Shipping and Permit Requirements for Biologicals

Objective

To describe policies and procedures related to the shipment, receipt, import, export and/or transport of potentially infectious materials and recombinant and/or synthetic nucleic acids. To describe the range of permits that may be required depending on the material to be transported.

Depending on the material to be transferred, the point of origin and/or the recipient, multiple regulatory agencies may require compliance with various regulations and permitting requirements. Due to the complexity of these regulations and permitting requirements active engagement with the Department of Biological Safety for assistance with these procedures is strongly recommended. Please note that these requirements may also apply to transfers within UK between Principal Investigators or laboratories depending on the material and the conditions under which initial approvals and/or permits were issued.

Definitions and Acronyms

Centers for Disease Control and Prevention - CDC

United States Department of Agriculture - USDA

Animal and Plant Health Inspection Service - APHIS

Department of Transportation – DOT

Export Administration Regulations – EAR

Shipper: Individual who will be initiating the transfer of material domestically. All personnel who will be packaging, shipping and/or receiving potentially infectious materials and/or recombinant nucleic acids must successfully complete DOT/IATA training. Training may be obtained from the Department of Environmental Health & Safety Environmental Management Department, http://ehs.uky.edu/classes/classes_env_0001.php#dot_iata.

Recipient: Individual who will be receiving material transferred domestically.

Importer: Individual who will be receiving material transferred from a foreign country.

Exporter: Individual who will be initiating the transfer of material to a foreign country.

Permit Holder: The individual who has successfully applied for and received a permit for the export, import and/or transport of a regulated material. This individual will be responsible for the direct oversight of the use of the material.

505 Oldham Court
Lexington, KY 40502-0473
Phone: (859) 257-1049
Fax: (859) 323-3838
Email: ehsbiosafety@uky.edu
Web: http://ehs.uky.edu/biosafety/

Responsible Official/Alternate Responsible Official: Individual(s) designated by an entity with the authority and control to ensure compliance with the Select Agent regulations.

Potentially Infectious Materials: Potentially infectious materials refers to viable microorganisms capable of causing infection in humans, plants or animals, DNA and RNA isolated from these microorganisms which may be infectious, tissues or other materials containing these microorganisms and non-pathogenic microorganism transformants containing recombinant nucleic acid from these microorganisms. All materials made non-viable must be accompanied by an explanation of the method used for inactivation.

Deemed Export: Release of technology, research data or other intangible information to a foreign national on United States soil.

Procedures

Shipment Procedure

- Consult with the Department of Biological Safety to determine specific requirements for your material.
- The Department of Biological Safety will assist the PI in determining what permits may be required. Consultation with Environmental Management will determine the proper hazard classification and packaging requirements for the material. All packaging, labeling, and shipping must adhere to applicable requirements of the Interstate Shipment of Etiologic Agents (42 CFR Part 72 and DOT/IATA requirements) and be performed by a trained shipper.
    - Typical hazard classes associated with shipment of biological materials:
        - UN 2814, Infectious Substances, Affecting Humans
        - UN 2900, Infectious Substances, Affecting Animals
        - UN 3373, Biological Substance, Category B
        - UN 1845, Carbon Dioxide, Solid
        - UN 3245, Genetically Modified Organisms or Genetically Modified Microorganisms
- All packaging or opening of primary containers containing potentially infectious materials will be performed in a biological safety cabinet located in a BSL-2 or 3 laboratory space depending on the material.

Permit Information

- APHIS Veterinary Services Import, Export or Transport Permits:
    - Permits are required for the import, export and/or interstate transport of any viable agent or materials containing any agent capable of causing disease in domestic livestock or poultry.
    - Permits may be completed online after users complete authentication procedures. It is strongly recommended that investigators who will routinely

