



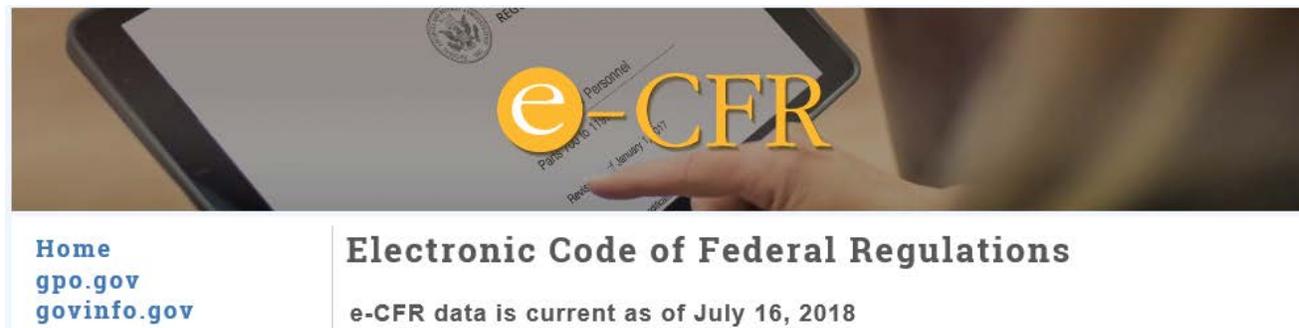
CDC Import Permit Program (IPP) Overview of Risk-Based Inspections & What to Expect During a Site Visit

2019 CDC Import Permit Program
Webcast

CDC Import Permit Inspection Overview

CDC Import Permit Regulations

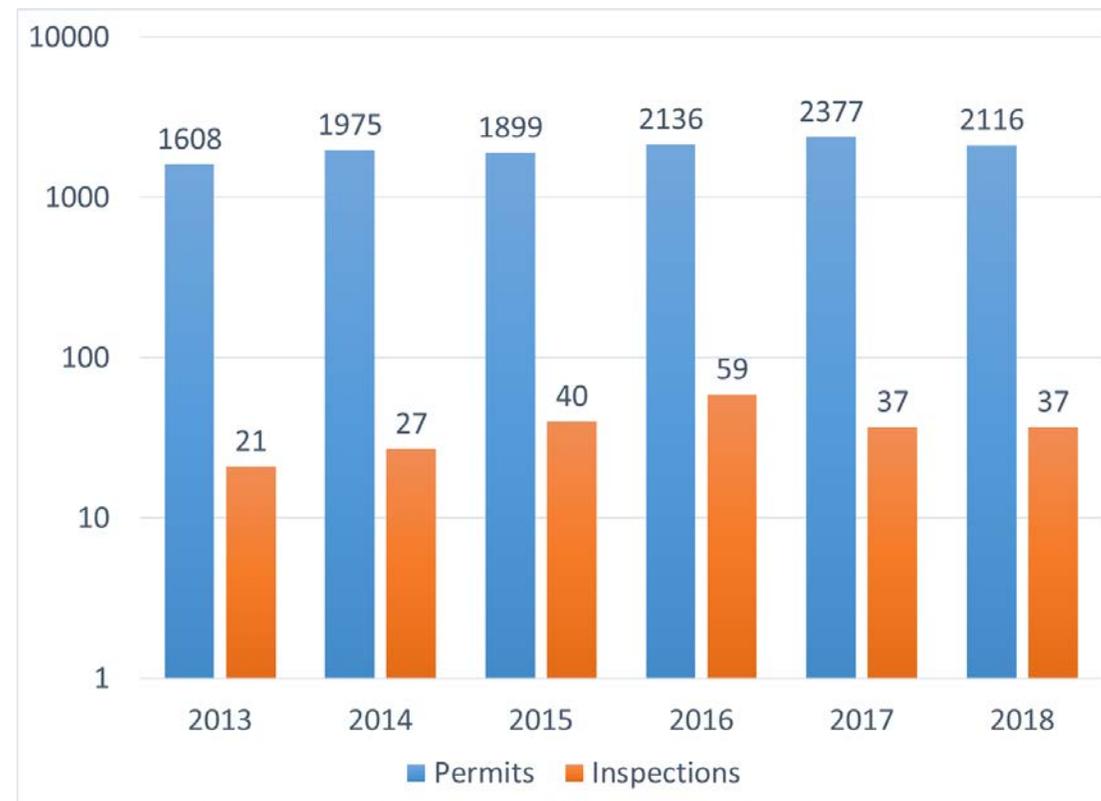
- In 2013, the regulations were amended, 42 CFR 71.54(h)
 - Issuance of a permit may be contingent upon an inspection of the importer's facility by the CDC to evaluate whether the importer's biosafety measures (e.g., physical structure and features of the facility, and operational and procedural safeguards) 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.



