• Changes to BL2+ containment implementation •

In June 2014, the Institutional Biosafety Committee (IBC) voted to accept a proposal from Occupational Safety and Environmental Health (OSEH) Biological Safety to change the implementation of BL2+ containment for recombinant DNA research.

This change will include a gradual phase-out of the general BL2+ designation* in favor of targeted practices to enhance containment when this is deemed necessary by the IBC. OSEH has devised a set of **additional practices** that go beyond standard BL2 containment and that are each intended to mitigate the risks of specific experimental procedures.

Recombinant DNA work previously designated for BL2+ containment will be assessed by the IBC and OSEH, *as IBC submissions come forward and during the lab inspection process*, to determine whether additional specific biosafety practices (beyond BL2) are needed.

Adherence to BL2 containment standards will continue to be emphasized for all laboratories where BL2 containment is considered appropriate, as well as for all laboratories where additional biosafety practices are assigned. The **accompanying documents** from OSEH describe the UM standards for laboratories working at BL1 and BL2 as well as the new **Additional Practices** and the rationale for each.

**Please note that BL2+ remains an option in Section 12 of the registration due to eResearch system limitations.*

Questions about biosafety level standards and additional practices:
Contact OSEHBiosafety@umich.edu, or 734-647-1143.

Questions about IBC registrations:
Contact ibcstaff@umich.edu, or 734-936-3934.

Source: IBC, revised 9/24/14

UM OSEH Biological Safety
Designated Standards for UM Laboratories

Applicability of Standard Microbiological Practices

Standard Microbiological Practices (SMPs) are generally defined as the basic "hygiene" practices that apply to **all** labs, regardless of biosafety containment level, that manipulate microorganisms or any biological materials that contain microorganisms. SMPs serve to minimize the spread of contamination generated through lab processes and to protect both personnel and the environment. As such, they are often cited by regulatory and granting agencies such as NIH, CDC, OSHA, and USDA and APHIS as the minimum standards to be followed in biological research laboratories. Therefore, SMPs apply to a broad spectrum of lab activities including:

- Manipulation of any microbes including bacteria, viruses, fungi, and protozoa.
- Manipulation of materials that may contain microbes including animal and plant tissues, soil samples, and water samples.
- Receiving, processing, and testing of diagnostic samples.
- Research involving recombinant DNA molecules, transgenic animals, or genetically modified plants.
- Manipulation of animals or plants that are experimentally infected with microbes.
- Work with biological toxins and other bioactive molecules.

Biosafety Level 1 (BSL1) Standards

*Labs designated as **BSL1** follow the practices, PPE, and facility requirements outlined here:*

Standard Microbiological Practices (SMP)

- Hands must be washed after working and before leaving lab
- NO food or drink in lab
- Safe sharps handling procedures
- Perform all procedures to minimize splashes and aerosols
- Decontaminate infectious material before disposal
- Signage to convey hazards within lab
- Personal protective equipment must be worn
- Labs must control access
- Nonporous surfaces/ easily cleaned

Personal Protective Equipment (PPE)

- Gloves
- Lab coat while working in lab
- Protective eyewear

Facility Requirements

- Doors for access control
- Non-fabric chairs and furniture easily cleanable
- Sink required
- Screens for windows opening to the exterior

Biosafety Level 2 (BSL2) Standards*

*Labs designated as **BSL2** follow the practices, PPE, and facility requirements outlined here:*

Standard Microbiological Practices (SMP), AND the following BSL2 Practices:

- Limited access
- Sharps precautions
- Laboratory specific biosafety manual defining waste decontamination and medical surveillance policies
- Lab personnel demonstrate proficiency (training must be documented)

Personal Protective Equipment (PPE)

- Gloves
- Lab coat, gown, uniform required
- Protective eyewear
- Face protection for splashes when handled outside of a biosafety cabinet or containment device

Facility Requirements

- Laboratories must have a sink, the location of which may be in an adjacent lab space even if the space is not designated as BSL2. (Biosafety Office will determine if alternatives can be implemented)
- Doors that can lock, and work **must** be conducted with door(s) closed.
- Non-fabric chairs and furniture that is easily cleanable
- Screens for windows opening to the exterior
- Protected vacuum lines
- Autoclave available or alternative method for decontamination as approved by OSEH.
- Eyewash available –(no more than 10 seconds to reach, one door permitted to separate users from eyewash, door cannot have a lock and must open toward eyewash)
- Laboratories should be under negative or neutral pressure, new constructions should be designed to be negative with no recirculation of air to spaces outside of the lab.

