NAHEMS GUIDELINES: BIOSECURITY

FAD PReP
Foreign Animal Disease Preparedness & Response Plan

NAHEMS
National Animal Health Emergency Management System

United States Department of Agriculture • Animal and Plant Health Inspection Service • Veterinary Services

This FAD PReP/NAHEMS Guidelines was produced by the Center for Food Security and Public Health, Iowa State University of Science and Technology, College of Veterinary Medicine, in collaboration with the U.S. Department of Agriculture Animal and Plant Health Inspection Service through a cooperative agreement. This Guidelines document has undergone review by USDA Legislative and Public Affairs.

This FAD PReP/NAHEMS Guidelines reflects updates to the 2013 version, completed in June 2016. Please send questions or comments to:

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THE IMPERATIVE FOR FOREIGN ANIMAL DISEASE PREPAREDNESS AND RESPONSE

Why Foreign Animal Diseases Matter

Preparing for and responding to foreign animal diseases (FADs)—such as highly pathogenic avian influenza (HPAI) and foot-and-mouth disease (FMD)—are critical actions to safeguard the nation’s animal health, food system, public health, environment, and economy. FAD PReP, or the Foreign Animal Disease Preparedness and Response Plan, prepares for such events and provides guidance for activities during a response.

The 2014–2015 HPAI outbreak in the United States cost $850 million, just for indemnity payments and response activities on premises. Studies have estimated a likely national welfare loss between $2.3–69 billion\(^1\) for an FMD outbreak in California, depending on delay in diagnosing the disease.\(^2\) The economic impact of an FAD outbreak results from lost international trade and disrupted interstate trade, as well as from costs directly associated with the eradication effort, such as depopulation, indemnity, disposal, and virus elimination. In addition, there are direct and indirect costs related to foregone production, unemployment, and losses in related businesses. The social and psychological impact on owners and growers can be significant. Diseases with zoonotic potential, such as HPAI and Nipah/Hendra, may also pose a threat to public health.

Challenges of Responding to an FAD Event

Responding to an FAD event—large or small—is complex and difficult, challenging all stakeholders involved. Response activities require significant prior preparation. There are imminent and problematic disruptions to interstate commerce and international trade.

A response effort must have the capability to be rapidly scaled up or down according to the needs of the specific incident. This involves many personnel, resources, and possibly veterinary countermeasures. Not all emergency responders have specific food and agriculture skills required in areas such as biosecurity, quarantine and movement control, epidemiological investigation, diagnostic testing, depopulation, disposal, and possibly emergency vaccination.

Establishing widely communicated and understood response goals and guidelines, as accomplished by the FAD PReP materials, helps to broaden awareness of common objectives as well as potential problems.

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Lessons Learned from Past FAD Outbreaks

The foundation of FAD PReP is the lessons learned from past FAD incidents. FAD PReP is based on the following:

- Providing processes for emergency planning that respect local knowledge.
- Integrating State-Federal-Tribal-industry planning processes.
- Ensuring that there are clearly defined, obtainable, and unified goals for response.
- Having a unified Incident Command with a proper delegation of authority that is able to act with speed and certainty.
- Employing science- and risk-based management approaches to FAD response.
- Ensuring that all guidelines, strategies, and procedures are communicated effectively to responders and stakeholders.
- Identifying trained personnel and resources that are required for an effective incident response.
- Working to resolve competing interests prior to an outbreak and addressing them quickly during an outbreak.
- Achieving rapid FAD detection and tracing.

FAD PReP Mission and Goals

The mission of FAD PReP is to raise awareness, expectations, and develop capabilities surrounding FAD preparedness and response. The goal of FAD PReP is to integrate, synchronize, and deconflict preparedness and response capabilities as much as possible before an outbreak by providing goals, guidelines, strategies, and procedures that are clear, comprehensive, easily readable, easily updated, and that comply with the National Incident Management System.

In the event of an FAD outbreak, the three key response goals are to: (1) detect, control, and contain the FAD in animals as quickly as possible; (2) eradicate the FAD using strategies that seek to stabilize animal agriculture, the food supply, the economy, and to protect public health and the environment; and (3) provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products. Achieving these three goals will allow individual livestock facilities, States, Tribes, regions, and industries to resume normal production as quickly as possible. They will also allow the United States to regain FAD-free status without the response effort causing more disruption and damage than the disease outbreak itself.

FAD PReP Documents and Materials

FAD PReP is not just one, standalone FAD plan. Instead, it is a comprehensive U.S. preparedness and response strategy for FAD threats, both zoonotic and non-zoonotic. The following section provides examples of the different types of FAD PReP documents available.

- Strategic Plans—Concept of Operations
  - APHIS Foreign Animal Disease Framework: Roles and Coordination (FAD PReP Manual 1-0): This document provides an overall concept of operations for FAD preparedness and response for APHIS, explaining the framework of existing approaches, systems, and relationships.
  - APHIS Foreign Animal Disease Framework: Response Strategies (FAD PReP Manual 2-0): This document provides significant detail on response strategies that will be conducted in an FAD outbreak.
  - Incident Coordination Group Plan (FAD PReP Manual 3-0): This document explains how APHIS headquarters will organize in the event of an animal health emergency.
– **FAD Investigation Manual** (FAD PReP Manual 4-0): This field-ready manual provides detailed information on completing an FAD investigation from start to finish.

– **A Partial List of FAD Stakeholders** (FAD PReP Manual 5-0): This guide identifies key stakeholders with whom the National Preparedness and Incident Coordination (NPIC) Center collaborates.

- **NAHEMS Guidelines**
  - These documents describe many of the critical preparedness and response activities, and can be considered as a competent veterinary authority for responders, planners, and policy-makers.

- **Industry Manuals**
  - These manuals describe the complexity of industry to emergency planners and responders and provide industry a window into emergency response.

- **Disease Response Plans**
  - Response plans are intended to provide disease-specific information about response strategies. They offer guidance to all stakeholders on capabilities and critical activities that would be required to respond to an FAD outbreak.

- **Standard Operating Procedures (SOPs) for Critical Activities**
  - For planners and responders, these SOPs provide details for conducting critical activities such as disposal, depopulation, cleaning and disinfection, and biosecurity that are essential to effective preparedness and response to an FAD outbreak. These SOPs provide operational details that are not discussed in depth in strategy documents or disease-specific response plans.

- **Continuity of Business Plans** (commodity specific plans developed by public-private-academic partnerships)
  - Known as the Secure Food Supply Plans, these materials use science- and risk-based information to facilitate market continuity for specific products in an outbreak.

- **APHIS Emergency Management**
  - APHIS Directives and Veterinary Services (VS) Memorandums provide important emergency management policy. These documents provide guidance on topics ranging from emergency mobilization, to FAD investigations, to protecting personnel from HPAI.

PREFACE

The Foreign Animal Disease Preparedness and Response Plan (FAD PReP)/National Animal Health Emergency Response System (NAHEMS) Guidelines provide the foundation for a coordinated national, regional, state and local response in an emergency. As such, they are meant to complement non-Federal preparedness activities. These guidelines may be integrated into the preparedness plans of other Federal agencies, State and local agencies, Tribal Nations, and additional groups involved in animal health emergency management activities.

The Biosecurity Guidelines are a component of APHIS’ FAD PReP/NAHEMS Guideline Series, and are designed for use by APHIS Veterinary Services (VS), and other official response personnel in the event of an animal health emergency, such as the natural occurrence or intentional introduction of a highly contagious foreign animal disease in the United States.

The Biosecurity Guidelines provide guidance for USDA employees, including other USDA APHIS emergency responders, on biosecurity principles for animal health emergency deployments. This document provides information for Biosecurity Group Supervisors and other personnel associated with biosecurity activities during an animal health emergency.

In addition, this document addresses biosecurity concepts intended to prevent the introduction of disease into naïve livestock populations with day-to-day management and procedures. Therefore, general principles discussed in this document may serve as a resource for livestock producers for making sound decisions regarding biosecurity. As always, it is important to evaluate each situation and adjust procedures to the risks present in the situation.

The FAD PReP/NAHEMS Guidelines are designed for use as a preparedness resource rather than as a comprehensive response document. For more detailed response information, consult the FAD PReP Standard Operating Procedures (SOP): 9. Biosecurity and plans developed specifically for the incident. Additional Biosecurity resources are included in the Appendix and in the references at the end of this document.

NOTE: This “FAD PReP/NAHEMS Guidelines: Biosecurity 2016” is the result of a content update to the FAD PReP/NAHEMS Guidelines: Biosecurity 2013.
APHIS DOCUMENTS

This “FAD PReP/NAHEMS Guidelines: Biosecurity” has corresponding disease-specific FAD PReP Standard Operating Procedures (SOP): Biosecurity.

Several key APHIS documents complement this “FAD PReP/NAHEMS Guidelines: Biosecurity” and provide further details when necessary. This document references the following APHIS documents:

- FAD PReP/NAHEMS Guidelines:
  - Cleaning and Disinfection
  - Health and Safety
  - Personal Protective Equipment (PPE)

- FAD PReP Standard Operating Procedures (SOP):
  - Health and Safety/Personal Protective Equipment
  - Biosecurity
  - Cleaning and Disinfection

- APHIS Foreign Animal Disease Framework: Response Strategies (FAD PReP Manual 2-0)

- Foreign Animal Disease (FAD) Investigation Manual (FAD PReP Manual 4-0)

These documents are available at http://www.aphis.usda.gov/fadprep.
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1. INTRODUCTION

A foreign animal disease (FAD) outbreak in the United States could have a severe, profound, and long lasting negative impact on agriculture and the general economy of the United States. The negative effects will be felt locally by livestock and associated industries. Nationally, cascading negative effects will result from loss of international trade, product availability, and subsequent price changes, as well as from loss of consumer confidence and public trust. This Foreign Animal Disease Preparedness and Response Plan (FAD PReP) National Animal Health Emergency Management System (NAHEMS) Guidelines: Biosecurity introduces biosecurity concepts and discusses the implementation of these concepts in livestock production facilities (herds and flocks) to prevent introduction of disease into naïve livestock populations. The implementation of biosecurity critical activities during a response to an animal health emergency, such as an FAD, to prevent the spread of disease is also covered.

Biosecurity is a cornerstone of livestock production systems (including poultry production) to maintain food safety and security, protect the environment, and facilitate continuity of business by protecting animals and animal products. In addition to the daily protocols to protect the health of livestock populations, biosecurity is crucial in containing disease in an FAD outbreak. Should the FAD also be zoonotic, biosecurity is necessary to protect public health. Local, State, and Federal governments and private sector partners (e.g., industry and academia) must work together in a coordinated, mutually supportive effort to implement biosecurity protocols and procedures to contain disease and protect naïve livestock populations. Biosecurity measures help to prevent the spread of pathogens and protect susceptible animals from exposure to any contagious disease – preventing the first exposure as the index case, as well as preventing exposure to subsequent animal populations.

Biosecurity can be defined as a collection of measures or management practices intended to protect animals or humans against the introduction and spread of disease or harmful biological agents. In broad terms, it refers to anything designed to prevent the transfer of disease-causing pathogenic agents, and can be described using three levels.

- Structural biosecurity is a level referring to the design and physical construction of the facility such as easy-to-clean surfaces.
- Operational biosecurity refers to procedures, both on-farm and off-farm, such as how those surfaces are cleaned between animal groups, in addition to sanitation of items before arriving on-site.
- Conceptual biosecurity is the third level involving the geospatial siting and conceptual design/size of a livestock facility in such a way to minimize the introduction or spread of disease.

Biosecurity concepts involve strategic decisions, adequate investment, management practices, movements of livestock, equipment and personnel. It also requires training, supervision, and accountability of personnel. For additional information, consult the disease-specific FAD PReP Standard Operating Procedures: Biosecurity. To access this document and other FAD PReP resources, a web link to the FAD PReP web site is provided in the For More Information section at the end of this document.
2. GENERAL BIOSECURITY CONCEPTS

Before developing and implementing biosecurity measures, an individual site risk assessment or hazard analysis should be performed. The assessment and analysis will consider the health status and species of the livestock. The management and site arrangements of animals raised indoors versus animals raised outdoors will require individual consideration and guide the selection of biosecurity protocols.

It is necessary to identify sources/areas of potential contamination and areas that need to be protected from contamination. Perhaps most importantly, a Line of Separation is established. A Line of Separation is a line or barrier – imagined or physical – separating dirty (potential sources of infection) from clean areas (non-infected). In some situations, this Line may be called the Clean/Dirty Line and may serve as the location for cleaning and disinfection (C&D Line). Once dirty and clean areas are distinguished, site-specific pathways which could enable a disease to move into, off, or within a facility are ascertained.

Routes of disease transmission and opportunities for livestock exposure to disease must be understood in the context of site-specific pathways for disease movement on a premises; then, biosecurity measures are prioritized based on risk, probability of occurrence, ease/cost of implementation, and consequences. Consequences involve economic loss and in some cases, adverse impact to genetics. For a company with multiple sites or facility arrangements, one set of procedures may not be sufficient; each site or each facility should be evaluated individually.

As part of this site-specific hazard analysis, critical control points should be identified in movement and work pathways. A critical control point is a point, step, or procedure where control can be applied to prevent the transfer of a disease agent (or in a more broad interpretation, to prevent harm). Points where the pathogen can be prevented from entering (or leaving) a premises, facility, or a barn unit (or perhaps all three) are identified as critical control points. Critical control points involve people, supplies and equipment, vehicles, feed, mortalities, and animals/animal products.

The goal is to prevent the transfer of a disease agent across a specific control point, whether the intention is to keep disease out (bioexclusion), or keep disease in (biocontainment). With multiple points of access and multiple work pathways, there will be an opportunity to establish multiple control points. The same concepts and principles are used in either direction and applied to both bioexclusion and biocontainment measures. The points of access between clean and dirty areas should be limited. Strategic preventative actions are implemented at these controlled access points. Cleaning and disinfection of people or things moving across the controlled access point is essential. In addition, other protocols and procedures will be necessary to more fully mitigate the risk.

As described previously, biosecurity measures can be divided into three levels. Biosecurity is most often regarded in terms of operational measures, those on-farm management actions that prevent the transfer of a pathogen from one area to another. Most operational biosecurity measures restrict movement and require cleaning and disinfection of things that are allowed to move either on to or off of the premises.

However, biosecurity measures can also be built into the structure of a facility. Structural biosecurity includes capital investments which prevent the spread of a disease agent. This may be as basic as fencing to separate populations of animals. The photo at right illustrates the need for fences and screens to prevent contact between wildlife and livestock to avoid risk of disease introduction. Other examples of structural
biosecurity are vehicle parking facilities built at a distance from animal housing, and more elaborate structures as truck washing bays anterooms and showers at the entry.

A third level, conceptual biosecurity, involves the geospatial location, scope, and size of animal production units and complexes. The closer facilities are in proximity, the higher the risk of disease transmission between facilities. Isolation, or enhanced distance of a facility to its neighboring livestock/livestock facilities, is protective. Conceptual biosecurity measures are evaluated at the time of construction or expansion, but they also impact the design of on-farm mitigation procedures.

Another important biosecurity principle is the establishment of auditable operational standards. These standards need to be clearly communicated and implemented by all personnel and visitors. Defined procedures need to be monitored so that standards are not relaxed. Corrective actions must be taken when there are lapses in biosecurity.

Assigning an individual with authority to be responsible for the site-specific biosecurity plan will enhance the success of biosecurity measures. This individual may be identified by different titles, such as manager, officer, or coordinator. This individual has the responsibility to assess the site, identify critical control points, design the mitigation, develop and implement the biosecurity measures, train all personnel, monitor and enforce compliance, and take corrective actions or modify procedures when necessary.

