

Centers for Disease Control and Prevention Import Permit Program



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Division of Select Agents and Toxins



Section 361 of the Public Health Service Act

- ❑ Authorizes the HHS Secretary to make and enforce regulations necessary to prevent:
 - Introduction,
 - Transmission, or
 - Spread of communicable diseases from foreign countries into the United States.



Section 361 of the Public Health Service Act



- ❑ Authorizes the HHS Secretary to use inspections as a public health measure to ensure that such regulations are carried out.

42 CFR 71.54

Import regulations for infectious biological agents, infectious substances, and vectors

- ❑ A person may not import into the United States any infectious biological agent, infectious substance, or vector unless:
 - It is accompanied by a permit issued by the CDC
 - The importer is in compliance with all of the permit requirements
 - The importer has implemented adequate biosafety measures for work being conducted.
 - The importer takes measures to help ensure that the shipper complies with all applicable legal requirements concerning the packaging, labeling, and shipment of infectious substances

Types of Material that Require an Import Permit

- ❑ 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.



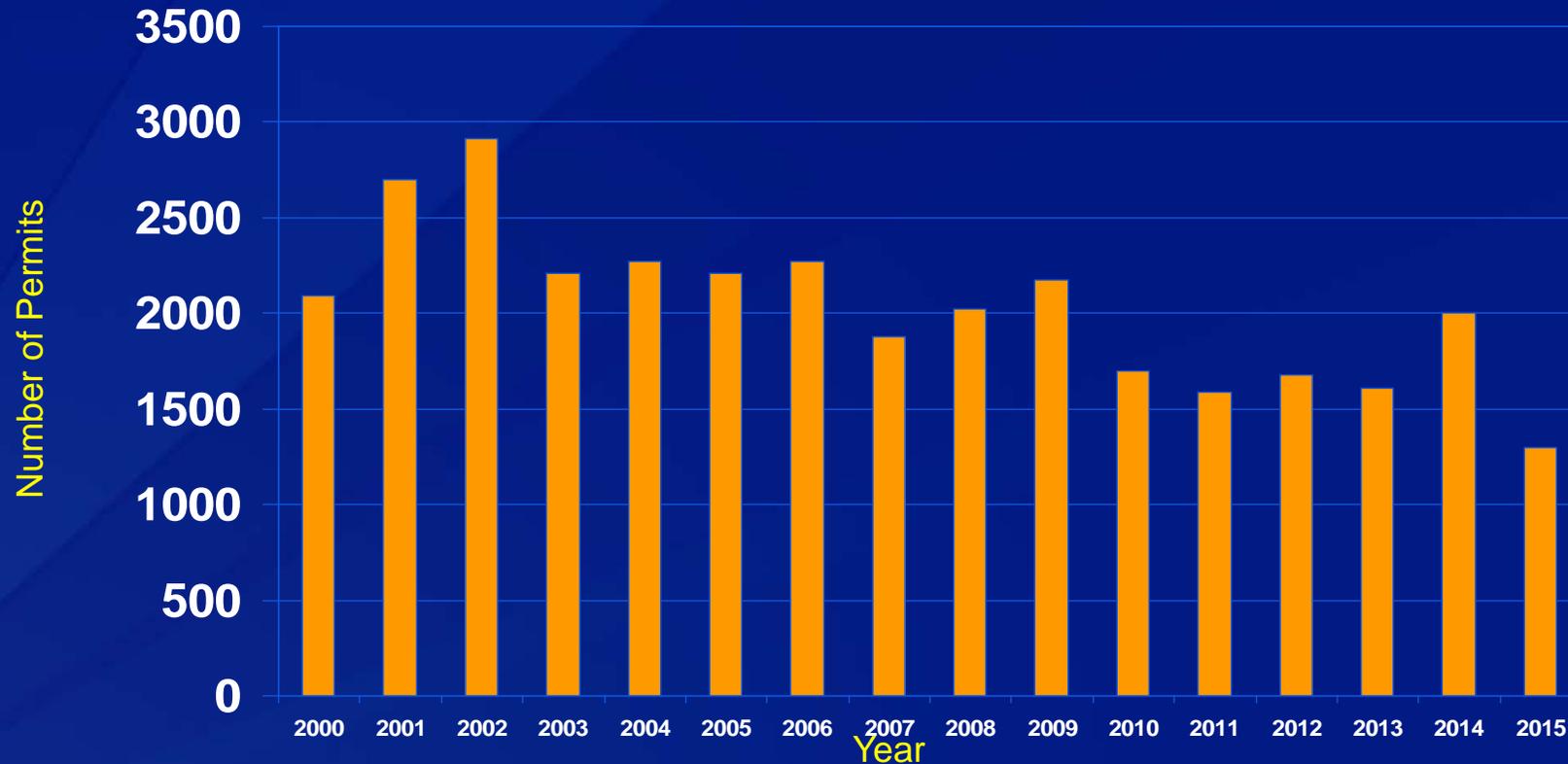
Types of Material that Require an Import Permit