- Over **270** inspections have been conducted to date.

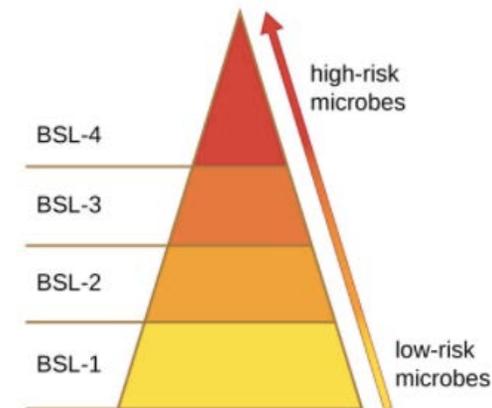
Number of Permits Issued vs Number of Inspections

- CDC IPP issues roughly **2,000** import permits per year and inspects roughly **40** facilities per year using a risk-based approach.



Risk-Based Inspection Selection Criteria

- **Guided by quantitative and objective scoring derived from the application and other sources.**
 - Factors include:
 - Risk group(s) of the agent(s) requested
 - Biosafety level(s) reported
 - Culture or propagation activities
 - Work with animals or arthropods
 - History of importation or shipping non-compliance (e.g., CDC Quarantine Stations, U.S. Customs and Border Protection, U.S. Department of Transportation)
 - Registration of laboratories with the Federal Select Agent Program (FSAP)