The biosecurity protocols implemented will vary from one facility, premises, commercial production site, or location to another. Depending on the type of livestock facility, measures can be implemented at the barn level and/or at the farm level.

2.1 Routes of Exposure to Disease

In order to develop a comprehensive, effective biosecurity plan, it is necessary to understand how each disease of concern is spread and how susceptible animals are exposed. Each disease has transmission pathways based on the nature of the pathogenic agent. Diseases may be spread between animals, and between animals and humans (zoonotic disease), in a variety of ways. A mitigating action which prevents the spread of one disease may not be effective against another.

Common routes of exposure to disease agents are through direct contact, aerosol, oral, and fomites. In addition, exposure to some diseases may occur through a vector. Exposure may occur by direct physical contact between the infected and susceptible animal, with direct transfer of the disease agent. While direct contact may be the most obvious route of exposure and the easiest to prevent, exposure by indirect means may provide the highest risk. Indirect exposure may occur through the environment or surfaces contaminated with secretions or infective materials. Exposure to environmental contamination by feces, urine, saliva, or other infective material from an infected animal, or exposure through a vector should not be overlooked. Human exposure to zoonotic diseases may occur through any of the five routes mentioned above. It should be emphasized that disease agents can be carried by animals without signs of infection.

2.1.1 Direct Contact

Direct exposure (Figure 1) occurs when a susceptible animal physically contacts an infected animal. The disease agent is transferred to the skin, mucous membranes or open wound of a susceptible animal through rubbing, biting, licking, or by contact with the blood, urine, milk, saliva, nasal secretions, or body lesions of an infected animal. Exposure may result from nose-to-nose contact. Exposure to some diseases occurs with the transfer of disease agents during breeding, or from dam to offspring during gestation, birth, and/or nursing. Pathogens can be transferred during the direct contact between animals of different
species. In general, disease agents that are spread exclusively by direct contact may be unlikely to survive for significant periods of time away from a host.

Examples of diseases spread by direct contact include:
- African swine fever (ASF),
- Contagious equine metritis (CEM),
- Q fever (also known as query fever), and
- Foot-and-mouth disease (FMD).

2.1.2 Aerosol

Exposure may occur through aerosols (Figure 2) as when infectious droplets containing pathogenic agents from an infected animal are inhaled by a susceptible animal, or make contact with the mucous membranes. Pathogenic agents in aerosol droplets that are spread through the air may be from respiratory secretions (sneeze or cough), urine, birthing fluids, or from feces of infected animals, as examples. Pathogens transmitted via aerosols may not survive for extended periods of time, particularly as moisture in the droplets is lost. A susceptible animal exposed by aerosol is most likely to be in close proximity to the infected animal for disease transmission to occur.

Examples of diseases spread by aerosols include:
- Newcastle disease (ND),
- FMD,
- Q fever, and
- Influenza.

2.1.3 Oral

Exposure may occur through contact with the disease agent orally (Figure 3). In addition to a susceptible animal licking or biting an infected animal during direct contact, exposure may take place when a susceptible animal ingests a pathogenic agent. Feces, urine, saliva, and other secretions containing disease agents can contaminate feed, water, or objects in the environment that animals lick or chew, such as feed bunks, equipment, fencing, water troughs, salt and mineral blocks, etc. Shared feed and water sources can contribute to the spread of the disease. A susceptible animal walking on ground contaminated by infectious feces is likely to be exposed when the animal licks itself.

Examples of diseases spread by oral transmission include:
- ND,
- FMD,
- Hendra,
- Nipah, and
- Q fever.
2.1.4 Fomites

Fomites are inanimate objects capable of transferring disease agents from an infected animal to a susceptible one (Figure 4). Fomites can include shovels and other tools, bowls or buckets, tack and brushes, clippers, and medical equipment such as needles. Vehicles and trailers with tires, wheel wells, undercarriages, and animal cargo areas contaminated with infectious disease agents can serve as fomites by leaving pathogens behind in the environment. Fomites such as contaminated clothing, shoes, or boots of humans are commonly the cause of disease agents moving within a facility or from one facility to another. Historically in outbreaks, lateral spread through fomites such as the movement of people with contaminated outerwear, equipment and vehicles has been high risk.

In addition to the traditional focus of movement through fomites, the movement of disease agents by a plume of dust particles or on wind-blown feathers has been studied. Feed, feed ingredients, feed containers, edible and non-edible animal products, and bedding/litter have been investigated as potential fomites. The risk of exposure from all types of fomites needs to be evaluated and mitigated, if possible.

Examples of diseases spread by fomites include:
- ASF,
- Influenza,
- FMD, and
- Classical swine fever (CSF).

2.1.5 Vectors

Exposure to some diseases can be through vectors (Figure 5). Vectors can be described as any living organism, including, but not limited to, arthropods, insects, rodents, feral animals, and scavengers that can carry disease causing agents from an infected animal to a susceptible animal. Generally, two types of vectors are recognized, biological and mechanical.

A biological vector transfers a disease agent from an infected animal to a susceptible animal after the disease agent has undergone some part of its life cycle within the vector. The vector acquires the agent from an infected animal, often through a blood meal. The agent replicates or develops within the vector. The disease agent is subsequently introduced to a susceptible host, usually through a bite. Fleas, ticks, and mosquitoes are common biological disease vectors.

A mechanical vector transfers a disease agent to a susceptible animal via external body parts of the vector, such as on the fur or feet; the pathogen does not undergo any development or multiplication while with (usually on) the vector. Many species of flies serve as mechanical vectors.
In developing biosecurity procedures, the potential for vector borne diseases and the risk of exposure to the vector needs to be assessed.

Examples of diseases spread by vectors include:
- Bluetongue,
- West Nile Virus (WNV), and
- Equine Infectious Anemia (EIA).

2.1.6 Zoonotic Disease Exposure

Zoonotic diseases are transmissible between animals and humans (Figure 6). Human exposure to zoonotic diseases may occur through any of the five methods described above, depending on the disease. Because of public health concerns of a zoonotic disease in livestock (herds and flocks), the risk to personnel, as well as risk to the public if the disease agent is not contained, should be considered in a biosecurity risk assessment; in reverse, exposure of livestock to zoonotic diseases from contact with infected humans needs to be assessed.

*FAD PReP*/NAHEMS Guidelines: Personal Protective Equipment (PPE) addresses the emergency responders’ use of PPE as a biosecurity measure as well as the selection, types and proper use of personal protection against zoonotic disease. *FAD PReP*/NAHEMS Guidelines: Health and Safety and *FAD PReP* Standard Operating Procedures: Health and Safety & PPE provide guidance to responders on health and safety issues they may encounter while on deployment, including exposure to zoonotic diseases. These documents can be accessed by a web link to the FAD PReP web site provided in the For More Information section at the end of this document.

Examples of zoonotic diseases include:
- Brucellosis,
- ND,
- Influenza,
- Hendra,
- Nipah,
- Q fever, and
- Tuberculosis.
2.2 Developing a Biosecurity Plan

The process of developing a biosecurity plan focused on bioexclusion and/or biocontainment involves similar concepts and considerations. An assessment of the existing situation needs to be conducted, evaluating the disease agent(s) and the routes of transmission, the physical facility, and options for mitigation.

To develop a biosecurity plan, consider a three step process.

1. Identify and Prioritize Diseases
2. Assess the Facility
3. Implement Processes and Procedures

Step 1: Identify and prioritize the disease agents of greatest concern to the facility.
Those disease agents will vary based, for example, on species, susceptibility, age, and production stage of the animals. The risk of exposure to specific diseases may depend on management, type of housing, and potential contact with wild or feral animals. Once the disease agents are identified and prioritized, the transmission and methods of exposure should be studied.

Step 2: Conduct an assessment of the facility.
Identify the pathways and processes that allow disease agents to be moved from one location to another. In cases of non-infected animals, identify movements that would allow exposure of susceptible animals to contaminants from outside the facility. For infected animals, identify movements that would allow the pathogen to escape containment or quarantine.

Movements may involve entering or leaving a facility, or movements within a facility that may spread disease between groups of animals. In this step, the critical control points are recognized, so that mitigation measures can be implemented.

Step 3: Implement processes and procedures that eliminate, prevent, or minimize the potential impact of animal disease by preventing movement of entities that may carry disease, or that inadvertently transport the disease agent.
Mitigation steps need to take into consideration the risk of movements of personnel, service crews, visitors, wild and feral animals, and pets/domesticated animals, as well as any vehicles, and the drivers of those vehicles. In addition, evaluate the handling and movement of equipment, manure, and animal carcasses. Assess the risk of deliveries that may transport pathogens, either in the product being delivered (feed, bedding), or on the delivery vehicle that may be contaminated from contact with other animals or premises.

Importantly, consider the movements of the animals themselves. A closed herd with herd additions coming from offspring within the herd, managed in small groups and isolated from others, will be more protected than a large group allowed to co-mingle. All-in/all-out management with less co-mingling between groups minimizes exposure to disease. Animals that leave the premise and are allowed to return pose a risk to the animals at home. A quarantine imposed on a herd/flock prevents movements of those quarantined animals.
Once the biosecurity procedures have been designed and established, they need to be institutionalized, consistently implemented, and enforced. It is advisable to appoint someone who is responsible for monitoring compliance at all times, and has the authority to stop procedural violations and take corrective actions. All employees and responders need to report violations immediately.

2.3 Levels of Biosecurity to Prevent Exposure to Disease

The scope of implementation will vary and depends on the individual livestock facility, the risk/benefit, and practicality of the measure. Once a specific biosecurity measure is chosen, it is only effective if it is implemented correctly and consistently.

Owners and producers are responsible for protecting their animals from disease. Ideally, day to day procedures should be stringent enough that in the face of a disease outbreak, no enhancements would be necessary. Practically, this may not be feasible. In the case of a zoonotic disease, special biosecurity precautions may be crucial to protect responders and the public.

If biosecurity is considered an investment in the protection of livestock health, the cost of this investment is weighed by each producer against the cost of the consequences. Consequences may not only be economic but, in some cases, may include significant loss of genetics. Biosecurity protocols will be based on the species and/or mixture of species to be protected, types of diseases, economic value of the animals, intended purpose and susceptibility of the animals, practicality, and facility lay-out.

The increased risk of disease is associated with:

- Farm density – other production facilities within a few miles;
- Animal movement – especially if animals leave, then return to the premises;
- Traffic on and off the premises – vehicles (feed, milk, garbage, rendering) and drivers;
- Human activity – employees, service personnel, visitors;
- Equipment sharing – between facilities, or between animal groups within the facility;
- Access by wildlife – such as insects, birds, rodents, feral animals;
- Animal housing construction that is difficult to clean and disinfect; and
- Mortalities disposed near animal housing.

In this section, examples of conceptual biosecurity, structural biosecurity, and operational biosecurity are presented as options to mitigate the risk of exposure to disease. Livestock producers are encouraged to incorporate these options in their routine biosecurity plans.

2.3.1 Conceptual Biosecurity

Conceptual biosecurity is the location, geospatial siting and orientation of the facility. It also includes the scope and size of animal production units and complexes. The greater the farm density, or the closer facilities are in proximity, the higher the risk of disease transmission between facilities. The closer facilities are to areas that attract wildlife, the higher the risk of disease introduction. As the number of animals managed as one population increases, the number of animals at risk and the consequences from one introduction of disease also increases.
Best practices include:
- Separation/isolation with enhanced distance to neighboring livestock/livestock facilities;
- Conceptual designs to manage smaller groups of animals as biosecure units;
- Enhanced distance to wildlife areas (ponds, grassy habitats, crops that may serve as wildlife feed); and
- Isolation from roads to avoid heavy volume of traffic nearby.

A producer’s evaluation of the facility’s conceptual biosecurity that may already exist can identify strengths and weaknesses that may need to be addressed with structural and/or operational biosecurity. Weaknesses or deficiencies may elevate the level of risk of exposure, render the facility more vulnerable, and enhance the magnitude of consequences.

As mitigating actions, it may be possible to eliminate wildlife habitat or alter the areas surrounding a facility to be less attractive to wildlife. It may be impossible to close or reroute traffic on public roads, but it may be possible to reroute traffic within the facility to avoid animal areas.

2.3.2 Structural Biosecurity

Structural biosecurity refers to the capital investment that enhances the ability to prevent disease spread. It includes the physical design, construction, and maintenance of a facility which help prevent the transfer or aid in the containment of disease. Producers should include enhancing structural biosecurity in their long term plans.

Examples of structural biosecurity measures include:
- Restricted entrance/egress points to limit access to the premises only through a point where operational biosecurity protocols are implemented and monitored (controlled access points).
- Roads and work paths that are routed around the premises to accommodate a barrier (Line of Separation) around the livestock, and a Perimeter Buffer Area.
- A specialized anteroom for entry into an animal building that serves to house the visible Line of Separation, or a Clean/Dirty Line, and prompts the appropriate biosecurity protocols prior to entering the building. This anteroom may be constructed using the Danish Entry System, or as a full shower-in and shower-out facility. Figure 7 shows a simplified example of the Danish Entry System. For a more detailed illustration along with more explanation, see Appendix B: Example - Danish Entry System.
- A building dedicated to cleaning and disinfecting vehicles. Cleaning of trucks and other vehicles may be accomplished by dry cleaning, then washing. Disinfection may be conducted with a solution ensuring appropriate contact time, or by an adequate duration of heating.
- Locations that facilitate the cleaning and disinfection of all equipment and vehicles entering/exiting the premises.
- On-site laundry to keep all clothes worn by personnel on-site.
- Paved employee/visitor parking area away from animal housing.
- Hard surface (concrete or asphalt) pads at entrances to animal housing units that facilitate decontamination by washing and sunlight.
- Fences, barriers, or gates that direct personnel and visitors to the appropriate entrance where biosecurity protocols are implemented.
• Barriers that separate traffic to avoid cross contamination – separating the delivery of new animals from the removal of live or dead animals.
• Structures serviced by outside vehicles, such as feed, milk, or mortality storage, located at a distance so service vehicle routes avoid animals and animal areas.
• Air filtration/ventilation of buildings of animals raised indoors – positive or negative pressure in association with filters to minimize pathogens that may enter as plumes.
• Water treatment, particularly if the source is from surface water that may be contaminated by wildlife.
• A sufficient supply of tools, so that all tools are kept on-site and no sharing is necessary.
• A shuttle for deliveries or removal of supplies, manure, mortalities, even people, to minimize outside vehicles from entering the premises.
• Designs that aid an all-in/all-out management system, or maintain one-way flow of animals from the point they enter the facility until they leave.
• Physical barriers to exclude vectors of disease – bird proofing poultry facilities, double fencing outdoor swine facilities, filling small holes where wildlife may enter animal housing.
• Fencing/spacing between animal populations to avoid direct/nose-to-nose/fence-line contact between populations on the premises, or with animals from neighboring premises.
• Structural and mechanical components that are easy to clean.
• Signage to warn of restricted areas.

Historically, structural designs have been based on costs of construction, labor, production, and energy; however, biosecurity considerations should also be an important component.

2.3.3 Operational Biosecurity

Operational biosecurity refers to those processes and protocols, management practices, or standard operating procedures implemented to exclude or contain disease. It addresses the movement of personnel – employees, contract crews, vendors, visitors, drivers of vehicles, and response personnel - as well as anyone who may live on the premises. Operational biosecurity pertains to procedures conducted on the premises, as well as the management of people, animals, supplies, equipment, vehicles, and other items related to disease control. Procedures should be chosen based on risk assessment of the individual situation, which may involve mitigating risks in the conceptual or structural biosecurity of the premises, as well as known disease in the area. A specific combination of measures should be chosen based on the specific circumstances of the site and of the operation. The following discussion provides examples of operational biosecurity measures to mitigate risk.

