

SANITATION QUESTIONNAIRE

Sample Response

The following responses to the questions and requests for information made in this questionnaire serve as an example to all foreign governments of how the United States expects the applicant to fill out the questionnaire. In order to answer the questions from your perspective, we have answered the questions as if the U.S. is applying for eligibility to ship meat products to Country-X.

For each question and request, we have cited the sections in our regulations or other reference material that governs our response(s). In addition, we have provided examples of any forms, charts, or other documents applicable to each question or comment.

A. Program Organization

- 1. For each of the products under this application, what governmental agencies enforce the relevant laws and regulations relating to the prevention and control of contamination? Include organizational charts for each of these agencies.**

REGULATORY AGENCIES

U.S. Department of Agriculture, Food Safety and Inspection Service

REGULATORY AUTHORITIES

Federal Meat Inspection Act (21 U.S.C. 601 et seq.)

Poultry Products Inspection Act (21 U.S.C. 451 et seq.)

A copy of the organization chart for the Food Safety and Inspection Service is attached.

References: Federal Meat Inspection Act (21 U.S.C. 609)

Poultry Products Inspection Act (21 U.S.C. 456)

- 2. What is the functional relationship among these government agencies and between these agencies and any separate activities at state, provincial, or local levels? For example, if different agencies/authorities apply different laws/regulations at different stages in the movement of product to the consumer, how do these agencies/authorities cooperate and work together to help prevent and control contamination?**

FSIS is the only government Agency involved. There are no separate activities at state or local levels.

3. What personnel, training, equipment/resources, and other facilities are utilized to enforce and fulfill the responsibilities of the meat and/or poultry inspection system regarding the prevention and control of contamination for each of the products under this application?

Under its statutes, FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Approximately 7400 Federal inspectors carry out inspection laws in about 6200 establishments. Inspectors check animals before and after slaughter, visually examining over 6 billion poultry carcasses and 125 million livestock carcasses each year. They prevent diseased animals from entering the food supply and examine carcasses for visible defects that can affect quality and safety. FSIS inspects products during processing, handling, and packaging to ensure that they are safe and truthfully labeled. FSIS also sets standards for certain slaughter and processing activities, such as establishment sanitation and thermal processing. Inspectors are also required to complete courses that emphasize the importance of basic sanitation and the use of standard sanitation operating procedures by establishments.

Specifically the duties and responsibilities of an FSIS inspectors include:

** Reinspecting imported meat and poultry are subject to FSIS scrutiny. The agency reviews and monitors the foreign inspection systems applicable to the products in questions to ensure that their prevention, control, and monitoring of product and facility contamination are equivalent to the U.S. system. In addition, when the products reach the United States, selected products are reinspected for contamination, unsound condition, pathological defects and other factors.*

** Setting standards for food safety, such as the microbiological contamination of food products, and inspecting imported and domestic product for wholesomeness. This includes the monitoring, prevention, and control of product contamination. FSIS inspects and regulates all raw beef, pork, lamb, chicken, and turkey sold in interstate and foreign commerce.*

** Inspecting livestock, slaughtering, and processed products for wholesomeness and contamination problems. FSIS inspectors check animals before and after slaughter, preventing diseased animals from entering the food supply and examining carcasses for visible defects that can affect safety and quality.*

** Setting standards for facilities, product contents, processing procedures, packaging, and labeling.*

** Analyzing products for microbiological and chemical adulterants, and educating consumers about foodborne illness and the dangers of product contamination by way of publications, educational campaigns, and a toll-free Meat and Poultry Hotline.*

** Testing for the presence of drug and chemical residues that violate Federal law.*

- * Evaluating and setting contamination and performance standards for food ingredients, additives, and compounds used to prepare and package meat and poultry products.*
- * And, collecting product samples to test for contamination by testing for the presence of pathogens and toxins such as Salmonella and Staphylococcal enterotoxin in ready-to-eat and other processed products. Exception of the "zero tolerance" for E. coli O157:H7 in raw ground beef, microbiological standards for raw products exist as a result of the Pathogen Reduction HACCP Rule of 1996 (with the).*

A description of mandatory training follows. Sanitation and SSOP are emphasized in these training courses.

