



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.



Import Permit Program

i
The CDC Import Permit Program, or IPP, regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S.
[More Information](#)

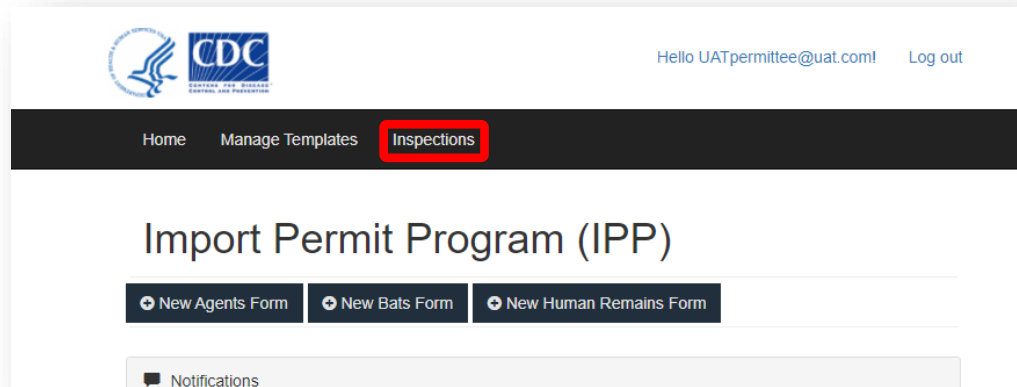
?
Materials requiring import permits include infectious biological agents capable of causing illness in humans, materials known or reasonably expected to contain an infectious biological agent, vectors of human disease.
[FAQ](#)

Person icon
A SAMS account is required to access electronic IPP.
[SAMS Registration](#)

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.

Inspections

Inspection	Application Num...	Permit Expiratiq...	Inspection	Inspection Category	Start Date	Stop Date	Lead Inspect	Inspection Status		
		Start Date End Date			Start Date End Date	Start Date End Date				
001202.1	20210628-0098H,...	08/29/2022	Announced	On-Site Verification,Hybrid	08/17/2021	08/17/2021		Inspection Closeout Act...	Details	History
001202	20210628-0098H,...	08/29/2022	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

Inspection	Application Num.	Permit Expiration	Inspection	Inspection Category	Start Date	Stop Date	Lead Inspect.	Inspection Status		
001202.1	20210629-0098H...	06/29/2022 Start Date End Date	Announced	On-Site Verification,Hybrid	08/17/2021 Start Date End Date	08/17/2021 Start Date End Date		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

Inspections

- The resources section provides quick access to application information.

The screenshot displays a software interface with a sidebar on the left and a main content area on the right. The sidebar, titled 'Resources', is highlighted with a red border and contains a list of sections from A to G. The main content area is titled 'Assigned Checklists' and features a button for 'Inspection Resolution' in the top right corner. Below the title, there are four checklist items arranged in a 2x2 grid, each with a 'View' button.

Assigned Checklists		Inspection Resolution
42 CFR 71.54 : ACL1 View	42 CFR 71.54 : BSL3 View	
42 CFR 71.54 : Mycobacterium tuberculosis View	42 CFR 71.54 : Influenza viruses View	

Checklists

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

The screenshot displays a web interface for inspection details. On the left is a vertical sidebar with a 'Resources' header and a list of sections from A to G. The main content area is titled 'Assigned Checklists' and includes an 'Inspection Resolution' button in the top right. A red rectangular box highlights four checklist items arranged in a 2x2 grid:

42 CFR 71.54 : ACL1 View	42 CFR 71.54 : BSL3 View
42 CFR 71.54 : Mycobacterium tuberculosis View	42 CFR 71.54 : Influenza viruses View

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.



Home Inspections

< Inspection List

Inspection Details

INSPECTION # 001204

Application Type:
Agents

INSPECTION STATUS

In Progress

Notifications

Filter:

Archive Selected Current Archived Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/>	Sys Admin	Inspections View	9/10/2021 12:18:10 PM	All inspection findings have been released for Inspection #001152.1.	<input type="button" value="Flag"/>
<input type="checkbox"/>	Sys Admin	Inspections View	9/10/2021 12:18:06 PM	Inspection #001152.1 UID:42-71-54-035500 with the status of Application Concern has been released for permittee review.	<input type="button" value="Flag"/>
<input type="checkbox"/>	Sys Admin	Inspections View	9/10/2021 12:18:06 PM	Inspection #001152.1 UID:42-71-54-037000 with the status of Application Concern has been released for permittee review.	<input type="button" value="Flag"/>

- 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.