2.3.3.1 Critical Control Points

Evaluation to determine the most effective operational biosecurity procedures is based on critical control points, focusing on inputs and outputs. Examples of operational biosecurity measures to include in a biosecurity plan are:

• Clearly identified critical control points where strategic controls can be applied to prevent the transfer of a disease agent. Control points may be entrances to/exits from the clean area of the premises (movements of inputs/outputs), work pathways, or related processes where biosecurity protocols, such as cleaning and disinfection, movement controls, and employment restrictions help to mitigate disease exposure.
• One or more clearly identified levels of separation - imagined or physical - between the area considered clean (non-infected, protected) and the area considered dirty (potential source of infection). For biosecurity purposes, the area where the non-infected animals are located is
considered clean, and is the area to be protected. Physical separation of areas may be identified by a Line of Separation, a Clean/Dirty Line, a C&D Line, and a Perimeter Buffer Area. As described above, the Line of Separation clearly demarcates non-contaminated from contaminated. On some livestock production operations, a Perimeter Buffer Area places additional separation between the non-contaminated and contaminated space, to reduce pathogen load in the buffer environment and reduce the risk of disease transmission. Identification is made visually on a map, and is physically marked for all present at the facility. Separation may be implemented at the farm or barn level. A point where movements cross the Line is a critical control point, and can be referred to as a controlled access point. See Appendix A: Example – Perimeter Buffer Area - Line of Separation to better visualize these concepts.

- Written operating procedures defining the critical control points and effectively addressing protocols to defend the control point. Written procedures, perhaps as standard operating procedures (SOP), specify processes associated with structural biosecurity features such as anterooms, wash stations and wash bays, directional barriers, etc., to prevent a disease agent from crossing the Line. See Appendix B: Example - Danish Entry System for operational procedures associated with a structural biosecurity feature.
- Single entry points to confinement buildings, if possible, where biosecurity procedures are implemented.
- Defined work pathways through specific control points where biosecurity procedures are performed.
- Protocols instituted to prevent transfer of pathogens between animal populations within the facility, such as the requirement to conduct cleaning and disinfection procedures at control points before moving from one population to another.
- Regular review of critical control points and procedures associated with them. Assessment of efficacy and compliance is conducted. Modifications are made to the written plan documents (or SOP documents) as needed.

### 2.3.3.2 People

The movement and behavior of people, including caretakers and emergency response personnel, can pose a risk of transferring disease agents. Examples of operational measures pertaining to people are:

- An individual assigned to develop a written, effective, and site-specific biosecurity plan who is responsible for implementation, consistent enforcement, and compliance.
- Documented training of all employees utilizing appropriate training materials, followed by test verification, periodic audits, and refreshers. Written training materials that incorporate diagrams and photos are encouraged. Language and cultural differences should be considered to ensure understanding. Compliance is enhanced if the purpose for the action is understood.
- A signed employee agreement to comply with all biosecurity requirements on file.
- Documented communication explaining biosecurity policies and requirements to delivery/service personnel, haulers, and visitors prior to arriving, and an on-site escort to ensure compliance.
- A standard to prevent the transfer of contamination on clothing. For all who enter/leave the facility or cross the Line of Separation, the Clean/Dirty Line, and/or enter the Perimeter Buffer Area, methods to achieve the standard may include:
- Arriving at the facility freshly showered wearing laundered clean clothes;
- Donning freshly laundered or disposable site-specific outerwear, including boots, provided by the facility (biosecurity attire);
- Cleaning and disinfecting boots/shoes, such as in a foot bath made of fresh solution;
- Removing all jewelry and washing hands or using a hand sanitizer;
- Showering into the facility, prior to donning outerwear provided by the facility;
- Showering out of the facility, leaving facility-provided outerwear behind; and
- Prohibiting drivers of delivery/pick up vehicles from exiting the vehicle, unless disposable boot covers provided by the facility are worn.

- A method to prevent the transfer of disease agents on cell phones and electronics. An example is to use a clear, waterproof, cell phone case, or even a water-tight zip-lock bag, that allows the cell phone to function, but also allows the phone to be submerged in disinfectant when crossing the Line of Separation. Prior to entering a non-infected premises, the cell phone secured in the case or bag is disinfected, and remains encased until exit. In reverse, prior to entering a contaminated premises, the cell phone is encased and then disinfected upon exit.

- An on-site shuttle to transport people from an entrance where biosecurity measures are implemented to an internal facility location, avoiding contamination in route.

- Employment conditions that minimize contact with outside animals through interactions that may pose a disease risk, such as:
  - Employees are restricted from caring for the same species owned/run by a separate company. For example, swine facilities may restrict employees from working at another swine facility to avoid cross contamination.
  - Employees are restricted from sharing a household with an employee of another similar animal production company.
  - Employees are restricted in the species of animals they may own or contact. For example, poultry facilities may prohibit employees from owning or being in contact with backyard birds.
  - Employees are restricted from hunting game that may be reservoirs of disease for animals on-site.
  - Employees are required to report contact with other animals, and report visits out of the country so that the appropriate downtime (time away from employment) can be observed, if necessary.

- Employees assigned and limited to care for one population of animals.

- Daily tasks scheduled to provide care to the most susceptible (younger) animals before less susceptible (older) animals. Sick animals receiving treatment are handled and cared for last.

- Visitor logbook to document history of visits and visitors’ recent prior animal contact.

- Signs posted to remind people of escort requirements and biosecurity procedures. Required biosecurity procedures may include observing restricted areas, maintaining the Line of Separation, donning appropriate outerwear, washing hands, and cleaning and disinfecting boots.
2.3.3.3 Vectors – Wildlife, Insects, and Household Pets

Living creatures can spread disease as mechanical vectors and/or biological vectors. Examples of operational measures pertaining to vectors include:

- The immediate cleaning of any spilled feed or material that may attract vectors.
- Control programs that eliminate vectors that may have entered the facility despite structural controls. This may include services of an outside pest control contractor, who also abides by all biosecurity protocols.
- Scheduled frequent mowing of grounds surrounding animal areas to reduce habitat.
- Wildlife and household pets excluded from entering restricted animal areas.

2.3.3.4 Equipment

Supplies and equipment, especially shared equipment, can harbor and transfer pathogens. Exposure of livestock to disease can occur through contact with the contaminated equipment, or through the environment contaminated by equipment. Examples of measures to mitigate risk include:

- Equipment dedicated to a population of animals to avoid the necessity of sharing between groups of animals or between facilities. This would include tools for maintenance of the facility.
- Effective cleaning and sanitizing protocols for all equipment and tools prior to crossing the critical control point or Line of Separation.
- Supply and delivery entrances that have associated strict biosecurity protocols to eliminate contamination. This may involve removing unnecessary packaging and decontaminating supplies with solutions, heat, or UV light prior to entry.

2.3.3.5 Vehicles

Vehicles, especially vehicles travelling between livestock facilities, may transport and introduce pathogens. The biosecurity examples below vary in their ease of implementation:

- Internal vehicles utilized to service the facility. These vehicles do not leave the facility (the Perimeter Buffer Area) and are frequently and thoroughly cleaned and disinfected. Internal vehicles may assist in moving people, equipment, and supplies within the facility.
- Exclusion of outside vehicles from crossing the Line of Separation. Employees and visitors are directed to park in designated lots outside a designated perimeter barrier (Perimeter Buffer Area). Vehicles are allowed to enter the Perimeter Buffer Area or cross the Line of Separation only through a critical control point (controlled access point) with required biosecurity measures (C&D).
- Cleaning and disinfection protocols for vehicles that must enter the Perimeter Buffer Area or cross the Line of Separation. Pay particular attention to wheels, wheel wells, and animal cargo areas.
- Deliveries received at a location at some distance from animals, and on-site shuttles move materials to permanent locations.
- Routes to keep necessary service vehicles (feed, milk, animal delivery/load-out trucks) from crossing other work paths.
- Cleaning and disinfection protocols for animal transport carriers between loads (exterior and cargo area of the carrier).
2.3.3.6 Carcass Disposal

Livestock deaths may or may not be due to disease, but are a biosecurity risk for the rest of the herd/flock. The handling and disposal procedures for carcasses should avoid exposing the rest of the livestock population. Examples of general protocols include:

- Disposal processes that prevent cross-contamination with carcasses from off-site, or other processes, such as feed delivery, or work pathways.
- Disposal in a manner that prevents attraction of wildlife, scavengers, and pets.
- Storage of carcasses prior to pick up (both short term and long term), and composting located at a distance from live animals.
- Carcass pick up by renderers at a distance from live animals, so that rendering trucks do not enter the perimeter barrier or Perimeter Buffer Area of the facility.

2.3.3.7 Manure/Litter Management

As with carcasses above, the intention is to prevent reintroduction of any pathogen that may be present in manure or litter back into the herd/flock or into other herds or flocks.

- Removal of manure and spent litter that prevents exposure to live animals and avoids cross-contamination of other processes, such as feed delivery or work pathways.

2.3.3.8 Animals

Animals, whether showing signs of disease or not, may be the most recognizable entity to move disease between populations. Examples of sound animal management practices include:

- Maintenance of a closed herd, where all new animals are offspring born and raised on the operation.
- Replacement livestock from sources with documented biosecurity practices and a history of freedom from infection, preferably based on diagnostic testing. This also applies to embryos and semen from outside sources.
- Transportation of arriving animals in freshly cleaned and disinfected carriers to limit disease exposure from previously transported loads.
- Isolation of new additions. In some cases, a 30 day isolation before comingling with the established animal population is recommended.
- All-in/all-out management of groups of animals. Groups stay together from the time of arrival, through growth, and until they leave for processing.
- Load-out area with the Line of Separation clearly marked so that animals, people or equipment that cross the Line to leave the facility do not return, unless full cleaning and disinfection procedures are used. Employees move animals to the trailer for load-out, but do not cross the Line. Truck drivers prevent the animals from escaping the trailer back into the facility.
- Animals that leave the premises do not return.
- Management protocols to eradicate vertically transmitted diseases.
- Daily care provided in order of disease susceptibility. Contact is made with young, more susceptible animals before moving to older, less susceptible animals on the premises.
- Segregation of sick animals for treatment to limit exposure to naïve animals. Care is provided to sick animals last, after care has been provided to healthy animals.
2.3.3.9 Feed, Replacement Bedding/Litter, and Water Supply

As other inputs can introduce contamination into a herd/flock, the feed, bedding and water should not be overlooked in contributing to risk of disease. Some examples pertaining to these inputs include:

- Grain, feed, and fresh bedding/litter delivered, stored, and handled in closed containers to prevent contamination by wildlife and/or disease agents.
- Outside deliveries accepted at a location remote from animal areas, and then shuttled by on-site equipment to internal locations.
- Grain spills immediately cleaned so as not to attract wildlife.
- Water from deep wells or sources treated to eliminate disease contamination.

2.3.3.10 Maintenance

Reducing environmental contamination that may unavoidably occur is part of any biosecurity plan, and is as important as the equipment maintenance plan. Maintenance tasks in the biosecurity plan may include:

- Routine regular cleaning and disinfection of all working parts of the facility to reduce environmental contamination. Some parts/items may be cleaned after use, when an item is moved from one location to another, or cleaned on a routine schedule.
- Thorough cleaning, disinfection, and downtime of housing areas between groups of animals.
- Regular maintenance of the outside area to discourage vectors, for example, mowing tall grass.

2.3.3.11 Security

Securing animal areas prevents breaches in the biosecurity protocol due to unauthorized access or a lack of vigilance after hours. Security considerations include:

- Buildings are locked when no one is present, preventing unauthorized access.
- Entry gates circumventing biosecurity procedures are locked at all times.

See FAD PReP/NAHEMS Guidelines: Cleaning and Disinfection for more detailed information on decontaminating people, equipment, vehicles, and premises. In addition, see Appendix F: Example - Producer Instructions - Quarantine/C&D for a summary of the C&D process.

Livestock owners and producers need to choose wisely from the list of biosecurity examples above. The list is not totally inclusive, but note that measures go beyond just cleaning and disinfection. All biosecurity measures should be chosen as best suited to the site and its operations to isolate animals as much as possible and protect them from exposure to disease.

See Appendix C: Checklist for Self-Assessment of Enhanced Poultry Biosecurity for an example of guidance that may assist the poultry industry in developing operational procedures for a biosecurity plan. This checklist may be modified to be applicable to other livestock industries. Another resource is the USDA HPAI Biosecurity Checklist, which can be accessed by the link under USDA Resources on the For More Information page at the end of this document.
3. PREMISES BIOSECURITY

The scope of recent livestock disease outbreaks in the United States, such as swine enteric coronavirus diseases (SECD) and both high and low pathogenicity avian influenza (AI), demonstrated that routine biosecurity practices for some livestock facilities were inadequate and need to be strengthened. In the event of an outbreak, quickly implementing major enhancements to structural biosecurity in existing facilities may not be possible. Recommendations in this section are intended to enhance operational biosecurity through mitigation of some common risks. However, producers need to consider enhancing both structural and operational biosecurity to reduce their overall vulnerability to disease.

The elements below are to be implemented as part of normal operating procedures. These basic concepts have been drawn from the options presented above, and may be considered the minimum for a production facility. If an FAD is detected, additional biosecurity procedures may be necessary.

Premises biosecurity is an important component of the continuity of business plans. These plans, also known as the Secure Food Supply Plans, are focused on managing non-infected premises, animals, and animal products in the event of an FAD outbreak. These plans address biosecurity for bioexclusion and provide guidance on permitting the movement in a Control Area of animals and animal products with no evidence of infection. To be eligible for managed movement, specific biosecurity standards must be met. Biosecurity standards are described in, and are specific to, each plan. Some standards are still in development. Details about these plans can be accessed through web links to the Secure Food Supply Plans provided in the For More Information section at the end of this document. See separate web sites for milk, pork and poultry. The Secure Poultry Supply Plan is in transition to include eggs, layers, broilers, and turkeys. In addition, the Secure Beef Supply Plan is in development.

3.1 Biosecurity Officer/Biosecurity Manager

Each production site (or integrated system) should have an individual assigned to designing and developing a site-specific biosecurity plan, and implementing effective biosecurity procedures. Under normal, day-to-day operations, a Biosecurity Officer or Biosecurity Manager assigned to this task may be associated with the facility. The plan should be institutionalized as clearly written procedures that are transparent and readily available. Details may be articulated in SOP documents or other training materials. This Biosecurity Officer/Manager is responsible for implementing the plan, training all personnel who enter the premises, and continuously monitoring the procedures for compliance with the plan. This individual should have the authority to stop violations, take corrective actions as needed, and adapt the plan to address changing risks. During an FAD response, Incident Command may assign a responder, possibly titled a Biosecurity Manager or Site Manager, to this same responsibility on an Infected Premises. The Biosecurity Officer/Manager should have the authority to certify that the biosecurity plan has consistently been followed by all.