FEDERAL SELECT AGENT PROGRAM

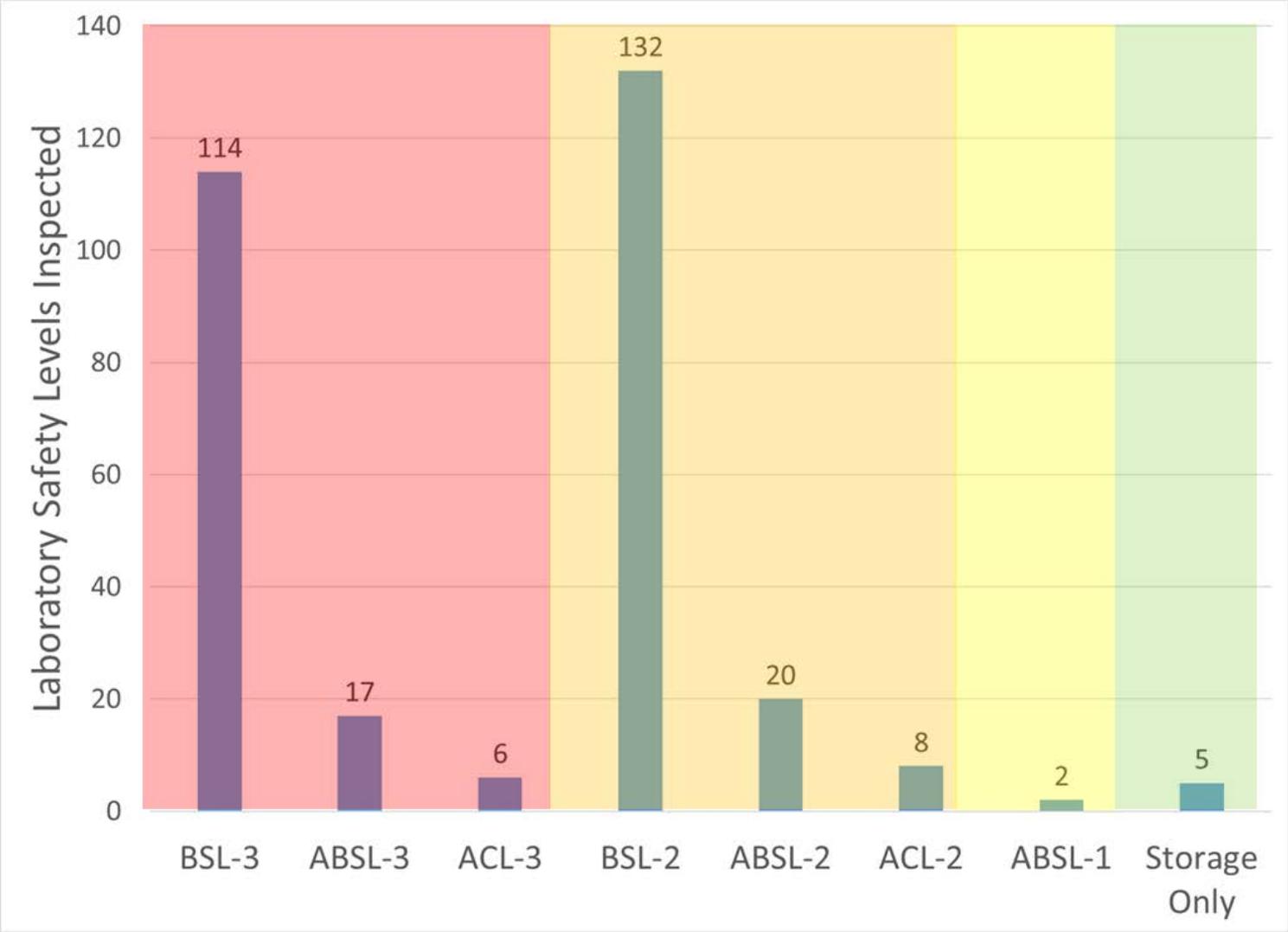


Common Agents Requests & High-Risk Agents

Most commonly imported agents (2017):	
1) Human Immunodeficiency Virus	11) Adenovirus
2) Escherichia coli	12) Klebsiella species
3) Zika virus	13) Plasmodium species
4) Hepatitis C virus	14) Shigella species
5) Hepatitis B virus	15) Enterobacter species
6) Dengue virus	16) Mycobacterium tuberculosis
7) Cytomegalovirus	17) Campylobacter species
8) Streptococcus species	18) Epstein-barr virus
9) Salmonella species	19) Proteus species
10) Staphylococcus species	20) Enterococcus species

Example high-risk agents for inspection consideration		
Mycobacterium tuberculosis	MERS-CoV	Zika virus
Chikungunya virus	Yellow fever virus	Hantaviruses

Biosafety Levels Inspected: 2013-2018

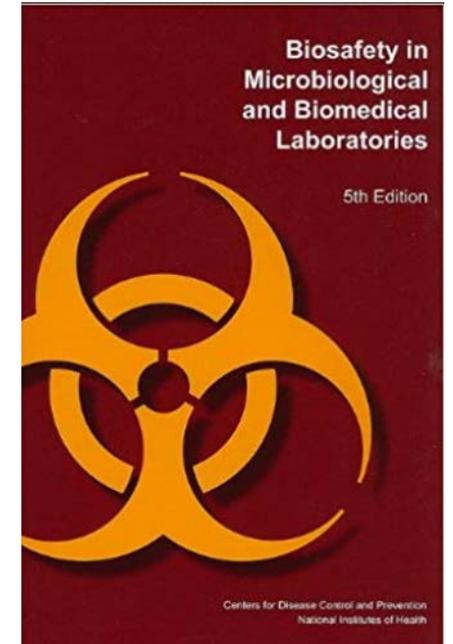


- Some inspections included multiple safety levels.

What to Expect During a Site Visit

Scope of IPP Inspections

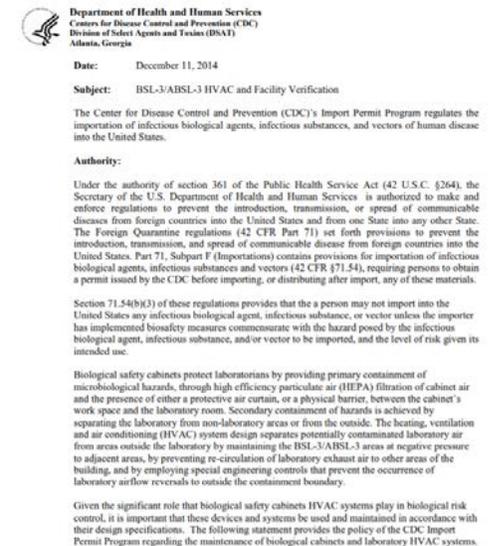
- **Verify that biosafety measures are appropriate for the risks of the agent and work.**
 - Are the practices and facility in line with nationally recognized standards of practice (i.e., *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th edition)?
- **Verify the information submitted on the application.**
 - Does the applicant have the safety level, primary containment, and personal protective equipment described on the application?
 - Is the work within the scope described on the application?
- **Has the permittee complied with the conditions of the permit?**



