



# **The Import Permit Program (IPP) Remote Inspection Process**

**Centers for Disease Control and Prevention (CDC)**

**Division of Select Agents and Toxins (DSAT)**

**Import Permit Program (IPP)**

Import Permit Webinar

December 2020

**If you apply for a permit from the CDC 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

- Onsite Inspections
  - Traditional in person review of facilities and paperwork
  - 2020 = 3
- Remote Inspections
  - Upload documents into the eIPP system in advance
  - Inspection via interviews, photos and videos
  - Through 3<sup>rd</sup> quarter of 2020 = 53
- Hybrid Inspection (future)
  - Combination of remote and onsite

# The Remote Inspection Process

# Prior to the Inspection

- Notice of Inspection
  - Email and message in the eIPP system
  - Set inspection dates
- Inspection Logistics
  - Lead inspector will contact the permittee prior to the inspection date
  - Document request list
  - Inspection itinerary
  - Inspection platform
    - Microsoft Teams, Skype, Zoom or Teleconference

# Prior to the Inspection

- Inspection team will review any documents uploaded prior to the inspection
  - Biosafety plan
  - A record of each importation
  - List of staff that work with imported materials
  - Training records
  - Annual biological safety cabinet certifications
  - HEPA filter certifications

## Upload Attachment

Any additional documents or information can be added here

General Attachments

Choose File No file chosen

Show file naming rules

Attachments

Biosafety Plan.docx	<a href="#">Download</a>
Biosafety Cabinet Certification 1 of 2.pdf	<a href="#">Download</a>



# Inspection Day

- Introductory / opening meeting
- Remote laboratory tour
- 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
  - Leadership
  - Legal
  - Technical Writer
- Report may contain:
  - Departures (Permittee must respond)
  - Concerns (Items for consideration regarding biosafety or application)

# Post-Inspection Days

- Inspection report will be uploaded and associated with your application/permit in eIPP 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

## Upload Attachment

Any additional documents or information can be added here

General Attachments

Choose File No file chosen Upload

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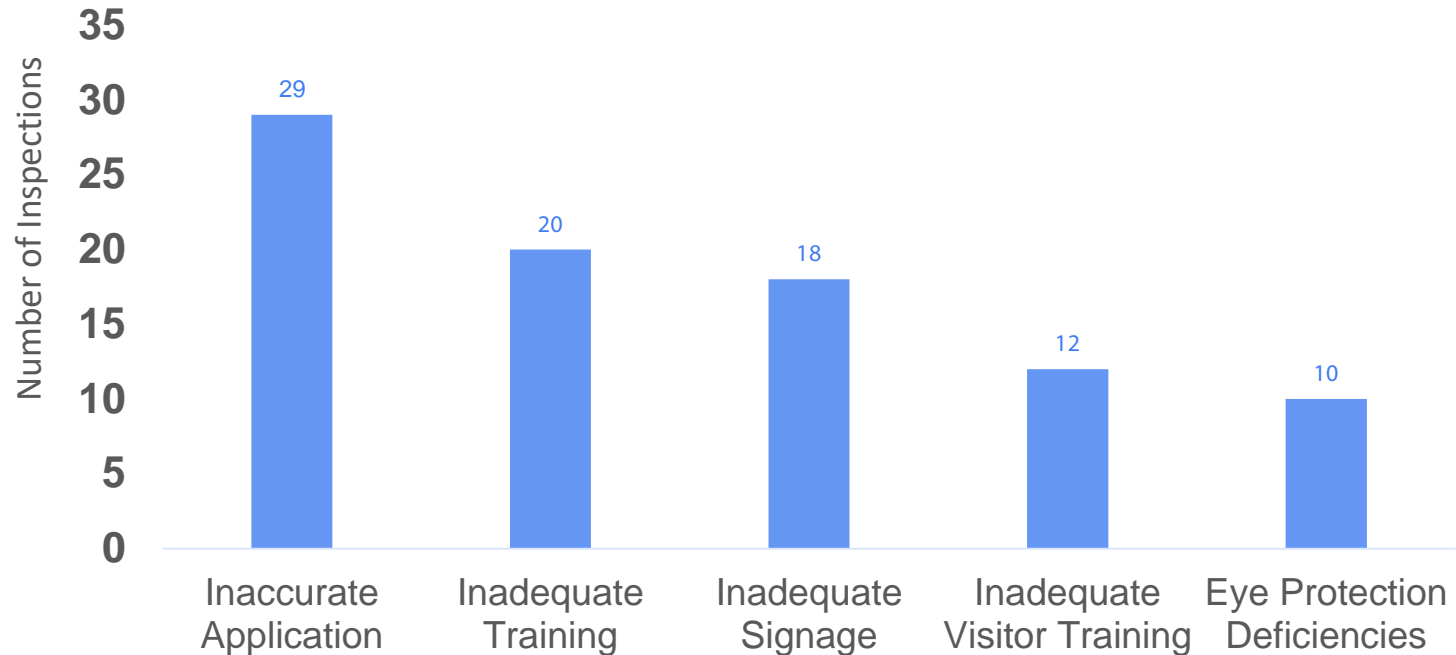
Attachments

Biosafety Plan.docx	Download
IPP Inspection Report - Organization Name (Permittee Name).pdf	Download
Biosafety Cabinet Certification 1 of 2.pdf	Download

# Results From Implementing Remote Inspections

- Several applications were **withdrawn** prior to inspection.
- Several applications were **revoked** because information provided on the application showed biosafety measures in place that were not adequate for the hazards.

# Most Common Departures in Remote Inspections



n= 53 total remote IPP inspections through third quarter of 2020

# Tips for a Successful Remote 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), 5<sup>th</sup> edition
  - <https://www.cdc.gov/labs/BMBL.html>
- Inspector Checklists
  - <https://www.cdc.gov/cpr/ipp/inspection/index.htm>
- Current CDC SARS-CoV-2 Guidance
  - <https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>

## CDC Import Permit Program

404-718-2077

[importpermit@cdc.gov](mailto:importpermit@cdc.gov)

<https://www.cdc.gov/cpr/ipp/index.htm>

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.

