Compartmentalization Interim Approved Changes

NOTE: This document updated on November 5, 2021 contains sections of the electronic Code of Federal Regulations (see weblinks immediately below) to reflect the interim changes that were voted on and approved by the General Conference Committee members at the NPIP's September 22, 2021 General Conference Committee Virtual Meeting. All interim changes are subject to final and full approval at the June 7-10, 2022 NPIP Biennial Conference.

eCFR :: 9 CFR 145.45 -- Terminology and classification; compartments.

eCFR :: 9 CFR 145.74 -- Terminology and classification; compartments.

eCFR :: 9 CFR 145.84 -- Terminology and classification; compartments.

The interim changes can be found below.

§ 145.45 Terminology and classification; compartments.

(a) ***US H5/H7 AI and/or ND Clean Compartment.*** The program in this section is intended to be the basis from which the primary turkey breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and APHIS to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI) and/or ND. This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and/or ND within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

(1) ***Definition of the compartment.*** Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the primary breeder company will define the compartment with respect to H5/H7 AI and/or ND. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for H5/H7 AI and/or ND that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must approve all documentation submitted to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of H5/H7 AI and/or ND. Guidelines for the definition of the compartment include:

(i) ***Definition and description of the subpopulation of birds and their health status.*** All birds included in the compartment must be U.S. H5/H7 Avian Influenza Clean in accordance with § 145.43(g) and/or ND Clean in accordance with § 145.43(h). The poultry must also be located in a State that has an initial State response and containment plan approved by APHIS under § 56.10 of this chapter and that participates in the diagnostic surveillance program for H5/H7 low pathogenicity AI as described in § 145.15. Within the compartment, all official tests for AI and/or ND, as described in § 145.14(d) and (e), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in § 147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current H5/H7 AI and/or ND-related data for reference regarding surveillance for the disease within the compartment. Upon request, the Official State Agency may provide such data for other commercial poultry populations located in the State.

(ii) ***Description of animal identification and traceability processes.*** The primary breeder company must also include a description of its animal identification and traceability records, including examples of Veterinary Services (VS) Form 9-5, “Report of Hatcheries, Dealers and Independent Flocks”; VS Form 9-2, “Flock Selection and Testing Report”; VS Form 9-3, “Report of Sales of Hatching Eggs, Chicks and Poults”; VS Form 9-9, ” Hatchery Inspection Report”; set and hatch records; egg receipts; and egg/chick invoices for the subpopulation. Documentation must also include breed identification (NPIP stock code). The Service should ensure that an effective flock identification system and traceability system are in place.

(iii) ***Definition and description of the physical components or establishments of the defined compartment.*** The primary breeder company must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to H5/H7 AI and/or ND. The documentation should include descriptions of:

(A) The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.

(B) Relevant environmental factors that may affect exposure of the birds to AI and/or ND.

(C) The functional boundary and fencing that are used to control access to the compartment.

(D) Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.

(E) The relevant infrastructural factors that may affect exposure to AI and/or ND, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

(iv) ***Definition and description of the functional relationships between components of the defined compartment.*** Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include:

(A) Requirements that company employees and contract growers limit their contact with live birds outside the compartment.

(B) An education and training program for company employees and contractors.

(C) Standard operating procedures for company employees, contractors, and outside maintenance personnel.

(D) Requirements for company employees and non-company personnel who visit any premises within the compartment.

(E) Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.

(F) Policies for management of vehicles and equipment used within the compartment to connect the various premises.

(G) Farm site requirements (location, layout, and construction).

(H) Pest management program.

(I) Cleaning and disinfection process.

(J) Requirements for litter and dead bird removal and/or disposal.

(v) ***Description of other factors important for maintaining the compartment.*** The company veterinary infrastructure will assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to H5/H7 AI and/or ND. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. Upon request, the Service will provide the company with information on the epidemiology of H5/H7 AI and/or ND and the associated risk pathways in which the components of the compartment are located.

(vi) ***Approval or denial.*** Based on this documentation provided under this paragraph (a)(1), as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency will approve or deny the classification of the compartment as U.S. H5/H7 Avian Influenza and/or ND Clean.

(2) ***Company activities for maintenance of the compartment.***

(i) The primary breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices must be conducted by the company's licensed, accredited veterinarians.

