

2014 Import Permit Program (IPP) Webinar



October 24, 2014



Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response

Presenters/Speakers

❑ Centers for Disease Control & Prevention

- Von McClee, Program Services Branch Chief
- Glen DeGruy, Senior Microbiologist/IPP Inspection Coordinator
- Susan Loring, Microbiologist/Facility Specialist, Division of Select Agents and Toxins
- Adam Langer, Importations and Personnel Contact Team Lead, Division of Global Migration & Quarantine
- Meranda Bradley, Health Scientist/Technical Reviewer, IPP

❑ Partners

- Deborah Dufficy, APHIS-USDA IPP, VS Organisms and Vectors
- Shirley Wager-Page, Deputy Director, APHIS-USDA
- Romelito Lapitan, Acting Branch Chief, Customs and Border Protection
- William “Bill” Stevens, Department of Transportation

Agenda/Topics

- 1:10 Overview of Import Permit Regulations, Von McClee
- 1:25 Import Permit Program Inspections, Glen DeGruy
- 1:45 HVAC Verification, Susan Loring
- 2:05 Issuance of Permits for Selected Animal Species, Adam Langer
- 2:25 What's New with IPP, Meranda Bradley
- 2:45 BREAK
- 3:00 APHIS Import Permit Program, Deborah Dufficy
- 3:15 USDA Pest Permitting Policy, Shirley Wager-Page
- 3:30 US Customs and Borders Protection, Romelito Lapitan
- 3:50 Transporting Infectious Substances Safely, Bill Stevens
- 4:10 Question and Answer Session, Marranda Scott
- 4:50 Closing Remarks, Mark Hemphill

Housekeeping

- Questions
 - The webcast is one-way audio only
 - At any time during the webcast send questions to IPwebcast@cdc.gov
 - We will respond to the e-mailed questions during a Q & A session following the last presentation
 - Answers to questions not addressed during the webcast, slides and a video of the proceedings will be posted on the CDC Import Permit Program website at <http://www.cdc.gov/od/eaipp/> following the broadcast

- Contact your IT Department for Technical assistance/difficulty

CDC Import Permit Regulations (42 CFR 71.54)



Von McClee, M.S.

Chief, Program Services Branch

CDC/Division of Select Agents and Toxins

October 24, 2014



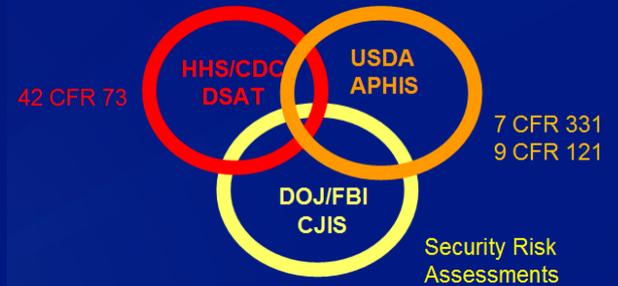
Centers for Disease Control and Prevention
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Division of Select Agents and Toxins

- **Federal Select Agent Program (42 C.F.R. Part 73)**
 - Regulates all entities that possess, use, or transfer biological agents or toxins that have the potential to pose a severe threat to public health and safety

- **CDC Import Permit Program (42 C.F.R. § 71.54)**
 - Regulates the importation of infectious biological agents, infectious substances, and vectors capable of causing communicable disease in humans

- **Promote laboratory safety and security**
 - Inspection Programs (Domestic and International)
 - Guidance on the regulations
 - Training
 - Developing biosafety guidelines



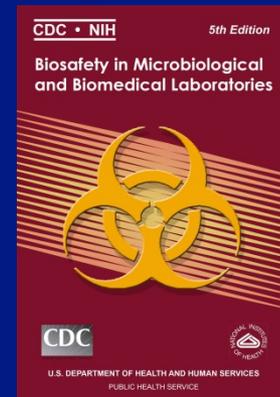
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

APPLICATION FOR PERMIT TO IMPORT BIOLOGICAL AGENTS OR TOXINS OF HUMAN DISEASE INTO THE UNITED STATES

Section A: Permitting Information

Section B: Importation Information

Section C: Final Distribution of Imported Biological Agent



Section 361 of the Public Health Service Act

- ❑ Authorizes the HHS Secretary to make and enforce regulations necessary to prevent:
 - Introduction,
 - Transmission, or
 - Spread of communicable diseases from foreign countries into the United States.



Section 361 of the Public Health Service Act (cont)

- ❑ Authorizes the HHS Secretary to use inspections as a public health measure to ensure that such regulations are carried out.



Import Permit Program

- Assists in protecting the United States public health and safety by ensuring that all imported infectious biological agents, infectious substances and vectors are imported safely into the United States.
- Ensures that appropriate safety measures are in place for the imported infectious agents.
- Provides oversight to prevent the **introduction, transmission, or spread** of communicable diseases

Rulemaking

- ❑ Needed to improve CDC's ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.
- ❑ October 14, 2011: CDC published a notice of proposed rulemaking to amend 42 CFR 71.54.
 - ❑ 60 day comment period
- ❑ February 4, 2013: CDC published Final Rule.
 - ❑ Effective Date: April 5, 2013

Overview of Import Regulations for Infectious Biological Agents, Infectious Substances and Vectors (42 CFR 71.54)

- ❑ Defines items that require an import permit
 - ❑ Infectious biological agent, infectious substances and vector
- ❑ Ensure adequate biosafety measures are in place
- ❑ Increase oversight through inspections
- ❑ Exemptions are listed
- ❑ Provide an appeals process for permit applications that are denied



Types of Material that Require an Import Permit (a)

- ❑ Infectious Biological Agents – A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.



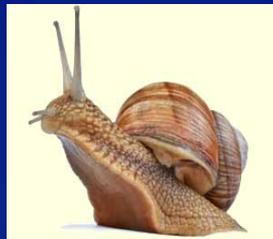
Types of Material that Require an Import Permit (b)

- ❑ Infectious substance - Any material that is known or reasonably expected to contain an infectious biological agent.
- ❑ Vector - Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal)



Types of Material that Require an Import Permit (c)

- ❑ Snails – Any freshwater snails (phylum Mollusca, class Gastropoda) capable of transmitting schistosomiasis.
- ❑ All non-human primate materials (NHP) and trophies (unless specifically treated and rendered non-infectious).



Types of Material that Require an Import Permit(d)

- ❑ Animals – Any member of the animal kingdom except a human including an animal product (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws).
- ❑ Arthropods – Any living insect including crustaceans, spiders, scorpions, etc. capable of being a host or vector of human disease.



Material That Does Not Require an Import Permit (a) 42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

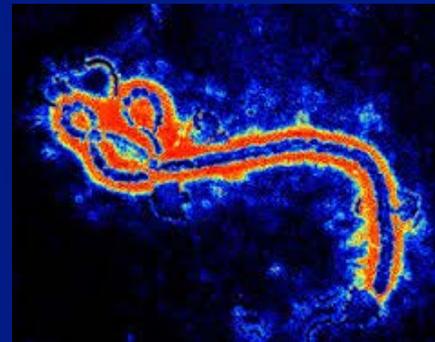
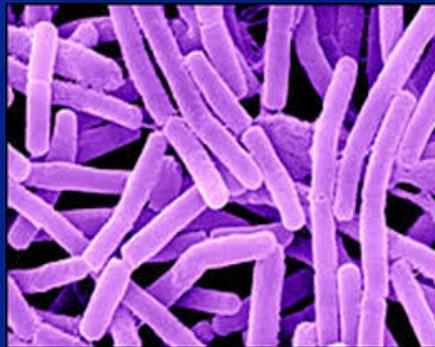
- ❑ With the exception of bat or nonhuman primate specimens, it is a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent.
 - Healthy human specimens or samples
 - Rendered non-infectious
 - Material that is non-pathogenic to humans; non-infectious disease
 - Non-infectious material (e.g., formalin-fixed slides, etc.)



Material That Does Not Require an Import Permit (b) 42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- ❑ It is a biological agent listed in 42 CFR Part 73 as a select agent and its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.
 - Transfer authorization (APHIS/CDC Form 2)
 - Examples: *Bacillus anthracis*, *Francisella tularensis*, Ebola Virus



Material That Does Not Require an Import Permit (c) 42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- ❑ It consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent

- ❑ Examples:
 - Extracted Deoxyribonucleic acid (DNA) from bacteria
 - Viral nucleic acids that cannot produce any infectious biological agent



Material That Does Not Require an Import Permit (d) 42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- ❑ Product that is cleared, approved, licensed, or otherwise authorized under any of the following laws:
 - The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or
 - Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262), or
 - The Virus-Serum-Toxin Act (21 U.S.C. 151-159).



Permit not Required Certification Statement

- ❑ A detailed description of the material and a statement on official letter head signed by the sender or the recipient clearly stating that
 - (1) the material is not known or suspected to contain an infectious biological agent and
 - (2) how the person making the certification knows that the specimen does not contain an infectious biological agent; or the basis of the belief that there is no reason to suspect that the specimen does not contain an infectious biological agent; or a detailed description of how the material was rendered noninfectious.



Date and Conditions of the Import Permit

□ Section 71.54(d)

The CDC permit is valid only for: (1) the time period and/or term indicated on the permit, and (2) only for so long as the permit conditions continue to be met.



Denials, Revocations and Suspensions

- ❑ A permit can be denied, revoked or suspended if:
 - (1) The biosafety measures of the permit holder are not commensurate with the hazard posed by the infectious biological agent, infectious substance, or vector, and the level of risk given its intended use; or,
 - (2) The permit holder fails to comply with all conditions, restrictions, and precautions specified in the permit.



Appeals

- ❑ Denial, suspension, or revocation of a permit under this section may be appealed to the CDC Director.
- ❑ The appeal must be in writing, and be submitted to the CDC Director within 30 calendar days



42 CFR 71.54 (h) Inspection

- ❑ 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 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.

CDC Import Permit Program Primary Partners

- CDC's Division of Global Migration and Quarantine (DGMQ)
- Department of Homeland Security/Customs and Border Protection (CBP)
- United States Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS)
- Department of Transportation (DOT)
- U.S Fish and Wildlife Service (FWS)

IMPORT PERMIT INSPECTION PROGRAM



Glen De Gruy, M.S.
Senior Microbiologist
Import Permit Program
Division of Select Agents and Toxins



Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response

Section 361 of the Public Health Service Act 42 USC § 264

- ❑ Authorizes the HHS Secretary to make and enforce regulations necessary to prevent:
 - Introduction
 - Transmission
 - Spread of communicable diseases from foreign countries into the United States.



Section 361 of the Public Health Service Act 42 USC § 264 (cont)

Authorizes the HHS Secretary to use inspections as a public health measure to ensure that such regulations are carried out.



42 CFR §71.54

- ❑ Import Regulations for Infectious Biological Agents, Infectious Substances and Vectors



- ❑ The following infectious biological agents, infectious substances and vectors would require a permit prior to entry into the United States.



42 CFR §71.54 (cont)

❑ Infectious biological agent

A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is *capable of causing communicable disease in a human*.

❑ Infectious substance

Any material that is known or reasonably expected to contain an infectious biological agent.

❑ Vector

Any animals including arthropods or any non-infectious self-replicating system or animal products known to transfer or capable of transferring an infectious biological agent to a human.



Working with Materials Regulated by 42 CFR §71.54

- ❑ Appropriate biosafety measures must be in place.
- ❑ Risk assessment
 - Identify the hazardous characteristics of an infectious agent, the activities that can result in exposure, the likelihood that exposure will cause a laboratory-acquired infection (LAI) and likelihood of release into the environment.



Working with Materials Regulated by 42 CFR §71.54 (cont)

Manage Risk

- Risk assessment should guide the selection of appropriate microbiological practices, safety equipment, and facility safeguards that can prevent exposures and reduce the incidence of LAIs.
- Aid in ensuring safe possession and use of infectious imported materials.



Inspection/Biosafety

- ❑ Prior to CDC issuing a permit, the permittee or applicant's facility may be inspected to evaluate the importer's biosafety measures (e.g., Physical structure and features of the facility, and operational and procedural safeguards).



Inspection/Biosafety (cont)

- ❑ Verify that biosafety measures are 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.



Criteria used to determine if an inspection may be required

- ❑ Biological safety level where work will be conducted
- ❑ Risk of the agent and work conducted
- ❑ May not be inspected if the laboratory has been inspected by the Federal Select Agent Program



Permittee Initial Notification of Inspection

- ❑ Send email notification to the permittee
- ❑ Contact the permittee by phone to coordinate the inspection
 - Date of Inspection
 - Duration of the inspection
- ❑ Request the following information:
 - Biosafety plan
 - Personal protective equipment (PPE) requirements
 - Laboratory floor plan
 - Entrance requirements
 - Directions to the facility



Notice of Inspection Letter

- ❑ **Send an Official Notice of Inspection letter:**
 - Authority to conduct the inspection
 - Date of the inspection
 - Identification of inspectors who will conduct the inspection
 - List the items that will be reviewed during the inspection



Day of Inspection

- ❑ **A brief introduction period**
 - Inspectors explain purpose of visit
 - Entity provide an overview of work
- ❑ **Begin the laboratory tours**



Laboratory Inspections

What to expect during laboratory inspections:

- A knowledgeable representative should guide inspectors during the site visit
- Inspectors may have questions directed to the applicant, laboratory and non-laboratory staff during inspection
- Review policies and safety procedures such as:
 - Donning and doffing procedures
 - Appropriate signage posted
 - Waste handling procedures
 - Training
 - Appropriate spill procedures



Biosafety Cabinet (BSC) Certification

Verify the following test were performed by the certifying organization:

- HEPA filter leak testing for any biosafety cabinet
- Testing of Class II cabinets
 - Down flow velocity
 - Face velocity
 - Airflow smoke patterns



Biosafety Cabinet Certification

Class II Type A1 BSC:

cabinet integrity test should be performed if the cabinet is new, has been moved, or if panels have been removed for maintenance.