- ❑ Infectious substance - Any material that is known or reasonably expected to contain an infectious biological agent.
- ❑ Vector - Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) that are known to transfer or are capable of transferring an infectious biological agent to a human.



CDC Import Permits Issued 2000-2015

(as of 09/1/2015)



Date and Conditions of the Import Permit

- Section 71.54(d)

The CDC permit is valid only for: (1) the time period and/or term indicated on the permit, and (2) only for so long as the permit conditions continue to be met.



Conditions of Issuance

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Centers for Disease Control and Prevention
Office of Health and Safety
Atlanta, Georgia 30333
TEL: 404-639-3226; FAX: 404-639-3226

CDC
CENTERS FOR DISEASE CONTROL
AND PREVENTION

Permit to Import or Transfer Etiological Agents or Vectors of Human Disease
In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulations, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in Item 1 below.

| | | |
|--|--|----------|
| PHS PERMIT NO. | 1993-03-001 | |
| DATES | ISSUED: | EXPIRES: |
| 1. DESCRIPTION OF MATERIAL | | |
| 2. PERMITEE (NAME, ORGANIZATION, ADDRESS) | TEL: FAX: Email: | |
| 3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY) | , ZZ | |
| 4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE | , DEFAULT | |
| 5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED | <input type="checkbox"/> Single Importation into the US <input type="checkbox"/> Single Transfer Within the US A. Record of each importation shall be maintained on permanent file by permittee. B. Enclosed label(s) must be forwarded to the shipper(s). C. One label shall be affixed to shipping container. Enclosed labels may be photocopied. <input type="checkbox"/> A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service. <input type="checkbox"/> B. All material is for laboratory use only - Not for use in the production of biologics for humans or animals. <input type="checkbox"/> C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines. <input type="checkbox"/> D. Additional Requirements: <input type="checkbox"/> File Form EA-101 with CDC (404-639-4418) for Select Agents as defined in 42 CFR 72.6 <input type="checkbox"/> IATA Packaged to preclude escape. <input type="checkbox"/> USDA permit may be required, 301-734-7830. <input checked="" type="checkbox"/> E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories". <input checked="" type="checkbox"/> F. Packaging must conform to 42 CFR Section 72 and 49 CFR Sections 171-180. <input type="checkbox"/> G. Select Agent. Receiving facility must be registered under 42 CFR Part 72.6. | |
| 6. COPY SENT TO <input checked="" type="checkbox"/> U.S. QUARANTINE STATION | 7. Signature of issuing officer <i>Mark L. Hempfl, M.S.</i> Mark L. Hempfl, M.S., Office of Health and Safety | |

CDC 0728 (P 13-40) REV. 2-91

42 CFR 71.54. Etiological agents, hosts, and vectors

(a) 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.

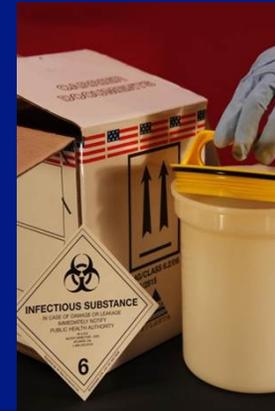
(b) Any import coming within the provisions of the section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

Note: Other permits may be required.

