ChemStores Loading Dock – *(for Havemeyer and Chandler Laboratories):*
Attn: PI Name (Lab Email)
3000C Broadway 119th Street
Chandler Hall, Room 154
New York, NY 10027

Pupin/CEPSR Loading Dock – *(for all other Morningside Laboratories):*
Attn: PI Name (Lab Email)
530 West 120th Street
Pupin 200
New York, NY 10027

Delivery address for JLGSC:

Columbia University
EHS Loading Dock – c/o "Insert Lab Name Here"
612 West 130th Street
New York, NY 10027

Discarding Empty Chemical Bottles

At Morningside, empty chemical bottles should be rinsed, defaced of their labels and discarded in the hallway yellow bins. This is the process by which a PI's inventory is updated to reflect chemical containers no longer in the laboratory. At JLGSC, the empty chemical containers are placed in the recycling receptacles in the laboratory provided by Facilities Operations. When the

chemical bottles leave the loading dock, the RFID tag is detected, and EH&S updates the inventory records.

At CUIMC, Lamont and Nevis, empty chemical bottles should be rinsed, defaced of their labels and discarded in a laboratory recycling container.

For more information about chemical waste disposal, see **Hazardous Waste Management and Disposal (Chapter IV).**

E. Training

EH&S offers online and instructor-led safety training sessions. Safety training records for both classroom attendees and online participants are maintained through Rascal, available at www.rascal.columbia.edu.

The EH&S training courses cover basic hazard identification, controls and emergency response, but do not replace protocol-specific instruction. Laboratory-specific and task-based training is required to be provided by the PI and/or an experienced senior level laboratory staff member. If you have questions about safety training, please contact safetytraining@columbia.edu for assistance.

Laboratory safety training courses are outlined below, including the training name, Rascal course number, training description, refresher training requirements, etc. Trainings relating to subjects other than Research Safety can be found elsewhere in this Handbook or in the other Handbooks published by the Office of the EVPR.

For a complete list of safety training courses, see **Determining Your Safety Training Requirements @ Columbia University** attached hereto as **Annex III-F.**

1. Laboratory Safety/Chemical Hygiene/Hazardous Waste Training

All University personnel and students using hazardous materials in a laboratory setting are required to complete the Laboratory Safety, Chemical Hygiene and Hazardous Waste Management training. This training covers responsibilities for safety in the laboratory environment, types of safety hazards, routes of exposure and preventive control measures, including engineering controls in the laboratory and PPE, emergency response procedures, chemical spill response, fire safety and fire response procedures and hazardous materials and chemical waste management.

The initial training must be taken during one of EH&S' regularly scheduled classroom sessions. Attendees can complete the training at CUIMC or Morningside throughout the year; no pre-registration is required. The link for the schedule is https://research.columbia.edu/safety-trainings. Additional on-campus training sessions are offered annually and semi-annually at Nevis and Lamont, respectively.

Attendees at the classroom training will receive credit for *TC4951: Laboratory Safety, Chemical Hygiene and Hazardous Waste Management Initial Classroom Training.*

Refresher training is required every two years, and may be completed by either re-taking the regularly scheduled classroom sessions or taking the Rascal online course *TC0950:Laboratory Safety, Chemical Hygiene and Hazardous Waste Management Refresher Training.*

2. Shipping with Dry Ice, Exempt Specimens, and Excepted Quantities of Dangerous Goods

Dry ice, when used to refrigerate samples being transported by air, is considered to be a "Dangerous Good" under the US DOT and IATA regulations. Personnel using dry ice must take the Rascal online course *TC0076: Shipping with Dry Ice, Exempt Specimens, and Excepted Quantities of Dangerous Goods* and pass a test with a score of 80% or better. PIs must also take this course even if staff are sending packages on their behalf. The course covers dry ice regulations and safety, biological materials classification, packing instructions, packaging material, package marking and labeling, documentation, package security, international shipping, record retention and inspections, and intercampus transport.

Refresher training is required every two years and may be completed by retaking *TC0076: Shipping with Dry Ice, Exempt Specimens, and Excepted Quantities of Dangerous Goods.*

3. Shop Safety Training

University personnel and students working in a machine shop or other area with machinery are required to take the Rascal course *TC0600: Shop Safety Training* and pass a test with a score of 80% or better. Personnel working with a particular machine must also receive machine-specific training provided by their department before use.

Shop Safety Training provides a basic overview of hazards associated with the use of hand and power tools that are found in academic machine shops. The training covers types of hazards, general shop safety rules, ways to keep the shop clean, and use of safe work practices and proper PPE for a given task. This training, however, is not a substitute for a machine-specific operation and safety training, which must be provided by an appropriate supervisor before researchers or students use any machine in the shop.

Refresher training is not required; however, machine-specific training frequency is determined by the department managing the shop.

4. Pyrophoric Materials Training

All pyrophoric materials users and any University personnel who are members of a laboratory group that uses or stores pyrophoric materials are required to take Rascal course *TC1850: Pyrophoric Materials Training* and pass a test with a score of 80% or better.

This training provides a basic overview of pyrophoric materials and associated hazards, including video content showing spontaneous ignition, basic handling and control measures, storage and disposal procedures and emergency response. This training, however, does not replace chemical-specific handling techniques. Bench-top training must be provided by a supervisor or knowledgeable senior member of the laboratory.

Refresher training is required on an annual basis by repeating the Rascal course *TC1850*: *Pyrophoric Materials Training*.

5. Hydrofluoric Acid Training

All users of hydrofluoric acid and University personnel who are members of a laboratory group that uses or stores hydrofluoric acid are required to take the Rascal course *TC1650: Hydrofluoric Acid (**HF**) Training* and pass a test with a score of 80% or better.

This training provides a basic overview of hydrofluoric acid and associated hazards, basic handling and control measures, storage and disposal procedures and emergency response. Bench-top training must be provided by a supervisor or knowledgeable senior member of the laboratory, and the faculty member must maintain a hydrofluoric acid spill kit for the laboratory that includes calcium gluconate gel.

Refresher training is required on a biennal basis by repeating the Rascal course *TC1650: Hydrofluoric Acid (HF) Training.*

6. Formaldehyde/Xylene Training

This training is required for all University faculty, staff and students using formaldehyde (i.e., paraformaldehyde or formalin solutions) or xylene outside of a chemical fume hood in quantities greater than 0.1ml.

Taking the Rascal online course *TC3750: Safe Use of Formaldehyde* and passing a test with a score of 80% or higher fulfill this requirement.

Refresher training is required annually and may be completed by retaking *TC3750: Safe Use of Formaldehyde.*

7. Chemical Storage and Segregation 101

University personnel working in a laboratory are encouraged, but not required, to take Rascal course *TC2100: Chemical Storage and Segregation 101*. This training covers the importance of

safe storage, chemical incompatibility hazards, and how to organize chemicals in a laboratory both safely and in compliance with OSHA and FDNY regulations. This is a one-time course with no refresher requirement.

8. Laboratory Autoclave and Automated Equipment Washer Safety and Hazard Awareness Training

University personnel who operate autoclaves or automated equipment washers are encouraged to take Rascal course *TC4501: Laboratory Autoclave and Automated Equipment Washer Safety and Hazard Awareness Training*. This training identifies the potential hazards associated with operating laboratory autoclaves and automated equipment washers, provides operational guidelines and risk mitigation, makes PPE recommendations and explains emergency response procedures. This is a one-time course with no refresher requirement.

F. Authorizations and Procurement

There are certain restrictions on ordering chemicals and laboratory equipment at the University.

1. Chemicals and Toxins

Laboratory chemical orders at Morningside and Manhatanville have specific delivery addresses to support chemical inventory management and are discussed under **Elements of the Columbia Research Safety Program: Chemical Inventory Management—Chemtracker (Section D(4))** above.

Research using chemicals or hazardous materials in animals must be approved by the Institutional Animal Care and Use Committee (**IACUC**). See **Preparing for a Study: Protocol Preparation – Elements of a Protocol (Chapter III, Section (C)(2))** and **Occupational Health and Safety: Working with Hazardous Agents (Chapter VIII, Section (C))** in the **Animal Research Handbook** for details.

For Dual Use Research of Concern, manufacturers have occasionally contacted the University to validate the research use for potentially suspicious purchases, e.g. organic fertilizers, prior to shipment. In these cases, the faculty member is contacted by EH&S, and the research use for the material is confirmed and relayed to the manufacturer. See **Biological Safety: Biomedical Materials Research-Dual Use Research of Concern (Chapter V, Section E(7))** for further information.

Lastly, certain biological toxins are deemed by the federal government to have the potential to pose a severe threat to public health and safety. These toxins are known as **Select Agent Toxins** and include tetrodotoxin, botulinum toxin, ricin, and Staphylococcal enterotoxins (for the full list of Select Agent Toxins see: http://www.selectagents.gov/SelectAgentsandToxinsList.html). Possession of such Select Agent Toxins, or nucleic acids that encode functional forms of the toxins, requires compliance with federal law and University policy. See **Biological Safety:**

Biological Materials Research- Select Agents and Toxins (Chapter V, Section E(6)) for more information about Select Agent Toxins.

2. Laboratory Equipment

Two types of equipment require prior approvals in ARC: refrigerators or freezers, and lasers or laser cutters. To purchase these items, the proper category code must be applied when placing the order. Each equipment type has two category codes, one numeric and one alphanumeric with the letters "CAP" to denote capital equipment. Capital equipment is defined under the University's policies as equipment/systems valued at $5,000 or more with a minimum useful life of two years.

Refrigerators and Freezers:

Purchase requests for refrigerators to be used in a research laboratory must be submitted through ARC, using the following category codes:

- Flammable material storage refrigerator or freezer: use category code 41103012, or 41103012CAP for a capital purchase
- Laboratory refrigerator or freezer: use category code 41112220, or 41112220CAP for a capital purchase

Additionally, a **Memorandum of Understanding (Refrigerator MOU)** must be submitted with the requisition for any household refrigerator or freezer. A sample MOU is attached as **Annex III-G.** The MOU acknowledges that storing flammable materials in refrigerators or freezers that are not rated for flammable storage or are not explosion proof is prohibited. The completed MOU includes a purchase order requisition number, location (building and room number) and signature of the purchasing investigator. The completed Refrigerator MOU is reviewed by EH&S prior to submission to ARC.

Improper storage of flammable materials in household refrigerators creates a safety concern as they are not designed to industrial specifications, and often contain unprotected internal wiring and components that can act as incidental sources of ignition, thus greatly limiting their capability for safe chemical storage. When flammable materials are stored in a household unit, flammable vapors can accumulate and ignite if an internal mechanism such as an interior light or a fan motor causes a spark; for this reason, no matter the quantity, concentration or duration of storage, no flammable liquids may be kept in refrigerators or freezers that are not designed and rated as either "explosion proof" or for the storage of "flammable materials." This requirement is strictly enforced by the FDNY during laboratory inspections. See also: **Fire Safety: Fire Hazards in Research Laboratories – Refrigerators and Freezers (Chapter VIII, Section F(5))**, below.

Lasers and Laser Cutters:

- Laser, including a laser cutter: use category code 41115307, or 41115307CAP for a capital purchase
- A Laser Registration Form, called an Appendix D, must be submitted along with the requisition. See **Laser Safety (Chapter VII).**

G. Protections

Working in a University laboratory comes with requirements for hazard control methods and programs for laboratory inspections and hazardous waste management. These services and resources are intended to supplement the efforts made by the PI to instill good laboratory practices. The principal protections available to laboratory members are: engineering controls, administrative practices and PPE.

Working safely in a laboratory begins with general attire. At the University, any person in a laboratory containing hazardous materials must cover the full length of their legs and feet. This applies to everyone, whether they are working with any hazards or not. It is strongly recommended that laboratory personnel keep a second set of clothes and shoes at their desk to change into as needed. Shorts, cropped pants or short skirts are prohibited in a laboratory. Likewise, sandals, open-toed shoes and shoes exposing the top of the foot such as a flat or pump must not be worn in a laboratory.

Good laboratory practices require personal clothing or the equivalent, such as scrubs, to cover exposed skin. It is important to pull back loose hair and avoid dangling jewelry, which may get caught in equipment or make incidental contact with hazardous materials.

1. Engineering Controls

Chemical Fume Hoods

The primary engineering control in the laboratory is the chemical fume hood (**CFH).** CFHs are connected to the building's HVAC system to ensure that any carcinogenic and reactive vapors are drawn into the CFH and exhausted away from the user's breathing zone. 100% of this air is vented to the outside using dedicated exhaust fans. CFHs should be used only for handling chemicals with significant inhalation hazards, such as those that produce toxic gases or vapors, volatile anesthetics (e.g., isofluorane), volatile radioactive materials, and respirable toxic powders.

EH&S personnel certify each CFH at least once annually. However, PIs and laboratory personnel may request more frequent performance checks, particularly when the fan/motor is serviced.

A CFH that is identified as not functioning properly must be reported immediately to Facilities Operations (CUIMC: (212) 305-7367; Morningside, Manhattanville and Nevis: (212) 854-2222; Lamont: (845) 365-8822) and a laboratory representative should place an "Out of Service-Do Not Use" sign on the hood.

Prior to using a CFH in any room, encourage members of the laboratory to become familiar with the locations of the nearest exit, emergency shower, eye-wash station and fire extinguisher. Ensure emergency equipment always remains unobstructed and ready to use. Experimental apparatus and chemical materials should be handled at a distance of at least six inches behind the sash opening to avoid disruption of airflow. The air inside a CFH can change when a window or door is opened and even by a change of position of the researcher at the hood. When working at a CFH, keep the sash open only to the minimum height necessary.

The vertical sliding sash is also intended to serve as a physical barrier in the event of chemical splashes within the hood. For this reason, the sash should be kept below eye level and breathing zone height to protect the user if hazardous materials escape the CFH. Everyone in the laboratory should remain alert to changes in airflow and be familiar with appropriate emergency procedures in the event of a CFH failure. All users of CFHs should report any exhaust failure to the PI and Facilities Management for repair.

For further details on CFHs, see the University's Chemical Fume Hood Policy.

Other Local Exhaust Ventilation

When hazardous chemicals cannot be used in a CFH, extractor arms and ventilation trunks may be needed to minimize exposure. Extractor arms allow for capture and exhaust of hazardous substances close to the source of use, before their release into the laboratory environment. Although not as effective as a CFH, these devices, if properly designed, installed and used, can be protective. Ventilated hazardous gas cabinets are another type of local exhaust ventilation, in which hazardous gases are stored and used to ensure segregation from the laboratory environment and ventilation of the hazardous gas in the event of a leak. Certain toxic gases must not be used without being contained in a ventilated gas cabinet. See EH&S Compressed Gas Safety Manual for further information.

Glove Box

A glove box is a sealed enclosure designed for the manipulation of highly hazardous substances in a safe manner, generally in an inert atmosphere such as nitrogen or argon. Gloves are built into its sides and arranged for the user to place his/her gloved hands into the box to perform tasks without breaking containment. The glove box is usually transparent to permit the user to see the

materials being handled inside. It is important to avoid using jewelry, watches or sharp objects when using a glove box, as they may puncture the gloves and breach containment.

2. Administrative Controls

Administrative controls encompass the habits and work practices of the laboratory members in running a given experiment and in managing the laboratory overall. These are often established through SOPs, chemical ordering thresholds and other policies specific to the laboratory work conducted, to minimize exposure risk. Setting group standards for certain experiments and documenting procedures and bench top training go a long way in the safe management of a transient research population.

Laboratory-specific SOPs should be developed by knowledgeable laboratory staff and reviewed with all laboratory personnel to ensure that the procedures are understood. The safety rules and policies set forth in the The National Academies of Sciences, Engineering and Medicine handbook, *Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards,* and those listed below can help minimize exposure to hazardous chemicals and should be employed in conjunction with laboratory-specific SOPs:

- Never eat, drink, chew gum, smoke or apply cosmetics in the laboratory;
- Select, use and maintain appropriate PPE;
- Store and segregate hazardous materials according to hazard class;
- Report unsafe conditions to a laboratory supervisor, PI or EH&S;
- Keep all work areas clean and uncluttered;
- Keep all aisles, doorways and emergency exits free from obstruction;
- Keep all emergency equipment, including fire extinguishers, fire blankets, overhead emergency showers, eye-face wash/drench hoses and chemical spill kits free from obstructions;
- Scale the size of the experiment and use the smallest amount of material necessary for the work to be done;
- Remove gloves and wash hands and arms with soap and water after removing gloves and before leaving the work area or handling common items like phones, instruments, door knobs, etc: and
- Properly manage and dispose of all hazardous substances.

3. Personal Protective Equipment (PPE)

The appropriate use of PPE is critical in reducing dermal and mucosal exposure to laboratory hazards and represents the last line of defense against potential exposure. PIs and/or Departments are responsible for purchasing and distributing PPE. PPE must be provided at no cost to applicable personnel and used whenever the potential for occupational exposure exists. In most instances, the minimum level of PPE for laboratory personnel consists of a laboratory coat, gloves, and eye protection.

The PI or laboratory manager is responsible for conducting a PPE hazard assessment. In performing this assessment, EHS' PPE Hazard Assessment Tool for Laboratory Activities can be used. EH&S is responsible for assisting laboratories in completing PPE hazard assessments and training laboratory personnel.

See the University's Policy for Personal Protective Equipment in Research Laboratories for additional information.

Laboratory Coats

A laboratory coat is required to be worn by all personnel in a laboratory whenever there is the potential for dermal exposure to hazardous materials. The PI and/or Department is responsible for providing laboratory coats and a means to launder them. A current list of approved vendors to buy or rent laboratory coats and launder them, can be found on the University's Finance Portal at http://finance.columbia.edu/content/uniforms. An alternative laundering option chosen by some Departments is to install a washer and dryer to facilitate onsite laundering. Installation of a washer and dryer must be completed with the assistance of Facilities Operations.

Laboratory coats must be selected to fit the individual, and new laboratory members should not inherit an unwashed laboratory coat, or a laboratory coat that is too big or too small. A good rule of thumb is to assign three laboratory coats per person in his/her size. Having three allows one to be worn by the individual, one to be kept in the laboratory as a backup in the event of an incidental spill or contamination, and one to be currently in the laundry. Laboratory coats must be changed immediately if they become contaminated and must not be worn outside of the laboratory. Grossly contaminated laboratory coats should be bagged and disposed of through EH&S as hazardous waste, and when appropriate, as radioactive waste. Laboratory coats must not be taken home for laundering under any circumstances to avoid contaminating personal clothing and home laundering equipment.

Liquid resistant aprons (vinyl or rubber, depending on the compound in use) are a good supplement to laboratory coats for activities with an elevated chemical splash potential. Fire-resistant laboratory coats made from materials such as Nomex or Kevlar are recommended for applications carrying a high risk of ignition or fire, such as those involving pyrophoric materials or large amounts of flammable materials.

Additional information on the various types of laboratory coats and the selection criteria for each can be found in EHS' Lab Coat Information Table.

Eye Protection

Eye protection is always required when handling hazardous materials. Eye exposure and eye injury can occur even at small volumes. A good rule of thumb is that if the material can burn or damage your eyes, eye protection is required when handling the material. This includes laboratory use of ultraviolet and other harmful radiation, in addition to solid, liquid and gaseous materials.

Provision of eye protection is the responsibility of the PI and/or Department and must fit the individual.

Safety glasses provide the minimum protection against chemical hazards, and for individuals who wear prescription glasses, safety glasses must be provided. When working with large amounts of hazardous materials, or when there is a significant splash risk, tight-sealing safety goggles with a face shield are recommended. Face shields may be indicated, either alone or in combination with other forms of eye protection, for procedures with a greater risk of injury or exposure to the face. Eyeglasses and contact lenses do not offer an appropriate level of splash or impact protection.

The American National Standards Institute (**ANSI**) has criteria and testing for eye protection under Standard Z87.1-2003, *Occupational and Educational Personal Eye and Face Protection Devices*. All eyewear meeting this standard are marked with "Z87+" on the eyewear.
For some research, such as that using lasers, specialty eye protection is required and must match the wavelength of the exposure. See **Laser Safety (Chapter VII)** for additional information on laser eye protection.

Hand Protection

PIs are responsible for providing hand protection to all members of their laboratories. Gloves are made in a variety of materials, and there is no one glove for all chemical hazards. As chemical hazards shift in the laboratory, glove choice should be reassessed to confirm that it is still appropriate for the particular application.

For most laboratory work, a nitrile glove is enough to create a thin skin barrier that allows the soiled glove to be removed and replaced before skin contact occurs. The University discourages the use of latex gloves due to skin sensitization and increasing number of cases of latex allergy. Gloves are often disposable, and not intended to be impermeable. Common glove manufacturers, such as Ansell, Marigold and VWR, publish glove guides for chemical compatibility and breakthrough times with their product lines.

Common examples of reusable gloves include cryogenic gloves and heat resistant gloves. Cryogenic gloves, for use when handling dry ice or cryogenic liquids, are insulated to prevent burns from extreme cold temperatures. They have different properties from gloves designed for hot temperatures. Cryogenic gloves with mid-arm or longer protection are recommended for transferring cryogenic liquids. Heat resistant gloves are made of absorbent fabric and should never be used to handle cryogens.

Additional information on various types of gloves and selection criteria for each can be found at https://research.columbia.edu/personal-protective-equipment-ppe

4. Handling Peroxide-Forming Chemicals

Over time, some chemicals have the potential to form peroxides that may present fire and explosion hazards. Due to the uniquely hazardous nature of peroxide-forming chemicals, the FDNY regulates their storage and handling.

The University manages time-sensitive chemicals following FDNY requirements. As part of the RFID barcoding program described in **Elements of the Columbia Research Safety Program: Chemical Inventory Management – ChemTracker (Section D(4))** above, bottles of peroxide-forming chemicals at Morningside and Manhattanville are tagged prior to delivery with a green sticker as a reminder to the researcher to date the bottle at the time of opening and test for peroxides every six months. The test results should be noted on the sticker. A sample **Peroxide Sticker** is attached hereto as **Annex III-H.** Bottles of peroxide-forming chemicals at CUIMC are also regulated by the FDNY and researchers must date and test all peroxide-forming chemicals despite the absence of a sticker.

The most common peroxide-forming chemicals cited in violation of proper testing or dating by the FDNY are:

- Acetaldehyde
- Diethyl ether
- Dioxane
- Ether
- Methyl methacrylate
- Tetrahydrofuran

5. Unattended Operations

The operation of laboratory equipment overnight or otherwise unattended is strongly discouraged, and when necessary for research procedures, special attention must be paid to it. The risk, along with the magnitude, of fire, flood, or hazardous material release associated with such operations, is greatly increased, compared to similar operations under regular observation. In the event of an emergency, such operations pose challenges for Public Safety, Facilities Operations, EH&S and other responding personnel who may have difficulty reaching responsible laboratory staff. When unattended operation of equipment is necessary, the researcher must:

- Post an **Unattended Operation of Equipment** Sign, a sample of which is attached as Annex III-I, on the exterior laboratory door describing any unattended process that might cause a hazardous condition if there is an experimental equipment or building services failure. The sign must include contact numbers for responsible parties, should the equipment or building services fail and cause a hazardous condition while unattended. The sign should be put on all doors where unattended work and/or equipment is located.
- Please contact an EH&S Safety Advisor to register unattended operations and for further information.
- Ensure that hose connections are secure, electrical and other connections pose minimal risk of accident, and proper drainage for operations requiring running water is provided.

6. Working Alone or During Off-Hours

Working with chemicals alone, at night, or otherwise in isolation, places individuals at special risk and should be avoided whenever possible. The PI is responsible for ensuring that employees and students perform only those tasks for which they are qualified by training and experience, especially during off-hours when they may be unsupervised or unaccompanied. PIs must also define for their staff any prohibited activities for laboratory personnel working alone or during off-hours, based on the hazard of the materials used or the activity performed. All personnel working alone in the laboratory must hold an applicable FDNY Certificate of Fitness. See **Fire Safety (Chapter VIII)** for additional information on Certificates of Fitness.

H. Chemical Storage and Segregation

Proper storage of chemicals in laboratories is a critical safety concern. Chemicals that have been stored improperly could react, forming hazardous products or resulting in a fire. Follow good storage practices no matter where the chemicals are stored (e.g., in cabinets, refrigerators or shelves). Carefully read the SDS and container label before storing a chemical as these will indicate any special storage requirements, as well as incompatibilities.

EH&S has developed a helpful Chemical Segregation and Storage Chart (**CSSC),** a copy of which is attached as Annex III-J, that delineates the class of chemical, the recommended storage method, examples of the chemical and incompatible substances**..**

See also: **Fire Safety: Fire Hazards in Research Laboratories (Chapter VIII, Section F).**

Good storage practices include the following:

- Chemicals should be segregated in accordance with good practice and the CCSC;
- Chemicals should be stored in approved, compatible containers;
- Chemicals should be stored below eye level with heavy objects stored on lower shelves;
- Corrosives should not be stored on bare metal shelves and should be stored in plastic storage bins or shelves or on metal shelves that have been covered with protective, plastic-backed paper (e.g., Bench-Kote); and
- When practical, chemicals in the same hazard class should be stored in corrosion-resistant secondary containers.

I. Transport and Shipment of Hazardous Materials

Researchers must be aware of and adhere to requirements governing the transport or shipment of hazardous materials. Nearly all laboratory chemicals are subject to these requirements. Accordingly, any researcher wishing to personally transport, or send via commercial carrier, any hazardous material, must comply with the requirements outlined below.

According to the US DOT regulations, a "hazardous material" (a **DOT Hazardous Material)** is any substance that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety and property when transported in commerce. This includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, materials designated as hazardous in the Hazardous Materials Table in 49 CFR 172.101 and other materials that meet the defining criteria for hazard classes and divisions in 49 CFR 172, Subchapter C, D and I (the **DOT Hazardous Material Regulations).**

The term DOT Hazardous Material is used for domestic shipment by motor vehicle or rail. The synonymous term when referencing multi-modal transport (air, water or international transport by motor vehicle or rail) is a "dangerous good" (a **DOT Dangerous Good).** This section only addresses DOT Hazardous Materials and DOT Dangerous Goods in the context of shipment by laboratory personnel of samples, unique chemical reagents, equipment containing hazardous materials or chemicals for analysis.

A DOT hazard class (**DOT Hazard Class)** is the category assigned to a material under the DOT Hazardous Material Regulations. A material may meet the defining criteria for more than one hazard class, but is assigned to only one DOT Hazard Class. There are nine DOT Hazard Classes, only some of which are applicable to laboratory chemicals. See the DOT Hazardous Material Regulations for a description of the DOT Hazard Classes and other information.

Specific packaging, labeling, marking and shipping documents, as well as training, are required for the transportation of DOT Hazardous Materials and DOT Dangerous Goods.

Transport of hazardous materials within a laboratory or between locations on campus must be accomplished using secondary containers and/or utility carts. Secondary containers can be made of rubber, metal or plastic, and should be large enough to hold the contents of the primary container and must not be made of a material that would react with the hazardous material being transported. These containers are available commercially through laboratory equipment suppliers and should be standard laboratory equipment. At Morningside, a limited supply of secondary containers is available on loan from the Biological Stock Room in Pupin and the ChemStore in Chandler.

Before moving any compressed gas cylinder, ensure that the valve is protected by securing the cap to the cylinder and securely strapping the cylinder to a cylinder cart.

The following items and hazardous substances should be transported via freight elevators and not via passenger elevators:

- Hazardous chemicals and samples, including dry ice;
- Chemicals in open containers;
- Compressed gas cylinders and cryogenic liquids; and
- Laboratory items requiring the use of a cart or hand truck.

The packaging, documentation and transportation of DOT Hazardous Materials or DOT Dangerous Goods by air, ground or water is regulated by the Federal Aviation Administration **(FAA),** the IATA**,** the US DOT and the International Maritime Dangerous Goods **(IMDG)** Code**.** These regulations may also apply to inter-campus transportation and shipments on public highways.

In order to perform any function associated with the transportation of DOT Hazardous Materials or DOT Dangerous Goods, individuals must be appropriately trained. Researchers planning to send a shipment that may contain DOT Hazardous Materials or DOT Dangerous Goods must first determine the nature of the hazard. EH&S has developed resources (https://research.columbia.edu/shipping-hazardous-materials) that can be used as a starting point for determining the proper shipping procedures and subsequently what steps should be taken to begin the shipping process. Based on the results of a preliminary classification, researchers may be directed to complete specialized training prior to sending the materials to the shipper. See **Training: Shipping with Dry Ice, Exempt Specimens and Excepted Quantities of Dangerous Goods (Section E(2))** above**.** Researchers may also be required to complete EH&S' Intent to Ship Hazardous Materials Form and submit it to EH&S for further instruction.

J. Laboratory Design and Construction

The University's Capital Projects Management (**CPM)** groups, based at CUIMC and Morningside, are the primary coordinators of laboratory renovation and construction projects. Any PI or other research group representative wishing to initiate a project within his/her laboratory should first contact his/her respective CPM team below to determine whether the work will necessitate a formal project scope.

- **Morningside/Manhattanville**: https://facilities.columbia.edu/capital-project-management
- **CUIMC:** https://www.cumc.columbia.edu/facilities-management/requesting-capital-project
- **Lamont:** Contact the office of the Assistant Director of Facilities and Engineering, at (845) 365-8843.
- **Nevis**: https://facilities.columbia.edu/capital-project-management

Laboratory relocations, renovations involving alteration of the laboratory's physical blueprint, significant cosmetic improvements, and other "major" installation work will generally be coordinated through the applicable campus' CPM team or its equivalent. Alternatively, certain routine maintenance, appliance installation, minor infrastructure or utility upgrades or other similar activities are examples of work that generally would be completed by the applicable campus Facilities Operations team and not likely require CPM engagement; when in doubt, contact CPM for guidance.

EH&S is an active participant in laboratory capital projects. From design, preparation and active project work, through completion and project closure, guidelines exist that are intended to inform

choices and expectations for successful project execution. These guidance documents, manuals and other instructions are relevant to a project's three phases: pre-construction, active construction and post-construction, and are variously supported and carried out by the relevant CPM team and laboratory staff.

1. Pre-Construction

For PIs and laboratory staff, the pre-construction phase primarily involves a variety of important design choices, as well as preparation of the existing laboratory for the project. All laboratories are required to meet the requirements of the NYC Fire Code, as well as other applicable standards promulgated by local, state and federal authorities. These design requirements are spelled out in the University's Laboratory Design Guidelines (**Laboratory Design Guidelines)** and are to be followed for all laboratory projects. Importantly, the Guidelines specify the permissible choices for critical safety and emergency equipment, including CFHs, overhead emergency showers, eyewash/deluge hose devices and other equipment.

In addition to equipment choice, suitability of purpose is also carefully considered during the pre-construction design period. For example, the proposed project site must be evaluated for its capability to provide the requisite ventilation, plumbing and other utility requirements, and storage to support the laboratory occupants' research. Likewise, space for the expected number of occupants and their work requirements should be considered at this time, as well as the need to provide safe and hygienic areas for non-laboratory activities (e.g., computational work, storage and consumption of food and beverages and storage of personal items). It is critical that these functional and infrastructural requirements be clearly communicated to the CPM team during this phase.

Among the critical items to be evaluated during pre-construction that the laboratory occupants must consider and clearly communicate to the CPM team are:

- **Environment**: The space and design must be able to support any requirements for temperature, humidity, vibration or other environmental conditions that may impact the work.
- **Layout**: Laboratories should be designed to properly route foot traffic away from critical ventilation infrastructure, and to ensure adequate aisle space for egress and access.
- **Storage**: Consideration should be given to ensure that storage areas are adequate to accommodate laboratory needs and are compliant with all code requirements.
- **Electrical**: The need for sufficient numbers and types of outlets should be evaluated by the CPM team to ensure that laboratory occupants do not use extension cords for permanent wiring installations. Specialized need for emergency power (i.e., generator back-up) must be evaluated by the CPM team. Researchers must inform the CPM team if isolated grounding mechanisms are required.
- **Plumbing**: The distribution of compressed gases via manifold systems, as well as any needs for reverse osmosis/deionized water, should be communicated to the CPM team prior to construction.

During a relocation, laboratories are responsible for a variety of tasks to prepare their existing space for construction, and safely and securely managing their stocks of hazardous materials, including:

- Determining which items (including chemicals, biological samples, radiological sources, Controlled Substances, and other hazardous materials) will remain, be moved or be discarded;
- Cleaning laboratory equipment in accordance with the EH&S Clearance Requirements, which outline procedures to ensure that contamination-prone equipment is safe to handle; and
- Contacting EH&S for assistance with coordinating services for specialty items, including compressed gas cylinders, biological safety cabinets, microscopes, etc.

Finally, the safety and protection of the construction team are addressed during the pre-construction period via the completion of the University's Procedures for Vacating a Laboratory. See **Laboratory Vacating and Closure (Section K)** below.

2. Active Construction

Once under active construction, the laboratory, or portion(s) thereof, are generally closed to all personnel except the construction team, CPM team, and other associated support personnel. PIs should remain in regular contact with the CPM team throughout construction, to advise of any changes to the project scope or other scenarios that may result in project modification.

3. Post-Construction

Laboratory activity may resume in renovated spaces following the completion of a Laboratory Commissioning Checklist. As the project nears closure, EH&S will arrange for a walkthrough with the CPM team, necessary contractors, and laboratory personnel to verify that safety-related items have been adequately addressed and that the laboratory meets all requirements for FDNY permitting. See **Fire Safety (Chapter VIII).** The CPM team is responsible for assembling all relevant paperwork necessary to obtain the laboratory permit, as specified in the Laboratory Commissioning Checklist. EH&S will also verify that safety and emergency equipment have been installed, tested as necessary, and are properly functioning. With guidance from the laboratory occupants, EH&S will provide necessary signs and labels for storage areas, exterior laboratory emergency contact cards, and specialized signage for radiation use areas, for example.

K. Laboratory Vacating and Closure

Prior to departure from or closure of a University laboratory, PIs are required to follow the University's Procedures for Vacating a Laboratory.

Whether planning a renovation, relocation or departure, vacating and/or relocating a University laboratory requires significant coordination and advance planning. Faculty and laboratory

personnel serve a primary role in helping to ensure that laboratories are left in a safe condition suitable for re-occupancy or renovation. EH&S works closely with PIs and laboratory staff, as well as with Facilities Management, to help prepare for the safe and efficient turnover of laboratory space, including shared equipment and tissue culture rooms.

The responsibilities of the PI in coordinating a laboratory move or departure include:

- A request must be submitted to EH&S to remove all chemical waste.
- Remaining chemical inventory must be relocated safely through a licensed chemical moving company
    - Intrabuilding moves can be achieved with PPE and sturdy laboratory carts with raised edges
    - EH&S is available to provide recommendations for chemical moving companies
- Arrangements for the proper disposition of Controlled Substances must be made. See **Controlled Substances** (**Chapter X**).
- Laboratory equipment that is to be left in place, moved, sold as surplus, or disposed of must be decontaminated with 10% bleach or 70% ethanol; notify EH&S so the items can be tagged.
- Biohazardous waste must be disposed of in accordance with the requirements described in **Biological Safety (Chapter V).**
- All debris should be removed from CFHs, bench tops and laboratory work surfaces. Bench tops, furniture, other surfaces, laboratory hoods, storage cabinets, and other fixed equipment should be cleaned and disinfected with freshly prepared 10% bleach and 70% ethanol solution.

Contact EH&S for the clearance statement for equipment and spaces, verifying that the space and all of its equipment are safely prepared.

If the laboratory uses radioactive materials**,** additional steps are required, including testing performed by EH&S to confirm that no radioactive contamination exists. See **Radiation Safety (Chapter VII)** and **Laboratory Clearance (Chapter IX)** in the **Research Radiation Safety Handbook** for more information.

It is essential that coordination of this process begin as soon as it is known that a move or departure will occur. EH&S performs a “clearance” of the laboratory space once the PI and laboratory group have completed the action items above. EH&S clearance enables the applicable Department and/or Facilities Operations to proceed with renovation or re-occupancy.

L. Laboratory Emergencies and Chemical Spills

1. Emergencies

When an emergency occurs in a laboratory, the first decision to make is whether additional support is needed. If anyone has been injured or exposed to a hazardous material, additional

support is required. Following the chart shown below, the first call is to Public Safety. Once contacted, Public Safety can triage with EH&S, emergency medical services, and local police as necessary.

When calling Public Safety in an emergency, be prepared to give the following information:

- Your name and UNI
- Callback number
- Building and room number
- If anyone is injured
- If applicable, the full chemical name (spelled out) and volume spilled

Have a member of the laboratory who is knowledgeable about the incident and materials in the laboratory available to provide information to emergency personnel.

The following chart lists the emergency contact numbers for Public Safety and EH&S:

Reporting a Laboratory Emergency		
Campus	**Public Safety (Emergency)**	**Environmental Health & Safety (Emergency)**
CUIMC	(212) 305-7979	(212) 305-6780
LDEO	X555 (Campus Phone) (911 – Fire/Injury)	
Morningside	X99 (Campus Phone) (212) 854-5555	(212) 854-8749
Manhattanville	(212) 853-3333	
Nevis	(914) 591-2870 (Campus Security)	
Barnard	(212) 854-6666	(212) 854-8749
NSYPI	(646) 774-5555	(212) 305-6780

2. Chemical Spills and Exposure

Laboratory personnel must know what procedures to follow in the event of a chemical spill. Chemical spills can be **manageable** and independently handled by laboratory staff, or **unmanageable** and require clean-up support from EH&S.

Manageable spills are spills that do not spread rapidly, do not seriously endanger people or the environment, and can be cleaned up safely by laboratory personnel familiar with the hazardous properties without the assistance of EH&S. All other spills are considered to be unmanageable spills.

Manageable Chemical Spill Procedures

- Alert people in the immediate area. Avoid breathing vapors and quickly determine which chemical has been spilled and the quantity spilled.
- Consult the applicable SDS for hazardous properties of the chemical and what substances the chemical is incompatible with, and don appropriate PPE (safety glasses, gloves, long sleeve lab coat).
- If the spill involves a flammable liquid, turn off all ignition and heat sources.
- If the spill involves finely divided solids such as nitrates, permanganates or perchlorates, they should not come into contact with combustible materials such as wood or paper, or reducing agents. Use a scoop or dustpan and hand broom to collect the solids in a plastic bag. Use an appropriate solvent to clean up any residue.
- Attend to any persons contaminated by chemicals by removing contaminated clothing, and when feasible, flushing the affected body area with water. A Human Resources incident form should be completed and the individual referred to emergency medical services.
- Confine spill to a small area. Absorb and neutralize the spill with appropriate material and create a dam around the perimeter. Use the appropriate spill kit or sodium bicarbonate for acids; citric acids for caustics; and vermiculite, dry sand, or diatomaceous earth for other chemicals. The residue should be placed in a container, labeled and disposed of as hazardous waste through EH&S.
- Clean spill area with soap and water.

With any spill, notify the Laboratory Manager and/or the PI. EH&S must be notified of any release of chemicals, even if deemed manageable.

Unmanageable Chemical Spill Procedures

- Do not attempt to clean up an unmanageable spill.
- Alert people in the immediate area. Avoid breathing vapors and quickly determine what chemical has been spilled and the quantity of material spilled.
- Consult the applicable SDS for the chemical's hazardous properties and what substances it is incompatible with, and don appropriate PPE (safety glasses, gloves, long sleeve lab coat).

- If the spill involves a flammable liquid, turn off all ignition and heat sources.
- Evacuate all personnel and close all doors leading to affected area. Keep all personnel away from affected area until EH&S can evaluate the situation. Attend to any persons contaminated by chemicals by removing contaminated clothing, and when feasible, flush the affected body area with water.
- Call EH&S and Public Safety for assistance and notify the Laboratory Manager and the PI.
- After hours spills should be immediately reported to Public Safety, which will contact EH&S for instructions. Be prepared to give the name of the chemical, the volume spilled, the location (building and room) and any other pertinent information.
- Ensure that a person knowledgeable about the incident is available to provide information to emergency personnel.

3. Chemical Spill Kits

All laboratories should have access to a chemical spill kit, capable of controlling a spill of any hazardous material used in the laboratory. A spill kit can be assembled by the laboratory and should include an organized collection of absorbent pads, corrosive neutralizers, handheld broom and dustpan, etc., or can be purchased from a laboratory supply company. All laboratory personnel should be familiar with the kit's storage location and use.

4. Emergency Drench Equipment

Eye-Face Wash/Drench Equipment

Laboratories where hazardous substances are used or stored should be equipped with an eye-face wash/drench hose as detailed in the Laboratory Design Guidelines. These devices are intended to provide a continuous stream of clean, flushing fluid to rinse the eyes or body in the event of a hazardous substance exposure. Laboratory personnel must perform a weekly test by activating the device for a period long enough to verify operation and ensure that clean flushing fluid is available.

Overhead Emergency Shower

Laboratories where hazardous substances are used or stored should be equipped with an overhead emergency shower as detailed in the Laboratory Design Guidelines. These devices are intended to provide a continuous stream of clean, flushing fluid to rinse the body in the event of a hazardous substance exposure. Facilities Operations is responsible for performing an annual test of all emergency showers.

5. Emergency Medical Services by Campus

The following are the locations for emergency medical services for each campus:

- **Morningside and Barnard:**
  - During Business Hours for **Staff and Students**: Student Health Services (**SHS**), John Jay Hall, 4th Floor, 519 W. 114th St., (212) 854-7426
  - After Hours (or for life-threatening emergencies): Mount Sinai Morningside Hospital Emergency Room, 1111 Amsterdam Avenue at 114th Street, (212) 636-3375
- **Manhattanville:** Harlem Hospital, 506 Lenox Avenue, (212) 939-1000
- **CUIMC:**
  - During Business Hours for **Staff:** Workforce Health & Safety (**WH&S**) – Harkness First Floor, (212) 305-7580
  - During Business Hours for **Students**: SHS – 100 Haven Avenue, (212) 305-3400
  - After Hours: NYP Emergency Department – Broadway & 167th Street
- **Lamont:** Nyack Hospital, 160 North Midland Ave., Nyack, (845) 348-2000
- **Nevis:** St John's Riverside Hospital Dobbs Ferry Pavilion, 128 Ashford Ave, Dobbs Ferry (914) 693-0700
- **NYSPI:** NYP Emergency Department – Broadway & 167th Street

For a comprehensive guide to emergency procedures, see https://research.columbia.edu/sites/default/files/content/EHS/Homepage/EmergencyProceduresTable.pdf

IV. HAZARDOUS WASTE MANAGEMENT AND DISPOSAL

A. Introduction

Proper management and disposal of chemical waste, including materials regulated as "hazardous waste" by the EPA, is an essential component of the University's overall commitment to environmental stewardship. This Chapter applies to waste management and disposal in laboratory research operations, including chemical waste disposal, chemical recycling and laboratory glassware recycling programs managed by EH&S. Although PIs and their associated research laboratories are not required to directly fund the disposal of hazardous waste, it is expected that waste is to be managed in accordance with all federal, state, and local regulatory requirements under the guidance of EH&S.

B. Regulatory Framework

Hazardous waste is regulated under RCRA, with its requirements enforced by the EPA, and in New York State, by the NYS DEC.

1. Resource Conservation and Recovery Act (RCRA)

Enacted in 1976, RCRA (42 USC 6901 et seq) is the principal federal law governing the disposal of solid and hazardous waste. Its primary goals are (a) the protection of human health and the environment, (b) the conservation of energy and national resources, (c) the reduction of the amount of waste generated and (d) the management of waste in an environmentally sound manner. RCRA established three distinct, yet interrelated, programs: the solid waste program, the hazardous waste program and the underground storage tank program.

RCRA regulations apply to generators of hazardous waste. A generator (**Generator)** is defined as "any person, by site, whose act or process produces hazardous waste" (40 CFR 262.10). Under this definition, the University is a Generator and any individual (i.e., a researcher or EH&S staff member) who is part of the "person" is also subject to RCRA.

Regulations (40 CFR 262, Subpart K) (**Subpart K)** intended to improve the environmental impact of teaching and research laboratories owned by eligible academic institutions were passed in 2008. However, the requirements in Subpart K are optional and universities and other academic institutions have the choice of managing their hazardous wastes in accordance with Subpart K or remaining subject to the existing generator regulations. The University has opted not to follow the Subpart K standards.

EPA's 2018 Hazardous Waste Generator Improvement Rule requires laboratory personnel generating chemical waste to make and document an accurate hazardous waste determination at the point of generation, which under the RCRA regulations is called a **satellite accumulation area (SAA)**, and indicate the chemical hazards on each hazardous waste label. Laboratories are permitted to accumulate up to certain amounts of waste in SAAs, so long as they comply with the requirements outlined in 40 CFR 262.15. See **Management of Laboratory Waste (Section E)** below.

RCRA gives the EPA, operating through the Office of Resource Conservation and Recovery **(ORCR)**, the authority to control hazardous waste from "cradle to grave". Thus, the law and regulations apply from the moment the chemical waste is generated in a laboratory, through its onsite collection, storage, shipment, processing or recycling and to its ultimate disposal or end product use. Therefore, the University is ultimately always responsible for the proper end disposal of chemical waste despite its shipment offsite to a permitted treatment, storage or disposal facility.

If waste is not managed in accordance with regulatory requirements, the EPA may enforce compliance through administrative actions, civil actions and criminal violations including financial penalties.

2. New York State

When RCRA was first enacted, Congress's intent was to allow the states to be responsible for its implementation. In New York State, the NYS DEC is authorized to implement and enforce the RCRA regulations and is thus New York is an "authorized RCRA agreement state". Any new federal requirement under RCRA must first be adopted by the NYS DEC before it is applicable to New York State institutions or persons. Any state may, however, implement more stringent requirements than those under the federal regulations.

Inspection of facilities that manage hazardous waste is a NYS DEC activity that protects human health and the environment. The inspection program is coordinated by the RCRA Compliance and Technical Support Section located at the DEC Central Office in Albany, and is implemented by trained inspectors in the nine DEC Regional Offices. The DEC conducts approximately 700 inspections annually (See:https://www.dec.ny.gov/chemical/8773.html).

3. New York City

The New York City Department of Environmental Protection (**NYC DEP**) has strict regulations regarding materials that may and may not be discarded into the city's sewer systems via drain discharge. These requirements are outlined in 15 RCNY Title 15, §19-03 (**RCNY Title 15)**. Relevant highlights include specific discharge limits on metals, solvents, certain chemical compounds and upper and lower pH limits for wastewater. Additionally, RCNY Title 15 bans dilution as a means to treat waste prior to sewer discharge. Accordingly, EH&S has

implemented a strict No Drain Disposal policy, that prohibits disposal, via a drain, of any laboratory chemical.

In summary, all hazardous wastes that are specifically listed or characteristically hazardous in accordance with RCRA regulations must be collected and properly disposed through EH&S. The NYC DEP prohibits the discharge of chemical wastes that are specifically listed or characteristically toxic, corrosive, reactive, or flammable into any sanitary sewer system within the five boroughs of New York City. Similar drain discharge regulations are applicable to Rockland and Westchester counties, where Lamont and Nevis, respectively, are located.

RCNY Title 15 also outlines the "Best Management Practices Plans for Persons Discharging Total Silver Halide Process Wastewater to the Public Sewer System". This regulation is specific to dental facilities and dark room applications where photo processing occurs. EH&S has implemented a silver recovery and recycling program that includes training and resources available to laboratory personnel. More information on this program may be found on the EH&S website for silver recovery at https://research.columbia.edu/content/silver-recovery. EH&S encourages laboratory personnel to consider digital processing in lieu of traditional photo processing methods.

C. Roles and Responsibilities

1. PIs

It is the responsibility of each PI to ensure that his/her laboratory is in compliance with all federal, state and city regulations pertaining to hazardous waste management and hazardous materials shipping. See **Management of Laboratory Waste (Section E)** below for technical details to ensure compliance with waste management regulations. Additional assistance regarding compliance is available from EH&S through training, laboratory surveys and laboratory consultations. PIs are responsible for the following waste management and chemical transportation program elements:

- Ensuring that they and their laboratory personnel who generate, manage or collect chemical waste are trained initially and refreshed biannually in waste management. Notifying EH&S of unmanageable spills of hazardous waste that result in waste generation that may require immediate collection due to space or collection container needs. Payment of shipping costs associated with hazardous materials shipments.
- Consulting with EH&S prior to generating a new waste stream or beginning a research project regarding new waste generation, and
- Implementing recommendations by EH&S regarding where substitution or elimination is strongly advisable due to either unsafe waste collection or management issues, or excessively high disposal costs such as: mercury containing wastes, pyrophoric radioactive materials, dioxin containing materials, single use cylinders (including lecture bottles**)**, damaged cylinders, unidentified wastes and mixed waste spill debris.

2. EH&S

EH&S maintains a comprehensive waste management program that achieves safe, compliant and cost-effective waste disposal. EH&S is responsible for:

- Providing timely waste collection services to research laboratories.
- Providing training and laboratory consultation on technical matters pertaining to waste generation, management and disposal.
- Shipping of hazardous materials, other than those in a category that may be shipped by trained laboratory personnel.
- Informing laboratory personnel of unsafe or non-compliant waste generation practices, including insufficient collection, missing or inaccurate labeling or improper waste management in SAAs.
- Informing laboratory personnel where safer, more sustainable or less-expensive chemical options may be available for substitution or elimination.
- Informing laboratory personnel and other applicable stakeholders when waste generation costs may not be covered by EH&S.
- Managing compliant recycling of materials that may contain hazardous and non-hazardous wastes such as solvents, batteries, electronics, lamps, mercury containing equipment, certain sharps, and scrap film.
- Maintaining compliance with annual reporting and waste minimization requirements.
- Managing all aspects of the University's relationship with professional vendors and service providers to sustain waste program operations.

D. Types of Waste

1. Hazardous Waste

According to the RCRA regulations, an unwanted laboratory chemical may either be a solid waste (**RCRA Solid Waste)** or a hazardous waste (**RCRA Hazardous Waste)**. For purposes of this handbook, a RCRA Hazardous Waste refers to a solid waste that exhibits certain hazardous properties or that is included on a specific list of wastes that the EPA has determined are hazardous. All RCRA Hazardous Wastes are RCRA Solid Wastes, but not all RCRA Solid Wastes are RCRA Hazardous Wastes. "Solid waste" in this regulatory context is not indicative of the physical state, as a solid waste may also be a liquid or a gas.

A RCRA Solid Waste is defined as a material that is no longer useful in its current state for its designed, intended use and which is being discarded. Once this state is reached, and before being moved from its point of generation, the RCRA Solid Waste must undergo a formal RCRA Hazardous Waste determination by the Generator, which consists of an evaluation of available information about the chemical, including the generator's own knowledge, to conclude whether or not it meets the definition of a RCRA Hazardous Waste. EPA's 2018 Hazardous Waste Generator Improvement Rule, added further requirements for laboratory personnel, including the need to document an accurate hazardous waste determination at the point of generation**.**

A RCRA Hazardous Waste is defined as a solid waste that exhibits certain hazardous properties (a **Characteristic Hazardous Waste)** or is included on a specific list of wastes that the EPA has determined are hazardous (a **Listed Hazardous Waste)**. EPA regulations define four hazardous waste characteristic properties in 40 CFR Part 261 subpart C: ignitability, corrosivity, reactivity and toxicity, described as follows:

- **Ignitability**: Ignitable wastes that create fires under certain conditions, are spontaneously combustible or have a flash point of less than 140°F, flammable solids, metal shavings or fine powders that can cause a fire through friction or absorption of moisture, ignitable compressed gases (materials which contain a mixture of less than13% with air that forms a flammable mixture), pyrophoric, water reactive or explosive materials, and oxidizers, which include peroxides, and compounds that readily yield oxygen to support combustion. Examples include waste oils and used solvents. For more details, see 40 CFR 261.21.
- **Corrosivity**: Inorganic and organic acids and bases (pH less than or equal to 2 or greater than or equal to 12.5) and/or are capable of corroding metal containers. Battery acid is an example. For more details, see 40 CFR 261.22.
- **Reactivity**: Pyrophoric, water reactive or explosive materials. Unstable items that react violently with air or when mixed with water, resulting in an explosion or generation of toxic gases, including cyanide- or sulfide-generating wastes, when exposed to pH conditions between 2 and 12.5. Examples include lithium-sulfur batteries and explosives. For more details, see 40 CFR 261.23.
- **Toxicity**: Heavy metals, including arsenic, barium, cadmium, chromium, lead, mercury, silver, and selenium and volatile organic compounds, including halogenated and non-halogenated solvents. For more details, see 40 CFR 261.24 Listed wastes have different waste codes depending on whether they are used/spent or unused. Specific F-codes are assigned for used non-halogenated and halogenated solvents, and degreasing agents that may also exhibit toxicity. The unused toxic and acutely toxic waste codes, P-listed (**P-listed)** and U-listed **(U-listed)** waste codes, typically consist of cyanides and salts, organophosphorous compounds, and unused organic solvents. These specific codes are detailed in 40 CFR 261 Subpart D.