(ii) Veterinary staff from the Official State Agency and NPIP staff will work in partnership with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors will conduct biosecurity and operational audits at least once every 2 years to ensure the integrity of the compartment. These audits will include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. H5/H7 Avian Influenza and/or ND Clean classifications, surveillance for H5/H7 AI and/or ND within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of H5/H7 AI and/or ND in primary breeder flocks. Baseline health status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza and/or ND surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

(iv) Documentation will be maintained in the company's database and will be verified as required by the Service and/or the Official State Agency.

(3) ***Service and Official State Agency activities for maintenance of the compartment.*** The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities will include:

(i) Oversight of the establishment and management of compartments;

(ii) Establishment of effective partnerships between the Service, the Plan, and the primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. H5/H7 Avian Influenza and/or ND Clean Compartments under paragraph (a)(1) of this section;

(iv) Official certification of the health status of the compartment, and commodities that may be traded from it through participation in the Plan for avian diseases, including the U.S. H5/H7 Avian Influenza Clean program as described in § 145.43(g) and/or ND Clean program as described in § 145.43(h) and diagnostic surveillance for H5/H7 low pathogenicity AI as described in § 145.15;

(v) Conducting audits of compartments at least once every 2 years to:

(A) Confirm that the primary breeding company's establishments are epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures; and

(B) Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter;

(vi) Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147 of this subchapter, risk evaluations in conjunction with the primary breeder industry (including disease surveillance such as VS

Form 9-4, “Summary of Breeding Flock Participation”), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with § 56.10 of this chapter; and

(vii) Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§ 145.15 and 145.43(g) and (h).

(4) ***Emergency response and notification.*** In the case of a confirmed positive of H5/H7 AI and/or ND in the subpopulation of the compartment, the management of the compartment must notify the Service. The Service will immediately suspend the status of the compartment. A compartment will be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that H5/H7 AI and/or ND is not present in the compartment and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

(b) [Reserved]

§ 145.74 Terminology and classification; compartments.

(a) ***U.S. Avian Influenza and/or Newcastle Disease Clean Compartment.*** This program is intended to be the basis from which the primary egg-type chicken breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and the Service to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI) and/or Newcastle disease (ND). This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and/or ND within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

(1) ***Definition of the compartment.*** Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the primary breeder company will define the compartment with respect to H5/H7 AI and/or ND. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for H5/H7 AI and/or ND that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must first approve all documentation submitted by the company to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of H5/H7 AI and/or ND. Guidelines for the definition of the compartment include:

(i) ***Definition and description of the subpopulation of birds and their health status.*** All birds included in the compartment must be U.S. Avian Influenza Clean in accordance with § 145.73(f) and/or ND Clean in accordance with § 145.73(h). The poultry must also be located in a State that has an initial State response and containment plan approved by APHIS under § 56.10 of this chapter and that participates in the diagnostic surveillance program for H5/H7 low pathogenicity AI as described in § 145.15. Within the compartment, all official tests for AI and/or ND, as described in § 145.14(d) and (e), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in § 147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current H5/H7 AI and/or ND-related data for reference regarding surveillance for the disease within the compartment. Upon request, the Official State Agency may provide such data for other commercial poultry populations located in the State.

(ii) ***Description of animal identification and traceability processes.*** The primary breeder company must also include a description of its animal identification and traceability records, including examples of Veterinary Services (VS) Form 9-5, “Report of Hatcheries, Dealers and Independent Flocks”; VS Form 9-2, “Flock Selection and Testing Report”; VS Form 9-3, “Report of Sales of Hatching Eggs, Chicks and Poults”; VS Form 9-9, ” Hatchery Inspection Report”; set and hatch records; egg receipts; and egg/chick invoices for the subpopulation. Documentation must also include breed identification (NPIP stock code). The Service should ensure that an effective flock identification system and traceability system are in place.

(iii) ***Definition and description of the physical components or establishments of the defined compartment.*** The primary breeder company must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to H5/H7 AI and/or ND. The documentation should include descriptions of:

(A) The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.

(B) Relevant environmental factors that may affect exposure of the birds to AI and/or ND.

(C) The functional boundary and fencing that are used to control access to the compartment.

(D) Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.

(E) The relevant infrastructural factors that may affect exposure to AI and/or ND, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

(iv) ***Definition and description of the functional relationships between components of the defined compartment.*** Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include but not be limited to:

(A) Requirements that company employees and contract growers limit their contact with live birds outside the compartment.