Class II Type A1 or A2 BSC:

should be either re-circulating or thimble-connected.

Thimble connections should be negatively pressurized to the room.



HVAC/Facilities inspection

An inspection of the HVAC will be conducted for all BSL-3/ABSL-3 laboratories.

Verify that the laboratory has a ducted air ventilation system.

Verify that the laboratory building exhaust air is dispersed away from occupied areas and building air intake locations or HEPA filtered.



HVAC/Facilities Inspection (cont)

Inspect the exhaust fan(s), associated duct work, and any exhaust air filtration systems.

Discuss preventative maintenance, frequency of filter changes, and decontamination procedures.



HVAC/Facilities Inspection (continued)

□ BSL-3/ABSL-3 Facility HVAC

- Meet with most knowledgeable facilities personnel
- Specific HVAC information such as:
 - Which supply and exhaust fan serve containment areas?
 - Do they serve other areas?
 - Is the duct work manifolded?
 - Are redundant exhaust fans present?
 - Are any power failure test performed?



Document Review

We ask that a location be made available for inspectors to:

- Review documentation
- Discuss findings
- Complete respective checklist



Review of Biosafety Measures

- ❑ A review of laboratory practices and procedures will be conducted to ensure proper biosafety measures have been implemented (e.g., biosafety plan)
 - This will include an inspection of the laboratories where the work will be conducted.
- ❑ Annual biosafety cabinet certifications
- ❑ HEPA filter certifications
- ❑ BSL-3 design and operational re-verification records
- ❑ DSAT recognizes the CDC/NIH publication, “Biosafety in Microbiological and Biomedical Laboratories” (BMBL) as the national biosafety standard and accordingly the entity must consider the guidance found in the BMBL when developing its biosafety measures.



Review of Biosafety Measures (cont)

BSL-3 Practices and Procedures

□ Inspectors will review:

- Practices to ensure procedures are performed to minimize the creation of splashes and/or aerosols
- Hand washing procedures
- Decontamination and waste handling procedures for cultures, stocks, equipment and other potentially infectious materials.
- Procedures for use of biosafety cabinet
- Proper use of PPE (e.g., eye protection, solid front gowns, gloves, respirators-if needed)



* Please note that this list is not all-inclusive

Review of Biosafety Measures (continued)

BSL-3 Laboratory Facilities

□ Inspectors will review:

- Hands free or automatically operated sinks
- Availability of eyewash stations
- Use and availability of autoclave
- Ducted air ventilation system
 - Draws air into the laboratory from “clean” areas toward “potentially contaminated” areas
 - Verification of directional airflow before entering laboratory



Inspection Close-Out Meeting

- ❑ Inform the entity of deficiencies that may be cited on the inspection report
- ❑ Opportunity to gain further insight regarding deficiencies or any other aspect of the inspection process
- ❑ Final opportunity to ask any questions of inspectors while on-site



Inspection Report

- ❑ An inspection report will be emailed to the permittee in one to two weeks following the inspection.
- ❑ Report will include :
 - Inspector observations during the inspection
 - A request for further information
- ❑ A written response to the report should be provided to CDC via email within two weeks.



Inadequate Response Letter

- ❑ A letter written by the CDC as a response to items that are deemed inadequate on the inspection report.
- ❑ Sent to the entity via email within one to two weeks.
- ❑ A response is required from the entity addressing this report within two weeks.



How to Avoid an Inadequate Response Letter

- ❑ Provide an adequate and concise responses to each specific observation noted during inspection.
- ❑ Responses can include pictures or other forms of documentation that permittee deems necessary to address each observations.
- ❑ Contact the Inspection Team.
 - There to provide clarification and any assistance necessary.



Adequate Response Letter

- ❑ Sent to the entity when all inspection deficiencies are adequately addressed.
- ❑ Letter will be sent to the entity via email.
- ❑ This letter signifies the inspection report is closed and no further information is required.



Import Permit Inspection Program

- ❑ Completed 47 Inspections since April 2013
- ❑ Inspected the following:
 - ❑ Biosafety Level -2
 - ❑ Animal Biosafety Level-2
 - ❑ Arthropod Containment Level -2
 - ❑ Biosafety Level -3
 - ❑ Animal Biosafety Level-3



Import Permit Inspection Program (cont)

- ❑ Common descriptions of work associated with Import Permit Inspections:
 - Human diagnostic testing
 - Animal studies
 - Molecular biology research



Import Permit Inspection Program (continued)

- ❑ Most common agents associated with Import Permit Inspections:
 - Mycobacterium tuberculosis
 - Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
 - Chikungunya virus
 - Prions



The Import Permit Inspection Program

- ❑ Common safety standard departures:
 - Donning and doffing procedures
 - Visitor training
 - Inappropriate signage
 - Storage methods
 - Failure testing (HVAC system)
 - Facility reverification



Compliance Inspection

- ❑ One Compliance Inspection
- ❑ Based on an anonymous complaint of biosafety concerns
- ❑ Unannounced - CDC Inspectors visit the entity without prior notice
- ❑ Biosafety concerns noted
- ❑ Compliance inspection report provided to entity
- ❑ All departures were addressed adequately



Changes Where Work with Imported Materials will be Conducted

- ❑ Two entities informed of inspection requirement
- ❑ Prior to initiation of the inspection, CDC was informed of the issues below.
- ❑ Entity 1
 - Biosafety Cabinets not able to meet certification standards
 - Issues with laboratory exhaust air flow
 - Laboratory shut down
- ❑ Entity 2
 - Issues with HVAC system not maintaining negative airflow



Changes Where Work with Imported Materials will be Conducted (cont)

□ Entity 1

- Work with imported materials moved to a laboratory previously inspected by the Import Permit Program.
- Inspection no longer required by the import permit program.

□ Entity 2

- Work with imported materials moved to Select Agent registered laboratory.
- Inspection no longer required by the Import Permit Program

Recommendations on the Performance of BSL-3/ABSL-3 HVAC Verification Tests



Susan Loring
Facility Specialist
Division of Select Agents and Toxins

Import Permit Program Webinar
October 17, 2014



Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response

Talk Outline

- ❑ Why perform HVAC tests?
- ❑ Failure conditions for testing
 - Single exhaust fan failure
 - Normal power failure and restart
- ❑ Options on test performance
- ❑ Information to capture in the results
 - The test performed
 - Floor plan monitoring points
 - Recorded results
- ❑ Acceptance criteria
- ❑ Examples – two different laboratories

Why perform HVAC tests?

CDC/NIH's *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th edition includes the following recommended best practice:

“The [laboratory/ABSL-3 animal facility] shall be designed such that under failure conditions the airflow will not be reversed.” (BSL-3 D9/ABSL-3 D6)

HVAC failure tests are a means to confirm that an airflow reversal does not happen after a failure condition.

Failure conditions of greatest interest for testing

- ❑ Mechanical failure of a single exhaust fan or fan component
- ❑ Normal power failure to supply and exhaust fan components
- ❑ Return from power failure to “normal” operating conditions

Options on test performance – Exhaust fan failure

If a laboratory is served by multiple exhaust fans, tests could be performed failing more than one exhaust fan at the same time, but a much more likely event is a single fan failure.

Options on test performance – Normal power failure and return to normal conditions

- ❑ If an emergency power supply is available for the laboratory HVAC system, the test could be performed as an actual load switch to generator power followed by the return to utility power.
- ❑ If no backup power supply is available, the test could be performed by interrupting the power to the laboratory HVAC system followed by the return to utility power.
- ❑ These are NOT, however, the only options....

Options on test performance - Normal power failure and return to normal conditions

Because of the disruptive effect that power interruptions can have on other building occupants, and because of the potential hazards to electrical components during power failure testing, another option for verifying the HVAC system performance during power failure/restart is:

- ❑ Simulation of power failure by simultaneously shutting off, and simultaneously turning back on, the supply and exhaust fans serving the laboratory.

Information to capture in the test results

- ❑ **Specifics on the test being performed, for example:**
 - Failure test of exhaust fan 1
 - Building load switch test

- ❑ **Floor plan monitoring points, for example:**
 - Clean corridor to lab anteroom results
 - Results for laboratory T293L to the containment corridor

- ❑ **Observations made, for example:**
 - Airflow observations between a laboratory and its anteroom
 - Room differential pressure trend readings collected over time

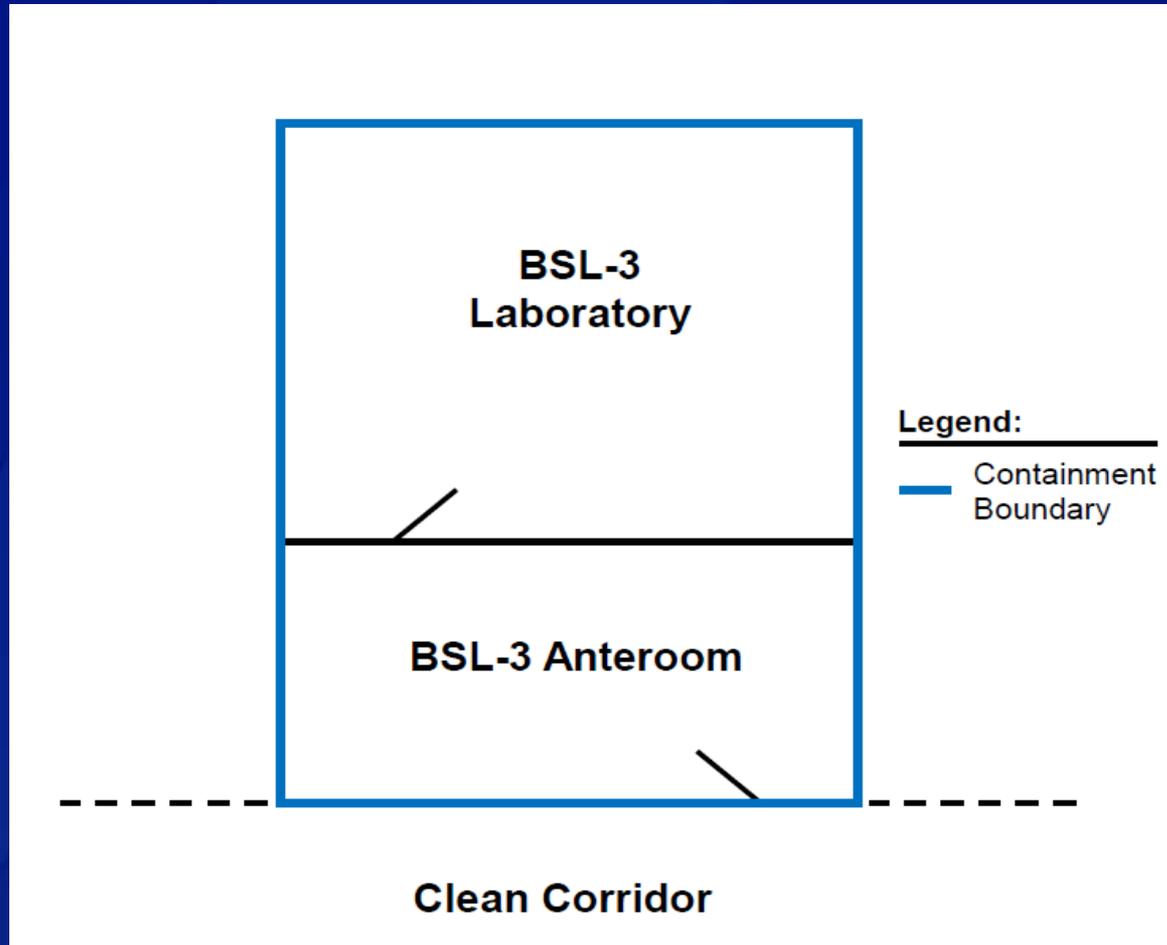


Airflow observations can be made by a witness outside the laboratory watching for smoke from a smoke stick, or vapor from dry ice in a container of water, used inside the lab at the base of the closed door.

Acceptance criteria

A BSL-3/ABSL-3 facility may be considered to pass the HVAC verification tests if laboratory-originating air does not cross the containment boundary under failure conditions.

The containment boundary varies with the facility floor plan.