Basic Livestock Slaughter Inspection

This 11-day course is designed for the newly hired livestock slaughter inspector. The following subjects are covered: the Federal Meat Inspection Act, as amended; safety; sanitation; Performance-Based Inspection System; Sanitation Standard Operating Procedures; humane slaughter; antemortem and postmortem inspection procedures; control of restricted products; control of condemned and inedible products; microbiology; epidemiology of foodborne disease (microbiology); HACCP Systems; wellness training; interpersonal relations skills; and other related areas. Off-line inspection procedures are covered in the Advanced Livestock Slaughter Inspection course.

Basic Poultry Inspection

This 8-day course is designed for the recently hired poultry inspector. The subjects covered are the Poultry Products Inspection Act and inspection regulations; wellness training; poultry antemortem and postmortem inspection; poultry anatomy; food microbiology; integrity; Performance-Based Inspection System and sanitation; Sanitation Standard Operating Procedures; HACCP concepts and trends; safety; streamlined inspection system presentation; interpersonal skills; and other related areas.

Pathogen Reduction and HACCP

This 8-day course is designed for inspection employees and supervisors; compliance officers and supervisors; and district office personnel. The training focuses on the following topics: FSIS philosophy and operations; principles and application of HACCP; working knowledge of HACCP systems development and the relationship to good manufacturing practices and sanitation standard operating procedures; regulatory and operational requirements for E. coli testing; regulatory and operational requirements for Salmonella testing; system's approach to inspection; changes made to the PBIS system; determining an establishment's compliance or noncompliance with pathogen reduction and HACCP requirements—SSOP, E. coli testing, HACCP implementation, and Salmonella testing; obtaining technical assistance and guidance; and information and techniques for use in building effective relationships, managing conflict, and communicating more effectively.

*References: FSIS, Office of Management, Human Resources Division
FSIS, Office of Field Operations
9 CFR Part 416—Sanitation*

B. Regulations and Guidelines

- 1. What regulations, directives, and guidelines control and prevent the contamination of meat or poultry products in the building and construction of official establishments, including:**
 - a. materials and surface finish of walls, ceilings, and floors?**
 - b. building ventilation systems?**
 - c. lighting at product inspection sites (i.e. level of illumination)?**
 - d. lighting in rooms/hallways, at equipment, etc. (i.e. level of illumination)?**
 - e. separation of toilet soil lines and establishment drainage lines?**
 - f. room/environmental temperature controls (i.e. such as in further processing rooms and finished product storage areas or rooms)?**

Appendix A of FR Vol. 62, No, 164 provides guidance on establishment facilities and equipment. The Guidebook is intended for use by meat and poultry establishments in considering decisions about design and construction of their facilities, as well as the selection of equipment to be used in their operations. The Agency is no longer making these prior approval decisions for inspected establishments. However, FSIS will continue to verify through inspection that sanitation requirements (9 CFR Section 308.3) are being met. A complete outline of the guidelines follows and can be applied to questions in this section:

LOCATION - When selecting a location, establishments will need to consider the physical environment of the site, accessibility, separation of the establishment premises from other businesses, common areas shared by other establishments, and whether or not the establishment will conduct uninspected businesses such as retail stores or custom slaughter on or near federally inspected premises. Potential building sites should be evaluated for sanitation hazards. The location should separate non-inspected businesses from the official establishment to keep product from becoming contaminated from the operation of an adjoining business.

The following part covers 1.a. above.

LAYOUT – When planning the facility or building layout, the establishment must consider such item as the placement of rooms and equipment, product flow and people traffic patterns. Not only does a poorly designed establishment affect productivity, but it may result in congested operations that can lead to insanitary conditions. There are ten areas to consider when planning an adequate layout. They are:

1. Flow of Operations – The direction that product moves or flows within an establishment can have enormous influence on sanitation and the safety of finished products. From a product flow standpoint, all raw meat and poultry products are considered as potentially microbiologically contaminated and handled accordingly. Product being processed should flow progressively from highest potential exposure to contamination to the least potential exposure to contamination, with intervening processes designed to remove or otherwise reduce the contaminants whenever possible. The flow of air and people should be just the opposite, moving from the cleanest areas progressively toward less clean areas. When designing product flow, consider the following:

- * Moving product from raw to final cooked product areas to systematically reduce the risks of contamination along the way.*
- * Locating trash dumpsters and receptacles so that they do not create a risk of product contamination.*
- * Selecting rooms large enough to permit the installation of all necessary equipment with space for establishment operations and inspection.*
- * Locating people passageways to provide maximum clearance to products, work areas, and production equipment.*
- * Keeping truckways unobstructed.*

