

# CDC Import Permits: A Retrospective

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# CDC Import Permits

- Background on the Import Permit Program
- Inspection Preparation
- In-Person Inspections
- Remote Inspections
- Lessons Learned

# CDC IPP

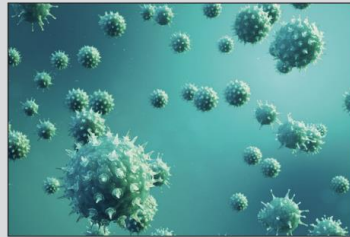
- The CDC Import Permit Program, or IPP, regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S. The program ensures that the importation of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the imported agents.

# What type of work requires a permit?

## DO YOU NEED AN IMPORT PERMIT FROM CDC?

The CDC Import Permit Program, or IPP, regulates infectious biological materials coming into the U.S. in order to prevent the introduction and spread of disease in humans. This helps to protect the health of laboratory workers and those in the surrounding communities.

**If you plan to import one of the following items, you will need an import permit from CDC:**



- Infectious biological agents capable of causing illness in humans (e.g., bacteria, viruses, fungi)



- Materials known or reasonably expected to contain an infectious biological agent (e.g., blood, tissues, fluids)



- Vectors of human disease (e.g., mosquitoes, ticks, bats)

# CDC IPP Assistance

## **For technical help with using the eIPP system:**

eIPP users can reach the **eIPP Help Desk** for assistance via the contacts listed below.

- Fill out the online [Customer Support Request Form](#)
- Email us at [eIPPSupport@cdc.gov](mailto:eIPPSupport@cdc.gov)
- Call us at 404-718-2077


### ***Note for New Users***

All potential applicants are required to have a SAMS (Secure Access Management Services) account – which protects the security of the information by requiring users to enter a user ID and password, or other secure credentials, before providing access to the system – in order to access the eIPP system to apply for a permit. If you do not yet have a SAMS account but would like to establish one in order to submit a new application, please contact us at the Help Desk via one of the methods above, and someone will be in touch with you soon.

## **For general questions related to the Import Permit Program (e.g., filling out the application, determining whether an import permit is needed):**

Please contact us via phone at 404-718-2077 or email at [importpermit@cdc.gov](mailto:importpermit@cdc.gov).

# Does a Filed Permit mean an Automatic Inspection?

Will my facility be inspected prior to issuance of an import permit? 

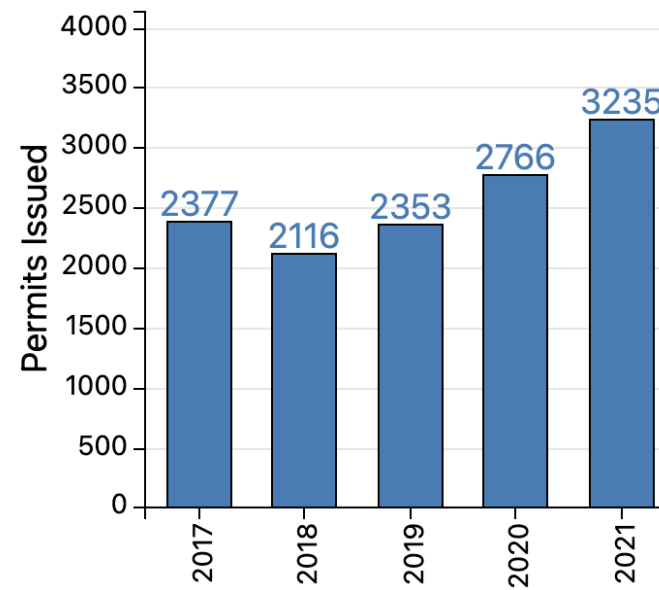
It depends. The Centers for Disease Control and Prevention's Import Permit Program may inspect an entity to verify the importer has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance and/or vector to be imported, and the level of risk given its intended use. Laboratories that have been inspected by either HHS/CDC or the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) under the HHS or USDA select agent regulations (42 CFR Part 73, 9 CFR Part 121, or 7 CFR Part 331) will not require an additional inspection.