3.2 Training of Personnel

The site-specific biosecurity plan should be communicated and distributed to everyone who accesses the facility. Responders, or in the case of normal operations, farm employees, contract crews, truck drivers, service personnel, and any visitors are trained on site-specific biosecurity procedures. Training materials should be provided in languages understood by those being trained. The training should be reviewed and documented. Everyone needs to understand the concepts and procedures that apply to their area of responsibility and understand the importance of all the steps. Audits and periodic refresher training should be ongoing.
3.3 Line of Separation

An essential component for improved biosecurity is to implement a line or barrier – imagined or physical – separating clean (non-infected) from dirty (potential sources of infection). This barrier may be termed the Line of Separation, the Clean/Dirty Line, and may serve as a Cleaning and Disinfection Line (C&D Line). In some cases, the barrier will be a physical obstruction that separates areas. This barrier or Line of Separation will be site-specific, and may be implemented at the farm level (e.g., the circumference of the farm), or at the barn level (e.g., the walls of each individual housing unit); some plans may establish this Line somewhere in between. The biosecurity plan must address how this Line will be defined and defended for each animal population when movement needs to cross this Line. The plan will identify essential versus nonessential movements across this barrier, and define the biosecure procedures to enable essential movement across this barrier. A location where movement crosses this Line becomes a critical control point to stop transfer of disease. For biosecurity purposes, limiting the number of controlled access points across this barrier will simplify mitigation. Ideally, limiting access across this barrier to only one location will greatly enhance compliance of strategic actions implemented there.

For an example of how this Line of Separation can be implemented, see Appendix B: Example - Danish Entry System.

3.4 Perimeter Buffer Area

Biosecurity plans, particularly plans for livestock raised indoors, may incorporate the Perimeter Buffer Area concept. Figure 9 is a simplified illustration of a Perimeter Buffer Area around an animal building, along with the Line of Separation. This peripheral buffer serves to place additional separation between the contaminated and non-contaminated space, and further protect the susceptible animals. Complete exclusion of disease in this area is not possible, but reducing pathogen load in the environment between the two spaces will reduce risk. Efforts include preventing visible contamination from entering the Perimeter Buffer Area and keeping premises traffic patterns within it. The Perimeter Buffer Area should be clearly delineated and located so that personnel comply with biosecurity procedures related to that area. When determining the buffer area, account for traffic patterns on the premises, the topography around the animal housing, weather extremes, and what is known about the pathogen and its infectivity. If personnel need to leave the Perimeter Buffer Area, they reenter through a controlled access point, following appropriate biosecurity measures. An operational cleaning and disinfection station is recommended to remove visible contamination from vehicles, equipment, and items needing to enter this area. See Appendix A: Example – Perimeter Buffer Area - Line of Separation for more detailed description of implementation.

3.5 Personnel

Personnel and their clothing/footwear may become contaminated by disease agents through direct and/or indirect exposure. Site-specific biosecurity procedures are intended to minimize the risk of transferring disease across the critical control points. It is mandatory that all personnel comply with the level of biosecurity implemented at that site.
3.6 Vectors – Pets, Wildlife, and Insects

Just as the routes of exposure to disease were discussed above, control measures should be implemented to prevent the transfer of disease by wildlife (i.e., wild birds, rodents), feral animals, and insects which can act as vectors. Commonly, pets reside on production facilities and can contribute to disease risk as mechanical vectors. Control measures should address the exclusion or elimination of these vectors. Measures also include avoiding environmental contamination through wildlife feces or infectious secretions, and preventing the movement of contaminated material. Protocols should mitigate situations and habitat that are attractive to wildlife and scavengers, such as spilled feed, disposal areas, or wildlife nesting areas.

3.7 Equipment

Biosecurity measures should diminish the opportunity for equipment to serve as fomites. Equipment should be effectively cleaned and sanitized before crossing the Line of Separation at a critical control point. Disease agents are easily transferred by the sharing of equipment by different animal populations. An important biosecurity measure is to have, provide, and use sufficient equipment to avoid sharing.

3.8 Vehicles

Vehicles are a source of contamination with pathogens from other farms or from other animals. If at all possible through structural measures or operational processes, exclude vehicles such as feed deliveries, milk haulers, load-out carriers, and employee and visitor cars from crossing the Line of Separation. Vehicles crossing into the protected area of the premises should be thoroughly cleaned and disinfected. Particular attention needs to be paid to wheels and wheel wells. The cargo area of animal transport vehicles needs to be thoroughly cleaned and disinfected between loads.

See FAD PReP/NAHEMS Guidelines: Cleaning and Disinfection for more detailed information on decontaminating equipment and vehicles. In addition, see Appendix F: Example - Producer Instructions - Quarantine/C&D for a summary of cleaning and disinfecting procedures.

3.9 Carcass Disposal

Carcasses should be disposed of in a manner that protects susceptible animals from disease exposure, particularly from cross-contamination with carcasses from off-site or other processes. The disposal process should also prevent the attraction of wild animals or scavengers.

3.10 Manure/Litter Management

Manure and spent litter should be removed in a manner to prevent exposure of susceptible animals. As mentioned above, biosecurity measures should prevent cross-contamination, in addition to discouraging scavengers.

3.11 Replacement Animals

Under normal conditions, additions to the herd/flock may be made from offspring born and raised on the operation, which is described as a closed herd. Any replacement livestock/poultry from outside the operation should come from herds/flocks with documented biosecurity practices and a history of freedom.
from infection. This also applies to embryos and semen obtained from outside sources. Live animals from outside sources should be isolated/quarantined for as long as 30 days before being allowed to comingle with the existing population. Surveillance testing on the source herd/flock and/or on individual additions helps to document health status.

Ideally animals should be managed as all-in/all-out, meaning groups stay together from the time of arrival, through growth, until they leave for processing. Animals of different groups, or ages are not mixed. Between one group leaving and the arrival of the next group, the housing is cleaned, disinfected, and left empty for a period of downtime to minimize carry over of pathogens from one group to the next.

Replacement animals should be transported in vehicles cleaned and disinfected (exterior and cargo areas) to minimize the risk of disease transmission from previously transported loads.

When a herd/flock is under quarantine, no animals are allowed to be added to or leave the premises without specific permission from the animal health official or Incident Command.

3.12 Feed, Replacement Bedding/Litter, and Water Supply

Feed, feed ingredients, bedding/litter, and water can be contaminated if they have been exposed to a disease pathogen through vectors or containers acting as fomites. Grain, feed, and fresh bedding/litter should be stored and handled so that it cannot be contaminated. Water should come from deep wells or sources that have been treated to eliminate any potential contamination with live pathogens.

This Guidelines document will focus on actions and activities, considered operational biosecurity, but will also encourage the appreciation of structural and conceptual aspects of biosecurity. Biosecurity protocols are recommended for day-to-day protection of livestock health as well as for emergency on-site response operations.

4. BIOSECURITY COMPONENTS - C&D AND BIOSECURITY ATTIRE/PPE

Biosecurity practices are site specific; however, two components are part of most every biosecurity plan – 1) cleaning and disinfection (C&D) and 2) biosecurity attire, most often called personal protective equipment (PPE). C&D procedures are used to reduce, inactivate or destroy biological pathogens thereby inhibiting or eliminating their further spread. PPE is utilized as a biosecurity tool to prevent contaminated clothing and footwear from serving as fomites. In a zoonotic disease event, PPE also serves as a barrier to protect personnel from the disease agent. Although these two components are highly significant, they are only a part of a complete biosecurity plan.

4.1 Cleaning and Disinfection (C&D)

Cleaning and disinfection (C&D) are standard practices in most biosecurity plans to reduce, remove, inactivate, eliminate, or destroy pathogenic microorganisms. C&D in some form, and sometimes in a combination of methods, is conducted on most items that cross the Line of Separation when moving from dirty to clean areas – people and their clothing, equipment, supplies, and larger items such as vehicles and heavy earth moving equipment. Since this Line may serve as the convenient location for C&D activities, it may also be called the C&D Line. Because the C&D process is time consuming, even for smaller items like eyeglasses, only essential items should cross the Line. As an alternative, choose items that can be disposed of in a biosecure manner.

C&D methods can involve the use of physical (e.g., heat or ultraviolet light) or chemical (e.g., detergents, sanitizers, disinfectants, sterilants) processes. Because disinfectants are less effective in the presence of
organic load, cleaning – either physical or chemical – is performed first to remove organic material. When using water for a C&D station for people, equipment, and vehicles, choose a convenient location between dirty and clean areas, and contain the run off of spent fluid to prevent it from seeping into open water or areas around nearby wells.

Disinfection processes vary in their level of destruction of microorganisms. Microorganisms vary in their susceptibility to disinfection. Other factors influencing the process include hardness of the water, the interaction with other chemicals, the type of surface or material to be disinfected, the caustic nature of some chemicals, and the effectiveness of the process in the presence of organic material. Appropriate contact time for a disinfectant must be followed, whether the application is physical, such as heat or ultraviolet light, or chemical as a solution. Some processes are not practical for the situation. All of these are important considerations when selecting and conducting C&D activities.

C&D is also used for environmental cleanup, to disinfect areas between groups of animals, as well as to eliminate the pathogen from an Infected Premises. In this case, certain equipment may need to be disconnected, protected, or turned off before the process begins. This equipment will need to be cleaned and disinfected separately with an appropriate and effective method.

In certain circumstances, heat treatment as a disinfection step has been an acceptable method of elimination of some pathogens, such as some viruses, in the environment; heat treatment was used in both the 2014–2015 and 2016 HPAI outbreaks. For more information on how heat treatment is used, consult HPAI Response, Cleaning and Disinfection Basics (Virus Elimination) on the USDA APHIS FAD PReP web site. A web link to the FAD PReP web site is provided in the For More Information section at the end of this document.

After C&D, final inspection should be conducted by authorized personnel, as appropriate. Any doubt or sign of inadequate procedures should prompt the process to be repeated. Once final inspection has occurred, downtime is usually required of a premises before restocking. Movement of a cleaned and disinfected item across the Line of Separation may occur.

For more detailed information on the process, disinfectants, and microbial sensitivities, see FAD PReP/NAHEMS Guidelines: Cleaning and Disinfection, and FAD PReP Standard Operating Procedures: Cleaning and Disinfection. These documents can be accessed by a web link to the FAD PReP web site provided in the For More Information section at the end of this document. Appendix F: Example - Producer Instructions - Quarantine/C&D provides a summary of movement restrictions and C&D steps.

4.2 Biosecurity Attire/Personal Protective Equipment (PPE)

The outer clothing worn by personnel presents a significant risk in transferring pathogens from one location to another. The risk needs to be mitigated in day-to-day protocols, as well as in FAD response. Biosecurity plans to prevent the introduction (bioexclusion) of disease may include the use of specific biosecurity attire. Disposable gloves, disposable boots or reusable boots that can be cleaned, and a change of outer clothes in preparation to enter an animal area may be required. Some facilities may provide specific outerwear for personnel crossing the Line of Separation into animal areas, and maintain/launder this outerwear on-site. The goal is to prevent exposure of livestock to potential contamination on street clothes, by either leaving street clothes on the dirty side, or covering street clothes with clean coveralls and footwear.
In an FAD response, PPE is the standard (biocontainment). PPE is intended as a barrier to protect the user from hazards, such as biological and chemical agents, loud noises, and trauma. PPE items include impermeable outer clothing, respirators, ear plugs, and hard hats. In livestock disease, PPE as outer clothing, along with the proper protocols, are also used to prevent the transmission/spread of pathogens via contaminated clothing. Disposable coveralls (e.g., Tyvek®), aprons, gloves, and boots (see examples at right), when properly utilized, prevent clothing from acting as a fomite. In an animal health emergency, disposable PPE is preferred, as opposed to outer clothing that needs laundering.

Only the appropriate selection, donning (putting on), doffing (taking off), use, and cleaning and disinfection/disposal of PPE will mitigate the spread of disease, as well as properly protect the responder. Multiple factors must be considered when selecting PPE to ensure a safe and effective response. The risks based on the specific working environment, the tasks, and the pathogen will determine the level of protection for the responder. The Occupational Safety and Health Administration (OSHA) classifies PPE into four levels of protection. The levels range from D (lowest level of protection) to A (highest level).

Level D includes minimal skin protection and no required respiratory protection. Work clothes, safety boots and safety glasses are part of the Level D PPE ensemble. Dust masks used on a voluntary basis may be part of the Level D PPE ensemble. Level C includes skin protection with an outer barrier of chemical resistant clothing, including disposable gloves, boots, and head cover. Eye protection, as with goggles or a face shield, and respiratory protection with an air purifying respirator are also required with Level C PPE. For certain circumstances, APHIS also describes Level D Modified as the same as Level D for respiratory protection, but the skin protection is increased to that of Level C.

The level of PPE for a particular response will be based on OSHA, Centers for Disease Control and Prevention (CDC), and APHIS guidance. Decisions will be made by the Incident Safety Officer, and direction will be provided in the Incident Health and Safety Plan (HASP) specific for the incident.

PPE needs to be donned and doffed in a proper sequence to effectively protect the wearer and to prevent the spread of the hazard. The order of donning is critical, and dictates the proper order of doffing to avoid cross contamination. The intent is to prevent the outerwear from serving as a fomite in disease spread. For additional details on the levels of PPE, and the sequence of steps for donning/doffing, consult FAD PReP/NAHEMS Guidelines: Personal Protective Equipment (PPE).

Some PPE may be bulky and interfere with the wearer’s normal range of motion, making walking and other movements more difficult. Some PPE may have limitations for the duration of safe use. In addition, working in PPE can create challenges for the wearer such as overheating. Precautions need to be taken to prevent slips and falls, and warning signs of physical stress need to be recognized. Be sure to understand and follow all established guidelines for the use and care of PPE. For more information on safety issues while wearing PPE, and other hazards that threaten responders’ health, see FAD PReP/NAHEMS Guidelines: Health and Safety.
5. BIOSECURITY IN AN FAD RESPONSE

The APHIS Foreign Animal Disease Preparedness and Response Plans (FAD PReP), including the APHIS Foreign Animal Disease Framework: Response Strategies (FAD PReP Manual 2-0), outline three response goals for an FAD outbreak in the United States:

1. Detect, control, and contain the disease in animals as quickly as possible;
2. Eradicate the disease using strategies that seek to stabilize animal agriculture, the food supply, and the economy and that protect public health and the environment; and
3. Provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products.

Achieving these three goals will allow individual livestock facilities, States, Tribes, regions, and industries to resume normal production as quickly as possible. The objective is to allow the United States to regain disease-free status without the response effort causing more disruption and damage than the disease outbreak itself.

Biosecurity plays a vital role in each of these goals, in controlling and containing an FAD on a premises that is potentially infected in order to facilitate eradication, and in protecting the health of non-infected animals on premises not considered infected to allow continuity of business. If an FAD is zoonotic, biosecurity protects responders’ health along with the public’s health. Biosecurity measures necessary to protect responders in a zoonotic event are explained in FAD PReP/NAHEMS Guidelines: Health and Safety and in FAD PReP/NAHEMS Guidelines: Personal Protective Equipment (PPE).

FAD response activities involve contact with infected animal populations, as well as with contaminated premises. Response activities also involve those premises with animals considered non-infected. Biosecurity applies to both biocontainment as well as bioexclusion. To meet the response goals above, measures are implemented to prevent the escape and/or introduction of pathogens. The farm, or the area outside the farm, may be considered the dirty or clean side depending on disease status of the animals on the farm. In their assigned duties, response personnel need to be aware of and respect all levels of biosecurity – the mitigation steps implemented in the operational protocols and the design of the structural biosecurity, as well as conceptual biosecurity in how the facility is sited.

During an FAD event, implemented biosecurity protocols will vary with the type of livestock facilities – small backyard, open outdoor facilities, confinement facilities including large and complex production units – as well as with the disease/health status of the livestock in the facility, the disease pathogen, and type of response activities ongoing. Cleaning and disinfection (C&D), although a significant component, is only part of the overall biosecurity program, whether a responder is assigned to the clean or the dirty side of operations. Employing the most practical and effective measures is based on site-specific risks.