2. People Traffic Flow – This addresses the flow of people through product operational areas and is one of the most serious risks for production contamination. People can act as carriers and bring outside contaminants such as dirt, debris, and vermin which can both directly and indirectly contaminate product. Ways to reduce and control the flow of people include the following:

- * Establishment design should not require personnel not routinely assigned to specific work areas to be routed through those work areas. For example, personnel working in the live animal areas should not be required to travel through cooked product areas to use welfare rooms.*
- * Welfare rooms, such as toilet rooms, dressing (locker) rooms, and cafeterias, should be designed to minimize contamination because of the traffic patterns of the people.*

3. Separation of Raw and Ready-to-Eat Product – Potential cross contamination of ready-to-eat product by raw products may occur if the layout does not provide for separation of these products. To prevent cross contamination in the preparation of products, the following are guidelines should be considered:

- * Exposed cooked product areas should be physically separated from other areas of the establishment. Non-pedestrian passage openings may be present for the transfer of product or supplies.*
- * A ventilation system should be used to direct airflow away from exposed cooked product areas.*
- * Environmental control equipment such as fans and evaporator condensation pans should not be located above the product.*
- * Welfare rooms, dry storage, maintenance, box/carton make up, packaging, and palletizing areas should be separate, but adjacent to, the exposed cooked product rooms.*

** Cooked product should be covered in rigid containers to protect it from contamination while in storage.*

** Separate coolers and/or freezers should be available to use for exposed cooked product.*

** All cooking apparatuses for exposed products should have separate entry and exit portals.*

** No cooked product wash or reconditioning sinks should be used.*

4. Perishable Product Rooms – This addresses the growth of microorganisms in operations which could contaminate product. In addition, care should be taken to prevent contamination from other operations such as where raw ingredients are prepared. Non-meat or non-poultry ingredients should be prepared in a room or rooms separate from meat processing rooms. For example, preparation of raw vegetables for use in product should be performed in a room separate from meat or poultry processing rooms.

5. Edible and Inedible Products Rooms and Areas - Edible product can be easily contaminated by contact with inedible products, grease or sewage from inedible product areas. In order to prevent this contamination from occurring, consider the following in the placement of these rooms:

** The flow of inedible and condemned product should be designed so that it does not come into contact with edible product.*

** An inedible products department should be separate and distinct from the areas used for edible products. Inedible product rooms, grease interceptors, and sewage treatment equipment must be located away from edible product rooms.*

** Hooded, closed chutes that lead directly from the slaughter room to the inedible handling room are designed to prevent objectionable odors from inedible and condemned products from entering edible products rooms.*

** If rendering facilities are not available at the establishment watertight storage facilities should be provided to hold these products before their removal to rendering plant. These storage facilities should be separate and apart from edible products rooms, and constructed to prevent unsanitary conditions including attraction or harborage for vermin.*

** Areas for inedible trucks should be paved and enclosed for ease of cleaning and to control odors and vermin.*

** Where necessary, the boiler room should be a separate room to prevent dirt and objectionable odors entering from it into rooms where meat products are processed or handled.*

6. Byproducts for Use in Animal, Pet, or Fish Food - Establishments that process byproducts into animal, pet, or fish food should provide rooms for decharacterizing, chilling, packaging, or otherwise preparing the byproducts. The following guidelines should be used when designing and constructing these rooms:

** Byproducts to be used as animal, pet, or fish food should be stored separately to prevent cross contamination and commingling with edible products.*

7. Coolers and Freezers - Coolers and freezers need to have enough space to refrigerate and store product. Product should be stored in a manner that will preclude conditions

that may lead to the contamination of product. The following guidelines will assist you in preventing conditions that could lead to contamination of your product:

** Coolers and freezers, including doors, should be constructed of materials that can be readily and thoroughly cleaned. They should be durable, rigid, impervious to moisture, non-toxic, and non-corrosive. Freezer doors should be constructed and installed to prevent accumulation of frost.*

** Coolers and freezers should be equipped with floor racks, pallets or other means to ensure protection of product from contamination from the floor.*