Laboratory 1 – single BSL-3 lab with anteroom

Laboratory 1 – no fancy design features

Laboratory 1 has the following design elements:

- A single dedicated exhaust fan
- A supply air handler unit that serves the entire building
- An emergency generator for the building
- A paper tell-tale strip hanging from the lab door frame
- Laboratory was built circa 1985

Laboratory 1 test documentation

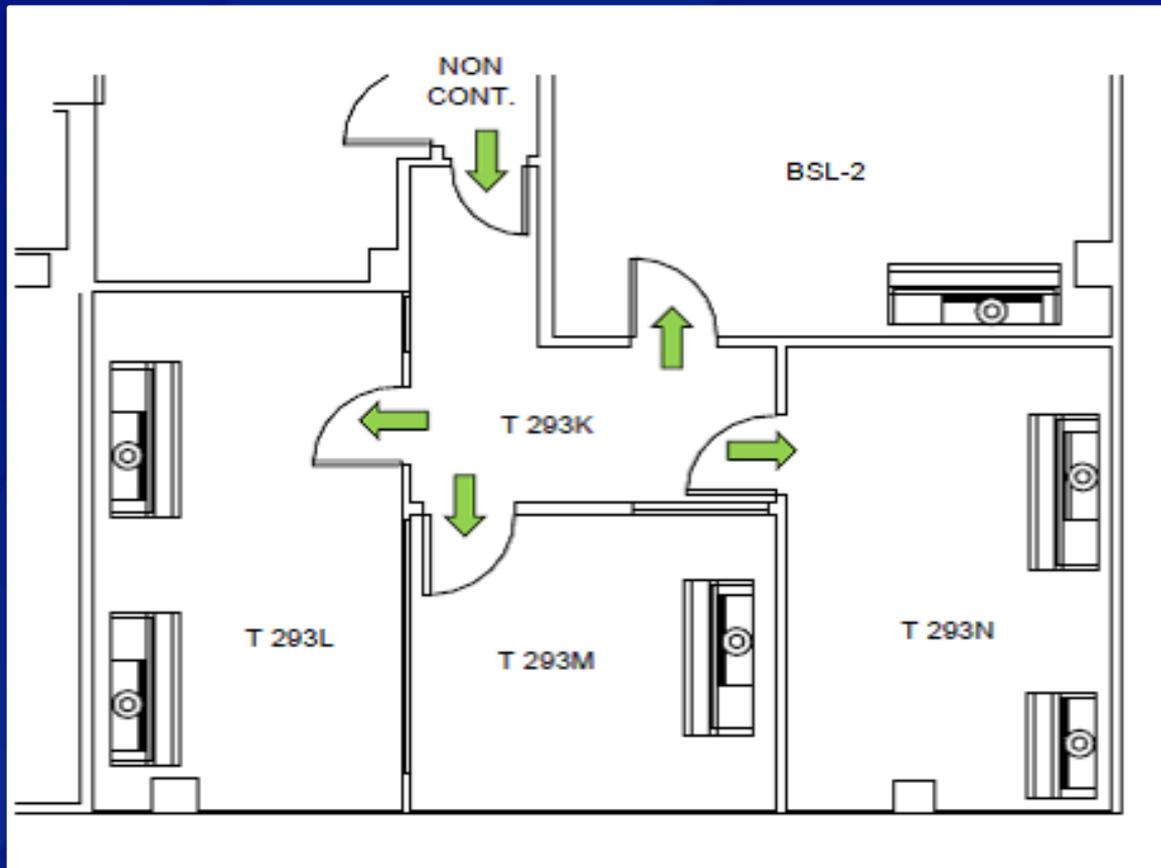
- ❑ Entity personnel did exhaust fan and power failure tests and made airflow observations using smoke sticks at the base of the outer anteroom door and at the lab door base from within the lab.
- ❑ A witness in the anteroom observed for smoke entering from the corridor or leaving the lab.

Laboratory 1 test method

- ❑ Narrative for one of the tests: “We failed the exhaust fan on August 3, 2010 while Jerry observed airflow in the anteroom and Sharon used a smoke stick in the clean corridor at the base of the door. The first observation made was under normal conditions, and the last was after the failed fan had stopped.”
- ❑ And the results were recorded like this: (next page)

Laboratory 1 exhaust fan test results

<u>Time</u>	<u>Airflow observation of anteroom door</u>
Baseline	Smoke drawn into anteroom from corridor
15 sec	Smoke drawn slowly in
30 sec	Smoke drawn slowly in (fan stopped)
45 sec	Smoke static
60 sec	Smoke drawn slowly in (fan turned on)
75 sec	Smoke rapidly drawn in



Laboratory 2 – a multi-room BSL-3 suite

Laboratory 2 – a more sophisticated design

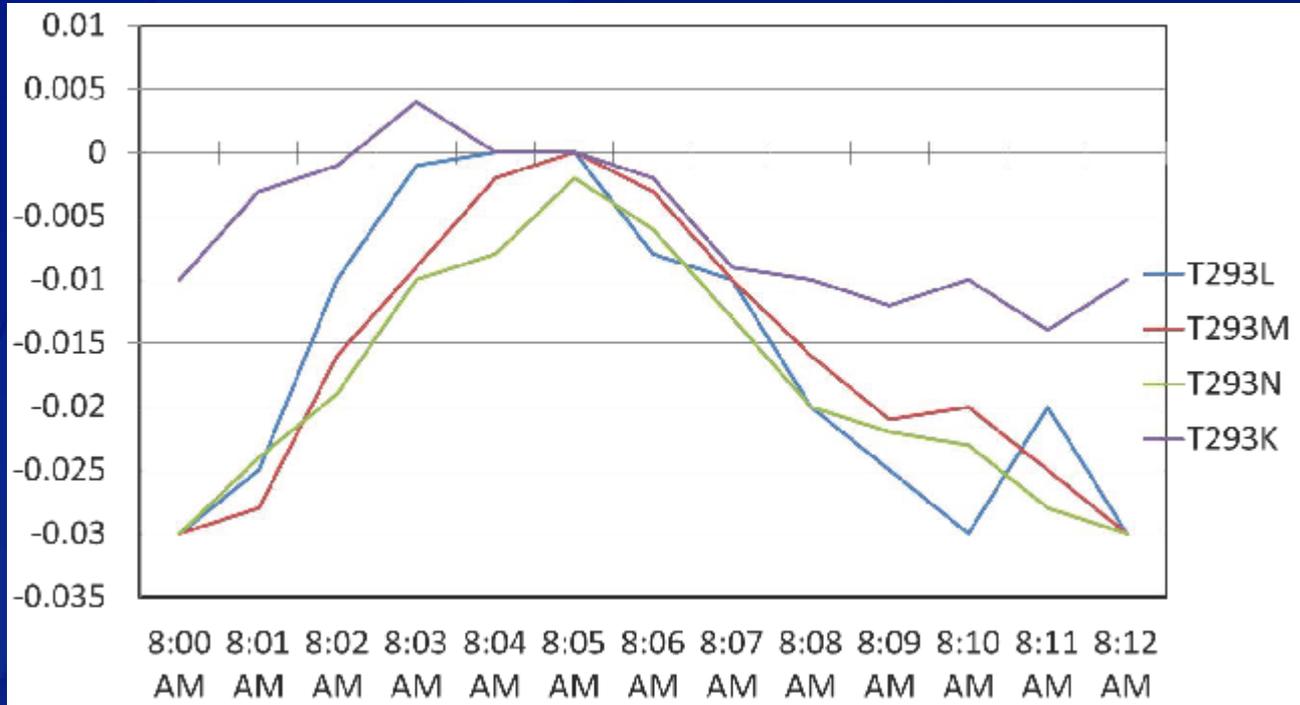
Laboratory 2 has the following design elements:

- Dedicated redundant exhaust fans
- Dedicated supply air handler unit
- An emergency generator for the building
- Pressure gauges at each lab room door, which communicate to a building automation system
- Laboratory was built in 2005

Laboratory 2 test documentation

Entity personnel did exhaust fan and power failure/restart tests, and the room differential pressure readings were captured and stored once a minute by the building automation system. The pressure trends were graphed, and a written narrative identified the time events of the tests.

Laboratory 2 power failure/restart test



Issuance of Permits for Selected Animal Species and Enforcement of all CDC Import Permit Requirements

Adam J. Langer, DVM, MPH, DACVPM
Importations and Animal Contact Team Lead

CDC Import Permit Program Webinar
October 14, 2014



Quarantine and Border Health Services Branch Mission



The mission of the Quarantine and Border Health Services Branch (QBHSB) is to protect U.S. communities from global disease threats.

QBHSB supports this mission by:

- Preventing the introduction and spread of communicable diseases
- Enhancing federal, state and industry partnerships
- Enforcing public health regulations

QBHSB Role in Import Permits

- **Issuance of selected permits and letters of permission**
 - Restricted live animals
 - Restricted animal products
- **Enforcement of import regulations at U.S. ports of entry**
 - CDC Quarantine Stations
 - Partnership with U.S. Customs and Border Protection and other federal, state, and local agencies

Issuance of Permits and Letters of Permission

- **Restricted live animals**
 - Family Viverridae (civets and related animals)
 - Freshwater turtles, tortoises, and terrapins <4 inches in length (including viable eggs)
 - Nonhuman primates
 - African rodents
- **Restricted animal products**
 - Family Viverridae (civets and related animals)
 - Nonhuman primates*
 - African rodents
- **Other live animals and animal products restricted by CDC IPP (e.g., bats, certain species of snails)**

* Nonhuman primate product import permits are currently issued by the CDC IPP after approval by QBHSB

Family Viverridae (Civets and Related Animals)

- **Severe Acute Respiratory Syndrome (SARS) outbreak in 2002-2003**
- **Civets linked to SARS transmission**
- **Emergency embargo effective as of January 13, 2004**
- **Still covered under embargo order authorized by 42 CFR 71.32(b)**



Family Viverridae (cont) (Civets and Related Animals)

- **Embargo includes all members of Family Viverridae**
 - Genets
 - Linsangs
 - Binturongs
 - Civets, except for African Palm Civet (Family Nandiniidae)
- **Applies to live animals and animal products**
 - Products may be imported without a permit if rendered noninfectious
 - Shipment must be accompanied by a statement of how the products were rendered noninfectious using one of the methods listed at <http://www.cdc.gov/animalimportation/animalproducts.html>
- **Permission letter application process**
 - Entry allowed only for science, education or exhibition
 - Submit request for letter of permission to import Family Viverridae via email to CDCAnimalImports@cdc.gov

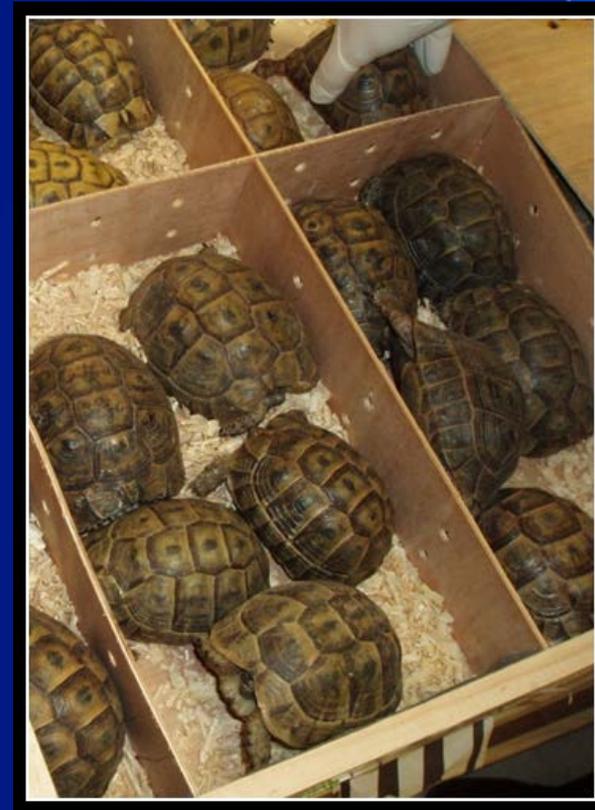
Freshwater Turtles, Tortoises, and Terrapins

- *Salmonella* infection outbreaks in children associated with contact with small turtles
- Commercial purposes
 - Turtles with carapace <4" may NOT be imported
 - Viable turtle eggs may NOT be imported
- Noncommercial purposes
 - Up to a total of 6 viable eggs or live turtles with carapace <4" may be allowed
 - More than 6 allowed for science, educational, or exhibition purposes, with CDC permission



Freshwater Turtles, Tortoises, and Terrapins (cont)

- CDC regulations do not apply to sea turtles
- Upon admission to the United States, turtles <4 inches in length become subject to FDA restrictions
- Submit request for letter of permission via email to CDCAnimalImports@cdc.gov



Nonhuman Primate (NHP) Import History

- NHP import regulations strengthened in 1990 following 1989 Ebola Reston outbreak in the United States
- NHP regulations revised further in 2013



1989 Outbreak of Ebola Reston

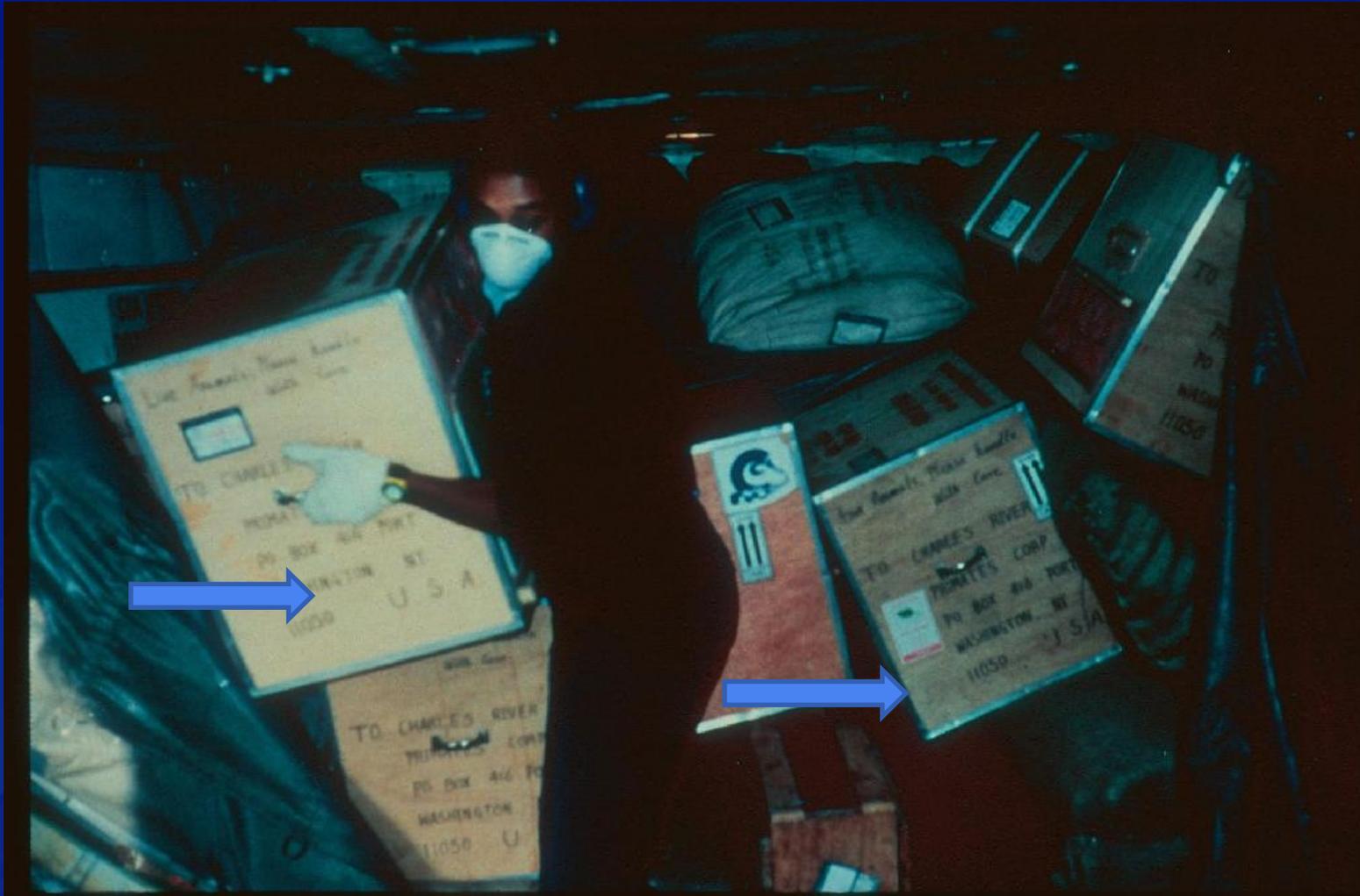
- Viral hemorrhagic fever in a group of imported NHPs
- First thought to be simian hemorrhagic fever
- Illness spread through monkeys at the facility
- Facility was depopulated — 500 animals euthanized
- Six people associated with this outbreak seroconverted
- No human illness



