VS Guidance

13401.1

Approval and Oversight of Privately Owned Avian Import Quarantine Facilities in the United States

1. Purpose and Background

This guidance describes the procedures for Animal and Plant Health Inspection Service (APHIS) approval and oversight of privately owned avian quarantine facilities. APHIS regulates the approval of privately owned quarantine facilities for imported animals. These facilities must have adequate safeguards to securely hold, monitor, and test (as applicable) quarantined animals; limit entry and egress to authorized personnel; and prevent the transmission of disease agents into or from the facility.

This guidance applies to privately owned facilities used to quarantine, with exceptions, any commercial import shipment of avian animals (including eggs for hatching). The exceptions are commercial import shipments of ratites, zoo-type avian animals bound for zoos, avian animals intended for research, and eggs for hatching of any of these.

In association with a cooperative service and trust fund agreement, APHIS personnel must inspect and approve a proposed quarantine facility for imported commercial birds or poultry (and eggs for hatching) before its initial use and before each subsequent use to ensure it is in good repair and meets standards. Procedures for completion of a cooperative service and trust fund agreement are further outlined in VSG 5510.1, "Procedures for Processing Cooperative Service and Other Agreements for Privately Owned Quarantine Facilities for Commercial Birds, Poultry and any Avian Eggs for Hatching."

This guidance represents the Agency's position on this topic. It does not create or confer any rights for or on any person and does not bind the U.S. Department of Agriculture (USDA) or the public. The information it contains may be made available to the public. VS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

2. Document Status

- A. Review date: March 31, 2020.
- B. This guidance replaces VSM 591.31, which is rescinded.

3. Reason for Reissuance

This is a new document.

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4. Authority and References

- A. Authorities (Code of Federal Regulations (CFR)):
 - 7 CFR 371.4
 - 9 CFR 71.10
 - 9 CFR 93.100
 - 9 CFR 93.106
 - 9 CFR 93.209
 - 9 CFR 93.210

B References

- VSG 5510.1, "Procedures for Processing Cooperative Service and Other Agreements for Privately Owned Quarantine Facilities for Commercial Birds, Poultry, and any Avian Eggs for Hatching."
- VSG 13403.1; "Cleaning and Disinfecting Avian Quarantine Facilities Following Outbreaks of Communicable Avian Diseases."
- VSG 13410.1, "Disease Testing and Sampling Requirements for Live Poultry and Birds (and Hatching Eggs of Poultry, Birds, and Ratites) During Entry Quarantines."

5. Audience

VS employees, other Federal and State agencies, and members of the public.

6. Guidance

A. Application

Facilities seek APHIS approval as privately owned avian import quarantines through facility owners or operators (or their agents). An applicant seeking approval of an avian import quarantine facility must submit a written application to the National Director, Animal Import Centers (NDAIC).

- 1) The application must include:
 - a. The applicant or facility's full name and mailing address.
 - b. The facility owner's name and address, if different.
 - c. The facility operator's name and address, if different.
 - d. The facility's street address (or other information that identifies the physical location of the facility).
 - e. Blueprints or detailed drawings of the proposed facility.

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- f. A description of the financial resources available for the construction, operation, and maintenance of the facility.
- g. The average and maximum number of avian animals, or eggs for hatching, to be quarantined.
- h. Expected frequency of shipments to the quarantine facility.
- i. Plans for handling, care, and feeding of the avian animals from the port of entry to the quarantine facility.
- j. Plans should also include the typical expected transportation routes and types.
- k. A contingency plan for the necropsy and disposal of avian animals or eggs for hatching held in the facility that may not hatch or die after hatching.

