

# **Laboratory Commissioning**

#### Guideline

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**Applies To**: Any researcher moving into laboratory space.

The University of Michigan requires that all newly assigned laboratory space receive a <u>commissioning</u> visit by the UM department of Environment, Health & Safety (EHS) staff in order to consult with the research team working in the space regarding potential hazards, methods to reduce the risk, training requirements, and proper use of protective equipment. The purpose of the consulting visit is to foster a strong safety partnership with the research staff in order to protect individuals and the facility, and to help ensure regulatory compliance. This guideline is issued under authority of the Executive Director of Environment, Health & Safety.

#### **Table of Contents**

Table of Contents	1
Summary	1
Scope	2
Reference Regulations and Policies	
Glossary of Terms	2
Responsibility	2
Departmental Chair	3
Facility/Department Managers, Key Administrators, or Chief Department Administrators	
Faculty, Lab Directors, and Authorized Users	
EHS	
Procedures	4
Related Documents	б
Technical Support	
••	
Additional Information	7

# **Summary**

A strong culture of safety in our research community is just one of many overarching goals for the University. The ultimate goal is that everyone gets to go home at the end of the day as healthy as when they arrived. Responsibility for safety touches everyone throughout the entire organization from the Executive Officers of the University on down through the individual technicians working in the

**Laboratory Commissioning** 

Issue Date: 03/08/16

**Back to Table of Contents** 

Page **1** of **7** 

laboratory. However, in research, the Faculty, Laboratory Director and Authorized Users have a special responsibility for ensuring everyone in the laboratory follows proper safety policies.

Setting up a new laboratory operation is a daunting task and learning about the University policies on safety can be difficult, but the first introduction to them should be an uncomplicated and beneficial process. This laboratory commissioning guideline will help you identify the applicable requirements and provide resources to meet the goals of the program. It also provides an opportunity for all researchers to raise questions or concerns on various health and safety topics.

The first step simply consists of providing EHS with the basic information requested on the Pre-Commissioning Consultation Form (Appendix A). Upon receipt, EHS consulting staff will contact you to set up a time to walk through your operation, assist with identifying potential hazards, provide recommendations on appropriate control measures, and confirm that proper controls are already available and operational in the facility.

The timely submittal of this checklist will permit EHS to best assist you. Please allow at least four weeks prior to starting your operations, so your staff have time to obtain the appropriate training and prepare documentation that might be necessary.

### Scope

This Guideline applies to any researcher moving into laboratory space. This includes relocating between buildings on campus or to another laboratory within the same building. It also applies to new rooms added to a current lab and/or non-lab space repurposed as lab space. **Note that this guideline does not apply to U-M Hospital clinical laboratories**.

## **Reference Regulations and Policies**

- MIOSHA Hazardous Work in Laboratories: MIOSHA Part 431
- MIOSHA Hazard Communication ("HazCom") MIOSHA Part 430
- Respiratory Protection: MIOSHA 451
- NRC Materials License No. 21-00215-04
- NRC Regulations: 10 CFR 20.1404 & 10 CFR 30.4
- UM Standard Practice Guides 605.01 and 605.02

## **Glossary of Terms**

Commissioning – The formal activation of a laboratory assuring the safety of the occupants and the facility. The commissioning process will involve an inspection or meeting by applicable EHS staff such as Research Health and Safety (RH&S), Biological Safety, Hazardous Materials Management (HMM), or, Radiation Safety Service (RSS).

# Responsibility

Everyone working at the University of Michigan has the right to expect a safe and healthy work environment. They also have a responsibility to help assure a safe and healthy environment for themselves and others. Details of these are in the University of Michigan Academic Laboratory and

<u>Research Safety Policy</u>, issued jointly by the Department of Environment, Health & Safety (EHS) and the Office of Research Ethics & Compliance (UMOR). Please click on the Policy link to view role specific responsibilities including but not limited to the following categories:

- All Faculty, staff, other employees and students
- Graduate Student Research Assistants/Trainees
- Post-Doctoral Trainee/Fellow
- Laboratory Director (Faculty/Lab Manager/Supervisor)
- Department Chair
- Facility Managers/Department Managers/Key Administrators/Chief Department Administrators
- Unit (School/College/Department) Safety Coordinators

Additional responsibilities specific to the implementation of this guideline follow.

#### **Departmental Chair**

- Notify the Faculty, Lab Director, or Authorized User of this guideline and the need to notify EHS for a
  commissioning visit when a new laboratory or new major process is ready to begin operations to
  ensure safety and environmental measures are in place.
- Assist, as needed, in preparing the laboratory for safe research activities.

