NPIP Standard E Program Standards & California Audit Guidelines for the "Biosecurity Audit Form for HPAI Indemnity Eligibility"

Standard E—Biosecurity Principles

Based on the flock size as stated in the 9 CFR 53.10, and including breeding flocks premises with at least 5,000 birds, the following minimum management practices and principles are designed to prevent the introduction and spread of infectious diseases.

(1) Biosecurity responsibility

The Biosecurity Coordinator is responsible for the development, implementation, maintenance and ongoing effectiveness of the biosecurity program. Depending on the type and size of poultry operation, the Biosecurity Coordinator's responsibility could be at the farm, production site, production complex, or company level. The Biosecurity Coordinator should be knowledgeable in the principles of biosecurity.

The Biosecurity Coordinator, along with the personnel and caretakers on the farms and production sites are responsible for the implementation of the biosecurity program. The Biosecurity Coordinator should review the biosecurity program at least once during each calendar year and make revisions as necessary.

- **1.1** Please provide the name and contact information of your Biosecurity Coordinator (BC). **1.2** Is there a site-specific biosecurity plan?
 - Site-specific biosecurity plans can be defined as either farm-specific or complexwide specific. Supporting documentation that is requested should reflect farmspecific or complex-wide specific as appropriate and should include a map for each individual premises.
- 1.3 Is the Biosecurity Coordinator knowledgeable in the principles of biosecurity?
 - The Biosecurity Coordinator must be able to describe and interpret their company's biosecurity program and how it meets the requirements of the Standard E biosecurity principles.
- **1.4** Does the Biosecurity Coordinator review the biosecurity plan at least once during each calendar year and make revisions as necessary?
 - The Biosecurity Coordinator must be able to provide recorded dates in which annual reviews were made and evidence of revisions to the biosecurity plan if any were necessary.
- **1.5** Does the biosecurity plan indicate there will be a review by the Biosecurity Coordinator in periods of heightened risk of disease transmission?
 - Documentation of compliance, including evidence of a discussion during periods of heightened risk can take any form (e.g., emails, letters, memos, phone logs, text messages, etc.). It is the responsibility of the Biosecurity Coordinator to clearly define and communicate the "period of heightened risk" in the biosecurity plan.

(2) Training

The biosecurity program should include training materials that cover both farm site-specific procedures as well as premises-wide and/or company-wide procedures as appropriate. All poultry owners and caretakers that regularly enter the perimeter buffer area (PBA) must complete this training. The training must be done at least once per calendar year and documented. New poultry caretakers should be trained at hire. Training records should be retained as stated in Title 9-CFR §145.12(b) and 146.11(e).

Audit Guidelines:

- **2.1** Does the biosecurity program include training materials that cover both farm site-specific procedures as well as company and/or complex-wide site-specific procedures, as applicable?
 - Supporting documentation (e.g., training logs, training completion sheets, sign-in sheets, certificates of completion, etc.) should be provided.
- **2.2** Do all poultry owners and caretakers that regularly enter the perimeter buffer area (PBA) complete this training?
 - Supporting documentation (e.g., training logs, training completion sheets, sign-in sheets, certificates of completion, etc.) should be provided.
- **2.3** Has the training been completed at least once per calendar year and documented?
 - Supporting documentation (e.g., training logs, training completion sheets, sign-in sheets, certificates of completion, etc.) should be provided.
- **2.4** Are new poultry caretakers trained at hire?
 - Supporting documentation (e.g., training logs, training completion sheets, sign-in sheets, certificates of completion, etc.) should be provided.
- 2.5 Are training records retained as stated in Title 9-CFR §145.12(b) and 146.11(e)?
 - Records must be maintained for at least 3 years.

(3) Line of Separation (LOS)

The Line of Separation (LOS) is a functional line separating the poultry house(s) and the poultry inside from exposure to potential disease sources. Generally, it is defined by the walls of the poultry building with practical deviations to account for entry points, structural aspects, or outside access areas. The site-specific biosecurity plan should describe or illustrate the boundaries of the LOS and clearly outline the procedures to be followed when caretakers, visitors, or suppliers cross it.

For poultry enclosed in outdoor pens, similar principles for the LOS can be applied for defining and controlling the LOS for each pen. In this circumstance, the walls of the outdoor pens would provide template for defining the LOS to be used when entering or exiting the pens.