2) Review of application

- a. The NDAIC or designee will review the application, and if complete, will forward it to other personnel in the APHIS Veterinary Services National Import Export Services (NIES) sector, Surveillance, Preparedness, and Response Services (SPRS) sector, or both for additional review and concurrence. The NDAIC or designee, in consultation with other NIES or SPRS personnel, will determine if APHIS has resources available to support the quarantine. If the application is incomplete, APHIS will contact the applicant for further information.
- b. The NDAIC or designee will write to the applicant regarding the application review result. The applicant will receive an estimate of user fees it may incur in the approval process.
- c. If the application is in order, the NDAIC or designee will contact the applicant to schedule an APHIS inspection of the facility. APHIS personnel will inspect the facility using the checklist for facility approval attached to this guidance.
- d. The facility should meet the criteria listed in the following sections and as referenced in the accompanying checklist.

B. Physical Requirements

- 1) The facility site must be within the immediate metropolitan area of the port of entry and at least 1/2 mile from any other locations of avian animals.
- 2) The shipments must be transported from the port of entry so as to mitigate the risk of disseminating disease to domestic poultry. The facility operator will submit a transport plan to the NIES or SPRS personnel who will manage the quarantine for review and approval before the shipment arrives at the port of entry.

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- 3) Construction of avian import quarantine facilities
 - a. The facility must be a single, self-contained building in good repair.
 - b. Floors and ceilings must be of solid construction materials. Surfaces in containment areas should be durable and impervious to fluids.
 - c. All construction materials in contact with avian animals must be able to withstand repeated cleaning and disinfection.
 - d. All openings to the outside must be double-screened. Interior screens may be metal or nylon mesh and must be intact. Exterior screens must be metal mesh and separated from interior screens by at least 3 inches.
 - e. The quarantine containment area must be of sufficient size to prevent overcrowding.
 - f. The water supply to the quarantine containment area must be adequate for cleaning as well as for animal maintenance.
 - g. Wastewater or other liquid wastes must drain to a municipal or septic waste treatment system and may not be discharged untreated to the exterior of the quarantine facility.
 - h. Access to the avian animal/hatching egg containment areas must be from within the building. Containment areas must not be directly connected to any areas exterior to the building, but must have a safety or buffer zone incorporated into any entrances from the exterior to limit the possibility of escape of any quarantined animals. Tamper-proof hasps and hinges on doors in which the pins cannot be removed are required for exterior doors leading into the facility and any other doors leading into bird containment areas.
 - i. The facility must comply with local ordinances for emergency exiting.
 - j. Indoor heating and ventilation systems must be adequate in design and capacity to control the ambient temperature, humidity, and odors at levels that are not injurious to quarantined animals or APHIS personnel.
 - k. Lighting must be adequate for APHIS inspections.
 - I. The feed and bedding storage areas must be kept vermin- and moisture-free.
 - m. Space must be designated as an office for recordkeeping.
 - n. The facility must contain a dedicated necropsy or sample collection area. A separate room must be available with refrigerated storage space for carcasses retained for laboratory examination.

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C. Biosecurity. The facility must have:

- 1) Adequate equipment and supplies to keep the facility clean and sanitary and to control pests.
- 2) A sufficient stock of disinfectant authorized in 9 CFR 71.10 (or otherwise authorized by APHIS) to disinfect the entire facility.
- 3) A separate area for washing equipment.
- 4) At least one unisex shower, for use by one individual at a time, or two walk-through showers, one for men and one for women, with an anteroom on either side of each for clothes storage and changing, at the entrance to the area of the facility involved in quarantine containment and necropsy (the dirty side of the showers). A receptacle to collect clothing worn on the dirty side of the showers must be present in the dirty-side anteroom of each shower. Showers must be kept clean; the facility must have a Standard Operating Procedure to help ensure this. Clean laundry, including towels and coveralls, must be available on the clean side of the showers.
- 5) A water supply to quarantine containment areas adequate for cleaning and animal maintenance. APHIS highly recommends an emergency water supply.
- 6) A way to dispose of quarantine waste that prevents release of pathogens to the environment, such as incineration or other APHIS-approved method. Alternatively, facility staff can bag and store waste on the premises until the end of the quarantine. At such times, with negative test results, facility personnel can dispose of the garbage at the operator's discretion. If the facility includes an incinerator, it must be located in a separate building on the premises. If the incinerator is on a local site away from the quarantine facility, an APHIS representative must oversee all transfer of materials to the incinerator. Such transfers must be made in a biosecure manner to prevent release of pathogens to the environment during transport, in accordance with all applicable local, State, and Federal regulations. Note: APHIS-operated incinerators are not for private use.