Live NHPs

- **Registration/permit process**
 - Importers must be registered with CDC
 - Entry allowed only for science, education or exhibition
 - For more information on registering as an NHP importer, contact CDC at CDCAnimalImports@cdc.gov
- **Strict procedures for shipping animals and transporting them to the CDC-approved quarantine facility**
- **Post-arrival quarantine period**
- **Quarantine facility inspection by CDC**

Prior to 1990 Regulations



After 1990 Regulations



NHP Products

- **NHP products include any tissue or sample from an NHP**
 - Trophies or souvenirs
 - Diagnostic or scientific samples
 - Other
- **CDC import permit required**
 - Products may be imported without a permit if rendered noninfectious
 - Shipment must be accompanied by a statement of how the products were rendered noninfectious using one of the methods listed at <http://www.cdc.gov/animalimportation/animalproducts.html>
- **Permit application process**
 - Entry allowed only for science, education or exhibition
 - Apply for permit through CDC Import Permit Program
 - Application routed to QBHSB for review and approval

African Rodents

- Restrictions followed a 2003 monkeypox outbreak in the United States
- Linked to African rodents imported for the pet trade
- A total of 71 human cases were investigated
- First human monkeypox cases reported outside of Africa



African Rodents (cont)

- Immediate embargo and domestic ban by Health and Human Services (HHS) effective June 11, 2003
- International import embargo later codified as a regulation, 42 CFR 71.56
- FDA domestic interstate movement restrictions lifted in September 2008



African Rodents (continued)

- **Embargo includes all African rodents**
 - All rodents imported directly from Africa
 - All rodents born in Africa, even if imported from a third country
 - All rodents with a native range that includes Africa, even if born outside of Africa
- **Applies to live animals and animal products**
 - Products may be imported without a permit if rendered noninfectious
 - Shipment must be accompanied by a statement of how the products were rendered noninfectious using one of the methods listed at <http://www.cdc.gov/animalimportation/animalproducts.html>
- **Permission letter application process**
 - Entry allowed only for science, education or exhibition
 - Submit request for letter of permission to import African rodents via email to CDCAAnimalImports@cdc.gov

ENFORCEMENT OF CDC IMPORT REGULATIONS

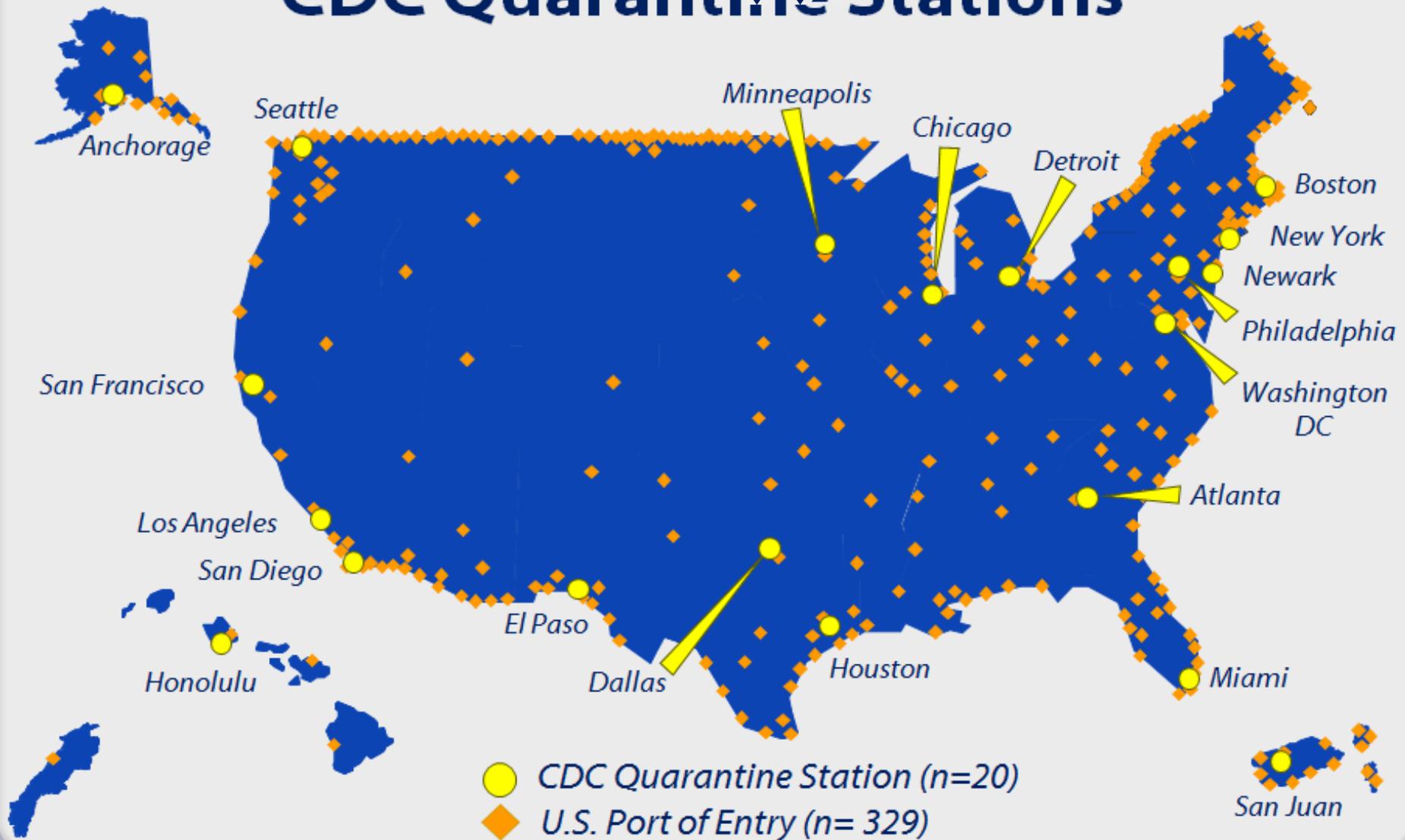
CDC Quarantine Stations and Partnerships at U.S. Ports of Entry

QBHSB Operations

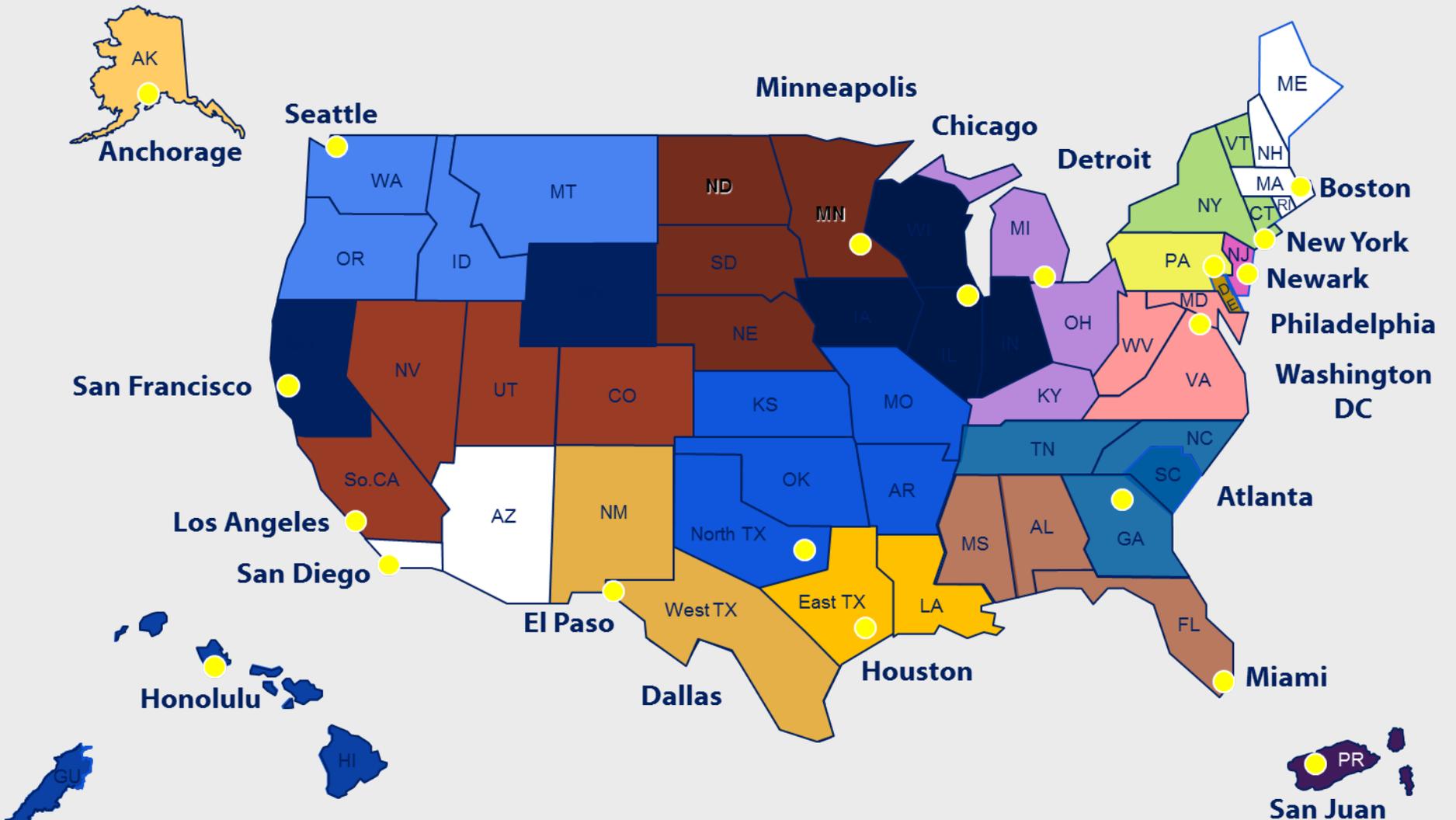
- Manage CDC Quarantine Stations and strategically lead the U.S. Quarantine System with key partners
- Execute federal authority for quarantine, isolation, and communicable disease surveillance at U.S. ports of entry



U.S. POE and CDC Quarantine Stations



CDC Quarantine Station Jurisdictions



● CDC Quarantine Station (n=20)

QBHSB Import Operations

- Provide support to U.S. Customs and Border Protection at ports of entry for CDC-regulated imports
- Coordinate with other federal, state, and local agencies as needed
- Make entry decisions on CDC-regulated imports
- Coordinate with CDC Import Permit Program to ensure that CDC-restricted imports have proper permits or documentation
- For assistance with an import issue at a specific port of entry, contact the CDC Quarantine Station with jurisdiction
 - <http://www.cdc.gov/quarantine/quarantinestationcontactlistfull.html>
 - Direct more general questions or requests for permits to the CDC Import Permit Program or Importations and Animal Contact Team

What's New with CDC Import Permit Program?



Meranda Bradley, Ph.D.
Health Scientist



Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response

Import Permit Program Policy Clarification

- The Import Permit Program published a policy statement regarding the date and conditions of the Import Permit on September 12, 2013. You can find the policy statement posted: <http://www.cdc.gov/od/eaipp/standard/index.htm>.

