The CDC Etiologic Agent Import Permit Facility Inspection Process:

TWO HIGH-CONTAINMENT LABORATORY EXPERIENCES

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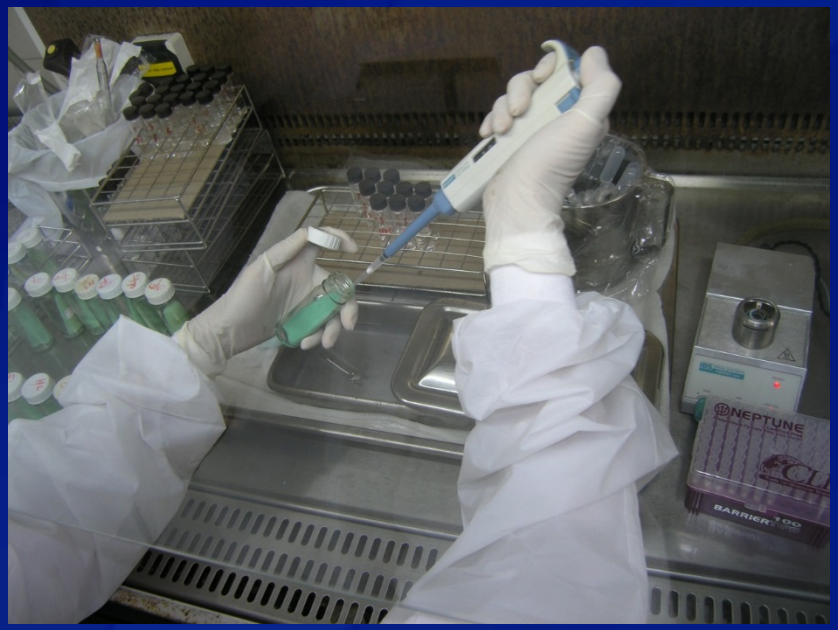
What the CDC International Laboratory Branch (ILB-GAP) Does

- DGHA's International Laboratory Branch (ILB) supports development of sustainable, integrated quality laboratory services for all the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) countries in support of HIV care and treatment, prevention, and HIV/tuberculosis (TB) co-infection. ILB provides training and testing support for quality control and quality assurance of HIV and TB laboratories and testing activities

- The branch conducts operational research to enhance the implementation of PEPFAR programs in laboratory test and instrumentation evaluations, incidence testing validation, infant diagnostics by polymerase chain reaction (PCR) testing, ART drug resistance testing, and new rapid TB diagnostics

Tuberculosis (TB)/Opportunistic Infections (OI) Unit



TB culture on LJ medium

Automated TB culture using MGIT 920

ILB's Tuberculosis (TB)/Opportunistic Infections (OI) Unit provides training and laboratory Quality management support for TB diagnostics, smear microscopy, TB culture, and drug susceptibility testing, and in culturing TB to detect potential drug resistance: multidrug resistant (MDRTB) and extensively drug resistant (XDRTB) for PEPFAR laboratories

Because of aerosol potential, all TB culture activities conducted under BSL-3 containment

The CDC Import Permit Program

Located within the Division of Select Agents and Toxins, the Centers for Disease Control and Prevention's Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States (CDC Import Permit Program (42 C.F.R. § 71.54))

Inspections authorized under Section 361 of the Public Health Service Act

Prior to issuing an import permit, IPP reviews all applications to ensure that entities (i.e., laboratory facilities) have appropriate safety measures in place for working safely with these imported materials

IPP may inspect applicants to ensure that the facilities have implemented the appropriate biosafety measures for the infectious biological agent, infectious substance, or vector to be imported

For more information:

http://www.cdc.gov/od/eaipp/

http://www.cdc.gov/od/eaipp/docs/overview.pdf

Import Permit 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*

Changes to Import Permit Regulations

- **Update regulatory definitions of items that require an import permit**
  - Infectious biological agent, infectious substances and vector
- **To ensure adequate biosafety measures**
  - *Require the applicant to have biosafety measures that 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*
- **Increase oversight through inspections**
- **Present an appeals process for permit applications that are denied**

Overview of the import permit process

1. The Import Permit Application and Import Permit

2. The Inspection Process:
   - Inspection notification
   - Day of the Inspection
   - Documentation and Records to be reviewed
   - Laboratory tour
   - Findings and Out briefing
   - Inspection report
   - Laboratory response

The Import Permit Application

The Import Permit Application:
http://www.cdc.gov/od/eaipp/forms/permit_to_import_biological_agent_or_vector.pdf

Guidance document for filling out the Import Permit application:
http://www.cdc.gov/od/eaipp/forms/guidance_document_for_completion_agents.pdf

FAQs
http://www.cdc.gov/od/eaipp/faq.htm

Import Permits are required to import any of these items into the United States from abroad:

- Infectious biological agents
- Infectious substances
- Vector
- Animals
- Arthropods
- Snails
- Bats
- Non-human primate material

