USDA APHIS VS and PPQ Permit Requirements
(Animal pathogens/materials, plant pathogens/materials, soil, other)

USDA APHIS PPQ Inspection Checklist

Overview of USDA APHIS PPQ 526 Permit Inspection

- Inspection Comments
- Facility Features
- List Permit Numbers, Organisms, Permittees and Expiration Date of permits for this facility
- Scientific and common names of plants and organisms in the facility that are not listed in PPQ-issued permits
- Is the facility recognized as a secure structure?
- Identify any agricultural zones, environmentally sensitive areas, high risk microclimates (known food zones) and other high-risk areas nearby

YES NO Don't Know Questions

- Are walls, ceilings and floors of the facility constructed to form a SEALED INTERNAL SHELL that is impenetrable to the contained organisms but can withstand repeated cleaning?
- Windows – are they impenetrable to the enclosed organisms?
- Doors – are exterior doors designed to secure the facility from unauthorized entry as well as escape of contained organisms?
- Vestibules – is there a vestibule present that is at least 8 feet long? (Describe any other vestibule safeguards designed to prevent the escape of contained organisms.)
- Heating, Ventilation and Air-Conditioning (HVAC) – Is the HVAC system designed to prevent escape of contained organisms through air movement? (this is applicable only when the organism is aerially dispersed)
- Benches, tables, furniture – are these items easy to inspect and clean?
- Specialized equipment – does the facility have a laminar flow hood eith HEPA filters or a Biosafety Cabinet?
    - What type of biosafety cabinet?
    - When was the equipment last inspected or certified?
- Sterilization – Does the facility contain sterilization or decontamination equipment sufficient to kill the organisms to be contained?
- Electrical – Does the electrical system maintain containment features under normal and emergency situations and is it sufficiently sealed to prevent the escape of any contained organism?
- Communication system – Does the facility have a communication system to enable verbal communication between inside and outside the facility to reduce the frequency of personnel and equipment entering and leaving the facility?

- Plumbing system – Is the plumbing system designed to prevent the escape of contained organisms?
- Containment officer or director – Does the containment officer maintain a copy of the Standard Operating Procedures (SOP) Manual for the facility and train employees in the SOPs?
    - Provide a copy of the SOPs with this inventory if required
- Authorized personnel – Is access to the facility restricted to authorized personnel to guarantee security of the facility?
    - What procedures are used for visitors?
- Inspection of apparel = How do employees and visitors handle personal apparel to minimize the risk of organism escape within the facility?
- Personal cleanliness – Do employees and visitors inspect clothing, shoes, and hair before leaving the containment area to minimize the risk of accidentally carrying organisms from the facility?
- Surface Decontamination – Do employees use effective procedures to decontaminate and disinfect all equipment and materials used in the facility?
- Incoming shipments – Is there an established area to open packages received from foreign sources?
    - Do employees autoclave or incinerate packing materials immediately after the removal of specimens?
    - Are propagules stored in appropriate containers to prevent their escape within the facility?
- PPQ Regulatory Requirements – Do employees understand and follow the requirements listed in the conditions of permits for organisms kept in the facility?

ESSENTIAL PERMIT REQUIREMENTS

FOR PERMIT HOLDERS

1. **Comply with all requirements and permit conditions.**

2. **Maintain a valid permit as long as the regulated materials are alive (present in your lab).**

3. **This permit cannot be assigned or transferred to others**

4. **The Permittee must maintain a residence in the U.S.**

5. **Safeguard and dispose of the regulated organisms during the term of this permit**

6. **Take all necessary precautions to prevent the unauthorized release of regulated organisms**

7. **Contain any/all organisms not authorized under this permit**

8. **Notify the permit unit of the receipt of unauthorized organisms**

9. **Notify the permit unit if facilities are destroyed or decommissioned for any reason**

10. **Maintain an official permanent work assignment at the address on the permit**

11. **Notify the permit unit in advance of any change in the permit holder's work assignment**

12. **Destroy all regulated organisms prior to departure unless other arrangements are confirmed with the USDA permit unit (and USDA approved in writing) prior to the permit holder's departure**