- **Policy Statement**
 - The issuance and expiration dates listed on the CDC import permit are only applicable to the window of time during which an import permit holder may actually import the infectious biological agents, infectious substances, and vectors listed on the import permit into the United States. The conditions for importation and continued possession listed on the CDC permit remain in effect until the importer is no longer in possession of the imported material
 - Effective June 11, 2014

Import Permit Program Application Changes & Highlights

□ Application revisions

- SECTION A - Person Requesting Permit in U.S. (Permittee)
- SECTION E - Description of Infectious Biological Agent(s)
- SECTION G - Biosafety Measures

SECTION A - Person Requesting Permit in U.S. (Permittee)

SECTION A - Person Requesting Permit in U.S. (Permittee)				
1. Permittee's Last Name	2. Permittee's First Name	3. MI	4. Permittee's Organization	
5. Physical Address (NOT a post office box)		6. City	7. State	8. Zip Code
9. Permittee's Telephone Number	10. Permittee's Fax Number		11. Permittee's Email	
12. Secondary Contact's Name	13. Secondary Contact's Telephone Number		14. Secondary Contact's Email	

Secondary Contact- Note this person is not a permittee

SECTION E - Description of Infectious Biological Agent(s)

4. Scientific name of known/suspected biological agent(s) including Genus and species	5. Strain Designation (list "N/A" if not applicable)	6. Location		7. Laboratory or Storage (Select one or both)		8. Laboratory Safety Level (Leave blank if storage only)	9. Person Responsible for Laboratory
				Lab	Storage		
Scientific Name	Strain Designation	Bldg	Suite/Room	Lab	Storage	Safety Level	Responsible Person
a.				<input type="checkbox"/>	<input type="checkbox"/>		
b.				<input type="checkbox"/>	<input type="checkbox"/>		
c.				<input type="checkbox"/>	<input type="checkbox"/>		
d.				<input type="checkbox"/>	<input type="checkbox"/>		

Notes:

#4- Scientific name of imported material

#5- Strain Designation- for example for Influenza A virus strain designation H1N1

SECT. E - Description of Infectious Biological Agent(s)



U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES
Public Health Service

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

FORM APPROVED
OMB NO. 0920-0199
EXP DATE 01/31/2017

Continuation Page of continuation pages

SECTION E continuation (Description of Infectious Biological Agent(s))

4. Scientific name of known/suspected biological agent(s) including Genus and species	5. Strain Designation (list "N/A" if not applicable)	6. Location		7. Laboratory or Storage (Select one or both)		8. Laboratory Safety Level (Leave blank if storage only)	9. Person Responsible for Laboratory
		Bldg	Suite/Room	Lab	Storage		
Scientific Name	Strain Designation	Bldg	Suite/Room	Lab	Storage	Safety Level	Responsible Person
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>

Continuation Form

SECTION G - Biosafety Measures

Item #4

SECTION G - Biosafety Measures			
<p>1. Primary Containment to be used <i>(Check all that apply)</i></p> <p><input type="checkbox"/> None (open bench)</p> <p><input type="checkbox"/> Class I</p> <p><input type="checkbox"/> Class II, Type <input type="text"/></p> <p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Fume Hood</p> <p><input type="checkbox"/> Other <i>(please describe)</i>:</p> <p><input type="text"/></p> <p><input type="text"/></p>	<p>2. Personal Protective Measures to be used <i>(Check all that apply)</i></p> <p><input type="checkbox"/> Gloves</p> <p><input type="checkbox"/> Protective Clothing</p> <p><input type="checkbox"/> Goggles and/or Face Shield</p> <p><input type="checkbox"/> Facemask</p> <p><input type="checkbox"/> Respirators: Type <input type="checkbox"/> N95/100 <input type="checkbox"/> PAPR</p> <p><input type="checkbox"/> Immunizations</p> <p><input type="checkbox"/> Other <i>(please describe)</i>:</p> <p><input type="text"/></p>	<p>3. Personnel Training provided <i>(Check all that apply)</i></p> <p><input type="checkbox"/> Risk(s) associated with the imported biological agent(s)</p> <p><input type="checkbox"/> Hazardous Material Packing/Shipping</p> <p><input type="checkbox"/> Laboratory Standard Practices</p> <p><input type="checkbox"/> Hazardous Waste Handling/Disposal</p> <p><input type="checkbox"/> Emergency Response Procedures</p> <p><input type="checkbox"/> Spill Procedures</p> <p><input type="checkbox"/> Other <i>(please describe)</i>:</p> <p><input type="text"/></p>	<p>4. Has the permittee 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?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes <i>(Plan may be required to be submitted)</i></p>

Highlights of Application Submission Changes

- ❑ **Customer Interfaced Web-Based Application**
 - Link to website: <http://eaipp.azurewebsites.net/>



United States Department of Agriculture

APHIS Animal and Plant Health Inspection Service

Veterinary Services Organisms and Vectors Permitting



U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services
National Import Export Services
Organisms and Vectors Permitting
October 2014

Outline

- Overview
- Authorities
- What does O & V regulate?
- Application process
- Best practices
- Useful information



APHIS Mission

- To protect the health and value of American agriculture and natural resources

Veterinary Services

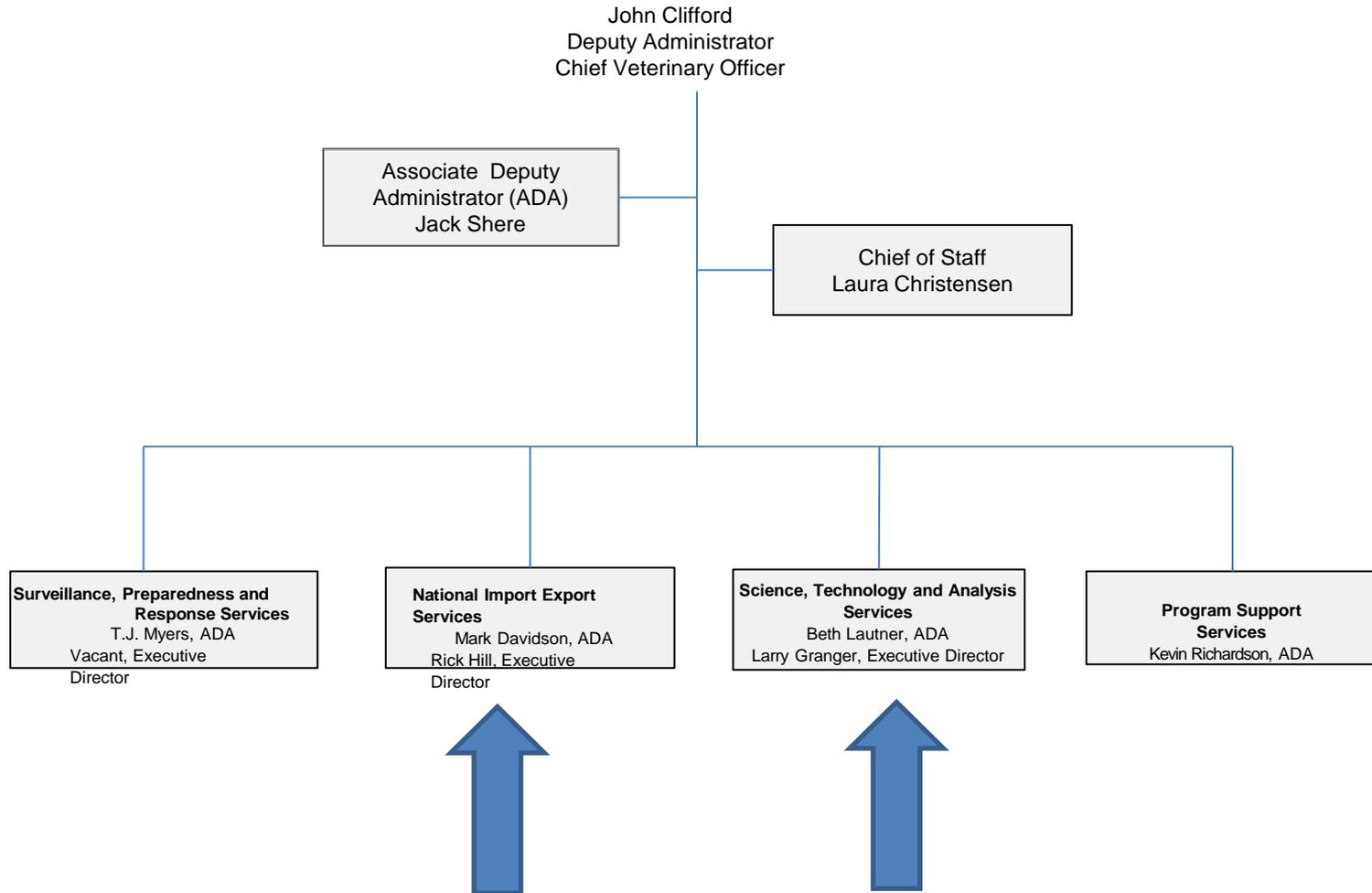
VS Mission

- As the recognized animal health leader and trusted partner, Veterinary Services safeguards the health of animals, people, and the environment.





Veterinary Services (cont)





VS Permitting

National Import Export Services

- Live animal permitting
- Animal products permitting
- Organisms and vectors permitting

Science Technology and Analysis Services

- Center for Veterinary Biologics

Authorities

- Animal Health Protection Act, 7 U.S.C. 8301
- Virus-Serum-Toxin Act , 21 U.S.C. 151
- Code of Federal Regulations 9 CFR
 - Part 101 definitions
 - Part 104 biological products
 - Part 122 organisms and vectors
 - Part 123 virus serum toxin act rules

Organisms and Vectors (O & V)

- Regulate the importation into the United States and interstate transport of organisms and vectors of pathogenic diseases of livestock and poultry



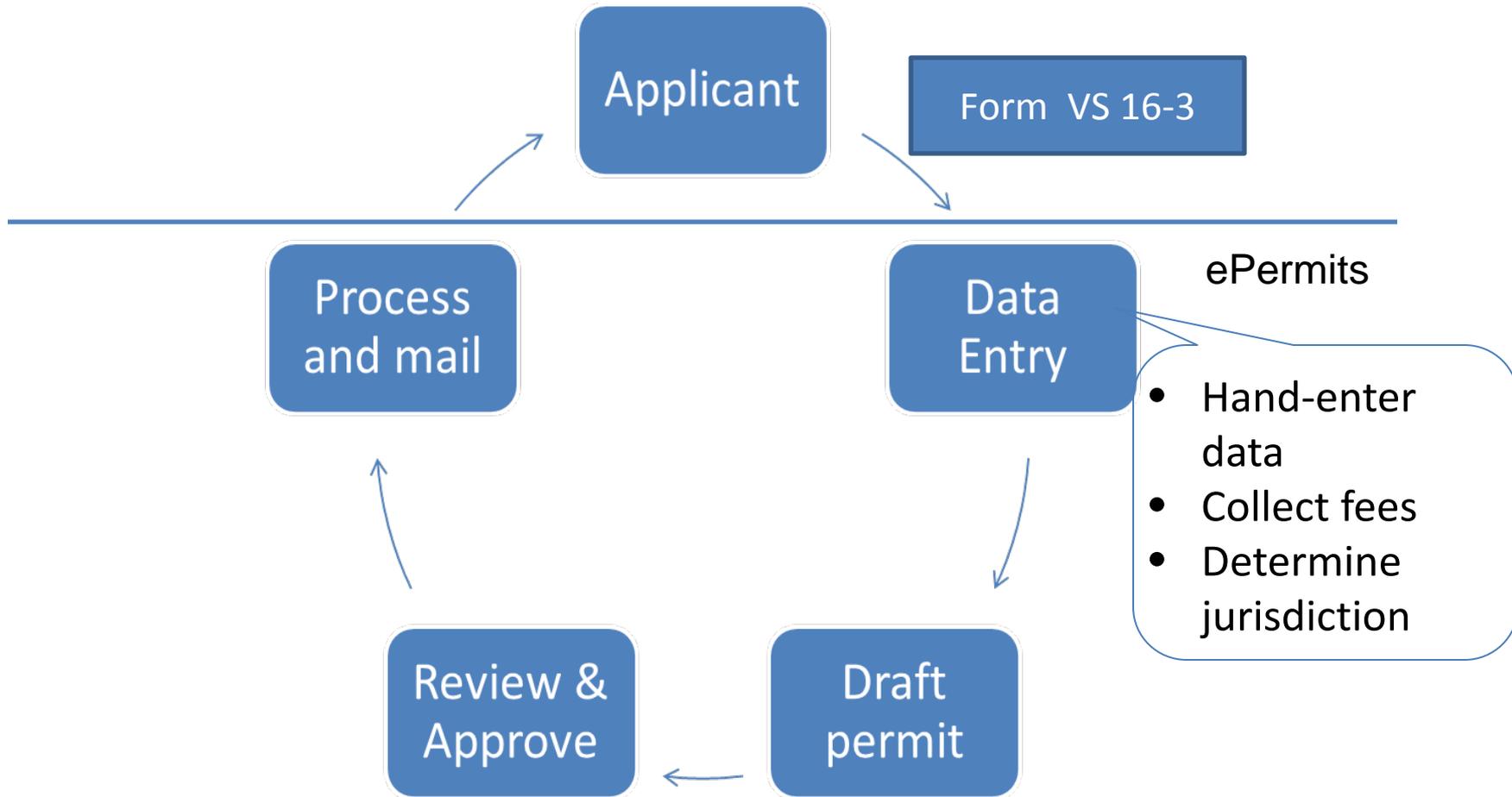
What does O & V regulate?