Page 1: Four sections

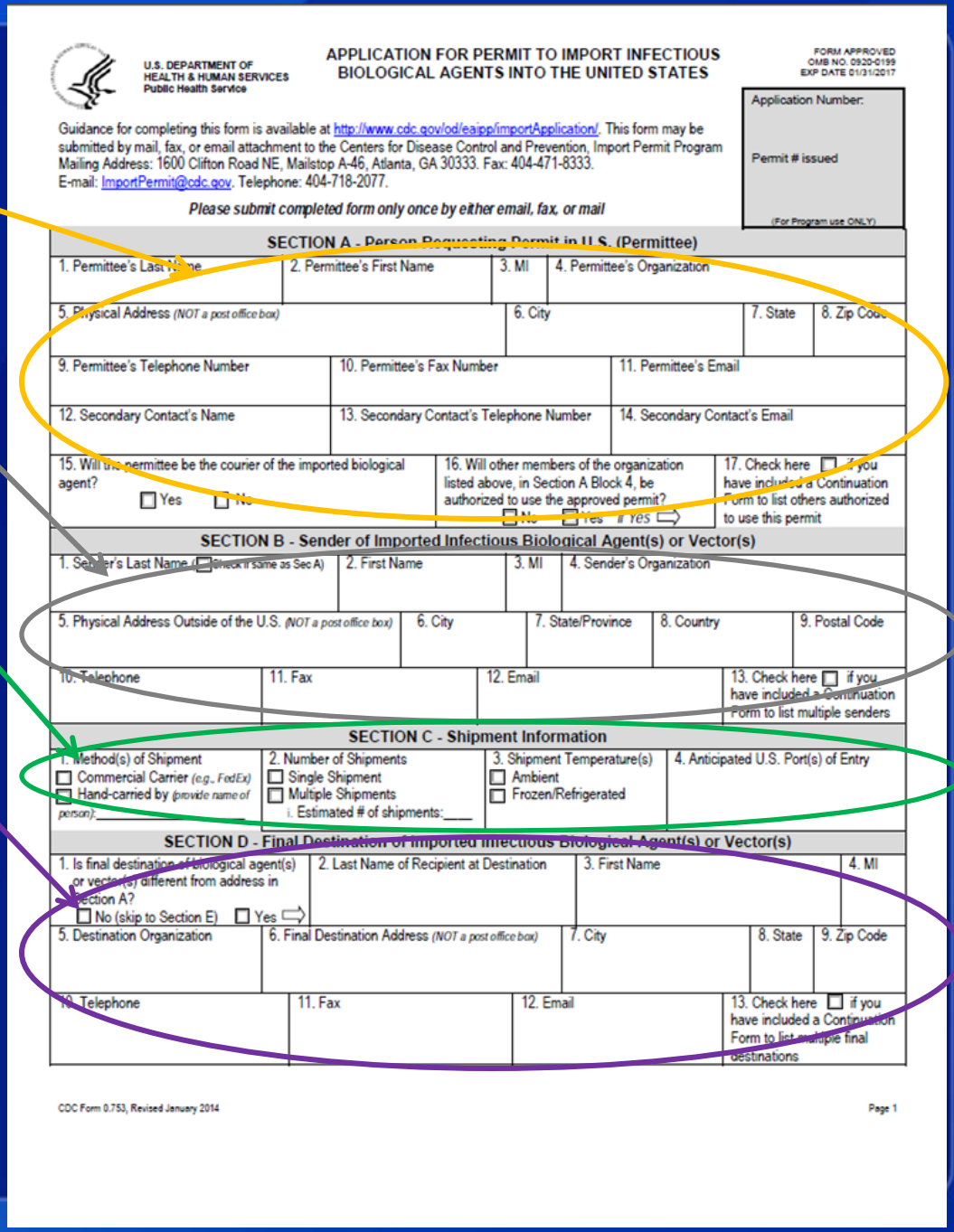
Section A: The Permittee

Section B: Who is sending the samples

Section C: Shipping info

Section D: Destination information

The Import Permit Application



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

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

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

Application Number:

Permit # issued

(For Program use ONLY)

Guidance for completing this form is available at http://www.cdc.gov/od/eaipp/importApplication/. This form may be submitted by mail, fax, or email attachment to the Centers for Disease Control and Prevention, Import Permit Program
Mailing Address: 1600 Clifton Road NE, Mailstop A-46, Atlanta, GA 30333. Fax: 404-471-8333.
E-mail: ImportPermit@cdc.gov. Telephone: 404-718-2077.

Please submit completed form only once by either email, fax, or mail

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
15. Will the permittee be the courier of the imported biological agent? ☐ Yes ☐ No
16. Will other members of the organization listed above, in Section A Block 4, be authorized to use the approved permit? ☐ No ☐ Yes *If Yes* ⇨
17. Check here ☐ if you have included a Continuation Form to list others authorized to use this permit

SECTION B - Sender of Imported Infectious Biological Agent(s) or Vector(s)

1. Sender's Last Name (☐ Check if same as Sec A) | 2. First Name | 3. MI | 4. Sender's Organization
5. Physical Address Outside of the U.S. *(NOT a post office box)* | 6. City | 7. State/Province | 8. Country | 9. Postal Code
10. Telephone | 11. Fax | 12. Email | 13. Check here ☐ if you have included a Continuation Form to list multiple senders

SECTION C - Shipment Information

1. Method(s) of Shipment
☐ Commercial Carrier *(e.g., FedEx)*
☐ Hand-carried by *(provide name of person)*:_____
2. Number of Shipments
☐ Single Shipment
☐ Multiple Shipments
i. Estimated # of shipments:____
3. Shipment Temperature(s)
☐ Ambient
☐ Frozen/Refrigerated
4. Anticipated U.S. Port(s) of Entry

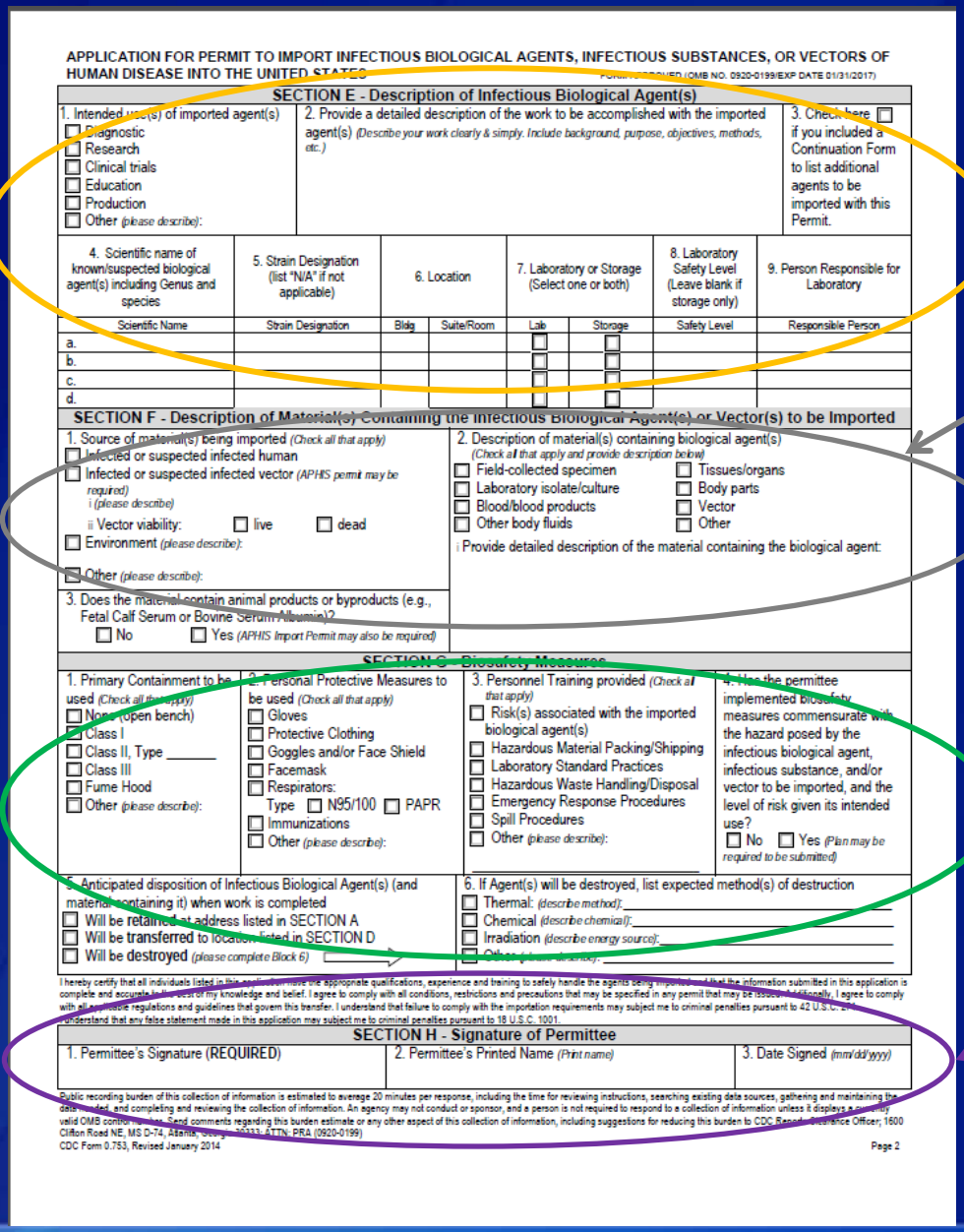
SECTION D - Final Destination of Imported Infectious Biological Agent(s) or Vector(s)