The screenshot displays a web interface for 'Inspection Resolution'. On the left is a vertical sidebar titled 'Resources' containing a list of sections from 'Section A' to 'Section G'. The main content area is titled 'Assigned Checklists' and features a red-bordered button labeled 'Inspection Resolution' in the top right corner. Below the title, there are four checklist items arranged in a 2x2 grid. Each item includes a title and a 'View' button with a list icon. The items are: '42 CFR 71.54 : ACL1', '42 CFR 71.54 : BSL3', '42 CFR 71.54 : Mycobacterium tuberculosis', and '42 CFR 71.54 : Influenza viruses'.

Checklist Title	Action
42 CFR 71.54 : ACL1	View
42 CFR 71.54 : BSL3	View
42 CFR 71.54 : Mycobacterium tuberculosis	View
42 CFR 71.54 : Influenza viruses	View

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”.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30329-4027

The Centers for Disease Control and Prevention (CDC) Import Permit Program (IPP) regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S.. Regulatory authority for the program is given to the Secretary of Health and Human Services through the Public Health Service Act.

The regulations for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54) require the implementation of 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, see 42 CFR 71.54(b)(3). CDC IPP inspects facilities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 71. The above referenced regulations and supporting guidance information may be found at www.cdc.gov/cpr/ipp/index.htm.

An inspection of your facility was scheduled in response to your request to import and conduct work with infectious biological agents, substances and/or vectors. The purpose of the visit was to assess whether the importer's facility 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.

The Import Permit Program will provide inspection findings through eIPP. Inspection findings may include departures from regulatory requirements, general concerns, application concerns, requests for additional information, or issues under review. Inspection departures fall within two categories: immediate actions, and final. Descriptions of each type of inspection finding are available [here](#).

Sincerely,

Chief, Program Service Branch
Division of Select Agents and Toxins
Center for Preparedness and Response
Centers for Disease Control and Prevention

[Go Back](#)

[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.

The screenshot displays the Inspection Resolution page interface. At the top right, there are two blue buttons: "Print Findings" and "Print Findings and Responses". Below these are three filter panels, each with a light gray header and a white body containing radio button options.

- Inspection Findings:** Contains three options: "All (8)" (selected), "Departure (6)", and "General Concern (1)".
- Departure Type:** Contains two options: "All (6)" (selected) and "Final (6)".
- Departure Status:** Contains three options: "All (7)" (selected), "Open (6)", and "Closed (1)".

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.

Initial Response Due: 09/15/2021	Status: Open
Current Response Due: 09/15/2021	
Assigned Application(s): 20210730-0200H	
CFR/Section 42 CFR 71.54 - (b)(3) - AISL3	Requirement 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.
Observation	
Staff were observed not wearing gloves during work.	
Corrective Action:	
Provide the measures in place to ensure that the permittee meets the requirement.	
Permittee Response	
<input type="text" value="Type your response here..."/>	
<input type="button" value="Upload"/> <input type="button" value="Save Draft"/> <input type="button" value="Send"/>	

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 screenshot shows three filter panels at the top of the page. Above the panels are two buttons: "Print Findings" and "Print Findings and Responses".

- Inspection Findings:** Radio buttons for "All (8)", "Under Review (1)", "Departure (6)", and "General Concern (1)".
- Departure Type:** Radio buttons for "All (6)" and "Final (6)".
- Departure Status:** Radio buttons for "All (7)", "Open (6)", and "Closed (1)".

- The upload section is at the bottom of the page. Click “upload” button to begin.

The screenshot shows a file upload interface with the following elements:

- A plus icon in a circle followed by the text "Upload a file".
- An "Upload" button with a plus icon in a circle.
- Two tabs: "Current Files" (active) and "Archived Files".
- A "Send to Archive" button.

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.

Upload a file

Step 1: Identify File Data

* = Required

Non-Form *

Inspection # *
30 characters remaining.

Sub-Category *

Inspection Documents *

Description
140 characters remaining.

Step 2: Select the File

No file chosen

Show file naming rules

Response Notification

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

<input type="checkbox"/>	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
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Inspection Details – Upload Center

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


⊕ Upload a file

⊕ Upload

Current Files

Archived Files

Send to Archive

Select All	Original Name	Unique File Identi...	Uploaded Date ..	Uploaded By	File Category	Review Status
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Start Date <input type="text"/> End Date <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	 Biosafety Plan.pdf	I-001152-9/10/202...	9/10/2021 12:02 PM	Permittee	Inspection	Not Reviewed

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.

