

## NIH POLICY MANUAL

### 1340-1 - Permits for Import or Export of Biological Materials

Issuing Office: OD/OM/ORS/DOHS (301) 496-2960

Release Date: 02/01/08

---

1. **Explanation of Material Transmitted:** This manual chapter describes the NIH policy and procedures concerning the requirements for the importation or shipment of etiological agents, their vectors, animals, and plants and for the exportation of biological materials. This chapter is being revised to update organizational references and to add 2 new required sections: Records Retention and Management Controls.
2. **Filing Instructions:**

**Remove:** NIH Manual 1340-1, dated 11/15/96

**Insert:** NIH Manual 1340-1 dated 02/01/08

**PLEASE NOTE:** For information on:

- Content of this chapter, contact the issuing office listed above.
  - On-line information, enter this URL:  
<http://www1.od.nih.gov/oma/manualchapters/>
  - To sign up for e-mail notification of future changes, please go to the [NIH Manual Chapters LISTSERV](#) Web page.
- 

#### **A. Purpose:**

This chapter describes the NIH policy and procedures concerning the requirements for permits for the importation or shipment of etiological agents, their vectors, animals and plants, and for the exportation of biological materials. This chapter is being revised to comply with the requirement that chapters be reviewed every 5 years. In addition, 2 new sections have been added (a) Records Retention and (b) Management Controls.

#### **B. Background:**

In recent years, the concern over the safe and secure transport of hazardous material has intensified in an effort to ensure personal and public safety during transport of etiological agents, their vectors, animals and plants, and for the exportation of biological materials. In the United States, all hazardous material packages that are offered for domestic transport are subject to the DOT

regulations. All hazardous material packages shipped internationally are subject to the requirements established by the United Nations International Civil Aviation Organization (ICAO) whose guidelines are adopted by the International Air Transport Association (IATA). Both regulatory bodies establish definitions and requirements for the classification, packaging, marking, labeling, and documentation of hazardous material packages. Personal, civil and criminal penalties have been established for willful violation of these regulations.

Failure to comply with import and export requirements may result in shipment release delays or shipment confiscation and destruction by the Quarantine Officer at the port of entry.

### **C. Policy:**

NIH will conform to all applicable laws and regulations for the importation and shipment of etiological agents and vectors.

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

No person at NIH shall make arrangements to receive or ship an etiological agent, vector, animal, or plant before ascertaining the necessity for a permit and obtaining a permit when required.

Etiological agents and vectors of human or animal disease cannot be transported in a privately owned vehicle (POV). To transport via land, a government vehicle may be used. All applicable packaging requirements of the U. S. Department of Transportation (DOT) regulations must be followed (49 CFR Parts 171- 178).

Any person at the NIH wanting to personally transport etiological agents and/or vectors of human or animal disease via air must have the material packaged by an appropriately trained and certified individual, following IATA packaging instructions. The material must be declared prior to departure.

No person at NIH shall transfer PHS-permitted materials to another laboratory or facility within NIH or to another Federal or private facility without prior authorization by the Division of Occupational Health and Safety, Quarantine Permit Service Office (QPSO).

NIH Policy Manual 1340-1 sets forth the responsibilities and specific requirements for acquiring appropriate import and export permits for shipping hazardous materials. All hazardous materials shipped from the NIH Bethesda

campus must be shipped through the Office of Logistics and Acquisitions Operations, Freight Forwarding Team. Remote NIH facilities must establish site specific requirements for the transport of hazardous material packages to facilitate compliance with this policy.

#### **D. References: Legislative Sources:**

1. Department of Health and Human Services, Public Health Service quarantine regulations task the Centers for Disease Control and Prevention (CDC) with management of human etiological agent import/transfer program. The regulation states: "A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director." (42 CFR 71.54).
2. U.S. Department of Agriculture (USDA) regulations state: "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).

**Note:** The USDA will not permit the importation of cell cultures, monoclonal antibodies, ascites fluid or bovine serum from countries where rinderpest and foot-and-mouth disease are present unless the imported materials are determined to be virus-free.