D. Security. The facility must:

- 1) Be kept locked at all times when facility personnel are not onsite.
- 2) Display visible Quarantine Area signs indicating that visitors are prohibited.
- 3) Provide APHIS with phone numbers for contact persons, at least one of whom can be reached at any time.
- 4) Use a security system adequate to review or deter unauthorized entry and the escape of quarantined animals. Examples of such systems include fences, guards, and video cameras.

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- 5) Either have a working television-type monitoring system for the containment quarantine areas or a window sufficient to provide a full view of the containment area (except for clothes-changing and showering areas).
- 6) Immediately report any breaks or suspected breaks in security to supervising APHIS personnel. Any quarantined animals that escape from the facility must also be reported immediately.
- 7) Record an initial count of animals entering the quarantine, using actual numbers for small consignments, or listing the inventory numbers on shipping documents for larger consignments (this should only be done when obtaining an actual number may be injurious to animal health). The facility must reconcile the initial count against a final count made under APHIS supervision prior to release of the animals from quarantine. The count should factor in all mortalities occurring during quarantine.

The NDAIC or designee will assign a veterinary medical officer or other APHIS personnel to monitor activities in the facility. APHIS personnel will also be responsible for applying, breaking, and recording of APHIS seals used at all entrances, as further set forth in E.1).

E. APHIS Oversight of Operations

- 1) APHIS representatives will be present for the arrival of the avian animals or hatching eggs at the facility and will seal the facility when entry activities have been completed and all facility personnel have exited. Subsequently, until the shipment has been released, facility personnel will not enter the facility unless APHIS representatives are present to unseal the facility, monitor the activities of the personnel, and, once all personnel have exited, reseal the facility. In addition:
 - a. APHIS representatives will visit the quarantine daily from day 1 through day 16 of the minimum 30-day quarantine period to review security and biosecurity, account for daily deaths, and collect samples, according to VS Guidance 13410.1. Additional visits will occur based on:
 - 1. Operator request.
 - 2. Animal husbandry needs.

APHIS user fees apply for these activities.

- b. Between day 17 and the date of release, APHIS representatives will visit the quarantine at least once every 5 days to review security and biosecurity and inspect the animals. Additional visits will occur based on:
 - 1. Operator request.
 - 2. Animal husbandry needs.

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- c. Any additional access requested by the facility operator must be coordinated with APHIS in advance to ensure appropriate sealing or re-sealing.
- 2) APHIS oversight of personnel (facility personnel and visitors)
 - a. Visitors may not access the quarantine containment area unless APHIS representatives have approved the visit or are present.
 - b. All personnel with access must sign an agreement stipulating that they will follow the terms of the cooperative service agreement (see VS Guidance 5510.2 for further information) and any related instructions from APHIS representatives pertaining to guarantine operations.
 - c. All personnel, except veterinary practitioners providing emergency care, must sign an affidavit before entering the quarantine area stating they will not have contact with any other birds or poultry during the quarantine period and for an additional 3 days afterward. Visitors must adhere to all biosecurity standards in effect at the facility when entering and leaving the facility.
- 3) Sanitary practices. APHIS must ensure that facility personnel carry out the following:
 - a. All equipment used to maintain the quarantine should only be used for this purpose. All equipment within the facility must be cleaned and disinfected before use.
 - b. Vehicles must be cleaned and disinfected before entering or leaving locations within any quarantined area.
 - c. Any area that has held quarantined avian animals or hatching eggs must be cleaned and disinfected after use under the supervision of an APHIS representative before a new lot may enter the area.
 - d. The operator must provide clean protective clothing and footwear for anyone granted access to the facility before entry into the guarantine area.
 - e. The operator is responsible for the proper cleaning and disposal of soiled and contaminated clothing used in the facility.