(B) An education and training program for company employees and contractors.

(C) Standard operating procedures for company employees, contractors, and outside maintenance personnel.

(D) Requirements for company employees and non-company personnel who visit any premises within the compartment.

(E) Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.

(F) Policies for management of vehicles and equipment used within the compartment to connect the various premises.

(G) Farm site requirements (location, layout, and construction).

(H) Pest management program.

(I) Cleaning and disinfection process.

(J) Requirements for litter and dead bird removal and/or disposal.

(v) ***Description of other factors important for maintaining the compartment.*** The company veterinary infrastructure will assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to H5/H7 AI and/or ND. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. Upon request, the Service will provide the company with information on the epidemiology of H5/H7 AI and/or ND and the associated risk pathways in which the components of the compartment are located.

(vi) ***Approval or denial.*** Based on the documentation provided under this paragraph (a)(1), as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency will approve or deny the classification of the compartment as U.S. Avian Influenza and/or ND Clean.

(2) ***Company activities for maintenance of the compartment.***

(i) The primary breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices must be conducted by the company's licensed, accredited veterinarians.

(ii) Veterinary staff from the Official State Agency and NPIP staff will work in partnership with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors will conduct biosecurity and operational audits at least once every 2 years to ensure the integrity of the compartment. These audits will include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. Avian Influenza and/or ND Clean classifications, surveillance for H5/H7 AI and/or ND within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of H5/H7 AI and/or ND in primary breeder flocks. Baseline health status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza and/or ND surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

(iv) Documentation will be maintained in the company's database and will be verified as required by the Service and/or the Official State Agency.

(3) ***Service and Official State Agency activities for maintenance of the compartment.*** The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities include:

(i) Oversight of the establishment and management of compartments;

(ii) Establishment of effective partnerships between the Service, the Plan, and the primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. Avian Influenza and/or ND Clean Compartments under paragraph (a)(1) of this section;

(iv) Official certification of the health status of the compartment, and commodities that may be traded from it through participation in the Plan for avian diseases, including the U.S. Avian Influenza Clean program as described in § 145.73(f) and/or ND Clean program as described in § 145.73(h) and diagnostic surveillance for H5/H7 low pathogenicity AI as described in § 145.15;

(v) Conducting audits of compartments at least once every 2 years to:

(A) Confirm that the primary breeding company's establishments are epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures; and

(B) Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter;

(vi) Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147 of this subchapter, risk evaluations in conjunction with the primary breeder industry (including disease surveillance such as VS

Form 9-4, “Summary of Breeding Flock Participation”), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with § 56.10 of this chapter; and

(vii) Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§ 145.15, 145.73(f), and 145.73(h).

(4) ***Emergency response and notification.*** In the case of a confirmed positive of H5/H7 AI and/or ND in the subpopulation of the compartment, the management of the compartment must notify the Service. The Service will immediately suspend the status of the compartment. A compartment will be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that H5/H7 AI and/or ND is not present in the compartment and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

(b) [Reserved]

§ 145.84 Terminology and classification; compartments.

(a) ***U.S. Avian Influenza and/or Newcastle Disease Clean Compartment.*** This program is intended to be the basis from which the primary meat-type chicken breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and the Service to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI) and/or Newcastle disease (ND). This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and/or ND within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

(1) ***Definition of the compartment.*** Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the primary breeder company will define the compartment with respect to H5/H7 AI and/or ND. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for H5/H7 AI and/or ND that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must first approve all documentation submitted by the company to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of H5/H7 AI and/or ND. Guidelines for the definition of the compartment include:

(i) ***Definition and description of the subpopulation of birds and their health status.*** All birds included in the compartment must be U.S. Avian Influenza Clean in accordance with § 145.83(g) and/or ND Clean in accordance with § 145.83(h). The poultry must also be located in a State that has an initial State response and containment plan approved by APHIS under § 56.10 of this chapter and that participates in the diagnostic surveillance program for H5/H7 low pathogenicity AI as described in § 145.15. Within the compartment, all official tests for AI and/or ND, as described in § 145.14(d) and (e), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in § 147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current H5/H7 AI and/or ND-related data for reference regarding surveillance for the disease and the health status of the compartment. Upon request, the Official State Agency may provide such data for other commercial poultry populations located in the State.