3. Similar USDA regulations are concerned with agents and vectors of plant disease (7 CFR 330). These regulations seldom affect the work of biomedical investigators but are applicable.
4. The United States Fish and Wildlife Service (USFWS), U.S. Department of Interior, is responsible for regulations involving the prevention and control of wildlife diseases and for the importation of wildlife and eggs thereof (50 CFR 23). In addition, the USFWS represents the United States to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). If biomedical investigators wish to use biological materials or tissues derived from fauna or flora listed in Appendices I, II or III of the convention, a CITES permit is required (50 CFR 23). The USFWS has granted the NIH a Designated Port Exemption permit to allow for the importation of materials transiting

through Washington Dulles International Airport, however, the importation of certain animals and birds is prohibited.

5. The U. S. Department of Commerce (DOC), Bureau of Industry and Security, is responsible for implementing and enforcing the Export Administration Regulations (EAR), which regulate the export and re-export of most commercial items.
  
6. Biological materials and etiological agents are subject to packaging and shipping requirements of various Federal and International regulations. Proper packaging is the primary consideration and of utmost importance in the safe transportation of hazardous materials. The DOT regulations (49 CFR 171 – 178) and IATA’s Dangerous Goods Regulations dictate the proper packaging requirements necessary for most biological materials.

**E. Delegation:**

The Centers for Disease Control and Prevention (CDC) Etiological Agent Import Permit Program Atlanta, Georgia, has authorized NIH to issue permits for the importation of etiological agents and vectors of human disease into NIH laboratories. It is a condition of this authorization that NIH maintains a record of each permit issued and documents the transfer of all PHS-permitted material.

NIH has established the Quarantine Permit Service Office (QPSO), Division of Occupational Health and Safety (DOHS), Office of Research Services (ORS), Building 13, Room 3K04 for matters involving the import or export of biological materials. Permit information is available by calling (301) 496-2960 or by going online at [http://dohs.ors.od.nih.gov/shipping\\_biological\\_material.htm](http://dohs.ors.od.nih.gov/shipping_biological_material.htm).

**F. Responsibilities:**

1. The NIH Quarantine Permit Service Office is responsible for:
  - a. Providing information and guidance to NIH components on the requirements for import or export of biological materials.
  
  - b. Issuing PHS import/transfer permits or letters of non-infectious import for biological materials arriving to the NIH.

c. Executing export declarations for biological materials leaving the United States.

d. Maintaining records and the submission of reports to regulatory agencies.

**Note:** In some cases, more than one permit may be required for the import/transfer or export of a biological material. Although the QPSO does not issue USDA or USFWS permits, the office will provide assistance in obtaining these permits. Should QPSO determine a DOC validated license is required for the export or re-export of a biological material, the office will notify the investigator and apply directly to the DOC on his/her behalf.

The transfer of select agents and toxins is managed by the NIH Select Agent Program, following the regulations promulgated in 42 CFR 73, "Select Agents and Toxins". The QPSO requires that a request for permit to import an etiological agent requiring Biosafety Level 3 (BSL3) or Biosafety Level 4 (BSL4) containment be submitted with the written concurrence of the IC Scientific Director.

2. IC Scientific Directors are responsible for:

a. Providing written concurrence for the import of an etiological agent requiring Biosafety Level 3 (BSL3) or Biosafety Level 4 (BSL4).

b. Ensuring staff compliance with QPSO policy and regulations involving the import and export of etiological agents, disease vectors, animals and plants, and other biological materials.

## **G. Procedures:**

1. Imports:

a. To ascertain the need for a permit to import or transfer a human etiological agent, vector of human or animal disease, animal or plant, contact the QPSO at least six weeks before the date of shipment in order to allow adequate time for processing the permit request.

b. A person wishing to import biological material, or transfer previously permitted material to another NIH/PHS laboratory, must obtain a PHS import permit by submitting the application, Form CDC 75-3,

"Application for Permit to Import or Transport Agents or Vectors of Human Disease" to the QPSO via fax (301) 480-0671. This form is available on the [DOHS](http://dohs.ors.od.nih.gov/forms.htm) website at <http://dohs.ors.od.nih.gov/forms.htm>. The QPSO will determine whether a PHS permit or letter of non-infectious import is required.