- Organisms that cause disease in livestock and poultry
- Vectors that could carry livestock and poultry diseases
- Biosafety
- Traceability

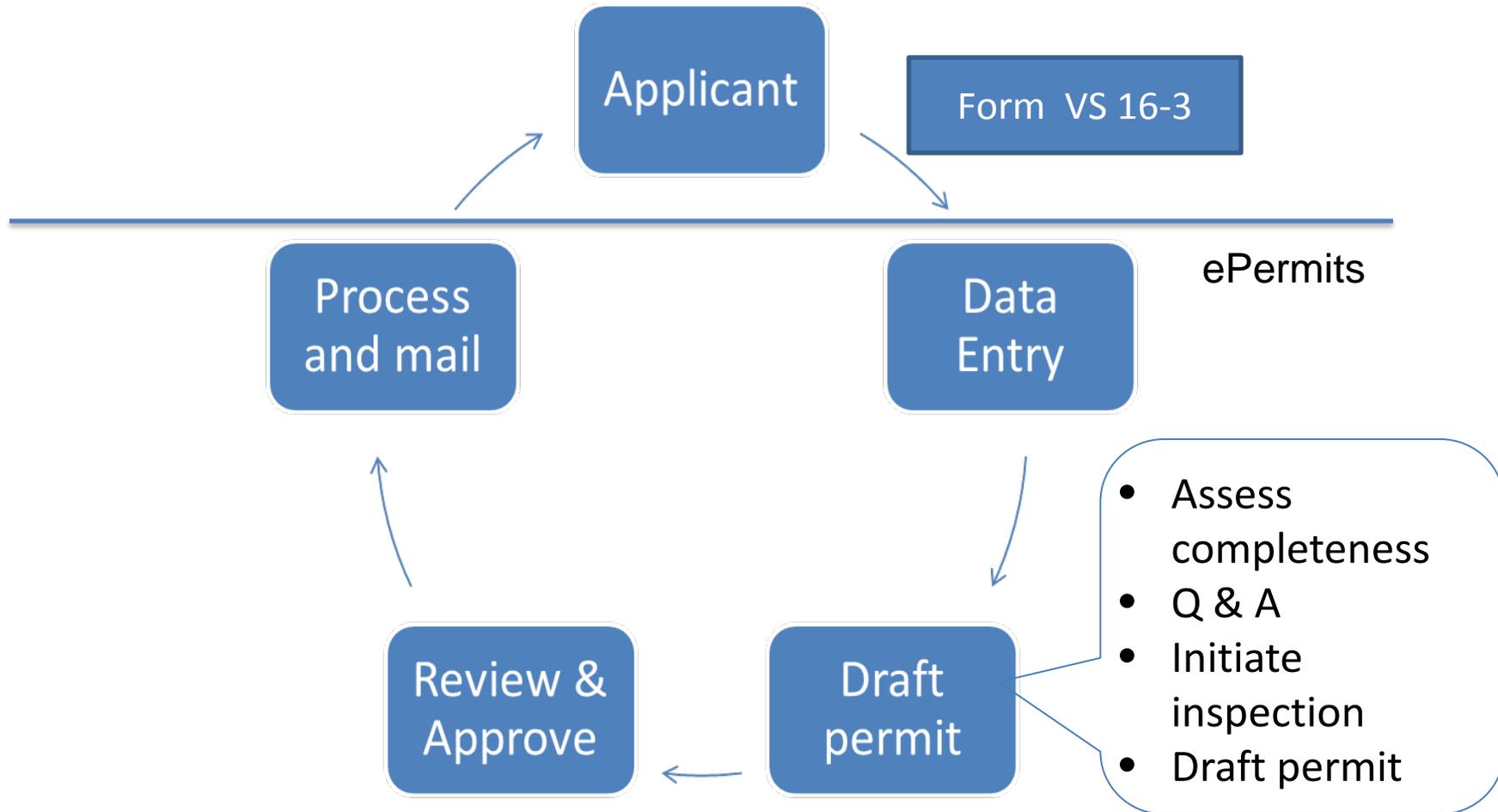
Inspections

- Major duty – ensure biosafety
- NIES Service Center inspectors
 - BSL 2, BSL 2+
 - ABSL 2, ABSL 2+
- Select Agent inspectors – BSL 3
- Impacts processing time

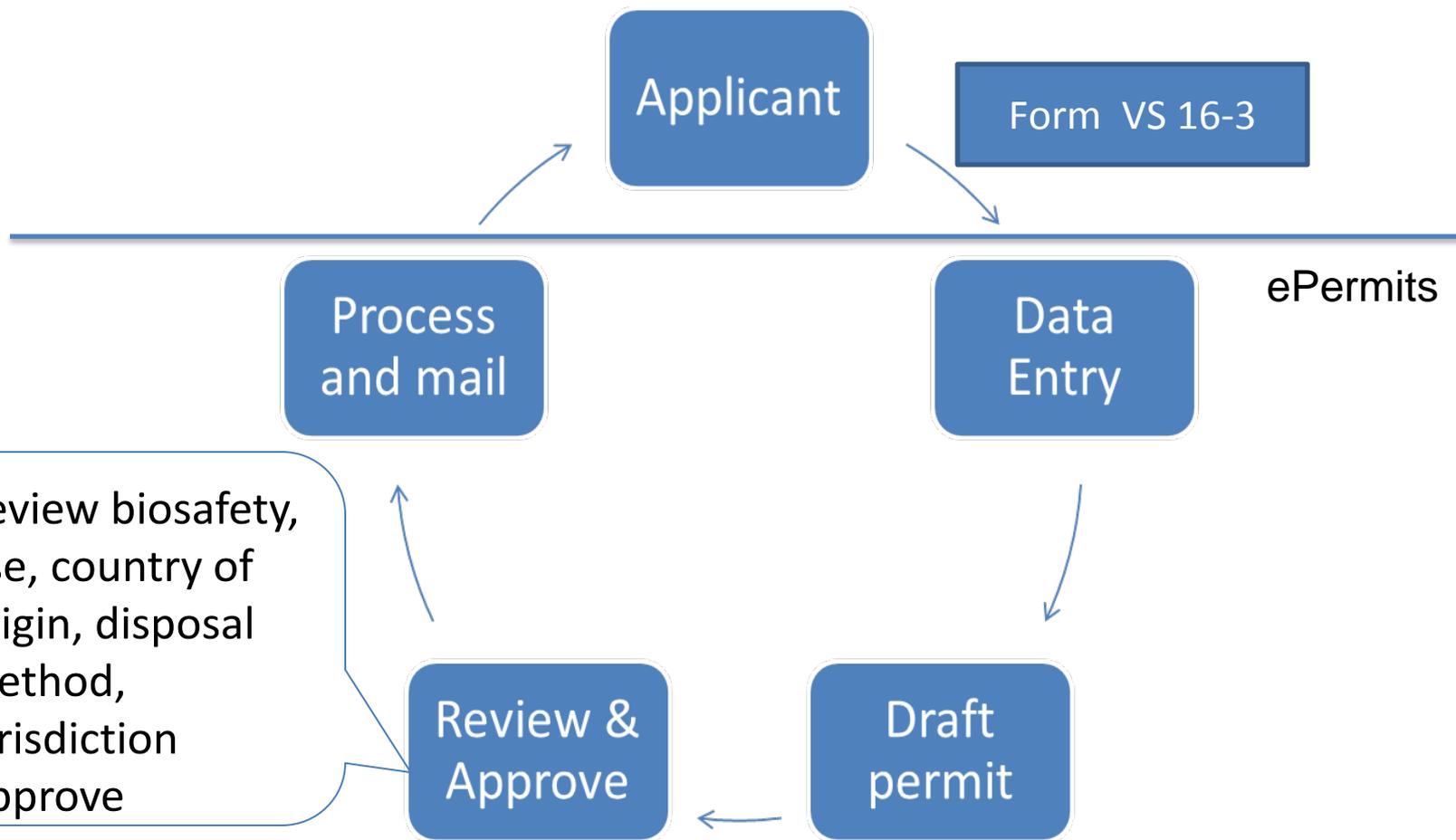
O & V Application process (a)



O & V Application process (b)



O & V Application process (c)



- Review biosafety, use, country of origin, disposal method, jurisdiction
- Approve

O & V Best Practices

- Electronic submission – ePermits system
- Guidelines – No permit required
 - Include guideline and documentation with shipment
- Import permit OR Transport permit
- Permit is for movement and RECEIPT of organism

O & V Best Practices, cont.

- **Imports**

- Full description of agent (genus, species, etc)
- Bacteria subcultured 4 times
- Country of origin
- Animal-origin nutrients/media
- Exposure to livestock/poultry
- Disease status of exporting country
- Method of inactivation

Web tools

- <http://www.USDA.APHIS.gov> -> Imports and Exports -> Animal and Animal Product
 - Application process
 - List of foreign country disease status
 - Guidelines - No permit required



O & V Contact information

- OV@aphis.usda.gov
- Telephone: 301-851-3300, option 3
- Fax: 301-734-3652



United States Department of Agriculture

Pest Permitting Policy: Protecting American Agriculture and the Environment

**Shirley Wager-Pagé, Ph.D, Chief
Pest Permitting Branch,
Plant Protection and Quarantine,
USDA APHIS
Riverdale, MD**





AUTHORITY

Under the authority of the Plant Protection Act, the Secretary of Agriculture may prohibit or restrict the movement into or through the United States, or interstate commerce, including Territories and Possessions, of plant pests, plants and plant parts, and associated articles. This authority is to prevent the introduction into, or dissemination within the United States of a plant pest or noxious weed in order to protect plant health.

PPQ issues permits for the movement of commodities including fruit, vegetables, plants, wood and wood products. The commodities are intended to be free of plant pests; therefore they will not be discussed further in this presentation.



AUTHORITY (CONT)

The Pest Permitting Branch issues permits and other documents authorizing the movement of plant pests. Permits include requirements that provide the appropriate level of safeguarding to prevent the dissemination of these pests into or through the United States. Impediments to foreign commerce and travel are minimized, whenever possible.





REGULATIONS

Part 7, Code of Federal Regulations (7CFR), specifically 7CFR 330 and 360, provide the authority to grant plant pest permits.

- A part 330 permit is required for the importation or interstate movement, and subsequent movements of plant pests, biological control organisms, and associated articles.
- Similarly, a part 360 permit is required for the importation, movement interstate, or release into the environment of Federal Noxious Weeds.
- Customs and Border Protection enforces these regulations at U.S. Ports of entry and border crossings



Who needs a plant pest permit?

Any U.S. resident who wants to move live plant pests, biological control agents, parasitic plants, Federal noxious weeds, or soil into, or through the United States by importation or interstate, needs a permit.

PPQ uses the ePermits database to process permit applications

The permit holder is the responsible party and not the exporter or shipper, and permits are non-transferable.

Permit Types According To Movement

Permits are issued for interstate movement, importation, environmental release and continued curation of the following:

- invertebrate organisms and arthropods that are plant pests,
- plant pathogenic microbes: fungi, viruses and bacteria,
- nematodes,
- mollusks,
- federal noxious weeds,
- soil,
- biocontrol organisms.

Plant pests can be designated either direct or indirect plant pests. An example of an indirect plant pest is a vector.

Continued curation extends the retention of a regulated article.

Permit Types According To Intended Use:

- Research in a lab, growth chamber and green house
- Field research, typically restricted to 10 acres or less
- Organism isolation and identification and/or taxonomic studies from soil or other related materials
- Diagnostic samples for identification of plant pests
- Organisms for taxonomic studies
- Evaluation of microbial biopesticides and biocontrol organisms properties



Additional Intended Uses of Regulated Organisms and Associated Articles

- Religious and cultural purposes
- Educational use
- Commercial sale and distribution
- Display
- Human and Animal Consumption

Intended use is a contributing factor to the potential plant health risk associated with regulated organisms.

Plant Pest Permit Regulatory Decisions (a)

An application for a pest permit can result in:

1. the issuance of a permit;
2. denial of application for permit;
3. withdrawal or voiding the application
4. cancelation or suspension of a permit, or
5. letter of no jurisdiction/no permit required.





Plant Pest Permit Regulatory Decisions (b)

Permit: A permit will be issued after evaluations and reviews of permit applications are completed, and it will specify required safeguards for the purpose of preventing the dissemination of plant pests into the United States.

Permit Conditions provide the required safeguarding measures to ensure safe movement, containment, use and disposal of regulated articles

Plant Pest Permit Regulatory Decisions (c)

Denial: An application for a permit will be denied if the needed safeguards cannot be arranged to prevent dissemination of plant pests into or throughout the United States.





Plant Pest Permit Regulatory Decisions (d)

Letter of No Jurisdiction or No Permit Required:

A letter of no jurisdiction is issued if the article is not a plant pest or biocontrol organism.

A letter of no permit required may be received for proposed movement of certain organisms recognized as common and widespread.



Intrastate Movement – Permitting Policy

Plant Protection and Quarantine does not have the authority to regulate intrastate (within the State) movement of organisms, unless a Federal permit was previously issued for the organism.

The original permit must be amended, or a new permit issued for this movement. The new destination and permittee information will be included on the permit as well as the origin, intended use and movement type previously authorized.

Containment of Plant Pests

Containment facilities are required for plant pests that are assessed by the Pest Permitting Branch to be of medium to high risk to agriculture or the environment. These plant pests need special containment features and/or handling procedures that will ensure that they are not disseminated into the environment.



Containment requirements - considerations

- Containment is typically required for organisms of foreign origin
- Level of pest risk, and consequences of unintended release
- Presence of hosts, climatic and ecosystem factors
- Mobility of the plant pest
- Spread: air-borne, water-borne, vectors
- Likelihood of introduction, establishment, and spread if released into the environment
- Availability of treatments to devitalize the organism



Compliance and Enforcement

Customs and Border Protection and PPQ Field Operations staff perform inspections and identifications, and they are responsible for enforcement actions pertaining to non-compliance that are taken at port and border crossing. PPQ personnel work in 17 plant inspection stations located throughout the United States.

PPQ Field Operations and Headquarters staffs are responsible for conducting periodic and unannounced compliance inspections of containment facilities. Violations of 7CFR330 in field locations are referred to APHIS Investigative and Enforcement Services or the Smuggling, Interdiction and Trade Compliance Staff.