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/>	Sys Admin	Inspections View	9/10/2021 12:04:03 PM	Inspection #001152 UID:42-71-54-037000 has been resolved.	Flag

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 redundancy during the follow-up visit.

Archive Selected Current Archived Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>					
<input type="checkbox"/>	Sys Admin	Inspections View	9/10/2021 12:05:32 PM	Inspection #001152.1 has been scheduled.	Flag

Inspection #	Application Number	Permit Expiration Date	Inspection Type	Inspection Category	Start Date	Stop Date
1152		Start Date End Date			Start Date End Date	Start Date End Date
001152.1	20210730-0200H	N/A (pre-approval)	Announced	On-Site Standard,Hybrid	09/21/2021	09/22/2021
001152	20210730-0200H	N/A (pre-approval)	Unannounced	Remote	07/20/2021	07/29/2021

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.

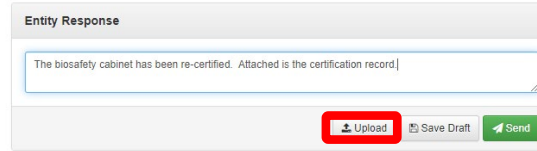
Application Concern UID: 42-71-54-037000

Initial Response Due: 09/15/2021	Status: 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.

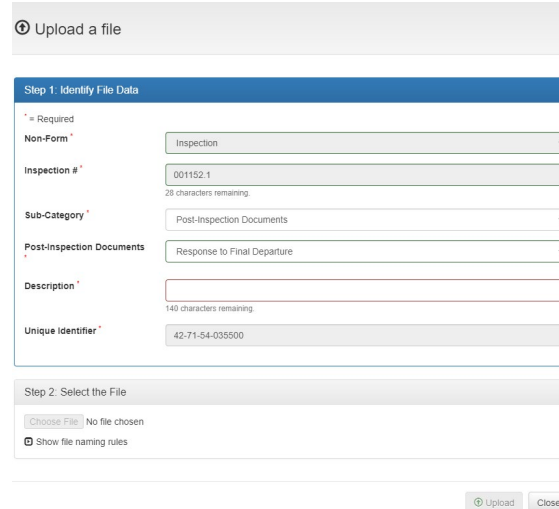
Enhancements to Uploads for Supporting Documentation

- 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.



The screenshot shows a form titled "Entity Response". It contains a text area with the text "The biosafety cabinet has been re-certified. Attached is the certification record!". Below the text area are three buttons: "Upload" (highlighted with a red box), "Save Draft", and "Send".

← “Upload” button



The screenshot shows a dialog titled "Upload a file". It has two steps: "Step 1. Identify File Data" and "Step 2. Select the File".

Step 1. Identify File Data

- Non-Form ***: Inspection
- Inspection # ***: 001152.1 (28 characters remaining)
- Sub-Category ***: Post-Inspection Documents
- Post-Inspection Documents**: Response to Final Departure
- Description ***: (140 characters remaining)
- Unique Identifier ***: 42-71-54-035500

Step 2. Select the File

Choose File No file chosen

Show file naming rules

Buttons: Upload, Close

← 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.

Inspections

Inspection #	Inspection Type	Start Date	Stop Date	Lead Inspector	Inspection Status		
7761	Announced	08/11/2021	08/11/2021	Branch Chief	Closed Conditionally	Details	History
7760	Unannounced	08/11/2021	08/11/2021	Branch Chief	Inspection Closeo...	Details	History

Inspection Status

Application Concern UID: 42-71-54-036500

Initial Response Due: 09/20/2021	Status: Closed Conditionally
Current Response Due: 09/20/2021	
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.

Observation

The director was not able to provide the emergency evacuation plan with the animal facility.

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.

Application Concern UID: 42-71-54-035500

Initial Response Due: 09/20/2021	Status: Closed Conditionally	Status for departures
Current Response Due: 09/20/2021		
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.

Observation

The director was not able to provide the emergency evacuation plan with the animal facility.

Corrective Action:

Provide the measures implemented to meet the regulations.

9/10/2021 12:22 PM

This finding has been closed conditionally for the following reason: Request Withdrawn. Note from Branch Chief: Permittee requested to withdraw permit

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.