# Facility/Department Managers, Key Administrators, or Chief Department Administrators

Assist Faculty and Laboratory Managers with accomplishing corrective actions, maintenance, repair, or renovation procedures in order to correct infrastructure issues that affect safety or environmental compliance in the academic and research areas.

Ensure adequate security measures are in place to meet Federal security requirements on select research materials or operations.

Educate yourself on the procedures and notify EHS when a new laboratory or new major process is ready to begin operations to ensure safety and environmental measures are in place.

## Faculty, Lab Directors, and Authorized Users

- Oversee the safety of all members of the research group, as well as individuals visiting the lab, to
  ensure that best practices are observed. In today's highly collaborative research environment,
   Faculty Members must be vigilant to ensure that compliant safety practices are observed in all labs
  where students and trainees do collaborative experiments and share resources.
- Set the tone for health and safety practices in the classroom and laboratory; and advise or report to supervisors or instructors any potentially unsafe practices or serious hazards.
- Identify potential hazards, emergency procedures, and proper protective equipment and ensure their use as common practice.
- Keep accurate records to validate completion of appropriate training.
- In cases of clinical research, the clinical lab setting brings a unique set of challenges and the Faculty/Lab Director must ensure that special safety needs of clinical research employees and

- subjects are appropriately addressed. In addition to this guideline, Clinical Research Faculty must also adhere to UMHS policies and procedures.
- Implement and document appropriate safety policies and procedures in accordance with the U-M Chemical Hygiene Plan (CHP).
- Ensure that adequate facilities, ventilation, and equipment are provided for the safe use of hazardous materials.

#### **EHS**

- Collaborate with and provide assistance to University departments to promote a safe and healthful workplace, protection of the environment, and compliance with applicable rules and regulations.
- Publish policies and guidance, and provide assistance and training.
- Perform inspections of campus facilities and operations and report safety and environmental
  concerns to the appropriate unit for corrective action. Elevate unresolved issues to University
  administration, appropriate oversight committees, or appropriate school or college administration
  as necessary.
- Work in partnership with units to develop safety and environmental protection procedures, to
  determine proper equipment and controls, and to resolve health, safety, and environmental issues
  and concerns in a timely manner.

#### **Procedures**

## I. Laboratory staff will:

- Notify EHS a minimum four weeks prior to beginning research within a University laboratory or relocating/expanding into other laboratory space within the university. The notification is simple; complete the <u>Pre-Commissioning Consultation Form</u> (Appendix A) and click on the "submit" button. This will send the checklist directly to EHS to begin the process.
- 2. Read and become familiar with the U-M <u>CHP</u> and prepare laboratory-specific documents to place into the <u>EHS Document Binder</u>.
- 3. Identify hazardous conditions or operations in the lab for discussion with your EHS consultant, and complete a list of hazardous chemicals in the lab using Mi Safety Portal (MISP).

## II. EHS staff will:

- 1. Receive the Pre-Commissioning Consultation Form submitted in item I-1 above, and assign appropriate staff to the lab based on the information provided by the Faculty or Lab Director. They will schedule a consulting visit with the lab to review the information provided in the checklist and provide advice on hazard mitigation, necessary protective measures, appropriate training requirements, and any other safety or environmental related questions the lab staff may have. This visit needs to be a very interactive, collaborative discussion in order to build a strong safety partnership.
- 2. Provide or assist with scheduling appropriate safety training for the laboratory staff or advice on other training needs that are outside of the EHS purview.
- 3. Assist with scheduling chemical or radioactive stock transfers, if transfers involve movement between unconnected buildings.

- 4. Provide information on how to schedule collection of hazardous wastes (chemical, biological, and radioactive) generated by the lab, and how to obtain appropriate packaging materials for waste collection, including waste labels and manifests.
- 5. Provide assistance with laboratory site evaluations and certification of engineering controls such as fume hoods, biological safety cabinets (BSCs), and local exhaust ventilation.
- 6. Notify the Faculty, Lab Director, Authorized Users, Facilities Management and the Departmental Chair of any outstanding issues as they relate to safe laboratory research. The Faculty, Lab Director or Authorized User will be responsible for ensuring the satisfactory and timely completion of all corrective actions.

**NOTE**: Laboratory occupancy and/or some aspects of research may be prohibited until the laboratory has been re-evaluated and EHS has granted final approval.