For poultry with non-enclosed outdoor access, the LOS is recommended but not required. Further, in an emergency disease state where the transmissible disease risk is heightened, it is highly recommended to enclose all poultry and enforce a LOS.

Audit Guidelines:

- **3.1** Does the site-specific biosecurity plan describe or illustrate the boundaries of the LOS? If not, please explain.
 - Provide a diagram, map, and/or a detailed description of the LOS. The LOS is recommended but not required for poultry with unenclosed outdoor access, but is highly recommended during periods of heightened risk.
- **3.2** Does the site-specific biosecurity plan clearly outline procedures to be followed when caretakers, visitors, or suppliers cross the LOS?
 - Provide the procedures (e.g., written instructions, signage, training videos, etc.) to be followed by caretakers, visitors or suppliers to cross the LOS.

(4) Perimeter Buffer Area (PBA)

The perimeter buffer area is a functional zone surrounding the poultry houses or poultry raising area that separates them from areas unrelated to poultry production on that site and/or adjoining properties. It is comprised of the poultry houses and poultry raising areas as well as nearby structures and high traffic areas involved in the daily function of the poultry farm. This would usually include but not be limited to such things as feed bins, manure sheds, composting areas, egg rooms, generators, pump rooms, etc. The site-specific biosecurity plan should describe or illustrate the boundaries of the PBA and clearly outline the procedures that caretakers, visitors, or suppliers must follow when entering and leaving the PBA.

Audit Guidelines:

- **4.1** Does the site-specific biosecurity plan describe or illustrate the boundaries of the PBA?
 - Provide a diagram, map, and/or a detailed description of the PBA.
- **4.2** Does the site-specific biosecurity plan clearly outline the procedures to be followed by caretakers, visitors, or suppliers when entering and leaving the PBA?
 - Provide the procedures (e.g., written instructions, signage, training videos, etc.) to be followed by caretakers, visitors, suppliers, etc. when entering and leaving the PBA.

(5) Personnel

The biosecurity program and/or the site-specific biosecurity plan should include provisions specifically addressing procedures and biosecurity PPE for site-dedicated personnel. The plan should likewise address the procedures and biosecurity PPE for non-farm personnel. The plan should also specify procedures which all personnel having had recent contact with other poultry or avian species should follow before re-entering the PBA.

- **5.1** Does the biosecurity program and/or site-specific biosecurity plan include provisions specifically addressing procedures and biosecurity personal protective equipment (PPE) for site-dedicated personnel?
 - PPE should be described in the biosecurity plan for each type of production facility.

- **5.2** Does the biosecurity program and/or site-specific biosecurity plan address the procedures and biosecurity PPE for non-farm personnel?
 - PPE should be described in the biosecurity plan for each type of production facility for non-farm personnel.
- **5.3** Does the biosecurity program and/or site-specific biosecurity plan specify procedures which all personnel having had recent contact with other poultry or avian species should follow before re-entering the PBA?
 - Supporting documentation (e.g., signed statements, acknowledgement forms, visitor log-in, signed policy documents, etc.) should be provided.

(6) Wild Birds, Rodents and Insects

Poultry operations should have control measures to prevent contact with and protect poultry from wild birds, their feces and their feathers as appropriate to the production system. These procedures should be reviewed further during periods of heightened risks of disease transmission. Control programs for rodents, insects, and other animals should be in place and documented.

Audit Guidelines:

- **6.1** Are there control measures in the biosecurity program and/or site-specific biosecurity plan to prevent contact with and protect poultry from wild birds, their feces and their feathers as appropriate to the production system?
- **6.2** Does the biosecurity program and/or site-specific biosecurity plan contain control programs for rodents, insects, and other animals?
- **6.3** Are these programs documented?
 - Provide description of control programs and examples of the documentation [e.g., log sheets, rodent control company contracts, Best Management Practices (BMP) audits, maintenance records, etc.].

(7) Equipment and Vehicles

The biosecurity plan should include provisions for procedures for cleaning, disinfection, or restriction of sharing of equipment where applicable. Vehicle access and traffic patterns should be defined in the site-specific biosecurity plan.

- 7.1 Does the biosecurity program and/or site-specific biosecurity plan include provisions for procedures for cleaning, disinfection, or restriction of sharing of equipment where applicable?
 - Supporting documentation (e.g., written instructions, signage, training videos, etc.) should be provided.
- **7.2** Are vehicle access and traffic patterns defined?
 - Provide a description of vehicle entry access and traffic patterns.