1. Is final destination of biological agent(s) or vector(s) different from address in Section A?
☐ No (skip to Section E) ☐ Yes ⇨
2. Last Name of Recipient at Destination | 3. First Name | 4. MI
5. Destination Organization | 6. Final Destination Address *(NOT a post office box)* | 7. City | 8. State | 9. Zip Code
10. Telephone | 11. Fax | 12. Email | 13. Check here ☐ if you have included a Continuation Form to list multiple final destinations

CDC Form 0.753, Revised January 2014

Page 1

The Import Permit Application cont.



APPLICATION FOR PERMIT TO IMPORT INFECTIOUS BIOLOGICAL AGENTS, INFECTIOUS SUBSTANCES, OR VECTORS OF HUMAN DISEASE INTO THE UNITED STATES

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

SECTION E - Description of Infectious Biological Agent(s)

1. Intended use(s) of imported agent(s)
- ☐ Diagnostic
- ☐ Research
- ☐ Clinical trials
- ☐ Education
- ☐ Production
- ☐ Other *(please describe)*:

2. Provide a detailed description of the work to be accomplished with the imported agent(s) *(Describe your work clearly & simply. Include background, purpose, objectives, methods, etc.)*

3. Check here ☐ if you included a Continuation Form to list additional agents to be imported with this Permit.

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
Scientific Name	Strain Designation	Bldg	Suite/Room	Lab	Storage	Safety Level	Responsible Person
a.				☐	☐		
b.				☐	☐		
c.				☐	☐		
d.				☐	☐		

SECTION F - Description of Material(s) Containing the Infectious Biological Agent(s) or Vector(s) to be Imported

1. Source of material(s) being imported *(Check all that apply)*
- ☐ Infected or suspected infected human
- ☐ Infected or suspected infected vector *(APHIS permit may be required)*
  - i *(please describe)*
  - ii Vector viability: ☐ live ☐ dead
- ☐ Environment *(please describe)*:
- ☐ Other *(please describe)*:

2. Description of material(s) containing biological agent(s) *(Check all that apply and provide description below)*
- ☐ Field-collected specimen
- ☐ Laboratory isolate/culture
- ☐ Blood/blood products
- ☐ Other body fluids
- ☐ Tissues/organs
- ☐ Body parts
- ☐ Vector
- ☐ Other

i Provide detailed description of the material containing the biological agent:

3. Does the material contain animal products or byproducts (e.g., Fetal Calf Serum or Bovine Serum Albumin)?
- ☐ No ☐ Yes *(APHIS Import Permit may also be required)*

SECTION G - Biosafety Measures

1. Primary Containment to be used *(Check all that apply)*
- ☐ None (open bench)
- ☐ Class I
- ☐ Class II, Type _____
- ☐ Class III
- ☐ Fume Hood
- ☐ Other *(please describe)*:

2. Personal Protective Measures to be used *(Check all that apply)*
- ☐ Gloves
- ☐ Protective Clothing
- ☐ Goggles and/or Face Shield
- ☐ Facemask
- ☐ Respirators: Type ☐ N95/100 ☐ PAPR
- ☐ Immunizations
- ☐ Other *(please describe)*:

3. Personnel Training provided *(Check all that apply)*
- ☐ Risk(s) associated with the imported biological agent(s)
- ☐ Hazardous Material Packing/Shipping
- ☐ Laboratory Standard Practices
- ☐ Hazardous Waste Handling/Disposal
- ☐ Emergency Response Procedures
- ☐ Spill Procedures
- ☐ Other *(please describe)*:

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?
- ☐ No ☐ Yes *(Plan may be required to be submitted)*

5. Anticipated disposition of Infectious Biological Agent(s) (and material containing it) when work is completed
- ☐ Will be retained at address listed in SECTION A
- ☐ Will be transferred to location listed in SECTION D
- ☐ Will be destroyed *(please complete Block 6)*

6. If Agent(s) will be destroyed, list expected method(s) of destruction
- ☐ Thermal: *(describe method)*:
- ☐ Chemical *(describe chemical)*:
- ☐ Irradiation *(describe energy source)*:
- ☐ Other *(please describe)*:

I hereby certify that all individuals listed in this application have the appropriate qualifications, experience and training to safely handle the agents being imported, that the information submitted in this application is complete and accurate to the best of my knowledge and belief. I agree to comply with all conditions, restrictions and precautions that may be specified in any permit that may be issued. Additionally, I agree to comply with all applicable regulations and guidelines that govern this transfer. I understand that failure to comply with the importation requirements may subject me to criminal penalties pursuant to 42 U.S.C. 264. I understand that any false statement made in this application may subject me to criminal penalties pursuant to 18 U.S.C. 1001.

SECTION H - Signature of Permittee

1. Permittee's Signature (REQUIRED)	2. Permittee's Printed Name *(Print name)*	3. Date Signed *(mm/dd/yyyy)*

Public recording burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0199)