This process of classifying chemical waste as a hazardous waste has been simplified for laboratory personnel at the University by use of a customized **Hazardous Waste Table** created by EH&S and attached hereto as **Annex IV-A.** It is also available at https://research.columbia.edu/sites/default/files/content/EHS/Waste_Hazmat/EPAHazWasteCharacteristicsTable.pdf. This table is specifically designed for the wastes most commonly generated in Columbia laboratories. The table includes a brief summary of the Characteristic Hazardous Wastes and Listed Hazardous Wastes, including toxic and acutely toxic P- and U-listed chemicals and links to the relevant EPA webpage https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes#character.

Hazardous wastes must not be diluted, neutralized, evaporated or treated by laboratory researchers.

2. Non-hazardous Chemical Waste

Many chemical wastes that are not suitable for drain disposal or municipal solid waste disposal (i.e., via regular trash) that are commonly generated in a laboratory **do not** meet the strict definition of a RCRA Hazardous Waste. These waste streams are known as non-hazardous wastes, and are described in further detail on the EH&S non-hazardous waste webpage, https://research.columbia.edu/sites/default/files/content/EHS/Waste_Hazmat/NHWList.pdf. It is important to note that although these materials are classified as "non-hazardous", specialized handling and disposal are required

3. Regulated Medical Waste (RMW)

Information on what constitutes RMW, the University's Guidelines for disposing of RMW and the RMW services that EH&S provides can be found in **Biological Safety: RMW Disposal (Chapter V, Section I)** below.

4. Radioactive Waste

A **Radioactive Waste** is a waste that contains radioisotopes. For information on Radioactive Waste, see **Radiation Safety (Chapater VI)** below and **Use of Radioactive Materials: Radioactive Waste (Chapter VII, Section D)** in the **Research Radiation Safety Handbook.**

5. Mixed Waste

Mixed Waste is a waste that has a hazardous component and a radioactive component. See also **Radiation Safety (Chapter VI)** and **Use of Radioactive Materials: Radioactive Waste (Chapter VII, Section D)** in the **Research Radiation Safety Handbook.**

6. Universal Waste

Universal waste (**Universal Waste)** is waste that contains otherwise regulated RCRA Hazardous Waste, but that the EPA has determined poses little risk to the environment when managed properly. Universal Waste is regulated in accordance with 40 CFR 273 Subpart B and 6 NYCRR Part 374-3.2, which have somewhat less restrictive requirements that allow for generation in greater quantities, extended accumulation periods, and simpler storage area rules. For example, a thermostat containing elemental mercury is classified as a Universal Waste, whereas if the mercury itself were to spill out of the thermostat it would be a RCRA Hazardous Waste. In its intact state, with the elemental mercury contained in a capsule-like part, the thermostat poses little chance of leaking into the environment, and therefore is eligible to be managed under the relaxed Universal Waste rules.

Generally, Universal Waste is found in household items, but may also be part of laboratory research or operations. Similar to RCRA Hazardous Wastes, these items of Universal Waste

must be collected and labeled for disposal through EH&S and not discarded in the municipal solid waste.

Universal Waste includes:

- Batteries (non-leaking and free from damage);
- Mercury containing equipment (**MCE**), that contains elemental mercury integral to its function, such as thermometers, thermostats and barometers; and
- Fluorescent light bulbs or "lamps" (intact).

Used Oil (**Used Oil)** is defined as any oil that has been refined from crude oil, or is synthetic oil, that has been used and as a result may have chemical or physical impurities. Used oil includes transmission fluid, hydraulic fluids, machine fluids and lubricating oils, and excludes petrochemicals, solvents, vegetable oils and animal fats. Common laboratory sources of Used Oil include centrifuge and vacuum pump coolant and other instrument lubricants.

Used Oil is subject to alternative requirements to the Hazardous Waste regulations including those found at 40 CFR 279 and 6 NYCCR Part 374-2.

For the management of Used Oil mixed with Hazardous Waste, there are two points of clarification:

- If the Used Oil is mixed with a Listed Hazardous Waste, it must be managed as a Hazardous Waste.
- If the Used Oil is mixed with a Characteristic Hazardous Waste and still exhibits that characteristic after mixing, then it must be managed a Characteristic Hazardous Waste. If it does not exhibit the characteristic after mixing, then it may be managed as a Used Oil.

Where the Used Oil is mixed with PCBs <50 parts per million **(ppm)**, it may be managed as Used Oil. If the Used Oil contains, or contained prior to dilution, ≥50 ppm PCBs, it is subject to the Toxic Substances Control Act (**TSCA**) regulations at 40 CFR 761 and 6 NYCCR Part 371.4(e).

PCB oils must be managed in New York State as a Hazardous Waste and labeled accordingly. The words "*contains PCBs in used oil*" should be included on the label and a mark placed in the the "toxic" box on the label. (More information on labeling is included in **Management of Laboratory Waste: The 5Ls (Section E(1))** below.

Where Used Oil is free from PCBs and does not exhibit any Hazardous Waste characteristic, and is mixed with a Listed Hazardous Waste, it is properly labeled Used Oil and not Hazardous Waste and may be stored in a closed container.

In accordance with the Columbia University Spill Prevention Control and Countermeasures Plan (**SPCC**) required under 40 CFR 112, any quantities of used oil ≥55 gallons must be stored in secondary containment, such as on a spill containment pallet.

E. Management of Laboratory Waste

1. The 5 Ls

The University has established a set of simplified waste management guidelines called the 5 Ls. The 5 Ls refer to the necessary steps to safely manage hazardous waste in compliance with regulations. See EH&S' Hazardous Waste Management Overview, for guidance https://research.columbia.edu/sites/default/files/content/EHS/Waste_Hazmat/5Ls.pdf.

The 5 Ls include:

- Co**LL**ect
- **L**abel
- **L**id
- **L**ocate
- **L**eaks.

For a discussion of the 5Ls as they relate to radioactive waste, see **Use of Radioactive Materials: Radioactive Waste – Waste Management – the 5Ls (Chapter VII, Section D(2))** in the **Research Radiation Safety Handbook.**

Collection

All chemical waste, including even minute amounts, that meet the criteria for being a RCRA Hazardous Waste must be collected in SAAs at the point of generation. SAAs may include collection containers within CFHs or elsewhere in the laboratory.

The following are the standards for hazardous waste containers located in a SAA:

Containers must be:

- In good condition
- Within the same room as the process that generates the waste;
- Always kept closed, except when adding or removing waste; for example, do not leave an open funnel in the hazardous waste container;
- Compatible with the container and any other waste in the container;
- Clearly and legibly labeled Hazardous Waste, with the full chemical name written without abbreviations or chemical formulas and, if known, the quantity (percentage) of the contents listed;
- Segregated by hazard class; for example, acids separated from bases and from flammables; and

- Checked by the laboratory personnel at least weekly for leakage.

EH&S provides containers for hazardous waste and labels that meet the above requirements. To request supplies or a pick-up service, any member of the laboratory may complete the Chemical/hazardous Waste Pick-up Form. EH&S will provide the service on the below schedules, unless alternate service arrangements have been made with your laboratory. Requests must be received by 5:00 pm the day before the applicable building's scheduled service day or the pick-up will be made the following week. The following is a list of pick-up times, by campus and building:

Morningside:

- Tuesday: Chandler, Dodge, Engineering Terrace, Fairchild, Havemeyer, Mudd, Schermerhorn, Schermerhorn Extension
- Friday: Chandler, CEPSR, Dodge, Havemeyer, Northwest Corner, Pupin

Manhattanville:

- Wednesday: JLGSC

CUIMC:

- Monday: Black, Children's Hospital, Eye Institute/Annex, VP&S, PH, Vanderbilt
- Thursday: Bard Towers, Hammer, ICRC, Kolb, Lasker, Mailman, Russ Berrie

Lamont:

- To arrange for disposal of hazardous waste, email: hazwaste@ldeo.columbia.edu; include building and room number, with a list of each container size and the contents of containers.
- The Lamont Safety Office supplies 1 gallon, 2.5 gallon and 5 gallon containers for waste collection. The containers and hazardous waste labels can be found in the Comer Basement Storage Room across from the loading dock, as well as in the Core Lab on the second floor.

Nevis:

- EH&S arranges shipment of Hazardous waste from Nevis on a quarterly schedule and coordinates pick-up on demand.

For questions or customer service regarding hazardous waste, contact EH&S as follows:

- Morningside: (212) 854-8749
- CUIMC: (212) 305-6780
- All campuses: email at hazmat@columbia.edu

Labels

EH&S provides labels to laboratories upon request, and only Columbia waste labels may be used. The EH&S labels are designed to address all labeling requirements, and must be accurately completed by laboratory personnel.

The chemical waste label should be completed when any waste is added to a collection container. The label is a regulatory requirement. If the container is lacking a label or the label is not fully filled out, the waste may not be removed from the laboratory by EH&S.

Directions for completing the **Chemical/Hazardous Waste Label,** a sample of which is attached as **Annex IV-B,** include the following:

- In legible English, complete the header information, including the PI's name, telephone number, building and room number where the chemical waste is located.
- List all the chemical constituents in the container. Note:
    - When there is more than one chemical present in the container, list the percentage of each chemical in the entire solution along with identifying information on the balance of any non-hazardous constituents of the solution.
    - In cases when solutions are added to the container over time, and when it is not possible or practical to list each of these entries on the waste label, a range may be used to estimate the final concentration of the waste. For example: "20-25% acetone, 5% methanol, balance ethanol" or "4% paraformaldehyde in a buffer solution"; list the specific buffer name as the balance.
    - "Buffer" is not a suitable waste description for an entire solution as there are numerous buffer types, many of which contain hazardous waste constituents. The name and/or type of buffer should be specified.
    - When RCRA heavy metals are included in the waste, ppm or a range may be used. Be as accurate and precise as possible as the processing of the waste depends on the amount of the metal present.
    - "Unknown" is not a suitable waste description. Every effort should be made to identify the class, family or category of chemicals present in the waste, at a minimum.
- Abbreviations, short-hand or formulas may not be used, except that abbreviations may be used when the full chemical name has previously been provided to EH&S, such as by adding a complete list of the contents and tucking it behind the waste label in a plastic label sleeve.
- Check the hazard boxes listed on the chemical waste label that best represent the hazards of the waste present in the container. This satisfies the RCRA requirement for conducting a hazardous waste determination.
    - EH&S has prepared two guidance documents for the University's most commonly generated laboratory chemical wastes to simplify the requirement for laboratories to make an accurate Hazardous Waste determination. There are two guidance documents: one for **Common Hazardous Wastes and Characteristics** and the other for **Common Non-Hazardous Wastes Requiring Proper Disposal**, which are attached hereto as **Annexes IV-C and IV-D**. They are also available at https://research.columbia.edu/hazardous-waste-determination.
    - EH&S has listed several chemical wastes that EPA does not specifically regulate as hazardous, but must still be collected for proper disposal through EH&S because

they present potential health and/or environmental hazards. These chemicals can now be accurately identified by checking the "Non-Hazardous Waste" box on the orange, **Chemical/HazardousWaste Label** provided by EH&S, a sample of which is attached as **Annex IV-B.**

- Laboratory staff should refer to the manufacturer's SDS or GHS hazard pictograms affixed to the chemical waste container. More information on GHS pictograms can be found on the EH&S website at https://research.columbia.edu/content/ghs-hazard-communication and in **Laboratory and Research Safety: Elements of the Columbia Research Safety Program – Hazard Communication (Chapter III, Section D(3))**. For assistance in completing a waste label, including checking the boxes representing the hazards of each chemical or for additional guidance in making an accurate hazardous waste determination email hazmat@columbia.edu.

· All Used Oil must be collected and labeled "*used oil*" in a closed container.

Lids

All hazardous waste containers must be kept closed when waste is not actively being added to the container. Note:

· Use a tight-fitting lid that will prevent spills should the container be accidentally knocked over.
· For waste containers attached to equipment with effluent lines or tubing, or in cases where waste generation and collection is an ongoing process, such as High Performance Liquid Chromatography (**HPLC**), a cap that allows tubes to be inserted through a tight-fitting seal must be used. In order to prevent evaporation and potential spills of chemical waste, tubes must not be loosely left in openings of a waste container. Contact EH&S at hazmat@columbia.edu for assistance with obtaining specialty lids or caps.
· Funnels must not be left in waste collection containers when waste is not being actively added. Where large collection containers are used, a funnel may be affixed to the drum, however a lid that latches must be utilized. This latch must be fastened closed when waste is not being actively added to the drum.

Location

All chemical waste must be initially kept in the laboratory's SAA under the control of the Generator. "Under the control of the generator" means within sight of the generator and in such a location as can be managed responsible and safely to avoid dangerous situations. Access or control may be managed by a swipe card, key or lockbox. Up to 55 gallons of non-acutely toxic waste or one quart or kilogram of acute hazardous waste may be accumulated in each SAA. Do not locate collection containers outside of the room in which the waste is generated; only EH&S personnel and authorized waste vendors are specifically qualified under RCRA regulations to move the chemical waste from the SAA to a Central Accumulation Area (**CAA).**

Leaks

All SAAs must be visually inspected by laboratory personnel at least once a week to check for any signs of leakage from waste collection containers. Contact EH&S immediately, at the numbers provided in **Waste Collection Service (Section 2)** below if damage to a collection container or leakage is observed.

2. Waste Collection Service

All hazardous waste must be processed through the University's Waste Management Program operated by EH&S. EH&S is the sole unit within the University that is authorized to handle hazardous waste outside of a SAA. Waste collection services can be requested by submitting a Chemical Waste Pickup Request Form.

Note: EH&S may not accept DEA Controlled Substances for waste collection, but can provide guidance with respect to their disposal. See **Controlled Substances (Chapter X)** below for additional guidance

Detailed steps to aid in the completion of the Chemical Waste Pickup Request Form include:

- **Step 1**: Complete the contact information for the Generator and location information of the chemical waste container(s) by entering the PI's name, the requester's name (i.e., the name of the person submitting the form), an email address (preferably a University email address), telephone number where the requester may be reached regarding potential access or waste collection issues, and the campus name. Then select "Next."
- **Step 2**: Select the building name from the dropdown list and enter the room number where the chemical waste is located. Note: the building list will customize to the previously selected campus.
- **Step 3**: Check the boxes at the top of the screen if supplies, such as labels or containers, are needed. Select the quantity of containers needed, if applicable. If no supplies are needed, then select "Next." Photos of the types of supplies available are displayed in the Laboratory Safety training, available through RASCAL at *TC0950: Lab safety, Chemical Hygiene, and Hazardous Waste Management Refresher*.
- **Step 4**: Select the phase or physical state of the chemical waste by clicking the button next to the description. Select the container size of the chemical waste container.
    - At Morningside, if solvents are being collected for recycling, select the appropriate solvent type.
    - At all other campuses, select NONE in this section.
    - Enter the chemical name, including a percentage or ppm value after each constituent. Enter a descriptive location of the waste in the SAA, for example, "under hood #3" or "near window by sink." Enter the number of waste container, of this same waste that are present in the SAA. To enter another waste type for collection, select "YES" for "Do you have other types of waste?" If this is the only chemical waste to be collected, select "NO", then select "Next."

- **Step 5**: In the comments box, enter any additional information regarding supplies needed, unique details regarding the waste that may present handling or storage issues, special instructions about where to leave the requested supplies, times that access may be restricted to the laboratory, or additional contacts in the laboratory where EH&S may seek information, if needed, during collection.
- **Step 6**: Verify that all the requirements for proper waste management have been met by selecting the boxes next to each statement. Select "Next" to complete and submit the request.
- **Step 7:** Review the screen that outlines when collection occurs per campus and check the appropriate boxes to verify that all of the waste is being managed according to the listed guidelines while it is in the SAA. An email will be automatically sent to the previously entered address confirming successful submission, and indicating when the collection will occur.

Chemical and radioactive waste services occur on the following schedule:

Morningside:

- Tuesday: Chandler, Dodge, Engineering Terrace, Fairchild, Havemeyer, Mudd, Schermerhorn, Schermerhorn Extension.
- Friday: Chandler, CEPSR, Dodge, Havemeyer, Northwest Corner, Pupin

Manhattanville: All chemical waste pickups occur on Wednesdays. All radioactive waste pickups are completed within one week of receipt of the Request Form.

CUIMC:

- Monday: Black, CHONY, Eye Institute/Annex, VP&S, PH, Vanderbilt.
- Thursday: Bard Hall, Hammer, ICRC, Kolb, Lasker, Mailman, Russ Berrie.

Lamont: All chemical and radioactive waste pickup requests are typically serviced within 24-hours, but may take up to three days. Laboratory personnel should send an email to the Lamont Safety Department at hazwaste@ldeo.columbia.edu. In the email include: building name, lab room number, list of each container size and all contents of container (full chemical name and volume). Include in email if the laboratory needs *Broken Glass Boxes* or *Chemically Contaminated Glassware* buckets picked up as well. **Note:** The Lamont Safety Department supplies: 1-gallon, 2.5-gallon, and 5-gallon containers for waste collection. The containers and hazardous waste labels are located in the Comer Building, basement storage room, across from the loading dock, and in the Core Lab building on the second floor. For any issues regarding pick up requests, please contact the Safety Department at (845) 365-8990.

Nevis: All chemical and radioactive waste pickup requests are scheduled for service periodically throughout the year. For a schedule of service or for an urgent service, please contact EH&S at hazmat@columbia.edu.

If the waste collection service does not occur as outlined above, and if communication regarding missed service has not been provided by EH&S, please contact EH&S at hazmat@columbia.edu to inquire about the status of the request.

See **Biological Safety: RMW Disposal (Chapter V(I))** above regarding schedules for RMW service and **Use of Radioactive Materials: Radioactive Waste (Chapter VII, Section D)** in the **Research Radiation Safety Handbook**.

3. Specialty Programs

College of Dental Medicine.

The College of Dental Medicine has a robust waste program. To learn more, please visit https://research.columbia.edu/college-dental-medicine

School of the Arts

Information regarding the waste program for the School of Arts is available at: https://research.columbia.edu/content/school-arts-hazardous-waste-management

Off-site Waste Generation

When research operations do not occur on a University campus, such as in a field research station located domestically or internationally, or at sea, different waste management practices may be utilized. Although the regulatory management for these waste services is often organized by EH&S and directly completed by a University approved waste vendor, the PI is ultimately responsible for the disposal. Arrangements for these services must be coordinated with EH&S at least one month before the beginning of the research project. EH&S will provide technical guidance regarding RCRA and US DOT compliance as applicable to the project and location. Please contact EH&S at labsafety@columbia.edu.

Photograhic Dark Rooms

All scrap film from traditional photo processing techniques must be collected from this process in the container provided by EH&S, labeled "*Scrap Film for Recycling*". All solutions from this process must pass through the photo processor trickle tank prior to drain discharge. For any service needs related to this process, please contact the supervisor or EH&S for assistance at labsafety@columbia.edu.

4. Management of Common Hazardous Materials

Aerosol Cans

Aerosol cans, such as those containing spray paints, glues or lubricants, are a commonly generated research laboratory waste. They may not be discarded in municipal solid waste containers, even if punctured. Aerosol cans typically contain a flammable propellant and are therefore classified as an ignitable waste. When collecting these containers, ensure that the manufacturer's cap has been replaced on the can prior to placing it in the collection container, or the spray nozzle has been removed so it does not accidentally discharge, potentially causing a dangerous pressurization and/or fire hazard.

Compressed Gas Cylinders

Compressed gas cylinders are a commonly generated laboratory research waste that can be classified as a hazardous or non-hazardous waste when discarded. They must not be vented into hoods and/or de-valved by laboratory personnel in lieu of disposal or return to the manufacturer. Compressed gases should always be ordered through University-approved vendors who are contracted to take back the unused or empty cylinders. Cylinders should be returned to the original manufacturer whenever possible to avoid high disposal costs. The smallest size possible should be ordered by researchers, and partially filled containers can also be requested from suppliers. Lecture bottles and single use cylinders are not suitable, in most cases, for return. More information about the University's compressed gas safety program, including illustration of these cylinder types, can be found on the EH&S website at https://research.columbia.edu/compressed-gas-safety-program.

Certain Pipettes

Used pipettes and pipette tips contaminated with acutely toxic, or P-listed, hazardous waste must be managed through EH&S. These materials must be collected in rigid containers provided by EH&S or in reusable, chemically compatible, empty reagent bottles that are rigid plastic (rather than glass or metal) and closeable. For additional guidance on the disposal of pipettes and other sharps, please refer to **Biological Safety: RMW Disposal (Chapter V(I))**.

5. Management of Common Non-Hazardous Waste

Silica

Silica generated from the filtering of solvents is commonly produced in Chemistry Department laboratories, and is classified as a non-hazardous waste. It must be labeled, collected and disposed of through EH&S.

Gels

Gels containing ethidium bromide, SYBRSafe™ or SYBRGreen™ used for electrophoresis are generated in many laboratories. They may not be discarded in the municipal solid waste even though they are classified as a non-hazardous waste. Gels must be labeled, collected and disposed of through EH&S.

Formalin Solutions

Formalin solutions, whether prepared as a 4% or 10% solution or as 37% formaldehyde, are commonly generated in laboratories. Although these solutions are classified as a non-hazardous waste, they may not be discarded in a sink drain. Formalin solutions must be labeled, collected and disposed of through EH&S.

Note: Unused formaldehyde solution/paraformaldehyde is a hazardous waste. It must be managed separately from used formalin solutions and must be labeled, collected and disposed of through EH&S.

Certain Pipettes

Used pipettes and pipette tips that do not contain free liquids and are not used with acutely toxic, P-listed hazardous wastes are managed as RMW sharps, through the University's RMW program. All non-hazardous RMW sharps are required to be disposed of in red, puncture resistant sharps containers provided by the University's medical waste vendor. For particularly odorous materials, the pipettes and pipette tips may be enclosed in an empty, chemically compatible, clear, plastic, bottle with an affixed lid to minimize the smell once placed in a sharps collection container. For additional guidance on the disposal of pipettes and other sharps, please refer to **Biological Safety: RMW Disposal (Chapter V, Section I)**.

6. Recycling of Laboratory Waste and Materials

EH&S has numerous recycling and green initiatives, including many that are implemented in the University's laboratories. More information on these initiatives is included on the EH&S webpage: https://research.columbia.edu/content/recycling-and-green-initiatives. This Section highlights recycling and green initiatives in the laboratory setting.

Solvents

EH&S began its recycling program in the Dermapathology and Pathology Laboratories at CUIMC where ethyl alcohol and xylene are used in a variety of tissue-processing and staining procedures. Following a successful pilot project at CUIMC 19 years ago to confirm that reuse of purified, recycled solvent would not have any impact on the quality of tissue processing activities, both laboratories implemented a recycling program that continues today. Please consult with EH&S or the lab manager in these locations for more information and training on the recycling process and program.

With the success of the program at CUIMC, EH&S now has solvent recycling programs at Morningside in the Chemistry (for acetone) and Biological Sciences Departments and at SEAS for other recyclable solvents. Laboratory personnel at Morningside may recycle their used ethanol, methanol and acetone solvents by submitting a Chemical Waste Pickup Request Form.

See **Waste Collection Service (Section 2)** above for instructions on completing the Request form. Upon receipt of the Chemical Waste Pickup Request Form by EH&S, specifically labeled collection containers are provided to the requesting laboratory. Following treatment by EH&S, the solvent is delivered to the applicable ChemStores location for pickup by laboratory personnel.

Note: Acidic wastes with a pH

outlined in **Types of Waste: Universal Waste (Section D(6))** above. These items must be labeled as "*Mercury Containing Equipment*" and include an accumulation date on the label that should not precede one year. For disposal, submit a Chemical Waste Pickup Request Form. If the MCE is broken, it must be collected (including any related spill debris), labeled and managed as a Hazardous Waste.

Electronics and Used Lamps

Electronics and used, intact lamps contain RCRA heavy metals such as lead, cadmium, and mercury, although subject to less stringent environmental regulations, must be recycled and disposed of through Facilities Operations and may not be discarded in municipal solid waste. Electronics must be placed in designated, labeled storage areas on campus.

Used intact lamps are subject to the Universal Waste regulations previously outlined in **Types of Waste: Universal Waste (Section D(6))** above. They must be labeled as "*Used Lamps*" and collected in containers with an accumulation date listed on the label not to precede one year. Where small quantities or sizes of used lamps are generated in a laboratory, they may be collected for disposal via a Chemical Waste Pickup Request Form.

If the electronic item or used lamp is broken, it must be collected (including its related spill debris), labeled and managed as a hazardous waste in accordance with this Chapter by submitting a Chemical Waste Pickup Request Form.

To arrange for the disposal of intact electronics and used lamps:

Morningside and Manhattanville: Call the Facilities Service Center at (212) 854-2222 to arrange for a pickup by Facilities Operations.

CUIMC: Call Facilities Operations at (212) 305-HELP (4357) extension 3.

Lamont: Call the Safety Department at (845) 365-8990.

Nevis: Call Facilities Operations at (914) 591-8883.

Glassware

Glassware is a common waste product in research laboratories. If uncontaminated, glassware may be recycled in collection containers found throughout laboratory buildings. Glassware that is perceived as grossly contaminated should be managed through EH&S as a non-hazardous waste.

At Morningside and Manhattanville where ChemTracker is in use, rinsed, intact and capped reagent bottles with their labels defaced and their barcode showing may be placed in the yellow bins for scan-out by ChemTracker staff.

Note: Any bottles marked with a pink dot indicating that they previously contained a P-listed RCRA acute toxic material may not be placed in these bins as the empty bottles must be managed as a RCRA Hazardous Waste. Please submit a Chemical Waste Pickup Request Form for these containers.

Unwanted, clean laboratory glassware should be discarded in a cardboard box designed for broken glass collection. Uncontaminated glassware should be packaged and sealed in cardboard boxes (either boxes designed specifically for disposable glassware or other empty boxes) and left for the applicable Facilities Operations staff to collect during custodial rounds. Glassware is delivered to a recycling staging area. EH&S does not service or supply cardboard boxes for the recycling of unwanted, clean laboratory glassware.

If a cardboard glass box is needed at Morningside, please visit ChemStores or the Biology Stockroom. When the cardboard glass box is full, please tape the lid closed and place it in a hallway for pickup by Facilities Operations for recycling. Complete a glassware container label – also obtained through the stockrooms – prior to placing it in the hallway for pickup. See the EH&S' Laboratory Container and Glassware Management Policy for guidance.

At Lamont, cardboard glass boxes and reusable pails for contaminated glassware are provided by the Safety Department. Requests for pickup should be made via email to hazwaste@ldeo.columbia.edu. In the email, include the building name and room number and state that the laboratory needs "*Broken Glass Boxes*" or "*Chemically Contaminated Glassware*" buckets picked up. Laboratory personnel may also obtain empty containers in the Comer Building basement storage room across from the loading dock, as well as in the Core Lab Building on the 2nd Floor.

Grossly contaminated glassware, typically found in the Chemistry Department and in the Comer Building and the Core Lab Building at Lamont, must be collected in the blue bins (at Morningside) or reusable, labeled pails (at Lamont) for disposal as a non-hazardous waste. Please submit a Chemical Waste Pickup Request Form at Morningside and follow the

instructions indicated for Lamont at **Management of Laboratory Waste: Waste Collection Service (Section 2)** above.

Recyclable Sharps Containers

Recyclable sharps collection containers are available at all campuses. For details regarding the recyclable sharps container recycling program and management details, please refer to **Biological Safety: RMW Disposal (Chapter V, Section I)**.

7. Scrap Film Recycling and Silver Recovery

Traditional photographic/film processing is a multi-step process that turns a latent image on film media into a permanent image. The chemistry behind this process involves "fixing" silver to the film media to create the image and washing away the "unfixed" silver. EH&S manages the silver recovery process since it is an environmental pollutant due to its toxicity and, under NYS DEC regulations, may not be directly discharged into a drain. EH&S outfits all image/photo processing equipment utilizing "wet chemistry" methods (i.e., fixer and developer) with equipment to recover silver halide from the wastewater effluent. Since other wastes generated in the processing of images/photos may contain silver, such as scrap film, all waste from these activities is collected and/or filtered in accordance with environmental regulations to avoid entering the environment in wastewater (e.g., equipment effluent) or as a municipal solid waste (e.g., scrap film media) by-product of image/photo developing activities.

The installation, maintenance and eventual end-of-life removal of the photo processing unit is the responsibility of the PI. Laboratory personnel who use the photo processor equipment are responsible for the items outlined in **Roles and Responsibilities: PIs (Section C(1))** above. For any EH&S issues relating to silver recovery or management, email labsafety@columbia.edu. For any infrastructure issues, such as electric service, trash removal, plumbing or drain issues, please contact Facilities Operations at the numbers listed above in this Section.

EH&S services darkrooms used at the University. Silver recovery equipment is inspected by EH&S at least once per calendar quarter and silver recovery equipment that has reached the end of its useful life is exchanged.

Laboratory personnel who use the photo processor equipment are responsible for:

- Completion of the EH&S-provided posted, *Use Log;*
- Visual inspection of the photo processor prior to use;
- Clean-up of manageable spills during the photo processor use;
- Notification to the photo processor provider of any functional issues;
- Notification to EH&S of any silver recovery filter or scrap film related issues;
- Notification to Facilities Operations of any infrastructure related issues such as custodial, electrical or plumbing issue; and

- Collection of used scrap film in the EH&S provided collection containers labeled, "*Scrap Film forRecycling*".

For more information regarding silver recovery and scrap film recovery, laboratory personnel are strongly encouraged to annually complete the RASCAL training, *TC5250: Dark Room Management Training*.

V. BIOLOGICAL SAFETY

A. Introduction

The University's Biological Safety Program (**Biosafety Program**) is responsible for anticipating, assessing and controlling risks posed by the handling and use of biological materials in research, such as bacteria, viruses, parasites, prions and biological toxins, as well as recombinant DNA, infectious agents, and potentially infectious human materials that may contain bloodborne pathogens.

The Biosafety Program supports the activities of researchers who work with biological materials at the University in a manner that:

- Protects University personnel and visitors from laboratory-acquired infections;
- Maintains the security and integrity of specimens and other research materials;
- Provides environmental protection to minimize risks to those outside the laboratory and beyond the confines of the University; and
- Ensures compliance with existing federal, state, and local health, safety, and environmental regulations and guidelines.

The most salient features of the Biosafety Program can be found in the University's Biological Safety Manual, which covers many of the subjects dealt with in this Chapter.

Biosafety Program personnel are available to assist laboratories in managing their responsibilities with respect to the use of biological materials. The Biosafety Program website at https://research.columbia.edu/content/biological-safety contains additional information on the Biosafety Program.

B. Regulatory Framework

Research with biological materials is subject to a number of laws, regulations and guidelines. The following is a brief outline of the most relevant federal agencies, regulations and guidance that will be referred to throughout this Chapter as the subject requires.

1. Department of Health and Human Services (DHHS)

The **National Institutes of Health (NIH) Office of Science Policy** (**OSP**) administers the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (July 2019) (the **NIH Guidelines**). The NIH Guidelines detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing such molecules. The Guidelines also describe the requirements for getting approval for various types of research.

The **Centers for Disease Control and Prevention** (**CDC**) has published an advisory document that is currently in its sixth edition, *Biosafety in Microbiology and Biomedical Laboratories*, which although not considered to be a regulatory document, contains many recommendations with respect to best practices for the safe conduct of work in biomedical and clinical laboratories from a biosafety perspective.

The **CDC/Division of Select Agents and Toxins** and the **United States Department of Agriculture** (**USDA**)/**Animal and Plant Health Inspection Service** (**APHIS**)/**Agriculture Select Agent Services** jointly administer the Federal Select Agent Program https://www.selectagents.gov/. The Select Agent Program regulates the possession, use and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.

The laws and regulations that regulate Select Agents and Toxins are:

- For human health, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a), together with DHHS regulations (42 CFR 73)
- For animal or plant health, the Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107-188 (7 U.S.C. 8401), together with APHIS regulations (7 CFR 331 and 9 CFR 121).

These laws and regulations cover the possession, use and transfer of Select Agents and Toxins, as well as the registration of entities using such materials. The CDC and APHIS coordinate regulatory activities for agents that are regulated by both agencies (**Overlap Select Agents**).

2. Department of Labor: OSHA

OSHA administers the Bloodborne Pathogens Standard (the **OSHA BBP Standard)** pursuant to 29 CFR 1910.1030. This Standard applies to all occupational exposure to blood or other potentially infectious materials.

C. Roles and Responsibilities

The primary oversight responsibilities within the Biosafety Program rest with the Institutional Biosafety Committee and the Biological Safety Officers. Together, they establish policies and procedures, oversee regulatory compliance, monitor Biosafety Program performance and support the highest quality research. PIs also have responsibilities under the Biosafety Program.

1. Institutional Biosafety Committee (IBC)

The IBC is the principal oversight committee at the University for research involving recombinant DNA and infectious agents, biosecurity and adherence to related regulations and standards. The members and Chair of the IBC are appointed by the EVPR. The complete IBC Charge is available at https://research.columbia.edu/system/files/EHS/BioSafety/IBCCharge.pdf. IBC membership consists of faculty members and administrative officials with relevant

knowledge of, and interest in, molecular biology, epidemiology, infection control, regulatory compliance, and research facility design. The IBC has two unaffiliated members.

The IBC is responsible for:

- Providing timely review of protocols for work involving:
  a. recombinant DNA for compliance with the NIH Guidelines;
  b. infectious agents requiring BSL-2 and above containment;
- Reviewing and advising on policies and procedures to mitigate exposure to infectious materials, maintain biosecurity and adhere to related regulations and standards;
- Reporting to NIH OSP significant research related accidents, illnesses and spills; and
- Ensuring that all recombinant DNA work involving human subjects is performed in compliance with the NIH Guidelines.

2. Biosafety Officers

The Biosafety Officers within EH&S ensure compliance with the NIH Guidelines, the CDC BMBL recommendations and the OSHA BBP Standard, and act as the Responsible Officials for the Select Agent Program. To assist PIs with risk assessments, the Biosafety Officers may seek input from the IBC, the Institutional Animal Care and Use Committee (**IACUC**), laboratory animal veterinarians from the Institute of Comparative Medicine (**ICM**), and the Institutional Review Boards (**IRB**).

The Biosafety Officers are responsible for:

- Serving as the Biosafety Officers for the IBC;
- Evaluating and providing IBC administrative approval of IACUC, IRB, and *in vitro* biosafety appendices;
- Evaluating research with collected clinical materials;
- Performing periodic safety surveys to inspect BSL-2 and BSL-3 containment laboratories and laboratories that perform animal research using hazardous materials;
- Performing periodic safety surveys for the procurement of infectious agents;
- Signing recombinant DNA and Biohazards Assurance Letters for grant proposals if the proposed work is registered with the IBC;
- Consulting on research design and hygiene practices;
- Performing accident investigations to comply with Columbia's OSHA-required Exposure Control Plan;
- Responding to spills of biohazardous materials;
- Assisting in the preparation of shipments of biological substances with dry ice; and
- Identifying Dual Use Research of Concern**.**

Contact information for Biosafety Officers can be found in the EH&S Directory: https://research.columbia.edu/environmental-health-safety-directory.

3. PIs

PIs are responsible for performing a risk assessment for work with biological hazards that must be activity- or agent-specific. PIs must also ensure that all personnel under their supervision are aware of biological hazards present in their work environment, and appropriately trained and informed of applicable regulations and guidelines, and that they are capable, based on academic background and hands-on experience, of working within the applicable regulations and guidelines.

The PIs are also responsible for:

- Complying with the NIH Guidelines, as well as the OSHA BBP Standard and all other relevant federal, state, and local regulations;
- Performing risk assessments to determine the containment levels required for recombinant DNA and/or infectious agent work;
- Submitting appropriate documentation relating to proposed recombinant DNA and/or infectious agent work to the IBC and/or related committees;
- Ensuring that laboratory workers are trained regarding the hazards of recombinant DNA and/or infectious agent work in the laboratory and comply with safe practices;
- Complying with all shipping requirements for recombinant DNA molecules, infectious agents, and clinical materials;
- Ensuring that staff undergo medical surveillance at WH&S based on anticipated exposure, in accordance with the Columbia University Medical Surveillance Policy; and
- Reporting to the IBC the following:
  - Any significant problem, any violation of the NIH Guidelines or any significant research related accident or illness;
  - If the research is conducted in a BSL-2 or BSL-3 laboratory, immediately upon occurrence, any spill or accident resulting in an overt exposure to organisms containing recombinant DNA molecules; and
  - For human gene transfer research, any serious adverse event that is unexpected and associated with the gene transfer product.

D. Biosafety Risk Assessment and Containment

The two most important principles of biosafety – **risk assessment** and **containment –** were introduced in 1984 with the first edition of BMBL and remain in effect today. **Risk assessment** is the process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material that enables the appropriate selection of microbiological practices, safety equipment and facility safeguards that can prevent laboratory-acquired infections **(LAIs).** The fundamentals of **containment** of potentially harmful biological agents include the microbiological practices, safety equipment, and facility safeguards that protect laboratory workers, the environment and the public from exposure to infectious microorganisms that are handled and stored in the laboratory.

1. Risk Assessment

The principal hazardous characteristics of an agent are: its capacity to infect and cause disease in a susceptible human or animal host, its virulence as measured by the severity of disease and the

availability of preventive measures and effective treatments for the disease. The NIH Guidelines assign agents to risk groups to assist in risk assessment. Agents are classified into four risk groups according to their relative pathogenicity for healthy adult humans by the following criteria: (a) **Risk Group 1 Agents** are not associated with disease in healthy adult humans; (b) **Risk Group 2 Agents** are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are **often** available; (c) **Risk Group 3 Agents** are associated with serious or lethal human disease for which preventive or therapeutic interventions **may** be available; and (d) **Risk Group 4 Agents** are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are **not usually** available.

Once the risk group of the agent is identified, a thorough consideration of how the agent will be manipulated must be undertaken. Factors to be considered in a risk assessment (the **Agent Risk Assessment Factors)** include:

- Pathogenicity or the ability of the organism to cause disease;
- Virulence or the severity of the disease;
- Transmission route, including parenteral introduction, ingestion, mucous membrane exposure or inhalation, with the last route being of the greatest concern;
- Agent stability or the survival of the agent in the particular environment or otherwise prolonged viability;
- Infectious dose, or the dose required to cause infection in humans or animals; and
- Antibiotic resistance.

The use of recombinant DNA may alter any of the above risk factors and investigators should take these modification into consideration when working with recombinant microorganisms.

All of the above factors are inherent in a particular microbe; external factors to be considered in a risk assessment (**External Risk Assessment Factors** and, together with the Agent Risk Assessment Factors, the **Risk Assessment Factors)** include**:**

- The titer or volume of material used, as the titer, upon culturing, may increase the effect of an agent by several orders of magnitude compared to levels in clinical samples;
- Availability of effective treatment or vaccine;
- Nature of activities, including the potential for splashes, volume used, complexity of manipulations, skills and training of investigators; and
- Health status of investigator, e.g., immune state, pregnancy, vaccination status, etc.

2. Containment

An important factor in reducing the risk of an agent is the quality of the physical containment where the agent will be manipulated or stored. However, in addition to facilities, the concept of containment also includes safe methods of work and equipment.

The BMBL describes four Biosafety Levels (**BSLs**) assigned to biological materials to characterize their risk. For each BSL, there is a unique set of safety equipment, facility design features, and practices that will reduce the risk of LAIs. The excerpts in this Section should be

considered general summaries; a complete description of work practices, safety equipment, and facility design features is available in the BMBL and, in particular, in Section IV thereof. See https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF. The NIH Guidelines also provide additional information and guidance for risk assessment of microorganisms and materials containing recombinant DNA, which may increase or decrease the risk of the activities.

Containment facilities at the University typically fall under the BSL-1, BSL-2, or BSL-3 categories; there are no BSL-4 high containment facilities at Columbia. The risk criteria that determines biosafety level depends on the Risk Assessment Factors.

Biosafety Level 1 (BSL-1) is the appropriate containment level for Risk Group 1 microorganisms that are not known to consistently cause disease in healthy adults. Examples include *B. subtilis*, *S. cerevesiae*, *Lactobacillus spp*., and non-pathogenic *E. coli*. BSL-1 recombinant DNA activities use non-pathogenic organisms as hosts for the expression of genes incorporated into bacterial plasmids or low risk viral vectors such as baculovirus or adeno-associated virus.

The BSL-1 requirements and recommendations include:

- Work practices: Standard microbiological practices and aseptic technique
- Safety equipment: None required
- PPE: gloves, laboratory coats and eye protection recommended
- Facilities: bench top sink available for hand washing.

Biosafety Level 2 (BSL-2) is the appropriate containment level for Risk Group 2 microorganisms that are associated with human diseases of varying severity. Examples include hepatitis B and C, human immunodeficient virus (**HIV)**, *salmonella spp., toxoplasma spp., S. typhi*, *S. aureus*, *S. pyogenes* and human retroviruses. BSL-2 recombinant DNA activities include the use of viral vector systems such as adenovirus and some retroviral vectors, particularly lentiviral vectors and transmission of recombinant DNA in BSL-2 organisms, herpes simplex virus and some retroviral vectors. Transmission risks to researchers include self-inoculation and other percutaneous injuries, accidental ingestion, and mucous membrane exposure. BSL-2 is appropriate when work is done with any human-derived blood, body fluids, tissues or primary human cell lines where the presence of an infectious agent may be unknown.

The BSL-2 requirements and recommendations include:

- Work practices: BSL-1 practices, with the addition of: limited access; Biohazard signage; sharps precautions; defined procedures for RMW disposal and medical surveillance (as needed)
- Safety equipment: Class I or II biological safety cabinets or equivalent containment for manipulations with potential for aerosolization or splashing
- PPE: gloves, laboratory coats and eye/face protection
- Facilities: BSL-1 facilities, with the addition of: available autoclave, directional airflow, no air recirculation, and disinfection/decontamination procedures in place.

Biosafety Level 3 (BSL-3) is the appropriate containment level for Risk Group 3 microorganisms that may cause serious or lethal diseases that are transmissible via aerosols. Examples include *M. tuberculosis*, St. Louis encephalitis virus, *Coxiella burnetii, F. tularensis,* certain coronaviruses, and West Nile virus and recombinant DNA activities using genetic material from BSL-3 organisms or such organisms as host cells. Transmission risks include aerosol inhalation, inoculation and other percutaneous injuries, ingestion, and mucous membrane exposure.

The BSL-3 requirements and recommendations include:

- Work practices: BSL-2 practices, with the addition of controlled access; on-site decontamination of all waste and laboratory clothing; and medical surveillance
- Safety equipment: Class II biological safety cabinets or equivalent containment for all open manipulations of agents
- PPE: gloves, laboratory coats, eye/face and respiratory protection (as needed)
- Facilities: BSL-2 facilities, with the addition of: physical separation from access corridors, double-door entry, directional airflow into laboratory, no recirculation of exhaust air, back-up ventilation and filtration systems, and an in-laboratory autoclave.

Biosafety Level 4 (BSL-4) is the appropriate containment level for Risk Group 4 microorganisms that pose the highest individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments. Examples include ebola viruses, nipah virus and variola viruses (e.g., smallpox). As Columbia does not have BSL-4 containment level capabilities, such containment practices will not be outlined in this Handbook.

E. Biological Materials Research

1. Recombinant and Synthetic Nucleic Acids

The purpose of the NIH Guidelines is to specify the biosafety practices and containment principles for constructing and handling recombinant and synthetic nucleic acids (collectively, **rDNA**). rDNA is defined in the NIH Guidelines as:

- Molecules (a) that are constructed by joining nucleic acid molecules and (b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; and
- Molecules that result from the replication of recombinant nucleic acids or synthetic nucleic acids.

Approval for Experiments

Section III of the NIH Guidelines specifies different requirements for approval and registration that must be met prior to or upon initiation of work with rDNA. The following describes the

experimental categories and corresponding review requirements for recognized categories of rDNA research.

- **Section III-A:** Experiments that require IBC and NIH Director approval before initiation, including:
  - Experiments involving the deliberate transfer of a drug resistant trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. These experiments are deemed to be **Major Actions** under the Guidelines.

- **Section III-B**: Experiments that require IBC and NIH OSP approval before initiation, including:
  - Experiments involving deliberate formation of rDNA molecules containing genes for the biosynthesis of certain toxin molecules that are lethal for vertebrates such as botulinum toxins, tetanus toxin, diphtheria toxin and neurotoxins with a "Lethal Dose, 50%" (**LD50**) greater than 100 nanograms per kilogram by body weight. LD50 is the amount of a substance required (usually per body weight) to kill 50% of the test population.

- **Section III-C:** Experiments that require IBC approval before initiation, including:
  - Experiments involving human gene transfer **(**i.e., the deliberate transfer of rDNA or DNA or RNA derived from rDNA into one or more human research participants). Note that IRB approval is also required.

- **Section III-D**: Experiments that require IBC approval before initiation, including:
  - Experiments using Risk Group 2, 3, 4 or Select Agents as host-vector systems.
  - Experiments involving the cloning of DNA from Risk Group 2, 3, 4 or Select Agents into non-pathogenic prokaryotic or lower eukaryotic host-vector systems.
  - Experiments involving the use of infectious or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.
  - Experiments involving whole animals in which the animal's genome has been altered by stable introduction of rDNA into the germ line (i.e., transgenic animals) and experiments involving viable rDNA-modified microorganisms tested on whole animals.
  - Experiments to genetically engineer whole plants.
  - Experiments involving more than 10 liters of culture.
  - Experiments involving high-risk influenza viruses.

- **Section III-E:** Experiments that require IBC notice simultaneous with initiation, including:
  - Experiments involving the formation of rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus if it is demonstrated that the cells lack helper virus for the specific types of defective viruses being used.
  - Experiments involving rDNA-containing plants and plant-associated microorganisms, such as experiments with rDNA-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area.

- Experiments involving the generation of transgenic rodents that require only BSL-1 containment

- **Section III-F**: Exempt Experiments that do not require IBC review, including:
  - *In vitro* experiments using only DNA segments from a single nonchromosomal or viral DNA source, although one or more of the segments may be a synthetic equivalent.
  - *In vitro* experiments that use only DNA from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species, or when transferred to another host by well-established physiological means).
  - Experiments in invertebrates that do not harbor vector-borne disease (e.g., *Drosophila melanogaster* or *C. elegans*.**)**
  - Synthetic nucleic acids that cannot be propagated.
  - DNA segments from a single non-chromosomal or viral DNA source.
  - Breeding of two different transgenic rodents, or breeding of a transgenic rodent and a non-transgenic rodent, if both parental rodents and the offspring of the new strain can be housed under BSL-1 containment.

PIs should contact the Biosafety Program if they want confirmation that their work falls under the Section III-F exemption.

Regardless of whether IBC approval is required, all rDNA-related research must be registered with the Biosafety Program by submitting a **Hazardous Materials Appendix A** in Rascal. See **Registrations and Authorizations: Rascal Hazardous Materials Registration: Appendix A (Section G(1))** below.

One new rDNA technology that is not specifically covered by the NIH Guidelines is the Clustered Regularly Interspaced Short Palindromic Repeats (**CRISPR**)-Cas system. CRISPR-Cas systems (e.g., **CRISPR-Cas9, CRISPR-Cas13**) give researchers the ability to change an organism's DNA easily, rapidly, and cheaply with higher throughput and broader applications, including alterations to the human genome. In the Final Action Under the NIH Guidelines published in April 2019 that described the most recent amendments to the NIH Guidelines, the NIH stated the following:

"Some comments [to the proposed amendments] requested additional guidance in the NIH Guidelines on specific areas of emerging technology, including CRISPR/Cas9 genome editing and T cell immunotherapy, perhaps by utilizing a task force to provide such guidance…These types of amendments were not the purview of this policy change, but the NIH is undertaking a long-term effort to consider further updates to the NIH Guidelines."

On the other hand, the NIH Guidelines indicate that "institutions and IBCs may always choose to expand the purview of their oversight as needed to maintain appropriate oversight over biosafety issues." Accordingly, although not covered in the NIH Guidelines, the University has adopted the following criteria for when IBC review is required in gene editing experiments:

- IBC review **is not** required for any gene editing experiment that is exempt from the NIH Guidelines. This includes in vitro experiments in Risk Group 1 prokaryotes, eukaryotic cell lines, or embryonic stem cells or embryos that are not implanted. Also exempt are experiments in invertebrates such as *D. melanogaster* or *C. elegans* (but excluding gene-drive experiments).
- IBC review **is** required for any gene editing constructs introduced by Risk Group 2 viral vectors such as lentiviral vectors whether *in vitro* or *in vivo.* Gene editing experiments in plant or invertebrate animals that are vectors of disease will require IBC review, as will gene editing in vertebrate animals and human subjects.
- IBC review **is** required for any experiments involving gene drives in any sexually reproducing organism, including animals (vertebrates and invertebrates), plants and fungi.

PIs should check the applicable box in LATCH if they are performing any work with gene editing tools or gene drives, regardless of whether IBC review is needed.

In general, note that:

- The current IACUC review of rDNA-related research in vertebrate animals includes review of gene editing through the submission of Appendix A.
- The current IRB review of rDNA-related research in human subjects includes review of gene editing through submission of Appendix M.
- All work with human embryos or human pluripotent stem cells requires review by the University's Human Embryonic and Human Pluripotent Stem Cell Research Committee.

See also the University's Recombinant DNA Policy for additional information on requirements for submission to and approval by the IBC and use of rDNA.
https://research.columbia.edu/requirements-submission-and-approval-use-recombinant-dna

2. Viral Vectors

A viral vector (**Viral Vector**) is a viral genome modified to deliver foreign genetic material into a cell. Viral genome modifications generally include deletions in some or all essential genes. The Viral Vector may be contained in and/or expressed by another vector, such as a bacterial plasmid or other virus. Common Viral Vectors include, but are not limited to, lentivirus, adenovirus, adeno-associated virus, moloney murine leukemia virus, pseudorabies, g-deleted rabies virus, vaccinia, and herpes simplex virus. rDNA activities utilizing Viral Vector systems fall under the NIH Guidelines and are described in **Recombinant and Synthetic Nucleic Acids (Section 1)** above. PIs must register work with Viral Vectors with the IBC via submission of an Appendix A in Rascal.

Viral Vectors that are replication-defective because of deletion of trans-acting genes are safest in terms of biosafety; however, there are instances when replication-competent Viral Vectors are utilized in research. Additionally, any strain that is known to be more hazardous than the parent or wild-type strain should be handled at a higher containment level. In either case, this does not

preclude using appropriate safety precautions in the laboratory based on the Risk Assessment Factors.

The PI risk assessment (with recommended consultation with the Biosafety Program) should include:

- Identification of the Risk Group of the Viral Vector;
- Consideration of how the agent is to be manipulated to determine the BSL containment level and where the experiment may fall under the NIH Guidelines;
- Consideration of pathogenicity, virulence, infectivity, transmissibility, agent stability and communicability;
- Consideration of gene product effects such as toxicity, physiological activity, and allergenicity; and
- Consideration of availability of vaccine or treatment.

3. Microorganisms and Infectious Agents

The Biosafety Program reviews the safe handling and containment of microorganisms used in research. When microorganisms cause infection in a host, they are considered to be an infectious (pathogenic) agent. When there is an invasion and growth of infectious agents in the host and tissue function is impaired, this is called disease. See **Biosafety Risk Assessment and Containment: Risk Assessment (Section D(1))** above for information on Risk Groups and BSL containment levels of different microorganisms.

