



# Import Permit Program (IPP) Inspection Process: Considerations & Findings

**CDC IPP Senior Microbiologist**

Import Permit Webinar

December 2, 2021

**If you apply for a permit from the Centers for Disease Control (CDC) Import Permit Program (IPP), you may be inspected.**

# Regulatory Authority to Inspect 42 CFR § 71.54(h)

- 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 (e.g., physical structure and features of the facility, and operational and procedural safeguards) 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.

AS THE PERMITTEE, YOUR FACILITY WILL BE SUBJECT TO INSPECTION AT SOME TIME IN THE FUTURE TO CONFIRM THAT THE IMPORTERS BIOSAFETY MEASURES ARE COMMENSURATE WITH THE HAZARD POSED BY THE ITEMS TO BE IMPORTED AND THE LEVEL OF RISK GIVEN ITS INTENDED USE.

# Primary Focus of Inspections

- Verify adequate biosafety measures are commensurate with the risk of the agent, given its intended use
  
- Verify information in the permit application

# Types of IPP Inspections

- On-site Inspections
  - Traditional in-person review of facilities and paperwork
  - Through 3<sup>rd</sup> quarter of 2021 = 41 total inspections
- Remote Inspections
  - Upload documents into the eIPP system in advance
  - Inspection via interviews, photos and videos
  - Through 3<sup>rd</sup> quarter of 2021 = 31 total inspections
- Hybrid Inspections
  - Combination of remote and on-site

# **The Inspection Process: Remote Inspections and On-Site Inspections**

# Prior to the Inspection

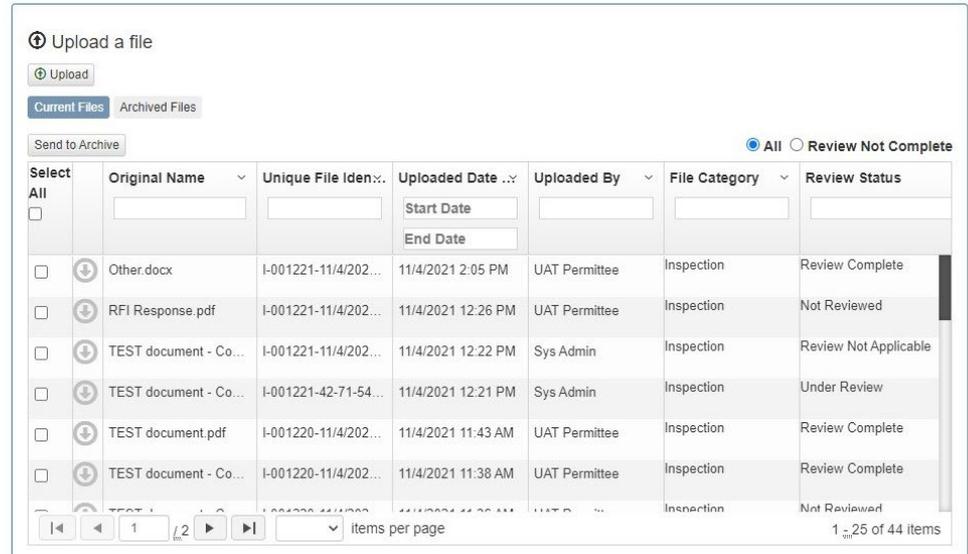
- Notice of Inspection
  - Email and message in the eIPP system
  - Set inspection dates
  - Inspection created in the new eIPP inspection module
- Inspection Logistics
  - Lead inspector will contact permittee prior to the inspection date
  - Document request list
  - Inspection itinerary
  - Inspection platform (remote or hybrid inspections)

# Prior to the Inspection

- Inspection team will review any documents uploaded prior to the inspection

- Biosafety Plan
- Importation records
- List of staff that work with imported materials
- Training records
- Annual biological safety cabinet certifications
- HEPA filter certifications

Inspection Files



Upload a file

Upload

Current Files Archived Files

Send to Archive

All  Review Not Complete

Select	Original Name	Unique File Identifier	Uploaded Date	Uploaded By	File Category	Review Status
<input type="checkbox"/>			Start Date End Date			
<input type="checkbox"/>	Other.docx	I-001221-11/4/202...	11/4/2021 2:05 PM	UAT Permittee	Inspection	Review Complete
<input type="checkbox"/>	RFI Response.pdf	I-001221-11/4/202...	11/4/2021 12:26 PM	UAT Permittee	Inspection	Not Reviewed
<input type="checkbox"/>	TEST document - Co...	I-001221-11/4/202...	11/4/2021 12:22 PM	Sys Admin	Inspection	Review Not Applicable
<input type="checkbox"/>	TEST document - Co...	I-001221-42-71-54...	11/4/2021 12:21 PM	Sys Admin	Inspection	Under Review
<input type="checkbox"/>	TEST document.pdf	I-001220-11/4/202...	11/4/2021 11:43 AM	UAT Permittee	Inspection	Review Complete
<input type="checkbox"/>	TEST document - Co...	I-001220-11/4/202...	11/4/2021 11:38 AM	UAT Permittee	Inspection	Review Complete
<input type="checkbox"/>	TEST document - Co...	I-001220-11/4/202...	11/4/2021 11:38 AM	UAT Permittee	Inspection	Not Reviewed

1 2 items per page

1 of 25 of 44 items

# Inspection Day

- Introductory meeting
- Laboratory walk through (virtually if remote inspection)
- Document review with touch points
- Interviews
  - Permittee
  - Laboratorians
  - Facility specialists
  - Shipping / Receiving staff
- Close-out meeting

# Post-Inspection Days

- Inspection Team provides debrief to IPP Leadership
- Report may contain:
  - Departures (Permittee must respond)
  - Concerns (Items for consideration regarding biosafety or application)

# Post-Inspection Days

Inspection report will be released in the eIPP inspection module within 30 business days.