CDC Form 0.753, Revised January 2014

Page 2

Page 2: Four sections

Section E: Agent Description

Section F: Specimen type

Section G: Biosafety measures

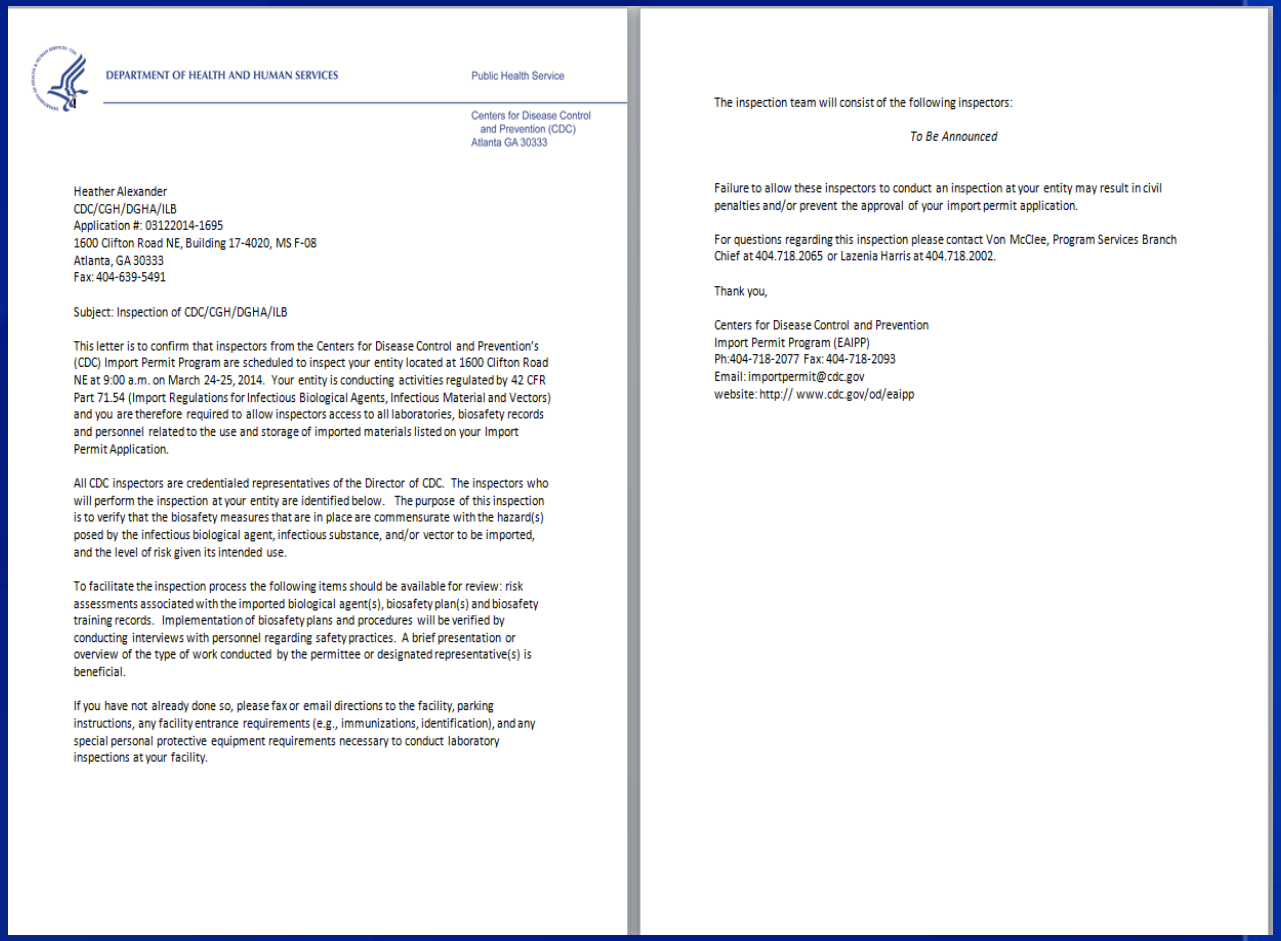
Section H: Signature

The Import Permit Inspection Process:

The Inspection Notification

Upon review of the application for import permit, the CDC Import Permit Program will contact your facility if an inspection is needed.

The notification will be by telephone and then followed up by an official "Notice of Inspection" letter.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

Heather Alexander
CDC/CGH/DGHA/ILB
Application #: 03122014-1695
1600 Clifton Road NE, Building 17-4020, MS F-08
Atlanta, GA 30333
Fax: 404-639-5491

Subject: Inspection of CDC/CGH/DGHA/ILB

This letter is to confirm that inspectors from the Centers for Disease Control and Prevention's (CDC) Import Permit Program are scheduled to inspect your entity located at 1600 Clifton Road NE at 9:00 a.m. on March 24-25, 2014. Your entity is conducting activities regulated by 42 CFR Part 71.54 (Import Regulations for Infectious Biological Agents, Infectious Material and Vectors) and you are therefore required to allow inspectors access to all laboratories, biosafety records and personnel related to the use and storage of imported materials listed on your Import Permit Application.

All CDC inspectors are credentialed representatives of the Director of CDC. The inspectors who will perform the inspection at your entity are identified below. The purpose of this inspection is to verify that the biosafety measures that are in place are commensurate with the hazard(s) posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use.

To facilitate the inspection process the following items should be available for review: risk assessments associated with the imported biological agent(s), biosafety plan(s) and biosafety training records. Implementation of biosafety plans and procedures will be verified by conducting interviews with personnel regarding safety practices. A brief presentation or overview of the type of work conducted by the permittee or designated representative(s) is beneficial.

If you have not already done so, please fax or email directions to the facility, parking instructions, any facility entrance requirements (e.g., immunizations, identification), and any special personal protective equipment requirements necessary to conduct laboratory inspections at your facility.

The inspection team will consist of the following inspectors:

To Be Announced

Failure to allow these inspectors to conduct an inspection at your entity may result in civil penalties and/or prevent the approval of your import permit application.

For questions regarding this inspection please contact Von McClee, Program Services Branch Chief at 404.718.2065 or Lazenia Harris at 404.718.2002.

Thank you,

Centers for Disease Control and Prevention
Import Permit Program (EAIPP)
Ph:404-718-2077 Fax: 404-718-2093
Email: importpermit@cdc.gov
website: http:// www.cdc.gov/od/eaipp

Day of the Inspection

- Reserve a comfortable conference room for the day
- Generally starts @9:00AM
- Expect 2 to 3 inspectors
- Include Lab supervisory personnel at inspection for questions
- Have Lab biosafety available for additional assistance/review
- Building facility personnel may be needed to answer facility questions
- Depending on laboratory size, biosafety level, questions/concerns, documentation reviews, HVAC/facility issues -- inspection will generally take about 1 day to complete.
- Out briefing

Documentation…

BIOSAFETY PLAN

CENTER FOR GLOBAL HEALTH

DIVISION OF GLOBAL HIV/AIDS

INTERNATIONAL LABORATORY BRANCH

TB/OI

ROYBAL CAMPUS

BUILDING 17

ROOMS 4083, 4095, 4097,4129, 4130

Branch Chief:

John Nkengasong,

CERTIFICATE OF IMMUNIZATION

Name: Date of Birth: / / Sex: M F

Please indicate vaccine type (e.g., DTaP-Hib, etc.)