(ii) ***Description of animal identification and traceability processes.*** The primary breeder company must also include a description of its animal identification and traceability records, including examples of Veterinary Services (VS) Form 9-5, “Report of Hatcheries, Dealers and Independent Flocks”; VS Form 9-2, “Flock Selection and Testing Report”; VS Form 9-3, “Report of Sales of Hatching Eggs, Chicks and Poults”; VS Form 9-9, ” Hatchery Inspection Report”; set and hatch records; egg receipts; and egg/chick invoices for the subpopulation. Documentation must also include breed identification (NPIP stock code). The Service should ensure that an effective flock identification system and traceability system are in place.

(iii) ***Definition and description of the physical components or establishments of the defined compartment.*** The primary breeder company must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to H5/H7 AI and/or ND. The documentation should include descriptions of:

(A) The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.

(B) Relevant environmental factors that may affect exposure of the birds to AI and/or ND.

(C) The functional boundary and fencing that are used to control access to the compartment.

(D) Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.

(E) The relevant infrastructural factors that may affect exposure to AI and/or ND, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

(iv) ***Definition and description of the functional relationships between components of the defined compartment.*** Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include but not be limited to:

(A) Requirements that company employees and contract growers limit their contact with live birds outside the compartment.

(B) An education and training program for company employees and contractors.

(C) Standard operating procedures for company employees, contractors, and outside maintenance personnel.

(D) Requirements for company employees and non-company personnel who visit any premises within the compartment.

(E) Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.

(F) Policies for management of vehicles and equipment used within the compartment to connect the various premises.

(G) Farm site requirements (location, layout, and construction).

(H) Pest management program.

(I) Cleaning and disinfection process.

(J) Requirements for litter and dead bird removal and/or disposal.

(v) ***Description of other factors important for maintaining the compartment.*** The company veterinary infrastructure will assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to H5/H7 AI and/or ND. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. Upon request, the Service will provide the company with information on the epidemiology of H5/H7 AI and/or ND and the associated risk pathways in which the components of the compartment are located.

(vi) ***Approval or denial.*** Based on the documentation provided under this paragraph (a)(1), as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency will approve or deny the classification of the compartment as U.S. Avian Influenza and/or ND Clean.

(2) ***Company activities for maintenance of the compartment.***

(i) The primary breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices must be conducted by the company's licensed, accredited veterinarians.

(ii) Veterinary staff from the Official State Agency and NPIP staff will work in partnership with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors will conduct biosecurity and operational audits at least once every 2 years to ensure the integrity of the compartment. These audits will include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. Avian Influenza and/or ND Clean classifications, surveillance for H5/H7 AI and/or ND within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of H5/H7 AI and/or ND in primary breeder flocks. Baseline health status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza and/or ND surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

(iv) Documentation will be maintained in the company's database and will be verified as required by the Service and/or the Official State Agency.

(3) ***Service and Official State Agency activities for maintenance of the compartment.*** The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities include:

(i) Oversight of the establishment and management of compartments;

(ii) Establishment of effective partnerships between the Service, the Plan, and the primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. Avian Influenza Clean Compartments under paragraph (a)(1) of this section;

(iv) Official certification of the health status of the compartment, and commodities that may be traded from it through participation in the Plan for avian diseases, including the U.S. Avian Influenza Clean program as described in § 145.83(g) and/or ND Clean program as described in § 145.83(h) and diagnostic surveillance for H5/H7 low pathogenicity AI as described in § 145.15;

(v) Conducting audits of compartments at least once every 2 years to:

(A) Confirm that the primary breeding company's establishments are epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures; and

(B) Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter;

(vi) Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147 of this subchapter, risk evaluations in conjunction with the primary breeder industry (including disease surveillance such as VS

Form 9-4, “Summary of Breeding Flock Participation”), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with § 56.10 of this chapter; and

(vii) Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§ 145.15 and 145.83(g) and (h).

(4) ***Emergency response and notification.*** In the case of a confirmed positive of H5/H7 AI in the subpopulation of the compartment, the management of the compartment must notify the Service. The Service will immediately suspend the status of the compartment. A compartment would be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that H5/H7 AI is not present in the compartment and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

(b) [Reserved]