8. Dry Storage - Packaging materials and ingredients should be stored to preclude conditions that may lead to contamination of product. The following guidelines will assist the establishment in the planning of the dry storage area:

** Dry storage materials should be stored in a room dedicated to dry storage only.*

** The dry storage area should be constructed so that racks can be spaced away from the walls and passageways maintained between rows. This facilitates cleaning of the area. In addition, the construction should allow for all meat or poultry ingredients and/or packaging materials to be stored in closed containers on racks or pallets.*

9. Incubation Room for Canned Products - A room or incubator for incubating samples of fully processed canned meat or poultry must be provided in all establishments conducting regular canning operations. Consider the following guidelines when building this room:

** An accurate time/temperature recorder must be provided. To prevent temperature variations, a means for air circulation should be provided.*

** Shelves should be provided to hold canned product. The shelves should be made of expanded metal or heavy gauge wire mesh and be removable for cleaning.*

** The floor in the room should be pitched to a floor drain equipped with a removable screw-plug.*

** The door of the room should be equipped for sealing by the inspector, if necessary.*

10. Vehicular Areas Outside the Building - Special care should be given in the design of vehicular areas outside the building, not only to provide room for trucks and other vehicles to operate without damaging your building, but to prevent unsanitary conditions which might contaminate product in the establishment. Establishments should consider the following in designing the vehicular areas:

** Areas outside the building where vehicles are loaded or unloaded should be paved with concrete or a similar hard surface. Hard surface areas allow these areas to be kept clean and eliminate the potential for water puddles or dust.*

** Areas outside the building where vehicles are loaded or unloaded should be drained. Drainage from the loading docks should be confined to the immediate area of the dock.*

** The vehicular areas should be large enough to accommodate the turning radius of the largest trucks or shipping vehicles used by the establishment.*

** The vehicular areas adjacent to the establishment should have hose connections for cleaning.*

The following part covers 1.d. and 1.e. above.

WELFARE FACILITIES FOR ESTABLISHMENT EMPLOYEES - Cross contamination from employee welfare facilities should be addressed when designing and locating employee facilities. The facilities should prevent overcrowding and congestion and provide enough handwash sinks and toilets for your employees. In making any modifications to or building any welfare facilities for your employees, the establishment should ensure that:

1. Dressing (Locker) Rooms - are provided for employees. In addition to privacy, these dressing rooms should be located where they will not be a potential source of cross contamination of product. The following guidelines apply for these dressing rooms:

** Dressing rooms should be separate from rooms or compartments where product is prepared, stored, or handled.*

** Dressing rooms should be separated from the toilet area.*

** Separate dressing rooms should be provided for each sex if both sexes are employed by the establishment.*

** Dressing rooms should have abundant, well-distributed light of good quality.*

** Separate dressing rooms for raw product and other product department employees will help prevent cross contamination of product.*

** Receptacles for soiled clothing should be provided adjacent to employees' dressing rooms.*

2. Lockers - are provided for employees clothing and personal items. To prevent insanitary conditions, the following guidelines for choosing locker type, arrangement, and location:

** To prevent the potential for cross contamination, the location of lockers should be separate from rooms or compartments where product is prepared, stored, or handled.*

** Lockers should be large enough to store a change of clothing and other personal items.*

** For ease of cleaning, lockers should be constructed of materials that are rigid, durable, non-corrosive, easily cleaned and inspected, impervious to moisture, a light, solid color, with a smooth or easily cleaned texture, and have sloping tops.*

** Lockers should either be installed so that there is enough room under them that they can be easily cleaned and inspected, or they should be sealed to the floor.*

3. Drinking Fountains – provide sanitary drinking water. The following guidelines should be followed when installing drinking water fountains:

** Drinking water fountains should be provided at convenient locations throughout the establishment to minimize the distance that employees need to travel to reach a fountain. This is especially important in preventing cross-contamination from employees working in raw or inedible areas and traveling to processing or ready-to-eat areas to use a fountain. The following locations should be considered for placing drinking fountains:*

*** welfare areas including cafeterias, dressing (locker) rooms, and toilet rooms*

*** inspectors' offices*

*** edible product areas including kill floor, deboning, and cut-up areas*

*** inedible product areas*

*** immediately outside freezers and coolers*

*** storage areas*

** Drinking water fountains should be connected to the potable water supply and either directly connected to the underfloor drainage system or should discharge through an air gap to a hub drain.*

