

*Insert Facility/Institute Logo Here*

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

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| Facility: | |
| SOP Title: *Transport and Shipping Security SOP* | |
| Document Number: *SOP-009-OP* | Version Number: *01* |
| Process Leader: | Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this SOP (i.e., manuals, SOPs, forms, records):   * Biorisk Management Manual: (Chapter V, Biorisk Assessment; Chapter VI, Emergency and Incident Planning; Chapter VII, Personnel Management; Chapter IX, Facility Access Determination; Chapter X, Entry and Exit Procedures; Chapter XI, Facility and Infrastructure; Chapter XII, Equipment; Chapter XIII, Work Practices; Chapter XV, Material Control and Accountability; Chapter XVI, Physical Security Systems; Chapter XVII, Information Control; Chapter XIX, Waste Handling and Disposal; Chapter XX, Transportation and Shipping; Chapter XXI, Emergency and Incident Response, Reporting and Investigation; Chapter XXII, Biorisk Management System Assessment and Improvement) (*4-00-001*) * Biosecurity Program Plan (*6-01-001)* * Personnel Reliability SOP (*SOP-011-OP*) * Material Control and Accountability SOP (*SOP-010-OP*) * Physical Security SOP (*SOP-012-OP)* * Information Security SOP (*SOP-013-OP*) * Transportation and Shipping Safety SOP (*SOP-0XX-OP*) | |

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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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INSTRUCTIONS: The Biorisk Management Manual and supporting Standard Operating Procedure (SOP) templates provide a general overview of common considerations and information that should be addressed within a biorisk management system and program. These templates are not exhaustive and facilities must customize each document to ensure it is locally applicable and relevant. This SOP template provides guidance on the range of specific types of mitigation measures that can illustrate graded and balanced mitigations for information security. The Biosecurity Program Plan provides specific guidance on how physical security; information security; transportation and shipping; personnel management; and material control and accountability interact with each other (so that you are balanced between these focus areas and within this information security focus area), and what should be considered for full implementation of biosecurity in terms of each focus area. Each focus area should be addressed, as mitigation efforts in only one or a few focus areas are insufficient to provide adequate biosecurity.

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

1. Purpose

The purpose of this document is to establish the procedures for external transport and shipping security for *[Insert Facility Name]*. This procedure will ensure the safe, secure, and efficient implementation of a transportation system, supported by sound policies and procedures that enable it to be resilient and adaptive.

1. Scope

This document applies to all personnel and visitors within *[Insert Facility Name]*.

1. Responsibilities

* Top and Senior Management will:
  + aid an organization to develop and enforce a biorisk management program: a set of tools, information and associated actions that are overseen, enforced and continuously improved upon by an organization’s senior management. This will ensure that a biorisk management system is properly implemented and maintained
* The Biorisk Management Committee:
  + is an institutional committee created to act as an independent review group for biorisk management issues; it reports to senior management
  + membership on the biorisk management committee should reflect the different occupational areas of the organization as well as its scientific expertise
* Process Leader ensures that:
  + This SOP is established, implemented and maintained effectively to align with local, national, and international laws and agreements to provide security during transport and shipping processes
  + Authorized users are trained on this procedure and competent prior to reliance on the prescribed security measures
* Facility personnel:
  + Follow the procedures outlined in this SOP
  + Report any problems to the Process Leader
* Scientific *Manager/Director:*
  + Determines the materials, items and information to be secured during the transport and shipping processes based on risk assessment and applicable local, national, and international guidelines, standards, and regulations
  + Determines transport and shipping security policies and procedures that oversee and ensure the safe and secure movement of materials, items and information in-line with their risk assessment
  + Determines which personnel are given the authority to package, release, transport, ship, accept and unpack secured materials, items and information
  + Determines resource needs and oversees resource allocation that will be necessary to implement this procedure
* Security *Manager/Officer*:
  + Provides expertise on effective and proportionate biosecurity measures to the team for risk assessment; may support investigations into biosecurity incidents; may provide regular security checks; may liaise with law enforcement
* Biorisk Management Advisor:
  + Provides advice and guidance on biorisk management issues. The role and knowledge of the biorisk advisor is key to develop, implement, maintain and continually improve a biosafety and biosecurity program based on a management system
* Members of the Workforce:
  + All members of the workforce are responsible for the proper implementation of transport and shipping security measures

1. Preparation *(Anything that needs to be in place prior to commencing the procedure)*
   1. Materials

* Valuable and/or sensitive materials, equipment, information and information systems *(as defined by the Scientific* *Manager/Director to include collections and reference strains of especially dangerous pathogens, sensitive information storage cabinets or computers, expensive assets, dual-use equipment, etc.)*
* Packaging materials providing safety and security as required by risk assessment as well as local, national, and international guidelines, standards, and regulations
* Hazard labels (biohazard, corrosive hazard, flammable, etc.)
  1. Equipment
* *Computers (e.g., if using electronic material control and accountability or electronic shipping software)*
* Means for secure on-campus, local, regional, national and/or international conveyance *(e.g., security measures such as lockable containers, tamper prevention, monitoring, trusted courier, escort)*
  1. Records and Forms *(to be retained for a period of time [e.g., five years, three years after an employee leaves the facility] as defined by the Scientific Manager/Director)*
* Custody Forms
* *Hazardous Shipping* *Forms*
* *Shipping Bill of Lading*
* Shipping Management System *(e.g., paper-based/notebook, electronic/spreadsheet/database)* and associated form(s) to record transport, shipping, and receiving
* *Third party records (e.g., contracts, agreements, personnel backgrounds, physical security assessments and features of vendors, suppliers)*