# Import Permit Trends

- Most permits are issued to laboratory facilities at government agencies and universities, or to private and commercial laboratories conducting research studies or diagnostic activities. In recent years, more than 2,500 import permits have been issued by the program annually, with a total of 3,235 issued in 2021.

# Import Permit Trends

## Import Permits Issued by Year



# Import Permit Inspections

- An inspection may be conducted before a permit is issued, in order to ensure the applicant's facility has appropriate measures in place to minimize the accidental release of biological agents capable of causing human disease. Inspections evaluate the applicant's biosafety measures (e.g., physical structure, operational and procedural safeguards). Applicants may be informed of inspections ahead of time, or they may be unannounced.
- In 2021, 91 Import Permit Inspections were carried out by the CDC IPP.

# Inspection Preparation

# Inspection Preparation

- The CDC Import Permit Program inspects entities using standardized checklists to verify that facilities have implemented the appropriate biosafety measures for the infectious biological agent, infectious substance, or vector to be imported.
- Checklists available include BSL-2, BSL-3, ACL-2, ACL-3, ABSL-2, and ABSL-3.

# Inspection Preparation

Revised May 2021

CDC Import Permit Inspection Checklist for BSL-3 Laboratories (BMBL 6 <sup>th</sup> Edition)					
Entity Name:		Insp. Date:			
Street Address:					
City, State, Zip:					
Lead Inspector:					
Other Inspectors:					
Building/Room(s):					
PI(s):					
Reference	Statement	Response			Comments
		Yes	No	N/A	
CFR: 71.54 (b)	Unless excluded pursuant to paragraph (f) of this section, a person may not import into the United States any infectious biological agent, infectious substance or vector unless:				
CFR: 71.54 (b)(1)	It is accompanied by a permit issued by CDC. The possession of a permit issued by CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.				
CFR: 71.54 (b)(2)	The importer takes measures to help ensure the shipper complies with all permit requirements and conditions.				
CFR: 71.54 (b)(3)	The importer has implemented biosafety measures 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.				
CFR: 71.54 (b)(4)	The importer is in compliance with all applicable legal requirements concerning the packaging and shipment of infectious substances.				
CFR: 71.54 (c)	If noted as a condition of the issued permit, subsequent transfers of any infectious biological agent, infectious substance or vector within the United States will require an additional permit issued by the CDC.				
<b>A Standard Microbiological Practices</b>					
BMBL: A1	The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.				
BMBL: A2	The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical				

# Inspection Preparation

## Information and Records for Remote-Only Import Permit Inspection

**Upload the records indicated into eIPP prior to the start of your inspection.** Electronic records can be, but are not limited to, scanned images, photographs, or databases converted into a PDF. Let your lead inspector know if you encounter any issues uploading these documents, are unable to convert a file into an electronic document, or do not have access to an electronic copy.

- Biosafety plan / manual
- Floor plan
- A record of each importation
- List of staff that work with imported materials
- Training records (Staff and visitor training)
- Annual laboratory self-inspection records
- Annual Biological Safety Cabinet certification records
- HEPA filter certification records, if applicable
- Autoclave performance testing records, if applicable
- Institutional Biosafety Committee meeting minutes, if applicable
- Insect/rodent control records
- Medical surveillance program documentation
- Documentation of BSL-3/ABSL-3 facility re-verification, if applicable [https://www.cdc.gov/cpr/ipp/docs/Policy\\_Import\\_BSL3\\_ABSL3\\_Verification.pdf](https://www.cdc.gov/cpr/ipp/docs/Policy_Import_BSL3_ABSL3_Verification.pdf)

**All required records must be available for a minimum of the last year, but additional records may be requested.**

# In-Person Inspection

# In-Person Inspection

- Inspection took place on September 11<sup>th</sup>, 2019.
- We were given a generous one month's notice prior to the inspection.
- Permitted material was in a large lab and consisted of both BSL-2 and BSL-3 bacterial pathogens from Singapore, Haiti, and South Africa.
- CDC sent three inspectors for a period of two full days.

