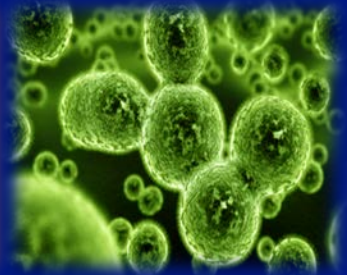
Revisions of the CDC Import Permit Regulations (42 CFR 71.54)



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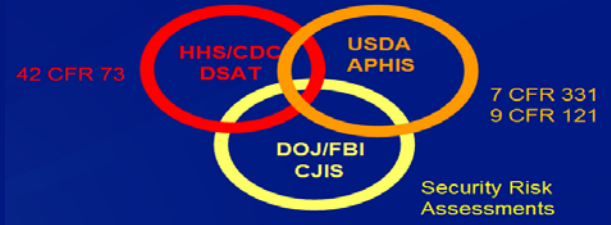
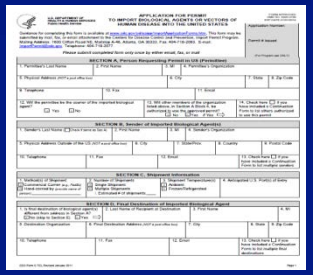
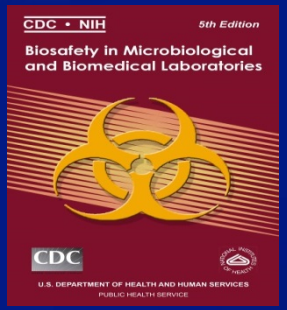
Chief, Program Services Branch
Division of Select Agents and Toxins

Division of Select Agents and Toxins

- **Federal Select Agent Program (42 C.F.R. Part 73)**
  - Regulates all entities that possess, use, or transfer biological agents or toxins that have the potential to pose a severe threat to public health and safety
- **CDC Import Permit Program (42 C.F.R. § 71.54)**
  - Regulates the importation of infectious biological agents, infectious substances, and vectors capable of causing communicable disease in humans
- **Promote laboratory safety and security**







CDC Import Permit Program

- Assists in protecting the United States public health and safety by ensuring that all imported agents are imported safely into the United States.
- Ensures that appropriate safety measures are in place for the imported infectious agents.
- Provides oversight to prevent the **introduction, transmission, or spread** of communicable diseases

Rulemaking

- Needed to improve CDC's ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.
- October 14, 2011: CDC published a notice of proposed rulemaking to amend 42 CFR 71.54.
  - 60 day comment period
- February 4, 2013: CDC published Final Rule.
  - *Effective Date: April 5, 2013*

Changes to Import Permit Regulations

- Add regulatory definitions of items that require an import permit
- Ensure adequate biosafety measures
- Increase oversight through inspections
- Exemptions are listed
- Provide an appeals process

Imported 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.
- Examples:
  - Healthy human specimens or samples
  - Rendered non-infectious
  - Material that is non-pathogenic to humans

Imported 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 is a biological agent listed in 42 CFR Part 73 as a select agent and its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.
  - Transfer authorization (APHIS/CDC Form 2)
  - Examples: *Bacillus anthracis*, *Francisella tularensis*, Ebola Virus

Imported 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

42 CFR 71.54 (f)

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

- Product that is cleared, approved, licensed, or otherwise authorized under any of the following laws:
  - 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).

42 CFR 71.54 (f)

A CDC Import Permit is not required for an item if:

- It is an animal or animal product listed in 42 CFR Part 71 and its importation has been authorized in accordance with 42 CFR 71.52, 71.53, or 71.56.

Permit Not Required Certification Statement

A statement confirming that the material is not known to contain or suspected of containing an infectious biological agent. Such items should be accompanied by:

- A description of the material;
- A statement that this material meets one of the above criteria (e.g., this material is not known or suspected to contain an infectious agent or vector of human disease);
- Verification that it has been packaged, labeled, and transported in accordance with all applicable regulations; and
- It must accompany the package being imported.

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.

Appeals

- Denial, suspension, or revocation of a permit under this section may be appealed to the CDC Director.
- The appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30 calendar days of the denial, suspension, or revocation of the permit.

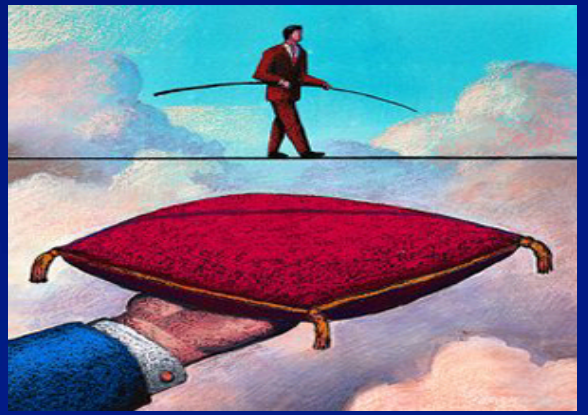
42 CFR 71.54 (h) Inspection

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.

Working with materials regulated by 42 CFR 71.54

Manage Risk

- Risk assessment should **guide the selection of appropriate microbiological practices, safety equipment, and facility safeguards** that can prevent exposures and reduce the incidence of LAIs.
- Aid in ensuring safe possession and use of infectious imported materials.



Criteria used to determine if an inspection may be required

- Biological safety level where work will be conducted:
  - BSL-3, BSL-4
  - Animal BSL (ABSL)-3, ABSL-4
  - BSL-3Agriculture laboratory work

- Risk of the agent and work conducted

- May not be inspected if the laboratory has been inspected by the Federal Select Agent Program

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

Problems Identified during Inspections

(As of April 2013)

- Inadequate biosafety plan
- BSL-3 laboratories without hands-free sink
- Personnel not trained
- 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)

Problems Identified during Inspections

(As of April 2013)

- Inoperable alarms for HVAC system failure
- Staff observed transporting infectious material through areas designated for eating and drinking
- Staff observed wearing gloves outside laboratory
- Holes and cracks observed in ceiling and walls of BSL-3 laboratories
- Lack of maintenance of HVAC system
- Laboratory doors propped open

Thank You




For more information please contact Centers for Disease Control and Prevention

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