- USDA permit may be required
- Work with the material restricted to areas and conditions meeting Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines
- Material must be packaged and labeled in accordance with:
 - all applicable laws
- Subsequent distribution prohibited
 - (e.g. Influenza A H7N9 virus, Middle East Respiratory Syndrome)

Hand-Carrying Infectious Material

- ❑ In order to ensure the safety of the public, CDC's Import Permit Program will not approve the importation of infectious material if it is being hand-carried in the cabin of a passenger aircraft.
 - 49 CFR 175.75 (b) No person may carry a hazardous material in the cabin of a passenger-carrying aircraft or on the flight deck of any aircraft, and the hazardous material must be located in a place that is inaccessible to persons other than crew members. Hazardous materials may be carried in a main deck cargo compartment of a passenger aircraft provided that the compartment is inaccessible to passengers and that it meets all certification requirements for a Class B aircraft cargo compartment in 14 CFR 25.857(b) or for a Class C aircraft cargo compartment in 14 CFR 25.857(c).



Denials, Revocations and Suspensions

- ❑ A permit can be denied, revoked or suspended if:
 - (1) The biosafety measures of the permit holder are not commensurate with the hazard posed by the infectious biological agent, infectious substance, or vector, and the level of risk given its intended use; or,
 - (2) The permit holder fails to comply with all conditions, restrictions, and precautions specified in the permit.



Material That Does Not Require an Import Permit 42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- With the exception of bat or nonhuman primate specimens, it is a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent.
 - Healthy human specimens or samples
 - Rendered non-infectious
 - Material that is non-pathogenic to humans non-infectious disease
 - Non-infectious material (e.g., formalin-fixed slides, etc.)



Material That Does Not Require an Import Permit 42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- ❑ It consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent

- ❑ Examples:
 - Extracted Deoxyribonucleic acid (DNA) from bacteria
 - Viral nucleic acids that cannot produce any infectious biological agent



Permit not Required Certification Statement

- ❑ A detailed description of the material and a statement on official letter head signed by the sender or the recipient clearly stating that
 - (1) the material is not known or suspected to contain an infectious biological agent and
 - (2) how the person making the certification knows that the specimen does not contain an infectious biological agent; or the basis of the belief that there is no reason to suspect that the specimen does not contain an infectious biological agent; or a detailed description of how the material was rendered noninfectious.



42 CFR 71.54 (h) Inspection

- ❑ Issuance of a permit may be contingent upon an inspection of the importer's facility by the CDC to evaluate whether the importer's biosafety measures are commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector, and the level of risk given its intended use.

Inspection/Biosafety

- ❑ Verify that work is commensurate with the hazard posed by the infectious biological agent, infectious substance and/or vector to be imported, and the level of risk given its intended use.



Criteria used to determine if an inspection may be required

- ❑ Biological safety level where work will be conducted
- ❑ Risk of the agent and work conducted
- ❑ May not be inspected if the laboratory has been inspected by the Federal Select Agent Program