5.1 Zones and Premises in an FAD Outbreak

Immediately after an FAD detection, a regulatory Control Area, comprised of an Infected Zone and Buffer Zone, will be designated to surround the Infected Premises. Premises designations reflect the disease or disease-free status of the animal population related to the FAD. If animals are no longer present, the designation reflects the infective risk of the location, as known at that time.

Infected, Contact, and Suspect Premises are considered infected/contaminated locations, or potentially infected/contaminated, and placed under quarantine. Once designated as an Infected Premises, depopulation, disposal, and cleaning and disinfection may be performed, termed dirty operations. In a disease response, even with strict biosecurity protocols, it is prudent to limit these responders to
assignments only on infected/contaminated premises to avoid unintentionally transferring a disease agent to unaffected animals. Biocontainment is the focus for personnel assigned to response activities on these premises.

Contact and Suspect Premises may be involved in an epidemiological investigation. The results of the investigation are needed to confirm the disease status of the animals as infected or non-infected. It is imperative to use biosecure methods of entry onto those premises, so as not to introduce disease, as well as biosecure methods of exit. “Dangerous Contact Premises” may be depopulated, like an Infected Premises, during an outbreak; if a premises is being depopulated, it should be treated like an Infected Premises.

At-Risk, Monitored, and Free Premises are considered locations with no evidence of disease. Response activities on these premises, such as surveillance, audits, or vaccination if implemented, are termed clean operations. Uninfected facilities located within a Control Area are at higher risk of becoming infected due to their proximity to infected neighbors. Surveillance of livestock on Free Premises in the Surveillance Zone (which is part of the Free Area), outside of the Control Area, will be conducted for early detection as well as for data collection on freedom from disease. Bioexclusion is the focus in preventing exposure of susceptible animals to the disease. The response zones, areas, and premises designations will change over the course of an incident as the outbreak expands, or is contained and eradicated, and as the premises are decontaminated.

The designations identify those premises that may be a source of infection, and those that may be at enhanced risk of exposure to disease. In addition, the designations indicate the type of activities that may be occurring at these locations and the type of biosecurity measures needed. See Appendix D: Zones, Areas and Premises for more detailed descriptions of designations and maps.

Specific biosecurity guidance will be provided by Incident Command. USDA’s FAD PReP Response Plans guide activities and address biosecurity measures on Infected, Contact, At-Risk, and Monitored Premises. Business continuity plans for Monitored Premises (those within the Control Area and affected by movement restrictions, but not infected with an FAD) provide biosecurity guidance for a premises to be considered eligible for movement of livestock and commodities out of a Control Area. Biosecurity standards are described in, and are specific to, each plan. Web links to the Secure Food Supply Plans for eggs, milk, turkeys, broilers, and pork are provided in the For More Information section at the end of this document.

5.2 Roles and Responsibilities during an FAD Response

In an FAD response, the Incident Command System (ICS) is the organizational management structure utilized to coordinate activities and delegate specific responsibilities. An Incident Management Team (IMT) composed of the Incident Commander and appropriate staff may be deployed to the incident. This structure is flexible and scalable based on the needs of the incident. The structure will depend on the size, scope, and nature of the incident. Biosecurity activities are conducted by personnel assigned to the Operations Section. An example of an organizational structure is provided in Appendix E: Example – Incident Management Team. Please note that this structure is only an example and may change at any time.

Implementing biosecurity measures is crucial, beginning with the first report of a potential FAD. The foreign animal disease diagnostician (FADD) is responsible for implementing initial biocontainment principles during the FAD investigation. If an FAD is suspected, the premises will be quarantined to prevent movements of animals; other types of movements on/off the premises will be restricted.
As an ICS organization is implemented, the responsibility of overseeing biosecurity will be delegated to one or more responders. For example, a Group Supervisor may lead the group responsible for biosecurity, and supervise teams and team members’ activities. The personnel within the Operations Section are responsible for ensuring that a site assessment of each contaminated premises is performed, a site-specific biosecurity plan is developed, and appropriate biocontainment measures are implemented to prevent the spread of disease off the premises. In addition, the group responsible for biosecurity determines resource needs, such as personnel, PPE, and C&D equipment, and verifies all personnel assigned to implement biosecurity activities are properly trained. All personnel responsible for biosecurity need to coordinate with other responders responsible for other on-site activities, such as C&D, depopulation, and disposal. Biosecurity plans and procedures must be followed by all.

Biosecurity Managers (may also be called Biosecurity Officers) appointed by Incident Command may report to a Biosecurity Group Supervisor, or other designee. This individual may be assigned to one or more premises to provide on-site management, coordination, and to gain compliance by personnel assigned to other response activities. He/she reports needs, problems, challenges, and biosecurity violations to the appropriate personnel per the chain of command. Biosecurity managers have the ability to halt operations or stop a worker from breaching biosecurity. In an FAD, it is anticipated that a variety of production systems may be affected; biosecurity plans need to be individualized, and constant attention to compliance is crucial.

The personnel responsible for biosecurity (for example, this may be a Biosecurity Group Supervisor or other designee) also develops the biosecurity plans for the clean side of operations, focused on bioexclusion and protecting naïve animal populations within the Control Area and the Surveillance Zone. Responders assigned to surveillance will look to these protocols in conducting surveillance activities.

**5.3 Biocontainment - Preventing Disease Spread off of a Premises Considered Infected**

In an FAD outbreak, some responders will be conducting activities on the dirty side of operations, on-site at contaminated premises, or at those considered contaminated. Once disease control zones are set up, these contaminated premises will be located within a disease Control Area, as described above. Infected Premises, Contact Premises, and Suspect Premises will be under quarantine. The activities conducted on these premises may include appraisal, depopulation, disposal, and cleaning and disinfection. Biocontainment of the pathogen will be the focus when conducting response operations.

In general, these premises are considered contaminated throughout the operation. However, responders need to confirm if any part of the operation has been treated as a biosecure unit, and should be treated as non-infected, as that will modify protocols presented here.

**5.3.1 Work Zones**

Traditionally, biosecurity principles at facilities with infected animals, or facilities suspected to be contaminated by infected animals, have been described using containment terms related to hazardous materials (HAZMAT) incidents. Containment areas have been described using Work Zones, designated as the Hot Zone or Exclusion Zone (EZ), Warm Zone or Contamination Reduction Zone (CRZ), and Cold Zone or Support Zone (SZ). By implementing these Work Zones, access to contaminated areas is controlled to prevent the transfer of the disease agent to other livestock or areas. These Work Zones also have a defined Decontamination Corridor described below, which serves as the point of access on or off the premises.
Work Zones are one method of creating a separation of the dirty area (potential source of infection) from clean area (non-infected). Once designated as a contaminated premises, usually the whole farm or operation is considered an infective risk. In this case, the Hot Zone - Exclusion Zone designates the dirty or contaminated premises associated with the infected herd or flock. The Cold Zone - Support Zone is the non-contaminated area outside the premises. The Warm Zone - Contamination Reduction Zone is regarded as having a reduced pathogen load in the environment and acts as a buffer further separating contaminated from non-contaminated. The Decontamination Corridor is within the Warm Zone - Contamination Reduction Zone. This corridor serves as access between the Hot and Cold Zones. It is the transition through which the pathogen load is reduced from Hot to Cold. Personnel, equipment and vehicles transition through the Decontamination Corridor before crossing the Line of Separation into the Cold Zone – Support Zone (SZ). The Decontamination Corridor is where biosecurity actions are taken to prevent the disease from “crossing the line” during necessary movements of people, equipment, and possibly vehicles.

The Work Zones are illustrated in Figures 10 and 11. Descriptions provide additional detail. Specific biosecurity protocols related to a premises considered infected are described below.

### 5.3.1.1 Hot Zone – Exclusion Zone (EZ)

This high-risk area is where infected animals are, or were, housed and is potentially contaminated and considered unsafe. Full personal protective equipment (PPE) must be worn. Appraisal, depopulation, disposal, and facility cleaning and decontamination of the site occur in this area. Personnel and equipment enter and exit the Hot Zone – Exclusion Zone (EZ) through designated access points at either end of the Decontamination (Decon) Corridor.

### 5.3.1.2 Warm Zone – Contamination Reduction Zone (CRZ)

In HAZMAT response, the Warm Zone - Contamination Reduction Zone (CRZ) is regarded as having a reduced hazard (pathogen) load in the environment, but is still a high-risk area due to the potential of
exposure to pathogens and chemical disinfectants. In an FAD response, all personnel are required to wear full PPE. Entry from the Warm Zone - Contamination Reduction Zone (CRZ) to either the Cold Zone - Support Zone (SZ) or Hot Zone - Exclusion Zone (EZ) occurs through the designated access points. For workers exiting the Hot Zone - Exclusion Zone (EZ) decontamination and disinfection is performed in the Decontamination Corridor of the Warm Zone - Contamination Reduction Zone (CRZ). Exiting the Warm Zone into the Cold Zone, the Line of Separation would be crossed. Site-specific protocols for PPE, decontamination, and disinfection must be strictly followed.

5.3.1.3 Cold Zone – Support Zone (SZ)

This is the “cleanest” work zone with the lowest relative risk of exposure to pathogens and other hazards, such as decontamination chemicals. In this zone, personnel are not required to wear PPE; however, facilities for donning PPE before entering other zones are provided. Administrative, clerical, and other support functions are based here. Medical support is provided to personnel in this zone. Facilities for personal needs such as eating, drinking, and bathroom use are provided. Contaminated articles and equipment are prohibited in this area. Decontamination activities in this zone are prohibited.

5.3.1.4 Decontamination (Decon) Corridor

The Decontamination (Decon) Corridor is located within the Warm Zone – Contamination Reduction Zone (CRZ) (Figure 11). The level of contamination should decrease along this transition corridor toward the Cold Zone – Support Zone (SZ). Movements between the Hot Zone - Exclusion Zone (EZ) and the Cold Zone - Support Zone (SZ) occur through the designated, controlled access points of the Decon Corridor. All response personnel are required to don full PPE before entering the Decon Corridor from the Cold Zone – Support Zone. All personnel are required to exit the Hot Zone - Exclusion Zone (EZ) through the Decon Corridor before crossing the Line of Separation into the Cold Zone. Site-specific protocols for PPE, decontamination, and disinfection must be strictly followed at this controlled access. Decontamination of personnel and equipment, including vehicles, occurs along the corridor with stations for depositing tools, equipment, and other items. Final decontamination and disinfection of PPE as well as final doffing of PPE occur in this corridor.

![Figure 11. Work Zones](image-url)
5.3.2 Biosecurity Protocols for Biocontainment

Biosecurity protocols for emergency personnel involved in response tasks on-site are well developed. Movement between contaminated and non-contaminated areas across the Line of Separation must occur through the Decontamination Corridor. Additional actions include steps taken prior to entry, while on-site, and upon leaving the Hot Zone. They pertain to people and their clothing, supplies and equipment, and vehicles. Protocols, when implemented correctly, help prevent the escape of pathogenic agents out of the dirty area of contamination, called the Hot Zone.

Prior to entering the Hot Zone:

- Understand all biosecurity protocols for the assigned task. Our example using the Work Zones above considers the farm/operation to be contaminated. Less often, based on individual biosecure units, the Decontamination Corridor may be located as an entry/exit to a portion of the operation.
- If not already established, identify the Hot, Warm and Cold Zones.
- Keep vehicles on the clean side, in the Cold Zone, on a hard surface if possible.
- Don PPE, which is used as a biosecurity measure, as well as personal protection needed for the assigned task. Disposable PPE is optimal, and is standard for outerwear in livestock disease situations. Examples of PPE include disposable coveralls (e.g., Tyvek®), boot covers, head cover, and gloves for biosecurity purposes, in addition to respiratory, head, and hearing protection, as needed. Reusable boots that can be cleaned and disinfected are often preferred footwear. Check all PPE items for tears/defects and don prior to exiting the vehicle to avoid contaminating street clothes.
- Don PPE in the appropriate order. The donning process is specific to facilitate the correct order of doffing to avoid inadvertent cross-contamination.
- Prepare to contain or handle used disposable items in a biosecure manner to avoid the transfer of pathogens. In wet or muddy conditions, waterproof or nylon coveralls may be necessary. Reusable outerwear is best laundered/cleaned and disinfected at the premises if possible.
- Do not wear jewelry or carry items such as cigarettes, gum, food, drink, etc. into the Hot Zone.
- Place cell phones and electronics in sealed plastic bags or waterproof cases to allow disinfection upon exiting the Hot Zone.
- If not already established, set up all supplies needed to clean and disinfect for a biosecure exit. These supplies will be used at the Decontamination Corridor before crossing the Line of Separation, which is also called the Clean/Dirty Line.
- Take only necessary supplies, tools, and equipment into the Hot Zone. Note that all supplies and equipment will either be cleaned and disinfected upon exiting, or disposed of. Due to the effort to clean and disinfect vehicles and large equipment, only essential equipment should enter the Hot Zone.
- Enter the Hot Zone through the proper access point.

While in the Hot Zone:

- Perform required tasks while minimizing unnecessary exposure to the pathogen.
- Avoid straying into other parts of the premises to prevent further spread of environmental contamination.
- Limit exposure and contact time of heavy equipment and vehicles with contaminated areas.

Upon leaving the Hot Zone:

- Exit only through the Decontamination Corridor.
- Clean and disinfect all supplies, tools, and equipment leaving the Hot Zone. This includes the outer plastic bags holding cell phones and electronic equipment. Items that cannot be decontaminated must be left behind for later cleaning, or disposal.
- Clean and disinfect vehicles and large equipment that are exiting the Hot Zone. In addition to the easily visible surfaces, take extra care cleaning the wheel wells and under carriage.
- Place all trash and disposable items in a plastic trash bag.
- Clean and disinfect reusable PPE, such as boots, paying extra attention to the soles and treads.
- Doff PPE in the proper sequence to avoid inadvertent cross-contamination. Take care to avoid contacts that may cause re-contamination.
- Dispose of PPE in the trash bag and tie off the bag. Double bag the trash, tie off the outer bag, and disinfect the outer bag prior to carrying it across the Line of Separation (C&D Line).
- Exit the Decontamination Corridor, crossing over the Line of Separation into the Cold Zone.
- Wash hands or use a hand sanitizer.
- As an extra precaution, spray vehicle tires and wheel wells with disinfectant prior to driving away.
- Avoid contact with other susceptible animal populations as directed by Incident Command.

During an animal health emergency response, some response personnel may be required to visit multiple premises during the course of a work day. These personnel must be aware that these activities increase the risk of disease transmission and must be especially diligent with respect to compliance with biosecurity practices.

5.4 Bioexclusion - Preventing Disease Spread onto a Premises Considered Non-infected

In an FAD outbreak, some responders will be conducting activities on the clean side of operations, on-site at premises not considered to be contaminated. At-Risk Premises and Monitored Premises will be located within a Control Area and have a higher risk of becoming infected than those outside the Area due to the proximity of Infected Premises. Compliance with biosecurity procedures upon entry is critical. Activities may also be conducted in the Free Area, which is the area not included in any Control Area and includes the Surveillance Zone. The clean side of operations may entail surveillance, sampling, and perhaps vaccination, if implemented. Surveillance to support freedom from disease for trade may be conducted in the Free Area. Bioexclusion will be the focus when conducting response operations.