(8) Mortality Disposal

Mortality should be collected daily, stored and disposed in a manner that does not attract wild birds, rodents, insects, and other animals and minimizes the potential for cross-contamination from other facilities or between premises. It is recommended that dead bird disposal be on-site, if possible. Mortality disposal should be described in the site-specific biosecurity plan.

Audit Guidelines:

- **8.1** Is there a mortality disposal plan?
- **8.2** Does the mortality disposal plan reference the frequency of removal, storage of mortality, and pest control around mortality storage and disposal areas?
 - Provide a description of the mortality disposal plan and examples of documentation [e.g., mortality sheets, company contracts, Best Management Practices (BMP) audits, disposal records, etc.]
- **8.3** Does the mortality disposal plan address procedures for handling mortality disposal in a way that minimizes the potential for cross-contamination from other facilities or between premises?
 - Supporting documentation should be provided (e.g., written instructions, videos, etc.) for proper handling of mortality to minimize the potential of crosscontamination.

(9) Manure and Litter Management

Manure and spent litter should be removed, stored and disposed of in a manner to prevent exposure of susceptible poultry to disease agents. Onsite litter and manure storage should limit attraction of wild birds, rodents, insects, and other animals.

Audit Guidelines:

- **9.1** Is the manure and spent litter handled in a manner that limits the spread of infectious disease?
 - Procedures (e.g., written instructions, manure/litter handling log sheets, protocols, permits, guidance for contractors, etc.) should be provided showing how disease risk from manure and litter handling has been addressed.

(10) Replacement Poultry

Replacement poultry should be sourced from health-monitored flocks which are in compliance with NPIP guidelines. They should be transported in equipment and vehicles that are regularly cleaned, disinfected and inspected. Biosecurity protocols should be in place for equipment and personnel involved in the transport of replacement poultry.

- **10.1** Is replacement poultry sourced from flocks which are in compliance with NPIP provisions and program standards?
 - Replacement poultry is defined as poultry from hatch to maturity intended to become laying hens or breeders.

- Provide supporting documentation (e.g., VS 9-2 form, VS 9-3 form and/or NPIP hatchery production records) showing that source flocks are active and compliant participants in the NPIP.
- **10.2** Is replacement poultry transported in equipment and vehicles that are regularly cleaned, disinfected and inspected?
 - Supporting documentation (e.g., written instructions, wash station reports and/or logs, inspection reports, invoices, etc.) should be provided. The biosecurity plan should be followed as written and clearly define "regular cleaning."
- **10.3** Are biosecurity protocols in place for equipment and personnel involved in the transport of replacement poultry?
 - Supporting documentation [e.g., signed statements, acknowledgement forms, visitor log-in sheets, policy documents, standard operating procedures (SOPs), Best Management Practices (BMPs), etc.] should be provided for personnel involved in the transport of replacement poultry.
 - Supporting documentation [e.g., written instructions, protocols, procedures, training videos, standard operating procedures (SOPs), Best Management Practices (BMPs), etc.] should be provided for equipment involved in the transport of replacement poultry.

(11) Water Supplies

It is recommended that drinking water or water used for evaporative cooling be sourced from a contained supply such as a well or municipal system. If drinking water comes from a surface water source, water treatment must be used to reduce the level of disease agents. If surfaces have been cleaned or flushed with surface water, subsequent disinfection should be employed to prevent disease transmission. If water treatment is not possible, a risk analysis should be performed to determine actions needed to mitigate risks.

- **11.1** Is drinking water or water used for evaporative cooling sourced from a contained supply such as a well or municipal system?
- **11.2** If water comes from a surface water source, is water treatment used to reduce the level of disease agents?
 - If yes, describe the water treatment used.
- **11.3** If water treatment is not possible, is a risk analysis performed to determine actions needed to mitigate risks?
 - The Biosecurity Coordinator should provide evidence that the risk of an untreated system has been considered and demonstrate steps to mitigate that risk if feasible.
 - Risk assessment should have considered risks from the water supply. This
 guidance does not require a peer-reviewed professional risk assessment to be
 performed.
- **11.4** If surfaces have been cleaned or flushed with surface water, is subsequent disinfection employed to prevent disease transmission?
 - If surfaces were cleaned or flushed with surface water and subsequent disinfection

- was employed, a description of the subsequent disinfection and/or supporting documentation should be provided (e.g., invoices for chemicals used and purchased treatment equipment, treatment plans, etc.)
- If surfaces were cleaned or flushed with surface water and subsequent disinfection was not employed, see item 11.3 above.

