NIH Policy Manual

1340-1 - Permits for the Import, Transfer, or Export of Biological Materials

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Transmittal Notice

1. **Explanation of Material Transmitted:**

   This chapter describes the National Institutes of Health (NIH) policy and procedures for acquiring appropriate import, transfer, or export permits to transport biological materials. This revision contains changes and additions to the policy in section C, definitions in section E, the NIH Quarantine Permit Service Office responsibilities in section F.4, import procedures in section G.1, export procedures in section G.2, and internal controls in section I.

2. **Filing Instructions**:

   Remove: Manual Chapter 1340-1, dated 06/07/2016

   Insert: Manual Chapter 1340-1, dated 10/17/2019

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Management Support, OMA on (301) 496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx.

A. Purpose

This chapter describes the National Institutes of Health (NIH) policy and procedures for acquiring appropriate import, transfer, or export permits to transport biological materials.

B. Scope

This policy applies to biological materials used in intramural research including vectors of human, animal, or plant disease (e.g. insects or bats) transferred to or from any NIH facilities. All NIH personnel must comply with this policy.

C. Background

In recent years, the concern over the safe and secure transport of hazardous materials has intensified. In particular, the enhanced regulation of infectious biological agents, infectious substances, and vectors of communicable disease has emanated from the understanding that a potential release of such biological materials could result in devastating consequences for humans, animals, and the economy. Federal and international regulations have been updated to more accurately characterize biological materials offered for transport, to more efficiently track their safe distribution, and to ensure appropriate biosafety measures are in place that are commensurate with their potential hazard.

The NIH is subject to Federal import, transfer, and export controls affecting the transport of biological materials. Federal agencies that control the transport of biological materials include, but are not necessarily limited to, the following: the Centers for Disease Control (CDC) and Prevention, the Animal and Plant Health Inspection Service (APHIS), the U.S. Fish and Wildlife Service, the Food and Drug Administration (FDA), the Department of Commerce Bureau of Industry and Security (BIS), the Department of Transportation Pipeline and Hazardous Materials Safety Administration (PHMSA), and U.S. Customs and Border Protection (CBP).

International regulations have been established to minimize risks associated with the transport of biological materials. The International Civil Aviation Organization (ICAO) issues the *Technical Instructions for the Safe Transport of Dangerous Goods by Air*. The International Air Transport Association (IATA) adopts the ICAO technical instructions and includes additional requirements to issue the *Dangerous Goods Regulations*. The *Dangerous Goods Regulations* establish definitions and requirements for the classification, packaging, marking, labeling, and documentation of hazardous material packages shipped around the world.

NIH has established the Quarantine Permit Service Office (QPSO), Division of Occupational Health and Safety (DOHS), Office of Scientific Resources (SR), Office of Research Services (ORS), located in Building 13, Room 3K04, for matters involving the import, transfer, or export of biological materials.

Failure to comply with import, transfer, or export requirements may delay the delivery of a shipment. Biological materials that are incorrectly imported or exported may result in confiscation and/or destruction of the package by CBP personnel at the port of entry. Personal, civil and criminal penalties have been established for willful violation of regulations related to biological transport.

D. Policy

NIH will conform to all applicable laws and regulations for the import, transfer, and export of biological materials.

No person at NIH shall make arrangements to import or export biological materials before receiving authorization through the Division of Occupational Health and Safety (DOHS), Quarantine Permit Service Office (QPSO).

No person at NIH shall receive or transfer biological material requiring a CDC transfer permit to another laboratory or facility without prior authorization from the QPSO.

It is the policy of the NIH to ensure that all packages being offered for transport comply with all Federal and international regulations for applicable ground and air transport in order to protect the safety of laboratory and support staff, the public and the environment.

Infectious biological agents, infectious substances, and/or vectors cannot be transported in a privately owned vehicle. To transport via land, a government vehicle may be used following NIH Manual Chapter 26101-38, Official Use of Government Motor Vehicles. All applicable packaging requirements established under the Department of Transportation (DOT) regulations must be followed (49 CFR 171 - 178).

Any person at the NIH wishing to transport infectious biological agents, infectious substances, and/or vectors via air must have the material packaged by an appropriately trained individual following IATA *Dangerous Goods Regulations*.

All inbound and outbound shipments of biological materials must comply with NIH Manual Chapter 26101-42-F, Shipping Policies and Procedures. Further information can be obtained by contacting the Office of Logistics and Acquisitions Operations, Division of Logistics Services, Freight Forwarding Section: (301) 496-5921.