Vaccine		Date	Vaccine Type
Hepatitis B (e.g., HepB, HepB-Hib, DTaP-HepB-IPV, HepA-HepB)	1		
	2		
	3		
	4		
Diphtheria, Tetanus, Pertussis (e.g., DTP, DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, DTaP-IPV/Hib, DTaP-IPV, Td, Tdap)	1		
	2		
	3		
	4		
	5		
	6		
	7		
***Haemophilus influenzae* type b** (e.g., Hib, HepB-Hib, DTaP-Hib, DTaP-IPV/Hib)	1		
	2		
	3		
	4		
Polio (e.g., IPV, DTaP-HepB-IPV, DTaP-IPV/Hib, DTaP-IPV)	1		
	2		
	3		
	4		
	5		
Pneumococcal Conjugate (e.g., PCV7, PCV13)	1		
	2		
	3		
	4		

Vaccine		Date	Vaccine Type
Rotavirus (e.g., RV5: 3-dose series, RV1: 2-dose series)	1		
	2		
	3		
Measles, Mumps, Rubella (e.g., MMR, MMRV)	1		
	2		
Varicella (e.g., Var, MMRV)	1		
	2		
Meningococcal Conjugate (MCV4) or Polysaccharide (MPSV4)	1		
	2		
Seasonal Influenza Inactivated (intramuscular) or Live (intranasal)	1		
	2		
	3		
	4		
H1N1 Influenza Inactivated (intramuscular) or Live (intranasal)	1		
	2		
Pneumococcal Polysaccharide (PPSV23)	1		
	2		
Hepatitis A (e.g., HepA, HepA-HepB)	1		
	2		
Human Papillomavirus (e.g., HPV quadrivalent, HPV bivalent)	1		
	2		
	3		
Other:			

Serologic Proof of Immunity		Check One	
Test (if done)	Date of Test	Positive	Negative
Measles	/ /		
Mumps	/ /		
Rubella	/ /		
Varicella*	/ /		
Hepatitis B	/ /		

* Must also check Chickenpox History box.

Chickenpox History

☐ Check the box if this person has a physician-certified reliable history of chickenpox.

Reliable history may be based on:

- physician interpretation of parent/guardian description of chickenpox
- physical diagnosis of chickenpox, or
- serologic proof of immunity

I certify that this immunization information was transferred from the above-named individual's medical records.

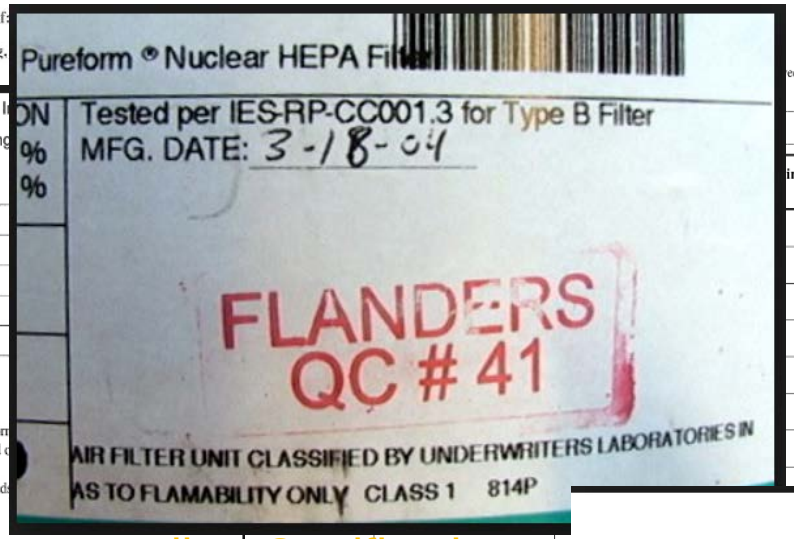
Doctor or nurse's name *(please print)*: Date: / /

Signature:

Facility name:

Certificate of Immunization — Massachusetts Department of Public Health 4-10

Medical



HEPA Filter Certification Re

Bloodborne Pathogen and Other I

Record of Training

Please Print

Name: _____

Department & Division: _____

Job Title: _____

Training Date: _____

Length of Training: _____

Instructor(s) & Job Title: _____

I was informed about:

- the Bloodborne Pathogen Standard;
- the epidemiology and symptoms of bloodborn
- the mode of transmission of bloodborne and c
- the Hospital's exposure control plan;
- a review of the use and limitations of method
  reduce exposure, including
  - engineering controls;
  - work practice controls, and
  - personal protective equipment;
- selection and use of personal protective equipment including gloves, gowns and eye protection;
- visual warning of biohazards including labels, signs and color-coded containers;
- information on Hepatitis B Vaccine;
- the procedure to follow if an exposure incident occurs;
- sharps disposal;
- handwashing;
- proper work practices.

This is to certify that the employee named above has completed the above training.

Employee's Signature Date

Supervisor's Signature Date

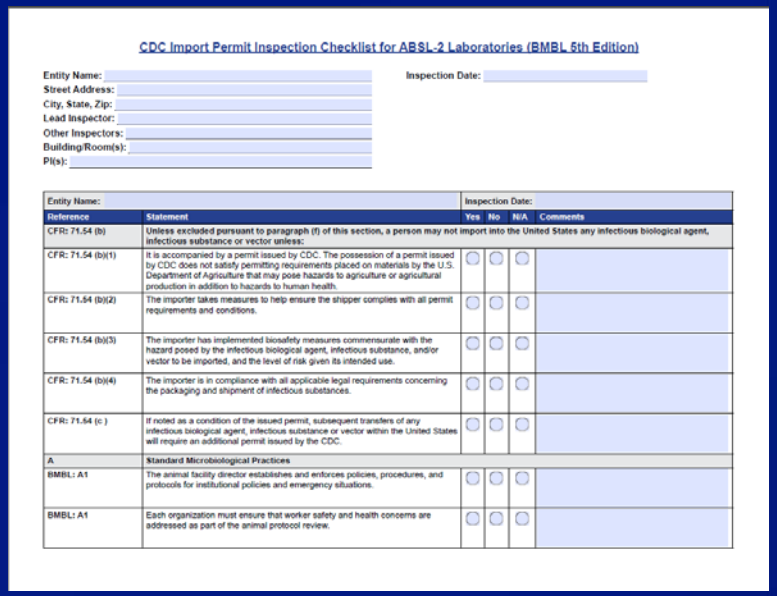
Keep this record for at least three years. Store in Department Office with other training records. This record must be made available upon request by County, Hospital or Environmental Health and Safety Inspectors.

Questions: Call the Biosafety Officer.