1. Procedure *(refer to Attachment A, Transportation and Shipping Security SOP Template Flow Chart)*
   1. Identify Assets Requiring Transportation and Shipping Security
      1. Herein transport will refer to the movement of materials, items and information while in the custody of *[Insert Institution/Facility]*’s authorized workforce
      2. Herein shipping will refer to the movement of materials, items and information while outside the direct custody of *[Insert Institution/Facility]*’s authorized workforce
      3. *Describe steps to determine the material, information and items that need to be secured during transport and shipping using questions and comments from flow chart step 1*
   2. Describe Required Security Features of Packaging
      1. *Identify steps to describe required security features of packaging including a description of their adequacy (whether they provide low- medium- or high- security) using questions and comments from flow chart step 2*
   3. Describe Security Features of Existing Packaging
      1. *Identify steps to describe security features of existing packaging including a description of their adequacy (whether they provide low- medium- or high- security) using questions and comments from flow chart step 3*
   4. Identify Packaging Items Which Must be Acquired
      1. *Describe steps to search for, find and evaluate packaging materials to cover unmet needs in secure packaging using questions and comments from flow chart step 4*
   5. Describe Security Features of Required Transport Methods
      1. *Identify steps to describe required security features of the movement of* *materials, items and information while in the direct custody of facility personnel whether on-campus or in a member of the workforce-operated conveyance, including a description of their adequacy (whether they provide low- medium- or high- security) using questions and comments from flow chart step 5*
   6. Describe Security Features of Existing Transport Methods
      1. *Identify steps to describe security features of existing transport methods including a description of their adequacy (whether they provide low- medium- or high- security) using questions and comments from flow chart step 6*
   7. Identify Transport Methods Which Must be Acquired
      1. *Describe steps to search for, find and evaluate transport methods which should be acquired by the facility using questions and comments from flow chart step 7*
   8. Describe Security Features of Required Shipping Methods
      1. *Identify steps to describe required security features of the movement of* *materials, items and information while outside of the direct custody of facility personnel, including a description of their adequacy (whether they provide low- medium- or high- security) using questions and comments from flow chart step 8*
   9. Describe Security Features of Existing Shipping Methods
      1. *Identify steps to describe security features of existing shipping methods including a description of their adequacy (whether they provide low- medium- or high- security) using questions and comments from flow chart step 9*
   10. Identify Shipping Methods Which Should be Acquired
       1. *Describe steps to search for, find and evaluate shipping methods which should be acquired by the facility using questions and comments from flow chart step 10*
   11. Acquire
       1. *Describe steps to acquire needed packaging, transport methods and shipping methods using questions and comments from flow chart step 11*
   12. Establish Transport and Shipping Policy
       1. *Describe steps to determine how transport and shipping security is implemented and enforced using comments and questions from flow chart step 12 (e.g., define who is allowed to package, receive and ship secured materials; requirements that must be adhered to; who, how and when incidents are identified, reported and investigated)*
   13. Establish Transport and Shipping Procedures
       1. *Describe steps to provide secure packaging, transport, shipping using comments and questions from flow chart step 13 (e.g., providing access methods to appropriate staff, establishing the procedures they use to access the spaces, procedures to be followed for visitors and third parties, procedures to be followed to withdraw access from individuals) see Information Security SOP*
   14. Establish Responsible Personnel
       1. *Describe steps to determine who is responsible and will have the access necessary for receiving, packaging, transport and shipping using comments and questions from flow chart step 14*
   15. Provide
       1. *Describe steps to provide packaging, transport and shipping necessities to responsible individuals using comments and questions from flow chart step 15 (e.g., training, forms, labels, materials, conveyances)*
   16. Monitor
       1. *Describe steps to determine when and how transported and shipped secured material, information and items are tracked using questions and comments from flow chart step 16 (e.g., continuous video surveillance, motion-activated video recording, unannounced inspections)*
   17. Maintain security features
       1. *Describe steps to complete scheduled performance testing and preventative maintenance of containers and conveyances using comments and questions from flow chart step 17*
   18. Investigate
       1. *Describe steps to further investigate a receiving, packaging, transport or shipping security incident to include real-time assessments and post-incident investigations using questions and comments from flow chart step 18*
   19. Report
       1. *Describe steps to report receiving, packaging, transport or shipping security incident investigative findings using questions and comments from flow chart step 19*
   20. System Validation and Reconciliation
       1. *Describe steps to reconcile and validate the security of receiving, packaging, transport or shipping using questions and comments from flow chart step 20* *(e.g.,* *scheduled performance testing, re-validations brought on by change, required reconciliations suggested by incidents)*
2. References
   1. World Health Organisation (WHO), Laboratory Biosafety Manual, 4th Edition, <https://www.who.int/publications/i/item/9789240011311>
   2. World Health Organisation (WHO), Biorisk Management: Laboratory Biosecurity Guidance, September 2006, <http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf>
   3. Salerno, RM and Gaudioso, J. Laboratory Biosecurity Handbook, CRC Press, Boca Raton, FL, 2007
   4. International Organization for Standardization. (2019). *Biorisk management for laboratories and other related organisations* (ISO Standard No. 35001:2019). <https://www.iso.org/standard/71293.html>
   5. Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition,

<https://www.cdc.gov/labs/BMBL.html>

1. Attachments
   1. External Transport and Shipping Security SOP Template Flow Chart
   2. Secured Transport and Shipping Custody Form
   3. Secured Transport and Shipping Log