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- f. Anyone granted access to the quarantine area must:
 - 1. Shower before entering and when leaving the quarantine containment areas.
 - 2. Wear clean protective work clothing and footwear provided by the operator.
 - 3. Wear disposable gloves when handling sick animals.

See VS Guidance 13403.1 for further information.

- 4) Handling of avian animals/hatching eggs in quarantine. APHIS personnel must ensure the facility handles animals and eggs in the following manner:
 - a. Avian animals/hatching eggs quarantined
 - Each shipment must be placed in the facility on an "all-in-all-out" basis.
 APHIS may allow sequential shipments (up to the stipulated holding capacity)
 to enter a quarantine facility, but the quarantine period begins with entry of
 the first shipment and extends until the last shipment has been in the facility
 for at least 30 days and all of the avian animals in the quarantine are eligible
 for release.
 - 2. Shipments of avians that were on the same plan, but destined for different Federal quarantines, must have negative test results before either quarantine has ended. If the shipments belong to different importers, APHIS must make each importer aware of the exposure on the plan and the date the quarantines end, if more than 30 days apart.
 - 3. Avian animals resulting from eggs that have hatched during the quarantine will remain in quarantine for at least 30 days after hatching.
 - 4. The operator must provide sufficient bedding and vermin-free, unspoiled feed.
 - 5. Facility personnel must point out to the APHIS representatives any losses, suspected illness, or deaths of avian animals observed. APHIS representatives will store (or direct facility personnel to store) carcasses in an onsite refrigerator for later removal or disposal if circumstances are such that they cannot be removed from the facility immediately. Eggs that have not hatched at the end of a hatching cycle must be destroyed under APHIS supervision.
 - 6. Avian animals that die en route from the port of arrival to the facility must be refrigerated on arrival and made available to APHIS for examination and determination of cause of mortality.

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- 7. All quarantined avian animals or eggs for hatching will be subjected to tests as deemed necessary by APHIS to determine health or disease status and at the importers' expense.
- 8. Psittacine type birds will receive a medicated feed ration containing minimally 1 percent chlortetracycline (CTC) with no more than 0.7 percent calcium for the entire quarantine period. The APHIS office overseeing the quarantine may waive this requirement.
- 9. APHIS may extend a quarantine period as needed to determine the health status of the animals involved before their release.
- b. Non-poultry avians may be vaccinated during an approved quarantine with an APHIS-approved vaccine and administered by a licensed veterinarian under APHIS supervision. Vaccines to prevent Newcastle disease or avian influenza cannot be used unless specifically authorized by APHIS in writing.

F. Facility Recordkeeping

- 1) The facility operator must keep a daily log of personnel entering and exiting the facility.
 - a. For psittacine birds: Within 7 days of entry into the quarantine, the facility must identify birds using a leg band (or another approved identification system) coded to the date and location of the quarantine facility.
 - b. The facility operator must keep all records related to the quarantine for at least 12 months after the release of the animals. The APHIS office overseeing the quarantine may waive this requirement.
 - 1. The facility operator must make these records available to APHIS on request.
 - The facility must maintain a daily log as approved by an APHIS
 representative. The facility operator must use the log to account for any
 mortalities, hatchings, or other quarantine events. The operator must also list
 all laboratory specimens removed from the facility.

G. APHIS' Granting or Denial of Approval

- 1) APHIS will determine whether to approve or deny approval for a facility after inspecting the facility, using the attached checklist.
 - a. If the facility meets the criteria in this guidance for APHIS approval, the NIES Associate Deputy Administrator or designee must sign the cooperative service agreement (see VS Guidance 5510.2) before the facility can be used. The original signed agreement should remain with the NDAIC (or designate), with copies sent to the operator.