5.4.1 Biosecurity Protocols for Bioexclusion

The biosecurity concepts for bioexclusion in an FAD outbreak are the same as for biocontainment. Again, the Line of Separation separates contaminated (dirty) from non-contaminated (clean). The efforts and activities are reversed. In this case, the animal side is considered clean, similar to the Cold Zone. The Hot Zone is considered to be all other areas due to potential contamination. Now the focus is on preventing pathogens from crossing the Line to get in. The location where this Line is crossed is a critical control point.

In this section on bioexclusion, a Perimeter Buffer Area is considered as a peripheral zone with a reduced level of pathogen contamination. Depending on the facility and the biosecurity plan in place, the biosecure unit may be the farm, or individual barns. The example in this discussion will illustrate entry into a clean operation through a Perimeter Buffer Area, and across a Line of Separation, applied at the barn level. Livestock raised outdoors, as in a feedlot, may not have a designated Perimeter Buffer Area. In those biosecurity plans, the Line of Separation may be at the farm gate, and biosecurity protocols are conducted there as the controlled access point. The intention is to prevent the introduction of disease into a non-infected, but susceptible population of animals.
The following are biosecurity steps for responders involved in entering a premises that is considered non-infected.

Prior to crossing the Line of Separation:

- Be sure the owner/manager of the premises is aware of your visit. Encourage a representative of the premises to serve as an escort to ensure only authorized areas are visited.
- Confirm all existing biosecurity requirements for entering the premises. The facility may have structural and operational biosecurity measures in place. As a minimum, comply with existing requirements. Steps described in this section may be followed in addition.
- If the premises has no biosecurity plan designating a Perimeter Buffer Area and Line of Separation, establish a Line to isolate animals from potential contamination for this visit. Defend this Line by preventing disease agents from crossing.
- Ensure that anything that needs to cross the Line of Separation has been disinfected and is free of contamination.
  - If site-specific outerwear is not provided, be prepared with disposable PPE or freshly laundered outerwear/coveralls, and cleaned and disinfected footwear/boots.
  - Foot baths for boots need to have fresh disinfectant and a brush to scrub the soles ensuring complete disinfection between the treads.
  - No supplies or tools should cross without thorough cleaning and disinfection. Items that have been exposed to another population of animals, even indirectly, are considered high risk.
- Organize your vehicle with separate clean and dirty compartments.
  - Keep all items that need to cross the Line of Separation in the clean compartment.
  - Keep clean and dirty compartments well separated physically.
  - Prepare a secure area, such as a washable tub with a tight lid, to receive any items that need to be cleaned and disinfected prior to the next premises visit.
- Prepare fresh cleaning and disinfection supplies to use at entry and exit.
- Arrive at the premises previously showered and wearing clean street clothes.
- Park the vehicle on a hard surface away from animal areas, or in the designated parking area. Park outside of any designated Perimeter Buffer Area.
- Leave unnecessary personal items, such as cell phones and jewelry, and all food in the vehicle.
- Don disposable PPE (coveralls, boot covers) or freshly laundered outerwear/coveralls, including cleaned and disinfected boots.
- Prior to entering the animal area, check with management personnel, and complete a visitor logbook. Comply with facility protocols on crossing their designated Line.
- Don new boot covers, or clean and disinfect boots, and wash hands prior to crossing the Line of Separation to enter animal areas.
After crossing the Line of Separation:

- If it is necessary to sample or have contact with several groups of animals, start with the most disease susceptible group, and finish with any groups showing clinical signs. An alternative is to change clothes, disinfect boots and all equipment, and use only clean supplies before contacting each group.

Exiting the Line of Separation:

- When crossing back to the outside of the Line of Separation to exit, follow the entry protocols in reverse.
- Clean and disinfect boots and any equipment. Doff facility-owned outerwear to be laundered on-site. Place used coveralls and all equipment that could not be disinfected on-site in the secure dirty compartment of the vehicle until cleaning and disinfection. Disposable PPE may be managed on-site or secured like reusable outerwear/coveralls for later disposal.
- Clean response vehicles between visits to animal production facilities. Cleaning should include interiors and floor mats. Vehicle carpets should be covered by plastic floor mats. Exterior cleaning should focus on any visible organic matter, tires and wheel wells. Commercial car washes with wheel-well washing provide adequate exterior cleaning. Tire sprays may be needed in some situations.

For visual illustrations of the concepts of bioexclusion at the farm level and at the barn level, see Appendix A: Example - Perimeter Buffer Area - Line of Separation, and Appendix B: Example - Danish Entry System at the end of this guidelines document.

### 5.5 Biosecurity for Surveillance and Epidemiology Activities During a Response

Disease investigation and diagnostic sampling will be performed within the Control Area on premises with animals that are potentially infected, such as Contact Premises and Suspect Premises. Environmental sampling following cleaning and disinfection of Infected Premises will be necessary before a quarantine will be released. Investigation activities will also be conducted on non-infected premises, such as At-Risk Premises and Monitored Premises to verify eligibility for movement. Also important, surveillance for disease will occur in the Surveillance Zone in the Free Area to collect data to support freedom of disease. Each of these situations may involve observational surveillance and/or diagnostic sampling. Biosecurity protocols need to be strictly followed to prevent disease introduction, and to prevent disease escape, particularly since responders may be visiting multiple premises in a day. Consider working in teams of two, so one member remains outside the Line of Separation and can assist the responder who enters the premises.

Both biocontainment and bioexclusion steps, as described previously in this document, are imperative for entering and leaving each premises. Establish the Line of Separation, across which pathogens are prevented to cross on entering. Defend this same Line upon exiting to prevent the transfer of pathogens off the premises. In addition to the steps taken to allow movement of people, equipment, and vehicles, diagnostic samples require additional steps, as potential disease agents are being removed from the premises.

- Before entering the premises across the Line of Separation, gather sample supplies. As much as possible, complete any documentation on submission forms. Prepare sample containers and/or sample bags with labels. Have clear zip-lock plastic bags ready to receive sample containers and documents/submission forms.
• Cross the Line to enter the premises, following proper bioexclusion steps.
• During the sampling process, protect samples and all containers to prevent cross contamination and minimize unintended contamination from the environment.
• Seal the diagnostic samples or containers (properly labeled) in plastic bags. Also seal documentation to submit with the samples in clear plastic bags with pertinent information turned outward to be read through the bag.
• Just prior to crossing the Line, disinfect the outside of the plastic bags – samples and documentation – by spraying or immersing them in disinfectant.
• As the bags cross the Line, double bag all samples, and spray outer bag containing samples with disinfectant. This step and the next steps for the samples may be completed by the assistant who remains outside the Line.
• Place the disinfected bags (samples and documentation) in a location where they will not be re-contaminated, such as directly into the clean cooler (on the clean side) for shipment to the laboratory.
• Ensure the necessary cold packs have been placed in the cooler. Place the lid on the cooler for transport.
• Cross the Line of Separation to exit the premises, following all biocontainment steps.

For more information, please see the Foreign Animal Disease (FAD) Investigation Manual (FAD PReP Manual 4-0). This document can be accessed by a web link to the FAD PReP web site provided in the For More Information section at the end of this document.

6. CONCLUSION

In conclusion, biosecurity helps to maintain food safety and security, protect the environment, and facilitate continuity of business by protecting animals and animal products. The importance cannot be over-emphasized in daily protocols intended to exclude disease, as well as in plans to contain disease. Plans and protocols are developed based on the assessment and evaluation of each individual site, and circumstances. Established biosecurity measures are effective only when they are consistently followed by everyone.

The concepts presented in this document, described as conceptual, structural and operational biosecurity, are presented as guidance to implement prior to an FAD threat and as concepts which must be implemented during an FAD response to prevent lasting negative impacts on the United States agriculture and general economy. In the face of a zoonotic disease, biosecurity, beyond the measures discussed here, is crucial to protect the health of responders and the public.
7. RESOURCES


Mount Sinai Hospital, Department of Microbiology. 1999. FAQ: Method of Disease Transmission. Available at: http://microbiology.mtsinai.on.ca/faq/transmission.shtml#two. Accessed 18 November 2015


8. FOR MORE INFORMATION

Canadian Food Inspection Agency
Annex B – Sample Standard Operating Procedures – Procedures for Barn Entry and Exit

Canadian Swine Health Board
The Danish Entry Principle - video
   https://www.youtube.com/watch?v=N4NNkd_Kfqw

Center for Food Security and Public Health, Iowa State University
Just-In-Time Training (JIT) funded by the Multi-State Partnership for Security in Agriculture
   Biosecurity for Animal Emergencies
   Cleaning and Disinfection
   Personal Protective Equipment (PPE) for Animal Health Emergencies
   Responder Health and Safety

National Institute for Occupational Safety and Health
Suggested Respirator Cleaning and Sanitation Procedures
   http://www.cdc.gov/niosh/npptl/cleaning.html

Ontario Pork Industry Council
Danish Entry System Poster – Keep Disease Out!
   (Accessed from the US Poultry and Egg Association web site)

Danish Entry Principle – The Hog Barn’s Physical Line of Defense
   (Accessed from the US Poultry and Egg Association web site)

Secure Food Supply Plans – Continuity of Business Plans
USDA Ready Reference Guide – Overview of the Secure Food Supply (SFS) Plans

Secure Milk Supply Plan
   http://securemilksupply.org/

Secure Egg Supply Plan*
   http://www.secureeggsupply.com/

Secure Broiler Supply Plan*
   http://www.securebroilersupply.com/
Secure Turkey Supply Plan*  
http://www.secureturkeysupply.com/

*Please note that these plans are being integrated into a single plan, which is in development. Please look to http://securepoultrysupply.com for further information on this consolidated plan.

Secure Pork Supply Plan  
http://www.cfsph.iastate.edu/Secure-Food-Supply/pork-supply.php  
http://www.securepork.org/plan-components.php

**United States Department of Agriculture (USDA) Resources**

Foreign Animal Disease Response (FAD PReP) materials (including HPAI resources)  
www.aphis.usda.gov/fadprep

FY2016 HPAI Response, Cleaning and Disinfection Basics (Virus Elimination)  

Listing of Potential Pesticides to Use Against the Causative Agent of FADs in Farm Settings  

USDA HPAI Biosecurity Checklist  

**U.S. Environmental Protection Agency**

Pesticide Emergency Exemptions  
www.epa.gov/opprd001/section18

Selected EPA-registered Disinfectants, including those labeled for Avian Influenza  
http://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants

**U.S. Poultry and Egg Association**

Poultry Biosecurity, Poultry Biosecurity Training Materials  
Including Poultry Biosecurity Officer Information Manual, Perimeter Buffer Area, Line of Separation, and signage  
http://www.poultrybiosecurity.org/
9. ACKNOWLEDGEMENTS


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10. PHOTO AND ILLUSTRATION CREDITS

Page 2  This photo showing Canada geese in a pond outside a livestock production facility is an example of wildlife potentially serving as vectors of a disease, such as avian influenza. Photo source: USDA Natural Resources and Conservation Service

Page 4  (Top) This illustration depicts disease exposure through direct contact. Graphic illustration by: Dani Ausen, Iowa State University  
(Middle) This illustration depicts disease exposure through aerosol. Graphic illustration by: Dani Ausen, Iowa State University  
(Bottom) This illustration depicts disease exposure through oral contact. Graphic illustration by: Dani Ausen, Iowa State University

Page 5  (Top) This illustration depicts disease exposure through fomites. Graphic illustration by: Dani Ausen, Iowa State University  
(Bottom) This illustration depicts disease exposure through vectors, such as flies. Graphic illustration by: Dani Ausen, Iowa State University

Page 6  This illustration depicts exposure to zoonotic disease. Graphic illustration by: Dani Ausen, Iowa State University


Page 11  Biosecurity protocols need to be clearly communicated with all personnel prior to their entering the facility. Graphic illustration by: Clint May, Iowa State University

Page 12  This is a photo of signage on an access door, and shows a view of visitors following biosecurity protocols in disposable boot covers being escorted through a livestock facility. Photo source: Danelle Bickett-Weddle, Iowa State University

Page 17  This is an example of implementation of a Perimeter Buffer Area and a Line of Separation protecting animals in one housing unit. Graphic illustration by: Sydney Heppner, Iowa State University

Page 18  This photo shows the cleaning and disinfecting of a vehicle paying particular attention to the wheels and wheel wells. Photo source: Danelle Bickett-Weddle, Iowa State University

Page 21  (Top) This is a photo of various types of disposable personal protective equipment, including coveralls, boot covers, and respiratory and eye protection. Photo source: Center for Food Security and Public Health, Iowa State University  
(Bottom) This photo shows a responder in Level C PPE, which includes a respirator. Photo source: Andrew Kingsbury, Iowa State University

Page 25  This illustration depicts Work Zones imposed on an Infected Premises. Graphic illustration by: Andrew Kingsbury, Iowa State University

Page 26  This illustration depicts Work Zones imposed on an Infected Premises, with a close up of the Decontamination Corridor and controlled access points. Graphic illustration by: Andrew Kingsbury, Iowa State University

Page 29  (Top) This photo depicts a bin which can be sealed to hold contaminated reusable coveralls until they are laundered, and prevent cross-contamination of clean items. Photo source: Danelle Bickett-Weddle, Iowa State University  
(Bottom) This is an example of a sign to direct visitors to check-in in order to sign the facility’s visitor log and be assigned an escort before entering the premises. Graphic illustration by: Dani Ausen, Iowa State University
This is an illustrated example of a Perimeter Buffer Area and Lines of Separation implemented at a production facility with animals raised indoors. Graphic illustration by: Andrew Kingsbury, Iowa State University

(Top) This photo was taken in an entry to an animal building showing a highly visible Line of Separation, and street shoes which have been left on the dirty side. Photo source: Pam Zaabel, Iowa State University  
(Bottom) This photo shows handwashing, prior to crossing the Line of Separation. Photo source: Pam Zaabel, Iowa State University

This is an illustrated example of a Line of Separation around a farm with animals raised outdoors. Graphic illustration by Sydney Heppner, Iowa State University


This is a photo of clean outwear and boots provided by the facility on the clean side of the Danish Entry System. Photo source: Danelle Bickett-Weddle, Iowa State University

These two maps show examples of zones, areas, and premises designations in an FAD outbreak. Content provided by: USDA; Graphic illustration provided by: Dani Ausen, Iowa State University

This is an example of an Incident Management Team organizational chart. Content provided by: USDA; Graphic illustration by: Dani Ausen, Iowa State University
Glossary

**All-In/All-Out Management**
A routine infection-prevention practice in which all animals are removed from an animal housing facility and the building is cleaned and disininfected before new animals are placed in it.

**Biocontainment**
Measures taken to prevent the spread of disease agents from infected animals to uninfected animals.

**Bioexclusion**
Measures taken to prevent the introduction of disease agents into a naïve population.

**Biological Vector**
A biological vector transfers a disease agent from an infected animal to a susceptible animal after the disease agent has undergone some part of its life cycle within the vector. (See Vector)

**Biosecurity**
A series of management practices designed to prevent the introduction of disease agents onto or prevents the spread from an animal production facility.

**Biosecurity Plan**
A plan or protocol that reflects biosecurity principles and procedures concerning the movement of personnel, vehicles, and equipment; examination of animals (alive or at necropsy); mass depopulation; and the disposal of animal carcasses, animal products, feed, water, straw, hay, and other materials potentially carrying a disease agent.

**Cleaning and Disinfection (C&D)**
Practices involving a combination of physical and chemical processes that kill or remove pathogenic microorganisms – a combination that is vital for the eradication of disease. Also known as virus elimination.

