

FACT SHEET

How to develop and write a Laboratory-Specific Standard Operating Procedure (SOP)

Lab-specific SOPs must be developed by all laboratories. These SOPs must be provided to the Institutional Biosafety Committee (IBC) for review and approval at the time the Principal Investigator (PI) registers their work with the IBC.

The IBC has developed detailed SOP/Biosafety Manual Templates for BSL-1, BSL-2 and BSL-2 enhanced (BSL-2+) laboratories that may be edited to meet the specific requirements of the laboratory. These can be accessed [here](#).

Prior to writing a Standard Operating Procedure (SOP) and initiating work with hazardous materials, the PI must conduct a Risk Assessment.

Guidelines on how to conduct a risk assessment for work with biological agents can be found [here](#) and summarized below. The risk assessment must take into account the intrinsic hazards of the agent, the effects of genetic modification on the pathogenicity of the agent, controls implemented to protect workers and their expertise and competence. Agent hazards are those risks that are intrinsic to the agent being handled such as the following:

- Capability to infect and cause disease in a susceptible human host.
- Severity of the disease
- Infectious dose
- Availability of preventative measures
- Availability of effective treatments
- How the agent is transmitted (i.e. route of exposure)
- Quantity, concentration, and total volume used
- Stability in the environment
- Zoonotic concerns
- Allergenicity

Exposure sources in the laboratory are hazards that could result in the infection of researchers or the public through work with biological agents. Some of the more common hazard considerations include the following:

- Aerosol generation (e.g. pipetting, mixing, blending, grinding, sonicating, vortexing, centrifuging, shaking)
- Manipulation with sharps
- Animal handling
- Contact with blood, bodily fluids, or other potentially infectious material
- Ingestion of agents via contaminated work areas
- Eye-splashes from liquid nitrogen storage

When performing a risk assessment of laboratory procedures, all potential routes of exposure should be addressed. Most laboratory-acquired infections have resulted from inhalation of aerosols, splashes or sprays, and needlesticks. It is good practice to look for potential exposures via ingestion, inoculation, inhalation, and contamination of skin and mucous membranes and attempt to identify safer alternatives and risk mitigation strategies.

A number of sources are available to assist in the risk assessment of biological agents, including [the Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 6th edition](#), [Pathogen Safety Data Sheets and Risk Assessment of the Public Health Agency of Canada](#), and the [Risk Group Database of the American Biosafety Association \(ABSA\)](#).

SOP Guidelines

The SOP must include:

- Date written, dates of revisions, name of person writing and/or editing the SOP
- Determine the types of exposure risk to the identified hazards that each step could present.
- Procedural materials and methods. These must be step-by-step procedures for all experiments and protocols and be sufficiently detailed to allow someone to complete the procedure.
- Descriptions of exposure controls:
 - * Administrative controls (e.g. required biosafety training, SOP, etc.)
 - * Engineering controls (e.g. biological safety cabinet, centrifuge secondary containment, sharps injury prevention, etc.)
 - * Personal Protective Equipment
 - * Work practices control (e.g. decontamination, immunization required or recommended, etc.)
- Biological waste disposal methods. Identify the types of wastes that will be generated and plan for how they will be treated/disposed of.
- Spill clean-up procedures.
- Exposure and accident procedures. List emergency procedures including location of emergency equipment, emergency contact information with phone numbers, and when and how to seek emergency medical care. Include who the worker should notify in case of an accident and how to file an accident report.
- Biosafety training requirements, including institutional training opportunities, such as Bloodborne Pathogen, BSL-2, ABSL-2 and Chemical Hygiene training, and lab-specific training: <https://ibc.utah.edu/training.php>.
- Record keeping requirements

Completed SOPs Must Be

- Used to train all new employees (remember to document training)
- Reviewed with employees as part of their annual laboratory-specific safety update training (document training)
- Reviewed annually for accuracy and completeness by supervisor and workers
- Available in the laboratory for worker reference
- Submitted with all IBC applications.

Refer to the [University of Utah Biosafety Manual](#) for additional guidance.

Adapted from University of Minnesota Guidance documents.



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