United States Department of Agriculture

For more information:

Customer Service: 301-851-2046, Toll Free 866-524-5421

Help: Pest.Permits@aphis.usda.gov



Additional Information

- Additional information is provided at: Plant Health Import Permits - http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml
- Regulated Organism and Soil Permits - [Regulated Organism and Soil Permits](#)
- ePermits: <https://epermits.aphis.usda.gov>
- To obtain an eAuthentication account: [Register online](#) for a **Level 2** eAuthentication account at the following address:
<https://identitymanager.eems.usda.gov/registration/selfRegistrationForm.aspx?level=2>
- For further information on eAuthentication, please email ePermitsHelp@aphis.usda.gov or call 1-866-794-2827

**U.S. Customs and Border Protection (CBP)
Office of Field Operations (OFO)
Agriculture Programs and Trade Liaison (APTL)**

CDC Import Permit Webinar

October 24, 2014

Romelito Lapitan, *Ph.D.*
Acting Branch Chief



U.S. Customs and
Border Protection

Field Operations



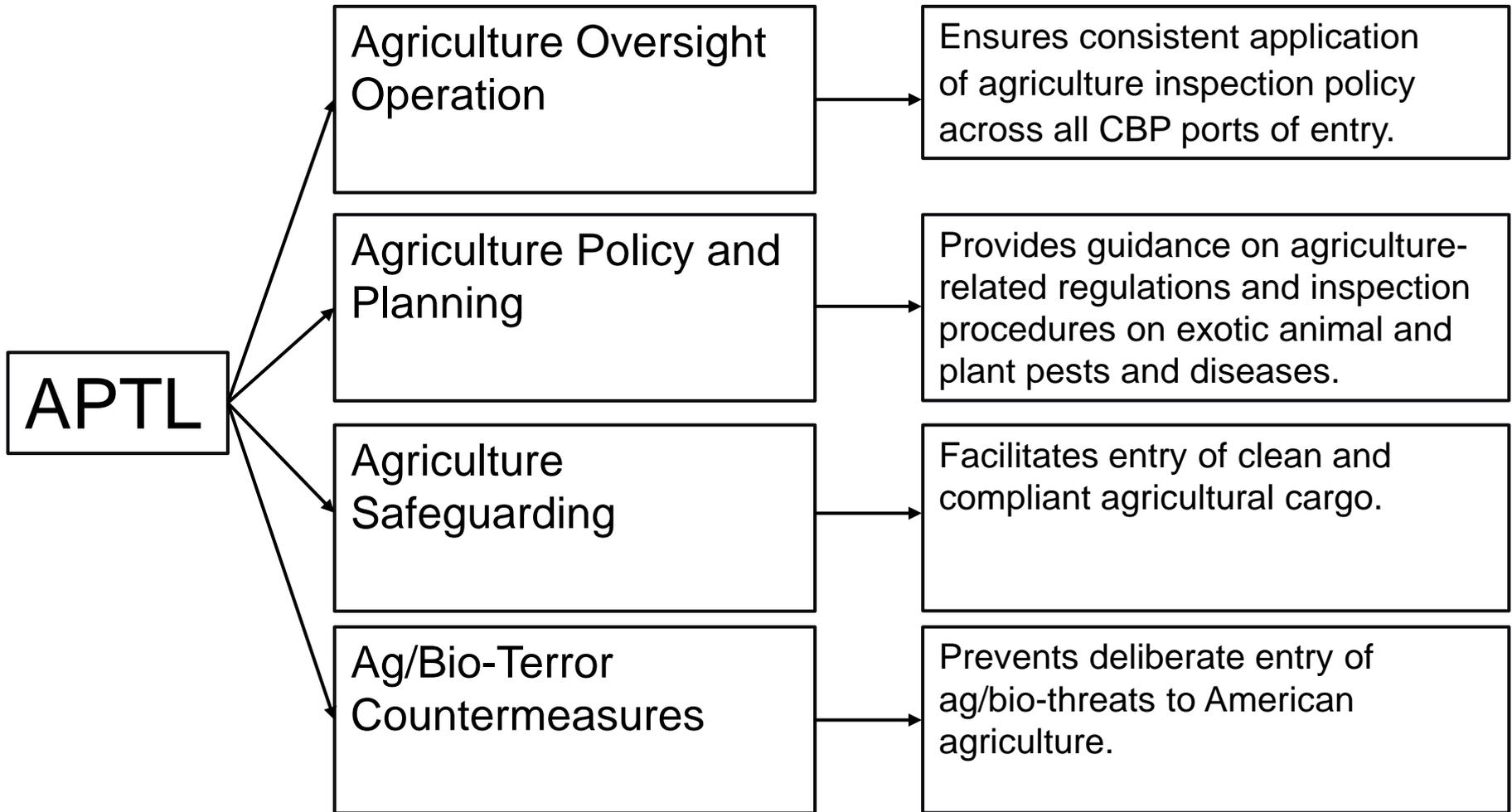
Objectives

- Mission & Focus of U.S. Customs and Border Protection, Agriculture Program and Trade Liaison Office
- Partnership with Other Agencies
- Regulatory Requirements for Importation of Infectious Biological Agents, Infectious Substances, and Vectors
- Enforcement and Actions
- Recommendations for Effective Enforcement of Import Regulations

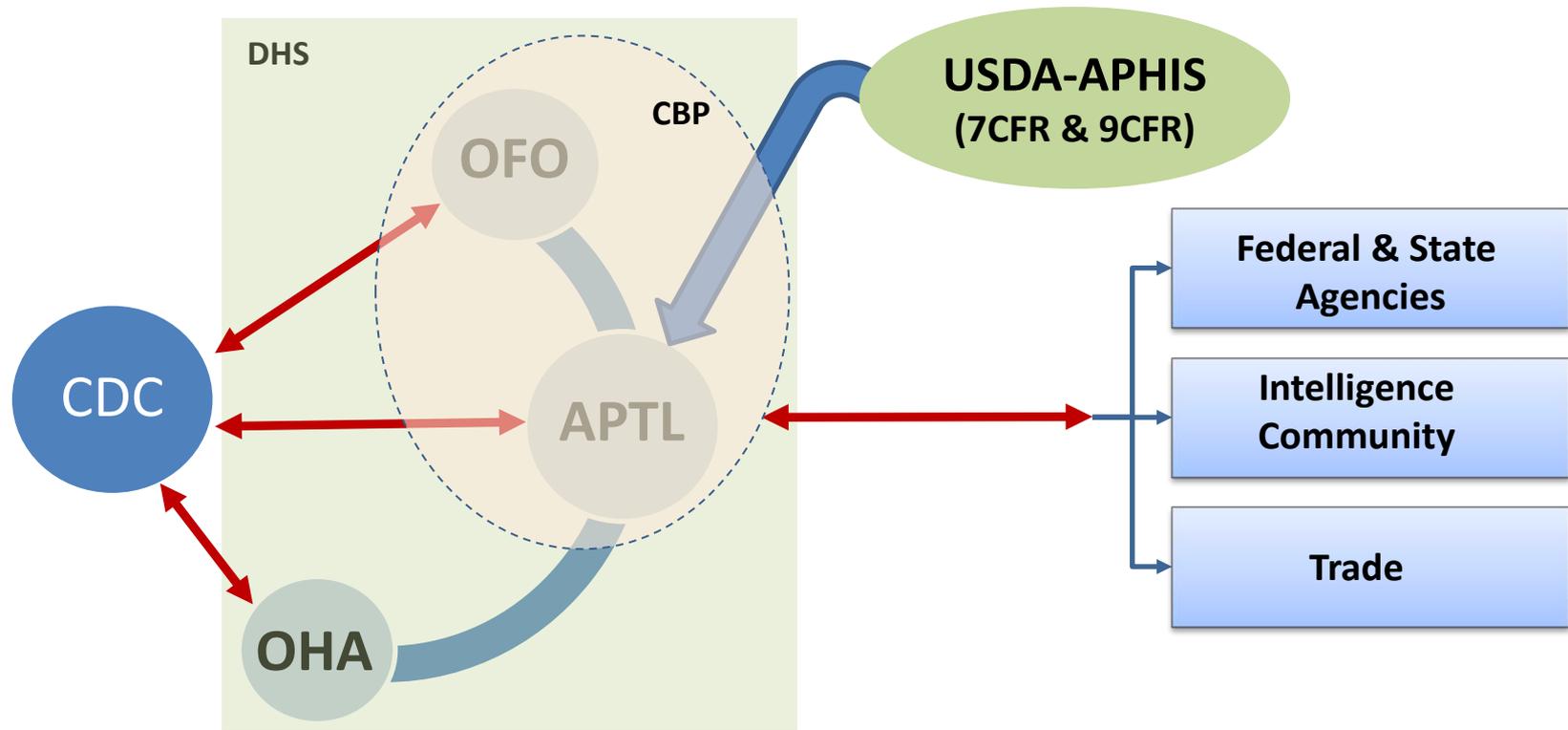


U.S. Customs and Border Protection

Agriculture Programs and Trade Liaison



CBP APTL Collaboration



U.S. Customs and Border Protection Ports of Entry

- U.S. Ports of Entry (POE): 328
- Pre-Clearance: 15
- Total Number of Agriculture Specialists (CBPAS): ~ 2,400
- Total Number of POE Staffed by CBPAS: ~180

Ports of Entry Restrictions for Select Agents (?)

- Anchorage, AK
- Chicago, IL
- Detroit, MI
- Honolulu, HI
- Indianapolis, IN
- Los Angeles, CA
- Memphis, TN
- Miami, FL
- Minneapolis/St. Paul, MN
- Newark, NJ
- New York, NY
- San Juan, PR
- Seattle WA
- St. Louis, MO



U.S. CBP Cargo Environment Process

CBP Advance Notification Requirements:

Air	≥ 4 hrs or wheels up
Sea	≥ 24 hrs
Land Border	≥ 2hrs
C-TPAT	≥ 0.5 hrs
Rail	≥ 2hrs

CBP POE

Formal Entry

CBP System

Advance Screening

Agriculture Inspection

Document Review

Compliant

- APHIS/CDC Form 2*
- Authorization Letter*
- Entry Manifest*,†
- VS/CDC Import Permit†
- Written declaration†

- Provide importer options
- Refer to USDA or CDC

Arrival

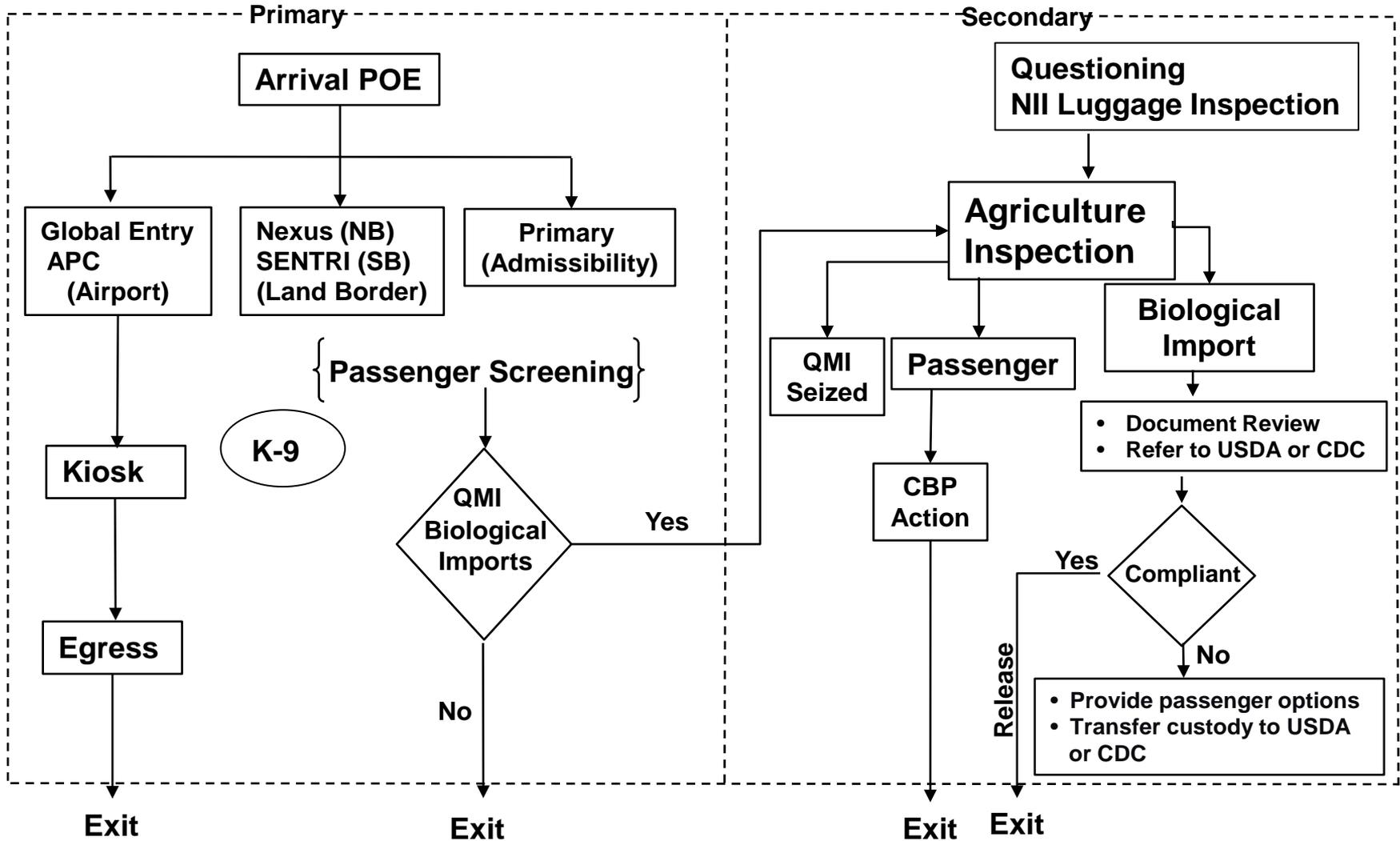
Yes Release

Exit

USA

- Biological Imports**
- Select agents & toxins
 - Etiologic agents
 - Cell/tissue culture
 - Histopathological slide mounts
 - Recombinant/non-recombinant
 - DNA/RNA, enzymes etc.
 - Vaccines, bacterin, or toxoid

U.S. CBP Passenger Environment Process (cont)



CBP Agriculture Specialist (CBPAS) Compliance Agreement

- Joint USDA/CBP effort
- Regulated Garbage Handling
- Compliance Agreements
- Training, Handling, Destruction
- Monitoring and Inspection
- Regulatory Enforcement



CBP APTL

Agriculture Enforcement

High profile prohibited agriculture interception at POE

Significant Agriculture Incident Report (SAIR) generated

CBP APTL and all POEs receive SAIR report

AEAs sent to 329 State and Federal agriculture representatives

CBP APTL releases Ag enforcement Alerts (AEA) 2x a week



CBP APTL

Agriculture Enforcement Alerts

- Laredo
- Land Border Bus
- Traveler from Peru
- Declared Live Vaccines for Treating Sheep: *Bacillus anthracis*, *Pasteurella clostridium*, Penicillin
- No VS permit
- Vaccines Seized and Referred to USDA VMO
- Traveler was Penalized for Undeclared Pork Meat and Hatching Eggs



CBP APTL

Agriculture Enforcement Alerts (cont)



- Washington Dulles and Philadelphia Airports
- Air Passenger
- Traveling from Cameroon, Ghana, and Togo
- Monkey head and fur, monkey meat, and grass cutter meat
- Monkey head and bushmeat seized, referred and transferred custody to FWS and CDC, then destroyed by incineration.