** Drinking water fountains should be other than hand operated, and if placed as part of handwash sink, should be located high enough to avoid splash from the sink.*

4. Toilet Rooms - are not a source of potential contamination of product. Care should be taken in the design of these rooms from their location in the establishment's layout to the number of toilets provided. Consider the following guidelines:

** Toilet rooms need to be separated from the rooms and compartments in which products are prepared, stored, or handled.*

** Toilet rooms that open directly into rooms where meat products are exposed should have self-closing doors and should be ventilated to the outside of the building.*

** Toilet rooms should be arranged so they are entered through an intervening dressing room or vestibule and not directly from a production or storage room.*

5. Eating Rooms and Areas – are located/constructed in such a way as to prevent employees from contaminating products or contaminating their food with microorganisms from the raw products or from their working environment. Establishments should provide separate eating rooms or areas for employees.

6. Handwash Sinks – are situated and used to prevent cross contamination of product by your employees by providing conveniently located handwash sinks. Handwash sinks are needed in toilet rooms, dressing (locker) rooms, and production rooms. Consider the following guidelines when making decisions as to where you need a handwash sink:

** Handwash sinks are needed near toilet rooms and dressing (locker) rooms. They should be other than hand operated. There should be hot and cold running water, soap, and towels. Single use towels should be used.*

** Handwash sinks in welfare rooms and areas should have a combination mixing faucet delivering both hot and cold water with an high enough above the rim of the bowl to enable the washing of arms as well as hands.*

7. Ventilation – is use in welfare rooms, such as toilet and dressing rooms. Care should be taken to make sure that they are ventilated to prevent odors from entering production areas. Consider the following guidelines:

** Welfare rooms that are not air-conditioned should be mechanically ventilated through an exhaust fan taking air to the outside. Airflow from welfare rooms should be released outside the establishment.*

** Toilet and dressing rooms that are located where no natural ventilation is available should be equipped with an exhaust fan (activated by a common switch with the lighting in the area) and a duct leading to the outside. Doors to dressing and toilet rooms ventilated in this manner should have a louvered section about 12 inches by 12 inches minimum in the lower panel to facilitate airflow.*

8. *Employees Working in Inedible Product Areas – are prevented from common areas with edible product employees. To minimize this risk to product, separate welfare rooms for employees working in areas such as hide cellars, condemned or inedible product rooms, or live animal holding areas, from welfare rooms of other employees working with raw or heat processed, exposed, edible product.*

The following part covers 1.a. above.

CONSTRUCTION - Construction design is the selection of appropriate construction materials for the establishment. The following guidelines should be used:

1. Building Construction Materials for Rooms (Finished Surfaces) - Production and storage areas need to be constructed with materials that are readily and thoroughly cleaned. Product in production and storage areas is at risk for contamination from indirect contact with materials used for construction of the building. In order to be readily and thoroughly cleaned, building construction materials in production and storage areas must be:

** Rigid and durable.*

** Non-toxic and non-corrosive.*

** Impervious to moisture.*

** A light, solid color such as white.*

** Smooth or textured with an easily cleaned, open pattern, for example, a pattern where the veins and depressed areas are continuous or have an outlet and are not enclosed.*

In addition, consider the following guidelines for selecting construction materials:

** In non-production and non-storage areas, building construction materials should be easy to clean thoroughly.*

** Special consideration should be given before using wood as a construction material.*

*** Wood is absorbent and can absorb water and other substances, including chemicals that create a risk for contamination of meat or poultry products.*

*** Wood is easily damaged and may create wood particles (splinters) that contaminate meat or poultry products.*

*** If wood is used as a construction material in exposed product areas of the official establishment, it is recommended that the wood be milled smooth and completely sealed with a coating to prevent the wood from adulterating meat or poultry product. The coating should be able to be readily and thoroughly cleaned durable, rigid, impervious to moisture, non-toxic, and non-corrosive.*

*** The use of hot linseed oil to treat or coat wood in exposed product areas is not recommended because it promotes the growth of molds and fungi.*

2. Floors - In addition to any obvious debris on a floor, product can become contaminated by the flooring or microorganisms living in debris in tiny crevices in the floor. In order to avoid these sources of contamination, consider the following guidelines when selecting and installing flooring in your establishment:

** Floors in areas where product is handled or stored should be constructed of durable, easily cleanable materials, and be impervious to moisture. Commonly used materials are concrete, quarry tile, brick, and synthetic material.*

** Floors should be installed and maintained to reduce the likelihood of cracks, depressions, or other low areas that would accumulate moisture.*

** Floors where operations are conducted should have a slip-resistant surface. Good results are obtained by using brick or concrete floors with abrasive particles embedded in the surface. Concrete floors should have a rough finish.*

** Floors should be sloped to avoid puddles or depressions within the slope where water will stand.*

3. Coving/Curbs - Coving is used at the wall-floor juncture, column (post)--floor juncture, and equipment support-floor juncture to provide a smooth transition for ease of cleaning and inspection. Consider the following guidelines when using coving or curbs:

** Coving in production and storage areas should include the following criteria:*

*** All seams should be tight-fitting and sealed to eliminate all cracks and crevices that may shelter insects, vermin, and microorganisms.*

*** The coving should eliminate any sharp angles that allow the accumulation of materials.*

** Curbs should be provided to protect walls and wall finishes. Curbs should be high enough to protect the walls from pallets, trucks, or containers used in the establishment. Coving should be provided at the base of the curb.*

4. Stairs - In selecting stairs consider the following:

** Stairs should have solid treads and closed risers and should have side curbs of similar material.*

5. Catwalks and Access Platforms - When installing catwalks and access platforms consider the following guidelines:

** Catwalks and access platforms in edible product handling departments should be constructed of materials that meet the same guidelines as flooring.*

** Open grating should not be used for the flooring of catwalks and access platforms inside the establishment, particularly in production areas. Dirt and other debris from shoe soles can be scraped off by the grating and contaminate product, packaging material, and equipment.*

** Catwalks and access platforms should not be installed over production lines and processing equipment.*

6. Interior Walls Including Posts and Partitions - To prevent product from becoming contaminated by contact with interior walls, care needs to be taken in selection of materials for the finished surface of walls. Consider the following when selecting a finish:

** Interior walls, in areas where product is stored or handled, should be finished with materials that will make them susceptible to being readily and thoroughly cleaned and impervious to moisture. Examples of such materials are glazed brick, glazed tile, smooth concrete, and fiberglass reinforced plastic (FRP).*

** Walls should have a smooth texture, not one that is rough or uneven.*

** Fasteners for wall covering material should be solid, smooth headed, and not have recesses which allows the collection of foreign material.*

7. Ceilings - Ceilings, in areas where product is stored or handled, should be constructed to prevent the collection of dirt or dust that might sift through from the areas above or fall from overhead collecting surfaces onto equipment or exposed products. Therefore, it is recommended that ceilings and overhead structures be maintained free of sealing paint or plaster, dust, condensate, leaks, and other materials or defects. In addition, ceilings in areas where product is stored or handled should be constructed and finished with materials that can be thoroughly cleaned and are moisture resistant. Examples of such materials are smooth concrete and fiberglass reinforced plastic.

8. Windows and Skylights - Windows (and skylights) can be a potential source of contamination of product by dirt, water, debris, or broken glass. Consider the following when selecting and installing windows:

** All outside windows, except for those in receiving and feed rooms, should have protection to exclude insects, birds, and other vermin.*

** Window ledges should be sloped about 45 degrees to prevent the accumulation of dirt, water, or debris.*

** To avoid damage to window glass from impact of hand trucks and similar equipment, the sills should be at least 3 feet above the floor.*

** Windows that are installed in walls in exposed product rooms should have panes of acrylic or polycarbonate plastic or other shatter-proof material.*

9. Doorways and Doors (General) - Doors are barriers that allow the movement of product and people, but also present a barrier to contamination such as dirt, insects, and other vermin as well as the microbiological hazards that they carry. The door type, construction material, and room in which the door is located are all important considerations when doors are installed in the establishment. Doors are important in maintaining sanitary conditions especially in production and storage areas. In production and storage area use the following guidelines for doors:

The most effective doors have the following characteristics:

** They are impervious to moisture.*

** They are tight fitting to minimize air exchange and to prevent the entry of insects and vermin into the establishments.*

** They are self-closing and used throughout the establishment, especially in areas where toilet rooms open directly into rooms where meat and poultry are exposed, to prevent contamination of products with odors and their associated contaminants.*