need permits complete the authentication procedure as it expedites and simplifies the process.
    - All conditions of the initial permit must be adhered to at all times. This includes storage and use locations. If the lab moves or the material is to be used by another lab within the department the permit must be amended. Permits are applicant specific and materials cannot be transferred to PIs who do not hold a current permit for the material.
    - There is cost associated with VS permit applications. It is recommended to call APHIS if there is any question as to the need for a permit as the application fee will not be refunded if it is determined that a permit is not needed.
- CDC Etiologic Agent Import or Transport Permits:
    - Permits are required for the import and/or domestic transport of etiologic agents or materials which may contain them.
    - The permit application is available at http://www.cdc.gov/od/eaipp/.
    - The CDC also has an e-Tool to help you determine if a permit is required for your material, http://www.cdc.gov/od/eaipp/docs/eTool.pdf.
    - There is no cost associated with CDC permit applications.
- CDC/USDA Select Agent Transfer Permits:
    - Select Agent transfers cannot be completed unless both entities have current Select Agent registrations.
    - Prior to deciding to initiate a Select Agent transfer it is important that communication be established between the RO/AROs of both institutions.
    - A Form 2, available at http://www.selectagents.gov/Forms.html, must be completed and approved by CDC and/or USDA prior to shipment of the material.
    - The shipper/exporter must complete their portion of the Form 2 and fax the document to the recipient/importer that will complete their section and submit the form to the CDC and/or USDA.
    - Once approved the transfer must occur within the approved timeframe given by CDC and/or USDA.
    - The RO/ARO will be either the shipper or recipient for Select Agent transfers.
    - The commercial carrier of the shipment must have a written policy for compliance with DOT/IATA security requirements and will be audited by the RO/ARO to ensure adequate security measures are in place.
    - Only the designated recipient will sign for and receive packages containing Select Agents. The designated recipient will ensure they are available when the package arrives by utilization of electronic tracking of the package. In the event of an unforeseen occurrence which prevents the designated recipient from being present, the RO, another ARO or a SRA approved individual will sign for and receive the package

Export Control Considerations for Biohazardous Material

Please note that export control regulations cover a wide variety of materials, technologies and information other than biohazardous material. Most research activities will fall under fundamental research exclusion in the regulations, however, it is strongly recommended that you be aware of these regulations if your research involves any international shipment or collaboration. If you are collaborating with individuals located in or visiting from a country or if

you are visiting a country which the United States currently has sanctions against or is considered a State Sponsor of Terrorism, it is recommended that the regulations be consulted to ensure no violations are occurring. For example, carrying certain personal electronic devices to certain countries or training foreign nationals (individuals in the USA without a green card) from certain countries in specific methods or on specific technologies may be prohibited. Information supplied to foreign nationals may also fall under the category of deemed exports.

- Export Control Regulations and Links:
  - Export Administration Regulation (EAR), http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear
  - Office of Foreign Assets Control (OFAC) provides listing of countries with current sanctions, http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx
  - International Traffic in Arms Regulations (ITAR) covers certain technologies and materials that could have a defense component, http://pmddtc.state.gov/regulations_laws/itar_official.html
  - State Sponsors of Terrorism, http://www.state.gov/j/ct/list/c14151.htm
- Fundamental Research Exclusion:
  - "'Fundamental research' means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons." - National Security Decision Directive 189, http://www.fas.org/irp/offdocs/nsdd/nsdd-189.htm.
  - The funding source of a project can change the applicability of the export control regulations. If there exists any clause in the agreement with the funding agency or sponsor that would prohibit the public dissemination of the research, such as sponsor review of data prior to publication or the maintenance of confidential business information, export control regulations may then be applicable.
- Commerce Control Export Licenses:
  - Exports of materials are carefully controlled by the Department of Commerce.
  - For shipments outside of the United States it is crucial to contact the Department of Biological Safety to determine if an export license is required for your material.
  - If a license is required, there is an online application process. There is no cost associated with the application, however, it should be noted that the application process can be quite lengthy.
  - The Department of Biological Safety can assist in contacting the Department of Commerce and facilitating your transfer.
    - Commercial Control List (CCL), http://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl
    - Alphabetical Index of CCL, http://beta-www.bis.doc.gov/index.php/component/docman/doc_download/13-commerce-control-list-index?Itemid=172

References and Regulations

- Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm
- NIH Guidelines for Research Involving Recombinant DNA Molecules, http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html
- CDC and USDA Select Agent Regulations, 42 CFR 73, 7 CFR 331, 9 CFR 121, http://www.selectagents.gov/
- DOT/IATA Regulations for Shipping and Receiving Hazardous Materials, http://www.phmsa.dot.gov/hazmat, http://www.iata.org/whatwedo/cargo/dangerous_goods/index.htm
- United States Department of Commerce Export Control Policies, http://www.bis.doc.gov/licensing/exportingbasics.htm
- CDC Etiologic Agent Import Permit Program, http://www.cdc.gov/od/eaipp/
- United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Center for Import and Export (NCIE) Permit Program, http://www.aphis.usda.gov/permits/index.shtml

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