Take Home Message

- **CBP oversees all imports and assists other agencies, including CDC, in enforcing their import regulations.**
- **CDC has specific statutory and regulatory responsibilities for protecting human health from risks posed by imports of select agents, toxins, organisms and vectors of human diseases.**



Requirements of Effective Enforcement

- **Need for clear guidance on importation of select agents and toxins from USDA-APHIS and CDC**
 - Documentation requirements
 - Pathway/carrier
 - Procedures and Processes for Detaining (Holding) and Handling Discrepancies
- **Notification Requirements**
- **Streamline Coordination of Response**
- **Subscription to CBP's Trusted Trade Program (e.g. C-TPAT)**





Transporting Infectious Substances Safely

**CDC Webinar
Atlanta, GA
Oct 24, 2014**





Infectious Substances Guide





Objective

- Provide a general overview of the regulatory requirements for transporting Division 6.2 materials:
 - Package Selection
 - Marking and Labeling
 - Shipping Papers and Emergency Response Information
 - “Transportation” Security Plan and Training





U.S. DOT Hazardous Materials Regulations (HMR)

The HMR govern the packaging and safe transportation of hazardous materials by air, highway, rail, and water within the US.

CFR 49





Category A Infectious Substance

- Identified as:
 - Infectious substances, affecting humans, UN2814, 6.2
 - Infectious substances, affecting animals *only*, UN2900, 6.2





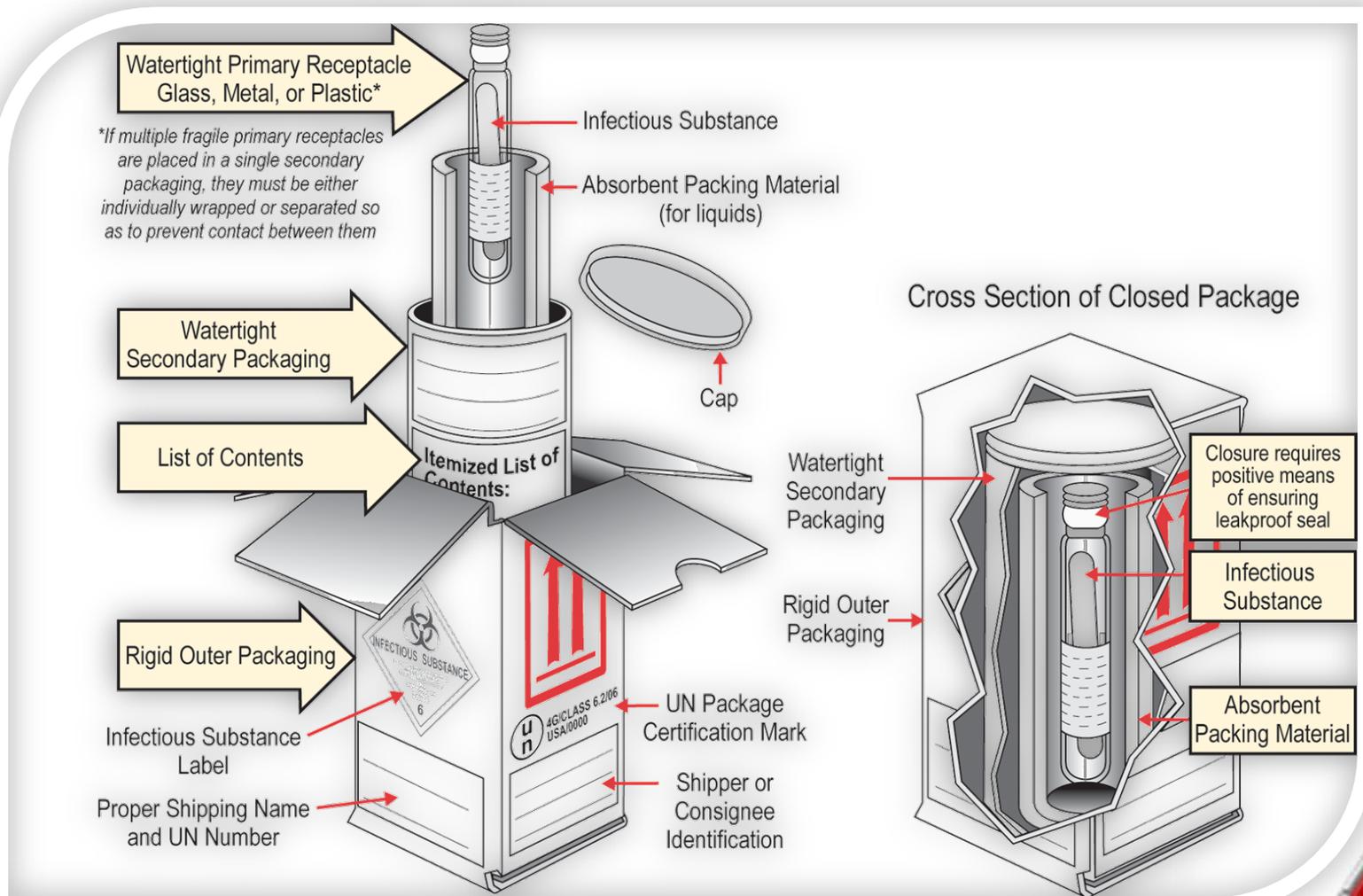
Packaging Requirements

173.24	General Packaging
173.24a	Requirements for all HAZMAT
173.24a(c)	Changes regarding Infectious Substances and mixed contents
173.134(b) 173.134(c)	Exceptions for: Division 6.2 Packaging Regulated Medical Waste
173.196	Category A Infectious Substance
173.197	Regulated Medical Waste
173.199	Category B Infectious Substance
178.609	6.2 Packaging Tests



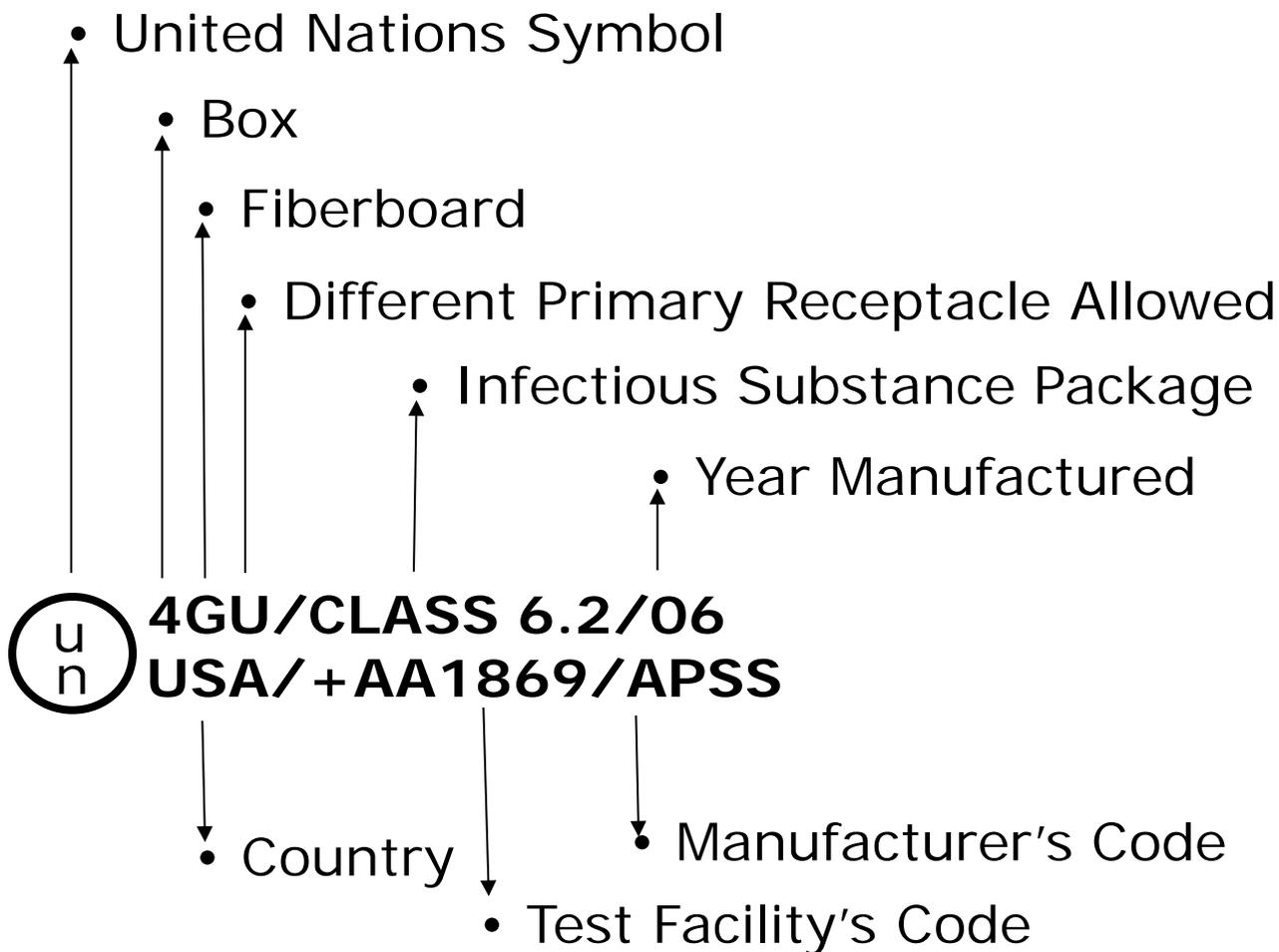


Category A Packaging





UN Packaging – Division 6.2 Category A





Testing of Packages

- Cat A Pkg: UN certified (4G or 4GU /Class 6.2)

Wet box for 1hr to represent 2" of rain per hr;
then drop from 30 ft.

Freeze pkg 24 hr at 0 degrees, then drop test.

Drop 1 ½" diameter, 15 lb steel rod, onto box or drop box
onto steel rod.

Dry Ice specific tests (if pkg intended to contain)

Variations: Smaller inner pkg; less number inner pkgs; fragile inner
pkgs





Marking and Label Requirements

- **Category A “PKG”**

- Proper shipping name, UN 2814 or UN 2900
(*No tech name on pkg per 172.301(b))

CDC Lost in the Crowd Concept for Tech Name

- Shipper or Consignee identification
- Infectious Substance Label
- Orientation arrows (as applicable)
- Dry Ice label (as applicable)





Division 6.2 Label

- Required label for:
 - Category A Infectious Substance
(Changes 1 ~ 1.1)





Shipping Papers

- **Category A**
 - Identification Number
 - Proper Shipping Name / Tech Name
 - Tech Name For CDC Select Agents Lost in crowd
Enter “Suspected Category A infectious substance”
 - Hazard Class/Division
 - NO Packing Group
 - Type Pkg/Unit of Measure (QTY)
 - Shipper’s Certification
 - Emergency Response Telephone Number





Sample Shipping Paper

- UN2814, Infectious Substance Affecting Humans, (Suspected Category A Infectious Substance), 6.2
- Emergency Response telephone number:

Importance





Other Requirements – Security Plan

- A TRANSPORTATION Security plan is required for: (172.802)
 - Select agent or toxin regulated by CDC under 42 CFR part 73
- The plan must include:
 - Assessment of security risks
 - Address personnel security, unauthorized access, and en-route security





Other Requirements – Training

- Federal hazardous materials transportation law 49 CFR, Part 172, Subpart H, requires training of *all* hazmat employees. Training must include:
 - General Awareness / Familiarization
 - Safety
 - Function Specific
 - Security Awareness
 - In-depth Security (when applicable)
- Anyone shipping infectious substances must have “knowledge and training”





Hazardous Material Info-Center

1-800-HMR-4922

(1-800-467-4922)

E-mail: infocntr@dot.gov
PHMSA.DOT.GOV/Hazmat

Hours of Operation: 9 am – 5 pm ET



- Obtain answers to HMR questions
- Request copies of Federal Register, special permits or training materials
- Report HMR violations
- Fax on Demand





William Stevens Investigator

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Administration**

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For more information about import permits visit:

- <http://www.cdc.gov/od/eaipp/whatsnew/index.htm>