Microorganisms include:

- Bacteria and other unicellular living organisms, including *S. aureus, B. subtilis, S. cerevisiae, E. coli, Lactobacillus* spp., etc.
- Viruses and other agents that replicate only in living cells, including influenza, HIV, hepatitis, etc.
  - Viral Vectors are a subset of viruses. See **Viral Vectors (Section 2)** above.
- Fungi and other multicellular living organisms, including yeast organisms *Candida* spp. or *S. cerevisiae,* and molds such as *Aspergillus* spp.
- Parasites and other agents that live in or on other organisms, and obtain nutrients at the expense of the host, including *Plasmodium* spp., *Giardia* spp., Nematodes, etc.
- Prions and other misfolded proteins with the ability to transmit their misfolded shape onto normal variants of the same protein. Prions cause diseases such as bovine spongiform encephalopathy ("mad cow disease"), transmissible spongiform encephalopathy, scrapie, etc.

The Biosafety Program is concerned about certain subsets of microorganisms and their related by-products:

- Risk Group 2 and above agents that are capable of causing infection and disease in health adults;
- Bloodborne pathogens;
- Biological toxins; and

- Select Agents and Toxins.

Research with BSL-2 and BSL-3 microorganisms and infectious agents must be registered with the IBC via submission of Appendix A in Rascal. Additional documents may be requested; up-to-date requirements will be listed on the EH&S website.

The PI risk assessment (with recommended consultation with Biosafety Program personnel) should include:

- Identification of the Risk Group of the microorganisms;
- Consideration of how the agent is to be manipulated to determine the BSL containment level;
- Consideration of Risk Assessment Factors; and
- Consideration of availability of a vaccine or treatment.

4. Bloodborne Pathogens

Infectious agents that are transmitted through human blood (or through other potentially infectious materials that may contain blood or blood products) and cause diseases are called bloodborne pathogens (**Bloodborne Pathogens**). Bloodborne pathogens include, but are not limited to, hepatitis B (**HBV**), hepatitis C (**HCV**), HIV, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob Disease, Human T-Lymphotrophic virus type 1, dengue virus, zika virus and viral hemorrhagic fever.

Materials that could contain Bloodborne Pathogens include:

- Human body fluids, including blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids even in situations where it is difficult to differentiate between different body fluids;
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- HIV-containing cell or tissue cultures, organ cultures, HIV- or HBV-containing culture medium or other solutions, and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

All University employees, including faculty, who work with materials that may contain Bloodborne Pathogens are subject to the requirements of the OSHA BBP Standard and should take standard precautions when working. Standard precautions with respect to infection control include treating all human blood and certain human body fluids as if they are known to be infectious, and requiring employees who encounter such materials to use hand hygiene, wear certain types of PPE, use safe injection practices and manage contaminated equipment and items. When processing clinical or human specimens, human cell lines, or infectious materials that may have the potential for harboring Bloodborne Pathogens, BSL-2 containment practices should be utilized as outlined in **Biosafety Risk Assessment and Containment: Risk Assessment (Section D(1))** above.

The OSHA BBP Standard also requires that a Bloodborne Pathogen Exposure Control Plan (**ECP)** be written and followed at institutions where there is occupational risk of exposure. Columbia's ECP can be found on the EH&S website as part of the University's Bloodborne Pathogens Exposure Control Policy. The ECP is applicable to all University employees, students and researchers who could be "reasonably anticipated", as a result of performing their job duties, to come in contact with blood and other potentially infectious materials. The ECP outlines the protective measures that should be implemented to eliminate or minimize employee exposure to blood and other potentially infectious material to reduce the risk of infection. These measures include:

- Availability of engineering controls, sharps container and engineered sharps, etc;
- Work practices using standard precautions;
- PPE, including gloves, laboratory coats and eye protection;
- Provision of HBV vaccinations by WH&S or SHS**;**
- Annual BloodbornePathogen training as described in **Training: Biological Safety/Bloodborne Pathogens/Infection Control (Section F(1))** below;
- Housekeeping and disinfection procedures, including PPE laundering;
- Appropriate segregation and disposal of RMW;
- Incident response and medical evaluations in case of Bloodborne Pathogen exposure;
- Biohazard labels and signage; and
- Recordkeeping, including medical and training records and medical incident reports.

The BBP Policy and the ECP are reviewed by EH&S on an annual basis.

5. Biological Toxins

Biological toxins comprise a broad range of poisons, either naturally derived from an animal, plant or microbial source or synthetically derived, that cause death or severe incapacitation at relatively low exposure levels. Certain biological toxins are regulated as Select Agents and are described in **Select Agents and Toxins (Section 6)** below.

Biological Toxins are produced by:

- Bacteria, such as diphtheria toxin, botulinum toxin, pertussis toxin and staphylococcal enterotoxins;
- Fungi, such as aflatoxin, fusarium and T-2 toxin;
- Animals, such as snake venom toxin, tetrodotoxin and conotoxin; and
- Plants, such as ricin.

Biological toxins do not replicate and are therefore not considered infectious. Laboratory work with most toxins, in amounts routinely employed in the biomedical sciences, can be performed safely with minimal risk to the worker and negligible risk to the surrounding community. However, they may be extremely toxic in very small quantities and must be managed like hazardous chemicals in the laboratory. The main laboratory risks are accidental exposures to toxins by direct contamination of the mouth, eyes or other mucous membranes; by inadvertent

aerosol generation; and by needle-sticks or other accidents that may compromise the normal barrier of the skin.

The following are some guidelines on training and laboratory planning, as well as safety equipment and containment. Most toxins are handled as BSL-2 level agents, except for the Select Agents that may require a higher biosafety level. As is always the case, PIs are responsible for all work done in their laboratories and special attention should be paid to work with biological toxins.

In general, toxins can be handled using established general guidelines for toxic or highly-toxic chemicals. Each laboratory should develop a specific CHP. Engineering controls, such as CFHs, should be selected according to the risk assessment of each specific toxin operation. Appropriate PPE, including gloves, laboratory coats, and eye/face and respiratory protection (as needed), should be made available to all personnel in the laboratory.

In addition to the training outlined in **Training (Section F)** below, each laboratory worker and researcher should be trained on the nature of practical hazards associated with laboratory operations. Laboratory-specific SOPs should be put in place, covering laboratory procedures, disposal and disinfection practices, medical surveillance and spill and exposure response. These SOPs must be maintained in the laboratory in hard copy. It is recommended that new workers undergo supervised practice runs before using active toxins.

Work with biological toxins (other than inert subunits such as cholera toxin B) must be approved in advance by EH&S. EH&S review is initiated for toxins produced by non-recombinant means (procured as preformed peptides or chemicals) by submission of an Appendix E in Rascal and for peptide toxins expressed by recombinant means by submission of Appendix A in Rascal, which may be subject to the NIH Guidelines and required to be reviewed by the IBC.

Additional information can be found in the University's Biological Toxin Policy that is available at https://research.columbia.edu/system/files/EHS/Policies/ToxinsBiological.pdf.

6. Select Agents and Toxins

The Federal Select Agent Program defines "Select Agents" as biological agents (**Select Agents)** and toxins (**Select Toxins)** that have been determined by the CDC and/or the USDA to have the potential to pose a severe threat to public health and safety, to animal or plant health or to animal or plant products. Examples include *B. anthracis, F. tularensis,* ebola virus, avian influenza virus, ricin and botulinum neurotoxins. There are currently 67 Select Agents and Select Toxins; the federal list of **Select Agents and Select Toxins** and certain exemptions is attached hereto as **Annex V-A** and can also be found at http://www.selectagents.gov/SelectAgentsandToxinsList.html.

Federal regulations require that entities in possession of Select Agents develop and implement routine and emergency preparedness measures to ensure their safety and security. The Select Agent Program at Columbia ensures compliance with all applicable federal regulations (7 CFR 331, 9 CFR 212 and 42 CFR 73), as well as the NIH Guidelines and the BMBL.

PIs wishing to acquire and use Select Agents or Select Toxins (above the exempt quantities set by the CDC and/or USDA) must first obtain CDC or USDA approval by demonstrating that the materials will be used in appropriately engineered facilities, with adequate security. This is verified with an on-site inspection by the appropriate federal agency. Approval is also contingent upon demonstration of appropriate SOPs relating to biological safety and biosecurity.

Acquisition and use of a Select Toxin (e.g., botulinum neurotoxins, tetrodotoxin) are exempt from the CDC and USDA registration and approval processes so long as the Toxin does not exceed a certain amount (the **Permissible Toxin Amount**). For a full list of Permissible Toxin Amounts, see https://www.selectagents.gov/PermissibleToxinAmounts.html.

Even if a PI possesses amounts smaller than the Permissible Toxin Amounts, he/she is still responsible for the following:

- Preventing a stockpile of toxins by not transferring toxins to other researchers unless the PI ensures that the recipient has a legitimate need to handle or use toxins and that the recipient will not hold toxins in amounts above permissible limits;
- Reporting to the Select Agent Program (via the Responsible Official or his/her Alternate) if he/she detects a known or suspected violation of federal law or become aware of suspicious activity relating to the toxin; and
- Completing an attestation in the Rascal course *TC4250: Select Agent Awareness Training and Attestation*.

7. Dual Use Research of Concern

Despite its value and benefits, certain types of legitimate research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called **Dual Use Research.** Dual Use Research of Concern (**DURC**) is a subset of Dual Use Research and is defined as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material or national security."

In 2012, the U.S. Government (**USG)** released the U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern: https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf (the **2012 Policy).** In 2014, the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf (the **2014 Policy)** was released to establish the requirements for institutional (i.e., non-USG) oversight of DURC.

The USG has designated 15 agents and toxins (**DURC Agents**) used in seven types of experiments (**Experimental Effects of Concern**) as DURC. The DURC Agents are listed in the 2012 Policy. Experimental Effects of Concern are defined in the 2014 Policy and include research that:

- Enhances the harmful consequences of the agent or toxin;
- Disrupts immunity or effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
- Increases the stability, transmissibility or ability to disseminate the agent or toxin;
- Alters the host range or tropism of the agent or toxin;
- Enhances the susceptibility of a host population to the agent or toxin; or
- Generates or reconstitutes an eradicated or extinct agent or toxin listed in the DURC Agents list.

At Columbia, a PI must submit for institutional review research that meets any of the following criteria:

- The research directly involves nonattenuated forms of one or more of the DURC Agents;
- The research with nonattenuated forms of one or more of the DURC Agents that also produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern; or
- The PI concludes that his/her research may meet the definition of DURC.

If a PI's research meets (or will do so in future research as determined during the grant-writing phase) any of the foregoing criteria, he/she must also assess whether the research produces, aims to produce or is reasonably anticipated to produce one or more of the Experimental Effects of Concern. Upon completion of such assessment, the PI must promptly notify the IBC by contacting EH&S and provide the IBC with documentation indicating the reasons for the conclusion that his/her research involves potential DURC and sufficient data to permit the IBC to complete its review. If the IBC concludes that the research is not subject to additional DURC oversight, it will notify the PI in writing. If the IBC concludes that the research does involve one or more DURC Agents and Experimental Effects of Concern, the IBC will refer the review to the EVPR, who will convene an ad hoc committee of experts to assess whether the research does or does not meet the definition of DURC. If the research involves DURC, the PI must develop a risk mitigation plan to be approved by the EVPR and submitted to the applicable funding agency for finalization.

The University's Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern is available on the EVPR website.

F. Training

All individuals, including PIs, involved in research with biological materials must take the requisite trainings. The following is a list of the principal training courses required for research personnel using biological materials. All initial training must be taken prior to commencing work with such materials. For a complete list of safety training courses, see **Determining Your Safety Training Requirements @ Columbia University** attached hereto as **Annex III(F)).**

Additional information about training courses, including schedules for classroom safety trainings and all online courses in Rascal, can be found on the EH&S website at https://research.columbia.edu/content/safety-trainings.

1. Biological Safety/Bloodborne Pathogens/Infection Control

All University faculty, staff and students working with human blood, body fluids, unfixed tissue, human or non-human primate cell lines or any materials deemed capable of transmitting HIV, HBV, HCV or other bloodborne diseases, and microorganisms, including viral vectors, are required to take Biological Safety/Bloodborne Pathogens/Infection Control training. The course covers many of the subjects included in this Handbook.

The initial training must be taken during a regularly scheduled classroom session. Attendees at the classroom training will be given credit for the following courses: *TC4850*: *Biological Safety/Bloodborne Pathogens Initial Classroom Training* and *TC4950: Biological Safety Cabinet Initial Classroom Training.*

Refresher training is required on an annual basis and may be completed by either retaking the regularly scheduled classroom training or by taking the Rascal online course *TC0509: Biological Safety/Bloodborne Pathogens Refresher Training* and pass a test with a score of 80% or better.

For personnel conducting research in clinical settings, EH&S recommends the Rascal online course *TC0025: Bloodborne Pathogens/Infection Control Training for Personnel in Human Research Studies and Clinical Settings*. It details what one must do to reduce one's risk of exposure to blood and bodily fluids capable of transmitting bloodborne diseases such as HIV, HBV and HCV. NYP Bloodborne Pathogen Training is an acceptable substitute, but note that this course credit will not show up in Rascal.

Refresher training is required on an annual basis and is completed by retaking *TC0025: Bloodborne Pathogens/Infection Control Training for Personnel in Human Research Studies and Clinical Settings.*

2. Biological Safety Cabinets

All personnel using a biological safety cabinet must take the Rascal online course *TC3550: Biological Safety Cabinet Refresher Training* and pass a test with a score of 80% or better.

Refresher training is required every two years and may be completed by retaking *TC3550: Biological Safety Refresher Cabinet Training.*

Biological safety cabinet training is a component of the classroom Biological Safety/Bloodborne Pathogens/Infection Control training, so attendees at such training will receive credit for *TC4950: Biological Safety Cabinet Initial Classroom Training*.

3. Recombinant DNA

PIs who use rDNA in research must take the Rascal online course *TC0508: Recombinant DNA and NIH Guidelines Training* and pass a test with a score of 80% or better. The course covers the requirements of the NIH Guidelines. Anyone may take this course, but it is only required for PIs.

Refresher training is required every three years and may be completed by retaking *TC0508: Recombinant DNA and NIH Guidelines Training*.

4. Viral Vectors

All personnel working with viral vectors in research must take *TC1150: Viral Vector Research-Handling and Biosafety* and pass a test with a score of 80% or better. The course covers the different features of commonly utilized viral vectors, how to perform a risk assessment of each viral vector, safety considerations, and safe work practices.

Refresher training is required every two years and may be completed by retaking *TC1150: Viral Vector Research- Handling and Biosafety*

5. Select Agent Toxins

PIs who utilize Select Agent Toxins in research must take the Rascal online course *TC4250: Select Agent Toxins Awareness Training and Attestation,* and answer a one-question attestation. The course covers compliance with the Federal Select Agent Program, inventory thresholds, purchasing, transfer or redistribution of toxins, the DURC policy, disposal, and accidents/exposures information.

6. Shipping Biological Materials

National and international regulations require that anyone who ships "biological materials" (human or animal materials or any substances that may contain infectious microorganisms) be provided with specific training. Taking the Rascal online course *TC0507: Shipping Biological (Infectious and Potentially Infectious) Materials and Genetically Modified Microorganisms* and passing a test with a score of 80% or better fulfills this requirement. PIs must also take this course even if staff are sending packages on their behalf. The course covers biological materials classification, packing instructions, packaging material, package marking and labeling, documentation, package security, international shipping, records retention and inspections, and intercampus transport.

Refresher training is required every two years and may be completed by retaking *TC0507: Shipping Biological (Infectious and Potentially Infectious) Materials and Genetically Modified Microorganisms.*

7. Laboratory Autoclave and Automated Equipment Washer Safety and Hazard Awareness

Researchers who operate autoclaves or automated washing equipment are encouraged to complete Rascal online course *TC4501*: *Laboratory Autoclave and Automated Equipment Washer Safety and Hazard Awareness Training* and answer a one-question attestation. See **Laboratory and Research Safety: Training – Laboratory Autoclave and Automated Equipment Washer Safety and Hazard Awareness Training (Chapter III, Section E(8)).**

8. Cryostat and Microtome Safety

Although not mandatory, it is recommended that personnel who use cryostats and microtomes in a laboratory take *TC4750: Cryostat and Microtome Safety* and answer a one-question attestation. The course guides users of cryostats and microtomes in potential hazards of operation such as sharp objects, cold temperatures and infectious agents. Risk mitigation provisions are introduced including work practice controls, PPE and medical response for accidents.

G. Registrations and Authorizations

1. Rascal Hazardous Materials Registration: Appendix A

Biological materials that are potentially hazardous may pose an occupational risk to researchers As a result, PIs who wish to work with such materials are required to fill out a Hazardous Materials Appendix A (**Appendix A)** in Rascal (https://www.rascal.columbia.edu/) prior to commencing work with certain biological materials.

The biological hazards that require submission of an Appendix A include:

- rDNA;
- Recombinant toxins;
- Viral vectors;
- BSL-2 and above infectious agents, including bacteria, viruses, fungi, parasites and prions;
- Human cell lines or materials that may harbor Bloodborne Pathogens; and
- Infectious agents used in invertebrates or invertebrates used within vertebrate animals (for example, ingestion of worms in a mouse study).

Appendix A is either attached to an IACUC or IRB protocol or submitted directly to the Biosafety Program as a standalone protocol. A sample Appendix A is attached hereto as **Annex V-B.**

A Biosafety Officer will initially screen the Appendix A for completeness and determine if it is eligible for review. The Biosafety Officer may request additional information to be submitted. Some Appendices A only need Biosafety Officer review and approval. Others require IBC review and approval after review by the Biosafety Officer. When deemed to be acceptable, the Appendix A and the related protocol, if any, are provided to the IBC for final approval. See **Roles and Responsibilities: Institutional Biosafety Committee (IBC) (Section C(1)**) above. The IBC will communicate with investigators via a Biosafety Officer regarding approval or the

need to modify a submission prior to approval. IACUC or IRB protocols are not approved until the attached Appendix A has been approved.

An Appendix A relating to *in vivo* work must be renewed annually and an Appendix A relating to *in vitro* work must be renewed every three years, by submitting a new Appendix A. When there is a significant change in the use of biological materials in research for which an Appendix A has been already approved, an Appendix A Modification must be submitted by copying the previously approved Appendix A, editing it for new changes, and resubmitting it within Rascal. The Biosafety Office will review the Modification.

2. Rascal Hazardous Materials Registration: Appendix E

PIs who wish to work with biological toxins or venoms in animals are required to fill out a Hazardous Materials Appendix E **(Appendix E)** in Rascal (https://www.rascal.columbia.edu/) prior to commencing work with these materials. See **Occupational Health and Safety: Use of Hazardous Materials in Animal Research (Chapter IX, Section E).**

3. Rascal Human Gene Transfer Registration: Appendix M

Prior to commencing any research involving human gene transfer, the PI must submit the following documents to the IBC, concurrently with IRB review:

- A completed Hazardous Materials Appendix M: IBC Application for the use of Recombinant DNA (rDNA) Molecules in Human Gene Transfer (**Appendix M)**;
- The related IRB protocol;
- The scientific abstract, including one from the grant proposal or in the Investigator Brochure; and
- The informed consent document that is currently (or will be) under consideration by the IRB.

For additional information, see Addendum 2 to the IBC Charge:
https://research.columbia.edu/system/files/EHS/BioSafety/IBCCharge.pdf

A sample Appendix M is attached hereto as **Annex V-C**.

Clinical research involving human gene transfer no longer requires prior submission to the NIH's Office of Biotechnology Activities. See https://osp.od.nih.gov/biotechnology/nih-guidelines/ In 2018, the FDA became the sole reviewing agency. The NIH has refocused the role of the NIH Recombinant DNA Advisory Committee (**RAC**) to be closer to its original mandate as a transparent forum for science, safety and ethics of emerging biotechnologies. The RAC has been renamed the Novel and Exceptional Technology and Research Advisory Committee (**NExTRAC**). Examples of clinical research that would be subject to NExTRAC review include human germ line gene editing or creation of human-animal chimeras. If NExTRAC review is warranted, the PI and the IRB will be provided with a written assessment from the IBC. The IBC may not approve a protocol until NExTRAC has completed its review.

A PI must report adverse events that are unexpected and possibly associated with human gene transfer intervention to the sponsor within the time frames indicated in **Unanticipated Problem, Adverse Event and Protocol Deviation/Violation Reporting (Chapter XIII)** of the **Clinical Research Handbook**.The PI must also report this information to the IBC (by notifying biosafety@columbia.edu as soon as possible after the event.

4. Procurement of Biological Materials

Setting up a new account with an external Cell Repository may require Biosafety Program approval. A Cell Repository (e.g., American Type Culture Collection or other similar company) is a central collection that distributes microorganisms, cell lines, and other materials. The Cell Repository may request that a Biosafety Officer sign the application to set up an account.

Prior to signing the application, a Biosafety Officer will survey the laboratory where the material will be used to confirm administrative and engineering controls, work practices and SOPs depending on the BSL laboratory status. The Biosafety Officer may request that the materials be registered with the IBC. If the laboratory controls and practices are acceptable, the Biosafety Officer will sign the application. The Biosafety Officer will not sign the application if the laboratory practices are not acceptable or if corrective actions have not been completed.

5. Material Transfer Agreements

If human materials (blood, serum, cell lines, etc.) or bacteria, viruses or other non-human biological materials will be distributed to researchers at the University or by University researchers to external recipients, the CTO, CTV or SPA will review and negotiate the relevant Material Transfer Agreement (**MTA**) depending on the affiliation of the PI (CUIMC vs. non-CUIMC) and whether or not the material is human or human-derived. See **Preparing a Sponsored Project Proposal: University Offices That Can Assist with Proposal Development and Submission and Other Agreements—Summary of Processing Responsibilities (Chapter IV, Section E(4))** in the **Sponsored Projects Handbook.**

H. Hazard Controls and Protections for Use of Biological Materials

The foundation of any biological safety program is the use of control measures appropriate for the risk posed by the activities and the agents in use. The following are various measures used by EH&S to control and protect researchers in their use of biological materials in research.

1. Work Practices

Although PIs are ultimately responsible for all activities in their laboratories, it is important that all individuals working in a laboratory bear primary responsibility for their own safety and health. The following are considered to be basic precautions for all laboratories working with biohazardous materials:

- Post a sign on the laboratory door that states the name and phone number of the PI, emergency contact number(s), any entry restrictions, and for laboratories that generate RMW or work with BSL-2 or BSL-3 organisms, the universal Biohazard symbol attached as **Annex V-D.**
- Keep doors closed in BSL-2 or BSL-3 laboratories.
- Prohibit drinking, chewing gum, applying cosmetics, or handling contact lenses in work areas. Food or beverages should never be stored in refrigerators or freezers used for research materials.
- Cover work surfaces with Benchkote Absorbent liner or other absorbent material; use disinfectant-soaked towels for work with highly infectious material or when splashing/spattering is anticipated.
- Decontaminate work surfaces at the end of procedures and immediately after a spill. Limit bench-top items to those in immediate use; cluttered areas are more likely than well-maintained spaces to be the sites of accidents and are harder to clean and disinfect.
- Place reusable sharps, such as surgical instruments, in puncture-resistant biohazard symbol-labeled containers with disinfectant solution after use. Develop detailed protocols for handling, cleaning, disinfecting and/or sterilizing reusable sharps.
- Minimize splashing and aerosol generation. When pipetting, expel liquids against the sidewall of a tube rather than against the tube bottom. If aerosols of infectious materials will be generated, work must be performed in a biological safety cabinet.
- Use secondary containers (e.g., trays, specimen transport bags) for long-term storage or transport of infectious materials. Whenever possible, researchers should replace glassware with plastic; glass Pasteur pipettes are prone to breakage, which may lead to injury.
- Never pipette by mouth. Use only mechanical pipetting devices and cotton-plugged pipettes; do not expel air through a pipette to mix suspensions containing infectious or toxic materials.

2. Engineering Controls

Engineering controls are devices and equipment that isolate and contain a hazard. The best engineering controls function with a minimum of user input and may to a degree compensate for human error.

Biological Safety Cabinets

Biological safety cabinets **(BSCs)** are the primary engineering control for the minimization of exposure to potentially infectious materials. BSCs combine directional airflow and high efficiency particulate air (**HEPA**) filters to protect researchers and the environment from aerosolized microorganisms. Most BSCs also protect the materials used within the BSC from contamination. All open manipulation of BSL-2 and above organisms and all manipulations of microorganisms requiring BSL-3 containment must be performed in a BSC.

The most commonly purchased and utilized type of BSC is a Class II, type A2 cabinet. Air enters the cabinet through the front, recirculates in the cabinet and is discharged from the cabinet into

the laboratory through a HEPA filter that removes 99.97% of particles with an aerodynamic diameter of 0.3 microns. HEPA-filtered air is also supplied to the work area and air stream meets incoming ambient air to create an "air curtain" that provides protection against environmental contamination. The other type of BSC that may be encountered in the laboratory is a Class II, type B BSC. These BSCs are connected to the HVAC system and air is discharged through a HEPA filter and out of the building. This is not a popular choice because Type B cabinets are difficult to install, balance, and maintain.

Some laboratories have a clean air bench or a laminar flow hood; these devices could be confused with a BSC because of their physical similarities. Clean Air Benches draw air through a filter and direct a filtered airstream (and any contaminants, if present) from the inside of the workspace out into the laboratory and into the face of the researcher. These benches or hoods are for handling sterile materials or when a dust-free environment is needed for the protection of the material, rather than the researcher and should never be used for handling infectious materials.

A qualified vendor must annually certify a BSC. A list of qualified vendors can be found on the EH&S website at https://research.columbia.edu/companies-accredited-certification-biological-safety-cabinets. Conditions when a BSC must be re-certified include:

- Following relocation (including within a room). BSC on castors/wheels may be moved carefully without subsequent re-certification;
- Following a HEPA filter change;
- Following service that may have affected containment ability; and
- If the airflow, indicated by magnehelic gauges on the BSC, falls out of an established range.

Semi-annual re-certification is recommended when the BSC is used for work with airborne-transmitted organisms and other high risk agents (e.g., *M. tuberculosis*).

If a BSC that is on castors/wheels must be relocated within a room, building, or conjoined building, all surfaces must be wiped down with a freshly made 10% bleach solution. Submission of a clearance request to EH&S is required; the form for the request can be found at https://research.columbia.edu/system/files/EHS/Forms/ClearanceRequestForm.pdf. Once EH&S has signed the clearance document, the BSC may be moved by a general moving company or Facilities Operations.

If a BSC is being moved from a building to a non-conjoined building using public streets or between campuses or to another institution, professional decontamination by a University-approved accredited vendor is required before EH&S can issue a clearance. Once re-positioned, the BSC must be re-certified by an accredited vendor.

If the laboratory is discarding a BSC or a PI is leaving it behind when exiting the University (without being bequeathed to another researcher), the BSC must have professional decontamination by a University-approved accredited vendor, as referenced above, prior to EH&S clearance.

BSCs should be located in low traffic areas within the laboratory away from air-supply grilles and doorways as drafts may disrupt protective air flow. In addition, do not block the front air intake or the rear exhaust grille.

When using a BSC, keep the following tips in mind:

- Work 4-6 inches from the front of the BSC, over the tray and not over the grille.
- Avoid rapid arm movements that can disrupt airflow.
- In order to minimize arm movements in and out of the BSC, place all needed materials in the BSC at the start of procedures, arranging them so that "dirty" items do not pass over "clean" ones.
- To prevent backflow of contaminated fluids into the HVAC system, use a vacuum line HEPA filter between the vacuum line and the aspiration flasks.
- Allow the BSC fan to run five minutes prior to and at the completion of work; wipe the interior with 70% ethanol before and after work.
- Remember to clean the work surface and the removed work surface to clean the area beneath. A schedule for regular removal of the tray and disinfection of the space beneath with 10% bleach followed by 70% ethanol is recommended.

Researchers must not use volatile or toxic chemicals inside a BSC. The HEPA filters do not capture gasses or vapors; additionally, the recirculating air will cause fumes to accumulate, which may cause lung injury or a fire hazard.

Researchers must not use a Bunsen burner inside a BSC. Open flames are not required to keep a microbe-free cabinet environment. An open flame in a BSC creates turbulence that disrupts the pattern of HEPA-filtered air being supplied to the work surface and may damage the cabinet or cause a fire inside it.

Environmental Rooms

There are also special considerations for environmental rooms, known more colloquially as warm and cold rooms, designed to control temperature and humidity. Environmental rooms are typically unventilated. Fresh air only enters the room when the door is opened. Therefore, the release of hazardous materials within an environmental room due to spills or vaporization poses potential health and safety hazards to occupants. Researchers should not keep food, beverages or hazardous materials in an environmental room. Spills or odors in these enclosed spaces may become a safety hazard.

Researchers must also minimize potential mold growth. Unabated mold growth on environmental room surfaces may lead to mycological contamination of research projects and pose potential health problems from inhalation of spores. Minimize mold growth by keeping cardboard out of the environmental rooms and report any leaks to Facilities Operations. Researchers should be aware that Facility Operations may require removal of all items from an environmental room to complete repairs or clean mold; removal of items is the researcher's responsibility.

3. PPE

The appropriate use of PPE is critical to reducing exposure to potentially infectious materials. In most instances, the minimum level of PPE for laboratory personnel consists of gloves, a laboratory coat, and eye protection.

It is the responsibility of the PI to ensure that laboratory staff wear the appropriate PPE whenever there is the potential for occupational exposure and PPE should be provided at no cost to the staff.

Gloves

Gloves must be worn whenever handling infectious materials as they are an effective barrier. Glove selection should be based on an appropriate risk assessment. Users of latex gloves may be at risk for developing allergies to latex or the chemicals used in manufacturing these gloves. Staff who prefer latex should use only powder-free gloves that are designated "low protein" by the manufacturer. Alternatives to latex gloves such as nitrile or vinyl gloves should be available.

Corrosives and organic solvents may penetrate gloves or diminish their protective ability; it may be necessary to stock more than one type of glove for the full range of a laboratory's activities. Glove compatibility information is available from glove manufacturers or consult the Biosafety Program about appropriate glove types.

Laboratory Coats

Researchers must wear coats that are resistant to liquid penetration for activities with splash potential or use a plasticized apron. For high-risk activities, a rear-fastening lab coat is recommended.

Laboratory coats must not be worn outside of the laboratory if they were used during work with infectious materials.

It is the laboratory’s responsibility to provide laboratory coat laundering services, as well as replacement coats. Employees should not launder contaminated laboratory coats at home.

More information about laundering services can be found at https://research.columbia.edu/content/personal-protective-equipment-ppe.

Eye Protection

Mucous membranes around the eyes can be an entry portal for infectious materials. Glasses routinely worn for vision correction do not provide the appropriate level of protection for work with hazardous materials. Safety glasses with side shields provide the minimum level of protection for handling any hazardous material. Goggles should be used when there are anticipated splashes or sprays of infectious or other hazardous materials or when microorganisms are handled outside of a BSC or other containment device. Goggles are used with a face shield

when an elevated risk of large quantity splashes exist or when working with highly toxic, corrosive or infectious materials. Eye and face protection must be decontaminated before reuse.

Surgical Masks

Masks will help prevent ingestion of liquid droplets and protect the mucous membranes of the nose and mouth. They do not provide sufficient protection against organisms transmitted by inhalation (e.g., *M. tuberculosis*); rather, they are intended to capture potentially infectious droplets and aerosols released by the wearer.

Respirators

Respirators are used when there is the risk of airborne exposure to organisms transmitted by inhalation and containment devices are unavailable or unable to provide sufficient protection. Researchers should consult with EH&S to determine if a respirator is required or if there are other options. If respirators use is deemed necessary, respirator users must have medical clearance through the Medical Surveillance Program and additionally undergo fit-testing and training.

4. Laboratory Equipment

In addition to electrical and mechanical considerations, laboratory equipment may pose hazards relating to the materials used in them. Some equipment may be one-of-a-kind requiring specialized training. Other equipment becomes obsolete relatively quickly and each new piece requires relearning some operational aspects. Be sure that Users' Manuals are readily accessible and when in doubt, contact the customer service representative of the manufacturer of the equipment. Do-it-yourself fixes are not only dangerous, but may invalidate warranties. Senior laboratory personnel are responsible for ensuring that new staff are familiar with the safe operation of equipment. There may also be specific requirements for moving sophisticated equipment, so that a customer service representative should be contacted or the Users' Manual carefully reviewed.

Water Baths

Water baths may become contaminated by organisms incubated in them or through amplification of water or airborne organisms. Iodine-based or phenolic disinfectants are recommended for intermediate temperature baths. A 10% dilution of household bleach is also effective, but may corrode water bath components. Never use sodium azide; it is fairly toxic and drain disposal is illegal and may result in the formation of explosive metal azides. Consult the manufacturer to determine the recommended disinfectant. Do not leave water baths on overnight or unattended for an extended period of time.

Cryostats

A **cryostat** is a device used to maintain low cryogenic temperatures of samples or devices mounted within the cryostat. Low temperatures may be maintained within a cryostat by using

various refrigeration methods such as liquid helium. In the biomedical sciences, cryostats are used in a process called frozen section histology. The cryostat is essentially an ultra-fine "deli slicer", called a microtome, placed in a freezer. The microtome slices tissue into pieces thin enough to be observed under a microscope.

Cryostats should be regularly decontaminated with a tuberculocidal or hospital disinfectant, such as Quat Plus TB. Trimmings and tissue section should be treated as potentially infectious. Never attempt to clear debris from a blade with your finger; always use a brush or other mechanical device to prevent contact with the blade. When changing blades, use protective gloves and handle the blades with forceps or tongs. Pre-soaking blades in a disinfectant solution prior to cleaning will reduce the number of viable microorganisms.

Mixers, Blenders and Sonicators

Mixers, blenders and sonicators are used in the laboratory to mix materials, extract compounds or disrupt cell membranes. A **sonicator** applies sound energy to agitate particles in a sample. Sonicators mix solutions, dissolve solids into liquids and remove dissolved gas from liquids.

Mixers, blenders and sonicators produce large quantities of aerosols. Models designed to contain aerosols are available. These devices should be operated within a BSC with disinfectant moistened towel placed over the top of the device. The device should be opened only after allowing time for aerosols to settle. If possible, avoid using glass bowls. Sonication may be safely performed by placing a tightly capped specimen tube in a beaker of water and putting the probe in the water rather than in the tube.

Lyophilizers

A **lyophilizer** or freeze dryer executes a water removal process, typically used to preserve perishable materials, to extend shelf life or transport materials. Lyophilization is a process in which water is removed from a product after it has been frozen and placed under a vacuum, allowing the ice to change directly from a solid to a vapor without passing through a liquid phase.

Lyophilizers produce a dry solid that is very easily dispersed. They should be fitted with a HEPA filter or vented to a BSC when used for drying suspensions of infectious material. Ampoules of lyophilized solids should be opened only in a BSC; a disinfectant-moistened pad should be placed over the scored line when opening the ampoule. Changer surfaces should be disinfected and any material collected in the vapor trap.

Needles and Syringes

Sharps such as needles and syringes should be used only when there is no plastic alternative available.

The following work practices are recommended:

- Use blunt needles, pipettes or canulas to aspirate fluids instead of hypodermic needles; substitute plastic for glass when possible.
- Use only needle-locking units or units in which the needle is an integral part of the syringe.
- Dispose of all needles properly in a sharps container immediately after use.
- Dispose of unused needles in sharps containers.
- Never recap, shear, break or bend needles under any circumstances. Expel air and bubbles into a disinfectant-moistened pad.

5. Occupational Health Program/Medical Surveillance

Columbia has established a Medical Surveillance/Occupational Health Program (**OHP**) to address hazards of biological, chemical and physical agents within the workplace. The OHP includes baseline hazard identification and risk assessment, as well as an initial medical evaluation and periodic follow up evaluations. Medical surveillance will be required of certain employee positions; additionally, in certain cases, there may be mandatory testing, immunization or other preventive procedure requirements.

Faculty, staff and non-Columbia students receive medical surveillance through WH&S at CUIMC. WH&S is located at CUIMC in Harkness, 1st Floor South (212) 305-7590. The PI should initiate the medical surveillance program for him/herself or for his/her staff by consulting the appropriate Department Administrator (**DA**), Human Resources (**HR**) Manager or Coordinator. The DA or HR staff will complete the Medical Surveillance Form and for students, will contact SHS. Medical surveillance appointments can also be made online by completing the medical surveillance registration form at https://secure.cumc.columbia.edu/hrforms/. The form can be accessed by managers through the CUIMC HR website: http://www.cumc.columbia.edu/hr/employment.

Columbia and Barnard students receive medical surveillance through their respective SHSs. An appointment can be set up by contacting SHS at the following numbers:

- Columbia (other than CUIMC): (212) 854-7426
- CUIMC: (212) 305-3400
- Barnard: (212) 854-2091

The following are the relevant SHS locations:

- Morningside campus: John Jay Hall
- CUIMC: 100 Haven Avenue
- Barnard: Brooks Hall Lower Level

The PI should inform the DA or HR representative if there are any special indicators that may be part of a person's job duties. Special indicators include:

- Potential Bloodborne Pathogen exposure;
- Work with human clinical specimens;
- Laboratory animal research or contact with animals (see also **Getting Started: Training – Occupational Health/Medical Surveillance (Chapter II, Section D)** of the **Animal Research Handbook)**;

- Non-human primate research or contact with non-human primates;
- Work with infectious agents where prophylactic vaccination is available (e.g., rabies, vaccinia, *S. typhi* etc.);
- Work with biological toxins where prophylactic vaccination is available (e.g., Diphtheria, Pertussis etc.); or
- N-95 Respirator Use (e.g., BSL-3 laboratory).

Faculty, staff and students should bring the following items to their initial medical surveillance appointment:

- Columbia ID card;
- Completed Health History Form;
- Request form signed by supervisor; and
- Immunization records, if available.

The medical surveillance examination will be routine. The components of the exam are as follows:

- Medical history;
- Physical examination with vital signs;
- Two-step purified protein derivative (**PPD**) administration;
- Review of immunity to rubella, measles and varicella;
- Tetanus-diphtheria vaccine (offered every 10 years);
- Bloodborne Pathogen exposure surveillance;
- Hepatitis B virus vaccine series (if applicable) or documented declination; and
- Surveillance for latex sensitivity.

The first visit will consist of drawing blood, planting a PPD and conducting a baseline physical examination, which should take approximately two hours. A second visit, which should take approximately 30 minutes, will be scheduled for PPD assessment within 48-72 hours after the PPD has been planted. A third visit, if necessary, will be scheduled by WH&S to plant a second PPD. A clearance form will be issued upon completion of this process. When indicated for a job title, periodic follow-up may be necessary. PIs should notify the employee when a periodic evaluation is indicated.

6. Disinfection, Decontamination and Sterilization

Disinfection refers to the elimination of virtually all pathogenic microorganisms on inanimate objects with the exception of large numbers of bacterial endospores. The goal is to reduce the level of microbial contamination. A researcher should choose his/her disinfectant based on the infectious materials risk assessment. Resistance to disinfection depends on the microorganism and the experimental parameters, but generally fungi, vegetative bacteria, and certain viruses (e.g., Herpes Simplex Virus, HIV, HBV) and non-enveloped viruses (e.g., adenovirus, coxsackieviruses, rotavirus) can survive for extended periods on surfaces and therefore require stronger disinfection and contact times.

Household bleach, which contains sodium hypochlorite, is a strong oxidizing agent that is an effective disinfectant for known and potential infectious materials. For most effective disinfection, researchers should use a 10% dilution, freshly prepared on a daily basis. Diluted bleach loses efficacy in a short time period, and undiluted bleach stock becomes ineffective within a year. The Biosafety Program recommends marking the stock bleach bottle with the date on which the bottle was received, with stock replacement after six months.

Bleach is not the only disinfectant that can be utilized. A **Summary of Disinfectant Activities** is attached as **Annex V-E**.

The OSHA BBP Standard allows disinfectants labeled "tuberculocidal hospital disinfectant" to be used on surfaces and equipment. Acceptable commercial products include Quat Plus TB, Cavicide, or Opti-cide. Researchers should consider the following factors when selecting and using disinfectants:

- Nature of work surface. Rough surfaces require a longer contact time than smooth ones.
- Surface compatibility. Bleach will corrode many metals, so after use, rinse with water or 70% ethanol; instruments vary in their ability to withstand disinfectants based on their composition.
- Organic matter will inactivate some disinfectants; a second application may be necessary once visible contamination or organic debris has been removed. The removal of visible ‘soil’ may be the single most critical factor in assuring effective decontamination.
- Resistance of microorganisms, e.g. bacterial endospore vs. vegetative bacteria.
- Number of microorganisms present, e.g., overnight culture (more organisms) vs. a recently inoculated one (fewer organisms).

When using any disinfectant, researchers should:

- Follow the label instructions for dilution and contact time needed for desired level of disinfection;
- Treat disinfectants that require pre-use dilution as hazardous chemicals during mixing, and wear the appropriate PPE.
- Clean contaminated surfaces as soon as possible and any surface that may have become contaminated at the end of the task.

Aspiration of tissue culture media into a collection flask, under vacuum, is one of the most commonly performed laboratory procedures. It is an EH&S policy that such media be decontaminated prior to disposal in the municipal sewer system. Researchers should perform the following: before aspiration, add undiluted bleach to fill 10% of the final volume of the collection flask. The bleach will turn the phenol red indicator in tissue culture media from pink to yellow/clear. Aspiration flasks containing pink liquid indicate insufficient bleach concentration, and should be topped off with fresh bleach until a yellow/clear color is achieved prior to additional aspiration or disposal. Researchers should empty the collection flasks when they are 3/4 full, or as needed.

Decontamination refers to any activity that reduces the microbial load to a level deemed suitable to prevent contamination or infection. The appropriateness of any decontamination

method is situation dependent such as the hardiness of microorganism (e.g., spore-forming or non- envelope).

Sterilization refers to the destruction of all microbial life, including bacterial endospores. Autoclaves provide the most efficient and reliable method of sterilization for most laboratory applications. The critical process factors are temperature, exposure time, and ensuring that packaging materials allow the steam to penetrate throughout the load. Sterilization time will vary in relation to the size of the load and the packing density of the chamber. Typical laboratory autoclaves operate at 121°C and 15 psi. All users must review the operating manual periodically. Autoclave instructions should be prominently posted. Users should use heat resistant gloves and face protection, particularly when removing processed material from the autoclave. For dry loads, researchers should add 250-500 ml of water to the load pan to aid in steam generation. Autoclave bags should be closed loosely to allow steam to penetrate; users must not tightly cap bottles and/or test tubes.

Autoclave tape is not a fail-safe indicator of sterilization. Tape blackens only after brief exposure to a temperature of 121°C, and does not indicate sustained temperature. Laboratories must use lead-free autoclave tape to eliminate the need to dispose of the tape as hazardous waste.

When used for sterilizing infectious waste, autoclave performance must be periodically validated by using *B. stearothermophilus* spore vials. Place a vial on the load and remove afterwards. Incubate as directed; a lack of turbidity or color change indicates that the autoclave is achieving sterilizing conditions.

I. RMW Disposal

RMW is the waste stream that may contain infectious materials such as blood, bodily fluids or microorganisms that pose a risk of transmitting infection. RMW is also referred to as "biohazardous" "biomedical" or "infectious" waste. RMW must be properly handled, collected, segregated, packaged, stored, labeled, transported and disposed of in order to minimize the risk of transmitting infection or endangering human health.

The following is considered RMW:

- Pathological waste such as tissues, organs, body parts, and body fluids removed during surgery or autopsies.
- Blood and blood products, serum and plasma.
- Microbiological waste such as discarded cultures and stocks of infectious agents, culture dishes and devices used to transfer, inoculate and mix cultures, stocks, specimens, live and attenuated vaccines and associated items.
- Sharps such as contaminated hypodermic needles, syringes, scalpel blades, Pasteur pipettes, and broken glass.
- Isolation waste generated by hospitalized patients isolated to protect others from communicable disease.
- Animal waste such as contaminated animal carcasses, body parts and bedding from animals intentionally exposed to pathogens in research.

The University's Regulated Medical Waste Policy (the **RMW Policy**) contains a more comprehensive description of what constitutes RMW.
https://research.columbia.edu/system/files/EHS/Policies/RMW.pdf

The OSHA BBP Standard regulates the handling and storage of RMW in laboratories and patient care areas. The following governmental agencies also regulate RMW decontamination, transport and disposal:

- The New York State Departments of Health (**NYS DOH)** (see the NYS-DOH Guidelines – Regulated Medical Waste (http://www.health.ny.gov/facilities/waste/)
- The NYS DEC (see the NYS-DEC Guidance for Regulated Medical Waste Treatment, Storage Containment, Transport and Disposal (https://www.dec.ny.gov/chemical/8789.html)
- The EPA (see the EPA Medical Waste Tracking Act of 1988 (https://archive.epa.gov/epawaste/nonhaz/industrial/medical/web/html/tracking.html)
- US DOT (see US-DOT 49 CFR Part171 Infectious Substances: Final Rule (https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-overview)

University-administered research laboratories follow stricter guidelines that those imposed by the NYS DOH in that waste contaminated with organisms that are handled at the BSL-1 level is also treated as RMW to protect Facilities Operations workers and reduce confusion among researchers segregating biomedical waste based on the agents that may be in it.

Furthermore, material that looks "medical" (e.g., petri dishes of food from *Drosophila melanogaster*) is also treated as RMW. Items that look as if they may have been used to handle material at the BSL-2 level or above (i.e., gloves) are treated as RMW. The NIH Guidelines specify that waste containing rDNA must be treated as RMW, unless the research is deemed exempt from IBC review.

However, investigators must be judicious about what they put into the RMW stream, as it is significantly more costly to dispose of RMW than municipal waste. Packaging materials (e.g., cardboard) and paper towels for hand washing, media bottles, etc. should not enter the RMW stream.

Most RMW is collected in rigid containers lined with red bags imprinted with the universal biohazard symbol or the word "Biohazard" and the address of the University (**Red Bags).**

The following are the University RMW guidelines from the RMW Policy:

- Any RMW sharps or materials that may puncture a Red Bag must be placed in a sharps disposal container whether or not contaminated with infectious agents. Sharps containers must be used for disposal of the following items used in research activities: hypodermic needles, syringes, scalpel blades, razor blades, slides, cover slips, serological pipettes (glass or plastic), plastic pipette tips, and glass Vacutainer blood collection tubes; and any

contaminated item that may tear a Red Bag during transport. Do not separate syringes and needles. Needles must not be recapped prior to disposal. Deposit unused sharps in sharps containers. Do not overfill sharps containers to the point where pipettes or other items stick out through the top; the RMW contracted provider will not collect overfilled containers with protruding items.

- The US DOT categorizes biological materials as **Category A** (dangerous or life threatening) or **Category B** (less dangerous or not life-threatening). Category A cultures or specimens (e.g., *M. tuberculosis*, rabies virus), Category B cultures (e.g., MRSA, *S. typhi*), and BSL-3 microorganisms or rDNA, must be treated by autoclaving or chemical deactivation, prior to entering the RMW stream. If researchers are unsure about the correct deactivation method, they should consult Biosafety Program personnel.
- Liquid RMW must be decontaminated prior to sewer disposal. Plastic tubes that are tightly sealed and contain small quantities of blood or other biomedical material (<50ml) can be placed directly into RMW. For larger amounts of liquid (>50 ml), these liquids must undergo chemical decontamination, with sufficient disinfectant concentration and contact time. If the chosen disinfectant is bleach, the final concentration should be 10% of the overall volume of the liquid to be disposed of, with 20 minutes of contact time. The liquid can then be poured down the sink, followed by plenty of water (the sink will emit a strong bleach odor if not sufficiently flushed with water). The empty tubes may go in the RMW.
- If RMW is mixed with a hazardous chemical, or is radioactive, researchers must decontaminate the RMW with a compatible chemical, and then manage the RMW as either hazardous chemical waste or radioactive waste, respectively. Autoclaves or incinerators should not be used for decontaminating such waste, . For additional information, see **Hazardous Waste Management and Disposal (Chapter IV)**.
- If tubes or jars contain tissues fixed in a hazardous chemical (e.g., formaldehyde, formalin), the liquid fixative must be decanted/strained off and treated as a hazardous waste. The tissue and the container may be deposited into a Red Bag. If jars containing large quantities of fixed tissue are being discarded (e.g., pig or human organs), contact Biosafety Program personnel for instructions.
- Animal carcasses are stored frozen and all carcasses must be returned to the ICM for disposal in fiberboard drums. Perfused animal carcasses that contain no free fixative may also be returned to the ICM. If a laboratory wishes to have direct carcass collection in fiberboard drums in the laboratory, researchers can contact Biosafety Program personnel for specific instructions. For carcasses containing radioactive materials, carcasses containing less than 0.05 microcuries/gram of 14C or 3H, or containing short-lived isotopes, researchers should contact Radiation Safety Program personnel for specific instructions about RMW disposal services. See **Animal Care and Use During a Study: Sanitation and Waste Disposal (Chapter VII, Section C(2))** in the **Animal Research Handbook** and **Use of Radioactive Materials – Radioactive Waste – Waste Disposal (Chapter VII, Section D(4))** in the **Research Radiation Safety Handbook.**

Red Bags and sharps containers are used exclusively for materials that meet the University's definition of RMW. Red Bags or sharps containers must not be used for regular trash e.g.,

packing materials, papers, cardboard boxes, paper towels, and cell media or buffer bottles that are otherwise free of biological contamination.

There are different RMW services depending on the campus where the laboratory is located. Information, including pick up schedules can also be found on the EH&S website. https://research.columbia.edu/regulated-medical-waste-management.

- At Morningside, EH&S administers RMW services. Researchers may submit an online pick up request form (a **Waste Pick Up Form)**. Red plastic RMW containers with Red Bag liners are supplied, removed and replaced by the University's contracted provider on a one-for-one exchange basis. Open containers lined with a Red Bag are acceptable in laboratories, but Red Bags and containers must be closed once they are moved to the hallway for collection. Laboratories must place the containerized waste into the hallway only on the morning of the RMW service collection.
- At Manhattanville, Facilities Operations administers RMW services. Researchers may obtain replacement/additional Red Bags and sharps containers (2 gallon and 17 gallon), at all freight elevator areas on every floor of JLGSC. If there is a shortage of these supplies in the freight elevator area, researchers may send an email to support@zi.columbia.edu. Researchers must place full Red Bags into the large gray dumpsters and full sharps container on the storage rack.
- At CUIMC, Facilities Operations administers RMW services. Researchers may contact (212) 305-HELP (4357), for replacement or additional Red Bags, sharps containers and other services. Reusable sharps containers are provided and removed by the University's contracted provider of RMW disposal services on a one-for-one exchange basis. To discard Red Bags, researchers must tie the Bags and place them inside the large gray dumpsters in the hallway (Hammer, Black, Vanderbilt, VP&S, Milstein, Harkness). Since these dumpsters are in common areas outside of a laboratory, they must be closed when they contain Red Bags (clean unused dumpsters are permitted to be left open). To reduce the likelihood of injury from inappropriately disposed sharps, researchers must carry tied-Red Bags to the dumpster within a rigid container and then lift the Bag into the dumpster. If the dumpster is full, researchers should transport the Red Bags to another empty dumpster. If a researcher has to transport a Red Bag to another floor, the freight elevator rather than the passenger elevator should be used. If full dumpsters are a persistent issue, call Facilities Operations to request additional dumpsters. In other buildings (Russ Berrie and ICRC), Red Bags are containerized in cardboard boxes. When the boxes are full, researchers must close the box and move it outside the laboratory for pick-up. Researchers must place all full sharps containers and cardboard boxes outside of laboratory first thing in the morning on the day of service.
- For the Lamont and Nevis campuses, RMW services are not routine. Researchers should consult with Biosafety Program personnel so that EH&S can arrange RMW services directly to the laboratory with the University's contracted vendor.

If a laboratory is moving or closing, it is important to notify EH&S as soon as possible. The following is the checklist for biological materials disposal:

- Place all sharps (syringes, Pasteur pipettes, serological pipettes, razor blades, etc.) in a sharps container and dispose of it as RMW.
- Dispose of all other potentially biohazardous waste from the laboratory in Red Bags as RMW.
- Dispose of all solid media and supplies in the laboratory as RMW.
- Decontaminate all liquid media by autoclaving or by treating for 30 minutes with 10% bleach solution before drain disposal.
- Decontaminate all work surfaces using freshly prepared 10% bleach solution (followed by 70% ethanol, if stainless steel).