**Closed Flock/Herd**
An operation that does not introduce new animals from outside sources. Growth occurs through the addition of offspring born and raised on the operation. This practice decreases the potential for the introduction of new disease agents onto the operation.

**Cold Zone – Support Zone (SZ)**
This is the “cleanest” work zone with the lowest relative risk of exposure to pathogens and other hazards such as decontamination chemicals. In this zone, personnel are not required to wear PPE; however, facilities for donning PPE before entering other zones are provided. Administrative, clerical, and other support functions are based here. Medical support is provided to personnel in this zone. Facilities for personal needs such as eating, drinking, and bathroom use are provided. Contaminated articles and equipment are prohibited in this area. Decontamination activities are also prohibited.
**Conceptual Biosecurity**
The location, geospatial siting and orientation, scope, and size of animal production units and complexes that influence the risk of introduction of disease, escape of disease, or spread of disease within the facility. Farm density is an example. The closer facilities are in proximity, the higher the risk of disease transmission between facilities. Isolation, or enhanced distance of a facility to its neighboring livestock/livestock facilities, is protective.

**Critical Control Point**
A point, step or procedure where control can be applied to prevent the transfer of a disease agent (or in a more broad interpretation, to prevent harm).

**Danish Entry System**
A biosecurity strategy that can be implemented in everyday practice, utilizing the strict separation of clean and dirty spaces often with a low physical barrier to minimize the likelihood of disease entering an animal farm/system.

**Decontamination (Decon) Corridor**
This is the controlled access point between the Hot Zone - Exclusion Zone (EZ) and the Cold Zone - Support Zone (SZ). All personnel are required to exit the Hot Zone - Exclusion Zone (EZ) through the Decon Corridor before crossing the Line of Separation into the Cold Zone. Decontamination of personnel and equipment, including vehicles, occurs along the corridor with stations for depositing tools, equipment, protective clothing, and other items. The level of contamination should decrease along this transition corridor from the Hot Zone - Exclusion Zone (EZ) to the Cold Zone - Support Zone (SZ). Emergency response teams enter and exit the Hot Zone - Exclusion Zone (EZ) through the controlled access points at each end of the corridor.

**Doffing**
Taking off personal protective equipment.

**Donning**
Putting on personal protective equipment.

**Fomite**
An inanimate object or material on which disease-causing agents may be conveyed (e.g., feces, bedding, harness, clothes, and vehicle tires).

**Foreign Animal Disease**
A terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories.

**Hot Zone – Exclusion Zone (EZ)**
This high-risk area is where infected animals are, or were, housed and is potentially contaminated and considered a risk for spreading infection. Personal protective equipment (PPE) must be worn. Appraisal, depopulation, disposal, and facility cleaning and decontamination of the site occur in this area. Personnel and equipment enter and exit the Hot Zone through the designated controlled access points in the Decontamination Corridor.
**Incident Command System**
A standardized, on-scene, all-hazards incident management approach that allows for the integration of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure; enables a coordinated response among various jurisdictions and functional agencies, both public and private; and establishes common processes for planning and managing resources. It is a flexible system that can adjust to the scale of the event.

**Isolation**
The complete physical separation of animals from those that may be carrying an infectious or contagious disease.

**Line of Separation**
A line or barrier – imagined or physical – separating dirty (potential sources of infection) from clean (non-infected). In some biosecurity plans, this line may also be called the Clean/Dirty Line, and serve as the location for cleaning and disinfection activities (C&D Line).

**Mechanical Vector**
A mechanical vector transfers a disease agent to a susceptible animal via external body parts of the vector, such as on the fur or feet; the pathogen does not undergo any development or multiplication while with (usually on) the vector. (See Vector)

**Operational Biosecurity**
Processes and protocols, management practices, or standard operating procedures implemented to contain or exclude disease. It addresses the movement of personnel – employees, contract crews, vendors, visitors, drivers of vehicles, response personnel, and those who may live on the premises, as well as management of animals, supplies, equipment, vehicles and other items related to disease control.

**Perimeter Buffer Area**
This area serves as a biosecurity measure to place additional separation between the contaminated and non-contaminated space, to reduce pathogen load in the buffer environment and reduce the risk of disease transmission. In some biosecurity plans, cleaning and disinfection may be necessary before entering the Perimeter Buffer Area.

**Personal Protective Equipment (PPE)**
Equipment used as a barrier between an individual and a hazard that could result in an injury or occupational illness. As a biosecurity measure, PPE as outer clothing (biosecurity attire), along with the proper protocols, are used to prevent the transmission of pathogens via contaminated clothing.

**Premises**
Includes a tract of land and all of its buildings, as well as a separate farm or facility that is maintained by a single set of services and personnel.

**Quarantine**
To place animals in strict isolation to prevent the spread of disease.
**Structural Biosecurity**
The capital investment that enhances the ability to prevent disease spread. It includes the physical design, construction, and maintenance of a facility which help prevent the transfer, or aid in the containment of disease. Examples include physical barriers to exclude vectors, and on-site laundry to clean and disinfect all clothes worn by personnel.

**Vector**
An insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surroundings.

**Warm Zone – Contamination Reduction Zone (CRZ)**
This is a high-risk area due to the potential of exposure to pathogens and chemical disinfectants. This area could be considered as a Perimeter Buffer Zone. In an FAD response, all personnel are required to wear full PPE. Entry from the Warm Zone - Contamination Reduction Zone (CRZ) to either the Cold Zone - Support Zone (SZ) or Hot Zone - Exclusion Zone (EZ) occurs through a designated access point. For workers exiting the Hot Zone - Exclusion Zone (EZ), final decontamination and disinfection of PPE and equipment as well as final doffing of PPE occur in the Decontamination Corridor of the Warm Zone - Contamination Reduction Zone (CRZ). Exiting the Warm Zone into the Cold Zone, the Line of Separation would be crossed. Site-specific protocols for PPE, decontamination, and disinfection must be strictly followed.

**Zoonotic Disease**
Diseases that are transmissible between animals and humans under natural conditions.


**Acronyms**

- **APHIS**
  Animal and Plant Health Inspection Service, an agency of USDA

- **ASF**
  African swine fever

- **C&D**
  cleaning and disinfection

- **CDC**
  Centers for Disease Control and Prevention

- **CEM**
  contagious equine metritis

- **CSF**
  classical swine fever

- **EIA**
  equine infectious anemia

- **EPA**
  U.S. Environmental Protection Agency

- **FAD**
  foreign animal disease

- **FMD**
  foot-and-mouth disease

- **HASP**
  health and safety plan

- **HPAI**
  high pathogenicity avian influenza

- **LOS**
  Line of Separation

- **NAHEMS**
  National Animal Health Emergency Management System

- **ND**
  Newcastle disease

- **OSHA**
  Occupational Safety and Health Administration

- **PBA**
  Perimeter Buffer Area

- **PPE**
  personal protective equipment

- **SOP**
  standard operating procedures

- **USDA**
  United States Department of Agriculture

- **VS**
  Veterinary Services; a division of APHIS

- **WNV**
  West Nile virus
APPENDIX A: EXAMPLE - PERIMETER BUFFER AREA - LINE OF SEPARATION

When possible, biosecurity plans for bioexclusion should incorporate the concepts of a Perimeter Buffer Area and a Line of Separation. These concepts have been introduced in previous sections of this document, and are discussed below. To visualize these concepts, the example below uses a production facility with multiple barns/buildings housing animals raised indoors. Implementation of these concepts can be adapted to a variety of production facilities. In this illustration the Danish Entry System serves as the controlled access point across the Line of Separation. The entry to each animal building has its own controlled access point across the Line of Separation. The pathway for dead animal disposal and access outside the Perimeter Buffer Area is also illustrated.

Indoor Raised Animals

The Perimeter Buffer Area (PBA) acts as an outer control boundary to keep vehicles, personnel and equipment which do not meet the biosecurity standards, from contaminating areas near the animal buildings. Complete exclusion of disease in this area is not possible but reducing pathogen load in the immediate environment will reduce risk. The PBA should be established so that non-essential vehicles do not have to enter the PBA, and therefore do not need to be cleaned and disinfected each time they arrive at the site. These would include personal vehicles, delivery vehicles, and product transport vehicles.

In this illustration the PBA is represented as the shaded blue area surrounding the animal buildings, with a defined perimeter boundary. When determining the buffer area, account for traffic patterns on the premises, the topography around the animal housing, weather extremes, and what is known about the
pathogen and its infectivity. Note the parking area for employees and visitors is located outside of the PBA. Also notice some of the structures (feed bins, carcass storage) are located to allow access without the service vehicle entering the PBA.

Essential movements, including vehicles, which need to enter the PBA should be visibly clean before entry. A C&D station is located just outside the PBA Access Point. Personnel entering the PBA should arrive at the site previously showered, wearing clean clothing and footwear. If personnel need to leave the PBA, they reenter through a controlled access point, following appropriate biosecurity measures. The PBA should have a visible boundary like a fence, flags or rope. In addition, it is advisable to secure the PBA by a fence or other barrier, and a locked gate or cable when no one is present.

**The Line of Separation (LOS)** is established to separate animals from potential sources of infection. The biosecurity plan details how the LOS is defended, preventing pathogens from entering by way of clothing, equipment, supplies, and vectors (wildlife, pets, insects).

In the illustration of the farm above with animals raised indoors, the LOS consists of the building walls separating the livestock from the outside. As shown, each barn/building has its own entry (utilizing the Danish Entry System) and separate LOS. The group of barns is surrounded by a PBA. Barns or buildings connected by enclosed walkways may all be within the same LOS. Each barn or group of connected animal buildings should establish a single entry for crossing to the animal side of the LOS, where biosecurity protocols are implemented and required by all. The LOS at this entry should be clearly marked with tape or paint and have appropriate signage. A bench or other low physical barrier is recommended. Site-specific coveralls or clothing and footwear and also supplies to clean and disinfect hands and equipment are provided at the LOS access point.

Personnel remove their footwear and outer clothing prior to crossing the bench/barrier that identifies the LOS. Hands are cleansed with running water and soap, or with hand sanitizer if soap and water are unavailable. Personnel cross the LOS and prior to having contact with animals, don site-specific, or barn-specific, coveralls and boots. Again, hands are cleansed with soap or hand sanitizer. Equipment and supplies must not cross the LOS until they have been cleaned and disinfected. Personal items, such as cell phones and jewelry, must be cleaned and disinfected or they should not cross the LOS. The same procedure will be followed in reverse when crossing back to the outside of the LOS.

Temporary modifications to the PBA and/or LOS may be needed for specific procedures such as moving livestock, equipment, manure or litter into or out of a barn. A site-specific biosecure entry procedure should be defined for procedures that require a modified PBA or LOS.

This illustrated example is adapted from the resources available on the U.S. Poultry and Egg Association, Poultry Biosecurity Training Materials. A web link is provided in the For More Information section.

See **Appendix B: Danish Entry System** as an example of operational biosecurity protocols for entry that support a structural biosecurity investment.
A second example on this page illustrates a farm with animals raised outdoors. In this case, designating a PBA may not be practical. However, the LOS is defined around the perimeter to separate off-farm from on-farm movements of vehicles, people, and animals, and to protect healthy herds and flocks from potential sources of contamination. Controlled access points across the LOS are identified where specific biosecurity measures are implemented for both vehicles and personnel. Non-essential movements are prohibited from crossing the LOS; the employee parking area is located outside the LOS. Cleaning and disinfection stations are set up at these controlled access points to implement biosecurity protocols.
APPENDIX B: EXAMPLE – DANISH ENTRY SYSTEM

The Danish entry system is a biosecurity strategy to minimize the likelihood of disease entering an animal farm/system that can be implemented in everyday practices. This illustration shows one type of configuration, utilizing a bench in the anteroom to separate clean and dirty spaces that provides a visual and physical Line of Separation.

The Danish Entry-going from dirty to clean side:
- Personnel enter the barn/animal housing from outside through a single entrance leading to an anteroom.
- The anteroom bench serves as a physical barrier that separates the dirty side where personnel enter from the outside with street clothes, from the clean side with the designated barn clothing.
- When the bench is reached, outer clothing is removed and hung on designated hooks. Street clothes/outer clothing does not enter the animal housing.
- Street shoes are removed and left on the dirty side.
- Cell phones and other nonessential items are also left on the dirty side of the anteroom.
- Hands are cleansed with soap or hand sanitizer.

The bench is crossed onto the clean side in socks. This physical barrier reminds personnel of the demarcation, and the intentional movement from the dirty (street) to the clean (animal) side.

- Site-specific or barn-specific coveralls and boots provided on the clean side are donned, as seen at right.
- Again, hands are cleansed with soap or hand sanitizer.
- The animal housing may be entered, once all biosecurity protocols have been completed.

The Danish Entry-going from clean to dirty side

- When leaving the animal housing, personnel reenter the Danish Entry on the clean animal side.
- Again, the anteroom bench serves as a physical barrier that separates the clean and dirty sides of the anteroom.
- When the bench is reached, barn clothing is removed and hung on designated hooks on the clean side.
- Boots are removed and placed in the designated area on the clean area.
- Hands are cleansed with soap or hand sanitizer.
- The bench is crossed back onto the dirty side in socks. This physical barrier reminds personnel of the demarcation, and the intentional movement from the clean, back to the dirty side.
- Don outside clothing and footwear.
- Exit the barn when all biosecurity protocols have been completed.

For an overview of the system, view the video “The Danish Entry Principle” at https://www.youtube.com/watch?v=N4NNkd_Kfqw.
APPENDIX C: CHECKLIST - ENHANCED POULTRY BIOSECURITY

The following pages are taken from the Checklist for Self-Assessment of Enhanced Poultry Biosecurity, accessible on the US Poultry and Egg Association Poultry Biosecurity website at: http://poultrybiosecurity.org/. These recommendations were developed after highly pathogenic avian influenza (HPAI) affected over 200 poultry premises in the upper Midwest in spring 2015. The scope of the detections demonstrated that the biosecurity of poultry facilities needs to be strengthened to reduce the risk of future infections as much as possible. To assist poultry producers in implementing effective biosecurity plans, the Animal and Plant Health Inspection Service (APHIS) worked with State, academic, and industry experts to develop this biosecurity checklist.

Checklist for Self-Assessment of Enhanced Poultry Biosecurity

Introduction

Biosecurity approaches fall into two categories. Structural biosecurity is built into the physical construction and maintenance of a facility. Operational biosecurity encompasses the standard operating procedures (SOPs) that minimize the chance of virus entering the poultry house and compliance with those SOPs. Major enhancements to structural biosecurity cannot be widely implemented by fall 2015; therefore, the recommendations in this document focus on enhancing operational biosecurity. Over the long term, poultry producers will need to consider both operational and structural biosecurity to reduce their overall risk of HPAI.

This document emphasizes the elements for improving biosecurity that are believed to be the most effective and that can be implemented before fall 2015. Based on expert opinion and experience in the recent outbreak, the highest risks for HPAI virus introduction are personnel who enter the poultry buildings, shared equipment and shared crews, procedures for disposal of dead birds, and manure management. These elements should be the highest priority in allocating resources for improved biosecurity. Further, three concepts may be new to most existing biosecurity plans and should be strongly considered for all commercial operations: a biosecurity officer, a line of separation for each building, and a perimeter buffer area.