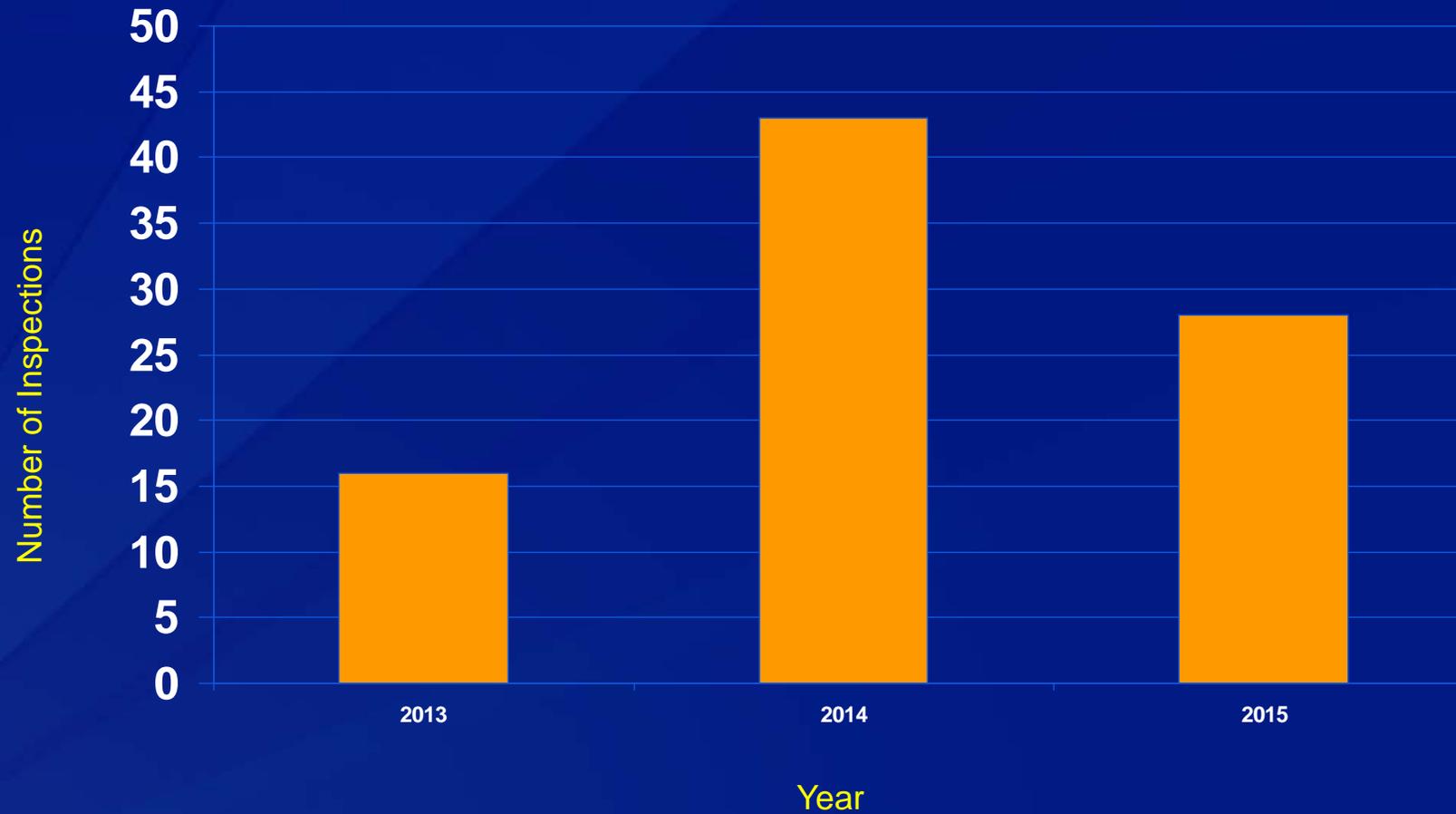
Import Permit Inspection Program

- ❑ Most common agents associated with inspections:
 - *Mycobacterium tuberculosis*
 - Middle East Respiratory Syndrome coronavirus
 - Chikungunya virus
 - Avian Influenza A H7N9 Virus
- ❑ Common descriptions of work:
 - Research
 - Human diagnostic testing
 - Animal studies
 - Molecular biology research



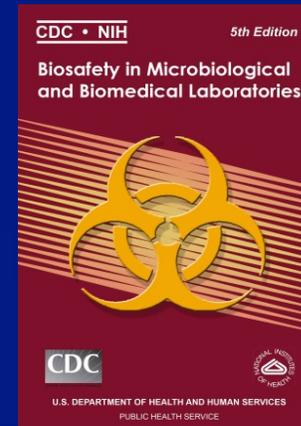
Inspections Conducted by Year

(Total = 87 inspections)



Review of Biosafety Measures

- ❑ A review of laboratory practices and procedures will be conducted to ensure proper biosafety measures have been implemented (e.g., biosafety plan)
 - This will include an inspection of the laboratories where the work will be conducted.
- ❑ Annual biosafety cabinet certifications
- ❑ HEPA filter certifications
- ❑ BSL-3 design and operational re-verification records
- ❑ DSAT recognizes the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) as the national biosafety standard and accordingly the entity must consider the guidance found in the BMBL when developing its biosafety measures.