J. Fluorescence-activated Cell Sorting (FACS)

Several core facilities at the University operate FACS equipment. FACS is a specialized type of flow cytometry that provides a method for sorting a heterogenous mixture of biological cells into two or more containers, one cell at a time, based on the specific light scattering and fluorescent characteristics of each cell. FACS analysis poses a unique hazard in the laboratory due to the relatively high potential for the aerosolization of materials that are subject to processing. Many unfixed cells may pose a potential hazard in the form of known and unknown pathogens, viral vectors used to transduce cells, genomic sequences of infectious agents, and chemical mutagens. When potentially infectious materials are processed in FACS analysis, special procedures and containment are often required to mitigate this unique hazard as outlined in the EH&S Policy for Fluorescence-Activated Cell Sorting (FACS).

A thorough risk assessment must precede FACS processing of potentially infectious agents. This assessment should consist of the identification of the agent to be manipulated or source of the sample cells; a description of the procedures to be performed (including sample preparation and manipulation); determination of the appropriate BSL for the procedures; and an assessment of the suitability of the equipment and facilities and the competency of the personnel to carry out the operations safely. The selection of the appropriate BSL should be made in consultation with a Biosafety Officer and must be in keeping with the BMBL Guidelines and the NIH Biosafety Policy for Cell Sorters (2012).

The risk assessment is the responsibility of the particular FACS Facility Manager or PI as procedures will differ between facilities depending on the equipment used and the nature of the materials to be processed. Any investigator who operates his/her own FACS equipment should consult with EH&S if assistance is needed with any risk assessment generally or with respect to a particular agent. Each laboratory should have its own SOPs and it is the responsibility of the Facility Manager or the PI to ensure that the SOPs are enforced.

Any researcher who wishes to submit materials to any of the FACS core facilities for processing is responsible for completing the requisition forms accurately and comprehensively. Each Facility may utilize its own registration form, e.g., iLab. Prior to submission, a researcher should prepare samples in accordance with each facility's SOPs. Any researcher who directly operates any equipment or devices in the core facilities must strictly adhere to any and all SOPs enforced by the respective core facility.

K. Transportation of Biological Materials

The relocation of biological materials depends on many factors: whether the materials are infectious or non-infectious, the biosafety level/risk group, and their shipping classification. Certain biological material shipments are regulated domestically by the US DOT and the Federal Aviation Administration (**FAA**), and internationally by the IATA. Other biological materials are exempt from US DOT, FAA or IATA regulations. Exempt materials are those that have a minimal likelihood of containing pathogens as determined by a professional based on the known medical history, symptoms and individual circumstances of the source and endemic local conditions. The EH&S Biological Materials Shipping Manual (the **Biological Materials Shipping Manual,** explains in more detail which specimens are considered to be exempt. If the laboratory is unsure as to how to classify a particular material, contact the Biosafety Program to ensure accurate classification.

The US DOT categorizes biological materials as either Category A (dangerous or life-threatening) or Category B (less dangerous or not life-threatening). See **RMW Disposal (Section I)** above for examples of Category A and Category B materials. See also the IATA website that lists the Category A infectious materials at https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf.

Compliance with shipping regulations is critical to ensure the successful arrival of shipments and the safety of personnel involved in the shipping, handling, and receiving of shipments, and to avoid the severe civil and criminal penalties that can result from non-compliance. Additional guidance for preparation of shipments or movement of biological materials and related equipment can be found in the Biological Materials Shipping Manual

1. Shipping Biological Materials and Dry Ice

Any University employee or student involved in packaging materials, preparing samples for shipping, handling such packages, preparing related paperwork, or signing to authorize shipments must undergo specific training and maintain records of this training. Following the completion of appropriate training, University personnel are qualified to prepare and ship packages containing dry ice, exempt specimens and/or Category B substances. The Biosafety Program is available for technical consultation throughout the shipping process regardless of shipment type or class. A **Classification Flowchart**, which includes training information, is attached hereto as **Annex V-F**.

International shipments also require a commercial invoice. A commercial invoice template is available at https://research.columbia.edu/content/commercial-invoice-template. Researchers and staff should contact EH&S well in advance of international shipments for guidance and to determine if export/import permits are required.

There are general guidelines for materials requiring cold transport; dry ice is considered by the US DOT to be a “Dangerous Good”. The University requires that all packages containing dry ice must

be picked up directly from the laboratory, and not left unattended at dropboxes. Laboratories may choose to transport temperature sensitive materials in refrigerators, freezers or temperature-controlled trucks via an approved vendor. EH&S can provide additional information on University-approved vendors.

2. Transport Within or Between Columbia Campuses

Transport Within a Building or Between On Campus Buildings

Laboratory staff may transport materials by hand or on a cart with raised edges, inside a durable transport container that will prevent spillage if dropped. Biological materials that are classified by the US DOT as Category B materials must be tripled packed. If the materials need to be frozen or cold, a Styrofoam box with a tight-fitting lid secured with tape is appropriate.

When viable microorganisms are moved through public spaces, elevators, stairwells or in the street, they should be in a secondary container with a closable top. A test-tube rack inside a tray or tubes/plates in an open ice bucket is not acceptable to move in public spaces. Gloves should not be worn in public spaces or elevators. The exterior of the secondary transport container should be wiped down with disinfectant prior to leaving the laboratory so that it can be transported without wearing gloves. If a spill were to occur outside the laboratory, the researcher should notify people in the immediate area to stay clear, and request that someone assist by staying at the location with the spill while the researcher returns to the laboratory to collect spill response materials. If no one can safeguard the spill, the researcher should call Public Safety, which will call EH&S.

Transport Between Campuses

Intercampus transport by investigators is permitted for specific classifications of biological materials. Transport is limited to University-owned or contracted vehicles/shuttle buses, licensed taxicabs or personal vehicles (and not on public transport, e.g., MTA buses and subways). If materials are transported in a personal vehicle, a researcher should check with his/her vehicle insurance carrier that this activity is covered. The EH&S website contains detailed information on intercampus transport https://research.columbia.edu/sites/default/files/content/EHS/BioSafety/IntercampusBioTranportTable.pdf.

Transport must be direct from campus to campus with no stops or detours. Packages must stay in the custody of the shipper throughout transport and delivered on the same day. Training must be taken prior to transporting any materials between campuses. See https://research.columbia.edu/content/shipping-training-matrix

Researchers should prepare a package for intercampus transport in the same manner as one prepared for transport by a professional courier, e.g., FedEx. This includes triple packaging so it will not pose a hazard to other passengers even if the package should break open in transit. Dry ice should be enclosed in a Styrofoam container. The transporter must bring a pair of disposable

nitrile or latex gloves in their pocket or bag. These are to be donned only in the event that the package is compromised, e.g. leaks. Gloves are not to be used to carry the package.

An Intercampus Transport of Biological Materials Table is attached hereto as **Annex V-G.**

3. Transport Outside the University

All biological material may either be shipped (e.g., by FedEx) or transported by an approved vendor. Researchers can consult with EH&S to determine the appropriate mode of transportation. If the material (other than Category A material) will be shipped, staff should refer to the EH&S website to determine their training requirements. See https://research.columbia.edu/content/shipping-training-matrix. For Category A materials, you must notify EH&S because only EH&S may prepare and ship packages containing Category A materials.

L. Emergency Response

1. Biological Spills

Researchers using infectious materials, including recombinant microorganisms, are generally responsible for cleaning up biological spills they may create in the laboratory. If needed, EH&S can consult on clean-up procedures and will assume responsibility for cleaning the spill if it is beyond the scope of the staff's ability, due to hazard level or resource limitation.

If there is a spill of a non-hazardous material in a common area, e.g., a hallway, bathroom, or lobby, researchers should contact Facilities Operations.

For spill cleanups in the laboratory, the following materials should be available in the laboratory:

- Disinfectant solution e.g., freshly prepared 10% bleach;
- Forceps, tongs, broom/dust pan in case of broken glass. To prevent injury, do not pick up materials directly;
- PPE: gloves, laboratory coat and eye protection (goggles and face shields);
- RMW Red Bag and/or sharps container; and
- Paper towels or other absorbent material.

Any personal exposure or injury takes priority over clean up. If a researcher is exposed, he/she should immediately remove any contaminated clothing and other PPE and wash the affected area(s) with soap and water. If injured, researchers must seek medical attention immediately.

Biological spills in BSL-1 and BSL-2 laboratories differ from chemical and radiological spills in that the primary hazard of a biological materials spill is direct contact. Accordingly, access to only the immediate area around the spill needs to be restricted.

The following are clean-up procedures for spills of **BSL-1 or BSL-2 microorganisms or toxins on the floor or benchtop**:

- Alert people in the immediate area.
- Don PPE: the minimum is laboratory coat, gloves, and eye protection.
- Cover an area twice the size of the spill with disinfectant soaked-paper towels or other absorbent material. Alternatively, surround spill with dry disinfectant as per label directions.
- Allow a 20-minute contact period.
- Wipe down any contaminated stationary equipment or furniture with disinfectant.
- Use forceps, tongs, or a broom to remove broken glass and other items; dispose of glass and spill materials in a sharps container or Red Bag.
- Remove towels and re-clean area with disinfectant solution.
- Decontaminate (autoclave or bleach) reusable clean-up items and other reusable equipment.
- Inform laboratory personnel when the clean-up is complete.

Procedures for BSL-1 and BSL-2 laboratories should incorporate a degree of flexibility. One could safely abridge the procedures above if l ml were spilled over a small bench top area. However, dropping 50 ml of culture on the floor necessitates a more detailed procedure.

The following are clean-up procedures for spills **inside a BSC**:

- Keep the cabinet running.
- Continue wearing PPE: the minimum is gloves, a laboratory coat and eye protection.
- Cover the area twice the size of the spill with disinfectant soaked-paper towels or other absorbent material. Alternatively, surround the spill with dry disinfectant according to the label directions.
- Allow a 20-minute contact period. If material has spilled into the catch basin beneath the work surface, add a volume of disinfectant equal to the quantity in the basin, wait 20 minutes, and absorb with paper towels or other absorbent material.
- Wipe down the back and side walls of the cabinet with disinfectant.
- After completion, allow the cabinet to run for additional 10 minutes before resuming work.

The following are clean up procedures for spills **inside a centrifuge**:

- Shut centrifuge off and do not open the lid for 20 minutes to allow aerosols to settle.
- Continue wearing PPE: the minimum is a laboratory coat, gloves, and eye protection.
- Use a squeeze bottle to apply disinfectant to all contaminated surfaces within the chamber, taking care to minimize splashing.
- Allow a 20 minute contact period and then complete the clean up of the chamber.
- Remove buckets and rotors to nearest BSC; disinfect and clean as per manufacturer's instructions.

The following are clean-up procedures for spills of **BSL-3 microorganisms on the floor or benchtop**:

- All personnel must secure any open microorganisms if possible, then leave the room, and close the door.
- Notify Public Safety, provide a call-back number, and instruct them to call a Biosafety Officer. The Biosafety Officer will provide further instructions.
- If the Biosafety Officer determines that staff can complete the spill clean-up, the researcher should wait 30 minutes to allow airborne organisms to settle before re-entry.
- Don BSL-3 appropriate PPE, including double gloves, Tyvek and N-95 respirator or PAPR.
- Collect all needed spill response supplies (note that the best practice is to keep a spill kit bucket inside the BSL-3 laboratory).
- Re-enter laboratory to clean up the spill in accordance with the actions described under clean-up procedures for spills of BSL-1 or BSL-2 microorganisms, as follows:
    - Cover an area twice the size of the spill with disinfectant soaked-paper towels or other absorbent material. Alternatively, surround spill with dry disinfectant as per label directions.
    - Allow a 20-minute contact period.
    - Wipe down any contaminated stationary equipment or furniture with disinfectant.
    - Use forceps, tongs, or a broom to remove broken glass and other items; dispose of glass and spill materials in a sharps container or Red Bag.
    - Remove towels and re-clean area with disinfectant solution.
    - Decontaminate (autoclave or bleach) reusable clean-up items and other reusable equipment.
    - Inform laboratory personnel when the clean-up is complete.
- Autoclave all spill-related materials and dispose in a sharps container or Red Bag.

See the EH&S Biological Spills – Response and Clean Up Policy for more information.

2. Biological Exposures

A biological exposure incident is parenteral, non-intact skin or mucous membrane (e.g., eye, nose, mouth) contact with rDNA, infectious microorganisms, human blood or other potentially infectious materials. A medical provider will assess whether skin is intact or not.

If an exposure occurs, researchers should immediately remove contaminated clothing and other protective equipment and wash affected areas with soap and water. For percutaneous injuries, immediately cleanse the injury with soap and water. For mucous membrane exposures, rinse with water for 10 minutes.

Researchers should seek medical attention immediately, if needed. For medical attention that requires Emergency Medical Services (**EMS**), researchers may contact Public Safety to arrange EMS services, or call 911 directly. Public Safety numbers are as follows for the different campuses:

- **Morningside**: (212) 854-5555

- **Manhattanville**: (212) 853-3333
- **CUIMC:** (212) 305-7979
- **Lamont:** (845) 359-2900
- **Nevis:** (914) 591-9244
- **Barnard:** (212) 854-6666
- **NYSPI:** (646) 774-5555

The following are the locations for emergency medical services for each campus. Researchers can also proceed directly to the following (or their own) providers to seek medical attention.

- **Morningside and Barnard:**
  - During Business Hours for **Staff and Students**: SHS, John Jay Hall, 4th Floor, 519 W. 114th St., (212) 854-7426
  - After Hours (or for life-threatening emergencies): Mount Sinai Morningside Hospital Emergency Room, 1111 Amsterdam Avenue at 114th Street, (212) 636-3375
- **Manhattanville:** Harlem Hospital, 506 Lenox Avenue, (212) 939-1000
- **CUIMC:**
  - During Business Hours for **Staff:** WH&S – Harkness First Floor, (212) 305-7580
  - During Business Hours for **Students**: SHS – 100 Haven Avenue, (212) 305-3400
  - After Hours: NYP Emergency Department – Broadway & 167th Street
- **Lamont:** Nyack Hospital, 160 North Midland Ave., Nyack, (845) 348-2000
- **Nevis:** St John's Riverside Hospital Dobbs Ferry Pavilion, 128 Ashford Ave, Dobbs Ferry (914) 693-0700
- **NYSPI:** NYP Emergency Department – Broadway & 167th Street

If researchers seek medical attention at hospitals or at their own provider, they should follow up with WH&S or SHS on the next business day. The incident should be reported to the applicable supervisor, and a Columbia University Employee Notification of Workplace Accident, found on the HR website at https://humanresources.columbia.edu/content/department-accident-report.

The Biosafety Program may require a detailed assessment of the incident to determine the risk of the exposure, including, if possible, the infectious status of the source and immune status of the exposed employee. This information will be used to determine the benefits of prophylactic treatment as well as to offer counseling, treatment, and tracking of infectious agents. The Biosafety Program also investigates sharps injuries to perform root cause analysis and prevent recurrence. An accident report is provided to the exposed employee and his/her supervisor.

Further information can be found in the University's ECP at https://research.columbia.edu/system/files/EHS/Policies/BBPECP.pdf.

3. Print & Go Sheets

Print & Go Sheets are short guidance documents that provide information that medical personnel can reference following an occupational exposure to a hazardous biological or chemical material. The Sheet identifies the immediate "first aid" actions that should be taken. A medical evaluation

should be sought immediately. The Print & Go Sheet does not provide individualized medical advice or treatment. The relevant sheet should be printed and taken to the medical provider. Print & Go Sheets are available for exposure to the following biological materials:

- Bloodborne Pathogens
- Diphtheria toxin
- Lentiviral vectors
- Macacine herpes virus 1 (herpes virus simiae, herpes B or B-virus)
- Pertussis toxin
- rDNA

Print & Go sheets can be found at https://research.columbia.edu/print-and-go-sheets.

4. rDNA Exposure and Spill Reporting

If the biological incident relates to rDNA, the Biosafety Program (on behalf of the IBC) will report to NIH OSP any significant research related accident or illness within 30 days as well as any significant problem or violation of the NIH Guidelines. Additionally, for research conducted in a BSL-2 or BSL-3 laboratory, any spill or accident resulting in an overt exposure to organisms containing rDNA molecules requires immediate reporting to the NIH OSP.

VI. RADIATION SAFETY

A. Introduction

The Columbia Radiation Safety Program is multi-campus, multi-institutional and complex. The Program is responsible for assisting the constituent communities in ensuring the safe use of ionizing radiation, radioactive materials and radiation producing equipment, and establishing compliance with applicable city, state, and federal regulations.

The Radiation Safety Program is integrated, but has two components: one covering "downtown" and the other "uptown". The downtown component (referred to as the **Morningside Program**) includes (1) Morningside, (2) Manhattanville, (3) Lamont, (4) Nevis and (5) Barnard. The uptown component (referred to as the **Joint Program**) covers (1) the four schools constituting CUIMC): VP&S, Mailman School of Public Health, College of Dental Medicine and School of Nursing, (2) NYP and (3) NYSPI. All of the foregoing institutions included in the Radiation Safety program are referred to collectively in this Handbook as the **Program Institutions.**

The Radiation Safety Program is operated under EH&S and is headed by a Chief Radiation Safety Officer. One or more individuals assisting the Chief Radiation Safety Officer may be designated as Radiation Safety Officers for a specific license or permit.

This Chapter gives the reader only a summary description of the Radiation Safety Program. The principal guidance for uses of radiation in laboratory and clinical research can be found in the University's Research Radiation Safety Handbook**.** The Research Radiation Safety Handbook provides an introduction to the basics of radiation and the biological effects of radiation, the regulatory framework of radiation safety and the roles and responsibilities of the Radiation Safety Program, as well as the authorization and trainings that are required for radiation users. It also provides detailed guidance on applications for non-human use and human use research, procurement and transfer of radioactive materials and radiation producing equipment, in addition to safe use of radiation in research. Applicable forms, guidelines, reports, sample signage and labels can also be found in the Research Radiation Safety Handbook. For more information, you may also contact Radiation Safety at rsocumc@columbia.edu or (212) 305-0303.

B. Regulatory Framework

The use of ionizing radiation, radioactive materials and radiation producing equipment is subject to a number of regulations at the federal, state, and local levels. The Program Institutions are also granted permission to use radioactive materials and radiation producing equipment through the issuance of licenses that include specific conditions that have equivalent force of law. Violations of applicable laws, regulations, or conditions could result in civil penalties (e.g., fines), criminal prosecution, sanctions or suspension or termination of licenses. For this reason, it is imperative that all faculty and staff be aware of and comply with the applicable requirements.

Regulation of radioactive materials is ultimately governed by federal law, principally under the rules of the Nuclear Regulatory Commission (**NRC**) contained in 10 CFR. Under Section 274 of the Atomic Energy Act of 1954 (42 USC §2021), the NRC may enter into an agreement with a state for the discontinuance of the NRC's regulatory authority over portions of such authority to license and regulate byproduct materials (radioisotopes), source materials (uranium and thorium) and special nuclear materials in quantities not sufficient to form a critical mass. Any such state is called an **Agreement State.** New York is an Agreement State and New York City is deemed to be an Agreement State by the NRC.

The use of radioactive materials at Lamont and Nevis is regulated by New York State, which has issued licenses to the University as required by Part 16 - Ionizing Radiation of Title 10 of the New York State Code of Rules and Regulations for the use of radioactive materials and radiation producing devices and equipment. Within New York City, radiation use is regulated by the NYC DOH. Title 24 of Rules of The City of New York, Article 175 – Radiation Control (**Article 175**) contains the relevant regulations for the University's radiation use program, including the standards for protection against radiation.

C. Roles and Responsibilities

Ultimate responsibility for the implementation and governance of the Radiation Safety Program lies with the President of the University, the President of Barnard, the President of NYP, and the Director of NYSPI. The President of the University has delegated his authority to the EVPR and the Executive Vice President for Health and Biomedical Sciences.

The primary oversight responsibilities within the Radiation Safety Program rest with the **Radiation Safety Committees**, the **Radiation Safety Officers** and the **Radiation Safety Program personnel.** Together, they establish policies and procedures, oversee regulatory compliance, monitor Radiation Safety Program performance and support the highest quality research.

There are two radiation safety committees at the University: (a) the Radiation Safety Committee (**RSC**) for the Morningside Program and (b) the Joint Radiation Safety Committee (**JRSC**) for the Joint Program. (The RSC and JRSC are referred to collectively as the **RS Committees**.) The Radiation Safety Officers have been delegated the authority to ensure the implementation of the Radiation Safety Program as described in Section 175.10 of Article 175. The **Authorized Users** and PIs (who may or may not be Authorized Users) also have responsibilities under the Radiation Safety Program. See **The Columbia Radiation Safety Program: Roles and Responsibilities (Chapter III(C))** in the **Research Radiation Safety Handbook**.

The Radiation Safety Program has two primary offices:

For Morningside, Manhattanville, Lamont, Nevis and Barnard: 419 W. 119th Street, New York, NY 10027
Telephone during business hours: (212) 854-8749. After normal business hours, call Public Safety at (212) 854-2797 or 854-5555 and request radiation safety assistance.

For CUIMC, NYP (including affiliated hospitals and faculty practices) and NYSPI: 630 W. 168th Street, Mailroom Box 70, New York, NY 10032.

Telephone during business hours: (212) 305-0303. After normal business hours, phone messages will direct calls to the applicable Public Safety or Security Office at CUIMC, NYP or NYSPI.

D. Authorizations

Any individuals wishing to use radiation at the University must apply for authorization and receive approval prior to beginning operations. Detailed guidance regarding the requirements and procedures for obtaining authorizations can be found in **Getting Started: Authorizations and Training- Applying for Authorization (Chapter IV(B))** in the **Research Radiation Safety Handbook**.

1. Non-Human Use of Radiation

Each PI of any study using radioactive materials or radiation producing equipment must be approved by the RSC or the JRSC for the specific use and the locations provided for in the application for such study submitted to the RSC or JRSC. Applications for non-human use of radiation are managed through LION. Details are available in **Preparation of Applications: Non-Human Use Application (Chapter V(B))** of the **Research Radiation Safety Handbook.**

2. Animal Use of Radiation

An animal use authorization permits the use of radioactive materials or ionizing radiation in animal studies. Applicants for this use of radioactive materials or ionizing radiation should submit an **Application for Use of Radiation Involving Animals** as Hazardous Materials Appendix G and attach it to the related IACUC Protocol in Rascal. See **Preparation of Applications: Animal Use Application (Chapter V(C))** of the **Research Radiation Safety Handbook**.

3. Human Use of Radiation

A human use authorization permits the use of radiation or radioactive material in studies with human subjects. Radiation exposure can come from a number of sources, from x-rays to PET scans to radioactive drugs.

The great majority of human use authorizations are processed through the JRSC. Applicants who wish to use radiation or radioactive materials in humans must submit a **JRSC Application for the Use of Radiation in Research Studies Involving Human Subjects** (the **JRSC Application**) in Rascal as Hazardous Materials Appendix H and attach it to the related IRB protocol in Rascal.

Under certain conditions, studies may instead fall under the **Radioactive Drug Research Committee (RDRC)**. Because RDRC research is so limited in scope, there are very few studies that are authorized under the auspices of the RDRC. RDRC Applications are also submitted through Rascal as an Appendix H, with different information required.

Further information about JRSC and RDRC Applications may be found in **Preparation of Applications: Human Use Application: JRSC** and **Human Use Application: RDRC (Chapters V(D)** and **V(E))** in the **Research Radiation Safety Handbook.**

E. Training

City, state and federal regulations require general and job-specific training on the safe use, storage and disposal of radioactive materials for all personnel whose work brings him/her into contact with iodizing radiation or radiation producing devices, or who supervises individuals working with radioactive materials or such devices. The training consists of initial training and an annual refresher course.

Initial training must be completed prior to beginning any work with radioactive materials or radiation producing equipment. The Radiation Safety Program offers classroom training to first-time users of radioactive materials and to individuals who have had training and experience at other institutions. The class includes instruction on the types and forms of radiation, interactions of radiation with matter, biological effects of radiation, regulations, best practices to reduce exposure, methods for surveying laboratories for contamination and proper waste disposal procedures. Training consists of an in-person lecture and completion of an online test in Rascal. See *TC1750: Initial Radiation Safety Course* for review slides and the mandatory test. The training dates, times and locations can be found at https://research.columbia.edu/safety-trainings.

Refresher training is required annually and may be completed by taking one or more online courses depending on your needs and assigned duties.

See also **Getting Started: Authorizations and Training-Training (Chapter IV(C))** in the **Research Radiation Safety Handbook.**

F. Procurement

Because licenses for the purchase, possession and use of radioactive materials are issued institutionally, and not individually, the University must maintain strict accountability and control over the procurement of radioactive materials and the purchase of radiation producing equipment. There is no exempt activity level or quantity with regard to procurement.

Radioactive materials and radiation producing equipment are considered to be restricted commodities and may not be purchased by credit card or a University-issued P-card.

Radiation sources may be acquired from other academic institutions or non-commercial suppliers outside the formal procurement process, but requests for any such acquisition must be submitted by email to the appropriate program office and approved in advance.

See also **Procurement and Transfer of Sources of Ionizing Radiation (Chapter VI)** in the **Research Radiation Safety Handbook.**

G. Working with Radioactive Materials and Radiation Producing Equipment

1. Security

Regulations require all sources of radiation be secured from unauthorized use. A user must control and maintain constant surveillance of radioactive materials when they are not in storage and prevent unauthorized access or removal. Radiation producing equipment must be secured against access by unapproved individuals.

See **Procurement and Transfer of Sources of Ionizing Radiation: Radioactive Material--Radioactive Material Security (Chapter VI(B)(4))** in the **Research Radiation Safety Handbook.**

2. Inventory and Recordkeeping

Regulations require all licensees to keep an inventory of radioactive materials. Non-human use of radioactive materials is tracked in LION. See **Use of Radioactive Materials: Surveys and Reports--By the Authorized User (Chapter VI(C)(1))** in the **Research Radiation Safety Handbook.** Human use of unsealed radioactive materials is tracked using proprietary software.

3. Signs and Labels

Any laboratory that possesses and/or uses radioactive materials is required to post signs informing workers of the rights and responsibilities and warning of potential hazards of working with radioactive materials, as well as contact information in the event or an emergency. Each container in which radioactive materials are stored should have a “Caution Radioactive Materials” label. “Caution X-ray" signs must be posted on the x-ray producing equipment. Other radiation signs and labels should be posted accordingly. See **Use of Radioactive Materials: Laboratory Safety—Signage and Labels (Chapter VII(B)(3))** in the **Research Radiation Safety Handbook.**

4. Safe Laboratory Practices

Each laboratory should develop specific SOPs for uses of ionizing radiation. The following sections describe some basic instructions for working with radiation in the laboratory. Additional precautions may be necessary for specific materials or uses. See **Personnel**

Protection: Safe Use of Radioactive Materials (Chapter VIII(C)) and **Use of Radioactive Materials: Radioactive Waste (Chapter VII(D))** in the **Research Radiation Safety Handbook.** Be sure to contact a Radiation Safety Program staff member before beginning any new use of radiation.

Radioactive Materials

- Designate a radiation work area. The area should be in a space away from high traffic areas and should contain all of the materials and resources necessary for the project. If it is not possible to place all of the materials in this area, you should have convenient access to them.
- Do not store food or drinks in a radiation work area or in any other area of a laboratory in which radioactive materials are used.
- Cover the work area, preferably with plastic backed absorbent paper, or use a tray made of impervious material such as porcelain or stainless steel large enough to contain any spills.
- Post area with warning signs and label all radiation sources as required.
- Wear PPE**.** The minimum requirements include a laboratory coat, safety glasses, gloves, long pants or the equivalent and closed toe shoes. Choose gloves that are appropriate to the work. Cotton gloves protect against dry contamination; rubber or plastic gloves protect against dry and wet contamination. If you are unsure of the type of glove to use, contact a Radiation Safety Program staff member.
- Dedicate equipment such as pipettes and glassware to radioactivity work and avoid cross-contamination.
- Plan your experiment to eliminate or minimize waste.
- Perform a "dry run" if possible to perfect technique and identify potential problems.
- Use automatic or remote pipetting devices. Never pipette by mouth.
- Allow sufficient time for frozen stock solutions to thaw before attempting to withdraw an aliquot.
- Handle volatile compounds that have the potential for vapor or gas release (such as NaI-125, S-35 Methionine or S-35 Cysteine) in a functioning CFH. See **Use of Radioactive Materials: Laboratory Safety—Use of Volatile Radioactivity (Chapter VII(B)(7))** in the **Research Radiation Safety Handbook.**
- Handle and dispose of spin (centrifuge) columns with care. Place used columns in a sealed container (capped tube or Ziploc® bag) prior to discarding them into the radioactive waste.
- Change your gloves often. Assume that gloves are contaminated until proven otherwise. Do not leave the laboratory or touch things outside of the work space with potentially contaminated gloves. Remove gloves carefully from the inside out. Ensure that gloves are disposed of properly and wash hands immediately after using radioactive material.
- Do not eat, drink, smoke, chew gum, apply cosmetics, manipulate contact lenses or touch exposed areas of skin while working in a room where radioisotopes are handled. Be careful not to rub your eyes, scratch exposed areas of skin or touch your hair when working with radioactive material.

- After working in areas that contain radioactive materials, survey your hands, clothing and shoes and wash your hands before eating, smoking, going about other work or leaving work.
- Lock-up and secure the unused radioactive material immediately after use.
- Promptly dispose of radioactive waste properly. Make a reasonable estimate of the amount of radioactivity in the waste and record it on a radioactive waste tag.
- Survey yourself and work area for contamination with an appropriate survey meter. Decontaminate if necessary. Remove protective clothing and wash hands thoroughly with warm water and soap before leaving the laboratory.
- Participate in the bioassay program as requested by Radiation Safety Program personnel.

X-ray Generating-Equipment

Appropriate shielding as determined by the Radiation Safety Officer must be in place for the use of x-ray generating equipment. Where open-beam x-ray systems are in use, such as for imaging procedures, lead aprons may be required. Lead aprons are a protective layer of lead worn over the body in order to prevent x-rays from penetrating the body. Lead aprons can absorb up to approximately 95% of any scatter x-rays that may be hitting the wearer. Lead aprons are to be worn by anyone who is within six feet of an active x-ray beam. If within three feet, an accompanying thyroid shield must also be worn. After using a lead apron, make sure to hang the apron so that it is not creased. Do not store the aprons folded or crinkled on a counter or table. This can cause cracks in the lead and can compromise the effectiveness of the apron. See **Personnel Protection: Safe Use of Radioactive Materials--Lead Aprons** and **–Shielding (Chapter VIII, Sections (C)4)** and **(5))** in the **Research Radiation Safety Handbook.**

5. Radiation Dosimetry

A radiation dosimeter (commonly referred to as a **Badge**) is a device worn by a person or placed in an area to measure external radiation exposures. Columbia manages the dosimetry badge program for the University, NYP and NYSPI. Badges are issued to assess occupational radiation exposure and to help develop strategies to reduce dose. For more information, see **Personnel Protection: Dosimetry Badge Program (Chapter VIII(D))** in the **Research Radiation Safety Handbook** and/or contact a Radiation Safety Program staff member.

6. Waste Management

Waste Management

The disposal of radioactive materials is strictly regulated under the University's licenses from the NYC DOH and the NYS DEC. In addition, certain wastes are also covered by guidelines of the NYS DEC, the EPA and the NRC.

Authorized Persons must ensure, prior to the procurement of radioactive material, that a method of disposal for the material presently exists or can be established to the satisfaction of Radiation

Safety Program personnel. The disposal plan is usually addressed at the time of the initial application by the investigator for permission to use radioactive materials. Each laboratory must maintain accurate records of the types, quantities and forms of radioisotopes that comprise radioactive waste. Completion of a Radioactive Use and Disposal Log fulfills this requirement.

Radioactive isotope usage is tracked by Authorized User. Therefore, in common-use rooms, radioactive waste must be kept separate from other Authorized Users' wastes, even if they are of the same type.

Details regarding the management and disposal of specific radioactive wastes is described in **Use of Radioactive Material: Radioactive Waste (Chapter VII(D))** in the **Research Radiation Safety Handbook.** See also **Hazardous Waste Management and Disposal (Chapter IV)** in this Handbook.

H. Laboratory Vacating and Closure

The Authorized User, laboratory manager or supervisor should notify a Radiation Safety Program staff member of his/her intent to permanently discontinue the use of radioactive materials in a laboratory. All radioactive material not designated as waste must be removed via transfers. Laboratory staff must perform both meter and wipe test surveys on all items that currently are, or previously have been, used with radioactive materials. This survey must be documented for future reference. After all equipment has been surveyed and removable contamination cleaned, laboratory staff must perform a routine monthly laboratory survey, which should include meter and wipe test surveys. Upon completion of the above, Radiation Safety Program personnel will issue a final clearance report, and the laboratory may be released to unrestricted use.

For a laboratory where x-ray equipment has been used, the equipment must either be transferred to another Authorized User, or must be disabled from use and disposed of. If any shielding material containing lead was used in the laboratory, this must be disposed as hazardous waste through EH&S. Otherwise, no particular clearance is needed for laboratories using only x-ray sources.

See, generally, **Laboratory Clearance (Chapter IX)** in the **Research Radiation Safety Handbook.**

I. Emergency Response

Incidents may occur during the use of radioactive materials, such as spills, accidental release into the air, contamination of the worker or work area and other problems. A radioactive material incident is when material contaminates an area, equipment or person not directly associated with an experimental use. Proper preparation and training before work with radioactive materials should minimize both the risks and impacts of spills.

The laboratory's initial response should follow the guidance indicated by the acronym **SWIM**:

Stop……the spill from spreading (e.g., cover with a paper towel)
Warn……..others in the area and isolate the area
Inform…….....Radiation Safety program personnel
Minimize……exposure by use of personal protective equipment

Spills of radioactive materials can occur, either singly or with another incident. When an incident occurs, you must first make a judgment as to whether the incident is a **minor incident**, a **major incident** or an **emergency.**

A **minor incident** with radioactive materials is an abnormal occurrence involving low amounts and small volumes of radioactive materials, where the worker handling the spill knows how to clean it up, has the decontamination materials on hand and can respond without incurring risk of exposures or spreading within a reasonably short time.

A **major incident** is an abnormal occurrence involving high amounts of radioactive materials, high risk nuclides, large areas contaminated, contamination of the skin, airborne radioactivity or any situation where contamination may have spread outside the authorized area. Major spills must be reported to Radiation Safety Program personnel immediately.

Radiation Safety Program personnel are on call 24 hours/7 days/week for emergency spills. In the event of a spill, call one of the following numbers and ask for radiation safety assistance:

During business hours:

Morningside, Manhattanville, Nevis and Barnard: (212) 854-4442
CUIMC and NYSPI: (212) 305-0303
Lamont: (845) 359-2900 or 555 on campus
Nevis:

After business hours:

Morningside and Nevis: Public Safety at (212) 854-2797 or (212) 854-5555
Manhattanville: Public Safety at (212) 853-3333 or at 3-3333 on campus
CUIMC: Public Safety at (212) 305-8100 or (212) 305-7979
NYSPI: Security at (212) 543-5555
Lamont: Safety/Security Office at (845) 359-2900 or 555 on campus
Barnard: Security at (212) 854-3362

An **emergency** is an incident that involves serious injury or death, fire, explosion or significant release of a health or life-threatening material, which is or may be coupled with a minor or major radiological incident. **DIAL PUBLIC SAFETY/SECURITY AND THE APPLICABLE RADIATION SAFETY PROGRAM OFFICE IMMEDIATELY IF AN EMERGENCY HAS OCCURRED.**

In the event of a **minor incident**, the following procedures should be followed:

- Notify persons in the area that an incident has occurred.
- Contain the spill. Cover with absorbent paper or absorbent pads.
- Isolate the area to prevent unnecessary spread and personnel exposures.
- Survey using the appropriate monitoring equipment in order to evaluate the presence of contamination on an individual's skin and/or clothing and on laboratory equipment. If skin or clothing contamination is present, a major incident has occurred. Follow the procedure indicated below and contact a Radiation Safety program staff member immediately.
- Using disposable gloves, carefully fold up the absorbent paper and pads and deposit them in an appropriate radioactive waste container.
- Survey the area of the spill to determine the extent of contamination. If the contamination is above 200 DPM, decontamination is required.
- Decontaminate the spill and resurvey.
- Continue until the area is decontaminated completely.

In the event of a **major incident**, the following procedures should be followed:

- Notify all persons in the area that a major spill or incident has occurred and evacuate unnecessary personnel.
- Contact the applicable Radiation Safety Program office or Public Safety immediately.
- If possible, prevent the spreading of the radioactive materials by using absorbent paper. Do not attempt to clean it up. Confine all potentially contaminated individuals in order to prevent the further spread of contamination.
- If possible, shield the source and/or absorbent pads, but only if it can be done without significantly increasing your radiation exposure.
- Leave the affected room and lock the doors in order to prevent entry. Attempt to prevent further contamination or spreading to unrestricted areas. (Hallways, non-radiation laboratories, etc., are unrestricted areas.)
- Remove all contaminated clothing and await instructions concerning cleanup from Radiation Safety Program personnel.
- If skin contamination has occurred, measure levels of contamination with a survey meter, record and begin decontamination.

In the event of an **emergency** in which radioactive materials are involved, the following procedure should be instituted:

- Notify all persons in the area that an EMERGENCY has occurred and evacuate the area if a risk to personnel present exists.
- Contact the applicable Radiation Safety Program office or Public Safety immediately. If someone is injured you may also dial 911. In either case, NOTIFY the dispatcher and responder of the nature of the emergency.
- WAIT FOR THE EMERGENCY RESPONDERS who will assist and provide direction, as well as contact any other necessary responders.

All incidents involving radioactive materials must be reported as soon as possible to the PI. If the PI is not available, notify a Radiation Safety Program staff member for advice and assistance.

Each laboratory should have an emergency spill kit on hand containing: nitrile gloves, Tyvek shoe covers, safety glasses, spill pads, tongs, general cleaner/detergents such as RadCon spray, “CAUTION – RADIOACTIVE MATERAL” labels, radioactive waste labels, clear plastic bags and wipe testing kit.

Further Information and guidance on proper decontamination procedures can be found in **Use of Radioactive Materials: Response to an Incident/Emergency (Chapter VII(E))** in the **Research Radiation Safety Handbook.**

VII. LASER SAFETY

A. Introduction

Although closely related to the Radiation Safety Program, the Research Laser Safety Program (the **Laser Safety Program)** of the University, NYSPI and Barnard has distinct features that reflect the fact that lasers emit non-ionizing radiation and have a set of risks that differ from those of ionizing radiation. Lasers are potentially hazardous unless used safely.

The Laser Safety Program at Columbia is University-wide and integrated across all campuses; it also includes laser safety at NYSPI and Barnard. However, the Laser Safety Program applies only to lasers used in research and does not cover the clinical use of lasers at NYP. The Program is operated by EH&S and is overseen by a Laser Safety Committee and a Laser Safety Officer.

The principal guidance document for the Laser Safety Program is the Columbia University, New York State Psychiatric Institute and Barnard Laser Safety Manual (the **Laser Safety Manual).**

This Chapter will provide some background information on lasers and the biological effects of laser exposure, the regulatory framework of laser safety and the roles and responsibilities of the Laser Safety Committee and individuals active in the Laser Safety Program, as well as the authorizations and trainings that are required for laser users. It also provides detailed guidance on the safe use of lasers in research.

B. Basics of Lasers

The word "laser" is an acronym for Light Amplification by Stimulated Emission of Radiation (**laser).** The theory of stimulated emissions was developed by Albert Einstein in the 1920's, but the operational use of lasers did not begin until the 1950's. There is a wide use of lasers today, in such applications as check out scanners, laser printers, laser light shows, industrial, medical and military uses, optical imaging and microscopes. Research uses of lasers usually include optical imaging and microscopes.

The term "light" in reference to lasers is not limited to visible light. Laser radiation is emitted over a wide range of the electromagnetic spectrum from the ultraviolet region through the visible to the infrared region, but rarely in microwave or other wavelength ranges. The most common unit used in expressing a laser's wave length is the nanometer (**nm).** The range of commonly available lasers is from 180 nm to 10.6 micrometers.

Laser light is very different from normal light. Laser light has the following properties:

- The light released is **monochromatic.** It contains one specific wavelength of light (i.e., one specific color).
- The light is **coherent.** It is organized, as each photon moves in step with the others. This means that all of the photons have wave fronts that launch in unison.
- The light is **directional.** A laser light has a very tight beam that is very concentrated and strong.

These properties occur because of **stimulated emission,** i.e., photon emission is organized either because a photon encounters another atom that has an electron in the same excited state as the first photon.

There are three principal operational modes of lasers:

- Continuous wave;
- Single pulsed; and
- Repetitively pulsed.

Continuous wave (**CW**) lasers emit a constant beam of laser energy, while pulsed lasers emit a short, concentrated packet of energy, and require a recovery period (from a fraction of a second to minutes or longer) before another pulse can be released. Pulsed lasers may be more dangerous than continuous wave lasers. As the pulse duration decreases, the peak power or concentration of energy increases. If the length of the pulse is short compared to the time needed to transfer heat energy, the result could be a rapid temperature rise or ablation of material. This is why repetitive pulse lasers can be so dangerous.

There are two forms of laser reflections that can have safety consequences: **specular reflection** and **diffuse reflection.**

Specular reflection is reflection of the beam off a flat surface such as a mirror, where the angle of reflection is equal to the angle of the incoming (or incident) light. This means that the overall beam quality is kept intact and the energy and wave length remain the same, but the direction of the travel of the light is changed and reflected like a mirror. Specular reflection can be caused by inadvertent reflection off a shiny reflective instrument, with the same damage (for instance, to the eye) can be produced by the reflected beam as well as the original beam.

Diffuse reflection is reflection of the beam off an uneven surface, so that the photons are scattered in different directions, spreading the beam out in a less concentrated form. This reduces the chance of eye and tissue damage, except that if the laser is powerful enough, diffuse reflection can still be damaging.

C. Regulatory Framework

In various jurisdictions, standards bodies, legislation and government regulations define classes of lasers according to the risks associated with them and define required safety measures for people who may be exposed to those lasers. The principal regulations and standards governing the use of lasers are as follows:

1. Code of Federal Regulations (CFR)

As provided for by the Radiation Control Health and Safety Act of 1968, manufacturers of lasers must comply with the Federal Laser Product Performance Standard **(FLPPS)** established pursuant to 21 CFR Subchapter J (Radiological Health), Parts 1010 and 1040. In particular, the FLPPS defines the different classes of lasers based on the potential safety risks that various types of lasers represent and imposes certain safety measures on the manufacturers of lasers, such as labeling lasers with specific warnings. The FLPPS applies technically only to manufacturers and not to users.

2. U.S. Occupational Safety and Health Administration (OSHA)

Laser safety in an occupational setting is regulated by OSHA. Although OSHA does not have a specific standard for lasers (with the exception of some requirements for construction practices that are not applicable to research use of lasers), safe work practices are required under the General Duty Clause **(GDC)** that states that employers must give employees a workplace that is "free from recognized hazards that are likely to cause death or serious harm". Under the GDC, OSHA guidance recognizes the American National Standards Institute (**ANSI**) Z136.1 Laser Safety Standard (the **ANSI Laser Safety Standard)** that governs the safe use of lasers as representing the industry standard. The University has committed to follow the ANSI Laser Safety Standard.

The ANSI Laser Safety Standard describes the following classification of lasers based on their capacity to cause injury to human beings:

Class 1 Lasers (**Exempt Lasers).** These lasers are very low power (<1 microWatt (**W))** such that they can be considered to be incapable of causing injury. Also, Class 1 Laser systems can contain higher class lasers within them; if the laser is fully enclosed with adequate protection and therefore not a risk to users, it can be redefined as a Class 1 Laser. Some examples of Class 1 Lasers are laser printers, CD players, DVD devices, geological survey equipment and laboratory analytical equipment. No one would be expected to be injured by a Class 1 Laser and therefore no safety requirements are imposed.

Class 2 Lasers (Low Power Lasers). These lasers are low power (<1 mW) lasers that always operate in the visible spectrum of wavelengths (400-700 nm). Some examples of Class 2 Lasers are laser pointers, aiming devices and range finding equipment. They are unlikely to cause injury because of the natural human aversion (i.e., blink) response (eye closure in <0.25 seconds). If viewed directly for a long time or with certain optical aids, they could be hazardous.

Class 3R Lasers (Moderate Power Lasers). These lasers are continuous wave (**CW),** intermediate power (< 5mW) devices. Class 3R Lasers have similar applications to Class 2 Lasers, with the most popular uses being laser pointers and laser scanners. A Class 3R beam could be hazardous to the eye if viewed directly or with specular reflection. The possibility of permanent injury is small.

Class 3B Lasers (Moderate Power Lasers). These lasers are intermediate power (5-500 mW) devices. Some examples of Class 3B Laser use include spectrometry, stereolithography and entertainment light shows. Direct viewing of the laser beam is hazardous to the eye; diffuse reflection of the beam is generally not hazardous.

Class 4 Lasers (High Power Lasers). These lasers are high power (>500 mW) devices. Some examples of Class 4 Laser use are surgery, research, drilling, cutting, welding and micromachining. Class 4 Lasers can be hazardous to the skin as well as the eye during direct specular reflection or exposure to diffuse reflection. Class 4 Lasers can also be a fire or air contaminant hazard.

D. Laser Hazards

1. Beam Hazards

The laser produces an intense, highly directional beam of light. If directed, reflected or focused upon an object, laser light will be partially absorbed, raising the temperature of the surface and/or the interior of the object, potentially causing an alteration or deformation of the material. The direct beam, diffuse reflection or specular reflection from a laser can damage the eye and skin. Direct intrabeam exposures and specular reflections from Class 3B and Class 4 Lasers can cause eye injury or blindness and skin burns, set fires and generate air contaminants. Diffuse reflections from Class 4 Lasers may also cause these hazards.

Eyes: Corneal, lens or retinal burns are possible from acute exposure. The location and extent of injury depends on the wavelength and the energy absorption characteristics of the ocular media. Lasers cause biological damage by depositing heat energy in a small area, or by photochemical processes. Infrared, ultraviolet and visible laser radiation are capable of causing damage to the eye. Corneal opacities (cataracts) or retinal injury may be possible from chronic, as well as acute, exposures to excessive levels of either visible or invisible laser radiation. Eye hazards are easily controlled by using laser safety eyewear that is appropriate for the specific laser system, or by other engineering safety controls. See **Safe Use of Lasers: PPE (Section I(1))** below.

The ANSI Laser Safety Standard recommends **maximum permissible exposure** (**MPE)** limits on the basis of retinal damage thresholds and light concentration by the lens. The MPE values are based on several factors, including wavelength, visibility and exposure time. The MPE values are less than known hazard levels. However, exposures at MPE values may be uncomfortable to view. It is good practice to maintain exposure levels as far below the MPE values as practical.

Skin: Skin burns are possible from acute exposure to high levels of laser radiation, especially in the infrared region. Erythema (skin reddening), skin cancer, and accelerated skin aging are possible effects in the ultraviolet wavelength range. Shielding the beam and reflections or covering the skin with opaque materials will help prevent skin effects. See **Safe Use of Lasers: Personal Protective Equipment (Section I(1))** below.

2. Non-Beam Hazards

Non-beam hazards are important and their risk of occurrence increases with the power output of the laser. Laser users shall be mindful about non-beam hazards, since they can be potentially fatal. Therefore, non-beam hazards should not be underestimated and should be taken very seriously, especially when working with Class 4 lasers.

Laser Generated Air Contaminants (LGAC): Air contaminants may be generated when certain Class 3B and Class 4 Laser beams interact with matter. Whether contaminants are generated depends greatly upon the composition of the target material and the beam irradiance. When the target irradiance reaches approximately 107 watts per square centimeter, target materials such as plastics, composites, metals and tissues may liberate carcinogenic, toxic and noxious airborne contaminants.

Fire: Combustible material such as paper and cardboard boxes can be ignited by the beam. Other potential fire hazards include electrical components and the flammability of Class 4 Laser beam enclosures. The risks of fire can be reduced by using only fire-resistant materials (e.g. IFR curtains) to contain the beams of Class 4 Lasers. Beam blocks and beam stops are preferred to be used as primary barriers.

Electrical Hazards: This is the most common non-beam hazard. Potentially lethal electrical hazards may be accessible in a laser system, particularly in high-powered lasers. High voltage components such as power supplies and discharge capacitators may present an electrical hazard. High voltage equipment should be appropriately grounded.

Hazardous Chemicals: Some material used in laser systems, especially gases and chemical solutions, may be hazardous or toxic substances. In addition, laser induced reactions may produce hazardous particles or gases around the laser system.

E. Roles and Responsibilities

The primary oversight responsibilities within the Laser Safety Program rest with the **Laser Safety Committee**, the **Laser Safety Officer** and the **Laser Safety Program personnel** in EH&S. Together, they establish policies and procedures, oversee regulatory compliance, monitor Laser Safety Program performance and support the highest quality research. The PIs and **Laser Users** also have responsibilities under the Laser Safety Program. The following briefly describes their roles and responsibilities.

1. Laser Safety Committee (LSC)

The purpose of the **LSC** is to administer the Laser Safety Program. The members and Chair of the LSC are appointed by the University's EVPR, the University's Executive Vice President for Health and Biological Sciences and the Director of NYSPI. The membership of the LSC includes (a) at least one PI from each of Morningside, Manhattanville, Nevis, CUIMC, NYSPI, and Barnard (b) a representative from EH&S and (c) the Laser Safety Officer. The LSC has the following responsibilities:

- Establishing and maintaining laser safety policies and guidelines;
- Establishing guidelines for the suspension of use of lasers in instances of noncompliance;
- Reviewing and approving updates to the Laser Safety Manual;
- Reviewing:
    - Reports regarding laser safety audits and Program performance;
    - Training requirements, materials and compliance; and
    - Laser safety controls for adequacy and effectiveness;
- Overseeing and approving new laser installations; and
- Recommending corrective measures in instances of noncompliance**.**

2. Laser Safety Officer

The Laser Safety Officer has the following responsibilities:

- Coordinating and managing the Laser Safety Program on a day-to-day basis;
- Executing the established policies of the Laser Safety Program and ensuring compliance with federal, state and local regulations;
- Supervising laser control activities as required by the LSC;
- Reviewing and approving registrations for Class 3B and Class 4 Laser use;
- Reviewing laboratory operations to determine compliance with the Laser Safety Program;
- Maintaining records of Program operations that are suitable for inspection by regulatory authorities;
- Halting operations involving lasers if unsafe or unacceptable conditions exist; and
- Suspending use of lasers in accordance with the guidelines established by the LSC.

3. Laser Safety Program Personnel

The Laser Safety Program personnel have the following responsibilities:

- Recommending revisions to the Laser Safety Manual to the Laser Safety Officer and the LSC;

- Conducting periodic inspections of laser areas to recommend action for compliance with the requirements of the ANSI Laser Safety Standard;
- Assisting with the proper selection of PPE;
- Upon request, assisting PIs or their staff with writing SOPs;
- Providing training to laser users;
- Responding to all inquiries on laser safety procedures and providing technical assistance; and
- Maintaining records of laser inventories, audits, survey forms and training attendance.

4. PIs

A PI has the following responsibilities:

- Supervising all laser activities in their laboratories;
- Developing and drafting SOPs for Class 3B and Class 4 Laser use;
- Maintaining and updating, as needed, all operating, alignment and emergency procedures for the laser and laser facility;
- Ensuring registration of all Class 3B and Class 4 Lasers and personnel who operate them;
- Maintaining an up-to-date list of all laser devices, facilities and users and communicating such list to Laser Safety Program personnel;
- Ensuring that personnel using lasers have attended Laser Safety Training prior to operating a laser;
- Performing and documenting work area specific training for all laser users prior to initial operation;
- Ensuring that the PPE recommended by the manufacturer for safe operation of the laser is available and is used by all employees and visitors to the laser facility;
- Supervising personnel in and visitors to the laser facility to ensure against unauthorized entrance or accidental exposure;
- Acting to or designating a knowledgeable person to (a) notify the Laser Safety Officer and EH&S of any changes in operational status, such as changes in location, purchases of, and modifications to, laser equipment, (b) revise SOPs in accordance with any modifications, (c) update all records, and (d) re-register a modified laser;
- Ensuring that all users have reviewed manufacturers' instructions for safe operation prior to the use of any equipment;
- Enforcing safe work practices outlined in the Laser Safety Manual;
- Ensuring that any exposure to lasers remains below the MPE values; and
- Reporting all incidents involving safety violations to the Laser Safety Officer.