General Discussion

Dear permittee,

Your inspection report has been issued and uploaded to <https://eipp.cdc.gov/>, "IPP Inspection Report – Organization Name (Permittee Name)". Please login to eIPP to view the report (see application YYYYMMDD-XXXXA). A written response is due by December 31, 2020. Please upload your responses to [eipp.cdc.gov](mailto:eipp.cdc.gov) and notify the lead inspector, Inspector Name ([inspector@cdc.gov](mailto:inspector@cdc.gov)).

If you have any questions or concerns, please feel free to contact the CDC Import Permit Program using the information below.

Thank you,  
Centers for Disease Control and Prevention Import Permit Program: 404-718-2077  
<https://www.cdc.gov/cpr/ipp/support.htm>

Type your message here...

Send

## Inspection Details

**INSPECTION #** 001223

**Application Type:**  
Agents

**INSPECTION STATUS**

In Progress

**INSPECTION DATES** 11/05/2021 - 11/05/2021

**Application Status:**  
Post-Approval

**LEAD INSPECTOR**

**Application Number(s):**  
20211105-0284A

**CO-INSPECTORS**

**Permit Expiration Date:**  
11/05/2022

**Non-IPP Program Participants**

## Notifications

Filter: Inspections

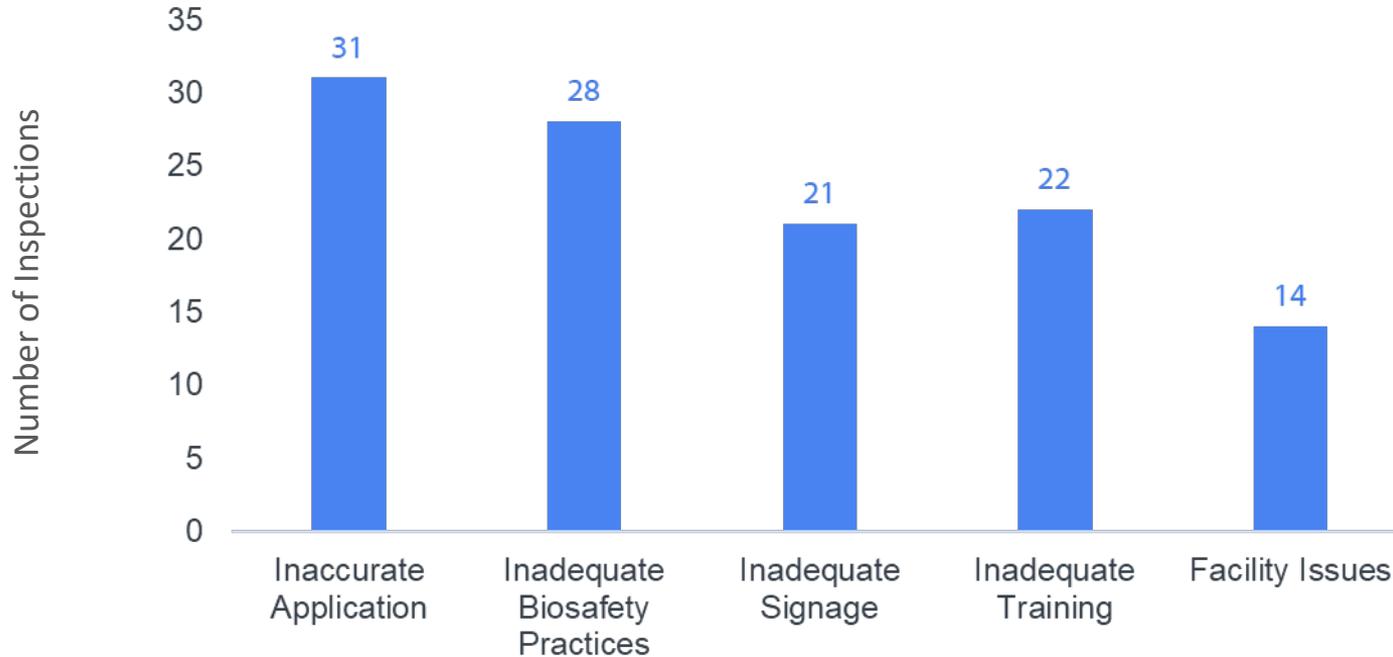
Archive Selected

Current  Archived  Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>	Sys Admin	Inspections View	11/5/2021 8:00:45 AM	All inspection findings have been released for Inspection #001223.	Flag
<input type="checkbox"/>	Sys Admin	Inspections View	11/5/2021 8:00:40 AM	Inspection #001223 UID:42-71-54-012300 with Departure Type of Final has been released for permittee review.	Flag

# Results from Inspections

# Most Common Inspection Departures



n = 72 total IPP inspections through third quarter 2021

# Tips for a Successful Inspection

- Verify information in application
  - Biosafety measures have been implemented and are commensurate with the risk
  - Training has been updated as necessary and provided
  - The work and location where work occurs is accurate on the application
- Organize and upload documents in advance
- Ask questions

# Resources

- Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition
  - <https://www.cdc.gov/labs/BMBL.html>
- Inspector Checklists
  - <https://www.cdc.gov/cpr/ipp/inspection/>
- Current CDC SARS-CoV-2 Guidance
  - <https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