Training Recor

Pest management documentation

Guidance for biosafety issues for CDC Laboratories is found in the BMBL
http://www.cdc.gov/biosafety/publications/bmbl5/



CDC Import Permit Inspection Checklist for ABSL-2 Laboratories (BMBL 5th Edition)

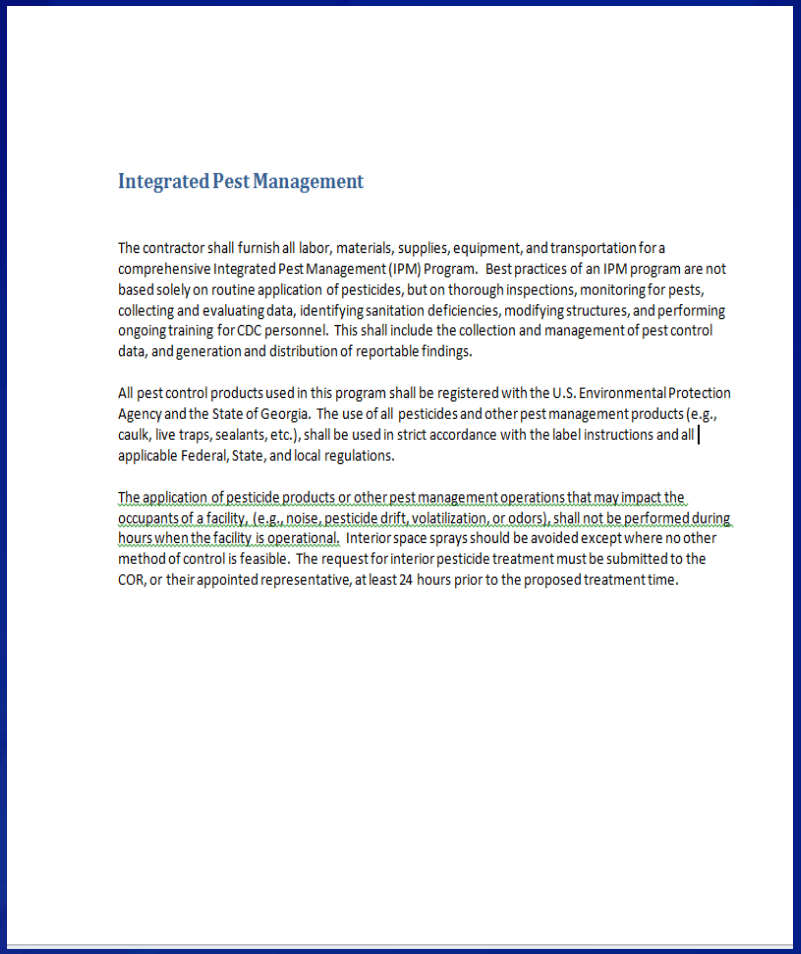
Entity Name:
Street Address:
City, State, Zip:
Lead Inspector:
Other Inspectors:
Building/Room(s):
PI(s):
Inspection Date:

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
CFR: 71.54 (b)	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:				
CFR: 71.54 (b)(1)	It is accompanied by a permit issued by CDC. The possession of a permit issued by CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.	☐	☐	☐	
CFR: 71.54 (b)(2)	The importer takes measures to help ensure the shipper complies with all permit requirements and conditions.	☐	☐	☐	
CFR: 71.54 (b)(3)	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.	☐	☐	☐	
CFR: 71.54 (b)(4)	The importer is in compliance with all applicable legal requirements concerning the packaging and shipment of infectious substances.	☐	☐	☐	
CFR: 71.54 (c)	If noted as a condition of the issued permit, subsequent transfers of any infectious biological agent, infectious substance or vector within the United States will require an additional permit issued by the CDC.	☐	☐	☐	
A	Standard Microbiological Practices				
BMBL: A1	The animal facility director establishes and enforces policies, procedures, and protocols for institutional policies and emergency situations.	☐	☐	☐	
BMBL: A1	Each organization must ensure that worker safety and health concerns are addressed as part of the animal protocol review.	☐	☐	☐	

Checklists for inspections can be found here:
http://www.cdc.gov/od/eaipp/inspection/index.htm

Biosafety Level 3
A. Standard Microbiological Practices, page 40.

10. An effective integrated pest management program is required. (See Appendix G.)



Integrated Pest Management

The contractor shall furnish all labor, materials, supplies, equipment, and transportation for a comprehensive Integrated Pest Management (IPM) Program. Best practices of an IPM program are not based solely on routine application of pesticides, but on thorough inspections, monitoring for pests, collecting and evaluating data, identifying sanitation deficiencies, modifying structures, and performing ongoing training for CDC personnel. This shall include the collection and management of pest control data, and generation and distribution of reportable findings.

All pest control products used in this program shall be registered with the U.S. Environmental Protection Agency and the State of Georgia. The use of all pesticides and other pest management products (e.g., caulk, live traps, sealants, etc.), shall be used in strict accordance with the label instructions and all applicable Federal, State, and local regulations.

The application of pesticide products or other pest management operations that may impact the occupants of a facility, (e.g., noise, pesticide drift, volatilization, or odors), shall not be performed during hours when the facility is operational. Interior space sprays should be avoided except where no other method of control is feasible. The request for interior pesticide treatment must be submitted to the COR, or their appointed representative, at least 24 hours prior to the proposed treatment time.

Document provided by CDC Facilities Management Office

The Laboratory Facility Review:

Facilities i.e.,

- Biosafety Level of importing laboratory
- Laboratory floorplan
- Laboratory walkthrough for entry/exit SOP
- Operating Hands-free sinks with soap and towels
- Eyewash and emergency shower checks and documentation
- Laboratory airhandling and HEPA Filter housings
- Directional airflow verification from outside the lab
- HEPA filtration certification (BSC and HVAC)

Findings and Out briefing:

Generally, during inspection you will have opportunity to do "on the spot corrections"

If findings make their way to report, do not argue with inspectors, but try to clarify the finding and what inspectors have observed

Inspection Do's and Don'ts:

Do

- Tell the truth
- Be honest and open to questions
- Answer only questions that are asked
- If you don't know – say so
- Answer "Yes" or "No" – don't continue to talk if not necessary
- Try to fix problems during the inspection whenever possible
- Ask the inspector to repeat questions for clarification