5. Laser Users

Any person using laser equipment has the following responsibilities:

- Becoming familiar with the laser equipment and the potential hazards that are associated with its use;
- Inspecting eyewear prior to use to ensure that it is in good condition;
- Wearing all PPE designated by the PI;
- Completing any required initial and refresher training;
- Complying with the Laser Safety Manual and any SOPs relevant to the laser facility used by the laser user;
- Maintaining a safe environment for all researchers and students in the laboratory; and
- Reporting laser hazards, including possible exposure to the beam, to the PI

F. Training

1. Initial Training

Initial laser safety training must be completed by all personnel prior to any use of Class 3b or Class 4 Lasers. The Laser Safety Program offers classroom training to first-time users of lasers and to individuals who have had training and experience at other institutions. The class includes instruction on:

- The biological effects of laser radiation;
- The physical principles of lasers;
- Classification of lasers;
- Control of laser areas;
- Best laser safety practices;
- A laser user's responsibilities;
- Basic safety rules;
- Use of PPE;
- Beam and non-beam hazards; and
- Emergency response procedures;

The PI is responsible for ensuring that all members of his/her staff who will be using lasers have taken the classroom training before they are allowed to operate a laser. In addition, the PI or a designated senior or knowledgeable individual, must provide on-the-job training for Class 3b and Class 4 Laser users that includes a thorough review of the hazards associated with each laser that a person may operate, the protection methods employed by the laboratory and the emergency contacts.

2. Refresher Training

Refresher training is required every two years and may be completed by taking the Rascal online course: *TC1600: Laser Safety*

G. Procurement, Transfer and Disposal of Lasers

1. Procurement

During the procurement process for a Class 3b or Class 4 Laser, the PI must complete a **Laser Registration Form** providing a description of the laser specifications (manufacturer, model, class, wavelength, pulsed/continuous wave, power, etc.), the location of intended use, and the PI's laboratory emergency contacts, etc. The Form should be emailed to the Laser Safety Officer at lasersafety@columbia.edu. After the Laser Safety Officer reviews and approves the Laser Registration Form, and sends it back to the PI, the Form should be uploaded into the ARC Portal System. Once the laser requisition is approved by the Laser Safety Officer on the ARC Portal System, Procurement may proceed with the laser purchase. If the PI does not submit a Laser Registration Form, Procurement will contact the Laser Safety Officer to determine if the Form is required. If so, the above process should be completed. Laser Registration Forms and the Laser Safety Officer's approval are not required for the purchase of lower class lasers (i.e., only for Class 3B and Class 4 laser systems). A sample Laser Registration Form is attached hereto as **Annex VII-A.**

2. Inventory

EH&S maintains an inventory of all Class 3b and Class 4 Lasers at the University, NYSPI and Barnard**.** A description of modifications to a laser that has either been purchased from an outside vendor or fabricated by a PI should be sent to EH&S to update the general inventory.

3. Transfer

A PI must report the transfer of any laser to another laboratory at the University, NYSPI or Barnard so that the EH&S database can be updated. All laser systems that are purchased or built in a University, NYSPI or Barnard laboratory and transferred to an external location in a manner that could be considered to be "in commerce" must meet the federal certification requirements (21 CFR 1040). The Office of General Counsel (**OGC**) will determine if those requirements apply.

4. Disposal

Certain types of research activities with lasers use organic solvents and toxic dyes. All waste mixtures must be collected and disposed of as hazardous waste through EH&S. Waste solvent/dyes should be collected in compatible containers (usually polypropylene) and labeled with a hazardous waste label as soon as the first material is added to the container. Do not attempt to evaporate waste in a CFH to reduce the volume, or to drain dispose of the waste. Laser systems that do not contain any hazardous material, can be disposed as general electronic waste. In any case of laser disposal, contact the Laser Safety Program personnel for support and guidance. See also **Hazardous Waste Management and Disposal (Chapter IV)**.

5. Laboratory Vacating and Closure

Before the PI departs from the University, he/she should contact the Laser Safety Officer for guidance. The PI is responsible for disassembling the laser set-up and packing it appropriately for the move. The Laser Safety Officer will remove the laser from the inventory.

H. Requirements for Laboratories Housing Lasers

1. Labels

For manufactured lasers, the manufacturer is responsible for providing the classification of the laser at the time of purchase. The PI is responsible for the classification of lasers prepared or modified in his/her laboratory, with advice from the Laser Safety Officer. Laser warning labels must be affixed to the equipment, close to the source of the laser light. In addition to information about laser parameters, labels should contain safety information.

2. Signage

Entrances to laser areas must have signage posted in accordance with the ANSI Laser Safety Standard. An illuminated warning sign outside of the area is recommended, preferably flashing and lit only when the laser is on.

Class 3B Laser facilities must have a **"Warning"** sign conspicuously displayed. See **Annex VII-B** for a picture of the Warning sign. Class 4 Laser facilities must have a **"Danger"** sign conspicuously displayed. See **Annex VII-C** for a picture of the Danger sign.

Laser safety door postings are provided by Laser Safety Program personnel upon request.

3. Laboratory Construction

All windows, doorways and portals of a laboratory where there is laser use should be covered or restricted to reduce transmitted laser beams.

For Class 4 Lasers that have open beam lines, the ANSI Laser Safety Standard requires interlocked doors (or sensors or pressure sensitive doormats) or devices that turn off or attenuate the laser beam in the event of unexpected entry into the area. However, under special conditions where an interlocked door could interfere with the proposed research activity, an alternate method of protection, such as a curtain or barrier, should be discussed with EH&S to provide the most appropriate means of intercepting or scattering a beam so that a person entering the room will not be exposed to the beam in excess of the MPE.

I. Safe Use of Lasers

The PI should prepare written SOPs, including Service and Maintenance Procedures, if these are performed by members of his/her research team, for each Class 3B and Class 4 laser present in his/her laboratory. Written alignment procedures should be kept near the equipment and be accessible to all laser operators. At a minimum, the most salient features of laser safety are to be located in a clearly visible manner near each laser installation. General exposure guidelines, special precautions, or unusual conditions should be outlined in SOPs. The Manufacturer's Manual should also be available to users. See **Annex VII-D** for a copy of a Laser SOP Template.

A SOP template is available from the Laser Safety Program, upon request.

1. PPE

Protective Eyewear

The ANSI Laser Safety Standard requires that protective eyewear be worn when working with Class 3B and Class 4 lasers or whenever hazardous conditions may result from laser radiation or laser related operations. These glasses attenuate the intensity of laser light while transmitting enough ambient light for safe visibility. No single lens material is useful for all wavelengths or for all laser exposures. In choosing protective eyewear, careful consideration must be given to the operating parameters, MPEs and wavelength. To minimize confusion, protective eyewear should be marked with its protective rating such as effective wavelength and optical density. Laser Safety Program personnel maintain a list of approved laser safety eyewear manufacturers, and can provide recommendations regarding the appropriate eye protection for each laser use.

It is extremely important that laser users wear the appropriate laser safety eyewear correctly. For example, only eyewear such as goggles specifically designed to fit over prescription glasses may be worn with prescription glasses. In addition, prescription laser safety glasses are readily available from most vendors of laser safety eyewear. Be mindful that general safety glasses, contact lenses, or sunglasses are not considered laser protective equipment.

PPE for Skin

Although skin injuries are less serious than eye injuries, skin injuries are more likely to occur, especially during beam alignment. During alignment procedures and when working with Class 4 lasers, a lab coat and nitrile gloves are highly recommended to be worn to prevent accidental exposure of the skin from direct or stray beams.

Laser Curtains

Curtains in any laboratory space are required to meet certain minimums of flame resistance. Although it is acceptable to buy curtains treated with a flame-resistant chemical, this is not recommended due to the required maintenance. Inherently Flame Resistant (**IFR**) curtains are more appropriate for the laboratory setting as curtains made from IFR materials do not require

maintenance. Furthermore, any fabric used in a laboratory, whether treated with a flame-resistant chemical or IFR, requires the filing of an affidavit certifying the material's flame resistance with the FDNY. EH&S can provide this service and it is recommended that laboratories consult with Laser Safety Program personnel before purchasing any materials that are to be used as laser curtains.

2. Safety Procedures and Controls.

General Safety Procedures

The following are general safety procedures that should be used with any Class 3B and Class 4 Laser:

- Do not enter a room or area where a laser is being energized unless authorized to do so.
- Do not work with or near a laser unless you have been authorized to do so.
- Remove any jewelry or other reflective objects to avoid inadvertent reflections.
- Before energizing a laser, verify that prescribed safety devices for the unit are being properly employed. These may include opaque shielding, non-reflecting and/or fire-resistant surfaces, goggles and/or face shields, door interlocks and ventilation for toxic material.
- Make sure that a pulsed laser unit cannot be energized inadvertently. Discharge capacitors can turn off power before leaving the laser unit unattended.
- Use appropriate eyewear during beam alignment and laser operation. Beam alignment procedures should be performed at the lowest practical power levels. When alignment has been completed, the laser output can be adjusted to the experimental requirements.
- Do not stare directly into the laser beam at any time, even with eye protection in place.
- Control access to laser facility. This can be done by clearly designating those who have access to the laser room. Implement access control by locking the door and installing warning lights or signs on the outside of the door.
- For invisible laser beams, use viewing cards or lower class visible lasers to define the beam path during alignment.
- Never leave the laser unattended when it is in operation.

Class 3B Laser Controls

In addition to the above procedures, the following are controls that should be used with Class 3B Lasers:

- Permit only experienced personnel to operate the laser.
- Enclose as much of the beam path as possible. Even a transparent enclosure will prevent an individual from placing his/her head in the beam path. Terminations should be used at the end of the useful paths of the direct beam and any secondary beams.

- Place shutters, polarizers, and optical filters at the laser exit port to reduce the beam power to the minimal useful level.
- Use a warning light or buzzer to indicate laser operation. This is especially needed if the beam is not visible (i.e., for infrared lasers).
- Operate the laser only in a restricted area such as a closed room without windows. A warning sign must be placed on the door.
- Place the laser beam path well above or well below the eye level of any sitting or standing observers whenever possible. The laser should be mounted firmly to assure that the beam travels only along its intended path.
- Always use proper laser eye protection if a potential eye hazard exists for the direct beam, or a specular reflection.
- Never directly view the beam or its specular reflection with optical instruments such as binoculars or telescopes without sufficient protective filters.
- Remove all unnecessary mirror-like surfaces from the vicinity of the laser beam path. Do not use reflective objects such as credit cards to check beam alignment. Note: the reflectivity of an object is a function of the wavelength of the laser beam.
- Install a key switch to minimize tampering by unauthorized individuals.

Class 4 Laser Controls

In addition to the controls above, the following are controls that should be used with Class 4 Lasers:

- Operate these lasers only within a localized enclosure, in a controlled workplace. If a complete local enclosure is not possible, indoor laser operation should be in a light-tight room with interlocked entrances to assure that the laser cannot emit energy while the door is open. However, under special conditions where an interlocked door could interfere with proposed research activity, an alternate method of protection such as a curtain or a barrier should be discussed with EH&S to provide a suitable barrier just inside the door or where ever most appropriate to intercept a beam or scatter it so that a person entering the room could not be exposed above the MPE limits.
- Require appropriate eye protection for all individuals working within the controlled area.
- If the laser beam irradiance is sufficient to be a serious skin or fire hazard, use suitable shielding between the laser beam and any personnel or flammable surfaces.
- Use remote firing with video monitoring or other remote (safe) viewing techniques when feasible.
- Use beam shutters, beam polarizers and beam filters to limit use to authorized personnel only. The flash lamps in optical pump systems should be shielded to eliminate any direct viewing.
- Use backstops to diffusely reflecting fire resistant target materials where feasible. Safety enclosures should be used around micro welding and micro drilling work pieces to contain hazardous reflections from the work area. Microscopic viewing systems used to

study the work piece should ensure against hazardous levels of reflected laser radiation back through the optics.

Laser Alignment Considerations

Although laser injuries are uncommon, laser operators must be especially mindful about their safety during laser alignment procedures. A laboratory should include written alignment procedures as part of its SOPs. During alignment, laser users tend to be closer to the beam, remove some engineering controls and rotate the system's optics. Therefore, the probability of the beam interaction with the eye or unprotected surfaces is higher. It is important to know that most laser injuries occur during beam alignment. Things to keep in mind are the following:

- Make sure only authorized personnel are present in the laser area.
- Communicate with others present in the same room that you plan to initiate alignment procedures.
- Make sure all present personnel are wearing the appropriate laser safety eyewear. In many occasions, special eye protection shall be considered for alignment. These glasses do not block the laser beam fully, and a portion of the beam can be transmitted through them, which allows partial visibility of the beam within acceptable levels (< MPE level).
- Remove any unnecessary reflective and flammable objects (including jewelry and ties) from the laser bench top.
- Turn down the beam power to the minimum needed in order to do the alignment.
- If the beam is invisible, utilize viewing cards or Infrared viewers.
- If the laser system you are using has a built-in, low power alignment laser, use that feature instead of the main beam.
- Contain the beam as much as possible in order to complete your laser alignment safely without exposure to the beam.

J. Laser Incidents

In the event that a laser user suspects that he/she has been injured by a beam or non-beam hazard, he/she should notify the applicable PI and the Laser Safety Officer immediately. The PI should file a laser incident report with the LSC.

Emergency Medical Services by Campus

If the injured laser user needs medical attention, the following is the location and contact information for emergency medical services:

- **Morningside and Barnard:**
  - During Business Hours for **Staff and Students**: SHS, John Jay Hall, 4th Floor, 519 W. 114th St., (212) 854-7426

    - After Hours (or for life-threatening emergencies): Mount Sinai Morningside Hospital Emergency Room, 1111 Amsterdam Avenue at 114th Street, (212) 636-3375
- **Manhattanville:** Harlem Hospital, 506 Lenox Avenue, (212) 939-1000
- **CUIMC:**
    - During Business Hours for **Staff:** WH&S – Harkness First Floor, (212) 305-7580
    - During Business Hours for **Students**: SHS – 100 Haven Avenue, (212) 305-3400
    - After Hours: NYP Emergency Department – Broadway & 167th Street
- **Lamont:** Nyack Hospital, 160 North Midland Ave., Nyack, (845) 348-2000
- **Nevis:** St John's Riverside Hospital Dobbs Ferry Pavilion, 128 Ashford Ave, Dobbs Ferry (914) 693-0700
- **NYSPI:** NYP Emergency Department – Broadway & 167th Street

For a comprehensive guide of emergency procedures, please see the link below: https://research.columbia.edu/sites/default/files/content/EHS/Homepage/EmergencyProceduresTable.pdf

VIII. FIRE SAFETY

A. Introduction.

The risk of fire is among the most common safety concerns in the research laboratory environment. Fire safety in University research laboratories encompasses best practices and safe behaviors in the conduct of research, laboratory design principles, emergency preparedness and compliance with applicable regulations.

All personnel conducting research in University laboratories are expected to participate fully in applicable fire safety programs, including training, fire drills, and other required laboratory-specific education.

EH&S staff are available to assist laboratories with managing their fire safety-related responsibilities throughout the research life cycle. From code compliance in laboratory design, to employing fire prevention strategies related to specialized research activities, such as work with pyrophoric chemicals or electrical equipment, laboratory staff are encouraged to reach out to EH&S with questions or concerns.

B. Regulatory Framework

Researchers should be familiar with the regulatory framework governing fire safety. International, federal and New York State regulations apply to all campuses of the University. Local regulations are established by New York City for Morningside, Manhattanville and CUIMC (the **NYC Campuses)**, by Rockland County and the Town of Palisades for Lamont, and by the County of Westchester and the Village of Irvington for Nevis.

1. International

The International Fire Code is designed to meet the need for uniform international standards of fire safety in buildings and dwellings. It has been adopted at the national and/or state level by 41 states, including New York.

2. Federal

OSHA General Industry Standards

The OSHA General Industry Standards, 29 CFR 1910 establish requirements for a variety of fire safety-related topics, including extinguishing systems, exit and egress routes, and other broad areas. These requirements are general in nature and the specific application of rules governing the construction of laboratories and the regulation of conduct within is covered under local regulations.

3. New York State

New York State Uniform Fire Prevention and Building Code

The New York State Uniform Fire Prevention and Building Code (the **NYS Uniform Fire Code**) https://www.dos.ny.gov/dcea/laws_regs.html prescribes minimum standards for both fire prevention and building construction. It is applicable to every municipality in the State (except New York City, which is permitted to retain its own Code)

4. Local

New York City

New York City Fire Code

The New York City Fire Code (**NYC Fire Code**) is the final standard regulating all matters of fire safety applicable to laboratories on the NYC Campuses. The NYC Fire Code also incorporates, by reference, partial requirements of more than 17 different compilations of industry standards and the rules of various states and federal agencies.

Taken together, the collection of regulations can be challenging to interpret. Accordingly, the University has established guidelines and requirements relating to training, laboratory design, chemical storage, equipment operation and other relevant matters addressed by these codes. It is recommended that all researchers first consult the University's guidance materials for matters relating to fire safety.

The Fire Department of the City of New York (**FDNY)** is the "Authority Having Jurisdiction" over fire safety on the NYC Campuses. Under the NYC Fire Code, Columbia laboratories are considered to be "non-production chemical laboratories".

Laboratory Permit

The NYC Fire Code requires laboratories to meet a variety of construction standards relating to ventilation, fire suppression and containment and the availability of emergency equipment such as fire extinguishers, eyewashes and overhead showers. The construction and operation of any non-production chemical laboratory in New York City requires a permit from the FDNY and the submission of an application and a number of other documents that are outlined in EH&S' Laboratory Commissioning Checklist. A permit is issued by the Fire Commissioner after the laboratory has been inspected and approved as acceptable for handling, storing and using flammable or combustible liquids and/or flammable gases. For laboratories built before July 2008, the presence or absence of sprinklers, together with the fire rating of the laboratory perimeter, determine the total quantity of allowable flammable material within the laboratory. Laboratories built or substantially renovated after July 2008 have limits assigned according to the square footage of the space. Please note that waste material is counted toward the

laboratory's permitted flammable material limit, and laboratories should manage their inventories accordingly.

Permits are valid for 12 months and the laboratory must be inspected by the FDNY prior to permit renewal. Permits are non-transferable.

Certificate of Fitness

The FDNY requires and issues Certificates of Fitness for different types of potentially hazardous occupations or activities. Columbia laboratories must be operated under the supervision of a holder of a C-14 Certificate of Fitness for Supervising Non-Production Chemical Laboratories (a **C-14 Holder).** See **Additional Certificate of Fitness Information (Section E)** below for a more complete description of the qualifications, training and responsibilities of a C-14 Holder.

Rockland County

Orangetown

The Lamont campus is subject to local requirements under the Fire Prevention Code of the Town of Orangetown. The code is intended to prescribe minimum requirements necessary to establish a reasonable level of safety and property protection from the hazards created by fire and explosion. The Code is designed to supplement and expand upon the requirements of the NYS Uniform Fire Code.

Westchester County

Village of Irvington

At Nevis, the Fire Prevention Code of the Village of Irvington, NY establishes the authority of the Irvington Fire Department and Code Enforcement Officer to conduct fire safety inspections, as well as the general requirements to maintain safe conditions at all properties in the Village. Comprehensive inspections of fire safety conditions are generally conducted on an annual basis by personnel from the Village of Irvington.

C. Roles and Responsibilities

1. PIs

PIs are responsible for ensuring that laboratory personnel attend the requisite training courses and that the C-14 Certificate Holders on his/her research team carry out the duties assigned to them by the FDNY. PIs also bear ultimate responsibility for overall compliance with applicable fire safety regulations.

2. C-14 Holders

The FDNY has delegated to C-14 Holders the responsibility for overseeing all fire safety in a University laboratory. As a result, a C-14 Holder is responsible for keeping up to date with regulatory mandates and, most importantly, at least one C-14 Holder must be present in a laboratory **at all times when the laboratory is in operation,** including evenings, weekends and holidays.

A C-14 Holder is responsible for the safe storage, handling and use of all hazardous materials in the laboratory where the C-14 Holder works and must be trained in aspects of the laboratory's emergency plan, including:

- Procedures for activating a fire alarm;
- Procedures for notifying and coordinating with all emergency response agencies;
- Procedures for evacuating and accounting for personnel, including primary and secondary evacuation routes, as applicable;
- Procedures for establishing requirements for rescue and medical duties for those personnel requiring or performing such duties;
- Procedures and schedules for conducting regular emergency drills;
- Procedures for shutting down and isolating equipment under emergency conditions, including the assignment of personnel responsible for maintaining critical functions or for shutting down processes;
- Appointment and training of personnel to carry out assigned duties, including steps to be taken at the time of initial assignment, as responsibilities or response actions change, and at the time anticipated duties change;
- Clearance of aisles designated as necessary for movements of personnel and emergency responders;
- Maintenance of fire protection equipment; and
- Safe procedures for startup to be taken following the abatement of an emergency.

Please note that if a laboratory has more than one C-14 Holder, all Holders must understand all the foregoing responsibilities.

3. EH&S

EH&S serves as the University's primary liaison with the FDNY on all matters of laboratory fire safety. The FDNY carries out weekly inspections of laboratories at the NYC campuses, and visits each laboratory on an annual basis to renew its permit. The FDNY Inspector is escorted at all times by an EH&S staff member. Upon arrival at a laboratory during an inspection, EH&S will engage with laboratory staff, announce the presence of the FDNY and explain the intention of the visit. As the inspection proceeds, input may be sought from the laboratory staff, and in general, EH&S will serve as an intermediary between the Inspector and laboratory personnel. In addition, if a non-compliant condition is observed, EH&S will work with the laboratory to enact corrective measures, whenever possible, ideally preventing a formal violation from being issued.

If a FDNY laboratory inspection results in a Violation (see **Laboratory Inspections (Section G)** below), EH&S will support the laboratory in identifying and affecting the necessary corrective actions to remedy the non-compliant condition. Correspondence regarding the Violation is exchanged via LION, and EH&S will also physically return to the laboratory to verify correction.

In support of overall compliance with fire safety regulations in the laboratory, EH&S also conducts periodic surveys of the University's research spaces. Surveys include fire safety-related criteria and conditions and are generally unannounced. For more information about laboratory surveys, see **Laboratory Inspections (Section G)** below.

EH&S remains abreast of relevant code updates and changes, as well as trends, developments and best practices relating to fire safety in the laboratory. This information is communicated to Facilities Operations and other stakeholders in areas of laboratory design, construction and related matters. EH&S is also responsible for ensuring that this updated information is included in current versions of C-14 training and other guidance issued to the University research community.

At Lamont and Nevis, primary support for fire and life safety issues is provided by the following offices; any general questions or concerns should be directed to those offices at the phone numbers below (see **Response to Fire Emergencies (Section I)** below for emergency contact information):

Lamont: Safety Office (845) 345-2900

Nevis: Security Office (914) 591-2870

D. Training

1. Laboratory Safety, Chemical Hygiene and Hazardous Waste Management

All researchers are provided basic information on fire safety during their Laboratory Safety, Chemical Hygiene and Hazardous Waste training. This training covers, in addition to fire safety, general laboratory safety, working with chemicals and management of hazardous waste. The initial training must be taken during one of EH&S' regularly scheduled classroom sessions. Refresher training is required every two years and may be completed by either retaking the regularly scheduled classroom sessions or taking the Rascal online refresher course: *TC0950: Lab Safety, Chemical Hygiene and Hazardous Waste Management.*

See the EH&S Safety Training Schedule pages for dates and times of classroom training:
Morningside
(https://research.columbia.edu/sites/default/files/content/EHS/Training/TrainingMS.pdf)
CUIMC
(https://research.columbia.edu/sites/default/files/content/EHS/Training/TrainingMC.pdf)

2. Certificate of Fitness Training

EH&S offers a C-14 Holder training course online in Rascal, and in classroom sessions. Anyone who wants to apply to be a C-14 Holder should also study the FDNY Study Material prior to taking the examination.

See the EH&S Safety Training Schedule page for dates and times of classroom training. To encourage groups of laboratory staff members to become C-14 Holders, EH&S will arrange on-site training for groups of six trainees or more.

3. Specialty Training

Certain research activities carried out in some laboratories may require the completion of a specialized Certificate of Fitness. Examples include welding with flammable gas, management of commercial quantities of cryogenic liquids, and the operation of certain medical gas distribution (i.e., manifold) systems. Please contact EH&S if any of the above are applicable.

E. Additional Certificate of Fitness Information

To facilitate meeting the University's requirement to have at least one C-14 Holder in all laboratories, EH&S administers an "Alternate Issuance Program" (**AIP)** whereby University personnel meeting certain minimum educational and experiential requirements as defined by the FDNY are eligible to complete the C-14 training course and examination on campus. Personnel who do not meet the minimum requirements are still eligible to obtain a C-14 Certificate of Fitness, but must complete the exam at FDNY headquarters at Metrotech Center in Brooklyn. Regardless of where the examination is taken, all fees are covered by EH&S.

1. Eligibility

Participation in the AIP requires a minimum of a bachelor's degree in a science-related discipline, plus two years of post-baccalaureate laboratory experience. Any experience gained prior to the receipt of a degree will not be accepted toward meeting the requirements of the AIP. Holders of MD, PhD, MS, MA, MPH degrees automatically qualify without the need for prior laboratory experience. An individual who does not meet these requirements is required to have at least 60 college credits, of which 21 must be in science related coursework, to qualify to be a C-14 Holder.

2. Documentation

In accordance with FDNY requirements, any applicant for a C-14 Certificate of Fitness using the AIP must furnish the following documents at the time of the EH&S training:

- Photocopy of his/her diploma or transcript stating the degree earned and date conferred. Any diploma or transcript issued by a non-U.S. school or university must be translated into English, if applicable
- Completed FDNY C-14 Application (A-20), a template of which is attached as **Annex VIII-A**
- Completed Employee Affirmation, a template of which is attached as **Annex VIII-B**
- Completed Employee Statement (not required for applicants holding a MD, PhD, MS, MA or MPH degree) a template of which is attached as **Annex VIII-C**
- Employer recommendation, a template of which is attached as **Annex VIII-D**
- Student or employee visa (for applicants without a U.S. Social Security number)

All of the above documents can be found on the EH&S Certificate of Fitness webpage.

3. Examination

All C-14 applicants are required to take an onsite examination, proctored by EH&S, upon completion of the requisite training. See **Training: Certificate of Fitness Training (Section D(2))** above for information on C-14 Holder training.

4. Submission of Application

Once EH&S has verified that an applicant meets the eligibility criteria and has passed the examination, it will submit a completed package of application materials to the FDNY. Within approximately six weeks, EH&S will notify an applicant of receipt of his/her C-14 identification card, which may be picked up at the EH&S Office at Morningside or CUIMC. It is important to note that a C-14 applicant is not officially certified until his/her physical identification card has been issued and is in his/her possession.

5. Renewal and Transfer

A C-14 Certificate of Fitness is valid for three years. C-14 Holders are entered into a database managed by EH&S. Prior to expiration of a C-14 Certificate of Fitness, each C-14 Holder will be contacted by email with a request to verify whether he/she wishes to renew or discontinue their certification. All renewals are processed by EH&S. If a C-14 Holder's certification has lapsed for more than one year, a new application must be submitted. In addition, individuals who obtained a C-14 Certificate of Fitness at another New York City institution must apply for new certification through the University. Certification is transferable, however, for individuals whose laboratory has relocated within the University**.**

F. Fire Hazards in Research Laboratories

The following section describes some of the most common fire hazards in a laboratory setting. The presence of any of these hazards will most likely result in the finding of a violation by the FDNY. See: **Laboratory Inspections: FDNY (Section G(1))** below. This section is not meant

to be an all-inclusive discussion of laboratory fire safety. For more comprehensive guidance on laboratory fire safety, please review the C-14 Study Material.

See also **Laboratory and Research Safety (Chapter III)** for additional information on laboratory hazards.

1. Chemical Management

The following chemical management conditions are prohibited: missing or illegible labels; un-tested or expired peroxide forming materials; the presence of expired chemicals; refrigerated storage of flammable materials; improper chemical segregation; storage of glass bottles on floors; permanent storage in CFHs; and improper acid storage, including the use of incompatible cabinets and improper segregation.

2. Cylinder Storage

The following cylinder storage conditions are prohibited: unsecured cylinders; failure to label empty tanks; storage of flammable gas within 10 feet of laboratory exits; failure to utilize protective caps on cylinders that are not in use; and storage of cylinders in corridors.

3. Housekeeping

The following housekeeping hazards are subject to violation: the presence of excess clutter and fire load materials such as paper, cardboard and rubbish; hazardous material storage above eye level and within close proximity to ceilings and sprinklers; inadequate aisle and egress path width; inoperable self-closing door(s); blocked emergency equipment; and missing, discharged or damaged fire extinguishers.

4. Chemical Storage

FDNY regulations mandate the segregation of incompatible chemical materials based on general chemistry and the potential for incompatible combinations to react and increase fire risk. Materials deemed incompatible must be stored separately from one another at either 20’ of distance, or by means of a non-combustible partition at least 18” above and to the sides of the stored materials. Steel cabinets and laboratory casework generally meet this requirement, but wood shelving and storage areas do not. Chemicals of the same hazard class may be stored in the same storage cabinet, but should be further divided by compatibility, as follows:

- Acids and Bases – Materials with a low pH (acids) and those with a high pH (bases) must be physically segregated.
- Inorganic acids must be separated by secondary containment from organic acids (e.g., hydrochloric acid must be segregated from acetic acid).
- Oxidizing acids (e.g., nitric acid) must be separated by secondary containment from all combustibles (e.g., acetic acid, organic solvents).

- Oxidizers – Materials that can accelerate combustion must be physically segregated from flammable materials. Examples of oxidizers include peroxides, perchlorates and permanganates, which must be segregated from solvents and other ignitable materials.
- Toxic materials – Chemical storage areas should be arranged as to avoid hazardous conditions, such as moisture, excess heat and light, where applicable. Examples of toxic materials include certain heavy metals, organophosphorous compounds, and other compounds with low LD50 values.
- General storage considerations – Chemicals should be managed to minimize the risk of breakage and spilling. Do not store chemicals on the edges of shelving. Do not store hazardous materials above "eye level" to minimize the risk of bodily contamination while retrieving and storing items. Check storage areas periodically for leaking, damaged or expired materials. Do not store full chemical containers on the floor, unless adequate secondary containment is utilized to prevent breakage.

5. Refrigerators and Freezers

The interior space of refrigerators and freezers does not provide air circulation and is therefore prone to the buildup and concentration of flammable vapors. Accordingly, the storage of flammable materials in "household" refrigerators (i.e., those without intrinsically safe internal electrical components) is strictly prohibited. Laboratories that require refrigerated storage space for flammable chemicals must use a specifically equipped flammable materials storage refrigerator designed to prevent the accidental ignition of chemical vapors inside the refrigerator. All "household" refrigerators must be labeled to indicate that storage of flammable materials is prohibited. Please contact labsafety@columbia.edu for the delivery of refrigerator labels, as needed.

See also **Laboratory and Research Safety: Laboratory Equipment – Refrigerators and Freezers (Chapter III, Section F(1))**.

6. Electrical Equipment

Misuse of electrical equipment may pose a fire hazard under a variety of conditions, including:

- **Improper use of extension cords**: Only small, benchtop equipment may be connected to an extension cord when necessary to reach an electrical receptacle. Extension cords must be properly rated for the amperage of the equipment to which they are connected, and cords must never be "daisy chained" together; only one extension cord may be used for any piece of equipment. "Permanent" equipment such as refrigerators and freezers, incubators, centrifuges, and other similar standalone items must be connected directly to a wall outlet. Regular cords, as well as extension cords, must never be run under carpets, floor mats or other combustible materials. Stretching cords across trafficked areas should be avoided, and where necessary, cords should be covered by protective conduit to reduce the hazard of slips, trips and falls.
- **Electrical Outlets/Receptacles**: Facilities should be consulted to verify that high-powered equipment with heavy voltage or amperage loads will not short or trip a laboratory's

standard wall outlets. The need for specialized outlets, breakers, switches and other equipment to support high voltage electrical devices must be evaluated via Facilities or a qualified electrician.

- **Maintenance and Certification**: Electrical cords and equipment should be inspected regularly for signs of wear, fatigue or other damage and should be taken out of service if compromised. All electrical equipment should be "rated" or certified by a recognized third-party safety testing service and should bear a mark or stamp from Underwriters Laboratories, FM Global, MET Laboratories or a similar organization.

7. Curtains

The use of curtains for light control, laser beam management, acoustical dampening or any other purpose in any occupational setting is strictly regulated by the FDNY. All curtains installed in research laboratories must be made of a material that is either inherently flame resistant, or that is chemically treated to achieve flame proofing. Curtains must be permanently tagged (i.e., sewn into the fabric) with a label to indicate compliance with the flame resistance or flame proofing standards of the National Fire Protection Association Code (NFPA Standard 701). In addition, the curtains must be certified by a holder of a Certificate of Fitness for Supervision of Flame Retardant Treatment (C-15) (a **C-15 Certificate of Fitness)** issued by the FDNY. Because a C-15 Certificate of Fitness involves highly specialized knowledge of application of flame retardants, the University does not sponsor applications for such Certificates and purchases of laboratory curtains should be transacted through vendors approved by EH&S. Please see EH&S Blackout Curtain guidance at or contact EH&S at labsafety@columbia.edu prior to purchasing curtains for your laboratory.

8. Hot Work and Specialized Research Scenarios

The use of torches for cutting, welding, brazing, grinding, soldering or similar application in a research laboratory requires specialized permitting, including advanced Certificate of Fitness qualifications. Torch use is generally referred to as "hot work" and must not be performed without prior approval from Facilities Operations and EH&S. Hot Work permits are issued by Facilities Operations in accordance with applicable policies, and generally require up to 48 hours advance notice, as well as a Fire Guard to be posted at the work site. For additional details, please visit:

- **Morningside**: Call the Facilities Fire Desk at (212) 854-2222 to be issued a hot work permit.
- **Manhattanville**: See the Fire Safety Director (**FSD**) in the main lobby of JLGSC to be issued a hot work permit. The FSD is present in the lobby 24 hours a day, seven days a week.
- **CUIMC**: Hot Work Permits are issued by the Facilities Management Fire Safety Office. Permits are valid for the day, the operation, and to the torch operator and fire guard team (with valid FDNY certificates of fitness) for which they are issued. Notify Facilities Operations at cumcfiresafety@columbia.edu at least 48 hours in advance of the intended hot work.

- **Lamont**: Contact the Safety Office at (845) 359-2900. Arrangements will be made on an as needed basis.
- **Nevis:** Contact Facilities at (914) 591-8883 to inquire about Hot Work permit requirements.

G. Laboratory Inspections

1. FDNY

The NYC Campuses are subject to weekly inspections by the FDNY. Over the course of each calendar year, the FDNY Laboratory Inspection Unit performs inspections of all laboratories that have been issued a FDNY Permit. The FDNY inspections carry the weight of law, and compliance with findings is mandatory. Failure to correct a finding may result in the issuance of a Summons, based on the severity of the noncompliance, and may ultimately require payment of monetary penalties or appearance at a New York City Environmental Control Board **(ECB)** hearing.

In the event that a noncompliant condition is observed by the FDNY during an inspection, the FDNY Inspector may issue a Violation Order (**VO**) to the University upon the first instance of the condition. If a VO is issued, EH&S will send a copy of the VO, together with a Corrective Action Notification Form (**CAN**), to the applicable PI within 24 hours via LION. A sample copy of a CAN is attached hereto as **Annex VIII-E**. Upon receipt, the PI or his/her designee should review the CAN, including the details of the violation and the corresponding corrective actions required. Upon completion of the necessary corrective actions, the laboratory must notify EH&S, via LION, that the condition has been corrected. Alternatively, the laboratory may utilize LION to indicate that additional assistance is needed. Under either circumstance, EH&S will visit the laboratory within two weeks of the issuance of the VO to verify correction of the violation. Once EH&S confirms that the violation has been corrected, it will complete the FDNY Certificate of Correction portion of the VO and return it to the FDNY.

If the same citation is identified during a follow-up inspection, the FDNY will issue a Summons which will necessitate an in-person visit to the ECB**.** An EH&S staff member will accompany a laboratory representative to the hearing.

The University will pay any fine resulting from the ECB decision unless there are recurrent violations in the same laboratory. In such case, EH&S may refer the issue to the EVPR for review. If the EVPR determines that the PI has been grossly negligent or in willful violation of FDNY rules, the University will take appropriate action, which may include holding the PI responsible for any fine relating to the VO. In all other cases, the University will pay the fine so long as the PI has demonstrated a good faith effort to prevent recurrence of the noncompliance and sustain compliance in his/her laboratory.

2. Local Municipalities

Local municipalities are responsible for the inspections of grounds and buildings at Lamont and Nevis, generally on an annual basis. At Nevis, this authority resides with the Village of Irvington Fire Department and the Code Enforcement Officer. Dangerous or hazardous conditions may be subject to enforcement during inspection. At Lamont, the Town of Orangetown Fire Prevention Bureau is empowered to enforce all laws and ordinances relating to fire prevention and conditions hazardous to life and property from fire or explosives. Likewise, inspections may result in orders to remedy dangerous conditions.

Additionally, at Lamont, the New York State Office of Fire Prevention and Control conducts annual, comprehensive inspections of the entire facility, including laboratories. These inspections are broad in scope, and include all general fire safety requirements of the NYS Uniform Fire Code,

H. Emergency Preparedness

All University research laboratories are provided with emergency equipment for use by personnel in the event of fire, bodily exposure to or contamination by chemical substances, or other applicable scenarios. Researchers should be thoroughly familiar with the location and operation of all emergency equipment present in the laboratory and should be prepared to use the equipment themselves, or to assist others in the event of an emergency.

The following are the most common types of emergency equipment found in laboratories:

Fire Extinguishers

There are three common classes of fire extinguishers categorized by the types of fires they are intended to fight:

- Class A – Ordinary combustibles such as wood, paper and fabrics
- Class B – Flammable liquids and gases, including solvents, paints and oils
- Class C – Live electrical equipment

Complications arise when fighting these fires because each type of fire must be fought with the extinguishing agent and procedure appropriate for it; the use of the wrong technique or extinguisher can be catastrophic. To simplify firefighting in the research environment, laboratories are equipped with multi-purpose (ABC) dry chemical or CO2 extinguishers that can be used on all types of fires other than those resulting from reactive flammable metals (which require specialized extinguishers). EH&S is available to provide consultation and risk assessment to determine extinguisher needs.

All campus extinguishers are inspected monthly and tested annually by a third-party vendor and are tagged to reflect their test dates. Extinguishers must be available within 50 feet of any point in the laboratory; large laboratories may therefore require additional units. Extinguishers must be readily available, must never be used as a door stop or coat hanger, and must be elevated from the floor, typically by a hook or integrated cabinet or casework fixture. For information on the

proper use of an ABC extinguisher, please see **Response to Fire Emergencies (Section I)** below. Activation of a fire extinguisher for any reason must be immediately reported to Public Safety so that a replacement can be arranged.

If a fire extinguisher requires inspection, recharging or replacement, at Morningside, call Facilities Operations at (212) 854-8749; at Manhattanville see the FSD in the main lobby of the JLGSC; at CUIMC, call Facilities Operations at (212) 305-4357; at Lamont, call Security at (845) 359-2900 and at Nevis, call Facilities at (914) 591-8883.

Personnel who have completed training via attendance at the general laboratory safety course or who have received other equivalent instruction are qualified to use an extinguisher in the event of a fire. No individual is obligated, however, to attempt to fight a fire with an extinguisher. The primary obligation of all individuals in the event of a fire is personal safety. See **Response to Fire Emergencies** (**Section I**) below, for additional information on what to do in the event of a fire.

Overhead Emergency Showers

FDNY, OSHA and other applicable standards require that all areas where corrosive materials are stored or used, or where solvents with the potential for injurious contamination to the eyes are used, be equipped with an overhead emergency shower. See also **Laboratory and Research Safety: Laboratory Emergencies and Chemical Spills (Chapter III, Section L(4))** for more information on overhead emergency showers.

Oxygen Sensors

In accordance with the NYC Fire Code, oxygen sensors are required in research laboratories where more than 60 gallons of cryogenic liquids are used or stored in order to alert occupants to the potential presence of an oxygen-deficient atmosphere. Laboratories that maintain permanently installed equipment that utilizes or is supported by large quantities of cryogens should install a permanently mounted, long-life sensor to monitor ambient atmospheric conditions. Locations where cryogens are present for routine dispensing (e.g., dewar container or cell freezers) are supplied with a wall mounted sensor by EH&S. These sensors must not be removed or tampered with, and if the alarm is activated, laboratory personnel should leave the area and notify Public Safety. EH&S inspects sensors on a bi-annual basis and removes from service any units that are out of calibration or that have reached end-of-life.

Upon closure of any University research laboratory, the applicable PI should contact EH&S to arrange for the removal of oxygen sensors.

Fire Drills and Alarm Testing

Personnel in University research laboratories are required to participate in any and all fire drills and related preparedness activities that may take place in their work area. Drills in laboratory research buildings on the NYC Campuses are conducted on each floor on a quarterly basis by the

respective Facilities Operations Fire Safety team; drills at Lamont are conducted twice annually by the Safety Office.

Generally, drills include a signal to assemble at a designated point outside of the laboratory, and a brief review of the building's fire alarm system, egress and escape route(s), fire extinguishing techniques, and related topics. Alarms are tested regularly for maintenance and during unplanned repair scenarios. Unless otherwise communicated, all alarms should be treated as real, and personnel should evacuate as instructed during drills.

Researchers at Nevis are instructed to follow instructions dictated by campus staff, and can contact Facilities Fire Safety with further questions, at (212) 854-8518.

I. Response to Fire Emergencies

Fire emergencies can happen unexpectedly and can be extremely dangerous to laboratory staff and emergency response personnel. All laboratory workers must be trained in the **RACE** and **PASS** procedures outlined in **RACE and PASS (Section 2)** below.

1. Classification of Fires

Before attempting to extinguish a fire that breaks out in a laboratory, the fire must first be judged as being controllable by laboratory personnel. This depends on the judgment of the person making the decision and the factors involved: the size and intensity of the fire, the nature of the burning material, the proximity of other flammable or explosive materials, the availability of escape routes and proper fire-fighting equipment, and the safety of personnel in the area.

Should the nature and size of the fire make it controllable, use the appropriate available extinguisher and proceed with the methods described below. Should the fire be judged "uncontrollable", follow the **Evacuation Procedures for Uncontrollable Fires (Section 4)** below.

There are four classes of fires:

- **CLASS A**: Ordinary combustibles, e.g. wood, paper, textiles, rubber. The ABC extinguisher can extinguish this type of fire.
- **CLASS B**: Flammable or combustible liquids, greases, petroleum products, solvents. Carbon dioxide or dry chemical ABC extinguishers should be used. Carbon dioxide extinguishers do not leave any residue, whereas dry chemical devices do. Pressurized water units should not be used since the immiscibility of solvents and water may result in spreading of the fire.
- **CLASS C**: Live electrical equipment involved in a fire. If possible, turn off the electrical power to the devices, and then use either the dry chemical extinguisher or a carbon dioxide or halon extinguisher, if available.

- **CLASS D**: Sodium, potassium, magnesium, titanium, zirconium and other reactive metals. If sodium, potassium, magnesium, or any other flammable metal powders are to be used in a laboratory, contact EH&S for guidance on the appropriate dry powder-extinguishing agent. A specific "Class D" (dry powder) extinguishing agent such as graphite, limestone, sand or sodium carbonate must be made available for fire emergency before work is started.

DO NOT USE pressurized water, carbon dioxide, dry chemical or halon extinguishers on metal or organometallic fires. The use of these extinguishers may introduce substances that are very reactive with the burning metal that may either make the fire grow or trigger an explosion. For more detailed recommendations on safely handling or fighting fires with pyrophoric materials, see the EH&S bulletin Safe Use of Pyrophoric Reagents.

2. RACE and PASS

IF YOU DISCOVER A FIRE – REMEMBER: **RACE AND PASS**

RACE:

R - RESCUE /REMOVE anyone in immediate danger
A - Activate the Manual Fire **ALARM** or pull station
C - CONFINE the fire (close the door)
E - EXTINGUISH small controllable fires/**or EVACUATE**

If using a fire extinguisher: PASS

P - PULL the pin
A - AIM the nozzle at the base or leading edge of the fire
S – SQUEEZE the handle
S – SWEEP from side to side

In all fire emergencies, call the following numbers as soon as the emergency is discovered

Morningside: Public Safety (212) 854-5555
Manhattanville: Public Safety (212) 854-3333
CUIMC: Public Safety (212) 305-7979
Lamont: 911, then notify Lamont Security by dialing 555 (from any campus phone) or call (845) 359-2900
Nevis: 911
Barnard: Public Safety (212) 854-6666
NYSPI: Safety Office (646) 774-5555

3. Extinguishing a Person Engulfed in Flames

The following procedures should be used if a person is engulfed in flames:

- If a person's clothing is on fire, he/she must not be allowed to run, as this will fan the flames and may cause a more serious burn. **Remember! STOP, DROP and ROLL**. Clothing fires must be extinguished immediately, before anything else is done, in order to minimize skin burns. Try not to use your hands as this may result in additional burns.
- Roll the person on the floor if necessary.
- Wrap him/her in a fire blanket, coat or whatever is available to smother the flames. Put the person under a shower or use an extinguisher.
- After calling the appropriate emergency number(s,) place clean, wet, ice-packed cloths on small burned areas. Wrap the person warmly to avoid shock, and secure medical assistance.
- Never attempt to remove any clothing that has been burned. Soak any burned fabric with tepid water while awaiting emergency crews.

4. Evacuation Procedures for Uncontrollable Fires

The following procedures should be used in the event of an uncontrollable fire:

Remember: RACE! RESCUE-ALARM-CONFINE-EXTINGUISH/EVACUATE:

- Leave the area of danger. DO NOT stay to fight a large fire.
- Rescue anyone in immediate danger. On your way out, if it can be done safely, turn off equipment and move any explosive or flammable materials away from possible contact with hot surfaces or other sources of ignition.
- Where available, using the laboratory's circuit breaker or Emergency Power Off switch (**EPO**) is often the quickest and most effective way to turn off all laboratory electrical equipment simultaneously. For this reason, the circuit breaker or EPO must always be readily accessible.
- Your safe exit, however, must be given the highest priority.
- Transmit the fire alarm by pulling the alarm box near any point of egress (stairwell doors and exits) and notify personnel on the floor.
- Leave by means of one of the predetermined evacuation routes for your laboratory area. If possible, confine the fire by closing doors as you leave. Evacuate promptly and meet outside the building away from the entrance at a pre-determined place. Conduct an attendance/person count of workers and make sure all are accounted for. If not, notify the FDNY immediately.

5. Fire-fighting Procedures for Controllable Fires

The following procedures should be followed in the event of a controllable fire:

- For all fires, the fire alarm must be transmitted immediately to ensure FDNY response.
- The decision of whether to fight the fire oneself or to wait for fire-fighting help must be made according to the type and size of the fire, its location and the circumstances of the

fire. A small fire in a container may be easily snuffed out by the placement of a nonflammable cover across the container opening. A small fire in an area free of other fuels can be extinguished with an appropriate available extinguisher after calling for help.

- To extinguish a minor fire with an extinguisher: **Remember: PASS! PULL the PIN-AIM the HOSE-SQUEEZE the HANDLE-SWEEP from SIDE to SIDE**
- When extinguishing a burning solid, direct the extinguisher discharge at the base of the flame; in the case of burning liquids, direct it at the leading edge. Larger or rapidly growing fires are best left to the Fire Department.
- No personnel are required to attempt to extinguish a fire. One should only attempt this action if he/she is comfortable and confident in his/her ability to use a fire extinguisher.
- Only one fire extinguisher may be used. If the extinguisher does not quench the flames, then all personnel are to leave the space immediately and report the attempt to the firefighters on scene.

6. Emergency Procedures for Fires Caused by Explosions

The following procedures should be followed in the event of a fire caused by an explosion:

- Immediately transmit the building alarm by activating the manual pull station.
- Alert and evacuate all personnel in the immediate area.
- Close all doors leading to the affected area and secure area until Public Safety or other personnel arrive to evaluate the situation. Do not attempt to re-enter the space.
- When you call the requisite University office indicated in **RACE and PASS (Section 2)** above, be prepared to give the chemical name, location (building and room), and any other pertinent information.
- Attend to any persons contaminated by chemicals by removing contaminated clothing, and when feasible, flush the affected body area with water. A University Accident Form should be completed.

In the event of an injury, the following is the location and contact information for emergency medical services:

- **Morningside and Barnard:**
  - During Business Hours for **Staff and Students**: SHS, John Jay Hall, 4th Floor, 519 W. 114th St., (212) 854-7426
  - After Hours (or for life-threatening emergencies): Mount Sinai Morningside Hospital Emergency Room, 1111 Amsterdam Avenue at 114th Street, (212) 636-3375
- **Manhattanville:** Harlem Hospital, 506 Lenox Avenue, (212) 939-1000
- **CUIMC:**
  - During Business Hours for **Staff:** Workforce Health & Safety (**WH&S**) – Harkness First Floor, (212) 305-7580
  - During Business Hours for **Students**: SHS – 100 Haven Avenue, (212) 305-3400
  - After Hours: NYP Emergency Department – Broadway & 167th Street
- **Lamont:** Nyack Hospital, 160 North Midland Ave., Nyack, (845) 348-2000

- **Nevis:** St John's Riverside Hospital Dobbs Ferry Pavilion, 128 Ashford Ave, Dobbs Ferry (914) 693-0700
- **NYSPI:** NYP Emergency Department – Broadway & 167th Street

Have a person knowledgeable of the incident and laboratory available to provide information to emergency personnel and health care providers, including the SDS for any chemical involved in the fire.

IX. OCCUPATIONAL HEALTH AND SAFETY

A. Introduction

The Occupational Health and Safety (**OH&S)** Program at Columbia is concerned with the health, safety and wellbeing of individuals in the workplace environment. OH&S Program personnel at the University are tasked with designing and implementing strategies for recognizing and assessing physical and chemical hazards in research spaces, utilizing risk assessment practices and advanced monitoring and analytical techniques. Working closely with other EH&S teams and with the research community, OH&S Program personnel assist researchers in the identification of hazards in their laboratories and support the implementation of effective controls that reduce the risk of exposure to potentially harmful chemical and physical hazards that arise during research operations.

The OH&S Program ensures compliance with federal, state and local regulations and adherence to non-governmental guidelines and best practices that guarantee the health and safety of the University's faculty, staff and students.

B. Regulatory Framework

Researchers should be familiar with the regulatory framework relating to safety and health in the workplace.

1. Federal

Occupational Safety and Health Administration (OSHA)

OSHA was created pursuant to the Occupational Health and Safety Act of 1970 (**OSH Act)** https://www.osha.gov/laws-regs/oshact/completeoshact**.** Its mission is to ensure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA is part of the U.S. Department of Labor. Although a number of states have OSHA-approved State Plans covering all employees, New York's State Plan covers only state and local government employees. Private sector employers, such as the University, and their employees (including faculty and staff) are covered by federal OSHA standards and regulations.

