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

CDC IPP Senior Microbiologist

Import Permit Webinar

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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 3rd quarter of 2021 = 41 total inspections

- Remote Inspections
    - Upload documents into the eIPP system in advance
    - Inspection via interviews, photos and videos
    - Through 3rd 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
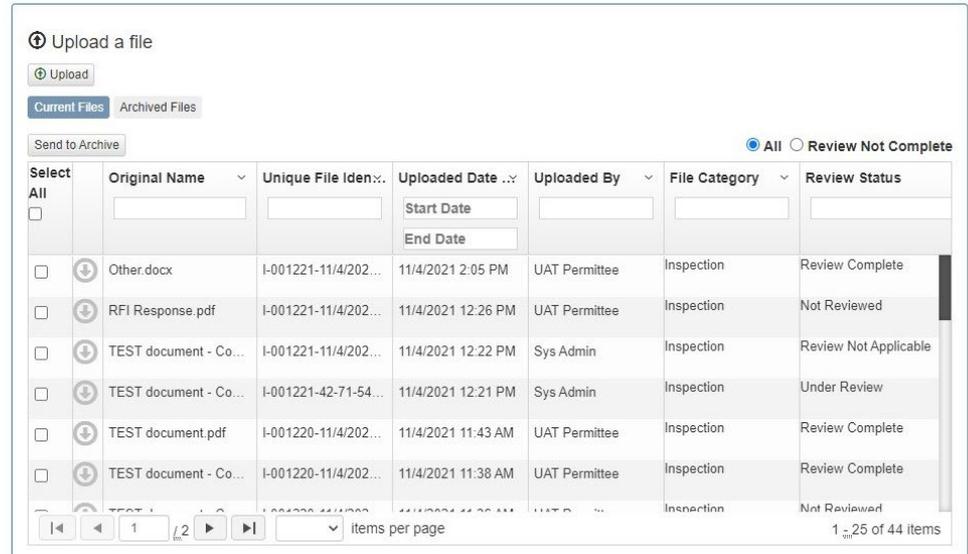
Upload a file

Upload

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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.

Results from Inspections

Most Common Inspection Departures
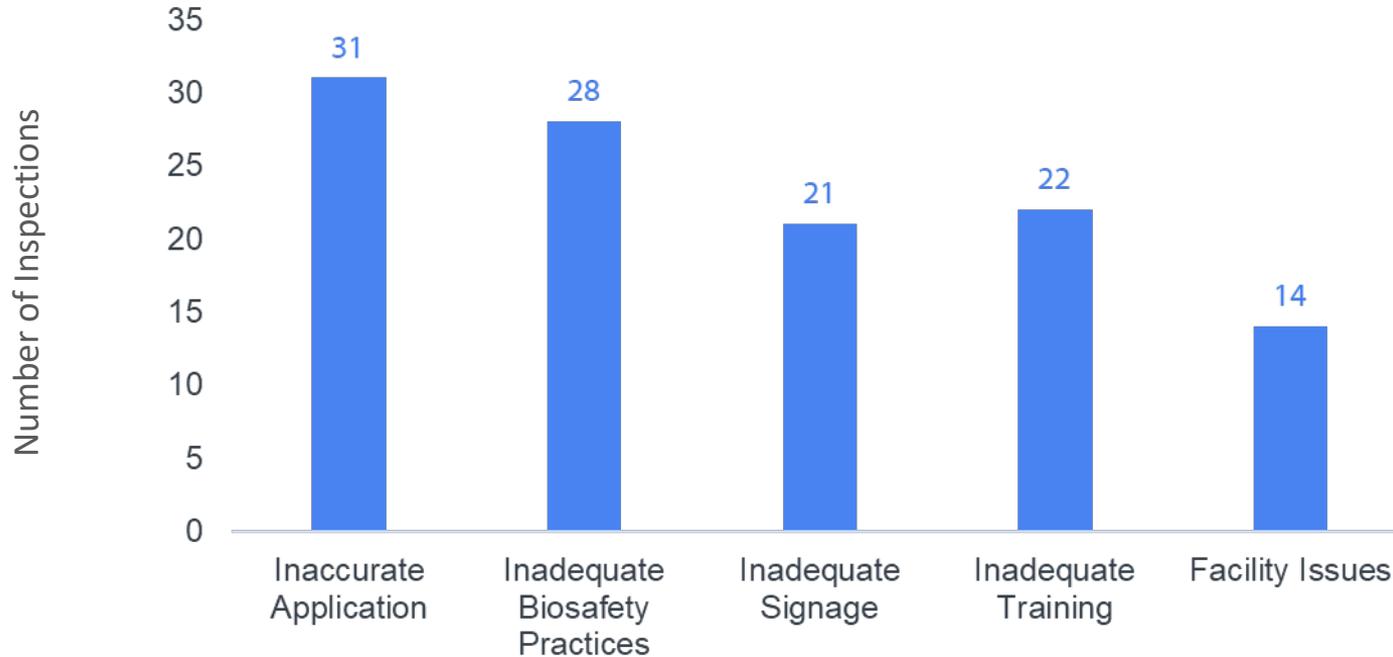
n = 72 total IPP inspections through third quarter 2021

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

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.