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- b. If the criteria for approval in this guidance are not met, APHIS will deny approval.
 - 1. APHIS will write to the operators regarding any violations or other compliance issues noted during the inspection that would bar approval.
 - 2. APHIS will give the operator a written timeframe to correct any violations or compliance issues and receive APHIS approval.
 - 3. APHIS will re-inspect the facility at the end of the allotted period. If the facility has not corrected the violations or compliance issues to the satisfaction of the APHIS inspector or if the facility continues to fail to meet approval criteria, the facility will not be approved for use as a guarantine facility.
- 2) Suspension or revocation of APHIS approval
 - a. APHIS may suspend a facility's approval if either of the following occurs:
 - 1. The facility is found not in compliance with the regulations or this guidance.
 - 2. The facility fails to prevent, contain, or eliminate an outbreak of a communicable avian disease.
 - b. APHIS will specify a time period for the operator to correct the deficiency or deficiencies that lead to the suspension. If the operator does not take sufficient remedial action by the end of the time period, APHIS will change the suspension to a revocation.
 - APHIS should coordinate suspension or revocation of approval for existing facilities through a discussion led by the NDAIC (or designate) and other APHIS personnel.
 - d. Any APHIS suspension or revocation of facility approval must be documented in writing and come from the NDAIC (or designate) to the operator of the facility.
 - e. APHIS will oversee operations at any facility that loses approval. The operator will incur all additional costs, including the costs of any extension of quarantine length resulting from the revocation, if applicable.
- 3) Before APHIS suspends or withdraws facility approval, the NDAIC (or designate) will write to or tell the operator (followed by a written communication) of the reasons for the proposed action. If the operator disagrees with the proposed action, he or she can write to request a hearing to contest the matter.

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- 4) APHIS may withdraw approval of an existing facility at any time before a final determination in a hearing if APHIS determines such action is necessary to protect animal health or the public health, interest, or safety. This withdrawal will continue in effect pending completion of the hearing and any judicial review, unless APHIS orders otherwise.
- 5) In addition to withdrawing approval for the reasons provided in this section, APHIS will also automatically withdraw approval when the operator of any approved facility notifies the NDAIC (or designate) in writing that the facility is no longer in operation.
- 6) APHIS can arrange to provide alternative quarantine services for a shipment of commercial birds, poultry, or hatching eggs, if the facility's operator is negligent. In such cases, APHIS may dispose of a shipment or take other measures to recoup APHIS expenses. The operator can request in writing from APHIS a copy of an inspection report that determined any negligence.

H. Re-Inspections

- A. A privately owned avian import quarantine facility must undergo a separate APHIS inspection and re-approval for each shipment of avian commodities, or after any outbreak of disease at the facility, to document:
 - a. Adequate cleaning and disinfection between shipments.
 - b. Continual adherence to APHIS approval criteria.
- B. If a facility has experienced an outbreak of an infectious disease, affected animals have been depopulated, and/or the facility has been cleaned and disinfected, it may not be re-inspected and approved for subsequent use until the guidelines in VS Guidance 13403.1 regarding disease outbreaks are met.

I. Facility Operator Request for Variances

- 1) Applicants or facility operators may seek a variance to the requirements in this guidance by requesting one from the NDAIC in writing at least 30 days before any avian animals or hatching eggs covered under a specific cooperative service agreement are scheduled to arrive at the facility. APHIS will only grant variances for justifications it finds acceptable.
- 2) During emergencies such as power failures or natural disasters, APHIS may at its discretion grant permission for the importer or facility operator to break intact USDA seals and enter the facility. However, even under these circumstances, quarantined animals or hatching eggs may not be removed from the facility during quarantine unless specifically approved in advance by APHIS personnel. Every effort will be made to have an APHIS inspector present even during these emergencies.