The following OSHA regulations have particular relevance to research operations:

Permissible Exposure Limits, Short Term Exposure Limits and Ceiling Values

OSHA has established occupational exposure limits for a number of chemicals and physical hazards. OSHA's occupational exposure limits are termed Permissible Exposure Limits (**PELs**)

and describe the maximum allowable exposure for a range of hazards. Exposures exceeding the established PELs are generally considered harmful and constitute a violation of the OSHA regulations. PELs are usually calculated as 8-hour Time Weighted Average (**TWA**) exposures to indicate the approximate exposure to harmful agents over a regular daily shift of workers in the United States. However, OSHA has also established Short Term Exposure Limits (**STELs)** for a number of agents. STELs are expressed as the maximum allowable average exposures over a 15-minute work period. Some agents have OSHA mandated Ceiling Values (**Ceiling Values),** which are the maximum allowable exposure limits that cannot be exceeded at any point and are usually relevant to particularly toxic chemicals.

It is not uncommon for materials with established OSHA PELs to be stored, used, or generated in laboratory spaces. Additional information on OSHA mandated exposure limits can be found on the OSHA website https://www.osha.gov/. Columbia affiliates can find information on OSHA exposure limits for specific chemicals by reviewing the relevant SDSs, by browsing the OSHA website, or by contacting EH&S. See additional information on SDSs at **Laboratory and Research Safety: Elements of the Columbia Research Safety Program -Hazard Communication (Chapter III(D)(3))**.

It is important to note that the majority of chemicals that are available in the U.S. market do not have an established OSHA PEL. There are many hazardous chemicals that can have adverse health effects in the event of exposure, for which the federal government has not established mandatory exposure limits. Furthermore, the majority of OSHA PELs were promulgated shortly after the OSH Act was signed into law. Since that time, available information regarding the toxicology and potential harmful effects of these chemicals may have been updated and the consensus of the scientific community relating to what constitutes a safe exposure level may have changed. Consequently, many of OSHA PELs are now largely considered outdated and, in some cases, inadequate for the protection of employee health and wellbeing. Furthermore, for many agents that can increase the risk of certain health outcomes upon prolonged or chronic exposure, no accepted safe exposure levels have been identified and any exposure can potentially contribute to an increased risk of disease or injury.

For all of the above reasons, the legally mandated OSHA exposure limits, although still enforceable, are not considered adequate for ensuring health and safety and EH&S may recommend or require that exposure to certain hazardous agents be maintained at levels lower than the OSHA standards, or even be minimized to approach zero exposure levels.

PPE

As described throughout this Handbook, PPE is used in many situations in research. OSHA requires that PPE for the eyes, face, extremities and body be made available to employees, maintained in good condition and used safely in accordance with relevant guidelines. For example, regulations relating to the use of respiratory protection are described in OSHA's Respiratory Protection Standard (29 CFR 1910.134).

Hazard-Specific Regulations

29 CFR Part 1910 includes a number of hazard-specific requirements intended to ensure safety and health in the workplace. Specific guidelines for categories of chemicals (e.g., toxic or reactive chemicals), or even specific compounds (e.g., formaldehyde and mixtures that contain it, nitrous oxide, etc.) describe OSHA's requirements when these hazards are present. A number of these hazards are described in other Chapters of this Handbook.

The National Institute for Occupational Safety and Health (NIOSH)

The OSH Act established NIOSH as a research agency focused on the study of worker safety and health, and empowering employers and workers to create safe and healthy workplaces. NIOSH is part of the CDC, tasked with conducting research and providing recommendations relating to occupational health and safety in the United States. It employs more than 1,300 individuals from a diverse set of fields, including epidemiology, medicine, nursing, industrial hygiene, safety, psychology, chemistry, statistics, economics and engineering, and in addition to research, performs health hazard evaluations.

Recommended Exposure Limits (RELs)

NIOSH establishes, reviews and updates occupational exposure limits **(OELs)** for a number of hazardous agents. NIOSH Recommended Exposure Limits (**RELs**) are not mandatory standards and in many cases are more stringent than OSHA's corresponding PELs.

Information on RELs for specific hazardous materials or workplace conditions can be obtained through the NIOSH Pocket Guide to Chemical Hazards which is available online at https://www.cdc.gov/niosh/npg/default.html, or by contacting EH&S. In most cases, EH&S will recommend or require that exposure be maintained at levels below the published REL.

2. State Guidelines

Some U.S. states have established comprehensive occupational health and safety regulations and enforcement mechanisms. EH&S may refer to state standards when these are deemed more protective or more applicable than federal guidelines, or when federal regulations have not yet been promulgated.

The Division of Occupational Safety and Health of the California Department of Industrial Relations (commonly referred to as **Cal/OSHA**) is considered among the most proactive state workplace safety agencies. Although Cal/OSHA guidelines are not legally enforceable in New York State, EH&S may recommend or require adherence to Cal/OSHA standards or guidelines for certain hazardous materials or conditions.

3. Non-Government Guidelines

In many cases legislators and regulatory agencies have not established mandatory guidelines for the safe use of certain hazardous materials. In the absence of government guidelines, or when government guidelines are considered inadequate for protecting health and safety, consensus or industry standards or guidelines from non-governmental organizations may be adopted or referred to by EH&S.

American Conference of Governmental Industrial Hygienists (ACGIH

The ACGIH is a non-governmental scientific organization that of occupational publishes standards similar to OELs called Threshold Limit Values (**TLVs** that often differ significantly from the mandatory OSHA limits and are generally considered more protective of employees. EH&S generally requires that exposure levels are maintained below TLVs where applicable, although these standards are not mandated by federal or state laws.

Student Health and Safety

Occupational health and safety regulations and guidelines are drafted for the purpose of protecting employees, and OSHA's standards do not apply to Columbia affiliates who are not employees. The EPA establishes legally binding limits for the general population, but these guidelines may not always be relevant to research environments or workplace settings as they generally aim at preventing environmental contamination of the air, water, soil and natural resources. As a result, EH&S may require that regulations and standards intended for the protection of employees be also adhered to in the case of students engaged in research activities.

C. Roles and Responsibilities

1. PIs

PIs are responsible for:

- Ensuring that laboratory personnel attend requisite trainings;
- Providing task-specific training for research activities that can create hazardous conditions in the laboratory;
- Providing appropriate PPE; and
- Notifying EH&S when there is an intent to use OSHA regulated chemicals.

2. EH&S

EH&S:

- Provides guidance to ensure compliance to OSHA regulations in laboratory spaces;
- Creates and provides specialized and general safety training relating to chemical and physical hazards;
- Is responsible for reviewing the contents of IACUC protocol Appendices E, E1 and E2;

- Conducts exposure assessments and generates formal reports with interpretation of the results and recommended actions for supervisors and their staff;
- Provides consultations and conducts hazard and risk assessments for researchers and other University affiliates;
- Is responsible for oversight of the respiratory protection program of the University;
- Remains updated on changes in OSHA regulations to ensure the compliance by the University; and
- Remains updated on emerging occupational safety hazards in order to update the University's policies.

D. Pregnancy Consultations

Some hazardous materials used for research purposes have the potential to cause harm to the unborn child. Pregnant women should not be exposed to chemicals that can exert toxic developmental effects in concentrations that can harm the developing fetus. OH&S Program personnel can provide consultations with respect to the risks relating to working with, or in proximity to, such materials.

After consulting with their health care providers, students, faculty and staff can request a pregnancy consultation with OH&S Program personnel by emailing occusafety@columbia.edu.

E. Use of Hazardous Materials in Animal Research

Investigators using certain categories of hazardous chemicals in animal research must follow the requirements set by the IACUC. Animal research protocols submitted for IACUC review must include hazardous material appendices to allow for EH&S to review manipulations and controls relating to the use of hazardous chemicals and to ensure safe practices.

OH&S program personnel are responsible for reviewing the contents of the IACUC protocol **Appendices E, E1** and **E2**. Samples of these Appendices are attached hereto as **Annex IX(A), IX(B)** and **IX(C).**

The following are examples of materials that must be listed in the Hazardous Materials Appendix E :

- Chemicals that are known or suspected to increase the risk of cancer in humans;
- Reproductive and developmental toxicants;
- Acutely toxic chemicals;
- Chemicals that are toxic by inhalation;
- Biological toxins and venoms;
- Chemicals regulated by federal, state or local agencies; and
- Other chemicals of concern, or emerging environmental health hazards, as requested by EH&S.

If isoflurane is used, it must be listed in an Appendix E1, with the controls applied to ensure that exposure to fugitive waste gas is reduced to safe levels described. For more information regarding the safe use of anesthetic gases in research, see **Safe Use of Anesthetic Gases and Isoflurane (Section H)** below.

If formaldehyde or its solutions are used, they must be listed in an Appendix E2 describing manipulations and controls relating to the specific chemical product used. For more information regarding the safe use of formaldehyde and its solutions in research, see **Safe Use of Formaldehyde (Section G)** below.

F. Exposure Assessments

OH&S Program personnel maintain specialized monitoring equipment and can conduct chemical and physical hazard exposure assessments and provide recommendations for controlling hazards. EH&S conducts exposure assessments for specific categories of employees on a regular basis or when otherwise identified that an assessment is needed. Investigators can contact EH&S to request a risk assessment and discuss appropriate controls. An assessment can be requested by completing and submitting a Laboratory Hazard Assessment Questionnaire.

EH&S offers the following exposure assessments:

1. Formaldehyde

OH&S program personnel conduct regular exposure assessments to determine exposure levels to formaldehyde vapors following 29 CFR 1910.1048 and the University's Formaldehyde Exposure Control Plan. In some cases, EH&S will conduct air monitoring to confirm that a procedure is done safely, and/or provide recommendations and guidance on engineering and administrative controls that can be implemented in lieu of a CFH.

See **Safe Use of Formaldehyde (Section G)** below for further information.

2. Xylene

Xylenes are used widely in tissue processing and staining. OH&S personnel conduct regular exposure assessments in pathology and dermatophathology laboratories, where staff work regularly with large volumes of xylene. A combination of proper engineering controls (e.g., use of CFHs, ventilation etc.), administrative controls (e.g., implementation of best management practices) and PPE (aprons, gloves, eye/face protection etc.) are implemented in order to protect the health and safety of the employees.

3. Isoflurane

For more information relating to exposure assessments for isoflurane, please refer to **Safe Use of Anesthetic Gases and Isoflurane (Section H)** below. To request an assessment, investigators may contact OH&S program personnel team at occusafety@columbia.edu.

4. Ammonia

Because ammonia is released by animal excrement, exposure to ammonia is measured by EH&S on a regular basis in the University's animal facilities**.** Historical data from EH&S's measurements suggest that ventilation in the animal facilities adequately reduces air concentrations of ammonia to levels below concentrations of concern.

5. Noise

OH&S personnel conduct regular noise exposure assessments in some areas where high noise activities take place. Examples include the cage washing areas in ICM facilities. For more information regarding noise in laboratory spaces, see **Noise (Section J)** below.

6. Heavy Metal Dust

In some laboratories that regularly conduct research that includes toxic metals, there is a potential for surface contamination of the surrounding areas. OH&S Program personnel conduct surface sampling to assess the effectiveness of proper housekeeping and decontamination methods, the degree of contamination, and the risk of exposure to toxic heavy metals.

7. Particulate Matter

Microscopic particles, if small enough to escape the natural defenses of the human body's upper respiratory system, can enter the lower respiratory system and cause adverse health effects by depositing matter deep into the lungs. OH&S Program personnel conduct dust monitoring to determine the concentration and size distribution of airborne particles. The respirable fraction of airborne particulates can be hazardous to health and must be maintained below levels described in OSHA regulations.

Regular (annual) dust monitoring is conducted in the animal facilities to ensure that employees are not exposed to hazardous levels of respirable dust.

G. Safe Use of Formaldehyde

Formaldehyde and related products (e.g., paraformaldehyde, formalin solutions, etc.) are used regularly in research for the preservation of cells, tissues, organs, animal carcasses and human cadavers. Exposure to materials that contain formaldehyde can cause acute health effects that can range from mild irritation of the mucosal membranes to serious corrosion or burns of the skin and airways and permanent tissue or organ damage. Formaldehyde is a known human carcinogen

that can increase the risk of cancer. The OSHA Formaldehyde Standard (29 CFR 1910.1048) (the **OSHA Formaldehyde Standard)** has established standards for the control of occupational exposures to formaldehyde through the use of action levels, permissible exposure limits, and short-term exposure limits.

Columbia University's Formaldehyde Exposure Control Plan, created and implemented by EH&S, ensures compliance with the OSHA Formaldehyde Standard and describes appropriate work practices for the safe use of formaldehyde solutions. The Chemical Abstracts Service Registry No. is 50-00-0. This number can be used to find a SDS for formaldehyde.

In general, the implementation of proper engineering controls is sufficient to reduce inhalation exposure to formaldehyde to negligible levels. The use of certified CFHs is in most cases sufficient in controlling vapors and protecting the user. Investigators may use other engineering controls to reduce exposure to formaldehyde vapors; examples include certified downdraft tables or local exhaust ventilation systems. See **Laboratory and Research Safety: Protections-Engineering Controls (Chapter III, Section G(1))**. To ensure that the engineering controls are effective in removing harmful airborne contaminants, EH&S can conduct air monitoring and exposure assessments to determine the efficacy of the ventilation systems and provide recommendations to improve user protection. Additional protections are provided through the use of PPE.

Certain categories of employees who work with large amounts of formalin solutions may need to be included in EH&S's regular assessment program, participate in annual medical surveillance provided by WH&S and receive annual specialized training by EH&S.

Very small amounts of formaldehyde (e.g., formalin solutions in volumes lower than 0.1ml) can be used on open bench tops, since the risk of unsafe exposure is minimal. For amounts larger than 0.1ml, and if appropriate engineering controls are not available, investigators should contact EH&S to discuss alternative solutions.

H. Safe Use of Anesthetic Gases and Isoflurane

Inhaled anesthetic agents are used in research to initiate or maintain anesthesia in animals. Halogenated anesthetic gases are among the most common inhaled anesthetic agents used in research settings. These gases have the potential to harm investigators if exposure exceeds safe levels. Chronic occupational exposure to halogenated anesthetic gases has been associated with adverse reproductive effects, neurological damage and diseases of the liver or kidney.

When using isoflurane, investigators can implement several measures to effectively reduce the amount of fugitive gas and minimize the risk of exposure.

Below are some examples of different measures that can be implemented to conduct research with isoflurane safely:

- Before using isoflurane, receive task specific training from an experienced laboratory supervisor;
- Ensure that the isoflurane vaporizing equipment is annually certified by the manufacturer or a qualified technician for proper operation;
- Select and utilize an appropriate scavenging system that includes activated carbon filters and a pump that collects waste anesthetic gas;
- Use a certified CFH;
- If using filtration systems, maintain and exchange them according to the manufacturer's and EH&S's recommendations; and
- Consult with EH&S to discuss the option of air monitoring to assess the exposure during an animal surgery.

EH&S can assess the safety of isoflurane setups and recommend amendments or alterations. In some cases, EH&S may conduct air monitoring to determine the actual concentration of waste anesthetic gas during a surgical procedure. Based on the assessment results, EH&S may recommend the implementation of additional measures to reduce exposure or suggest administrative changes to the procedure.

I. Safe Use of Cyanide Compounds

Most cyanide compounds present acutely toxic properties and can be harmful via different routes of exposure. Working safely with toxic cyanide containing solids, such as potassium cyanide, requires establishing detailed SOP, utilizing necessary engineering controls (e.g. , CFHs), receiving hands-on training by experienced researchers, and implementing additional administrative controls (e.g., implementing a "buddy system", reviewing SDSs and emergency procedures). Working with gaseous cyanide compounds such as hydrogen cyanide is only permitted after review by and written approval of EH&S.

J. Noise

Exposure to high levels of noise can be harmful and may result to temporary or permanent health effects, including hearing loss, changes in hearing, inability to concentrate, psychological effects etc.

Some equipment used in research environments can generate noise that in some cases can become a nuisance for investigators working in that space. Refrigerators and freezers, CFHs, mechanical pumps, sonicators, and other commonly used devices generate noise when in operation. In most cases, noise levels do not reach harmful levels, but prolonged exposure to medium levels of noise can potentially create an uncomfortable or even unhealthy environment.

OSHA has established maximum allowable levels for noise exposure in the workplace. These rules are described in 29 CFR 1910.95. OSHA requires that if the TWA of employee noise

exposure (calculated over eight hours) equals or exceeds 85 A-weighted decibels (**dBA)**, the employer must take action to implement a hearing conservation program. In addition, if noise exposure reaches or exceeds the 85 dBA limit during the workday, OSHA requires that a monitoring program is established to quantify the level of exposure.

K. Respiratory Protection

Respirators are a special category of PPE designed to filter out airborne contaminants, purify the air, or provide fresh air. There are different types of respirators that are only effective against the types of hazards for which they are designed. In cases where respiratory protection is needed, adequate protection is only possible if the below requirements are met:

- The right type of respirator is selected;
- The respirator is in good condition and properly maintained;
- The respirator works properly;
- The user is medically cleared to use the specific type of respiratory protection; and
- Other parameters are met (e.g., the contaminant concentration does not exceed levels that the respirator can mitigate, etc.)

The use of respiratory protection is generally not necessary in University laboratories. The implementation of proper engineering and administrative controls is usually sufficient to reduce the risk of exposure to airborne contaminants.

In the case when respiratory protection is needed, users must comply with OSHA's Respiratory Protection Standard (29 CFR 1910.134) (the **OSHA RP Standard**) This Standard outlines the requirements for medical clearance, annual fit testing, training, recordkeeping, maintenance and proper use. Users must also abide by the Columbia University Respiratory Protection Policy (the **RP Policy)** that has comprehensive information about Columbia-specific requirements with respect to training, fit-testing, using and caring for a respirator and record keeping

Whenever a respirator is deemed necessary, it is essential that EH&S lead the process for selecting the proper respirator for the user since not all respirators will protect against all potential airborne hazards. As such, the purchase and/or use of any NIOSH-approved respirator, including N-95 respirators, must not occur until a work practice and exposure assessment is performed.

When respiratory protection is deemed necessary, a user must:

- Obtain medical clearance from WH&S, SHS (if applicable) or a personal healthcare provider, as necessary;
- Receive annual fit-testing from EH&S, SHS or NYP, as applicable;
- Receive training on the proper use, handling, storage, inspection and maintenance of the respirator;

- On a monthly basis, inspect the respirator and keep records of inspection;
- Wear the respirator only for its intended use;
- Notify his/her supervisor and EH&S when the scope of work that required respiratory protection changes;
- Communicate to a health care provider if a significant health event occurs; and
- Take all other actions necessary to comply with the RP Policy.

Improper use of respirators can be harmful to the user and can result in significant adverse health effects or injury.

When a risk assessment concludes that respiratory protection is not necessary, investigators who wish to conduct work with respiratory protection must follow the requirements outlined in the OSHA RP Standard. OSHA requires adherence to guidelines relating to the voluntary use of respiratory protection. Interested University affiliates can contact EH&S to discuss these requirements.

L. 3D Printer and Laser Cutter Safety

3D printer use in research settings has greatly expanded in recent years. 3D printers may generate microscopic particles (termed ultrafine) that when inhaled can enter the deep lung and penetrate into the systemic circulation, and volatile organic compounds that may also adversely affect health. Due to the emerging nature of these hazards, no agencies have established legally binding exposure limits, and the use of 3D printers is still minimally regulated.

EH&S provides recommendations on the safe use of 3D printing equipment. Some of the parameters that affect the safety of 3D printers, and that must be considered before purchasing 3D printing equipment, are the following:

- Adequate mechanical ventilation in the space where the equipment is to be used;
- Type of printer and material used (e.g., use of metal powders can create a significant risk of explosion and toxic exposure if used without adequate controls in place);
- Type of enclosure to separate the printer from the user and reduce the dispersion of particles; and
- Other hazards, such as noise, heat and electrical hazards.

Laser cutting equipment can also generate particulate matter and VOCs during operation. The main hazards associated with the use of laser cutters relates to fire safety considerations, and generation of toxic or otherwise hazardous combustion materials. EH&S provides guidance on how to determine which materials can be used with specific laser cutters.

The University may impose certain restrictions on the acquisition of 3D printers and laser cutters, and an assessment by EH&S may be required in order for purchasing approval to be granted.

X. CONTROLLED SUBSTANCES

A. Introduction

Controlled Substances are drugs or other substances, or immediate precursors thereof, listed in any of Schedules I - V of the federal Controlled Substances Act (21 U.S.C. §§ 801-971) or the New York State Controlled Substances Act (Article 33 of the NYS Public Health Law) (**Controlled Substances**).

Controlled Substances are divided into five categories, called Schedules, according to their potential for abuse, whether the Substance has a currently accepted medical use in the United States, and its potential for physical and psychological dependence. Classification of a Controlled Substance in a particular Schedule affects the licensing, recordkeeping and security and storage requirements, with those in Schedules I and II being subject to the most stringent regulations.

Any individual who uses or synthesizes Controlled Substances for research under the auspices of the University must be (1) licensed with the NYS DOH Bureau of Narcotic Enforcement and registered with the U.S. Department of Justice Drug Enforcement Administration **(DEA**) (a **Licensed Individual**) or (2) authorized under the license of a Licensed Individual with respect to such research (an **Other Authorized Individual).**

Common research applications for Controlled Substances in University laboratories include anesthetic and analgesic agents in animal-based research, as well as both human and animal subjects research on psychoactive, behavioral or therapeutic effects of Controlled Substances. The University does not hold an institutional license for the distribution of Controlled Substances. Therefore, all Columbia researchers planning to use Controlled Substances in research must obtain an individual NYS DOH license and a DEA registration.

The University has a Policy for the Acquisition, Use and Disposal of Controlled Substances in Research, which describes in detail the regulations with respect to the licensing and registration, acquisition, storage and recordkeeping requirements for Controlled Substances.

B. Regulatory Framework

Researchers planning to work with Controlled Substances should be familiar with the following regulations governing their acquisition, storage, use and disposition.

1. Federal

The principal federal law governing the use of Controlled Substances is the Controlled Substances Act (21 U.S.C. §§ 801-971) (the **US CSA).** The DEA is the primary federal agency

responsible for the enforcement of the US CSA. The DEA's statutory responsibility is twofold: to prevent diversion and abuse of Controlled Substances while ensuring that an adequate and uninterrupted supply is available to meet legitimate medical, scientific and research needs. In carrying out this mission, the DEA works in close cooperation with state and local authorities such as the NYS DOH, and other federal agencies.

Under the framework of the US CSA, the DEA is responsible for ensuring that all Controlled Substance transactions take place within the "closed system" of distribution established by Congress. Under this "closed system", all legitimate handlers of Controlled Substances—manufacturers, distributors, physicians, pharmacies and researchers—must be registered with the DEA and maintain strict accounting for all distributions.

The drugs and other substances that are considered to be Controlled Substances under the US CSA are divided into five Schedules. A complete list of the Schedules is published annually on an updated basis in the DEA regulations, 21 CFR 1208.11-1308.15. Substances are placed in their respective Schedules based on whether they have a currently accepted medical use in treatment in the United States and their potential for abuse and likelihood of causing dependence when abused, with Schedule I including drugs that have no accepted medical use and have a high abuse potential (e.g., heroin, marijuana and LSD) and Schedules II-V including drugs that have medical uses, but vary in the potential for abuse, with Schedule II drugs having the highest abuse potential with severe psychic or physical dependence possible (e.g., morphine, codeine and dexedrine) and Schedule V drugs having the lowest abuse potential (e.g., limited quantities of certain narcotic and stimulant drugs for antitussive, antidiarrheal or analgesic purposes).

2. New York State

The New York State Controlled Substances Act (Article 33 of the NYS Public Health Law) (the **NYS CSA)** states that its purpose is to combat illegal use of and trade in Controlled Substances, while allowing the legitimate use of Controlled Substances in health care, veterinary care, research and other uses authorized by the law. It defines the requirements for the acquisition, use, recordkeeping and destruction and disposal of Controlled Substances used in research in New York State. Researchers planning to use Controlled Substances in Columbia research laboratories must adhere to all New York State requirements.

C. Roles and Responsibilities

The following briefly describes the roles and responsibilities of researchers and other University stakeholders with respect to Controlled Substances.

1. Licensed Individual

The Licensed Individual holds primary responsibility for compliance relating to research use of Controlled Substances. Typically, the Licensed Individual is the PI on the research project. The

Licensed Individual is responsible for obtaining and renewing both the NYS DOH license and the DEA registration and for ensuring that all acquisition, storage, security, inventory, disposal and record-keeping requirements are met. See **Licensing and Registration (Section D)** below.

2. Other Authorized Individuals

The Licensed Individual may authorize members of his/her staff to work with Controlled Substances under the Licensed Individual's NYS DOH license and DEA registration as Other Authorized Individuals. However, the Licensed Individual retains overall responsibility for meeting all regulatory requirements. Other Authorized Individuals must be listed on the Licensed Individual's Controlled Substance Protocol submitted with the NYS DOH license application. See **Licensing and Registration (Section D)** below.

Licensed Individuals may not name as Other Authorized Individuals any person who (a) has been convicted of a felony offense relating to Controlled Substances, or (b) at any time, has had an application for registration with the DEA denied, a DEA registration revoked or has surrendered a DEA registration for cause.

3. EH&S

EH&S provides guidance and support to the research community on topics relating to the use of Controlled Substances. Upon acquisition of the requisite license(s) and submission of a new Appendix I (see **Rascal Appendix I (Section D(3))** below), EH&S will arrange an outreach visit with the laboratory and will deliver a binder containing information on all aspects and requirements of Controlled Substances research, including:

- Training
- Controlled Substance Scheduling
- Licensing and Registration
- Procurement
- Recordkeeping
- Storage and Security
- Disposal
- Loss, Theft and Unauthorized Use

Binders become the property of the Licensed Individual and can serve as an organizational tool for the laboratory for the management of Controlled Substances paperwork.

D. Licensing and Registration

Authorization to acquire Controlled Substances for research is a two-step process: (a) licensing with the NYS DOH; and (b) registration with the DEA. All researchers must obtain the NYS DOH license regardless of whether they possess a clinical prescriber's license. DEA registration

is necessary for all researchers who: (a) do not otherwise possess a clinical prescriber's license, and (b) all researchers engaged in the use of Schedule I Controlled Substances, regardless of other medical licensing.

1. NYS DOH Licensing and Registration

Section 3300 of the New York State Public Health Law **(NYS PHL)** requires any person conducting research with Controlled Substances in New York State to obtain a license from the NYS DOH. Under the NYS PHL, licenses are issued based on the activity in which the applicant intends to engage (e.g., manufacturer, distributor, researcher). The NYS DOH issues two classes of research licenses: Class 4 (Researcher (Schedules II-V)) and Class 7 (Research and Instructional Activities (Schedule I).

In order to apply for a NYS DOH license, a researcher must complete a **License Application to Engage in Controlled Substance Activity (DOH-4330**). The form of Application, together with the Instructions for Form DOH-4330, are attached hereto as **Annex X-A**. The Application and Instructions can also be found on the EH&S website at https://research.columbia.edu/policy-acquisition-use-and-disposal-controlled-substances-research

The NYS DOH License Application must include the following information:

- The C.V. of the individual responsible for overseeing the Controlled Substance activity (typically, the PI)
- A Controlled Substance Protocol, which includes the nature and objective of the project, a listing of the Controlled Substances to be used, the quantity of the Controlled Substances, the DEA registration number of both the researcher who will be ordering the Controlled Substances and the distributer or manufacturer providing the Controlled Substances, and the names and C.V.s of the Other Authorized Individuals working with Controlled Substances on the project. A template of a **Controlled Substance Protocol** is attached hereto as **Annex X-B.** A Columbia University IACUC protocol should not be used as a substitute for a Controlled Substance Protocol.

Note: Because a new applicant must obtain a NYS DOH license before he/she registers with the DEA, he/she should indicate on the Application that he/she is a new applicant and does not yet have a DEA registration number.

- If animals will be used in the project, the species, number of animals, dose regimen and route of administration of the Controlled Substance must also be included in the Controlled Substance Protocol.
- If the research involves the dispensing, administration or prescribing of Controlled Substances to human subjects, the corresponding IRB approval must be submitted.

NYS DOH licenses must be renewed every two years. It is the responsibility of the Licensed Individual to ensure that the license does not lapse. The renewal of a license will still require the submission of a Form DOH-4330.

2. DEA Registration

Every person who handles Controlled Substances must be registered with the DEA or be exempt by regulation from registration. The DEA registration grants individuals federal authority to handle Controlled Substances, but they may only engage in activities that are authorized under state law.

If you are already registered with the DEA as a medical practitioner, you are not required to register for research involving any drug in Schedules II-IV. All researchers must register with DEA for work involving Schedule I substances.

To obtain a DEA registration, a researcher must apply using a DEA Form 225—Application for New Registration. A sample DEA Form 225 is attached hereto as **Annex X-C** and can be obtained on line. The Form may be filed electronically at https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm. Registration procedures, including detailed instructions for submitting Form 225, are available at https://www.deadiversion.usdoj.gov/drugreg/process.htm and https:///www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm

The DEA registration must include the licensee's state license number and identification of the Controlled Substances used. For work with Schedule I Controlled Substances, applicants must attach three copies of a more detailed Schedule I Controlled Substance Protocol. A template of the **Schedule I Controlled Substances Protocol** is attached hereto as **Annex X-D**. Note that the Protocol requires the Licensed Individual to provide a "statement of security provisions" in accordance with DEA regulation 21 CFR 1301.75, which should be reviewed prior to signing the Form 225. Depending on the nature of your research, your statement may read as follows: "All controlled substances will be stored in a securely locked cabinet of substantial construction. Access to controlled substances will be limited to authorized personnel." See **Working with Controlled Substances—Safety and Security (Section G(1))** below for additional information on safety and security.

DEA registration must be renewed annually. It is the responsibility of the Licensed Individual to ensure that his/her registration does not lapse.

3. Rascal Appendix I

PIs working with Controlled Substances in research must complete Appendix I in Rascal to describe the use and management of such materials. When working with animals, the Appendix will be attached to the applicable IACUC protocol. A copy of **Appendix I** is attached hereto as **Annex X-E**.

4. Amendments to Licenses and Registrations

If a Licensed Individual wishes to use additional Controlled Substances that are not listed on the Controlled Substance Protocol submitted with his/her most recent NYS DOH license application or renewal, he/she must submit a license amendment to the NYS DOH that includes the additional Controlled Substance. Likewise, if a Licensed Individual begins a new research project involving Controlled Substances that is not within the scope of the Protocol described on their application, a Protocol for the new project must be submitted as an amendment. Amendments are submitted using the NYS DOH's Form 4330.

Subsequent to notification to the NYS DOH, the Licensed Individual must also submit an amendment to his/her DEA registration by visiting the following link on the DEA website https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp.

E. Training

All personnel involved in any aspect of Controlled Substances research at the University must complete the online course in Rascal entitled *TC0502: Controlled Substances Use and Management in Research* prior to procuring or using any Controlled Substance. The training must be renewed every three years.

F. Procurement of Controlled Substances

All purchase requisitions for Controlled Substances must be processed only through the University's Procurement Department. Purchase orders must be accompanied by the purchaser's NYS DOH license, DEA registration and a copy of his/her Rascal training certificate evidencing completion of *TC0502: Controlled Substances Use and Management in Research.*

All purchase requisitions for Controlled Substances that are submitted to the Procurement Department must:

- Use the correct commodity code (currently 51142200);
- Include the documents indicated above; and
- Ensure that the ship-to location matches the address on the purchaser's DEA registration (the **DEA Registration Location)**.

Investigators may not use an E-Z PO, P Card or Travel and Business Expense Reimbursement Form to purchase Controlled Substances.

Controlled Substances may not be obtained by a Principal Investigator or Licensed Individual for use by another party, other than those listed on the Licensed Individual's protocol.

G. Working with Controlled Substances

1. Storage and Security

Controlled Substances must be properly safeguarded and securely kept at the applicable DEA Location. Access to any storage area must be limited to the Licensed Individual and/or Other Authorized Individuals.

Unlike other chemicals, Controlled Substances must be stored in locked cabinets. Security requirements differ depending on (a) whether the storage is for "working stocks" or "reserve or main stocks", and (b) the Schedule of the Controlled Substance. Controlled Substances used for research purposes are generally considered "working stocks." See **Storage and Security Resources** attached hereto as **Annex X-F** for a useful Decision Tree and specifications.

If larger quantities are required, please contact controlled@columbia.edu for additional guidance.

2. Reporting Loss, Theft or Unauthorized Use

Each incident or suspected incident of possible theft, loss or diversion of a Controlled Substance must be immediately reported to the Licensed Individual and Public Safety. Thereafter the Licensed Individual must promptly report the incident to the NYS DOH on Form DOH-2094. Finally, the Licensed Individual must report to the DEA on Form DEA 106 the theft or "significant" loss of any Controlled Substance within one business day following discovery of the incident. According to the DEA, there is no single standard as to what constitutes "significant" loss. Licensed Individuals should determine, based on their activities and work environment, whether the loss of a Controlled Substance is considered significant. It is advised that Licensed Individuals err on the side of reporting a loss if in doubt.

The NYS DOH Form 2094 and instructions can be found at http://www.health.ny.gov/forms/doh-2094.pdf and DEA Form 106 and instructions can be found at https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.

3. Recordkeeping

The Controlled Substances regulations require significant record keeping at every point in the substance's life cycle, including initial receipt, use and disposal. See N.Y. Pub. Health L. §§ 3300-3397 and 10 N.Y.C.R.R. §§ 80.37 and 80.112 and 21 CFR 1304.03 and 04. The Licensed Individual is responsible for maintaining all documentation with respect to Controlled Substances used in his/her research. The records must be easily produced in the event of an inspection by the NYS DOH or the DEA.

The following sections include more specific information on the recordkeeping requirements.

Initial Receipt Documentation

The Licensed Individual must keep a record of the receipt of all Controlled Substances. The record must include the following information in addition to the name of the Licensed Individual and the location of where the Controlled Substance is maintained:

- Date of receipt;
- Name, address and the registration number of the vendor;
- Invoice number;
- Name and quantity of the drug received;
- Number of units per container and the total number of containers; and
- Assigned internal container ID number.

A duplicate invoice or separate itemized list furnished by the vendor will suffice if it includes all such information and the quantities are verified. Quantities should be verified and documented as soon as possible after receipt of the Controlled Substance.

Templates of a Controlled **Substances Receipt Log Schedule I-II** and a **Controlled Substances Receipt Log Schedule III-IV** are attached hereto as **Annexes X-G and X-H,** respectively.

Use Documentation

The Licensed Individual must keep a record of each use of a Controlled Substance by the Licensed Individual or any Other Authorized Individual. The record must include the following information in addition to the name of the Licensed Individual for each Controlled Substance used:

- Name of Controlled Substance;
- Assigned internal container ID number;
- Starting amount (by unit of measure);
- Location where Controlled Substance is used or stored;
- Concentration in finished form (e.g., ug/ml, mg/ml, mg/tablet);
- Date of use;
- Previous balance (i.e., amount on hand since last use of the Substance)
- Quantity used;
- Name of user; and
- Description of use of Controlled Substance.

The Licensed Individual must develop his/her own internal container ID inventory numbering system and assign numbers to each container (e.g., J. Smith-001).

A template of a **Controlled Substance Use Log is** attached hereto as **Annex X-I.**

Inventory Documentation

Each Licensed Individual must keep an inventory of the stock of all Controlled Substances under his/her registration, from the day after his/her DEA registration is received, when research with/possession of Controlled Substances begins and then biennially thereafter.

The biennial inventory form must include the following, in addition to the Licensed Individual's name, DEA registration number, NY DOH license number, date and time of inventory, **for each Controlled Substance held by the Required Individual:**

- Form of Controlled Substance (e.g., tablet, capsule, solution);
- Concentration per unit (e.g., 100mg/capsule);
- Number of units per container (e.g., 100 capsules/bottle);
- Total number of containers;
- Total content of all packages (e.g., 3 containers @ 100 capsules/container = 300 total capsules); and
- Additional identifying information (NDC number, lot number, expiration date, internal reference number).

A template of a **Controlled Substances Biennial Inventory Form** is attached hereto as **Annex X-J.**

Intercampus Transfers

If a Licensed Individual relocates to another campus, any Controlled Substances should be transferred in a University Public Safety vehicle. Prior to the transfer, the Licensed Individual must complete a Chain of Custody form and submit it to Public Safety.

A template of a **Chain of Custody (COC) Document** is attached hereto as **Annex X-K**.

4. Disposal of Controlled Substances

Unlike standard laboratory chemicals and reagents, EH&S may not accept Controlled Substances for disposal through its hazardous waste management program. Licensed Individuals should make every effort to minimize the amount of Controlled Substances needing disposal through active inventory management. Controlled Substances should be ordered only in quantities needed in the immediate term (e.g., three months of research), and fully used for their intended purpose, whenever possible. Disposal and/or surrender of Controlled Substances must be carried out in accordance with applicable laws and regulations including, among others, 10 NYCRR §§ 80-51-52 and 21 CFR §§ 1307.21.

If a Controlled Substance has expired or otherwise requires disposal, the preferred method of disposal is **Reverse Distribution**. Reverse distribution involves packaging and shipping Controlled Substances to a secure facility where they are destroyed by licensed personnel. The NYS DOH maintains a list of approved reverse distribution facilities. The Licensed Individual

should contact a NYS DOH approved distributer and arrange for the return of the Controlled Substance.

Any person disposing of a Controlled Substance must maintain a written record that includes the following:

- Date of return or destruction;
- Name, form, quantity of the Controlled Substance returned or destroyed;
- Name, address and registry number of the person making the return; and
- Name, address and registry number of the supplier, manufacturer or reverse distributor to whom the Controlled Substances are returned.

In very limited circumstances, it may be possible to arrange an alternative means for the disposal and destruction of Controlled Substances, including on-site destruction. Please contact controlled@columbia.edu for more information.

ANNEX I-A

GLOSSARY OF ACRONYMS AND ABBREVIATIONS

BSC: Biological Safety Cabinet

BSL: Biosafety Level

CAS#: Chemical Abstract Service number

CDC: Centers for Disease Control and Prevention

CFH: Chemical Fume Hood

CFR: Code of Federal Regulations

CUIMC: Columbia University Irving Medical Center

DURC: Dual Use Research of Concern

EH&S: Environmental Health and Safety

EPA: U.S. Environmental Protection Agency

EVPR: Executive Vice President for Research

FDNY: Fire Department of the City of New York

GHS: Globally Harmonized System for Classification and Labeling of Chemicals

IACUC Institutional Animal Care and Use Committee

IATA: International Air Transport Association

ICRC: Irving Cancer Research Center

IHSC: Institutional Health and Safety Committee

JLGSC: Jerome L. Greene Science Center

LATCH: Laboratory Assessment Tool and Chemical Hygiene Plan

LION: Laboratory Information Online Network

NYC DEP: New York City Department of Environmental Protection

NYPH: NewYork-Presbyterian Hospital

NYS DEC: New York State Department of Environmental Conservation

NYSPI: New York State Psychiatric Institute

OSHA: U.S. Occupational Safety and Health Administration

PH: Presbyterian Hospital

PI: Principal Investigator

PPE: Personal Protective Equipment

RCRA: Resource Conservation and Recovery Act

rDNA: Recombinant Deoxyribonucleic Acid

RFID: Radio-SFrequency Identification

RMW: Regulated Medical Waste

SAA Satellite Accumulation Area

SDS: Safety Data Sheet

SHS: Student Health Services

SOP: Standard Operating Procedure

USDA: U.S. Department of Agriculture

US DOT: U.S. Department of Transportation

WH&S: Workforce Health and Safety

VP&S: Vagelos College of Physicians and Surgeons

ANNEX III-A

LABORATORY HAZARD ASSESSMENT QUESTIONNAIRE

COLUMBIA UNIVERSITY
Environmental Health and Safety

Laboratory Hazard Assessment Questionnaire

EH&S is available to assist with the recognition, evaluation and control of laboratory hazards. This form is to be used to help evaluate possible hazards reported by members of the Columbia University research community. Please use the fields below to specify your laboratory information and additional descriptive information regarding the experiment or potential hazard, including, frequency of use of the chemical(s), engineering control(s), PPE. Upon receipt of this form, EH&S will arrange a visit to your laboratory to collect additional detailed information and develop a plan of work, in conjunction with the lab staff, to produce the needed recommendation, Standard Operating Procedure(s), or other information.

Name **UNI**

Campus **Building & Room Number**

Type of Hazard to be Assessed:

Indicate if any of the following chemicals are used:

Acrylamide	Arsenic (inorganic and organic)	Benzene
Cadmium (or compounds)	Carbon tetrachloride	Chlorine
Chloroform	Chromium (VI)	Ethylene oxide
Fluorine	Formaldehyde	Isoflurane
Lead (or compounds)	Mercury (inorganic and organic)	Acrylonitrile
Crystalline Silica	Methyl methacrylate	Methylene chloride
Nitrous oxide	Vinyl chloride	Sodium Azide
Pyridine	Other	

Physical State of Compound of Concern (if solution state solvent and concentration):

Brief Description of Experimental Procedure (including amount used and stored):

Planned Frequency of Described Procedure:

Daily Weekly Monthly Other

Personal Protective Equipment to be Used:

Gloves Respirator (Mask) Protective Clothing Eye Protection

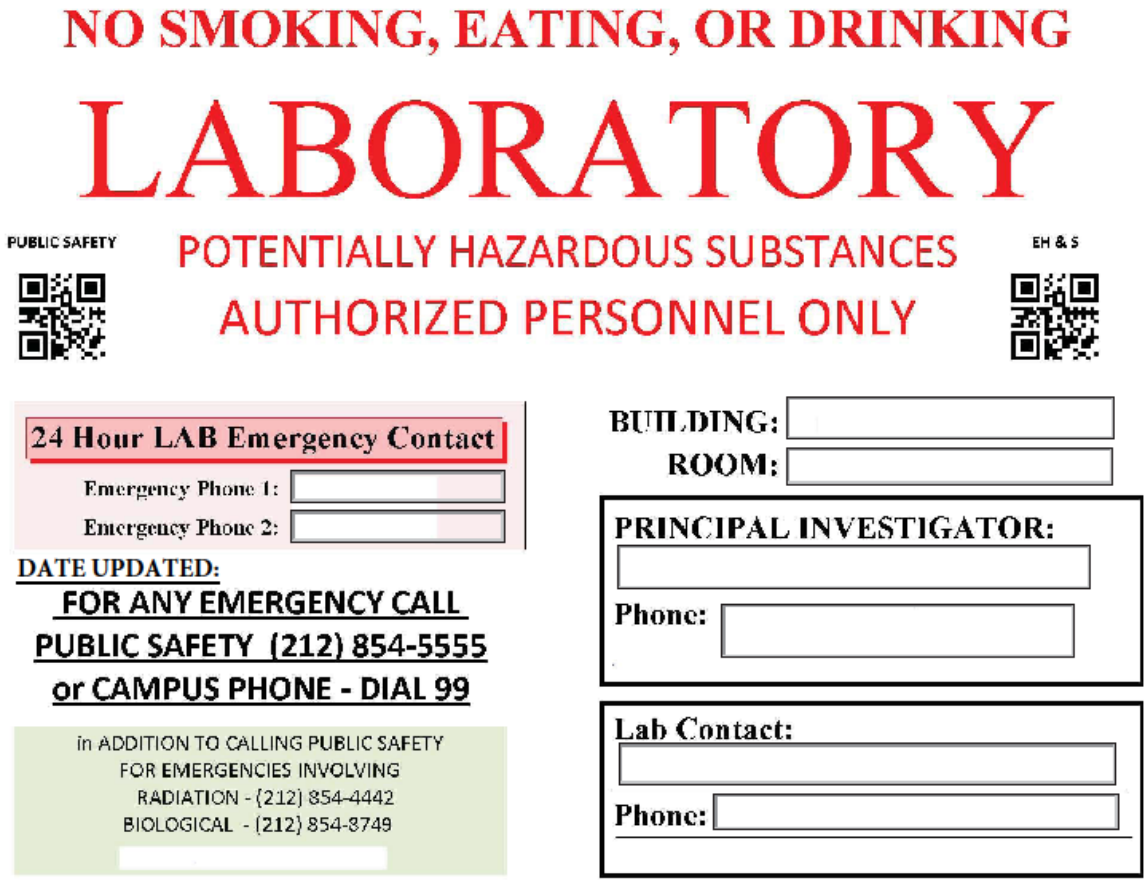
Other

Engineering Controls to be Used:

Please indicate availability to meet to discuss the information provided in this form (MM/DD/YYYY):

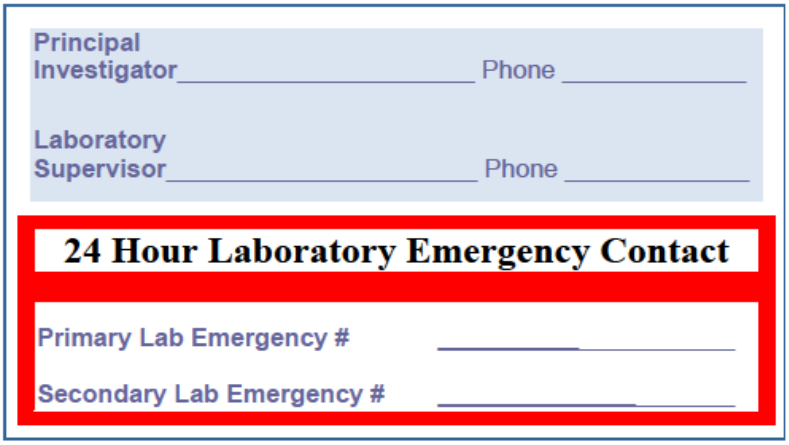
Additional Information:

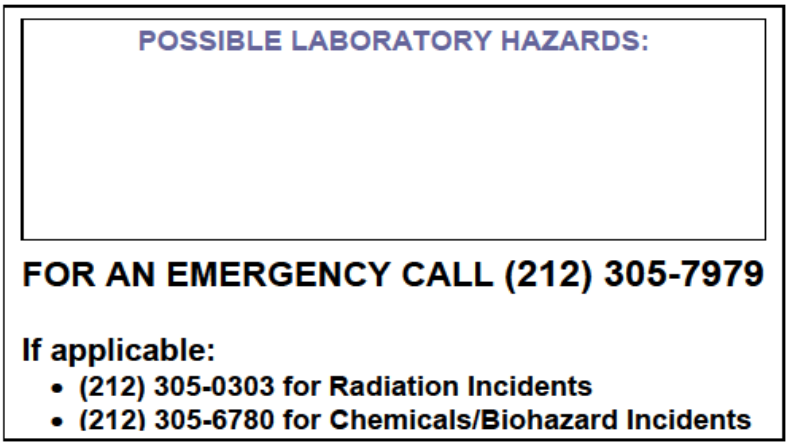
SAMPLE LABORATORY DOOR SIGN
(CUIMC)



ANNEX III-C

SAMPLE LABORATORY DOOR SIGN
(NON-CUIMC CAMPUSES)



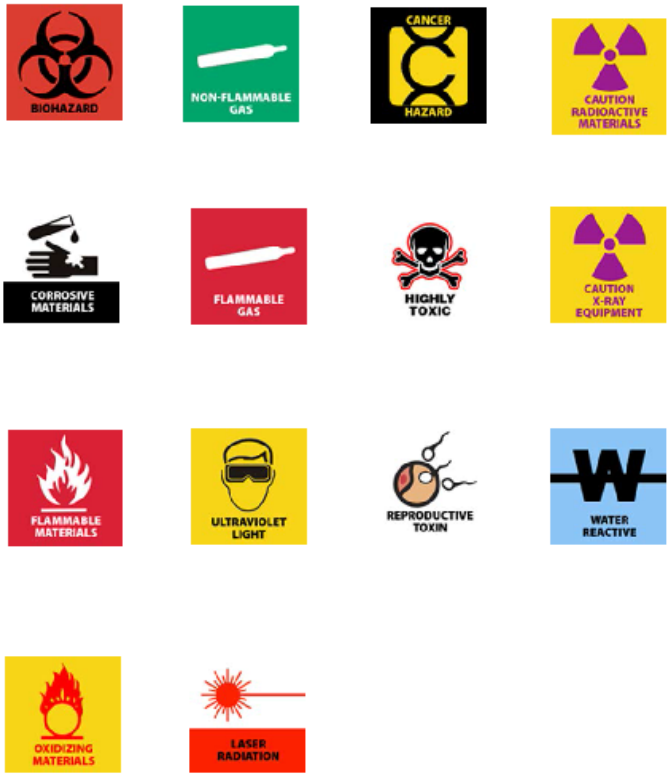


ANNEX III-D

HAZARD SYMBOLS

Hazard Symbols for Signage

Appropriate hazard symbol(s) should be included in the "Possible Laboratory Hazards" box of the Medical Center Door Sign PDF. It is important to note that you can only insert the hazard image by pressing Control (Ctrl) V. The mouse can then be used to adjust the image in the box.



ANNEX III-E

GHS INFORMATION SHEET

THE GLOBALLY HARMONIZED SYSTEM (GHS) OF CLASSIFICATION AND LABELING OF CHEMICALS

What You Need to Know

There are several key changes to current practices of chemical labeling and hazard communication that will affect laboratory workers under the GHS

Pictograms and Hazards -Under the new system, label **borders** must be **red** in color, with the **pictogram** appearing inside the frame; no blank labels are permitted.

For the complete GHS pictogram list refer to http://www.osha.gov/dsg/hazcom/ghs.html

Within the **workplace**, employees may utilize different labeling systems, such as the HMIS or NFPA systems, as long as they convey the same types of information as a GHS label, and as long as they do not create a conflict with existing labels.

Employers who become **newly aware** of any significant **information** regarding the hazards of a chemical shall **revise** the **labels** for the chemical within six months of becoming aware of the new information.

Complete GHS Training Online http://www.rascal.columbia.edu

Who –The US Department of Labor Occupational Safety and Health Administration, OSHA, and the international community of manufacturers, suppliers and users of hazardous chemicals.

What – Updated standards for classification and labeling of hazardous chemicals.

When – As of March, 2012, OSHA has adopted the GHS. Employers are required to train employees on certain elements of the GHS by December, 2013. This flyer is part of those training efforts.

Why – OSHA has adopted the standard in an effort to improve safety conditions for workers. By employing the GHS, OSHA hopes to eliminate confusion over labeling differences, and ensure consistency of hazard communication information.