Do not

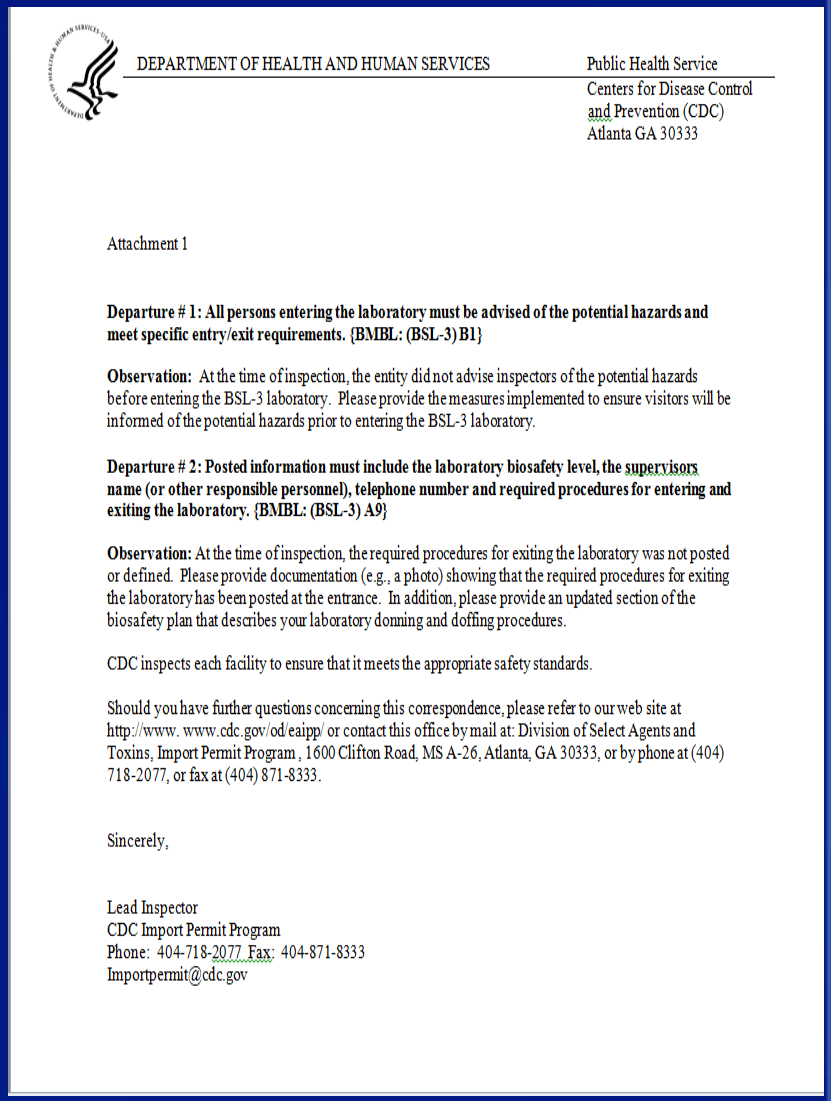
- Don't argue
- Don't speculate, guess, or make stuff up
- Don't keep talking – just answer the question – don't even explain it unless asked
- Don't take anything personally
- Don't lie
- Don't panic
- Don't cry! "There is no crying in audits."

Inspection report:

Inspection report to lab within 2 weeks – findings listed on attachment

Lists deficiencies viewed by inspectors as "departures"

Expect "departures" (…but try to make sure they aren't "big ones")



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

Attachment 1

Departure # 1: All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements. {BMBL: (BSL-3) B1}

Observation: At the time of inspection, the entity did not advise inspectors of the potential hazards before entering the BSL-3 laboratory. Please provide the measures implemented to ensure visitors will be informed of the potential hazards prior to entering the BSL-3 laboratory.

Departure # 2: Posted information must include the laboratory biosafety level, the supervisors name (or other responsible personnel), telephone number and required procedures for entering and exiting the laboratory. {BMBL: (BSL-3) A9}

Observation: At the time of inspection, the required procedures for exiting the laboratory was not posted or defined. Please provide documentation (e.g., a photo) showing that the required procedures for exiting the laboratory has been posted at the entrance. In addition, please provide an updated section of the biosafety plan that describes your laboratory donning and doffing procedures.

CDC inspects each facility to ensure that it meets the appropriate safety standards.

Should you have further questions concerning this correspondence, please refer to our web site at http://www. www.cdc.gov/od/eaipp/ or contact this office by mail at: Division of Select Agents and Toxins, Import Permit Program , 1600 Clifton Road, MS A-26, Atlanta, GA 30333, or by phone at (404) 718-2077, or fax at (404) 871-8333.

Sincerely,

Lead Inspector
CDC Import Permit Program
Phone: 404-718-2077 Fax: 404-871-8333
Importpermit@cdc.gov

Laboratory Response to Inspection Findings:

Respond simply and with appropriate documentation

May include photographic documentation

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

Attachment 1

Departure # 1: All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements. {BMBL: (BSL-3) B1}

Observation: At the time of inspection, the entity did not advise inspectors of the potential hazards before entering the BSL-3 laboratory. Please provide the measures implemented to ensure visitors will be informed of the potential hazards prior to entering the BSL-3 laboratory.

The following document addresses informing visitors of hazards prior to entering the laboratory

ILB100P14 section 6.1.4

This a revision of a Branch standard operating procedure (SOP) document. All SOPs are reviewed by all by all Branch staff annually and upon revision.

Departure # 2: Posted information must include the laboratory biosafety level, the supervisors name (or other responsible personnel), telephone number and required procedures for entering and exiting the laboratory. {BMBL: (BSL-3) A9}

Observation: At the time of inspection, the required procedures for exiting the laboratory was not posted or defined. Please provide documentation (e.g., a photo) showing that the required procedures for exiting the laboratory has been posted at the entrance. In addition, please provide an updated section of the biosafety plan that describes your laboratory donning and doffing procedures.

The following attached revised section of the biosafety plan and job aid address departure #2 for donning and doffing PPE.

ILB120G036A Donning and Doffing PPE job aid
ILB Biosafety Plan _Donning and Doffing PPE

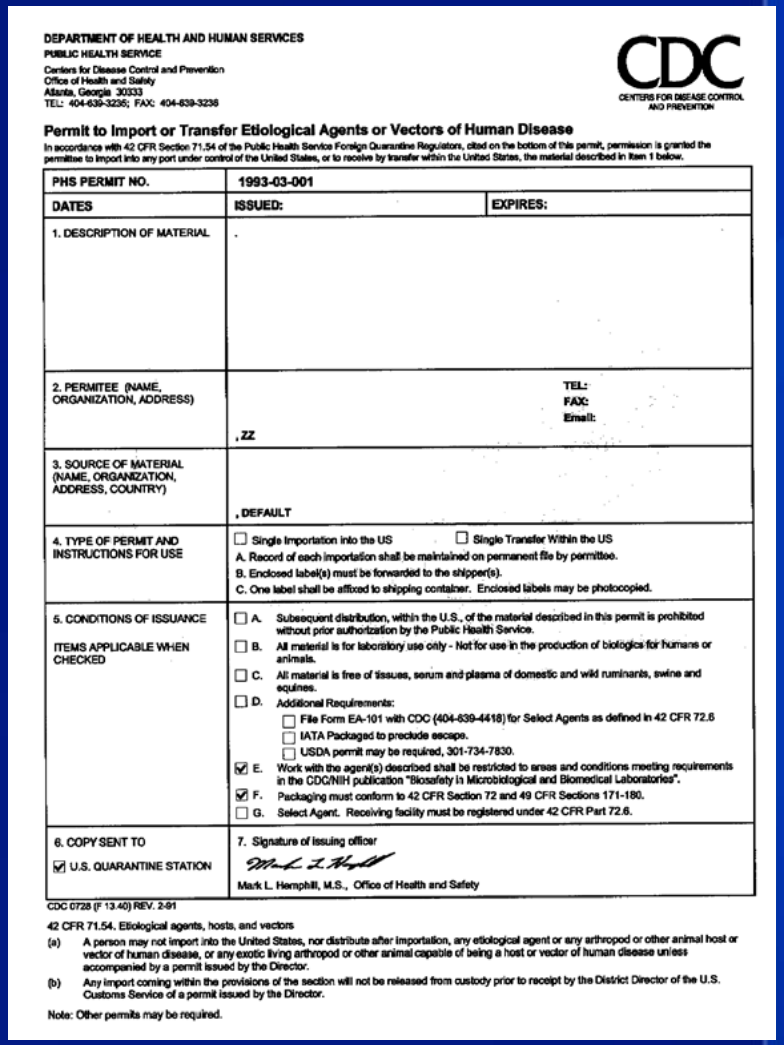
The attached 3 photographs provide documentation that the procedures for exiting the laboratory now are posted in the BSL3 changing room.