13. **Notify the permit unit of the destruction of regulated organisms**

USDA Permit Requirements for ALL PERMITS

YES / NO	Permit Requirements
	Approval is only for the locations listed on the permit. Permitted materials may not be moved to a new location that is not on the permit until a permit is updated to include that location.
	Permit Holder must initial all permit conditions and sign the permit to complete the permit approval
	ALL who use permitted materials must document that they have read the permit and understand the permit conditions. • All persons with access to the containment facility must be listed on the SOP • These users can also sign or initial the permit conditions to show that they have read them • The record of the signed permit conditions must remain readily available in the lab and presented during inspections (an electronic record can be created) • This must be done at least annually as part of their training on the permit conditions Training for the PI and lab staff is documented annually to review permit conditions.
	Make sure that ALL Use, Storage, and Autoclave room locations are on the permit. MATERIAL MAY NOT BE MOVED FROM AN AUTHORIZED LABORATORY Includes back-up autoclave locations (back-up autoclave is also tested quarterly) No permitted materials may leave the facility unless autoclaved
	Permits are not transferable and issued only to the person at the facility located at the address identified on the permit.
	The Permit does not authorize importation, interstate movement, or release into the environment of permitted materials. genetically engineered viruses (BRS will handle these)
	The USDA Permitted facility must have: • Doors, door sign (USDA Permitted facility) • Restricted access (physical security/key card access) • Lockable storage (freezers, cabinets, cryo-tanks, incubators) • Windows (with 30 mesh pest control screens if they open) • Walls suitable, solid, easy to decontaminate • Monolithic lab flooring (easily cleanable) • Work benches can be decontaminated • Written SOPs present in the lab, read and signed by all authorized users • SOPs must meet USDA SOP Guidelines • Personal Protective Equipment present and adequate for the work • Signed/completed USDA permits
	A Biosafety Cabinet is used to open and inspect all shipments of microorganisms (all permitted packages received)

	• The Biosafety Cabinet is tested, serviced and certified annually
	All packages must be opened in a laminar flow Class II Type A Biosafety Cabinet (Or a biosafety cabinet that meets or exceeds Class II Type A)
	Upon receipt of permitted material, all packaging material, media, substrate, shipping containers shall be sterilized or destroyed immediately after removing regulated materials
	If you discover the organisms you receive are not authorized by the permit, contain the materials and notify the USDA Permit Unit and request to speak to a compliance officer
	No work with lab or domestic animals (poultry, cattle, sheep, swine, horses, etc.) are allowed on standard permits. Work shall be limited to in vitro work (unless otherwise specified)
	Must notify the USDA within 48 hours of failure to receive a shipment of materials
	All permitted materials will be kept locked while in storage (e.g. freezer, cabinet, refrigeration), with access limited to authorized personnel – or – they will be in a restricted building that requires keycard entry and access is restricted to authorized personnel only; or will be in a locked room with access restricted to authorized personnel only.
	Regulated material will be imported in a securely closed, watertight container (primary container, test tube, vial, etc.), which shall be enclosed in a second durable watertight container (secondary container). Several primary containers can be in a s single secondary container. Space inside the secondary container (above, sides, and bottom) are filled with a non-particulate absorbent sufficient to absorb the entire contents of the container in the event of a spill or breakage. Sets of primary and secondary containers can be placed in an outer shipping box.
	Autoclaving Waste • Must be 121 C for 30 minutes (minimum) • Autoclave tape or other indicators must be placed on each bag or container prior to treatment • Tape or indicator must be checked to verify color change after each run prior to disposal • An autoclave log must be completed by each user for each autoclave cycle with all parameters noted as listed on the log for each autoclave load • The autoclave log must include the: Date, Person, Autoclave tape on outside of all containers, # of containers or bags, Temperature reached during the run (121 C), Time (30 min), Whether the color indicator changed
	Note on the Autoclave Log: • If the autoclave does not attain the minimum time and temperature (or) the autoclave tape does not change color, a notation must be made in the comment section of the autoclave log. • The load must be re-autoclaved after placing new tape on the material • If it fails again, notify facilities and EHS – and retreat at a different (approved) autoclave

	Thermometers on the autoclave must be calibrated annually, and a written record must be maintained. • This should be done by an authorized autoclave service company during routine servicing.
	Every 3 months, a commercially available biological spore indicator test must be used to verify autoclave performance
	Penalties up to 250,000.00, fines up to 10,000.00, an imprisonment of up to 5 years may be levied for unauthorized use of a permit
	Permits are non-transferable and only issued to the PERSON ON THE PERMIT AT THE FACILITY LOCATED AT THE ADDRESSES IDENTIFIED ON THE PERMIT.
	The Permit Holder is responsible for maintaining a valid permit as long as the regulated organisms are living and in possession by the permit holder (e.g. frozen storage).
	No permit renewals or extensions are allowed • A permit holder must submit a new permit application at least 3 months prior to the expiration of their permit, and obtain a new permit to continue uninterrupted authorization for species approved under their permit.
	Permit holder must maintain an official permanent work assignment at the address identified on the permit. • The permit holder must notify the compliance officer if this changes immediately (within one business day) • Pest.permits@usda.aphis.gov • Fax: 301-734-4300
	Permit holder must destroy all regulated organisms prior to departure • Unless permission is granted by the USDA for other disposition • To cancel a permit – follow the USDA permit specific termination conditions • Obtain approval to transfer the permit to a new location and get a permit to a new location • Transfers the permit to a qualified person, who obtained a permit for these materials before departure of the original permit holder.
	The USDA can inspect at anytime during work hours
	Any modifications to the containment of the organisms must be approved prior to making any changes to an inspected containment facility
	Notify the USDA immediately if permit materials are accidentally released into the environment (includes accidental or intentional release from containment). Failure to report can result in cancelation of the permit. • Phone at 301-734-6343 followed by a written report
	Upon completion of research – all cultures are destroyed by autoclaving. Glassware and other materials used to conduct research must be decontaminated. Material can be soaked in a fresh bleach solution of 10% for at least 30 minutes, in 70% Ethanol, flamed with Ethanol, or treated with Quaternary Ammonium compounds.

