Electronic Import Permit Program (eIPP) Information System

Inspection Module Overview

CDC IPP Microbiologist

Import Permit Webinar

December 2, 2021

Electronic Import Permit Program (eIPP) System Basics

- **Two-way portal released in 2018.**

- **All applications must be submitted in https://eipp.cdc.gov/.**

- **Maintains comprehensive history of applications, correspondence, permits, and inspections.**

- **Review status can be monitored in real time with daily email summaries when changes occur.**

New Inspection Module Overview

Inspections

- To access the Inspections Module, the permittee must log in to eIPP and then click "Inspections" on the homepage.
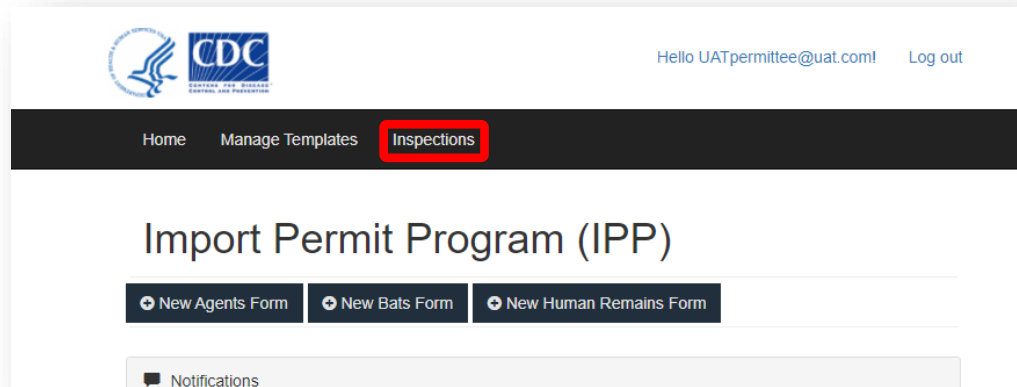
- "Inspections" tab only displays after the first inspection is scheduled in eIPP.

Inspections Tables

- Starting in late 2021 the Inspections Table includes current and previous inspection.
- Data will display once inspections are scheduled.

Inspection ⌄	Application Num⌄	Permit Expiratio⌄	Inspection⌄	Inspection Category ⌄	Start Date⌄	Stop Date⌄	Lead Inspect⌄	Inspection Status ⌄	⌄	⌄
		Start Date			Start Da	Start Da				
		End Date			End Da	End Da				
001202.1	20210629-0098H,...	06/29/2022	Announced	On-Site Verification,Hybrid	08/17/2021	08/17/2021	▓▓▓▓	Inspection Closeout Act...	Details	History
001202	20210629-0098H,...	06/29/2022	Announced	Remote	08/15/2021	08/15/2021	▓▓▓▓	Closed	Details	History
001198	20210628-0082A	N/A (pre-approval)	Announced	On-Site Verification	08/14/2021	08/17/2021	▓▓▓▓	Inspection Resolution	Details	History

- The table includes inspection number, inspection type, start date, stop date, lead inspector and inspection status.

Inspection Status Events

- For each status change described below, the permittee receives a notification in eIPP, and a daily email summary based on actions executed by IPP.

    - **Scheduled** – Inspection is scheduled but has not occurred.

    - **In Progress** – Inspection is currently in progress based on beginning and end dates.

    - **Inspection Closeout** – Inspection has occurred and is under internal review.

    - **Inspection Resolution** – IPP has released at least one finding for entity review.

    - **Inspection Closed** – A final determination has been made on inspection observations (i.e, no open observations).

    - **Closed Conditionally** – One or more departures have been closed conditionally and there are no open observations.

    - **Canceled** – Inspection has been canceled.

Inspections Details Page

- **Click "Details" to access comprehensive information on a specific inspection.**
  - **Inspection correspondence, checklists, and findings.**
  - **Respond to an inspection report.**

Inspections

- **The resources section provides quick access to application information.**

Checklists

- **Inspection checklists are listed on the Inspection Details page. Only checklists applicable to a scheduled inspection will display.**

Checklist Details

- **A description for each checklist item will display allowing entities to see what items will be assessed.**

Inspections - Checklist

INSPECTION #: 001168   **CHECKLIST:** 42 CFR 71.54 - BSL3

UID	CFR/Section	Description
42-71-54-012000	42 CFR 71.54 (b)(3)	The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory [BMBL: (BSL3) A1]
42-71-54-012100	42 CFR 71.54 (b)(3)	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 hazards, splashes, aerosolization) and that appropriate records are maintained. [BMBL: (BSL3) A2]
42-71-54-012200	42 CFR 71.54 (b)(3)	Personnel receive annual updates and additional training when equipment, procedures, or policies change. [BMBL: (BSL3) A2]

Notifications

- **As inspection findings are released and additional information is requested, a notification will display on the Inspection Details.**

- **eIPP can share compliance information faster. With eIPP, departures can be released as soon as they are finalized, and the user can get the information that they need to be compliant quicker.**

Inspection Resolution

- The Inspection Resolution page details inspection findings.

Inspection Resolution (cont.)

- When you navigate to Inspection Resolution, you will see a splash page. To view inspection findings, click "Acknowledge and View Inspection Findings".

