

*Insert Facility/Institute Logo Here*

**STANDARD OPERATING PROCEDURE (SOP) *TEMPLATE***

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| Facility: | |
| SOP Title: SOP to Develop, Evaluate, Validate, Approve, and Revise SOPs | |
| Document Number: | Version Number: *00*  Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this SOP (i.e., manuals, SOPs, forms, records):  Blank SOP Template  SOP Worksheet | |

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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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INSTRUCTIONS: The Shipping and Transportation Manual and supporting Standard Operating Procedure (SOP) templates provide a general overview of common considerations and information that should be addressed when shipping and transporting possibly infectious biological substances domestically or internationally, no matter the mode of transportation. These templates are not exhaustive; facilities must customize each document to ensure it is locally applicable and relevant.

* **Black text** can be considered generic text that may be appropriate for inclusion in a facility’s operations manual and SOPs.
* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.

1. Purpose
   1. This procedure should be followed to develop, evaluate, validate, revise, and approve standard operating procedures (SOPs) for employees and visitors at the *<facility name>*. SOPs should support the facility-wide policies and programs to promote a safe and secure workplace. The Blank SOP template is the starting point for all SOPs for common formatting and prompts for all require components, and the end result should be fully validated and approved Standard Operating Procedures.
2. Scope
   1. All authors or approvers of SOPs should follow this procedure during the development, evaluation, validation, revision, or approval of standard operating procedures.
3. Responsibilities
   1. **Scientific Manager/Director**: Approves drafted SOPs and ensures validation steps are followed. May request a revision to SOPs following incidents, near-misses, or when performance metrics or validation metrics indicate an issue. May be involved in facility-wide SOP development, or specific procedures which are part of the Scientific Manager’s daily duties.
   2. **Biological work technicians**: Drafts SOPs, participates in the evaluation and validation steps. Should draft revisions when procedures change, supplies change, new pathogens or equipment is introduced into the facility, or any other indicator that procedures are no longer valid, or at the request of the Scientific Manager.
4. Preparation
   1. Materials
      1. Blank SOP Template
      2. SOP Worksheet
5. Procedure
   1. Developing SOPs
      * 1. Biological work technicians routinely familiar with specific procedures should be assigned to the development of SOPs relating to that work.
        2. Biological work technicians use the SOP worksheet to document all the required components for an SOP.

Note: As technicians become more skilled at SOP development, they can skip the worksheet and move directly to the Blank SOP template.

* + - 1. Biological work technicians use the completed SOP worksheet to fill in the appropriate sections of the Blank SOP template
         1. Every SOP must answer the following questions:

Why should the SOP be used?

Where should the SOP be used?

What is the input (starting point) and output (desired result)?

Who should use the SOP?

When should the SOP be used?

* + - * 1. Every SOP needs to establish clear responsibilities.
        2. Every SOP should detail all assumptions for the starting point, including materials, equipment, supplies, possibly even skills or training required for personnel performing the procedure.
        3. The steps of the procedure should be short, direct, clear, and attainable.
        4. References or attachments for the use of the SOP should be included.
        5. Some procedures are more effective if a one page visual or flow chart is available to copy from the SOP and post near the piece of equipment or biological work area for the activity as a job aid. (i.e. donning/doffing order in the anteroom, or BSC use/cleaning adjacent to the BSC.)

Be certain that flow chart placement does not impede work or impact the operation of the equipment. (i.e. Do not block the front grill of the BSC, covering large sections of the sash of the BSC can limit field of vision, do not cover the cooling fan on the computer, do not place it on surfaces that must be frequently decontaminated, etc.)

Be certain job aids are listed as attachments in the SOP so they will be updated if the SOP is revised.

* 1. Evaluating SOPs
     1. Once the SOP is drafted, it should be given to a different biological work technician who is familiar with the procedure for review.
     2. This evaluator should review the written SOP for accuracy, ensuring all the components from the development step are adequately covered, and the steps are clear and concise.
     3. The evaluator should perform the procedure as written, and provide feedback to the author.
        1. If the procedure cannot be performed as written, the author must revise it.
        2. After revision, the SOP must be re-evaluated.
        3. This cycle continues until the SOP can be performed as written.
  2. Validating/Approving SOPs
     1. Once the SOP has been evaluated by someone familiar with the procedure, the Scientific Manager/ Director should be notified that it is ready for validation and approval.
     2. The Scientific Manager/ Director reviews the SOP for completion of components detailed in the development step.
     3. The Scientific Manager/ Director assigns a different biological work technician who is less familiar with the procedure to follow it, while under observation.
     4. The biological work technician follows the steps of the procedure while Scientific Manager/ Director observes.
        1. If procedure is performed successfully, Scientific Manager/ Director will sign or initial to approve, and effective date is given.
        2. If procedure is not performed successfully, the author must complete the development and evaluation steps again until it passes the validation step.
     5. Approved SOPs are distributed to those who perform the task described, and made readily available at a location near the equipment or activity described.
        1. *Training requirements for new SOPs can be detailed here, referencing training plan or SOP.*
        2. Flow charts or important reminders relating to SOPs are posted/updated, if necessary. (i.e. Wash Hands sign, waste segregation guidelines by disposal area, donning/doffing order in the anteroom)
     6. Once distributed, communication on expectation that SOPs must be followed is necessary.
        1. Communicate importance of SOPs: to keep employees safe and secure, to protect the environment from dangerous diseases, to protect families and community from exposure to dangerous diseases, etc.
        2. *Detail consequences for non-compliance with SOPs. Safety infractions and security infractions may have different consequences, or it may take certain number of minor infractions to trigger a consequence. Some SOPs could be so critical that any infraction triggers a major consequence.*
     7. Behavioral Observation Data (BOD) or other metrics should be determined to demonstrate compliance or performance of SOPs. These can be assessed for audits, performance, compliance, and to indicate revision or communication of SOP is necessary.

1. Examples of BOD:
   * + - * Proper PPE worn *(double gloves, buttoned lab coats, respirators or eye protection, as indicated by SOPs)*
         * Tracking supply inventory numbers (frequency of purchase of gloves or other disposable PPEs, biohazard disposal bags, bleach or other disinfectant, soap)

If ordering less than anticipated, or less than historically, it could indicate these supplies are not being used appropriately.

* + - * + Access Control observations (piggy-backing, keys left in doors, unmonitored visitors, lost keys, doors propped open, emergency exit used for non-emergencies, security guard routines)
  1. Revising SOPs
     1. Procedures should be reviewed and revised:

1. At least every other year to ensure accuracy and compliance.
2. If BOD or other metrics (including numerous “close calls”) indicate an SOP is ineffective.
   * If SOP review does not indicate a problem with the SOP as written, review training requirements, explore consequences of non-compliance, or work on communication or visibility of SOP requirements, including signage, creating a flow chart to display, or other job aids.
3. If new pathogens are introduced using similar techniques.
4. If new equipment is introduced into the biological work area(s).
5. If supplies are changed (new manufacturer, new product, changing materials).
6. When personnel changes impact the responsibilities section of the SOP
7. When an incident takes place (large spill, occupationally-acquired exposure, needle stick, security failure, disgruntled employee, etc.)
8. Revisions should follow the same evaluation and validation steps.
9. References
10. Attachments
    1. Blank SOP Template
    2. SOP Worksheet