GHS COLUMBIA UNIVERSITY Environmental Health and Safety http://www.ehs.columbia.edu OSHA

Determining Your Safety Training Requirements @ Columbia University

Columbia-specific training is mandatory for numerous positions and job functions at the University. Please consult the following guide to determine which safety courses are required based on your job function, and the requirements for maintaining your training currency.
Find schedule and information for "live" trainings here: https://research.columbia.edu/safety-trainings

In accordance with COVID-19 recommendations concerning group events and out of an abundance of caution, please be advised all safety training will be conducted online via Columbia University's RASCAL training system until further notice: https://www.rascal.columbia.edu/

Job Function or Activity	Required Safety Training	Initial Training Method	Refresher Training Method	Training Frequency
General Research Safety Courses				
Working in a "laboratory" or with chemicals (*Examples: PIs, research staff, post-docs, students*)	**Laboratory Safety, Chemical Hygiene and Hazardous Waste Management Training** *Course #: TC4951*	"Live" initial training Attendees will b given credit for *Course #: TC4951*	RASCAL *Course #: TC0950*	Initial training at the time of hire or before involvement in such activities; refresher every 2 years or sooner if determined by EH&S
Working in a laboratory or with chemicals at CUMC or Morningside campus	**Certificate of Fitness for Supervision of Chemical Laboratories (C-14)**	"Live"	Self-review of FDNY C14 examination study material	Per FDNY certification Renewal requirements

(Examples: PIs, research staff, post-docs, students who qualify)			upon renewal of certification	
COVID-19 Safety Courses				
For the broader Columbia University Community	**COVID-19 Awareness Training**	EH&S Website	Refresher is not required	This course is an optional informational awareness module for anyone interested in basic background related to SARS-CoV-2 and COVID-19.
For trained scientists who work with materials	**Biosafety Precautions with Clinical Specimens from COVID-19 Patients** *Course # TC5500*	RASCAL	RASCAL *Course #: TC5500*	Initial training at the time of hire or before to involvement in such activities; annual refresher
All Columbia University faculty, staff and students (personnel) working in research	**COVID-19 Training: Safe Research at Columbia University** *Course # TC5550*	RASCAL	Refresher is not required	All faculty, staff and students working in a Columbia University research laboratory must complete this module. Training is required either before returning to campus, or while continuing to work on campus, as applicable.
		EH&S Website & CU ELM	Refresher is not required	All faculty, staff and students – *other than*

For all other Columbia University personnel (this is a general training that does not include content specific to research)	**COVID-19 Training: Working Safely at Columbia University**			*those working in a research laboratory* – must complete this training module. Training is required either before returning to campus, or while continuing to work on campus, as applicable.
Radiation Safety Courses				
Working in a lab that uses Radioactive Material (RAM) or X-ray producing machinery *(Examples: all users of RAM)* or X-ray producing machinery *(Examples: all users of RAM)*	**Radiation Safety and Radioactive Waste Training** *Course #: TC1750*	"Live" initial	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; Annual refresher
Using an irradiator (*Example: irradiating cell lines, etc)*	**Increased Control of Radioactive Materials and Unescorted Access** *Course #: TC2500* **NOTE: requires prior approval by Human Resources**	RASCAL	RASCAL	Annual at intervals not to exceed 12 months
Human Use of Radioactive Materials (ex. F-18) or X-ray emitting devices (ex. CT, DEXA, Radiographs)	**Radiation Safety Training**	"Live" initial	"Live" or RASCAL/NYP COLE	Live initial training at the time of hire or before involvement in such activities; Annual refresher via RASCAL or NYP COLE
Biological Safety and Shipping Courses				

Working with: human blood, body fluids, cell lines or unfixed tissue, infectious microorganisms (capable of causing disease in healthy adults), or viral vectors (*Examples: PIs research staff, post-docs, students, all "active" staff listed on Appendix A, B, or C forms*)	**Biological Safety/ Bloodborne Pathogen Training** *Course #: TC4850*	"Live" initial Attendees will be given credit for *Course #: TC4850 & Course #: TC4950 Biological Safety Cabinet Training*	RASCAL *Course #: TC0509*	Initial training at the time of hire or before involvement in such activities incl. approval of new or renewal submissions to the Institutional Biosafety Committee (RASCAL Appendix A, B or C); annual refresher
Working in a biological Safety cabinet	**Biological Safety Cabinet Training** *Course #: TC3550*	RASCAL	RASCAL *Course #: TC3550*	Initial training before involvement in such activities; refresher every 2 years
Working with viral vectors in research (Note: replication-deficient vectors are NOT exempt)	**Viral Vector Research – Handling and Biosafety** *Course #: TC1150*	RASCAL	RASCAL	Initial training before approval of new or renewal submissions to the Institutional Biosafety Committee (RASCAL Appendix B); refresher every 2 years
Principal Investigators working with recombinant DNA in research (Note: replication-deficient vectors are NOT exempt)	**Recombinant DNA Training** *Course #: TC0508*	RASCAL	RASCAL	Initial training before approval of new or renewal submissions to the Institutional Biosafety Committee (RASCAL Appendix A); refresher every 3

				years
Shipping specimens/viable microorganisms known to or reasonably expected to contain material that may cause disease in humans or animals with Dry Ice (*Examples: anyone involved in any shipping function, including labeling, packaging, or paperwork completion*)	**Shipping Biological (infectious and potentially infectious) Materials, Genetically Modified Microorganisms (GMMOs)** *Course #: TC0507*	RASCAL; "live" session available upon request by department or group	"Live" or RASCAL (individual's preference)	Initial training before involvement in such activities; refresher every 2 years
Shipping non-hazardous materials with Dry Ice (*Examples: anyone involved in any shipping function, including labeling, packaging, or paperwork completion*)	**Shipping with Dry Ice, Exempt Specimens and Excepted Quantities of Dangerous Goods** *Course #: TC0076*	RASCAL; "live" session available upon request by department or group	"Live" or RASCAL (individual's preference)	Initial training before involvement in such activities; refresher every 2 years
Activity- or Hazard-Specific Research Safety Courses				
Working with Formaldehyde, Paraformaldehyde, and Formalin **(> 0.1 mL)** on a lab bench or downdraft table (*Examples: PIs, research staff, post-docs, technicians, students*) Note: **If you work with these chemicals <u>exclusively</u> in a certified chemical fume hood or at concentrations less than 0.1 mL, you are not required to take Formaldehyde Training.**	Initial training: Safe Use of Formaldehyde *Course #: TC3750* and Employee required to contact EH&S at occusafety@columbia.edu	RASCAL	RASCAL	Initial training at the time of hire or before involvement in such activities
Working in a lab that operated laboratory	**Laboratory Autoclave and Automated**	RASCAL	RASCAL	Initial training at the time of hire or before

autoclaved and automated equipment washers (AEW)	**Equipment Washer Safety and Hazard Awareness Training** *Course #: TC4501*			involvement in such activities
Working with Controlled Substances *in vitro* or *in vivo*, under IACUC-approved protocols (*Examples: License/permit applicants, all users of controlled substances in research*)	**Controlled Substances Use and Management in Research** *Course #: TC0502*	RASCAL; "live" session available upon request by department or group	RASCAL; "live" session available upon request by department or group	Initial training before procurements and/or use of Controlled Substances; refresher every 2 years or sooner per EH&S determination
Working in a lab that uses cryostats and microtomes	**Cryostat and Microtome Safety** *Course #: TC4750*	RASCAL	RASCAL	Initial training at the time of hire or before to involvement in such activities
Working in a lab that uses cyanide or cyanide-containing substances (*Examples: PIs, research staff, post-docs, technicians, students*)	**Cyanide Safety Training** *Course #: TC0085*	RASCAL; "live" session available upon request by department or group	RASCAL; "live" session available upon request by department or group	Initial training at the time of hire or before to involvement in such activities
Working with Hydrofluoric Acid (*Examples: PIs research staff, post-docs, students, all Clean Room users*)	**Hydrofluoric Acid Safety Training** *Course #: TC1650*	RASCAL; "live" session available upon request by department or group	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; refresher every 2 years or sooner if determined by EH&S

Working with Class 3b or 4a Lasers. Personnel working with other lasers are encouraged, but not required, to attend. (*Examples: all users of lasers*)	**Laser Safety Training** *Course #: TC1600*	"Live" initial	"Live" or RASCAL (individual's preference)	Initial training at the time of hire or before involvement in such activities; refresher every 2 years
Working in a lab that stores, handles or uses pyrophoric materials (Examples: PIs, research staff, post-docs, technicians, students)	**Pyrophoric Materials Training** *Course #: TC1850*	"Live" as determined by EH&S or available upon request by department or group	"Live" as determined by EH&S or available upon request by department or group	Initial training at the time of hire or before to involvement in such activities
Working in a machine shop or other area with machinery. Personnel working with a specific machine must also receive machine specific training provided by their department before use. (*Example: all users of machinery*)	**Shop Safety Training** *Course #: TC0600*	RASCAL; "live" session available upon request by department or group	Refresher is not required RASCAL; "live" session available upon request by department or group	Initial training before working in a shop or with machinery.

ANNEX III-G

REFRIGERATOR MOU

Columbia University
Morningside: 212-854-8749 Environmental Health & Safety Medical Center: 212-305-6780
www.ehs.columbia.edu

MEMORANDUM OF UNDERSTANDING AND AGREEMENT

PROHIBITION OF STORAGE OF FLAMMABLES IN REFRIGERATORS AND FREEZERS THAT ARE NOT CERTIFIED FOR FLAMMABLE STORAGE

By signing this memorandum, the Principal Investigator certifies that he or she will not place, or allow to be placed, flammable substances in the refrigerator or freezer identified below and that all laboratory personnel have been so instructed.

Flammable substances are substance having flashpoints below 100°F. (For example: acetone, methanol, ethanol, isopropanol, and diethyl ether.

He or she also certifies that no food or beverage will be stored in units which laboratory chemicals, including radioactive materials and biohazardous materials, are stored.

INFORMATION

New York City Fire Department Codes (RCNY Chapter 10) and the National Fire Protection Codes prohibit the storage of flammables in "ordinary household" refrigerators and freezers to prevent explosions caused by ignition of flammable fumes by incidental sparks from the compressor motor of the units.

The storage of food and beverages in refrigerators containing chemicals violates good laboratory practice (e.g. Prudent Practices for Research Laboratories, the National Academy of Sciences) since the potential for contamination of the food and subsequent accidental ingestion is greatly increased.

"Flammable" refrigerators are usually clearly labeled as such; any refrigerator not so labeled is considered to be of "ordinary household" type.

When the unit is delivered, notify EH&S (labsafety@columbia.edu) so that we may place the appropriate caution labels on its door.

Purchase Requisition Number:

Location of unit(s): Building: Room(s):

Purchaser (if different from Principal Investigator):

Principal Investigator (print or type):

Principal Investigator (signature): Date:

E-mail completed form to labsafety@columbia.edu to obtain prior approval required for EZ-PO.

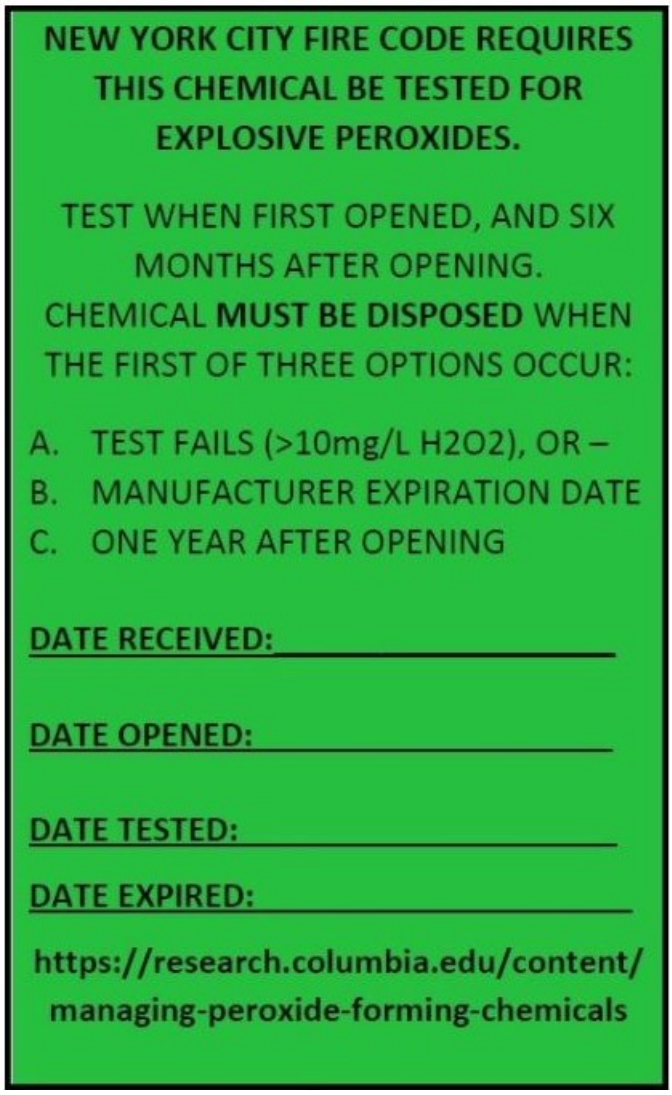
Scan to go to our website

Scan to get a blank copy of this form

October 2011

ANNEX III-H

SAMPLE STICKER FOR PEROXIDE-FORMING CHEMICALS



ANNEX III-I

SAMPLE UNATTENDED LABORATORY SIGN

UNATTENDED LABORATORY OPERATION

AN UNATTENDED LABORATORY OPERATION THAT MIGHT CAUSE A HAZARDOUS CONDITION IF THERE IS EQUIPMENT OR BUILDING SERVICES FAILURE IS INSIDE THIS LABORATORY.		
The following hazards or hazardous materials could be present:		
Continuously Running Water (e.g., equipment cooling water)	Radioactive Materials	Corrosives (eg. shaker, rocker, rotator containing acid or base)
In-process Hazardous Material Application (e.g., western blot)	Flammables	Compressed Gasses
Continuously Energized Magnetic Fields or Electricity	Odorous Substances	Noise Generating Equipment (eg. sonicator)
Dates Posted are Valid: From:		To:
The following people should be contacted in the event of an emergency:		
Primary Contact Name:	24-Hour Phone Number:	
Secondary Contact Name:	24-Hour Phone Number:	
If a hazardous condition is suspected, notify Public Safety immediately!		

Morningside	Medical Center	Manhattanville	LDEO
212 854 5555	212 305 7979	212 853 3333	845 365 8822

Special shut off instructions if applicable:

PLEASE E-MAIL A COPY OF THIS SIGN TO LABSAFETY@COLUMBIA.EDU

COLUMBIA UNIVERSITY

CHEMICAL SEGREGATION and STORAGE CHART

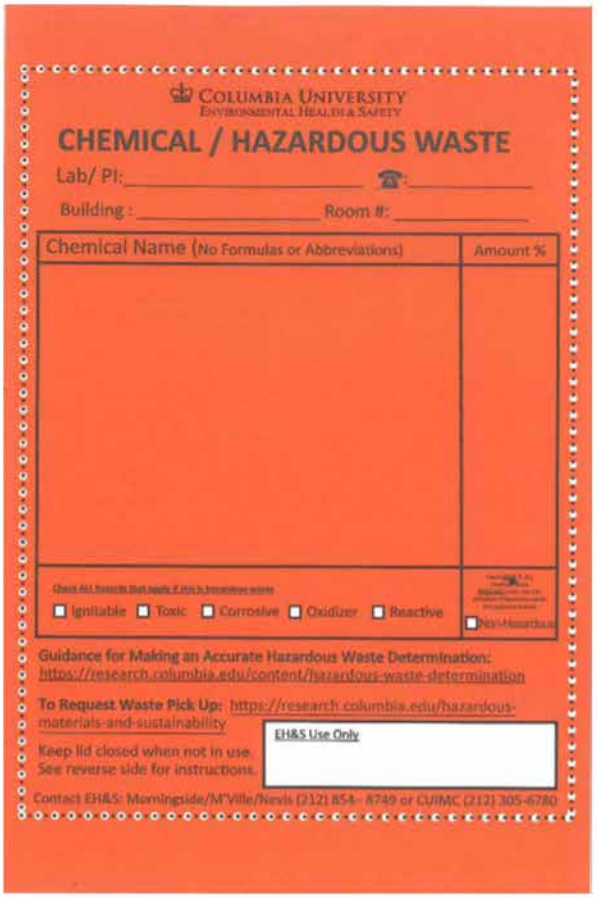
CLASS OF CHEMICALS	RECOMMENDED STORAGE METHOD	CHEMICAL EXAMPLES	INCOMPATIBLES SEE MSDS IN ALL CASES
Compressed Gases - Flammable	Store in a cool, dry area, away from oxidizing gases. Securely strap or chain cylinders to a wall or bench top.	Methane, Acetylene, Propane	Oxidizing and toxic compressed gases, oxidizing solids. *"Lecture-sized gas cylinders are not to be stored in cabinets with hazardous liquids"*
Compressed Gases - Oxidizing	Store in a cool, dry area, away from flammable gases and liquids. Securely strap or chain cylinders to a wall or bench top.	Oxygen, Chlorine, Bromine	Flammable gases. *"Lecture-sized gas cylinders are not to be stored in cabinets with hazardous liquids"*
Compressed Gases - Poisonous	Store in a cool, dry area, away from flammable gases and liquids. Securely strap or chain cylinders to a wall or bench top.	Carbon monoxide, Hydrogen sulfide	Flammable and/or oxidizing gases. *"Lecture-sized gas cylinders are not to be stored in cabinets with hazardous liquids"*
Corrosives – Acids INORGANIC	Store in a separate, lined/protected acid storage cabinet, or in deep corrosion-resistant spill trays. *"DO NOT store acids directly on metal shelves"*	**Inorganic (mineral) acids** - Hydrochloric acid, Hydrofluoric acid, Phosphoric acid, Sulfuric acid, Chromic acid, Nitric acid	Flammable liquids, flammable solids, bases, and oxidizers. **Organic acids**
Corrosives – Acids ORGANIC	Store in a separate, lined/protected acid storage cabinet, or in deep corrosion-resistant spill trays. *"DO NOT store acids directly on metal shelves"*	**Organic acids** - Acetic acid, Trichloroacetic acid, Lactic acid, Oxaly	Flammable liquids, flammable solids, bases, and oxidizers. **Inorganic acids**
Corrosives - Bases	Store in a separate storage cabinet or segregate with a deep, corrosion-resistant spill tray.	Ammonium hydroxide, Potassium hydroxide, Sodium hydroxide	Flammable liquids, oxidizers, poisons, and acids.
Explosives	Store in a secure location away from all other chemicals. Do not store in an area where they can fall.	Ammonium Nitrate, Nitro Urea, Sodium amide, Trinitroaniline, Trinitroanisole, Trinitrobenzene, Trinitrophenol/Picric acid, Trinitrotoluene (TNT)	All other chemicals. *"Keep away from sources of ignition"*
Flammable Liquids	Store in a flammable storage cabinet. *"Peroxide forming chemicals must be dated upon opening; e.g. Ether, Tetrahydrofuran, Dioxane"*	Acetone, Benzene, Diethyl ether, Methanol, Ethanol, Hexanes, Toluene	Acids, bases, oxidizers, and poisons. *"Keep away from sources of ignition"*
Flammable Solids	Store in a separate dry cool area away from oxidizers, corrosives.	Phosphorus, Carbon, Charcoal	Acids, bases, oxidizers, and poisons. *"Keep away from sources of ignition"*
Water Reactive Chemicals	Store in a dry, cool location. Protect from water and the fire sprinkler system, if applicable. Label location - WATER REACTIVE CHEMICALS-	Sodium metal, Potassium metal, Lithium metal, Lithium Aluminium hydride, Sodium Hydride	Separate from all aqueous solutions, and oxidizers.
Oxidizers	Store in a deep spill containment tray inside a non-combustible cabinet, separate from flammable or combustible materials and reducing agents.	Sodium hypochlorite, Benzoyl peroxide, Potassium permanganate, Potassium chlorate, Potassium dichromate. The following are generally considered oxidizing substances: Peroxides, Perchlorates, Chlorates, Nitrates, Bromates, Superoxides	Separate from reducing agents, flammables, and combustibles and organic materials.
Reducing Agents	Store in a deep spill containment tray inside a non-combustible cabinet, separate from oxidizers.	Lithium Aluminum Hydride, Sodium amalgam, Sodium Borohydride, Diisobutyl Aluminum Hydride, Formic Acid, Oxalic Acid	Oxidizers, Arsenic, Selenides
Poisons/Toxic	Store separately in a vented, cool, dry, area in chemically resistant secondary containers.	Cyanides, heavy metal compounds, i.e. Cadmium, Mercury, Osmium	Flammable liquids, acids, bases, and oxidizers.
General Chemicals -Non-Reactive	Store on general laboratory benches or shelving.	Agar, Sodium chloride, Sodium bicarbonate, and most non-reactive salts	See MSDS

Questions: Please contact the EH&S office at 4-8749 (MS) or 5-6780 (CUMC) and ask for a Lab Safety Officer
This form is available at: http://www.ehs.columbia.edu/chemSegChart.pdf updated: 10/13/09

EPA HAZARDOUS WASTE CHARACTERISTICS

EPA Hazardous Waste Characteristics https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes#character		
EPA Waste Characteristic	**Hazardous Waste Parameters**	**Notes**
Ignitability	1. the waste is a non-aqueous liquid with >24% alcohol by volume and has a flash point <140ºF. 2. the waste is a pyrophoric, water reactive or explosive material. 3. the waste is an ignitable compressed gas 4. the waste is an oxidizer such as chlorates, permanganates, nitrates, and inorganic or organic peroxides.	All waste containing ignitable liquids should be handled as ignitable waste, regardless of concentration or flash point, with the ignitable hazard classification marked on the orange Chemical/Hazardous Waste label. If you believe your waste containing ignitable constituents may not meet the EPA definition of ignitable hazardous waste contact EH&S at hazmat@columbia.edu for assistance in making a hazardous waste determination.
Corrosivity	1. the waste is a liquid or aqueous solution that has a pH of <2 or >12.5	If the waste pH is greater than 2.0 or less than 12.5, the waste is not corrosive per EPA, however should be collected for disposal by EH&S as non-hazardous waste because NYCDEP sewer rules prevent corrosive liquids from entering the sewer system. Corrosive waste that is NOT EPA hazardous waste should be marked as "Non-Hazardous" and the measured pH should be noted on the orange Chemical/Hazardous Waste label by the lab.
Reactivity	1. unstable items, explosives, reacts violently with air or when mixed with water resulting in an explosion or generation of toxic gases, is a cyanide or sulfide generating waste when exposed to pH conditions between 2 and 12.5	
Toxicity	1. includes 8 heavy metals, several pesticides and specific Volatile Organic Compounds (VOCs)	If the waste contains any of the following 8 metals, EPA established specific concentrations that are considered hazardous. Contact EH&S at hazmat@columbia.edu for assistance in making a hazardous waste determination. 1. Arsenic (As) 2. Barium (Ba) 3. Cadmium (Cd) 4. Chromium (Cr) 5. Lead (Pb) 6. Mercury (Hg) 7. Selenium (Se) 8. Silver (Ag)
Listed hazardous waste	1. F listed waste from non-specific sources 2. U and P listed waste which are toxic or acutely toxic 3. Polychlorinated biphenyls (specifically listed NY State hazardous waste	The F-list includes many common spent halogenated and non-halogenated solvents used in research labs. All halogenated and non-halogenated solvents must be collected as hazardous waste. EPA has an extensive list of U- and P-listed chemicals. For common examples see the hazardous waste determination webpage. If you are still unsure, refer to the GHS pictogram and/or SDS and if the toxic pictogram is shown, select "toxic" on the orange Chemical/Hazardous Waste label or contact EH&S at hazmat@columbia.edu for assistance in making a hazardous waste determination.

SAMPLE CHEMICAL WASTE LABEL



COLUMBIA UNIVERSITY
ENVIRONMENTAL HEALTH & SAFETY

CHEMICAL / HAZARDOUS WASTE

Lab/ PI: _____ ☎: _____

Building : _____ Room #: _____

Chemical Name (No Formulas or Abbreviations)	Amount %

☐ Ignitable ☐ Toxic ☐ Corrosive ☐ Oxidizer ☐ Reactive ☐ Non-Hazardous

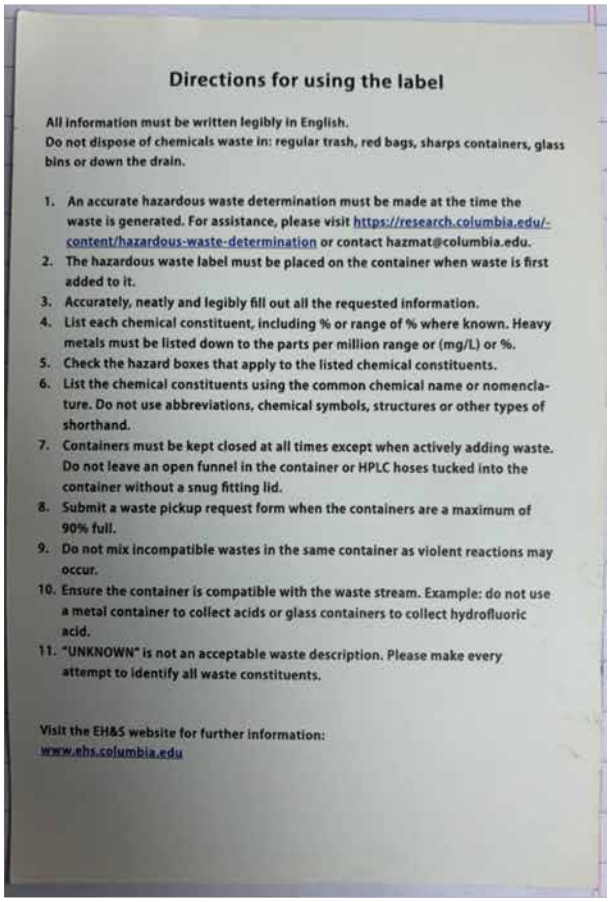
Guidance for Making an Accurate Hazardous Waste Determination:
https://research.columbia.edu/content/hazardous-waste-determination

To Request Waste Pick Up: https://research.columbia.edu/hazardous-materials-and-sustainability

Keep lid closed when not in use.
See reverse side for instructions.

EH&S Use Only

Contact EH&S: Morningside/M'Ville/Nevis (212) 854- 8749 or CUIMC (212) 305-6780



Directions for using the label

All information must be written legibly in English.
Do not dispose of chemicals waste in: regular trash, red bags, sharps containers, glass bins or down the drain.

1. An accurate hazardous waste determination must be made at the time the waste is generated. For assistance, please visit https://research.columbia.edu/-content/hazardous-waste-determination or contact hazmat@columbia.edu.
2. The hazardous waste label must be placed on the container when waste is first added to it.
3. Accurately, neatly and legibly fill out all the requested information.
4. List each chemical constituent, including % or range of % where known. Heavy metals must be listed down to the parts per million range or (mg/L) or %.
5. Check the hazard boxes that apply to the listed chemical constituents.
6. List the chemical constituents using the common chemical name or nomenclature. Do not use abbreviations, chemical symbols, structures or other types of shorthand.
7. Containers must be kept closed at all times except when actively adding waste. Do not leave an open funnel in the container or HPLC hoses tucked into the container without a snug fitting lid.
8. Submit a waste pickup request form when the containers are a maximum of 90% full.
9. Do not mix incompatible wastes in the same container as violent reactions may occur.
10. Ensure the container is compatible with the waste stream. Example: do not use a metal container to collect acids or glass containers to collect hydrofluoric acid.
11. "UNKNOWN" is not an acceptable waste description. Please make every attempt to identify all waste constituents.

Visit the EH&S website for further information:
www.ehs.columbia.edu

COMMON HAZARDOUS WASTES AND CHARACTERISTICS

COMMON HAZARDOUS WASTES and CHARACTERISTICS

EH&S prepared this list for Columbia University laboratories to reference for the most commonly generated laboratory chemical wastes and the EPA hazard characteristic(s) that apply. This is intended to aid laboratories in making an accurate hazardous waste determination by identifying relevant hazard characteristics so the appropriate check box(es) can be indicated on the CHEMICAL/HAZARDOUS WASTE label.

Waste Category	Common Examples	Specific Examples	Additional Guidance
Ignitable	Alcohols	• Butanol • Ethanol • Isopropanol • Methanol • Propanol	Non-aqueous liquids with a flash point <140°F
	Ethers and ketones	• Acetone • Benzene • Ethyl ether • Toluene • Xylene	
	Metals (alkali metals)	• Aluminum, finely powdered • Lithium • Potassium • Sodium	Flammable solids, metal shavings or fine powders that can cause a fire through friction or absorption of moisture
	Alkanes, alkenes, alkynes, arenes	• Acetylene • Butane • Ethane • Methane • Propane	Ignitable compressed gases (contains a mixture of <13% with air that forms a flammable mixture)
	Hydrides, metals, alkali metals, amides	• Butyl lithium hydride • Nitrocellulose, dry or plasticized • Lithium aluminum hydride • Magnesium Powdered • Sodium amide, deteriorated • Picric acid, dry	Pyrophoric, water reactive or explosive materials
Corrosive	Inorganic and organic acids including oxidizing acids	• Acetic acid • Hydrochloric acid • Hydrofluoric acid • Nitric acid	Inorganic and organic acids and bases. Aqueous solutions with a ph $\leq$ 2 or $\geq$ 12.5. Liquids that corrode steel.
	Inorganic and organic bases including hydroxides and amines	• Potassium hydroxide • Sodium hydroxide • Trimethyl amine	

Waste Category	Common Examples	Specific Examples	Additional Guidance
Toxic	Halogenated and nonhalogenated solvents	• Benzene • Cresol • Cyclohexanone • Ethyl benzene • Methanol • Methylene chloride • Methyl ethyl ketone • Methyl isobutyl ketone • Pentachlorophenol • Pyridine • Tetrachloroethylene • Vinyl chloride • Xylene	Volatile organic compounds including many solvents
	Heavy metals	• Arsenic • Barium • Cadimum • Chromium • Lead • Mercury • Silver • Selenium	
	Cyanides and salts, organophosphorous compounds, warfarin and salts when >0.3%, unused organic solvents	• Acrolein • Arsenic compounds • Cyanide compounds • Fluorine • Formic acid • Formaldehyde • Hydrogen cyanide • Lead compounds • Malic anhydride • Nickel carbonyl • Nicotine • Nitric oxide • Osmium oxide • Osmium tetroxide • Phenol • Pyridine • Phosgene • Phosphine • Sodium azide • Thallium oxide • Thiophenol	Acutely toxic and toxic materials
	tri-, tetra-, pentachlorophenol	• Aldrin • Endrin • Parathion • Toxaphene	Pesticides

Waste Category	Common Examples	Specific Examples	Additional Guidance
Reactive	See above examples under ignitable, water reactive, pyrophoric or explosive materials		Pyrophoric, water reactive or explosive materials.
	Cyanides, sulfide generating compounds	• Hydrogen cyanide • Hydrogen sulfide	Unstable items that reacts violently with air or when mixed with water, resulting in an explosion or generation of toxic gases, including cyanides or sulfide generating waste when exposed to pH conditions between 2 and 12.5
Oxidizer	Chlorates, perchlorates, dichromates, permanganates, nitrates, inorganic hypochlorites	• Activated carbon, finely powdered • Aluminum permanganate • Ammonium nitrate • Lead perchlorate • Silver nitrate • Uranyl nitrate	Yields oxygen readily to support combustion
	Inorganic or organic peroxides	• Dibenzoyl peroxide • Dicumyl peroxide • Methyl ethyl ketone peroxide • Peroxyacetic acid • Tert-butyl hydroperoxide	Peroxides

ANNEX IV-D

COMMON NON-HAZARDOUS WASTES REQUIRING PROPER DISPOSAL

COMMON NON-HAZARDOUS WASTES REQUIRING PROPER DISPOSAL

EH&S prepared this list for Columbia University laboratories to reference for the most commonly generated laboratory chemical wastes that DO NOT meet the strict definition of EPA hazardous waste, but MUST be collected and managed for proper disposal through EH&S. Laboratories may utilize the "Non-Hazardous" check box on the CHEMICAL/HAZARDOUS WASTE label for these wastes.	
Chemical Specific	**Additional Guidance**
Batteries, intact, non-leaking (alkaline, Ni-Cad, Lead Acid, Lithium button cell)	Place used, intact batteries in the nearest battery collection container. A list of campus locations may be found here https://research.columbia.edu/sites/default/files/content/EHS/Waste_Hazmat/BatteryRecyclingReceptacleLocations.pdf Leaking batteries or large Lead Acid batteries should be submitted a chemical waste pickup request to EH&S for disposal.
Chemically contaminated sharps (including pipette tips or pipettes) not containing P or U-listed toxic or acutely listed wastes	
Ethidium bromide solutions, electrophoresis gels and contaminated debris	
Formalin solution	Used or spent solutions only
Lamps, intact, not broken	Submit a chemical waste pickup request at https://research.columbia.edu/hazardous-materials-and-sustainability for disposal of used lamps as universal waste.
Liquid scintillation cocktails that do not have any hazardous waste characteristics.	
Mercury containing equipment, intact, not leaking such as mercury lamps, barometers and thermometers	
Paraformaldehyde solution	Used or spent solutions only
Non-toxic salts and buffers	Examples include: tissue culture media solutions, vitamins, yeast extracts, tris buffer, and EDTA solutions. Note, excludes buffers containing Coomassie blue.
Silica and celite waste	If there are trace solvents present, please contact EH&S at hazmat@columbia.edu for additional classification guidance.
Solvent contaminated rags and towels contaminated with various solvents such as trace: hexane, mineral spirits, methanol, monochloronaphthalene, and dye.	The solvent contaminated rags and towels must have no free liquids.
Used oil	Please label with a USED OIL label provided by EH&S. If you do not have these labels, please use the chemical waste label and check the nonhazardous waste box.

ANNEX V-A

SELECT AGENTS AND TOXINS LIST

SELECT AGENTS AND TOXINS LIST

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. Here is a list of excluded agents and toxins.

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

1. Abrin[5]
2. *Bacillus cereus* Biovar *anthracis**
3. Botulinum neurotoxins*,[5]
4. Botulinum neurotoxin producing species of *Clostridium**
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1,5]
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol[5]
9. Eastern Equine Encephalitis virus[3,4]
10. Ebola virus*
11. *Francisella tularensis**
12. Lassa fever virus
13. Lujo virus
14. Marburg virus*
15. Monkeypox virus[3]
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Ricin[5]
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)[4]
20. Saxitoxin[5]

OVERLAP SELECT AGENTS AND TOXINS

36. *Bacillus anthracis**
37. *Bacillus anthracis* Pasteur strain
38. *Brucella abortus*
39. *Brucella melitensis*
40. *Brucella suis*
41. *Burkholderia mallei**
42. *Burkholderia pseudomallei**
43. Hendra virus
44. Nipah virus
45. Rift Valley fever virus
46. Venezuelan equine encephalitis virus[3,4]

USDA SELECT AGENTS AND TOXINS

47. African horse sickness virus
48. African swine fever virus
49. Avian influenza virus[3]
50. Classical swine fever virus[4]
51. Foot-and-mouth disease virus*,[4]
52. Goat pox virus
53. Lumpy skin disease virus
54. *Mycoplasma capricolum*[3]
55. *Mycoplasma mycoides*[3]
56. Newcastle disease virus[2,3]
57. Peste des petits ruminants virus
58. Rinderpest virus*
59. Sheep pox virus

HAZARDOUS MATERIALS APPENDIX A

GENERAL

I. General Information

The appendix will be:

Project Title:

Describe methodologies/manipulations of the work performed. In brief describe the lab's research goals and the methodologies involved to accomplish these goals. If applicable, include any recombinant DNA gene manipulations such as gene editing (e.g., CRISPR, TALENs, zinc fingers)

Are there any relevant vaccinations or work restrictions/considerations that should be acknowledged in regards to work with the biological material?

[ ] Hepatitis B Vaccination

[ ] Rabies Virus Vaccination

[ ] Immunocompromised Status

[ ] Pregnancy

[ ] Not-Applicable

[ ] Other:

If a lab acquired infection were to occur, what therapy is available?

II. Collaborations/Procurement

Where will the biological materials (viral vector/bacteria/virus/clinical specimen/cell line/other microorganism) be procured from?

[ ] Company/Core Facility/Repository:

[ ] Collaborator (Name/University):

[ ] Other:

Will this project be a research collaboration where recombinant DNA or infectious material is shared between different campuses at Columbia?

Will this project be a research collaboration where recombinant DNA or infectious material is shared between different institutions?

III. Dual Use Research of Concern (DURC)

Dual Use Research of Concern (DURC) is defined as: life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

Does the research in question meet the definition of dual use research of concern?

IV. Laboratory Locations

V. Recombinant DNA

Is Recombinant DNA being used?

VI. Microorganism Information

Is a viral vector being used?

Is virus being used that is NOT a viral vector (aka wild-type)?

Are bacteria (BSL-2 and above) being used?

Are fungi being used?

Are microorganisms, other than bacteria/virus/fungi, being utilized? Examples may include Parasites (e.g., Plasmodium spp), Prions, or other microorganisms.

VII. Human Tissue and Cell Culture Section

Will human tissue (e.g., blood, stem cells, organs etc) or cell lines be utilized?

VIII. Safety Equipment and Practices Section

Will a Biosafety Cabinet (BSC) be utilized?

Disinfectant used:

[ ] 10% freshly prepared bleach
[ ] 10% freshly prepared bleach followed by 70% Ethanol
[ ] Chlorine Dioxide based (commercial disinfectant)
[ ] Other disinfectants:

How will waste be disposed of?

[ ] Chemical Disinfection
[ ] Regulated Medical Waste (red bags/sharps)
[ ] Autoclave

Personal Protective Equipment used when working in the Laboratory:

[ ] Lab Coats
[ ] Gloves (Nitrile or Latex)
[ ] Double Gloves
[ ] Safety Glasses or Goggles
[ ] Head Covers
[ ] Shoe Covers
[ ] Surgical/Dusk Mask
[ ] Face Shield
[ ] Other:

Will unfixed virally-transduced cells or human clinical specimens be used for flow cytometry or FACS analysis?

Will the laboratory work with biohazardous agents in any of the following aerosol-producing devices or procedures? Note: Aerosol producing procedures of infectious agents BSL-2 and above should be performed within a Biosafety Cabinet.

[ ] Aspirators
[ ] Pressurized Vessels
[ ] Blenders
[ ] Large Volumes (10L)
[ ] Shakers
[ ] Centrifuges
[ ] Necropsy
[ ] Sonicators
[ ] Homogenizers

[ ] Pipetting Infectious Liquids
[ ] Vortexers
[ ] Other:

Will needles be used in the experimental protocol?

Will recombinant DNA or infectious materials be transported within or between campus buildings, if applicable?

PERSONNEL

ATTACHMENTS

PROTOCOL/PROPOSAL

HAZARDOUS MATERIALS APPENDIX M

GENERAL

I. General Information

Principal Investigator: N/A
Department Affiliation: N/A
IRB Number: N/A
Project Title:

Select the recombinant material(s)/product(s) to be administered, and fill in the specific Trade name:
[ ] Lentivirus:
[ ] Adeno-Associated Virus:
[ ] Adenovirus:
[ ] Herpes Simplex Virus:
[ ] Glycoprotein-deleted Rabies Virus:
[ ] Murine Moloney Leukemia Virus:
[ ] Vaccinia:
[ ] Plasmid:
[ ] Other:

Sponsor:
Company Name:
Address:
Contact Person and Title:
Phone Number:

Is the recombinant material coming from the Sponsor?
Is this part of a multi-center study?
If applicable, will the trial be registered with the NIH Office of Science Policy (OSP)?
How will Safety Data, Serious Adverse Events, incidents, and other unanticipated events be reported and who will be responsible for reporting?
Will the following vaccines/personnel limitations be applicable to those who will handle, administer, or otherwise have exposure to the product? (Check all that apply):
[ ] Hepatitis B Vaccination
[ ] Other Vaccination:
[ ] Immunocompromised Status
[ ] Pregnancy
[ ] Not-Applicable
[ ] Other:

II. Dosing Information

Route of Administration:
Dose:
Dose Frequency:

If drug is to be injected will "Safe Needles" be used?

Where will the material be received, stored, prepared, and administered?

ATTACHMENTS

PROTOCOL/PROPOSAL

How will the material be prepared for administration?

Describe the procedures in the event of spill:

III. Recombinant DNA information

Describe briefly the vector/gene insert construct and provide a description of the cells in which it is produced.

If the vector is designed to be replication incompetent, note how this was accomplished. You may copy or cite the relevant page(s) from the clinical investigators' brochure to provide this information.

Provide a history of testing for replication competent virus if applicable to the product, and if any such testing will be done as part of this project? You may copy or cite the relevant page(s) from the clinical investigators' brochure to provide this information.

Identify and summarize any biosafety concerns for patients administered this therapy. These could be (1) hypothetical concerns based on the nature of the therapy, (2) concerns based on preclinical data, or (3) anticipated adverse events from past clinical studies.

Does data on localization and shedding exist?

PERSONNEL

ANNEX V-D

UNIVERSAL BIOHAZARD SYMBOL

ANNEX V-E

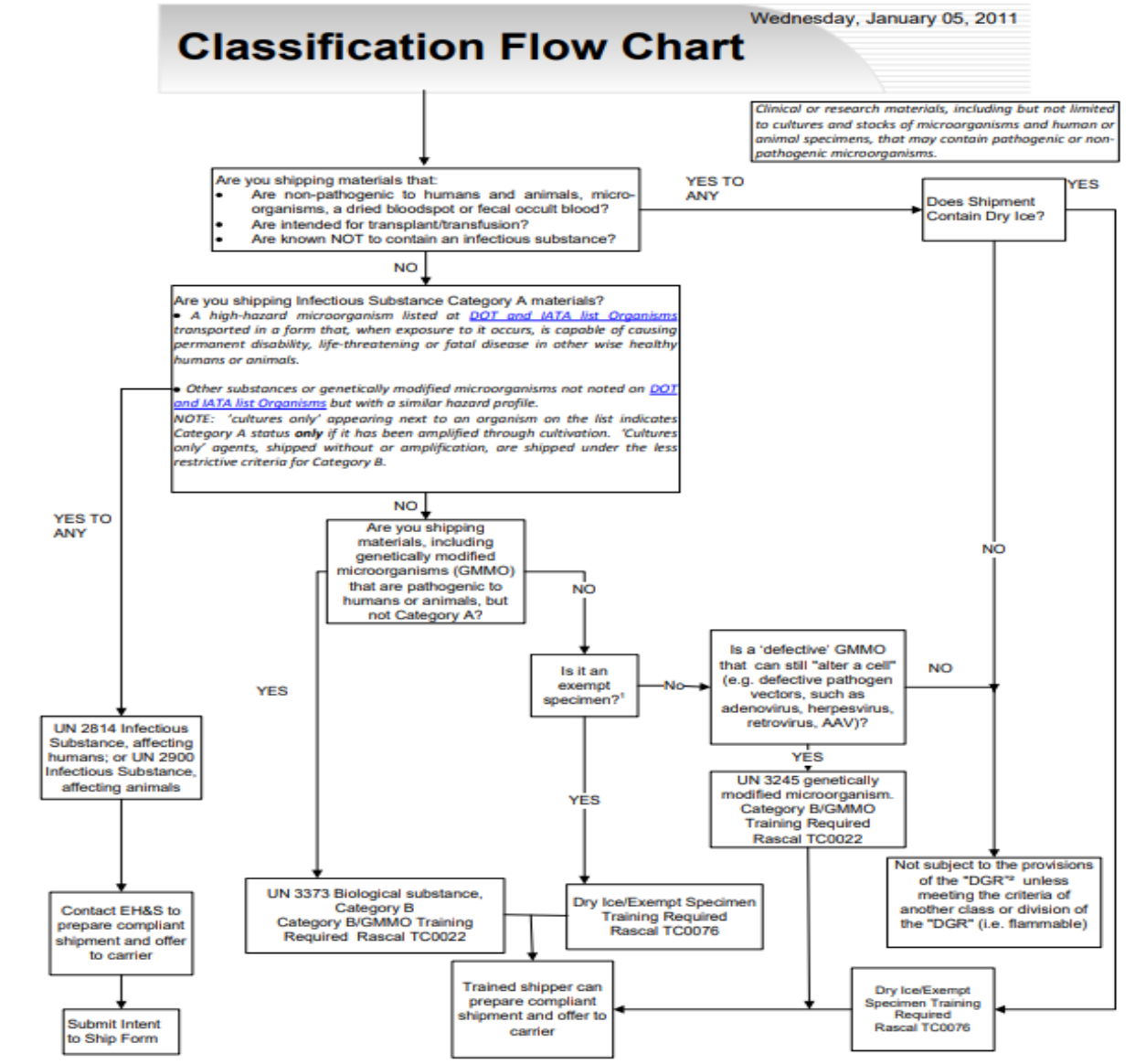
SUMMARY OF DISINFECTANT ACTIVITIES

Summary of Disinfectant Activities

Disinfectant	Disinfection Level	Bacteria	Lipophil. Viruses	Hydro-Philic Viruses	M. tuber-culosis	Fungi	Comments
Alcohols (ethyl and isopropyl) 60-85%	intermediate	+	+	-	+/-	+	Not sporicidal; evaporates quickly so that adequate contact time may not be achieved, high concentrations of organic matter diminish effectiveness; flammable.
Phenolics (0.4%-5%)	intermediate	+	+	+/-	+	+	Not sporicidal; phenol penetrates latex gloves; eye/skin irritant; remains active upon contact with organic soil; may leave residue.
Glutaraldehyde (2-5%)	high	+	+	+	+	+	Used to sterilize surgical instruments that cannot be autoclaved; strong odor; sensitizer; use with adequate ventilation. Not for use on Environmental surfaces.
Quaternary Ammonium (0.5-1.5%)	low	+	+	-	-	+/-	May be ineffective against Pseudomonas and other gram – bacteria; recommendation limited to Environmental sanitation (floors, walls). Low odor, irritation.
Iodophors (30-1,000 ppm iodine)	intermediate	+	+	+	+/-	+/-	Inactivated by organic matter.
Chlorine (100-1,000 ppm)	intermediate	+	+	+	+/-	+	Not sporicidal; inactivated by organic matter; fresh solutions of hypochlorite (chlorox) should be prepared daily; corrosive; irritating to eyes and skin.

ANNEX V-F

CLASSIFICATION FLOW CHART



ANNEX V-G

INTER-CAMPUS TRANSPORT OF BIOLOGICAL MATERIALS TABLE

Inter-campus transport of biological materials table:

Material	Category A Infectious substance	Biological Substance Category B	Exempt human/animal specimen	Non-regulated biological material	Preserved Biologicals	Dry Ice
Example	Ebola virus M., tuberculosis	HIV-infected blood specimens. Blood for infectious disease testing. Cultures of infectious material; MRSA, herpes simplex	Blood specimens with low likelihood of infectious materials. Urine. Mouse brains. Cell lines.	DNA samples. Anitbodies.	Formalin (10%) - preserved tissue. Ethanol-preserved tissue.	
DOT-Hazmat by ground?	Yes	Yes	No	No	No restrictions at low volume and concentration	No
Risk	High	Medium	Low	None	Low	Low
University vehicle – Shuttle bus, Public Safety	Not Permitted	Not Permitted	Permitted	Permitted	Permitted	Permitted
Personal Vehicle	Not Permitted	Not Permitted	Permitted	Permitted	Permitted	Permitted
Taxi Cab	Not Permitted	Not Permitted	Permitted	Permitted	Permitted	Permitted
Mass Transit (MTA)	Not Permitted	Not Permitted	Not Permitted	Not Permitted	Not Permitted	Not Permitted
Notes	Use a professional dangerous goods courier such as FedEx.		Materials must be triple-performance packaged.		Only permitted at DOT-exempt amounts. Formaldehyde concentration not to exceed 3.75%. Volume per tube not to exceed 30 ml. Materials must be triple-performance packaged.	Dry ice must be packaged according to DOT specs (insulated, gas-ventable container.)
Required training	EH&S is responsible for preparing compliant Category A shipments. No faculty, student, or staff member, regardless of training status, is certified by EH&S to ship Category A substances.	Shipper must also be DOT/IATA-trained.	Shipper must be DOT/IATA-trained (RASCAL TC0507)		Shipper must be DOT/IATA-trained (RASCAL TC0076)	

LASER REGISTRATION FORM

Appendix D -- Environmental Health & Safety (EH&S)

LASER REGISTRATION FORM

Principle Investigator **MUST** complete Appendix D when proposed research involves use oflaser (class 3 or 4) or they already have one in their laboratory. A separate registration form must be submitted for each piece of equipment in this category. Call EH&S at (212) 854-8749 (MS) or (212) 305-6780 (CUMC) or e-mail lasersafety@columbia.edu if you have any questions or need any assistance.

(PLEASE TYPE OR PRINT)
PI NAME: _____ DEPARTMENT: _____

BLDG/ROOM: _____ OFFICE PHONE: _____EMERGENCY PHONE: _____

LASER SYSTEM LOCATION: BLDG _____ FL/ROOM # _____

USER'SNAME PHONE #

Are safety signs posted on door? Yes No Are safety glasses/goggles used? Yes No
Are written SOP's developed? Yes No Are users trained on the SOP·? Yes No

Will laser curtains be used for this laser? Yes No

LASER DESCRIPTION: PLEASE DESCRIBE SPECIFICATIONS/CHARACTERISTICS OF THIS EQUIPMENT:

1. Type: _____

2. Manufacturer: _____

3. MODEL No: _____ SERIAL No: _____

5. LASER CLASS: CLASS 3A CLASS 3B CLASS 4

6. TYPES OF OPERATION: (A) C.W. _____ (B) PULSED _____

(C) MULTIPLE PULSED _____ (D) OTHER _____

7. RATED POWER OR ENERGY OUTPUT: _____ 8. PULSE REPETITION FREQUENCY: _____

9. OPERATING WAVELENGTHS: _____10. BEAM DIAMETER: _____

11. MAXIMUM EXPECTED EXPOSURE DURATION PER DAY _____

12. OTHER PERTINENT INFORMATION:
_____
_____

13. Is LASER SERVICE DONE: IN HOUSE? YES NO CONTRACTED OUT YES NO

IF CONTRACTED OUT, COMPANY _____

14. MOST RECENT DATE THIS EQUIPMENT WAS SERVICED _____

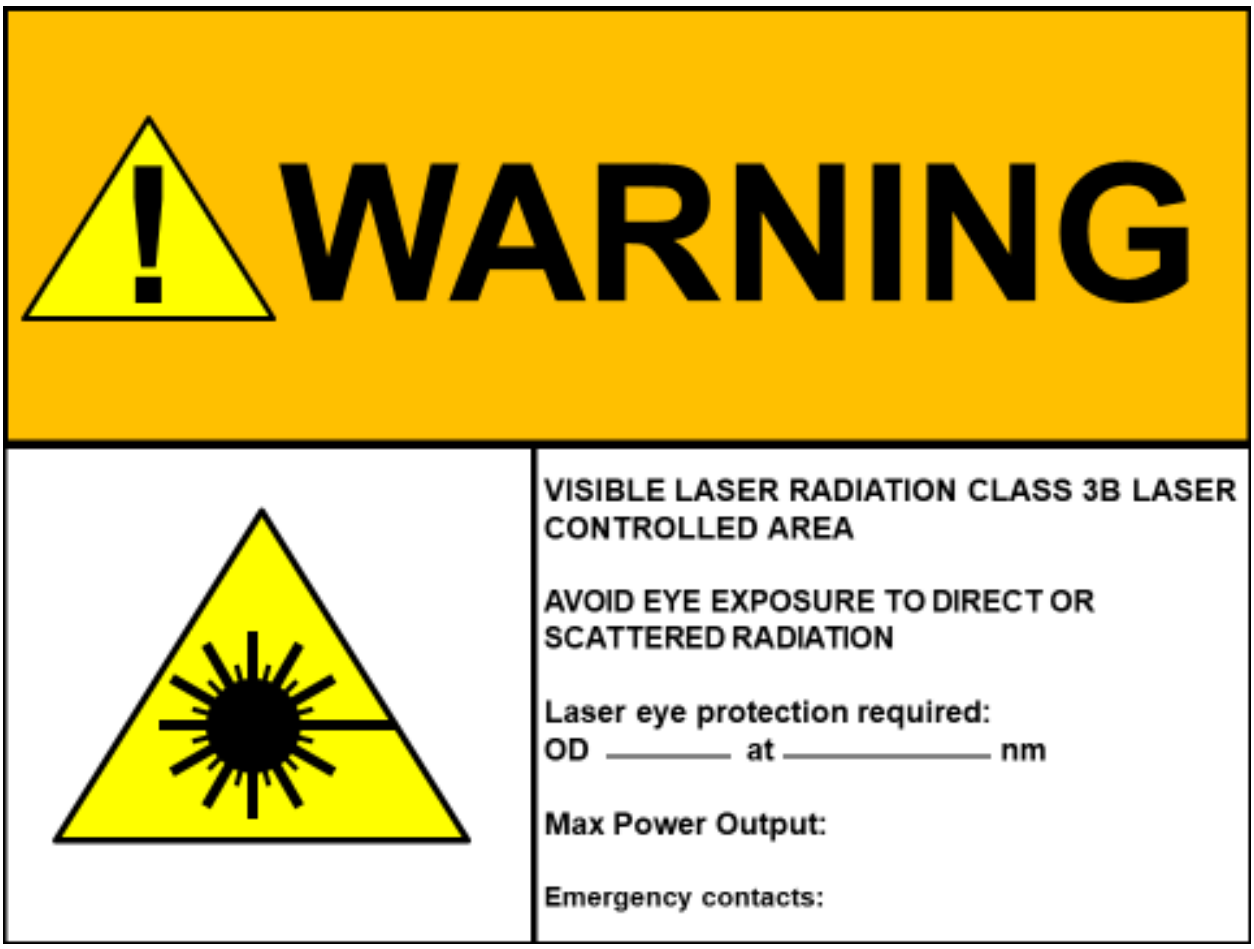
MANUFACTURERS RECOMMENDED FREQUENCY OF SERVICE

_____ _____
REGISTRANT'S SIGNATURE DATE

_____ _____
EH&S APPROVAL SIGNATURE DATE EHS APPROVAL No. _____

ANNEX VII-B

LASER WARNING SIGN



ANNEX VII-C

LASER DANGER SIGN

Laser Standard Operating Procedures - Template

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

SAMPLE Standard Operating Laser Procedures

This document represents the Standard operating Procedures (SOP), related to the following laser system. It includes the safe use and procedures for the laser system and it is intended to be a comprehensive guide of the laser operation, for all the authorized users.
It is responsibility of the Principal Investigator to complete it and to ensure that it is followed by the laser users. The Laser Safety Officer (LSO) can provide guidance for the SOP's completion if it is requested. SOPs are required by ANSI Z136.1 2014 for all 3b and 4 class lasers systems. The SOP document has to be located at the control panel or next to the laser system. The laser users shall know its location prior laser operation.