### III. Lab staff will, prior to beginning operation:

- 1. Develop written Standard Operating Procedures (SOPs) for hazards beyond those identified in the CHP, where possible to know up front, including select carcinogens (also known and potential human carcinogens identified by IARC or NTP), reproductive toxins, and chemicals with high acute or chronic toxicity, highly reactive chemicals or higher risk experimental procedures.
- 2. Create an approval process for the use of restricted chemicals or procedures.
- 3. Ensure staff has completed the EHS, UMOR or ULAM required <u>safety training</u>. Train personnel on internal lab procedures to perform their work safely and maintain records of all training provided.
- 4. Maintain appropriate and functional personal protective equipment such as gloves, safety glasses, and lab coats.
- 5. Ensure the proper labeling, storage, and segregation of all chemical, biological and radiological materials and equipment.

# IV. Additional actions that may be necessary, depending on the research activity, prior to operation that requires specific authorization:

**NOTE**: The timeline for these approvals are generally not controlled by EHS and may be much longer than the 4-week notification for commissioning. To avoid delays in beginning research operations, make contact on these items as early as possible.

- 1. Radioisotope and Radiation Producing Equipment: Obtain approval from the UM Radiation Policy Committee (RPC) to become an Authorized User of radioactive material. Faculty intending to apply for approval for non-human use of radioactive materials must complete and submit to Radiation Safety Service (RSS) an Application for Authorization to Use Radioactive Material (RSS-101 Form). Prior to locating/relocating to the new facility, the Radiation Policy Committee (RPC) must approve new radioactive material laboratory locations. If approved, RSS will notify Authorized Users of approval, and process orders of radioactive materials. RSS will deliver the materials to the lab after receipt at EHS's offices. Machines capable of generating ionizing radiation must be registered annually with the Department of Licensing and Regulatory Affairs (LARA) prior to operation. RSS will process the registration and renewal applications for these machines.
- 2. Potentially Hazardous Biological Materials: Register and obtain approval from the <u>UM Institutional</u> <u>Biosafety Committee (IBC)</u> for all experiments using:

Issue Date: 03/08/16 Revision Date: 04/15/20

**Laboratory Commissioning** 

- Recombinant DNA and synthetic nucleic acid molecules (this includes <u>human gene transfer</u> studies)
- b. Infectious agents
- c. Biological toxins
- d. Human-derived tissues, fluids, cells
- e. Certain animal-derived tissues, fluids, cells
- f. Federally-regulated Select Agents, experiments with Dual Use Research of Concern potential, and research requiring BSL3 containment recombinant DNA (rDNA), non-recombinant infectious agents, biological toxins, and blood, body substances or cells from humans or non-human primates before initiation of experiments.
- 3. Review the U-M <u>Biosafety Manual</u> (BSM), which is applicable to all laboratory, research, teaching, and support activities that may involve biohazards. Biohazards are microorganisms, microbial toxins, or other biological agents that can infect or cause disease in humans, animals, or plants. Biohazards may include bacteria, biological toxins, viruses, fungi, rickettsia, prions, protozoans, parasites, genetically modified organisms, and recombinant or synthetic nucleic acid molecules. In addition, biohazards include human blood, body fluid, tissues, and cell lines of human origin and certain animal-derived tissues, fluids, and cells.
- 4. Bloodborne Pathogens: Review the U-M <u>Exposure Control Plan (ECP)</u>, which is applicable to labs employing various groups of employees who have a reasonably anticipated risk of exposure to human blood and other potentially infectious materials when performing their required job duties.
- 5. Lasers: Contact EHS regarding the purchase of any Class 3B or Class 4 lasers via the Request to Purchase a Laser Form. If Class 3B or 4 lasers will used in the lab, the RSS Laser Safety Officer will schedule a review of the laser operations including engineering controls, SOPs, and personal protective equipment (PPE).

#### **Related Documents**

- U-M Chemical Hygiene Plan
- Animal Handler Environment, Health & Safety Program
- Biosafety Manual
- Biological Safety Cabinets
- BL2 Inspection Checklist
- Compressed Gas Use
- Cryogenic Liquids Use
- Door Sign Request
- Engineered Nanomaterials
- Exposure Control Plan Bloodborne Pathogens
- <u>Laboratory Fume Hoods</u>
- Laser Safety
- Laboratory Self-Inspection Checklist
- Personal Protective Equipment, General
- Relocating Laboratory Hazardous Materials

**Laboratory Commissioning** 

Revision Date: 04/15/20

# **Technical Support**

All reference guidelines, regulations, and other documents are available through EHS (647-1143).

## **Additional Information**

- Planning Safe Research at U-M
- Research Resources
- Appendix A Pre-Commissioning Consultation Form