APHIS urges producers to develop a site-specific plan to implement enhanced operational biosecurity as soon as feasible. In addition, effective biosecurity requires vigilance; producers should put a system in place to verify that biosecurity enhancements are being followed. Lastly, this checklist assumes that infections are limited to animals. Special precautions will be needed if the virus mutates to affect people.
Recommendations for Biosecurity

1. Biosecurity Officer

Each production site (or integrated system) should have a Biosecurity Officer capable of designing and implementing effective biosecurity procedures. The Biosecurity Officer should be an experienced poultry veterinarian or should consult with one. He or she is responsible for developing a site-specific biosecurity plan and training all personnel who enter the farm. The Biosecurity Officer should have the authority to ensure compliance with biosecurity protocols and take corrective action as needed. He or she continuously adapts the plan and procedures to address changing risks.

2. Training of Employees and Other Personnel

The Biosecurity Officer ensures that farm employees, contract crews, truck drivers and service personnel are trained on site-specific biosecurity SOPs. Training materials should be provided in languages understood by employees. The site-specific biosecurity plans should be distributed to every employee, and training should be reviewed and documented to make sure every employee understands the concepts and procedures that apply to their area of responsibility.

3. Line of Separation

An essential component for improved biosecurity is to implement a line of separation for each building. The walls of the poultry house normally form the line of separation and should separate poultry from potential sources of HPAI virus. The line of separation is a critical control point for preventing HPAI virus exposure of poultry. A plan must address how this line will be defined and defended for each poultry house or set of connected houses.

4. Perimeter Buffer Area

Biosecurity plans should incorporate the perimeter buffer area concept, which is aimed at reducing virus entering and contaminating the production site. Complete exclusion is not possible but reducing virus load in the outside environment will reduce risk. The perimeter buffer area should be clearly delineated and located so that personnel do not leave the buffer area in the course of their daily tasks — or if they do, they use a specified entrance.
5. Personnel

Personnel and their clothing/footwear may become contaminated by AI virus through a variety of activities and contacts when they are off-site. Showering and changing into clean clothes immediately prior to arriving at a poultry site, or upon arrival, will greatly reduce the risk of AI virus introduction. This would apply to anyone who will enter the perimeter buffer area or cross the line of separation at a minimum.

In place □ In progress □ Not In place □

6. Wild Birds, Rodents and Insects

Poultry operations should have control measures to protect poultry from wild birds, their feces and their feathers. Rodent and insect control programs should be in place.

In place □ In progress □ Not In place □

7. Equipment

Equipment should be effectively sanitized between uses. Sharing of equipment should be minimized.

In place □ In progress □ Not In place □

8. Dead Bird Disposal

Dead birds should be disposed of in a manner that prevents the attraction of wild birds, rodents and other animals and avoids the potential for cross-contamination with dead birds from other facilities.

In place □ In progress □ Not In place □

9. Manure and Litter Management

Manure and spent litter should be removed in a manner to prevent exposure of susceptible poultry (either on or off the farm of origin) to disease agents.

In place □ In progress □ Not In place □
10. Replacement Poultry

It is not possible to prove that a bird or flock is free of AI virus; it is only possible to demonstrate lack of evidence of infection. Replacement poultry should come from sources with documented biosecurity practices and a history of freedom from HPAI infection. There should be recent surveillance testing on the source flock. Replacement birds should be transported in vehicles cleaned and disinfected appropriately to minimize the risk of AI transmission from previously transported birds.

In place □ In progress □ Not in place □

11. Water Supplies

Water should come from deep wells or sources that have been treated to eliminate any potential contamination with live virus. If water comes from a surface water source, experts in water treatment should be consulted on how to continuously treat the water to eliminate viable virus.

In place □ In progress □ Not in place □

12. Feed and Replacement Litter

There is no evidence that contaminated feed or litter contributed to HPAI virus introduction in the recent outbreak. However, feed, feed ingredients and fresh litter can be contaminated if they have been exposed to wild waterfowl or other birds or if they contain insects or rodents that might be carrying the virus. Grain, feed, and fresh litter should be stored and handled so that it cannot be contaminated with AI virus.

In place □ In progress □ Not in place □
**APPENDIX D: ZONES, AREAS AND PREMISES**

This information on Zones, Areas and Premises designations in an FAD response is summarized from the *APHIS Foreign Animal Disease Framework: Response Strategies (FAD PReP Manual 2-0)*.

In general, an animal disease outbreak response may involve seven types of zones/areas. These zones and areas are: 1) Infected Zone (IZ); 2) Buffer Zone (BZ); 3) Control Area (CA); 4) Surveillance Zone (SZ); 5) Free Area (FA); 6) Containment Vaccination Zone (CVZ); and 7) Protection Vaccination Zone (PVZ).

Table 1 provides a summary describing these zones/areas.

<table>
<thead>
<tr>
<th>Zone/area</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infected Zone (IZ)</td>
<td>Zone that immediately surrounds an Infected Premises.</td>
</tr>
<tr>
<td>Buffer Zone (BZ)</td>
<td>Zone that immediately surrounds an Infected Zone or a Contact Premises.</td>
</tr>
<tr>
<td>Control Area (CA)</td>
<td>Consists of an Infected Zone and a Buffer Zone.</td>
</tr>
<tr>
<td>Surveillance Zone (SZ)</td>
<td>Zone outside and along the border of a Control Area. The Surveillance Zone is part of the Free Area.</td>
</tr>
<tr>
<td>Free Area (FA)</td>
<td>Area not included in any Control Area. Includes the Surveillance Zone.</td>
</tr>
<tr>
<td>Vaccination Zone (VZ)</td>
<td>Emergency Vaccination Zone classified as either a Containment Vaccination Zone (typically inside a Control Area) or a Protection Vaccination Zone (typically outside a Control Area). This may be a secondary zone designation.</td>
</tr>
</tbody>
</table>

An animal disease outbreak may involve six types of premises: 1) Infected Premises (IP); 2) Contact Premises (CP); 3) Suspect Premises (SP); 4) At-Risk Premises (ARP); 5) Monitored Premises (MP); and 6) Free Premises (FP). If emergency vaccination is used, there will be a seventh type, Vaccinated Premises (VP).

Table 2 provides a summary describing premises designations.

<table>
<thead>
<tr>
<th>Infected Premises (IP)</th>
<th>Premises where a presumptive positive case or confirmed positive case exists based on laboratory results, compatible clinical signs, case definition, and international standards.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Premises (CP)</td>
<td>Premises with susceptible animals that may have been exposed to the FAD agent, either directly or indirectly, including but not limited to exposure to animals, animal products, fomites, or people from Infected Premises.</td>
</tr>
<tr>
<td>Suspect Premises (SP)</td>
<td>Premises under investigation due to the presence of susceptible animals reported to have clinical signs compatible with the FAD. This is intended to be a short-term premises designation.</td>
</tr>
</tbody>
</table>

Table 1. Summary of Zone and Area Descriptions

Table 2. Summary of Premises Designations
<table>
<thead>
<tr>
<th>Premises Type</th>
<th>Description</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>At-Risk Premises (ARP)</td>
<td>Premises that have susceptible animals, but none of those susceptible animals have clinical signs compatible with the FAD. At-Risk Premises objectively demonstrates that it is not an Infected Premises, Contact Premises, or Suspect Premises. At-Risk Premises may seek to move susceptible animals or products within the Control Area by permit. Only At-Risk Premises are eligible to become Monitored Premises.</td>
<td>Infected Zone, Buffer Zone</td>
</tr>
<tr>
<td>Monitored Premises (MP)</td>
<td>Premises objectively demonstrates that it is not an Infected Premises, Contact Premises, or Suspect Premises. Only At-Risk Premises are eligible to become Monitored Premises. Monitored Premises meet a set of defined criteria in seeking to move susceptible animals or products out of the Control Area by permit.</td>
<td>Infected Zone, Buffer Zone</td>
</tr>
<tr>
<td>Free Premises (FP)</td>
<td>Premises outside of a Control Area and not a Contact or Suspect Premises.</td>
<td>Surveillance Zone, Free Area</td>
</tr>
<tr>
<td>Vaccinated Premises (VP)</td>
<td>Premises where emergency vaccination has been performed. This may be a secondary premises designation.</td>
<td>Containment Vaccination Zone, Protection Vaccination Zone</td>
</tr>
</tbody>
</table>

Figure 13 provides a visual example of the location of premises within zones and areas.

**Figure 13. Zones, Areas and Premises**

Note: Figures are not to scale. The Vaccination Zone can be either a Protection Vaccination Zone or Containment Vaccination Zone.
APPENDIX E: EXAMPLE – INCIDENT MANAGEMENT TEAM

This is an example of an Incident Management Team based on the Incident Command System organizational structure. This organization of responders that may be deployed to an incident is flexible and scalable. Its structure will depend on the size, scope, and nature of the incident.
APPENDIX F: EXAMPLE - PRODUCER INSTRUCTIONS - QUARANTINE/C&D

Quarantine
This premises _______ IDENTIFIED _____________ has been quarantined to prevent the spread of a contagious livestock disease.

As owner/agent _____ NAME ______, you are responsible to comply with all quarantine procedures on your premises to prevent disease transmission, which can occur by direct or indirect means.

Quarantine prohibits all except essential movements onto and off from the premises. Essential movements must meet specific criteria detailed below. Movement of animals/animal products, people and things may carry the disease agent from one location to another.

Security
- Acknowledge the quarantine boundary defining the premises under quarantine.
- Secure all fences and points of entrance/exit to prevent unauthorized access to the premises, or inadvertent escape of livestock. Maintain one point of access/egress where quarantine procedures can be implemented and monitored.

Animals/Animal Products (milk, shell eggs, liquid eggs, manure, etc.)
- Prohibit movement of all animals/animal products onto or off from the premises, unless an official movement permit has been issued by Incident Command.

Line of Separation
- Institute a visual Line of Separation, also called a Cleaning/Disinfection Line, such as a line painted on the ground, demarcating and establishing separation between contaminated (sources of potential infection) and clean (non-infected) areas. Cleaning and disinfection of essential movements must occur before leaving the contaminated area.
- A cleaning/disinfection area/station should be assembled and located at this Line. Avoid recontamination prior to leaving.
- Ensure clean and disinfection protocols are complete prior to any movement exiting across this Line. See additional instructions under Equipment and Vehicles, and under Cleaning and Disinfecting Procedures, both below.

People
- Limit people on-site to employees essential to care for the animals, those who live on the premises, and authorized response personnel. Note: limit employees to only those deemed essential. Visitors are not allowed on the premises at this time.
- Wear outerwear that can be cleaned and disinfected, such as coveralls and boots.
- Before leaving the premises, ensure compliance with one of the biosecurity protocols below, avoiding any contamination of clean clothes when leaving premises.
  a. Shower and change into clean clothes including clean footwear.
  b. Remove coveralls, thoroughly wash hands, and clean and disinfect boots.
• Leave contaminated clothes on-site to be laundered, or place contaminated clothes in a plastic bag to be immediately laundered off site. Boots and any plastic bag containing contaminated clothes should be cleaned and disinfected before leaving the site.

Equipment and Vehicles
• Clean and disinfect all equipment prior to leaving the premises. Every type of equipment (tools, shovels, skid loaders, vehicles) must be dry cleaned, and then washed to remove all organic matter (dirt/manure). Power wash vehicles, paying special attention to the undercarriage. Vehicles and equipment must be rinsed and allowed to dry. Appropriate disinfection (by solution or heat application) must be implemented according to directions prior to crossing the Line. See Cleaning and Disinfecting Procedures.

Deliveries
• Do not allow delivery vehicles or delivery personnel to cross the Line to enter the premises, unless explicitly allowed by permit. Arrange to meet deliveries, and if possible shuttle feed and supplies to prevent unnecessary traffic on-site.

Wildlife
• Be aware of wildlife movement around the premises. This will guide mitigation efforts, as needed.

Media
• Do not allow media access to the premises. It is recommended to refer media questions to NAME/PHONE NUMBER.

One or more authorized members of the response team may be assigned to assist in implementing this quarantine.

For questions, contact NAME/PHONE NUMBER.

By signing, I agree to implement these procedures.

Owner/agent signature___________________________________________________________

(Note: This is only an example of instructions. Each state may have its own official quarantine forms.)
Cleaning and Disinfecting (C&D) Procedures

Safety

- Enforce all safety protocols when handling, mixing and applying chemical disinfectants to prevent harm to personnel, equipment and the environment. Read Material Safety Data Sheets (MSDS) listing the stability, hazards, personal protection needed, and first aid for all chemical disinfectants. Use appropriate personal protective equipment (PPE) including gloves, face and eye protection.
- Follow all product label instructions on the detergent and on the EPA-registered disinfectant (dilution, handling, contact time, stability, storage, and disposal).

Cleaning

- Dry clean all surfaces before entering the cleaning/disinfection area.
  - Scrape/dry brush to remove all visible dirt and organic matter.
- Wash all surfaces and rinse within the identified cleaning/disinfection area.
  - Wash items thoroughly with detergent using a soft brush, cloth or sponge.
  - Rinse items with clean water.
  - Contain runoff water. Do not allow runoff water to drain into other water sources or into “clean” uncontaminated areas.
  - Allow items to dry prior to disinfection.

Disinfecting

- Disinfectant Application
  - Prepare fresh solutions of the EPA-registered disinfectant according to the product label to ensure efficacy.
  - Apply disinfectant solution to all surfaces with a low pressure sprayer, or by wiping, or immersing the items in the solution. (*Virkon instructions can be substituted.*)
  - Use high pressure sprayers with caution to avoid further spread or aerosolization of the disease agent.
  - Ensure all areas are covered thoroughly with the solution and remain “wet” throughout the necessary contact time; reapply if necessary.
- Rinse and Dry
  - Rinse thoroughly with clean warm water – rinsing is essential as detergents or disinfectants dried on components may cause deterioration of rubber or metal parts if not completely removed.
  - Allow items to air dry. Some items may be placed in the sunlight for drying and additional disinfection.
- Alternate methods of disinfection may be allowed. Follow guidance provided by Incident Command.

People – personal protective equipment (PPE)

- Conduct personnel (and PPE) C&D in a systematic manner to ensure efforts are effective.
- Follow cleaning and disinfecting steps of reusable PPE as above. Pay close attention to soles of boots and footwear.
- Carefully remove outerwear (doff PPE) to avoid cross contaminating inner clothing.
- Leave clothes to be laundered on-site.
• Place disposable clothing items in plastic garbage bags. Spray the outer surface of the bag with disinfectant solution, and dispose in a manner that would prevent the spread of the disease.
• Ensure people do not cross the Line of Separation (Cleaning and Disinfection Line) in clothes that may have been contaminated.

Equipment
• Prevent any piece of equipment from leaving the premises without first being thoroughly cleaned and disinfected.
• Use an alternative disinfection method such as heat (steam, bake, flame), or ultraviolet radiation (sunlight), if equipment may be damaged by chemical solutions.
• Wipe or spray air-tight electronic equipment.

Vehicles
• Ensure a disinfection station is constructed to accommodate vehicles.
• Berm the area to contain water runoff.
• Remove any loose items out of the vehicle interior for individual C&D.
• Use brooms, shovels, manure forks, brushes and scrapers to remove all visible organic material from vehicle exterior before entering the cleaning/disinfection area.
• Mechanical scrubbing and scraping may be necessary to remove oils, grease or exudates from rough surfaces, deep cracks, or other surface irregularities.
• Pre-soak surfaces and items that are caked with organic materials first, if necessary.
• Pay special attention to the wheel wells and undercarriage.
• Thoroughly clean and disinfect the interior of the vehicle, especially if the driver has left the cab while on the quarantined premises.
• Allow to sit 5-10 min to drip off rinse water before applying disinfectant.
• Keep the disinfectant in contact with all surfaces for the appropriate contact time.
• If alternate methods of disinfection are allowed after a thorough dry cleaning, follow guidance provided by Incident Command.