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

Typical Site Visit Time Frame & Outline

- **Initial notice of inspection sent roughly 30 days in advance**
 - Unannounced inspections can occur
- **Generally within the hours of 9:00 AM – 5:00 PM**
- **Opening meetings and presentations**
- **Laboratory and storage area tours**
- **HVAC and support space tours**
- **Interviews with staff (1-6 staff members)**
- **Document review**
 - Plans, standard operating procedures (SOPs), training materials
 - Facility performance verifications
 - Training records
- **Closeout meeting**



1. Policy Statement, BSL-3/ABSL-3 HVAC Verification:

Post Inspection Correspondence

- An inspection report is issued within 30 business days.
- Documented corrective actions may or may not be required.
- A response is due within 30 business days.
- Additional requests are sent until all observations requiring corrective action have been adequately resolved.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30329-4627

October 28, 2019

Applicant Name
Address Line 1
Address Line 2

RE: Entity Inspection Report
Entity Name (Applicant: Applicant Name)

Dear applicant name:

An inspection of your facility was scheduled in response to your request to import and conduct work with list infectious agent(s). The purpose of the Centers for Disease Control and Prevention (CDC) Import Permit Program (IPP) 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.

Inspectors from the CDC IPP visited your facility located at Street address, City, State on date of inspection. A list of laboratories inspected on these dates is on file with this letter at CDC.

The following personnel from the CDC IPP inspected the facility]

Lead, Lead Inspector
Co-inspector

A list of individuals from entity's name present was provided to you at the close of the inspection.

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). To determine whether your facility meets this regulatory requirement, CDC uses the nationally recognized biosafety guidelines contained in the Biosafety in Microbiological and Biomedical Laboratories (BMBL, <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>).

As a condition of being issued an import permit, the importer (applicant name) at organization must address each of the items described in Attachment 1, including the specific actions or changes to be adopted. A detailed response should be received by this office no later than 30 calendar days from receipt of this report. Send an electronic copy of your response to lead inspector at importpermit@cdc.gov.

Sincerely,

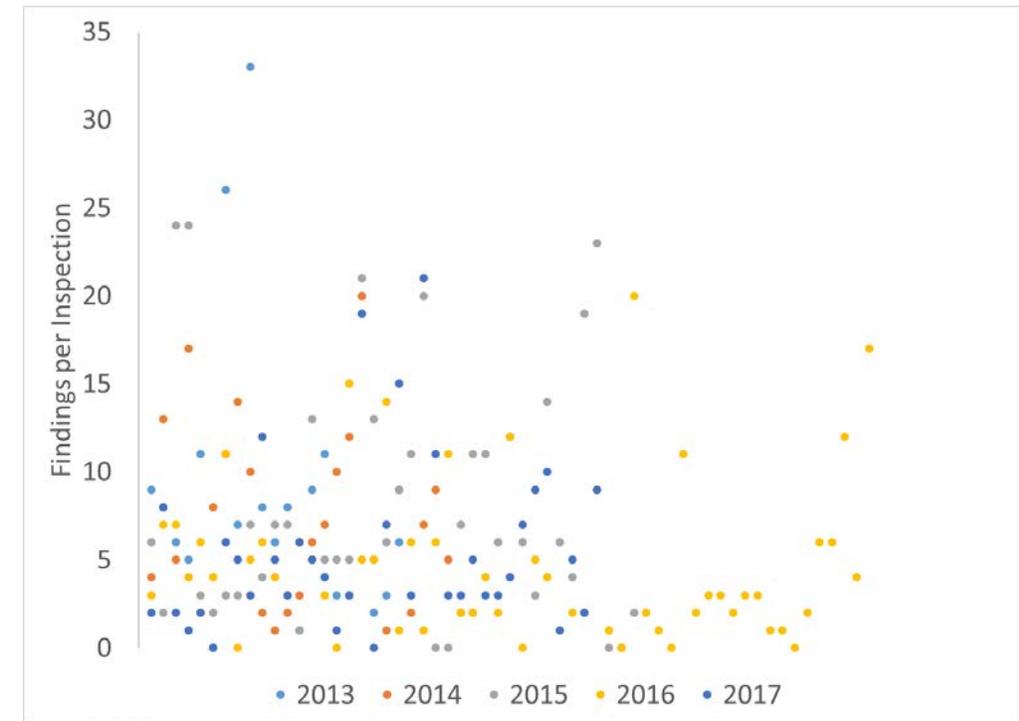
Glen DeGruy
Team Lead, Import Permit Program
Division of Select Agents and Toxins
Office of Public Health Preparedness and Response