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7. Inquiries

Please direct any inquiries to:

APHIS Veterinary Services, National Center for Import Export Services (NIES) Animal Permitting and Negotiation Services, phone: (301)-851-3300, option 2; email: VS.Live.Animals.Import.Permits@aphis.usda.gov.

Attachment:

Checklist for Privately owned Avian Quarantine Facilities

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USDA APHIS Veterinary Services Privately Owned Avian Quarantine Facility Approval Checklist

(Includes Approval Criteria for Facilities Housing Commercial Birds or Poultry Eggs for Hatching)

Please complete each item.

1. Name and Address of	2. Name and Address of
Facility (include Zip	Facility Operator
Code)	

Task/	Area Inspected	Acceptable/ Unacceptable (A or UA)	Remarks
Locat	tion		
3.	Location is within the immediate metropolitan area of the port and at least half a mile from location of other avian		
Const	animals. ruction		
4.	Facility is single, self-		
4.	contained building in		
	good repair.		
5.	Construction is of materials that are impervious to fluids and can withstand repeated cleaning and disinfection.		
6.	All openings to the outside prevent entry of vermin or other animals.		
7.	Quarantine containment area(s) is (are) of sufficient size for shipment.		
8.	Heating, ventilation and /or air conditioning systems control the		

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ambient temperature,	
humidity, and odors to	
acceptable levels.	
Lighting is adequate for	
VS inspections.	
10. Feed and bedding storage	
area is vermin- and	
moisture-free.	
11. Designated office is	
available for use by	
APHIS or facility	
personnel.	
12. Water supply to	
containment areas is	
adequate for animal	
maintenance and for	
cleaning.	
Biosecurity	
13. All equipment used in	
quarantine containment	
areas is dedicated to only	
that use.	
14. Clean reusable or	
disposable protective	
clothing (e.g., coveralls,	
boots, hats, gloves) is	
provided on clean side of	
showers for all who need	
to enter quarantine	
containment areas.	
15. A protocol for	
implementing facility	
biosecurity is available.	
16. Area for washing	
equipment is adequate.	
17. A separate showering area	
for personnel entering or	
leaving quarantine	
containment areas is	
provided, with room for	
change of clothes and	
receptacle for dirty	
clothes/ towels on the	
quarantine side (this is	
required for commercial	
bird facilities and is	

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highly recommended for	
poultry/ hatching egg	
facilities).	
18. Footbaths with	
disinfectant are present at	
all entries/ exits to	
quarantine containment	
areas.	
19. A disposal plan for wastes	
and other materials is	
acceptable (via incinerator	
•	
or other approved method on the premises OR	
facility provides adequate	
biosecure holding	
capacity until the end of	
quarantine).	
Security	
20. Facility has adequate	
locks provided to be used	
at all times.	
21. Facility displays visible	
signs that indicate	
"Quarantine" status and	
that prohibit unauthorized	
visitors.	
22. Operator has provided	Phone number:
APHIS with 24-hour	
contact phone number.	
23. An acceptable security	
system is installed and	
operational.	
Personnel	
24. Statements from	
authorized employees	
(stipulating non-contact	
with other avians until 72	
hours after quarantine has	
ended) are maintained for	
APHIS review.	
25. Agreements by authorized	
personnel to follow	
cooperative service	
agreement are maintained	
for APHIS review.	
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banding, or other sy		
30. For psittacine birds: APHIS approved identification system		
use by all personnel visitors.	and	
29. Daily log (APHIS-approved) is provide	ed for	
adequate. Recordkeeping		
28. Mortality handling procedures were rev by APHIS and foun		
with no more than 0 percent calcium.		
minimally 1 percent chlortetracycline (C		
Facility has medicat ration containing		
vermin-free. 27. For psittacine birds:		
26. Litter in quarantine containment areas is	S	

Print Name and Office Location

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Acknowledgement of Receipt of Inspection Report

I hereby acknowledge receipt of this inspection report on the below listed date.

34. Signature of responsible official/operator at facility	35. Title	36. Date