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)
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 3rd 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
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.
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

- Inaccurate Application: 29
- Inadequate Training: 20
- Inadequate Signage: 18
- Inadequate Visitor Training: 12
- Eye Protection Deficiencies: 10

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), 5th edition
  - [https://www.cdc.gov/labs/BMBL.html](https://www.cdc.gov/labs/BMBL.html)

- Inspector Checklists
  - [https://www.cdc.gov/cpr/ipp/inspection/index.htm](https://www.cdc.gov/cpr/ipp/inspection/index.htm)

- Current CDC SARS-CoV-2 Guidance
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.