

FACT SHEET

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

Laboratories working at Biosafety Level 2 (BSL-2) or higher containment must create lab specific written standard operating procedures (SOP). These must be provided to the Institutional Biosafety Committee (IBC) for review and approval at the time the Principal Investigator (PI) registers the work with the IBC.

The IBC has developed detailed SOP/Biosafety Manual Templates for 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.

A detailed description of how to conduct a risk assessment for biological agents can be found [here](#) and summarized below. The risk assessment must take into account both the intrinsic hazards of the agent as well as considerations of individuals handling the agents, addressing the potential for emergent hazards from rDNA work, and hazards associated with the vectors used for insertions. 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:

- [Section VIII of the Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 5th 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: a template can be found [here](#)
- Exposure and accident procedures: a template can be found [here](#). 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, can be located on [Bridge](#). Lab-specific training. Institutional training opportunities can be identified on the [Research Administration Training Series \(RATS\)](#).
- 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. The IBC application in BioRAFT has sections requesting information that is part of the SOP. The PI may:
- Copy and paste the information from each relevant section of the SOP into the BioRAFT forms, or
- In the BioRAFT forms refer to the SOP, e.g, see Section XX of the SOP dated NN/NN/NNN

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



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