**Additional Practices*

Biosafety level 2 research may require additional practices beyond those outlined above.
Additional practices are assigned based on a risk assessment of the research being conducted.

Questions or Concerns: Contact UM OSEH Biological Safety: OSEHBiosafety@umich.edu (734-647-1143)

Additional BSL2 Practices: Additional practices are assigned by the IBC and OSEH based on a risk assessment of the research being conducted.

All BSL2 labs that require additional practices will ALWAYS follow the bulleted practices listed below (*rationale in blue italics*), in addition to specific practices outlined in the IBC approval letter (example additional practices listed in the table below).

- **Daily decontamination of lab bench, equipment, and biosafety cabinet before and after use**

Good laboratory hygiene is expected at every containment level, requiring daily decontamination decreases fomites and reduces the risk of unintended exposures through regular lab contact with lab furniture.

- **Waste held in lab for transport to autoclave for immediate treatment**

Infectious waste that is taken to the autoclave and then left behind untreated because autoclave is in use poses safety hazards for those that may have to handle waste to move it.

- **Use of personal electronic devices prohibited i.e. devices and accessories for listening to music**

Devices can easily become contaminated by touching buttons or controls while working in the lab. Poor aseptic technique can contribute to cross-contamination and potential safety issues.

	SPECIFIC ADDITIONAL PRACTICES	**RATIONALE**
1	All work must be conducted in a biosafety cabinet.	Contain aerosols of infectious materials to prevent possible personnel exposures.
2	Pencils, pens, and note pads used in the lab must remain there. Care should be taken to prevent contamination of lab notebooks, if removed from lab.	Infectious agents that have a low infectious dose, or high concentrations of moderate to high infectious dose agents, can be easily transmitted if care is not taken when handling paper materials and other personal items that are used in the lab.
3	Double gloves used: outer gloves removed inside biosafety cabinet and inner gloves removed before leaving the lab. Hand sanitizer must be used, followed by hand washing with soap and water as soon as possible.	BSL2 facility with less than ideal access to required hand-washing sink. Double gloves in this situation help to prevent contaminated hand contact with lab doors or other common lab equipment or furnishings. Waterless hand sanitizers may be used as a temporary means of reducing contamination until a source of running water and soap can be reached.
4	Double gloves used and *Needle Injury Guide* posted.	The volume of infectious agent that personnel may be exposed to is significantly reduced by simply wearing two pairs of gloves during needle injections. Refer to the *Needle Injury Guide* for after care instructions.
5	Use of disposable lab coats or, alternatively, fabric lab coats that must be autoclaved prior to being sent out for laundry service.	To prevent unintentional exposure of laundry service personnel to lab coats contaminated with infectious agents that could be transmitted from handling soiled lab coats.
6	Spill kit stored in the lab and spill procedure posted.	Spill response materials must be immediately available and the SOP posted to inform lab personnel how to safely handle spills outside of BSC. This will prevent the need to leave the immediate area (possibly spreading spilled material) to locate spill clean-up materials and/or procedures.
7	Lab space must contain all equipment (e.g., centrifuge with safety cups, ultracentrifuge, microscope, shaker, sonicator, etc.)	Safely contain all techniques that may be utilized to conduct research with infectious agent to one lab space to prevent unintentional exposures. Recommended for high aerosol risk, easily transmitted infectious agents.
8	Dedicated lab coat or gown with knitted cuffs **or** disposable sleeves/arm guards, if lab coat does not have knitted cuffs, must be worn.	Designate a lab coat for specific use based on techniques used or infectious agent being manipulated, to ensure that contaminants on lab coat are not spread (e.g., contaminated lab coat taken to different lab space then placed on table or chair could contaminate furniture with fomites for unsuspecting personnel).
9	Administration of infectious agents to animals must take place in biosafety cabinet.	Contain aerosols of infectious materials to prevent possible personnel exposures.

These additional practices are not an exhaustive list and may be added to or altered based on risk assessment. Questions: OSEHBiosafety@umich.edu