Personnel Qualifications			
Personnel who will use laser system are appropriately trained			
Name	C.U.ID #	STATUS (student/staff/faculty)	Date of Training Received (Initial/Refresher)
Tom Jones	tg1234	Ph.D student	5-5-14 / 8-4-15
Bill Paterson	bp5678	Lab Manager	4-4-14 / 8-5-15

Laser System information			
Manufacturer/Model	Type of Laser	Classification	Serial Number
Coherent Verdi 10	DPSS	IV	V10 - 1234556778
Laser Registration or Appendix D			
Crystallization of silicon films			

Training
Training shall be provided to any individual routinely working with or potentially exposed to Class 3B or Class 4 laser radiation. The level of training shall be commensurate with the degree of potential laser hazards, both from the laser radiation and non-beam hazards.

Any new member of Columbia University, who intents working with lasers, shall be given the initial training by EHS in Morningside Campus. Registration with EHS is needed. For more information visit the following link: http://www.ehs.columbia.edu/TrainingSchedule.html

Refresher training will be required periodically (every two years). This can be given by EHS or by completion of the Rascal Laser Safety Training TC1600.

1

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

SAMPLE Standard Operating Laser Procedures

Emergency Procedures

Emergency Procedures		
Controls	Click if applicable	Comments
Do not remove the laser housing/electrical shock danger	☒	
Push the emergency button to shut down the laser	☒	
Contact LSO or laser supervisor	☒	
Use key switch to restart the laser	☒	

Additional emergency procedures /Comments

Computer program is responsible for start-up, shut-down and restart the laser system.
A class IV laser may be hazardous to the eyes and skin from direct, specular and diffuse reflections. It is also presents a fire hazard. In emergency situations a hand switch, located besides the computer system can shut-down the laser system immediately.

Laser safety contacts / Emergency contacts		
Title	Name	Contact details
Laser supervisor:	Bill Paterson	212-123-4567
Maintenance/repair:	Bill Paterson	212-123-4567
EHS Emergency-LSO:	Max Amurao	212-305-0303

2

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

SAMPLE Standard Operating Laser Procedures

Laser Safety-Responsibilities

Laser Supervisor

1. The supervisor shall be responsible for the issuance of appropriate instructions and training materials on laser hazards and their control to all personnel who may work with lasers that are operated within the supervisor's jurisdiction.
2. The supervisor shall not permit the operation of a laser unless there is adequate control of laser hazards to employees, visitors, and the general public.
3. The supervisor shall be responsible for writing the standard operating procedures for each 3b and 4 class laser, providing them to the users, updating and maintaining the SOP's, and ensuring they are readily accessible to all users.
4. The supervisor shall enforce the safe work practices outlined in the SNSI Standards Z136.1 and the University's laser safety program.
5. Unattended use of Class 3B and 4 lasers shall be permitted only when the LSO has implemented appropriate control measures such as beam traps, barriers, windows, other means of area control, or laser safety training that provide adequate protection to those who may enter the laser controlled area during times of unattended use.
6. The supervisor shall be responsible of the availability of correct protective eyewear.
7. The supervisor shall provide information to LSO regarding names of laser operators, training and medical surveillance. He also shall be aware for reporting accidents resulting from a laser operation, to the LSO.
8. The supervisor shall submit laser registration forms for 3b and 4 class laser installations, to LSO for approval. He also shall notify the LSO prior to a laser being disposed or transferred.

Laser operators other than laser supervisor

1. A laser user shall comply with safety rules and procedures prescribed by the supervisor and the LSO. The employee shall be familiar with all applicable operating procedures.
2. A laser user shall not energize or work with or near a laser unless authorized to do so by the supervisor.
3. Laser users shall wear the appropriate eyewear and other PPE during laser operation.
4. Laser user shall report any accident or safety concern to the supervisor or LSO.
5. Laser user will ensure the safety of any personnel or unauthorized individual, entering the laser room.
6. Laser users are responsible of labeling laser equipment and maintaining postings of lab area in good condition.

3

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

SAMPLE Standard Operating Laser Procedures

Before start-up laser procedures

Before start-up laser procedures		
Controls	Click if applicable	Comments
User Manual is followed throughout laser operation	☒	User Manual is on the vertical table.
Warning lights are on	☐	There are no warning lights for this laser system. No "beam in use" light outside the door.
Laser warning signs are provided at entrances	☒	Class IV "Danger" signs at the entrance and outside the controlled area are posted.
All individuals in the room are warned verbally prior laser operation	☒	Authorized laser user warns all individuals outside controlled area.
A controlled area is established prior to laser operation. All personnel remain outside of the control area during laser operations.	☒	Chain barrier is applied to establish controlled area. Only authorized related to the experiment, are inside the controlled area.
All objects that can affect the beam path or cause any hazards are removed. (flammable, reflective, explosive materials)	☒	
Be aware of specular and diffuse reflections	☒	
Obtain appropriate eyewear (wavelength-OD) or skin protection	☒	Safety goggles and lab coat are worn.
Remove jewelry and ties, and all loose or dangling clothing and objects.	☒	
Confirm by double-checking that all systems are in place before operationalizing the laser	☒	
Turn the key control switch to the "ON" position and follow the manufacturer's recommended steps	☒	Laser is switched on by the use of computer system.

Additional start-up procedures / Comments

4

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

SAMPLE Standard Operating Laser Procedures

Alignment procedures

Alignment procedures		
Controls	Click if applicable	Comments
Use of lower power lasers (Class 1,2,3R) for path simulation of 3B and 4 class lasers	☐	
Exclude unnecessary personnel from the laser controlled area	☒	
Appropriate eye and skin protection is available and worn	☒	Only eye protection available
Beam display devices, such as image converter viewers or phosphor cards are used to locate beams, in invisible laser beams alignment.	☐	Laser beam is visible. No phosphor cards are used.
Verify lowest possible power level is used during laser alignment	☒	During alignment the laser average power is reduced to 1W.
Beam blocks and/or protective barriers are used, where alignment could stray into uncontrolled areas	☒	Protective barriers and beam blocks are used at optical table.
Shutters or beam blocks are used to terminate high power beams.	☒	
Beam blocks are placed behind optics to terminate beams that might miss mirrors during alignment	☒	
All beams and reflections are properly terminated before high-power operation	☒	

After the completion of the above procedures, the laser's power could be increased.

Additional alignment procedures / Comments

The laser system was initially set-up when we obtained the laser. Protective barriers, beam blocks, optics are used and are precisely placed on the optical table. Minor or no changes of the optics' position are performed, during laser alignment. A laser beam of average output of 1W is used in order to locate the laser beam path. When the beam path is determined and after verification that no stray beams emanate from the laser system, we increase the output power for normal laser operation.

5

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

SAMPLE Standard Operating Laser Procedures

Control Measures

Control Measures		
Controls	Click if applicable	Comments
Laser is enclosed in a protective housing	☒	Protective housing of the manufacturer.
Interlocks are applied	☐	No door interlock is applied. Door is locked manually when the laser is operated.
A master switch (key or coded access) is used to initiate and terminate the laser beam	☒	Laser is initiated and terminated by the use of computer program.
Viewing windows and diffuse display screens are used and maintain radiation levels below MPE	☐	Laser is sitting on the optical table and is enclosed peripherally by protective barriers, sufficient to maintain radiation levels below MPE.
Collecting optics (lenses, microscopes etc.) incorporate suitable means such as interlocks, filters, attenuators, to maintain radiation levels below MPE	☒	Beam blocks are attached behind optics to terminate stray beams.
Visible or audible warning device **prior** to entering the laser's controlled area, is used	☐	
Visible or audible warning device, usually a single red light located on the laser or its control panel, is used **within** the controlled area	☒	Sounds that arise from auxiliary equipment (e.g fan) and are associated with the emission of laser beam, can be considered as audible warnings.
Visible warning device signal is visible through protective eyewear	☐	
Establishment of laser's controlled area has been performed	☒	
Beam path is above or below eye level in any standing or sitting position	☒	
Curtain, screen or blocking barrier, is used to prevent laser beam from exiting controlled area	☒	Blocking barriers are used
Class 3b and 4 lasers shall be operated, maintained and serviced only by authorized personnel	☒	Only authorized users operate the laser.
Spectators are permitted within the laser controlled area only with the approval of the laser supervisor	☒	No spectators are allowed to use the laser.

For fully and limited open beam lasers, hazard analysis is performed by LSO for determination of the nominal hazard zone (NHZ). For enclosed beam lasers, the requirements of Class 1 are fulfilled and no further controls are required.

6

Additional control measures / Measures

Laser system is enclosed. Beam can be considered open from the laser aperture till the end of the beam path. Beam is passing through lenses in the open air and thus the laser system is classified as a Class IV.

Please provide a description of the exact procedure that you follow in order to start-up, operate and shut-down the laser system. If you just follow the instructions from the user manual then provide the page's numbers. All laser users shall have easy access to the SOP's and user's manual, therefore ensure that everyone knows their location.

Coherent Verdi 10 is a diode pumped solid state laser with a wavelength of 532nm. It is capable of delivering up to 30 watt of continuous wave radiation. For our experiment we place the laser within 1 meter from the operating field. Blocking barriers are placed peripherally of the laser. Connect the power cord and the computer program, which start-up the laser. We check the laser alignment, we energize the laser at the minimum possible power of 1W as a test exposure, in order to determine the beam path, and then we increase at the nominal power value. A Power meter is connected to the beam, which shows the beam power. We can adjust the output of the laser through the system. If there are stray beams or loss of output from any reason, we can find out from the output value displayed in the computer. Moreover, an error message will be displayed. Appropriate safety goggles are worn prior and during laser operation. The laser is operated for 3 hours per day. To shut down the laser we select the right option from the computer. For running the laser pages 55-58 are followed from the user's manual. User manual are located next to the computer and is easy accessible to all authorized users.

Maintenance – Service

Maintenance refers to frequently required tasks, such as cleaning and replenishment of expendables. Maintenance may or may not require beam access. Service functions are usually performed with far less frequency than maintenance functions (these may include replacing the laser resonator mirrors or repair of faulty components) and may require access to the laser beam by those performing the service functions. Service functions are delineated in the service manuals of the laser or laser system.
The LSO shall confirm that service personnel have the education and safety training to apply service to the laser system. All enclosures, interlocks, and safety devices must be replaced and verified operational prior to returning the laser to regular use.

Who is responsible for maintenance and service of the laser system?

Laser supervisor is responsible for maintenance and service of the laser. Instructions from the respective chapters of the user's manual are followed.
All other authorized users are responsible to maintain the safe operation of the laser and to indicate possible deficiencies to the supervisor, but they are not responsible for providing service to the system.

There is a danger of electrical shock when the laser's housing is removed.

I have read and understood the above procedures, my responsibilities as a user, the hazard that can be caused by the laser operation. As an authorized user of this laser I agree to operate the laser following the user's manual and the above procedures.

Name	Signature	Date
Tom Jones		8-6-15
Bill Paterson		8-6-15

CERTIFICATE OF FITNESS APPLICATION TEMPLATE

Fire Department, City of New York • Bureau of Fire Prevention

CERTIFICATE OF FITNESS APPLICATION

PLEASE PRINT ALL INFORMATION CLEARLY
(See reverse for important information)

SOCIAL SECURITY NUMBER	ENTER THE TYPE OF CERTIFICATE APPLYING FOR:	OFFICIAL USE ONLY
___-___-____	TYPE: _____	INACTIVE: _____

LAST NAME	FIRST NAME	M.I.

DATE OF BIRTH	GENDER	DAYTIME PHONE NUMBER
__-__-____	☐ MALE ☐ FEMALE	___-___-____

MAILING ADDRESS	APT	CITY	STATE	ZIP CODE

HEIGHT	WEIGHT	EMAIL ADDRESS
-		

EXPERIENCE TYPE (CHECK IF APPLIES)	EXPERIENCE-LENGTH OF TIME
☐ PRACTICAL EXPERIENCE REQUIRED ☐ TRAINING SCHOOL REQUIRED	____ YEARS ____ MONTHS

COMPANY AND WORK ADDRESS INFORMATION

APPLICANT'S COMPANY NAME

FALSIFICATION OF ANY STATEMENT HEREIN IS AN OFFENSE PUNISHABLE BY FINE OR IMPRISONMENT OR BOTH (NYC PENAL LAW ARTICLE 175)

APPLICANT'S WORKSITE ADDRESS	CITY	STATE	ZIP CODE

APPLICATION MUST BE SIGNED TO BE PROCESSED

X _____
APPLICANT'S SIGNATURE DATE

OFFICIAL USE ONLY (DO NOT WRITE BELOW THIS LINE)

DATA ENTRY FDNY PERSONNEL: _____ (INITIALS)

TEST RESULT: ☐ PASS _____ ☐ FAIL _____

A-20 form (05/18)

EXAM INFORMATION

- The application for Certificate of Fitness is available at FDNY Headquarters, 9 MetroTech Center, Brooklyn, NY. Enter through the Flatbush Avenue entrance (between Myrtle Avenue and Tech Place).
- Government issued photo ID is required to enter the building (examples: non-driver's license, driver's license, passport, or an IDNYC Municipal ID Card.
- Before entering the FDNY Headquarters, all visitors and their items that enter the building are screened. The following items are **not allowed** in the FDNY Headquarters: weapons, metal utensils, sharp or pointed tools including Leatherman type tools.
- Written exams without appointments are conducted Monday through Friday (except legal holidays) 8:00 AM to 2:30 PM.
- Written exams requiring an appointments are available at 2:45pm, 5 days a week (M-F) except legal holidays. Appointment can be scheduled on the following website: http://www1.nyc.gov/site/fdny/business/all-certifications/cof-online-scheduler.page
- Individual appointments for most Certificate exams are not required except the following exams: **F89, F80, Q01, P13, S11, S12, S13, S14, S15, S56, S98.**
- Groups of ten (10) applicants or more MUST schedule an afternoon appointment, for all exams. Applicants of a group that do not schedule an appointment will not be processed to take an exam.
- Exams are "touch screen" computer-based multiple choice tests. **Exams are only offered in English. Paper copy dictionary is allowed. No other outside papers, books, or electronic devices may be used during the test.**
- Applicants requesting oral tests must telephone for an appointment at 718-999-1988.

APPLICATION FEE

- Pay the application fee in person by one of the following methods: cash, credit card (*American Express, Discover, MasterCard, or Visa*), debit card (*MasterCard or Visa*), personal or company check or money order (*made payable to the New York City Fire Department).* A convenience fee of 2.49% will be applied to all credit/debit card payments. **The fee for most exams is $25, but few exams may vary. Please read study guide/Notice of Exam (NOE) for more information.**
- For fee waivers submit: ***(Only government employees who will use their C of F for their work- related responsibilities are eligible for fee waivers.) (1)*** A letter requesting the fee waiver on the Agency's official letterhead stating applicant's full name, exam type and premises address; ***AND (2)*** Copy of identification card issued by the agency.

ORIGINAL APPLICATIONS (MINIMUM QUALIFICATIONS)

1. Applicants must be at least 18 years of age.
2. Applicants must have a reasonable understanding of the English language.
3. Applicants must submit a letter of recommendation from the applicant's employer/prospective employer. Such letter shall be on the letterhead of such employer and signed by the employer (and indicate such officer's title); contain the following information:
   - the full name of the applicant
   - the length of time the applicant has been known to the employer
   - employment/ training and the length of time such employment
   - the building address where the Certificate will be used
   - information attesting to the character, relevant or required work experience or training of the applicant and the applicant's physical condition to perform required duties.
4. Applicants not currently employed may take the exam without the recommendation letter. If the applicants pass the exam, FDNY will issue a temporary letter with the picture for the job seeking purpose. However, a letter from an employer will be required before a Certificate is issued.
5. Applicants must provide two forms of identifications; at least one form of identification must be government issued photo identification, such as a State-issued Drivers' License or Non Driver's License or a passport.
6. Different Certificates may require other additional documents or qualifications, please look in the study material/NOE for more information.

RENEWALS

1. A Certificate may be renewed 90 days before the expiration date.
2. A Certificate that has exceeded 1 year from the expiration date cannot be renewed. Applicants must apply for a new Certificate.
3. The renewal fee is $15. After 90 days (up to one year) from the expiration date an additional $25 penalty will apply. **A convenience fee of 2.49% will be applied to all credit/debit card payments.**
4. Most Certificates can be renewed **On-line, by mail or in Person.**
   - To renew online
     Visit: https://a836-citypay.nyc.gov/citypay/FDNYCOF
   - To renew by mail
     Mail all the required documents along with the fee payment to: NYC Fire Department (FDNY) Cashier's Unit, 9 MetroTech Center, 1st Floor Brooklyn, NY 11201
   - To renew in person
     Submit all the required documents along with the fee payment at FDNY Headquarters, 9 MetroTech Center, Brooklyn, NY.
5. Fee exempted applicants cannot renew online, only by mail or in person. The fee waivers must submit: ***(Only government employees who will use their C of F for their work- related responsibilities are eligible for fee waivers.) (1)*** A letter requesting fee waiver on the Agency's official letterhead stating applicant full name, exam type and address of premises; ***and (2)*** Copy of identification card issued by the agency.

For more information call 718-999-1988 & study material visit http://www1.nyc.gov/site/fdny/business/all-certifications/all-certifications.page

ANNEX VIII-B

CERTIFICATE OF FITNESS EMPLOYEE AFFIRMATION

Revised 5-7-14

Certificate of Fitness Alternative Issuance Procedure - Employee Affirmation Form

This form must be completed by the applicant for the application to be valid.

Application can be submitted individually or through an employer. Please type or print legibly and place an "X" in the applicable box:

□ **Individual** *(Notarization of this application is required) (Complete Section 1, 2, and 4)*
□ **Employer** *(designated coordinator) (Complete All Sections 1, 2, 3 & 4)*

Instructions: Please type or print legibly. Place an "X" in the boxes next to the Sections statements to which you affirm.

Section 1: Personal Information *(required for all applicants)*

First Name: _____ **Last Name:** _____ **Last 4 digits of SSN: XXX-XX-**__ __ __ __
Certificate(s) of Fitness (names or category numbers): _____
Employer Company name: _____
Address_____ **City** _____**ST**_____ **Zip Code**_____

Section 2: Education and Experience *(required for all applicants)*

□ I affirm that:

- I have received training and I understand the pertinent:
  1. Fire Code sections _____
  2. Fire Department rules section _____
  3. National Fire Protection Association _____
- I have studied _____ -_____ study material that apply to this Certificate of Fitness test. I understand that I may be tested on the material.
- I thoroughly know the fire protection systems and other fire safety equipment and procedures at my work location.
- I have not taken and failed the examination for the Certificate of Fitness for which I am applying.

Section 3: Affirmation Granting Authority to Act *(Complete this section ONLY if your employer is submitting the application for you)*

□ I affirm that:

- I hereby authorize my employer to represent me before the City of New York in connection with my Certificate of Fitness application(s).
- I understand that I will be legally bound by what is stated in the application(s), and will be responsible for any false statements or inaccurate information.
- If I wish to cancel this authorization to act on my behalf I must do so by writing to the FDNY Director of Licensing, at 9 MetroTech Center, Brooklyn, NY 11201, or by going to the Licensing Unit at that address.

Section 4: Statements and Signatures *(Notary signature and seal is required for individual applicant)*

I understand that I will be legally bound by what is stated in the application(s), and will be responsible for any false statements or inaccurate information. I hereby do solemnly swear under oath and subject to penalty of perjury that the information provided by me in this document is true and accurate to the best of my knowledge.

_____ *Applicant's print name*	Notarization *(required for individual applicant)* State of New York, county of: Sworn to or affirmed under penalty of perjury _____day of _____ 20_____	Notary Seal
_____ *Applicant's signature*	Notary Signature	
_____ *Date*	_____	

ANNEX VIII-C

CERTIFICATE OF FITNESS EMPLOYEE STATEMENT

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Date _____

New York City Fire Department
Bureau of Fire Prevention
9 Metro-Tech
Brooklyn, New York 11201 – 5884

To Whom It May Concern:

I _____ request issuance of a Certificate of Fitness as a C-14 Laboratory Supervisor on the basis of a:

Type of Degree: _____ (BS, BA, MS, MA, MPH, PHD)

Degree In (Major): _____ (Medicine, Biology, Chemistry, etc.)

and _____ years of experience in Laboratory Facilities.

I will be employed at: _____ and I have been trained in Fire Code sections 2701-2703 & 2706, the C-14 study material and applicable sections of NFPA 45 (2004 Edition) and that I am thoroughly familiar with the fire protection and fire suppression systems in the premises where I am employed, including portable fire extinguisher location and usage.

_____
(Signature)

_____
(Name Printed)

EMPLOYEE STATEMENT LETTER

ENVIRONMENTAL HEALTH & SAFETY 419 W. 119th Street, New York, NY 10027 212-854-8749

ANNEX VIII-D

CERTIFICATE OF FITNESS EMPLOYER RECOMMENDATION

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Fire Department
Bureau of Fire Prevention
9 Metro Tech Center
Brooklyn, NY 11201-3857

Date: _____

To whom it may concern:

The purpose of this letter is to document the applicant _____ (full name of applicant) qualifications for a C-14 Certificate of Fitness. _____ (Name of the applicant) has _____(years), _____months) of experience in laboratory operations and will be working at _____ (name and address of employer)

Applicant has been trained how to safely store, handle or use of all hazardous materials available in the laboratory where the applicant will be employed. In addition, this applicant has been trained on the emergency plan, the plan includes:

(1) Procedures for activating a fire alarm;
(2) Procedures for notifying and coordinating with all emergency response agencies;
(3) Procedures for evacuating and accounting for personnel including primary and secondary evacuation routes, as applicable;
(4) Procedures for establishing requirements for rescue and medical duties for those requiring or performing these duties;
(5) Procedures and schedules for conducting regular emergency drills;
(6) Procedures for shutting down and isolating equipment under emergency conditions to include the assignment of personnel responsible for maintaining critical functions or for shut down of process operations;
(7) Appointment and training of personnel to carry out assigned duties, including steps to be taken at the time of initial assignment, as responsibilities or response actions change, and at the time anticipated duties change;
(8) Aisles designated as necessary for movement of personnel and emergency response;
(9) Maintenance of fire protection equipment; and
(10) Safe procedures for startup to be taken following the abatement of an emergency.

Applicant is of GOOD CHARACTER and is PHYSICALLY ABLE to perform the functions required by the holder of this Certificate of Fitness.

_____	_____	_____
(Printed name of Employer)	(Employer's title)	(Signature of Employer)

CORRECTIVE ACTION NOTIFICATION FORM

COLUMBIA UNIVERSITY
Environmental Health and Safety

Date: Date
To: (PI Name/Department)
From: Fire Life Safety EH&S
Re: FDNY Laboratory Inspection – Violation Order (VO)

FDNY CORRECTIVE ACTION NOTIFICATION FORM

On (date) the NYC Fire Department (FDNY) conducted a laboratory inspection of (Bldg, room) and issued a Violation Order (VO) for the item(s) listed below. Failure to correct the violation(s) by the due date noted below may result in a Notice of Violation (NOV) - a higher level citation - being issued, and may be subject to further escalation including a mandatory court hearing and fine. Once all violations have been corrected, please sign and date this Corrective Action Notification (CAN) Form in the space provided below and email/scan to fire-life@columbia.edu. Upon receipt, EH&S will complete the formal response to the FDNY.

For assistance, please contact fire-life@columbia.edu.

VO Number	Date Due	Safety and Compliance Issue
XXX12396	7/30/15	Location: (Bldg., room) Finding: FDNY flammable liquid limit (30 gallons) for a Type 1 laboratory was exceeded. Corrective Action: Ensure flammable liquids in excess of 30 gallons are removed from the laboratory.
XXX12378	7/30/15	Location: (Bldg., room) Finding: Flammable liquids stored in a standard (non-explosion proof) refrigerator. Specifically, a bottle of acetone was observed in the refrigerator. Corrective Action: 1. Remove flammable chemicals from non-explosion proof refrigerator. 2. Ensure that if flammable chemicals must be refrigerated, then an explosion-proof or flammable-proof refrigerator/cold room are utilized.

The corrective action(s) have been completed and any required documentation is attached.

Signature _____ P.I. Print Name _____ Date _____

Corrective action(s) confirmed by EH&S.

Signature _____ Print Name _____ Date _____

Updated August 2015; EH&RS/EH&S May 2007
Reviewed by EMS Research Work Group 4/17/07, 5/10/07 and 6/5/07; Legal Counsel; EVP Research, VP Research Operations and Sr. Associate Dean Health Affairs (CUMC) April and May 2007.

COLUMBIA UNIVERSITY
Environmental Health and Safety

Date: Date
To: (PI Name/Department)
From: Fire Life Safety EH&S
Re: FDNY Laboratory Inspection – Notice of Violation (NOV)

FDNY CORRECTIVE ACTION NOTIFICATION FORM

On (date) the NYC Fire Department (FDNY) conducted a laboratory inspection of (Bldg, room) and issued a Notice of Violation (NOV) for the item(s) listed below. Failure to correct the violation(s) by the due date noted below may result in a Summons and a subsequent mandatory court hearing and fine. Once all violations have been corrected, please sign and date this Corrective Action Notification (CAN) Form in the space provided below and email scan to fire-life@columbia.edu. Upon receipt, EH&S will complete the formal response to the FDNY.

For any assistance, please contact fire-life@columbia.edu.

NOV Number	Date Due	Safety and Compliance Issue
XXX12398L	7/30/15	Location: (Bldg., room) Finding: FDNY flammable liquid limit (30 gallons) for a Type 1 laboratory was exceeded. Corrective Measure: Ensure flammable liquids in excess of 30 gallons are removed from the laboratory.
XXX12379X	7/30/15	Location: (Bldg., room) Finding: Flammable liquids stored in a standard (non-explosion proof) refrigerator. Specifically, a bottle of acetone was observed in the refrigerator. Corrective Action: 1. Remove flammable chemicals from non-explosion proof refrigerator. 2. Ensure that if flammable chemicals must be refrigerated, then an explosion-proof or flammable-proof refrigerator/cold room are utilized.

The corrective action(s) have been completed and any required documentation is attached.

Signature _____ P.I. Print Name _____ Date _____

Corrective action(s) confirmed by EH&S.

Signature _____ Print Name _____ Date _____

Updated August 2015; EH&RS/EH&S May 2007
Reviewed by EMS Research Work Group 4/17/07, 5/10/07 and 6/5/07; Legal Counsel; EVP Research, VP Research Operations and Sr. Associate Dean Health Affairs (CUMC) April and May 2007.

COLUMBIA UNIVERSITY
Environmental Health and Safety

PROCESS FOR HANDLING an FDNY NOTICE OF VIOLATION (NOV)

(Approved by EMS Steering Committee 6/13/2007 and IHSC 6/14/2007)

1. FDNY issues a Notice of Violation (NOV) to Columbia University for violations found in a [permitted] laboratory and delivers it to EH&S.

2. EH&S delivers a copy of the NOV along with a Corrective Action Notification (CAN) Form to the Principal Investigator (PI) or Department designee within 24 hours of receipt. Notification includes itemized violation(s) and required corrective measure(s). Upon request, EH&S e-mails the CAN Form to the PI or designee.

3. PI or designee signs and returns the CAN Form (via hand-delivery or e-mail) to EH&S by Date Due noted on Form.

4. EH&S visits laboratory within two weeks of NOV issuance to assist with implementation of any corrective measure(s) and verifies that violation(s) have been corrected.

5. Upon receipt of the CAN Form and verification of corrections, EH&S completes and notarizes the FDNY Certificate of Correction portion of the NOV, along with the PI or designee signature and returns the NOV to the FDNY. EH&S notifies PI or designee of completed certification of the NOV via e-mail, including the NOV Number.

6. If the same citation is identified upon an ensuing FDNY audit of the NOV, the FDNY will issue a Summons for the repeat violation which will necessitate an in-person visit to the Environmental Control Board (ECB). An EH&S representative will accompany a Department representative (i.e., Departmental safety liaison, Administrator, Laboratory Manager) to attend the mandatory ECB hearing.

7. The University will pay any fine resulting from the ECB decision unless there are recurrent violations in the same laboratory. If there are recurrent violation(s), EH&S may refer all relevant documentation concerning the NOV to the Executive Vice President for Research (EVPR) for his/her review. If the EVPR determines that the PI has been grossly negligent or in willful violation of FDNY rules, the University will take appropriate action, which may include holding the PI responsible for any fine relating to such NOV. In all other cases the University will pay the fine provided the PI has demonstrated a good faith effort to prevent recurrence and sustain compliance.

8. This process, including review of the data collection on issued Notice of Violations (NOVs) and Violation Orders (VOs), will be reviewed by EH&S on a periodic basis for effectiveness.

Updated August 2015; EH&RS/EH&S May 2007
Reviewed by EMS Research Work Group 4/17/07, 5/10/07 and 6/5/07; Legal Counsel; EVP Research, VP Research Operations and Sr. Associate Dean Health Affairs (CUMC) April and May 2007.

HAZARDOUS MATERIALS APPENDIX E

Appendix E Number: AAAH1007
Created on: 10/20/2020
Created by: Christopher Pitoscia

GENERAL

I. General Information

The appendix will be:
Project Title:

III. Laboratory Locations

IV. Chemical Identification

V. Engineering and Administrative Controls

Containment Type:

Personal Protective Equipment (PPE): Additionally, Laboratory appropriate clothing, such as long pants and closed-toed shoes must be worn at all times.
Disposable gloves: [ ] Nitrile [ ] Latex [ ] Vinyl
[ ] Lab Coat
[ ] Safety Glasses/Goggles
[ ] Respirator

VI. Emergency Response

What are the emergency procedures in the event of personnel exposure?
Acute symptoms of exposure:
Actions taken in event of exposure:

Emergency procedures in the event of a spill (facility or environmental contamination):
Location of Spill Kit:
Actions taken in event of contamination/spill:

Methods for detecting contamination of skin, clothing, apparatus, etc.:
Is a biological toxin used?

Describe the use of the compounds in subjects, fill as applicable:
What is the biological 1/2 life of the administered compounds?
What is the toxicity (if any) of excreted metabolites?

Describe the excretion pathways and metabolic products of the compounds, if applicable:

If special waste containers must be used or specific waste instructions are to be given, please email hazmat@columbia.edu.
The OSHA regulation Occupational Exposures to Hazardous Chemicals in Laboratories (29 CFR1910.1450) requires that persons working with chemical(s) attend a Laboratory Safety and Chemical Hygiene Orientation (LSCHO) Session INITIALLY. These sessions are offered twice monthly by EH&S and can be scheduled locally if desired. It is also important to note that these initial trainings do expire and refresher trainings must be taken online through RASCAL.

PERSONNEL

Name(UNI)	Access Level	
Pitoscia, Christopher (cp2175)	Edit	
Trainings	**Lab Safety Haz Waste Int. (TC4951)**	**Lab Safety Haz Waste Refresher (TC0950)**
	Incomplete	08/19/2019

ATTACHMENTS

PROTOCOL/PROPOSAL

HAZARDOUS MATERIALS APPENDIX E1

Appendix E1 Number: AAAJ7155
Created on: 10/20/2020
Created by: Christopher Pitoscia

GENERAL

I. General Information

The appendix will be:
Project Title:

II. Amount and Equipment

Isoflurane Amount:
L/Min of Oxygen:

III. Laboratory Locations

IV. Hazard Control

The laboratory is utilizing at least one of the engineering controls listed while working with isoflurane:

[ ] Certified Chemical Fume Hood
[ ] Ducted Biological Safety Cabinet (Class II, Type B1 or B2)
[ ] Active Engineering Control (Vacuum Pump w/Charcoal Canister)
[ ] Passive Engineering Control (Charcoal Canister)
[ ] Laboratory works on an open bench top without any engineering controls and has been assessed by Environmental Health and Safety
[ ] Other:

The laboratory will be implementing one or all of the below administrative controls during work with isoflurane:

[ ] Utilization of a digital vaporizer
[ ] Lab will calibrate their isoflurane vaporizer from an outside vendor
[ ] Canisters will be weighed and the weights recorded before and after each use
[ ] Follow time limit guidelines as recommended by EH&S to minimize isoflurane exposure
[ ] Lab will limit ordering and on-site storage to amounts used
[ ] Canisters will be disposed of as hazardous waste

The laboratory will be utilizing the appropriate personal protective equipment including nitrile gloves, lab coat, and safety glasses or goggles:

[ ] Lab Coat
Disposable gloves: [ ] Nitrile [ ] Latex [ ] Vinyl
[ ] Safety Glasses/Goggles
[ ] Respirator

PERSONNEL

Name(UNI)	**Access Level**	
Pitoscia, Christopher (cp2175)	Edit	
Trainings	**Lab Safety Haz Waste Int. (TC4951)**	**Lab Safety Haz Waste Refresher (TC0950)**
	Incomplete	08/19/2019

ATTACHMENTS

PROTOCOL/PROPOSAL

ANNEX IX-C

HAZARDOUS MATERIALS APPENDIX E2

Appendix E2 Number: AAAI9153
Created on: 10/20/2020
Created by: Christopher Pitoscia

GENERAL

I. General Information

The appendix will be:
Project Title:

II. Chemical Used For

Chemical used for:

III. Type of Formalin/Formaldehyde

[ ] Formalin/Formaldehyde
[ ] Paraformaldehyde (PFA)

IV. Laboratory Locations

V. Hazard Control

The laboratory is utilizing at least one of the engineering controls listed while working with formaldehyde:
[ ] Certified Chemical Fume Hood
[ ] Glove Box
[ ] Downdraft Table
[ ] Ducted Biological Safety Cabinet (Class II, Type B1 or B2)
[ ] Laboratory works on an open bench top without any engineering controls and has been assessed by Environmental Health and Safety
[ ] Other:

The laboratory will be implementing one or all of the below administrative controls during work with formaldehyde:
[ ] Lab will limit ordering and on-site storage to amounts used
[ ] Proper storage and labeling of chemicals and hazardous waste
[ ] Work on an open bench top with amounts smaller than 0.1 mL
[ ] Work on an open bench top with amounts larger than 0.1 mL and have contacted Environmental Health and Safety at occusafety@columbia.edu

The laboratory will be utilizing the appropriate personal protective equipment including nitrile gloves, lab coat, and safety glasses or goggles:
[ ] Lab Coat
Disposable gloves: [ ] Nitrile [ ] Latex [ ] Vinyl
[ ] Safety Glasses/Goggles
[ ] Respirator

PERSONNEL

Name(UNI)	Access Level
Pitoscia, Christopher (cp2175)	Edit

Name(UNI)	Access Level	
Trainings	Lab Safety Haz Waste Int. (TC4951)	Lab Safety Haz Waste Refresher (TC0950)
	Incomplete	08/19/2019

ATTACHMENTS

PROTOCOL/PROPOSAL

LICENSE APPLICATION TO ENGAGE IN CONTROLLED SUBSTANCE ACTIVITY

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement

License Application to Engage in a Controlled Substance Activity

****PLEASE PRINT OR TYPE****

APPLICANT INFORMATION			CONTACT INFORMATION
Legal Name			Name
d/b/a			Title
Street *			Telephone
City			Fax
State	Zip	County	E-Mail
Controlled Substance License #		* If using a PO Box, a street address must be included.	

APPLICATION TYPE		
☐ NEW	Note: New applicants and those reporting a relocation or a change in ownership will be subject to an on-site facility inspection (excluding out-of-state applicants).	Date proposed for controlled substance activity to begin. _____/_____/_____
	☐ Name Change	Prior Name: New Name:
	☐ Address Change ☐ Postal Only ☐ Relocation	Prior Address: New Address:
	☐ Ownership Change	Prior Owner(s): New Owner(s):
☐ RENEWAL	☐ No Change since most recent license	
☐ AMENDMENT	Attach narrative outlining change(s) requested.	

LICENSE CLASSIFICATION (check only one box)			New License/ Renewal Fee	Amendment Fee
☐ Class 1 Manufacturer			$1200	$250
☐ Class 1a Manufacturer (Out-of-State)			$1200	$250
☐ Class 2 Distributor	☐ Check if Reverse Distributor		$1200	$250
☐ Class 2a Distributor (Out-of-State)	☐ Check if Reverse Distributor		$1200	$250
☐ Class 3 Institutional Dispenser	Operating Certificate #		$100	N/A
☐ Class 3a Institutional Dispenser Limited	Operating Certificate #		$100	N/A
☐ Class 4 Researcher (Schedules II-V)	☐ Individual	☐ Institutional	$40	$20
☐ Class 5 Instructional Activities (Schedules II-V)			$40	$20
☐ Class 7 Research/Instructional (Schedule I)	☐ Individual	☐ Institutional	$40	$20
☐ Class 8 Analytical Laboratory			$40	$20
☐ Class 9 Importer			$1200	$250
☐ Class 9a Importer Broker			$1200	$250
☐ Class 10 Exporter			$1200	$250
☐ Class 10a Exporter Broker			$1200	$250
☐ Class 11 Pharmacy - Automated Dispensing System (ADS)			NO FEE	N/A

Office Use Only

Cashline:

☐ Approved ___/___/___
☐ Other ___/___/___

Comment(s)

Reviewer:_____

- ✓ New York State, county and municipal agencies are **exempt** from licensing fees.
- ✓ Applicants registered with the New York State Board of Pharmacy (BOP) must submit a copy of their registration.
- ✓ Applicants registered with the Drug Enforcement Administration (DEA) must attach a copy of their registration.
- ✓ Class 1, 1a, 2, 2a, 9, 9a, 10 and 10a applicants must list all Schedule I controlled substances to be manufactured, distributed, imported and/or exported.
- ✓ Class 1, 1a, 2 and 2a applicants must provide the name, residential address, and title of each officer, director and any person having 10% or greater proprietary, beneficial, equitable or credit interest in the applicant.
- ✓ Class 3 and 3a applicants must **submit a copy** of their current authority to operate (i.e., Operating Certificate) issued by the Department of Health or other State agency.
- ✓ Class 4, 5, 7 and 8 applicants must submit specific information consistent with Sections 3325 and 3326 of the Public Health Law (see associated instructions).
- ✓ Class 11 Pharmacy – ADS applicants must submit a copy of their ADS policy.

DOH-4330 (8/16) Page 1 of 2

CONTROLLED SUBSTANCE PROTOCOL

Please complete and submit the following information along with ***License Application to Engage in a Controlled Substance Activity*** (DOH-4330) for Class 4 and 7 applications.

==========

Investigator:

(i) Curriculum vitae of the individual overseeing the controlled substance activity (Please attach cv).

Research project:

(i) Nature and objective of the project(s). (Provide a concise summary in the field below)

(ii) Name of the controlled substances involved and the amount of each needed.

(iii) DEA registration number of researcher ordering the controlled substances.*****

(iv) DEA registration number of the distributor or manufacturer providing the controlled substances.

(v) If animals are used in the research, please provide,

Specie	Number of animals	Dose Regimen (e.g., 10mg/kg, three times/week for five weeks)	Route of Administration

** Since DEA registration is obtained <u>after</u> a DOH license, first time license applicants can leave this blank.*

ANNEX X-C

SAMPLE DEA FORM 225

Form-225

APPLICATION FOR REGISTRATION
Under the Controlled Substances Act

APPROVED OMB NO 1117-0012
FORM DEA-225 (04-12)
FORM EXPIRES: 9/30/2021

INSTRUCTIONS

Save time - apply on-line at *www.deadiversion.usdoj.gov*

1. To apply by mail complete this application. Keep a copy for your records.
2. Mail this form to the address provided in Section 7 or use enclosed envelope.
3. The "MAIL-TO ADDRESS" can be different than your "PLACE OF BUSINESS" address.
4. If you have any questions call 800-882-9539 prior to submitting your application.

IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ON-LINE.

DEA OFFICIAL USE:

Do you have other DEA registration numbers?
☐ NO ☐ YES

MAIL-TO ADDRESS Please print mailing address changes to the right of the address in this box.

FEE FOR ONE (1) YEAR - see Section 2
FEE IS NON-REFUNDABLE

SECTION 1 APPLICANT IDENTIFICATION ☐ Individual Registration ☐ Business Registration

Name 1 (Last Name of Individual -OR- Business or Facility Name)

Name 2 (First Name and Middle Name of Individual - OR- Continuation of business name)

PLACE OF BUSINESS Street Address Line 1

PLACE OF BUSINESS Address Line 2

City | State | Zip Code

Business Phone Number | Point of Contact

Business Fax Number | Email Address

DEBT COLLECTION INFORMATION
Mandatory pursuant to Debt Collection Improvements Act

Tax Identification Number (*if registration is for business*)
Provide TIN or SSN. See additional information note #3 on page 4.

Social Security Number (*if registration is for individual*)

SECTION 2
BUSINESS ACTIVITY
Check one business activity box only
Researcher - See page 4 for required attachments

☐ Analytical Lab.....fee for one year is $244	☐ Exporter.....fee for one year is $1523
☐ Researcher w/Sched I.....fee for one year is $244	☐ Importer.....fee for one year is $1523
☐ Researcher w/Sched II - V.....fee for one year is $244	☐ Reverse Distributor.....fee for one year is $1523
☐ Canine Handler.....fee for one year is $244	☐ Manufacturer.....fee for one year is $3047
☐ Distributor.....fee for one year is $1523	☐ Manufacturer BULK.....fee for one year is $3047

SECTION 3
A. DRUG SCHEDULES
Check all that apply
Enter drug codes on page 2.

☐ List 1 (L1) - manufacturers & importers ONLY ☐ Schedule 2 Narcotic ☐ Schedule 3 Narcotic ☐ Schedule 4
☐ Schedule 1 ☐ Schedule 2 Non-Narcotic (2N) ☐ Schedule 3 Non-Narcotic (3N) ☐ Schedule 5

☐ Check this box if you require official order forms - for purchase of schedule 2 controlled substances.

B. MANUFACTURERS ONLY
Mark each box with an 'X' to indicate which drug schedule is handled in each manufacturing stage

L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 1 Bulk synthesis/extraction	L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 3 Package / Repackage Label / Relabel
L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 2 Dosage form manufacture	L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 4 Non-human consumption

NEW - Page 1

Schedule I Controlled Substance Protocol

Please complete and submit the following information in triplicate to US DEA long with your Registration Application (Form 225) for Schedule I Controlled Substances.

==========

Investigator:

(ii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications). Please attach.

Investigator's Name	Address	Institutional Affiliation	DEA Registration Number (if any)
		Columbia University	

Research project:

(vi) Title of Project and Statement of Purpose. (Provide a concise summary in the field below)

(vii) Name of the controlled substances involved and the amount of each needed.

(viii) Location where the research will be conducted.

(ix) DEA registration number of the distributor or manufacturer providing the controlled substances.

(x) If animals are used in the research, please provide,

Specie	**Number of animals**	**Dose Regimen and Project Duration (e.g., 10mg/kg, three times/week for five weeks)**	**Route of Administration**

(xi) Statement of the security provisions for storing the controlled substances (in accordance with *21CFR 1301.75)* and for dispensing the controlled substances in order to prevent diversion.

(xii) If the investigator desires to manufacture or import any Schedule I controlled substance, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.

Authority:

(i) Institutional/IACUC approval.

(ii) Indication of an approved active *Notice of Claimed Investigational Exemption for a New Drug* (number), if applicable.

(iii) Indication of an approved funded grant (number), if any.

HAZARDOUS MATERIALS APPENDIX I

Rascal Appendix I Datasheet

Appendix I Number: AABB9353
Created on: 09/01/2020
Created by: Christopher Pitoscia

GENERAL

I. General Information

The appendix will be:
Project Title:

II. Controlled Substances

III. Laboratory Locations

IV. Licensing Information

Is the Principal Investigator is in possession of a New York State Department of Health (NYS DOH) Class 4 (researcher, individual, schedules II-V) or Class 7 (researcher, individual, schedule I only)? This appendix must be accompanied by an attached copy of the PI's NYSDOH Controlled Substance license in the "Attachments" section.	No
The Principal Investigator is in possession of a Drug Enforcement Administration(DEA) registration?	No
DEA Registration #:	

PERSONNEL

Name(UNI)	**Access Level**
Pitoscia, Christopher (cp2175)	Edit
Trainings	**Controlled Substances (TC0502)**
	Expired

ATTACHMENTS

PROTOCOL/PROPOSAL

ANNEX X-F

STORAGE AND SECURITY RESOURCES

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Storage and Security Resources

Narcotic Locker Selection Guide and Spec/Pricing Sheets

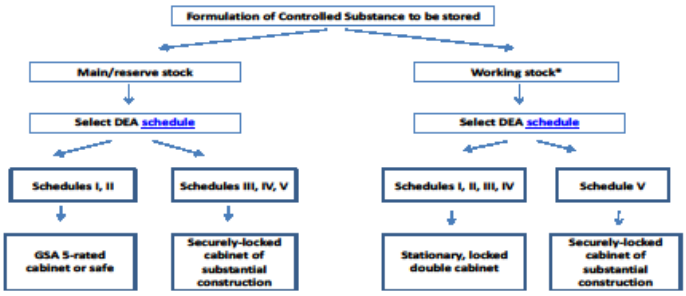
The University has contracted with Empire Safe, a locally-owned and operated distributor of secure storage units, to service researchers' controlled substance storage needs. The storage units located at the links below are designed to meet the requirements for the respective Schedules and formulations of controlled substances as determined by the Decision Tree. Please use the Decision Tree to select the storage unit that meets your needs, and select an option from the links that follow.

For questions, inquiries and to place orders for the storage units listed below, please contact Empire Safe:

- Gail Auger, Security Consultant – (212) 684-2255, x227; Cell (310) 923-1443
- email - gaila@empiresafe.com

For internal Columbia purchasing questions, please contact Procurement Services:

- Michelle Cooper, Contract Officer – (212) 854-7326
- email – mc3081@columbia.edu



Use this decision tree to determine the information to be added to page 2 of DOH Application Form 4330

*Please note – It is anticipated that most investigators will be handling/storing Working Stocks of Controlled Substances. Please contact EH&S to clarify if your quantity should be considered Working Stock.

Main Stocks – Schedule I and II

Working Stocks – Schedule I, II, III and IV

Working Stocks – Schedule V controlled substances

Additional Security Considerations

January 2010

ANNEX X-G

CONTROLLED SUBSTANCE RECEIPT LOG SCHEDULE I-II

COLUMBIA UNIVERSITY
CONTROLLED SUBSTANCES RECEIPT LOG SCHEDULE I-II

Licensed Individual: _____ **Laboratory/Storage Location:** _____

Date of Receipt	Name and address of vendor/distributor	Vendor's DEA #	Invoice or document reference #	Name of controlled substance	Quantity of controlled substance received	Number of units per container or package volume (e.g., 100 ml bottle or 20 capsule blister pack, etc.)	Total number of containers (e.g., 4 x 100-tablet bottles, 6 x 3 ml vials, 2 x 20 capsule blister packs, etc.)	Assigned internal container ID #s (shown as a range if more than 1 per line item)*

Notes:
*The PI/Licensed Individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001)
File a copy of the purchase receipt with this receipt log and mark the date of receipt on the invoice
Do not use abbreviations, except for standard metric units
All records must be maintained for a period of at least 5 years from the date of the last recorded purchase, transfer, use or other transaction per NYS Title Section 80.112(b)

Created December 2009, revised May 2011

ANNEX X-H

CONTROLLED SUBSTANCE RECEIPT LOG SCHEDULE III-IV

COLUMBIA UNIVERSITY
CONTROLLED SUBSTANCES RECEIPT LOG SCHEDULE III-V

Licensed Individual: _____ **Laboratory/Storage Location:** _____

Date of Receipt	Name and address of vendor/distributor	Vendor's DEA #	Invoice or document reference #	Name of controlled substance	Quantity of controlled substance received	Number of units per container or package volume (e.g., 100 ml bottle or 20 capsule blister pack, etc.)	Total number of containers (e.g., 4 x 100-tablet bottles, 6 x 3 ml vials, 2 x 20 capsule blister packs, etc.)	Assigned internal container ID #s (shown as a range if more than 1 per line item)*

Notes:
*The PI/Licensed Individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001)
File a copy of the purchase receipt with this receipt log and mark the date of receipt on the invoice
Do not use abbreviations, except for standard metric units
All records must be maintained for a period of at least 5 years from the date of the last recorded purchase, transfer, use or other transaction per NYS Title Section 80.112(b)

Created December 2009, revised May 2011

ANNEX X-I

CONTROLLED SUBSTANCE USE LOG

COLUMBIA UNIVERSITY
CONTAINER SPECIFIC CONTROLLED SUBSTANCE USE LOG*

PI/Licensed Individual: _____ Assigned internal container ID #: _____ Starting amount (include units of measure): _____

Laboratory/Storage Location: _____ Name of controlled substance: _____ Concentration in finished form (e.g., ug/ml, mg/ml, mg/tablet): _____

Schedule I or II (yes/no): _____

Date of Use	Previous Balance	Quantity Used	New Balance	Name of User (Print Full Name)	Use of Controlled Substance**

Notes:
*The PI/Licensed individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001)
**Protocol number may be used or example of application such as mouse anesthetic.
New Balance = previous/starting balance - quantity used. The previous balance is the amount on hand since the last use of the substance.
All record entries must be in English.
Do not use abbreviations, except for standard metric units

Created December 2009, revised May 2011

ANNEX X-J

CONTROLLED SUBSTANCE BIENNIAL INVENTORY FORM

COLUMBIA UNIVERSITY
CONTROLLED SUBSTANCES BIENNIAL INVENTORY FORM*

DEA Registrant Name: _____ **DEA Registration #** _____ **NYSDOH License #** _____

Date of Inventory: _____ **Time of Inventory:** _____ (must be taken at start or end of business day)

	Name of Controlled Substance	Form of Controlled Substance *(e.g., tablet, capsule, solution, etc.)*	Concentration per unit or container *(e.g., 10mg/tablet, 10 mg/ml, etc.)*	Number of units per container or package volume** *(e.g., 100 ml bottle or 20 capsule blister pack, etc.)*	Total number of containers *(e.g., 4 x 100-tablet bottles, 6 x 3ml vials, 2 x 20 capsule blister packs, etc.)*	Total content of all packages	Additional Information (NDC #, Lot #, Expiration Date, Internal reference #)
1st substance inventoried **							
2nd substance inventoried							
3rd substance inventoried							
4th substance inventoried							
5th substance inventoried							

*Biennial inventory must be taken every 2 years from the initial receipt of controlled substances and subsequently within 2 years of the previous biennial inventory *(DEA Title 21 CFR, Section 1310.11 and NYCRR Title 10, Section 80.112)*.

**All closed/intact containers or packages of the same controlled substance (i.e., form, concentration, etc) may be inventoried together as a single entry. Containers or packages that have had substances removed (i.e., for use, transfer or disposal), must be inventoried as a separate entry from closed/intact containers.

Notes:
Biennial Inventory Forms must be maintained for at least 5 years from the date of last purchase or transfer
All entries must be made in English
Do not use abbreviations, except for standard units of measure

Created December 2009, revised May 2011

CHAIN OF CUSTODY DOCUMENT TEMPLATE

Chain of Custody (COC) Document

Instructions:

ALL TRANSFERS MUST BE RECORDED

- All intercampus transport of controlled substances must be recorded in the Chain of Custody (COC) document.
- The COC document must be reviewed and signed by Principal Investigator.
- The COC document must be filed in a logbook for future reference.
- Public Safety maintains their own internal documentation.

Signature of Principal Investigator: _____ Date: _____