c. A person wanting to apply for an import/export/re-export permit of wildlife samples and/or biomedical samples collected from an endangered species must complete USFWS Form 3-200-29, "Import, Export, Re-export of Wildlife Samples and/or Biomedical Samples". This permit application is submitted directly to USFWS and is available online at: <http://www.fws.gov/permits/>. Applicants should be prepared to wait 60-90 days for a determination and be aware that an application fee applies. Once approval is granted, a copy of the USFWS permit must be forwarded to the QPSO.

d. A person wanting to apply for a USDA Animal and Plant Health Inspection Service (APHIS) permit must submit the permit application directly to the USDA using the ePermit system available at <http://www.aphis.usda.gov/permits/>. Both USDA and PHS permits may be required for the importation of some biological materials. An application fee applies. Once approval is granted, a copy of the USDA permit must be forwarded to the QPSO. Applicants must contact the QPSO prior to shipment if live animals are to be received at the Washington Dulles International Airport under the NIH designated port exemption.

e. No person at the NIH shall distribute a permitted etiological agent or vector of human disease unless the intended recipient provides a copy of the appropriate permit authorizing the receipt of the material.

## 2. Exports:

a. In general, biological materials may be exported to most countries under the provisions of the Export Administration Regulations (EAR), DOC. A person wanting to export a biological material must submit Form NIH-2388, "Declaration for Exportation of Biologic Materials", to the QPSO. This form is available on the NIH Forms website at <http://forms.nih.gov/adobe/procurement/NH2388.PDF> and can be faxed to (301) 480-0671. Authorization is dependent upon the nature of the biological agent or material, recipient, proposed country of destination, and commercial value of the shipment.

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 an import permit is required, the permit

number or a copy of the import permit must be included with the “Declaration for Exportation of Biologic Materials”, and provided to the QPSO.

### 3. Interstate Shipments:

In general, indigenous etiological agents and vectors are not subject to control by Federal or other agencies for U.S. interstate shipments, however there are exceptions (e.g., establishment of a colony of *Aedes aegypti* mosquitoes, interstate transport of plant pests, blue tongue virus, etc.). Contact the QPSO for guidance before transporting etiological agents that may be subject to interstate shipment 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 International Air Transport Association (IATA) Dangerous Goods Regulations. Shipments known or suspected to contain a pathogen or toxin are subject to additional packaging and shipping requirements described in these regulations.

Only a person that has been properly trained may package hazardous materials for shipping. All packaging must follow DOT and IATA regulations. For information on packaging and shipping training, visit the DOHS website at [http://dohs.ors.od.nih.gov/Resources\\_main.htm](http://dohs.ors.od.nih.gov/Resources_main.htm).

## **H. Records Retention and Disposal:**

For this chapter, records pertaining to NIH Permits For Import or Export of Biological Materials are retained and disposed of under the authority of NIH Manual [1743](#) "Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule," Item 1300-B-3, safety management subject files.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of the Inspector General may request access to, or copies of, e-mail messages. E-mail messages must also be provided to Congressional oversight committees, if requested, and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same request as the original messages.

## **I. Management Controls:**

The purpose of this Manual Chapter is to establish the NIH policy and procedures concerning the requirements for permits for the importation, transfer, export or shipment of etiological agents, their vectors, animals and plants.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter (Issuing Office):** Through this Manual Chapter, the Quarantine Permit Service Office (QPSO), Division of Occupational Health and Safety (DOHS), Office of Research Services (ORS) is responsible for the method used to ensure that management controls are implemented and working.
2. **Frequency of Review:** Annual review
3. **Method of Review:** The QPSO, DOHS will maintain oversight and ensure compliance with this policy.

The QPSO shall maintain a registry of all NIH personnel who have completed the DOHS sponsored *Shipping Infectious Substances* training course. The QPSO shall also maintain files of all export declarations and import/transfer permits issued. In addition, the QPSO shall maintain a database of all shipping related incidents which are reported to the DOHS.

**4. Review Reports are sent to:**

The QPSO is required to submit an annual summary report to the CDC regarding the total number of imports/transfers of biological material.

The QPSO will provide an annual report at the end of the calendar year of the issued import/transfer permits, export declarations and shipping incidents investigated to the Director, DOHS, the Associate Director for Research Services and the Deputy Director for Management.