Additional Plant Permit Requirements

YES / NO	Requirements
	Vector control must be present within the plant growth chambers (incubators). A yellow sticky card is an example
	The SOP must verify that all imports have a valid USDA PPQ Form 599 Red/White label attached and includes: Permit #, Expiration Date, Label #, and address of a USDA APHIS PPQ Plant Inspection Station
	If researchers are bringing materials from outside the US to the lab, make sure that they have the "HAND CARRY" designation on their permit.
	The USDA APHIS PPQ MUST BE NOTIFIED IF: • A package arrives without a PPQ Form 599 • The address on the airway bill does not match the address on the PPQ Form 599 Red/White Label • The permitted shipment arrives by hand carrying, in personal luggage, or by personal automobile without a hand carry authorization. YOU MUST SEIZE THE SHIPMENT AND FORWARD TO THE NEAREST USDA APHIS PPQ PLANT INSPECTION STATION
	When you receive a shipment • Make sure the permit is valid and not expired • Make sure the permit # matches the permit # on the PPQ Form 599 Red/White label • Confirm that the package is adequate to prevent the escape of the enclosed organisms
	Permit is valid for lab research only and not valid if the organism(s) will be used in field research or released into the environment
	All cultures or soil must be destroyed by autoclaving at the completion of research
	A Greenhouse Manual, site-specific biosafety manual, including SOPs must be present
	Plants allowed to reach a vegetative state must be covered to prevent dispersal of reproductive cells and spores
	Growth chambers used for infected plant material is located at a reasonable distance away from the growth chamber for healthy plants, the insectary or the outside door`
	Pest control methods are available (black lights, yellow sticky boards, insecticides) must be placed inside the growth chamber.
	Vector transmission is NOT permitted under standard permits
	Inoculated plants in a greenhouse are not authorized on standard permits
	Growth chamber effluent is collected in a pan and either autoclaved or decontaminated.

Additional SPECIALIZED Plant Permit Requirements

YES / NO	Requirements
	Plant incubators are allowed using sterile plant material in sealed containers
	Imported stem material must be held in containment and not propagated
	Sinks or lab water that may contain nematode life stages, soil, infested growth media, infected plant materials, must be equipped with traps that allow collection of waste water treatment of this waste water before release to the sewer system.

Additional Soil Permit Requirements

YES / NO	Requirements
	All soil or cultures will be kept locked while in storage (e.g. freezer, cabinet, refrigeration), with access limited to authorized personnel – or – they will be in a restricted building that requires keycard entry and access is restricted to authorized personnel only; or will be in a locked room with access restricted to authorized personnel only.
	No use of soil in growth chambers, greenhouses or in the field
	Sinks or lab water that may contain nematode life stages, soil, infested growth media, infected plant materials, must be equipped with traps that allow collection of waste water treatment of this waste water before release to the sewer system.
	Maintain a log book for receipt of soil shipments (# shipments by year)
	Permit does not authorize the use of soil for growing purposes, for isolation of culture organisms, or for extracting and concentrating organisms from soil
	Further distribution of soil is not allowed without prior approval
	Soil is kept locked while in storage in an approved lab, with access limited to authorized personnel only
	Soil is handled as quarantined material until sterilized. Keep soil enclosed in containers when not in use. Label all containers, storage areas with "Quarantine Soil: Sterilize Before Use" signs
	All packing materials must be sterilized or destroyed after opening
	All unconsumed soil, containers, effluent must be autoclaved/incinerated/sterilized by the permittee at the conclusion of the project.
	Dry heat treatment of soil must be done at the following parameters 230 – 249 F – 16 hours 250 – 309 F – 2 hours 310 – 379 F – 30 minutes 380 – 429 F – 4 minutes 430 – 450 F – 2 minutes
	Equipment used with soil must e decontaminated by: Soak in 10% bleach 30 minutes Soak in 70% Ethanol Flamed with Ethanol Treated with Quarternary Ammonium compounds
	Requirements for all hand-carry events: Notify PPQ Compliance Officer 20 days before each hand-carry event by email BlackWhiteGreenYellow.labelrequest@aphis.usda.gov To provide: Hand carrier's identify Anticipated first port of arrival in US Actual date of arrival in US

	Detailed description of transport method (car – license plate, air – flight #)
	Present PPQ Form 550 Black/White label corresponding to permit at Customs upon entry (Valid hand carry PPQ Form 550 Black/White label)
	Hand carried soil must be transported directly to the containment facility authorized in the permit
	Permit unit must be notified of the arrival of the soil by an independent 3rd party (BSO, Chair, Containment Facility Director), etc. within 24 hours of the first business day via fax (301-734-5392) or email blackwhitegreenyellow@aphis.usda.gov Include with the notification: Permit #, Label #, Date of Arrival, Origin of the soil, Quantity Permit lists people or permit authorized to hand carry – update this