(12) Feed and Replacement Litter

Feed, feed ingredients, bedding, and litter should be delivered, stored and maintained in a manner that limits exposure to and contamination by wild birds, rodents, insects, and other animals. Feed spills within the PBA (outside of the LOS) should be cleaned up and disposed in a timely fashion.

Audit Guidelines:

- **12.1** Is feed, feed ingredients and litter stored and maintained in a manner that limits exposure to and contamination by wild birds, rodents, insects, and other animals?
- Guidance applies to the feed ingredients and litter which are under the direct control
 of the entity being audited. A description or examples (e.g., written instructions,
 feed or replacement litter handling, log sheets, protocols, permits, guidance for
 contractors, etc.) should be provided showing how exposure to and contamination
 by wild birds, rodents, insects, and other animals is limited. Occasional exceptions
 may be necessary (e.g., seasonal storage, acts of God, etc.).
- **12.2** Does the biosecurity plan address feed spills within the PBA (outside of the LOS)?

(13) Reporting of Elevated Morbidity and Mortality

Elevation in morbidity and/or mortality above expected levels, as defined by the biosecurity plan, should be reported as required in the site-specific biosecurity plan and appropriate actions should be taken to rule out reportable disease agents.

- **13.1** Does the biosecurity plan address elevated morbidity and/or mortality above expected levels?
 - A description of the actions and/or documentation (e.g., evidence of investigation, tracking graphs, mortality/morbidity patterns, case reports, mortality logs, etc.) used to monitor morbidity and/or mortality should be provided. The Biosecurity Coordinator is responsible for communicating what constitutes elevated morbidity and/or mortality in the biosecurity plan.
- **13.2** Is there a plan to report to responsible authorities and take appropriate action should you suspect and need to rule out reportable disease agents?
 - Provide the written procedure to report and take appropriate actions when disease agents are suspected. The Biosecurity Coordinator is responsible for providing the written procedures.
 - The written procedure should identify the responsible reporting authorities. The Biosecurity Coordinator is responsible for clearly communicating who the

responsible authorities are.

(14) Auditing

Auditing of the biosecurity principles is based on flock size as outlined in 9 CFR 53.10, and shall include breeding flocks premises with at least 5000 birds. Audits shall be conducted at least once every two years or a sufficient number of times during that period by the Official State Agency to ensure the participant is in compliance. Each audit shall require the biosecurity plan's training materials, documentation of implementation of the NPIP Biosecurity Principles, corrective actions taken, and the Biosecurity Coordinator's annual review to be audited for completeness and compliance with the NPIP Biosecurity Principles.

- **14.1** Auditing of the biosecurity principles is based on flock size as outlined in 9 CFR 53.10.
 - Premises exempted from auditing are those which: raise fewer than 100,000 broilers annually for meat, raise fewer than 30,000 turkeys annually for meat, have fewer than 75,000 table egg layers, raise fewer than 25,000 raised for release upland game birds annually, and raise fewer than 25,000 waterfowl birds annually.
- **14.2** Audits shall be conducted at least once every two years or a sufficient number of times during that period by the CDFA to ensure the participant is in compliance.
 - Audits conducted shall be an on-site assessment of the participant's biosecurity plan.
- 14.3 Each audit shall require the biosecurity plan's training materials, documentation of implementation of the Standard E Biosecurity Principles, corrective actions taken (if necessary), and the Biosecurity Coordinator's annual review of the biosecurity plan to be audited for completeness and compliance with the NPIP Biosecurity Principles.
 - The participant will be provided an opportunity to offer corrective actions for any non-compliances noted during the initial audit. Corrective actions will be reviewed by the CDFA prior to finalizing the inspection report. If corrective actions do not result in compliance, the participant may elect to take further actions. See guidance listed in 14.5.
- **14.4** An audit summary report containing satisfactory and unsatisfactory audits will be provided to the Avian Coordinator for documentation.
- **14.5** Those participants who failed the initial document audit conducted by the CDFA may elect to have a check audit performed by a team appointed by CDFA Headquarters.
- **14.6** If these participants seek to be reinstated as being in compliance with the Biosecurity Principles, they must demonstrate that corrective actions were taken following the audit, by the team appointed by CDFA Headquarters.