Remote NIH facilities must comply with NIH Manual Chapter 26101-42-F, Shipping Policies and Procedures, Section C. Policy, and coordinate their activities with the NIH Transportation Officer to establish consistent requirements for the transport of hazardous material packages.

All transfers of select agents and toxins must be coordinated and shipped through the site-specific Select Agent Program.

All transfers of rodents, rodent products, and rodent pathogens for *in vivo* use must comply with NIH Manual Chapter 3043-1, Introduction of Rodents, Rodent Products and Rodent Pathogens.

The procurement of live nonhuman primates is outside the purview of this manual chapter. Importers must be registered with the CDC Division of Global Migration and Quarantine, follow the requirements for importers of nonhuman primates (42 CFR 71.53), and comply with NIH Manual Chapter 3044-1, Nonhuman Primate Quarantine.

The import, transfer, or export of proprietary biological material may require the completion of a Material Transfer Agreement. Applicants should contact the NIH Office of Technology Transfer for further information: (301) 496-7057.

E. References and Legislative Sources

1. The Department of Health and Human Services (HHS) Secretary is authorized under the provision of Section 361 of the Public Health Service Act to make and enforce such regulations as in their judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or possessions of the United States and from one State or possession into any other State or possession (42 USC 264).

The Foreign Quarantine regulations (42 CFR 71) set forth provisions to prevent the introduction, transmission, and spread of communicable human disease resulting from importations of various animal hosts or vectors or other etiological agents from foreign countries into the United States. Part 71, Subpart F(Importations) contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54). A CDC permit must be issued before the importation of these materials, and in certain cases, before the subsequent transfer of some of these materials after importation.

1. The United States Department of Agriculture(USDA) Secretary is authorized to prohibit or restrict the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock (7 U.S.C. 8303). No organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit issued by the Secretary and in compliance with the terms thereof: […]" (9 CFR 122.2). Similar USDA regulations are concerned with agents and vectors of plant disease (7 CFR 330).

1. The Food and Drug Administration(FDA) mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws which are designed to protect consumers' health and safety. These laws apply equally to domestic and imported products. With the exception of most meat and poultry, all food, drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation, as defined in the FD&C and related Acts, are subject to examination by FDA when they are being imported or offered for import into the United States.

Note: The import of biological materials intended only for testing in a clinical laboratory or for basic scientific research, and that are not articles intended for the prevention, treatment, diagnosis, or cure of diseases, injuries, or conditions in human beings, are not considered to be subject to FDA licensure.

1. The U.S. Fish and Wildlife Service(FWS), Department of the Interior, is responsible for regulating the importation, exportation, and transportation of wildlife in the United States (50 CFR 14). In addition, the FWS represents the United States to the Convention on International Trade in Endangered Species of Wild Fauna and Flora(CITES). The aim of CITES is to regulate international trade in wildlife and plants, including parts, products, and derivatives, to ensure it is legal and does not threaten the survival of species in the wild (50 CFR 23). A CITES permit may be required if investigators wish to use biological materials or tissues derived from fauna or flora listed in CITES Appendices I, II or III.

1. The Bureau of Industry and Security(BIS), Department of Commerce, advances U.S. national security, foreign policy, and economic objectives by ensuring an effective export control and treaty compliance system. The agency is responsible for implementing and enforcing the Export Administration Regulations (15 CFR 730 -774) which regulate the export and re-export of most commercial items.

1. The Department of Transportation(DOT) serves the United States by ensuring a fast, safe, efficient, accessible and convenient transportation system that meets vital national interests and enhances the quality of life of the American people. The Department issues regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce (Title 49 USC, Subtitle III, Chapter 51).

1. The Pipeline and Hazardous Materials Safety Administration(PHMSA), Department of Transportation (DOT), protects people and the environment through the implementation of regulations concerned with the transport of hazardous materials offered for domestic transport (49 CFR 171 – 178).

1. The International Civil Aviation Organization(ICAO) issues the *Technical Instructions for the Safe Transport of Dangerous Goods by Air*. The International Air Transport Association (IATA) adopts the ICAO technical instructions and includes additional requirements to issue the *Dangerous Goods Regulations*. The *Dangerous Goods Regulations* establish definitions and requirements for the classification, packaging, marking, labeling, and documentation of hazardous material packages shipped around the world.