# In-Person Inspection

- Day one:
  - Program overview
  - Containment visitor training
  - Tours of the BSL-2 laboratory areas
  - Tours of the BSL-3 laboratory areas
- Day two:
  - Document review
  - Close-out

# In-Person Inspection Findings

- Facilities in good standing, with two minor findings:
  - The permit needed to be updated to reflect the spaces where the materials were being used.
    - The inspection encompassed these areas but it was not spelled out correctly.
  - There was a researcher observed in one of the permitted areas wearing gloves while not touch contaminated devices.
    - This was something we pushed back on but we did come to a compromise with signage and training improvements to display to our staff about the complacency of glove wearing and the potential hazards it can lead to.

# Remote Inspection

# Remote Inspection

- This inspection took place on March 9<sup>th</sup>, 2021.
- We were informed of the inspection on January 29<sup>th</sup>, 2021 and given a wide selection of dates to choose from for the inspection.
- This was another large laboratory at our institute, different from the laboratory inspected in 2019.
  - There were some overlapping spaces.
  - The main focus was on spaces that had not previously been inspected but they were still looked at on a high level.

# Remote Inspection

2021. This inspection will be a virtual meeting through Microsoft Teams (please see call-in/connection information below). A tentative schedule and agenda for the day will be:

1. **9:00AM EST Opening Meeting:** Introductions, brief overview by Hackensack Meridian Health regarding the work being conducted with the imported material
2. **9:30-11:30AM:** Virtual Tours of the laboratory/freezer space: We will ask that someone familiar with the lab and lab work take us through a virtual walk-through of your floor plans and discuss the work being done in the laboratory.
3. **11:30-12:30 Break for lunch**
4. **12:30-2:30** CDC will continue to review documentation; Hackensack Meridian Health staff do not need to be on the line during this time, we can meet back during the close-out meeting
5. **2:30-3:30:** One on One staff interviews (we would like to take 15-20 minutes to interview staff working in the lab with the imported material).
6. **3:30/4:00 (Exact time TBD):** Close-out meeting to review findings

# Remote Inspection Findings

- There were no significant findings.
- Of note, it was pointed out that work that was occurring at our facility with foreign isolates of SARS-CoV-2 from BEI had arrived without the filing of a CDC import permit.

# Lessons Learned

# Use your Tools



**Laboratory Safety  
Guidance**

**NIH GUIDELINES FOR RESEARCH  
INVOLVING  
RECOMBINANT OR SYNTHETIC  
NUCLEIC ACID MOLECULES  
(NIH GUIDELINES)**

**APRIL 2019**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
National Institutes of Health

# Contextualize the Inspection

- The specificity of the permit inspection allows for a focus on that work and not a broad scoped general facility inspection.
- We were diligent to give them exactly what was asked for and nothing more.
- For the remote inspection, we were very clear in the floor plans and picture tours of the areas that were used with the permit.

# Materials for Review

- Binders, Binders, and more Binders
  - For the in-person inspection, our paper documentation filled a conference room.
  - At the time, there was not an option to provide materials ahead of time.
  - For the remote inspection, we were allowed to provide materials digitally ahead of time.
  - This significantly cut down on the document review time as expected.
  - Allowed for time to generate responses before the inspection concluded, providing a clean inspection report.

# Digitize Records

- This may seem like common sense these days, but the ability to digitally store and maintain records allowed for the inspection process to move incredibly smoothly.
- Scanning is your friend.
  - We inevitably had things that were paper-only records but scanning and collating that material allowed us to have answers to all inquiries at the touch of a finger.
  - This can be a daunting task but well worth it to maintain.
  - A great project for summer interns!

# CDC IPP Checklists

- Easily available online and concisely pulled from the regulations and guidance.
- We filled these out in addition to our internal annual checklist and it really provided the inspectors a straightforward interpretation that didn't require any translation or comparability.

# Digestible Materials

- We placed ourselves in the shoes of the inspectors once given their list of requirements.
- This allowed us to frame the inspection materials in a way that directly addressed what was being sought in a timely manner.
- We did not give them anything in excess that would have required any digging through onerous volumes of records.

Questions?