Inspection Resolution Page

▪ **The Inspection Resolution page lists findings by severity. Users can filter information by status, departure or compliance determination. The status filter will show open departures, requests for information (RFI) and items under review.**

View and Respond to Inspection Findings

- **On the Inspection Resolution page, the permittee can view and respond to findings.**

- **Currently, no other individuals can respond on behalf of the permittee.**

Note: If the permittee departs from the organization prior to closure of the inspection, then please contact eIPP Support at https://www.cdc.gov/cpr/ipp/support.htm or email importpermit@cdc.gov.

- **For items identified as application concerns, please complete the corrective action through the application.**

Upload Inspection Documentation

- **The permittee can upload supporting documentation for an inspection from the Inspection Resolution page.**

- **The upload section is at the bottom of the page. Click "upload" button to begin.**

Upload Document

- **Identify document data and upload.**

- **Avoid any special symbols in the file name.**

- **File names can be repeated, but that is discouraged.**

- **Unique file identifier is automatically assigned to differentiate file uploads.**

Response Notification

- **A notification will appear on the entity home page and the Inspection Details page when a response is submitted.**

| ☐ | Permittee | Inspections View | 9/10/2021 11:58:53 AM | Inspection #001152 UID:42-71-54-037000 has been responded to by the permittee. | 🏳 Flag |

Inspection Details – Upload Center

- **The uploaded files will appear in the Upload Center on the inspection.**
- **Details page and on the entity home page.**

Mark as Resolved Notification

- **If IPP staff identifies observation has been resolved, the permittee will receive a notification in eIPP and a daily summary email.**

Hybrid Inspections

- **eIPP now links an initial remote inspection with an on-site follow-up visit.**

- **Follow-up inspections are denoted with a ".1" appended to the original inspection number.**

- **Inspector's checklists alert them to items previously assessed remotely to reduce redundance during the follow-up visit.**

Departures and Concerns from Biosafety Requirements

- **Departures and concerns from biosafety requirements display the specific applications/permits to which the findings are related.**

- **Provides greater context of departures and concerns.**

- **Allows permittees to identify issues specific to non-overlapping permits.**
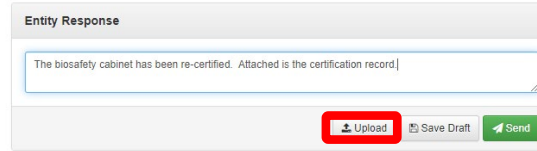
Application Concern   UID: 42-71-54-037000

Initial Response Due:	**Status:**
09/15/2021	Closed
Current Response Due:	
09/15/2021	

Assigned Application(s): 20210730-0200H

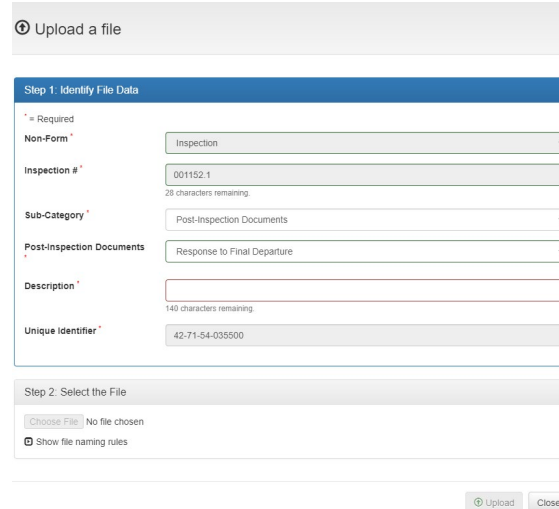| CFR/Section	Requirement
42 CFR 71.54 - (b)(3) - ABSL3	Unless excluded pursuant to paragraph (f) of this section, a person may not import into the United States any infectious biological agent, infectious substance, or vector unless: The importer has implemented biosafety measures commensurate with 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.

Enhancements to Uploads for Supporting Documentation

- **Each departure or request for information contains an "upload" button that automatically associates the document with the correct unique identifier (UID).**

- **This feature allows uploaded documents to be linked to specific observations.**

"Upload" button

Pre-populated checklist UID

Closed Conditionally Status for Inspections and Departures

- **eIPP supports a "Closed Conditionally" status for inspections and departures.**

- **Inspection will have the "Closed Conditionally" status if one or more departures are not fully resolved, but no further action is needed at that time.**

- **However, it may be necessary in the future to fully close the requirement if there is a change in work plans by the permittee.**

Inspection Status

Departure Status

Closed Conditionally Status for Departures

- **Possible reasons a departure may be closed conditionally:**

  - **Removal of laboratory space or safety level**

  - **Modification or removal of a work objective**

  - **Withdrawal of a pending application**

  - **Revocation of a permit**

- **IPP will provide a justification when a departure is closed conditionally.**

Status for departures

CDC response with justification

Additional Contact Information

- **For technical assistance with eIPP, or for assistance with the Secure Asset Management System (SAMS), please submit a help request ticket at [eIPP Customer Support Request Form](), email [eIPPSupport@cdc.gov](), or call 1 (833) 271-8310.**

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.