1. The U.S. Customs and Border Protection(CBP), Department of Homeland Security, is responsible for securing national borders and for facilitating lawful international trade.

F. Definitions

1. **Biological material:** Any substance derived from an organism.
2. **Communicable disease:** An illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly, or indirectly through an intermediate animal host, vector, or the inanimate environment.

3. **Dangerous Goods:** Dangerous goods are articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the IATA *Dangerous Goods Regulations* or which are classified according to those regulations.
4. **Diagnostic specimen:** Specimens of human and animal matter (including tissue, blood, body discharges, fluids, excretions or similar material), or environmental samples.
5. **Genomic material:** Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) comprising the genome or organism's hereditary information, that may be singe-stranded or double-stranded, and in a linear, circular, or segmented configuration and may be positive sense (same polarity as mRNA), negative sense, or ambisense (mixture of the two).
6. **Hazardous material:** a substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has designated as hazardous under Federal hazardous materials transportation law (Title 49, Subtitle III, Chapter 51, §5103).
7. **Infectious biological agent:** A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human, animal, or plant.
8. **Infectious substance:** Any material that is known or reasonably expected to contain an infectious biological agent.
9. **Select agents and toxins:** Biological agents and toxins listed in 42 CFR 73, 9 CFR 121, and 7 CFR 331.
10. **Vector:** Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products that are known to transfer or are capable of transferring an infectious biological agent to a human.

G. Responsibilities

1. Director, NIH: Through DOHS and the Deputy Director for Intramural Research (DDIR), provides executive leadership in the development and implementation of biological safety policies, standards and procedures applicable to the NIH. The DOHS provides staff necessary to effectively administer a comprehensive occupational safety and health program.

1. Deputy Director for Intramural Research (DDIR): The DDIR is the principal liaison with the NIH intramural research community regarding safety and health matters. The DDIR receives safety policies approved by ORS and communicates them to the IC Scientific Directors. Further, the DDIR raises safety concerns to ORS as they are brought to the DDIR's attention from the intramural research community.

1. Designated Agency Safety and Health Official (DASHO): The Institutional Official responsible for management and administration of the NIH occupational safety and health program. This authority is delegated by the Director, NIH as noted in NIH Delegation of Authority Program: General, No. 46: NIH Designated Safety and Health

Official.

1. NIH Transportation Officer: the individual responsible for the overall operation of the Shipping Activities at an agency. This authority is held by the Director, Division of Logistics Services, OLAO, as noted in NIH Manual Chapter 26101-42-F, Shipping Policies and Procedures.

1. The NIH Quarantine Permit Service Office (QPSO) is responsible for:

    a. Providing information and guidance to NIH components on the requirements for import, transfer, or export of biological materials.
    b. Reviewing requests to import biological materials to the NIH and determining the need for a regulatory permit.
    c. Issuing NIH letters for the import of non-infectious biological materials.
    d. Executing NIH export declarations for biological materials leaving the United States.
    e. Maintaining records (e.g., all export declarations and import/transfer permits issued) and the submission of reports to regulatory agencies.
    f. Reporting shipping related incidents to the DOHS Director for remediation.
    g. Ensuring management controls are implemented and effective to ensure compliance with this policy.

1. Institute/Center (IC) Scientific Directors are responsible for:

    a. Ensuring staff compliance with NIH policy and regulations involving the import, transfer, and/or export of biological materials.

1. Permit holders are responsible for:

    a. Following all conditions, restrictions, and precautions specified in the permit.
    b. Implementing biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported or transferred.
    c. Taking measures to help ensure that the shipper complies with all applicable legal requirements concerning the packaging, labeling, and shipment of infectious substances.

1. Principal Investigators are responsible for including all required import permits and transfer permits (CDC, APHIS, FWS) in their appropriate biological material registration.

H. Procedures

1. **Imports:**

a. To find out if there is a need for a permit to import, transfer, or export biological material, contact the QPSO at least four weeks before the intended date of shipment to allow adequate time for processing. (See Responsibilities Section F.7.)

   Note: In some cases, more than one permit may be required for the import of a biological material. Although the QPSO does not issue regulatory permits, the office will provide assistance in obtaining these permits.