CDC inspects each facility to ensure that it meets the appropriate safety standards.

Should you have further questions concerning this correspondence, please refer to our web site at

The Import Permit

- Should receive an Import Permit within 2 to 3 weeks of inspection if responses are deemed "Adequate".
- A permit to import is valid only for the time period indicated on the issued permit
- Requests to renewal an existing import permit requires a new application and signature of the permittee. To prevent lapses in the import permit status, it is recommended that permit renewal applications are submitted at least 60 days prior to the expiration date on the current permit.
- The issuance of an import permit <u>is not an authorization to hand carry</u> the imported material into the United States.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Centers for Disease Control and Prevention
Office of Health and Safety
Atlanta, Georgia 30333
TEL: 404-639-3235; FAX: 404-639-3236

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Permit to Import or Transfer Etiological Agents or Vectors of Human Disease

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulators, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in Item 1 below.

PHS PERMIT NO.	1993-03-001	
DATES	ISSUED:	EXPIRES:
1. DESCRIPTION OF MATERIAL	.	
2. PERMITEE (NAME, ORGANIZATION, ADDRESS)	, ZZ	TEL: FAX: Email:
3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)	, DEFAULT	
4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE	☐ Single Importation into the US ☐ Single Transfer Within the US A. Record of each importation shall be maintained on permanent file by permittee. B. Enclosed label(s) must be forwarded to the shipper(s). C. One label shall be affixed to shipping container. Enclosed labels may be photocopied.	
5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED	☐ A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service. ☐ B. All material is for laboratory use only - Not for use in the production of biologics for humans or animals. ☐ C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines. ☐ D. Additional Requirements: ☐ File Form EA-101 with CDC (404-639-4418) for Select Agents as defined in 42 CFR 72.6 ☐ IATA Packaged to preclude escape. ☐ USDA permit may be required, 301-734-7830. ☑ E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories". ☑ F. Packaging must conform to 42 CFR Section 72 and 49 CFR Sections 171-180. ☐ G. Select Agent. Receiving facility must be registered under 42 CFR Part 72.6.	
6. COPY SENT TO ☑ U.S. QUARANTINE STATION	7. Signature of issuing officer Mark L. Hemphill, M.S., Office of Health and Safety	

CDC 0728 (F 13.40) REV. 2-91

42 CFR 71.54. Etiological agents, hosts, and vectors

(a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of the section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

Note: Other permits may be required.

Emory University's Import Inspection Permit Experience

Import permit required to obtain clinical *Mycobacterium tuberculosis* isolates from S. Africa

- CDC Import permit office communicated the inspection date and sent a checklist to Emory (Annual internal inspection is conducted and all lab SOPs are reviewed to update changes)
- Preparing for the inspection was not an additional burden

Day of inspection :

- Inspectors reviewed all documents
- Interviewed key personnel
- Walked through the labs

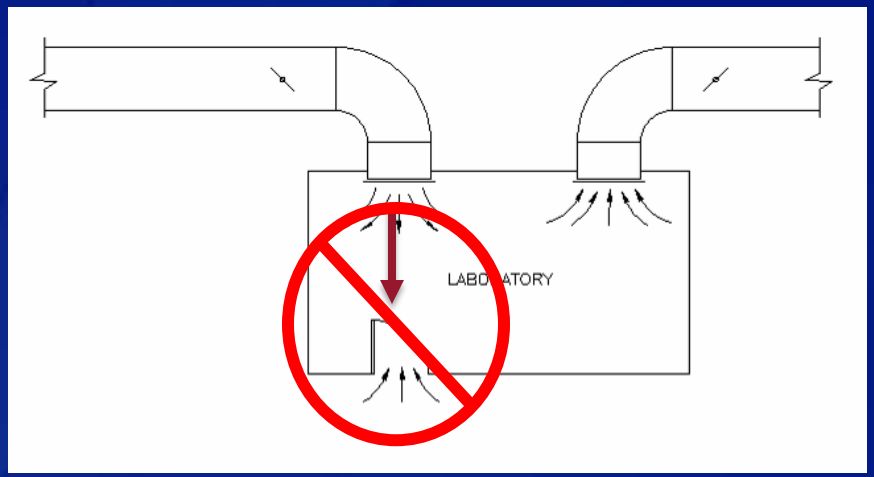
Outcome:

Verification test results of BSL-3 HVAC system were not available at the time of the inspection to confirm the ability of the HVAC system to prevent the reversal of air flow under failure conditions from potentially contaminated BSL-3 laboratory space into non-containment areas. After receiving the Inspection Report, the HVAC verification document was submitted to IPP and Emory subsequently received the import permit.

BSL-3/ABSL-3 HVAC and Facility Verification

DSAT Policy Statement on BSL-3/ABSL-3 HVAC and Facility Verification is provided to each requesting permittee, and can be found at:

http://www.cdc.gov/od/eaipp/docs/policy_import_bsl3_absl3_verification.pdf



Common Issues Identified during Import Permit Inspections

- Inadequate biosafety plans
- BSL-3 laboratories lacking hands-free sinks
- Laboratory personnel not trained
- Infectious materials placed in non-leak-proof cardboard boxes for transport
- Improper decontamination procedures
- Lack of use of centrifuge safety cups during centrifugation

Common Issues Identified during Import Permit Inspections cont.

- Inoperable indicators for HVAC system failure
- Observations of staff wearing gloves outside laboratory
- Unsealed penetrations and cracks observed in containment envelope of BSL-3 laboratories
- Lack of maintenance of HVAC system
- Laboratory doors propped open

Acknowledgements

Kalpana Rengarajan, PHD, RBP, Emory University
Heather Alexander, CDC ILB
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Carole Moore, CDC ILB
CDC Environment Safety and Health Compliance Office (ESHCO)
CDC Facilities Team
Bill Howard
Ken Walpole
CDC Import Permit Program inspectors
Von McClee, CDC Import Permit Program
Lois Diem, CDC Division of TB Elimination

Thank you

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: http://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.