Review of Biosafety Measures

BSL-3 Practices and Procedures

□ Inspectors will review:

- Practices to ensure procedures are performed to minimize the creation of splashes and/or aerosols
- Hand washing procedures
- Decontamination and waste handling procedures for cultures, stocks, equipment and other potentially infectious materials.
- Procedures for use of biosafety cabinet
- Proper use of PPE (e.g., eye protection, solid front gowns, gloves, respirators-if needed)

*Please note that this list is not all-inclusive

Review of Biosafety Measures

BSL-3 Laboratory Facilities

□ Inspectors will review:

- Hands free or automatically operated sinks
- Availability of eyewash stations
- Use and availability of autoclave
- Ducted air ventilation system
 - Draws air into the laboratory from “clean” areas toward “potentially contaminated” areas
 - Verification of directional airflow before entering laboratory

*Please note that this list is not all-inclusive

Import Permit Inspection Program

- ❑ **Common observations noted:**
 - Improper donning and doffing procedures
 - Laboratory not maintaining negative airflow
 - Infectious material placed in non-leak-proof cardboard boxes for storage, processing, or transport
 - Improper decontamination procedures
 - Lack of use of centrifuge safety cups during centrifugation (production of aerosols)



Import Permit Inspection Program

- ❑ Common observations noted:
 - Inadequate biosafety plan
 - Improper use of Personal Protective Equipment
 - Lack of maintenance of HVAC system
 - Inoperable alarms for HVAC system failure
 - Facility re-verification
 - Personnel not trained



Inspection Report

- ❑ An inspection report will be emailed to the permittee in one to two weeks following the inspection. In some cases, additional information will not be needed.
- ❑ Report will include :
 - Inspector observations during the inspection
 - A request for further information
- ❑ A written response to the report should be provided to CDC via email within two weeks.

Inadequate Response Letter

- ❑ A letter written by the CDC as a response to items that are deemed inadequate on the inspection report.
- ❑ Sent to the entity via email within one to two weeks.
- ❑ A response is required from the entity addressing this report within two weeks.

How to Avoid an Inadequate Response Letter

- ❑ Provide an adequate and concise responses to each specific observation noted during inspection.
- ❑ Responses can include pictures or other forms of documentation that permittee deems necessary to address each observations.
- ❑ **Contact the Inspection Team.**
 - There to provide clarification and any assistance necessary.

Adequate response letter

- ❑ Sent to the entity when all inspection deficiencies are adequately addressed.
- ❑ Letter will be sent to the entity via email and fax.
- ❑ This letter signifies the inspection report is closed and no further information is required.

Frequently Asked Questions

❑ Is there a fee for obtaining a CDC import permit?

No. Currently, there is no fee for processing a CDC import permit

❑ Is an import permit required to import material that has received approval from U.S. Food and Drug Administration?

No. Any product that is cleared, approved, licensed, or otherwise authorized under any of the following laws would not require a CDC Import Permit:

- The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or
- Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262), or
- The Virus-Serum-Toxin Act (21 U.S.C. 151-159).

❑ Am I able to amend (e.g., add/remove permittees, senders, or infectious biological agents) a current import permit?

No, import permits cannot be amended. For any changes to an import permit, the applicant must submit a completed application form.

Frequently Asked Questions

- ❑ **Is an import permit required to import a select agent or toxin or transfer the material within the United States?**

No. A CDC import permit is not required for select agents and toxins listed in 42 CFR §§ 73.3, .4 or 9 CFR § 121.4 as long as its importation has been authorized in accordance with 42 CFR § 73.16 or 9 CFR § 121.16.

- ❑ **What are the responsibilities of the importer once an import permit has been issued?**

The CDC import permit is issued only to the importer located in the United States. The importer is responsible for assuring that the foreign personnel package, label, and ship the infectious material according to Federal regulations and international standards.