   Note: The NIH Select Agent Program manages the import of select agents and toxins following the regulations promulgated in 42 CFR 73, "Possession, Use, and Transfer of Select Agents and Toxins."

b. A person wishing to import any biological material or vector of human disease must first request authorization from the QPSO. Requests may be submitted electronically through the QPSO webpage. The QPSO will determine the need for a CDC import permit or a NIH letter for non-infectious import and will direct the researcher to the required approval process. Please allow 14 days for review and approval of CDC import permits. Once a permit is issued, the appropriate biological registration for the material must be updated with the permit (see Responsibilities Section F.7). General questions may be submitted to the QPSO via email (qpso@mail.nih.gov) or by calling 301-496-2960. For further information on CDC permits, researchers may contact the CDC Import Permit Program: 404-718-2077.
c. A person wishing to import organisms or vectors of pathogenic diseases of livestock, poultry, or plants must first request authorization from the QPSO. Requests may be submitted electronically through the QPSO webpage . The QPSO will determine the need for a USDA permit or an exemption document and will direct the researcher to the required approval process. Please allow 14-30 days for review and approval of USDA permits. Once a permit is issued, the appropriate biological registration for the material must be updated with the permit (see Responsibilities Section F.7). General questions may be submitted to the QPSO via email (qpso@mail.nih.gov) or by calling 301-496-2960. For further information on USDA permits, researchers may contact the USDA National Import and Export Service: (301)851-3300.
d. A person wishing to import rodents or other live animals from outside the United States to the NIH must coordinate with the QPSO, their Institutional Animal Care and Use Committee, and their IC Rodent Import Officer (for rodents).
e. A person wishing to import specimens from a species listed in CITES Appendix I must first request authorization from the QPSO. Requests may be submitted electronically through the QPSO webpage. The QPSO will determine the need for a FWS permit and will direct the researcher to the required approval process. Please allow 60-90 days for FWS approval and be aware that application fees may apply. Once a permit is issued, the appropriate biological registration for the material must be updated with the permit (see Responsibilities Section F.7). General questions may be submitted to the QPSO via email (qpso@mail.nih.gov)

or by calling 301-496-2960.For further information, researchers may contact FWS: (800) 344-9453.

f. No person at the NIH shall further distribute an imported infectious biological agent, infectious substance, vector, diagnostic specimen, or genomic material until applicable permits and/or authorizations are granted.

2. **Exports:**

a. In general, biological materials may be exported to most countries under the provisions of the Export Administration Regulations (EAR). A person wishing to export biological material must submit Form NIH-2388, "Declaration for Exportation of Biologic Materials," to the QPSO. The form may be submitted to the QPSO via email (qpso@mail.nih.gov) or mail. (See Section F.4.) Authorization is dependent upon the nature of the biological material, the recipient, the proposed country of destination, and the commercial value of the shipment. An export license may be required in some cases.

Note: Should the QPSO determine a validated license is required for the export or re-export of a biological material, the office will notify the applicant and apply directly to BIS on his/her behalf. Please allow 30-60 days for BIS determination.

b. The recipient's country may impose import restrictions or require that the recipient obtain an import permit from the appropriate issuing agency in the recipient's country. If a foreign import permit is required, the permit number and a copy of the foreign import permit must be included with the "Declaration for Exportation of Biologic Materials" provided to the QPSO.

c. A person wishing to export diagnostic specimens from a species listed in CITES Appendix I or II may be required to obtain a regulatory permit from FWS.Applicants should allow 60-90 days for a FWS determination and be aware that application fees apply. Once FWS approval is granted, a copy of the FWS permit must be forwarded to the QPSO. For further information regarding CITES permits, researchers may contact FWS: (800) 344-9453.

3. **Domestic Shipments:**

Domestic shipments may require the issuance of a transfer permit. For example, CDC import permits may prohibit the further distribution of imported biological materials without the issuance of a transfer permit. The CDC and/or APHIS may also require transfer permits for the domestic transport of specific infectious biological agents, regardless of their source of origin. Additionally, select agents and toxins may only be transferred after authorization from the CDC Division of Select Agents and Toxins through the issuance of APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins". Contact the QPSO for guidance before transporting infectious biological agents, infectious substances, or vectors that may be subject to transfer restrictions.

4. **Packaging Requirements:**

Biological materials, including diagnostic specimens, are subject to packaging

requirements described in the DOT regulations (49 CFR 171 - 178) and the IATA *Dangerous Goods Regulations*. Only a person that has been properly trained may package hazardous materials for shipping. All packaging must follow DOT and IATA regulations. Information on packaging and shipping training is available on the DOHS website.

I. Records Retention and Disposal

All records pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743,"Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedules" (as amended). These records must be maintained in accordance with current NIH Records Management and Federal guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information.