Inspection Observations



Biosafety/Containment Findings From Inspections: 2013-2018

- Inspections that required corrective actions = **94%**
- Average number of inspection observations = **6.5**
 - Deficiencies in biosafety
 - Inaccurate applications
- Range of inspection observations
 - Minimum = **0**
 - Maximum = **33**
- **39%** of inspections had 3 or fewer observations



Note: Inspection findings can be grouped together if there are multiple deficiencies due to a common observation. Formatted reports may show a lower number of “observations.”

Biosafety/Containment Findings From Inspections: 2013-2018

- Top 10 BSL-2 inspection findings:

#	BSL-2	Standard
90	A9	Laboratory signage
77	B1	Advising personnel of hazards and entry requirements
45	A11	Training and information on personal health status
33	C3	Eye protection and decontamination before reuse
24	A2	Hand washing
21	C1a	Use of Biological Safety Cabinet (BSC) for procedures with aerosol/splash potential
20	D1	Self-closing lab doors and locks (according to policies)
19	C4c	Hand washing / glove use
18	C2	Use of laboratory coats/gowns
14	A5d	Broken glassware clean up procedures/equipment

Biosafety/Containment Findings From Inspections: 2013-2018

- **Top 10 BSL-3 inspection findings:**

#	BSL-3	Standard
65	A9	Laboratory signage
53	B1	Advising personnel of hazards and entry requirements
50	D9	Air flow shall not be reversed under failure conditions
36	C3	Eye protection and decontamination before reuse
30	A11	Training and information on personal health status
28	D15	Documented annual re-verification of BSL-3 parameters
26	D3	Laboratory can be easily cleaned/decontaminated
24	B10	Use of BSC/physical containment for manipulations
14	D9a	Visual monitoring device to confirm directional air flow
14	D2	Hands-free sink for hand washing

Application Inaccuracies: 2016-2018

- Inspections allow for verification of information submitted on an application.
- Applications inspected that were inaccurate = **47%**
 - In many cases, mistakes or omissions were simple errors.
 - In some cases, permittees misrepresented their facilities and capabilities.

APPLICATION FOR PERMIT TO IMPORT INFECTIOUS BIOLOGICAL AGENTS INTO THE UNITED STATES

20191105-0516A

Section A
PERSON REQUESTING PERMIT IN U.S.(PERMITEE)

Primary Permittee Request

1. Primary Permittee's Last Name *
Cramer

2. Primary Permittee's First Name *
Thomas

3. Primary Permittee's Organization *

4. Physical Address (NOT a post office box) *

5. City *

6. State *
Georgia

7. Zip Code *

8. Permittee's Telephone Number *
() - ext.

9. Permittee's Email *

10. Will the permittee be the courier of the imported biological agent? *

Yes
 No

11. Secondary Contact's Name

12. Secondary Contact's Telephone Number
() - ext.

13. Secondary Contact's Email

14. Institutional Biosafety Officer's Name

15. Institutional Biosafety Officer's Telephone Number
() - ext.

16. Institutional Biosafety Officer's Email

Additional Authorized User(s)

Last Name First Name

Add From Template Add User

Compliance Metrics

- **12 permits have been revoked.**
 - 10 permittees did not have the biosafety level, containment, or facilities as described in the application for their permit.
 - 2 permittees did not allow inspection of their facility.
- **2 permit applications were voluntarily withdrawn in response to the inspection findings.**
 - Permittees were not able meet ABSL-2 or ABSL-3 facility standards.

Compliance Metrics

- **2 permit applications were denied.**
 - 1 permittee did not have their ABSL-3 facility constructed at the time of the inspection.
 - 1 permittee was suspended by their organization for non-compliance.
- **2 permittees were unable to adequately address all inspection observations after 1 year.**
 - Inspection findings were related to deficiencies in the HVAC of BSL-3 facilities.
 - Both were placed on a watch list to prevent future issuance of permits, until corrective actions could be confirmed.

Conclusions

- **The 2013 revision to the import regulations, including an inspection provision, has made a positive impact on biosafety and public safety.**
- **On-site inspections by IPP benefit organizations and individual permittees to identify and develop mitigation strategies to reduce overall risk of handling these imported materials.**