** They are high and wide enough to allow the movement of exposed product through the doorways without it coming into contact with the door or jamb.*

** They are rigid and durable, and the junctions at jambs, walls, and floors are sealed to eliminate all cracks and crevices for debris, insects, and dirt to collect.*

** Doors that open directly to the outside of the building from production rooms should have an intervening closed space, such as a vestibule or enclosed lock, to prevent the direct access of contaminants and microbial organisms to areas inside the establishment.*

10. *Types of Doors - In selecting a type of door for your establishment you need to consider the location of the door and whether or not product will be traveling through it. The following guidelines for different types of doors may be useful to you when selecting a door:*

** The horizontal double-swinging, impact door is a bi-parting, inflexible panel door with plastic windows (vision panels) that swings only in the horizontal plane. If you select this door, consider the following:*

*** This door may be useful in rooms with dimensions that would not permit the use of a roll-up, vertical sliding or horizontal sliding door.*

*** Because this door must be manually opened, the door can be damaged creating sanitation and maintenance problems.*

** The horizontal sliding door (manual and automatic) is a single or bi-parting, inflexible door that moves only in the horizontal plane. If you select this door, consider the following:*

*** This door may be useful in rooms with dimensions that would not permit the use of a roll-up or vertical sliding door.*

*** The automatic opening option is recommended not only for sanitation reasons, but it also prevents damage.*

** The vertical sliding door (manual or automatic) is a single, inflexible panel door that moves only in the vertical plane. If you select this door, consider the following:*

*** This door may be useful in rooms with dimensions that would not permit the use of a roll-up or horizontal sliding door.*

*** The automatic opening option is recommended not only for sanitation reasons, but it also prevents damage.*

** The overhead garage-type door (manual or automatic) is a hinged, multi-paneled door that moves from the vertical to the horizontal plane. If you select this door, consider the following:*

*** This door may be an excellent choice for sheds or buildings used to store equipment, such as a lawn mower, that is used for the outside maintenance of the establishment's property.*

*** It is recommended that these types of doors not be used in exposed product areas or areas subject to wet clean-up because these doors have spaces between the panels that allow the collection of product, such as meat and fat, as well as contaminants.*

** The roll-up door (manual or automatic) is a single flexible panel door that moves only in the vertical plane and when open, coils tightly onto a drum assembly. If you select this door, consider the following:*

*** This door can be an excellent alternative especially where space for opening a door is limited.*

*** Several additional features should be installed on this type of door to make it an effective barrier against contamination.*

** The air curtain or air door is a door that uses a layer of air generated by mechanical fans to separate two rooms or areas. If you select this door, consider the following:*

*** This door needs to be carefully selected, installed, and maintained to be effective.*

*** If an air imbalance (pressure imbalance) develops at the door opening, the separation effect may be diminished or eliminated. Air imbalance can occur from airflow changes from any other openings in the rooms, especially other doors.*

*** The movement of the air can stir up contaminants, such as dirt and dust, if the area around the door is not kept clean.*

The following part covers 1.b., 1.c., 1.d., and 1.f. above.

LIGHTING, VENTILATION, REFRIGERATION, AND EQUIPMENT - Controlling the manufacturing environment maintains a sanitary environment in meat and poultry operations.

1. Lighting - Well-distributed, good-quality artificial lighting is needed at all places where natural light is unavailable or insufficient. Lighting is critical to maintaining a sanitary environment for slaughter and processing operations. Without adequate lighting, insanitary conditions are often difficult to see and correct. When selecting and installing lighting systems, consider the following requirements:

** Light fixtures in rooms where exposed meat or poultry is handled should ensure maximum safety, to preclude contamination of products with broken glass and prevent the collection of dirt, product, and debris on lamp surfaces, including fixture surfaces not easily cleaned or inspected.*

** Lighting must be intense enough to allow both the establishment and inspection personnel to see insanitary conditions and product contamination. The intensity of lighting is measured in foot-candles. The guidelines provide recommendations for minimum foot-candles for artificial lighting.*

2. Ventilation - There should be enough ventilation for all areas of the establishment including workrooms, processing, packaging, and welfare rooms to ensure sanitary conditions. A good ventilation system is important to the production of wholesome meat and poultry products. Without controlling the quality of the air coming into the establishment, products may become contaminated with dust, insects, odors, or condensation. When designing your ventilation systems, you should consider the following guidelines:

** The ventilation system should be designed so that turbulence is avoided. The longer the distance the air has to flow, the greater the resistance the air encounters not only from static air, but also from solid objects such as walls, equipment, people, and product.*

** The ventilation system should be designed with the size of the establishment in mind. The larger the facility, the greater the volume of air that must be moved.*

** The ventilation system should be designed to compensate for changes in outside temperature and humidity that cause condensation problems within the establishment.*

** Screens and filters should be used where needed to screen out dust, odors, and insects brought in from the outside to prevent product contamination.*

** Mechanical ventilation should be used to bring in fresh air to areas where natural ventilation is inadequate.*

** Ventilation should prevent vapor formation, such as steam or fog, that would affect sanitation or interfere with the inspector's ability to perform inspection.*

** When exhaust fans are installed, provision should be made to provide enough outside make up air to prevent air from being drawn into and through docks, coolers, and production areas to the area served by the exhaust fan.*

3. Equipment (General Design and Construction) - Equipment materials should comply with 21 CFR, Parts 170-190 of the Food and Drug Administration (FDA) regulations for direct food contact. Equipment and utensils used for handling as preparing edible product or ingredient in any official establishment should be easily cleaned and not be a source of contamination. Consider the following guidelines when selecting equipment.

** All direct product contact surfaces should be smooth; maintained free of pits, cracks, crevices and scale; corrosion and abrasion resistant; non-absorbent; shatterproof; nontoxic; and not capable of migrating into food products.*

** Equipment should not be painted on areas in or above the direct product contact area.*

** Construction materials that are sources of contamination include cadmium, antimony or lead as plating or the plated base material, lead exceeding 5 percent in an alloy and enamelware and porcelain used for handling and processing product.*

** Equipment should be designed and installed in such a way that foreign materials, such as lubricants, heat exchanger media, condensate, cleaning solutions, sanitizers and other nonfood materials, do not contaminate food products.*

** Equipment is self-draining or designed to be evacuated of water.*

** All product contact surfaces allow contact with cleaning solutions and rinse water.*

** Clean-in-place (CIP) systems should have sanitation procedures that are as complete and effective as those for cleaning and sanitizing disassembled equipment. To remove all organic and inorganic residues, CIP systems should meet the following criteria:*

*** Cleaning and sanitizing solutions and rinse water should contact all interior surfaces of the system.*

*** The system should be self-draining, with no low or sagging areas.*

*** The pipe interiors should be highly polished (120-180 grit) stainless steel for easy inspection.*

*** Easily removable elbows with quick-disconnect mechanisms should be installed at each change of direction. Elbows should be short enough to permit verification that the interior has been cleaned.*

The following part covers I.e. above.

WATER SUPPLY - The water supply should be ample, clean, and potable with adequate pressure and facilities for its distribution in the establishment and its protection against contamination and pollution.

1. Potable Water - An adequate supply of fresh clean water is of primary importance in plant operations. The first requirement is that the water supply to the plant be potable or safe for human consumption or food processing. The plant water supply must meet the potability standards in the National Primary Drinking Water Regulations issued by the Environmental Protection Agency (EPA).

2. Backflow - Public health officials are concerned about cross-connections that may permit backflow in potable water supply distribution systems. Cross-connections may

appear in many forms and in unsuspected places. Reversal of pressure and flow in the water system may be unpredictable. Plumbing cross-connections between a potable and nonpotable water supply may constitute a serious public health hazard.

There are numerous cases where cross-connections have been responsible for contamination of potable water and have resulted in the spread of disease. These concerns, as they relate to meat and poultry plants, deserve special attention. The problem is continual as potable water and piping systems are installed, repaired, replaced, or extended

Two basic types of hazard may be created in piping systems: the solid pipe with valved connections and the submerged inlet. The solid pipe connection is often installed to supply an auxiliary piping system from the potable source. It is a direct connection of one pipe to another pipe or receptacle. Solid pipe connections may be made accidentally to waste disposal lines when it is incorrectly assumed that the flow will always be in one direction. An example would be connecting a line carrying used, nonpotable cooking water from a water jacket or condenser directly to a waste line without an air gap (see below). "Backflow" will occur with a submerged inlet if the pressure differential is reversed without an air gap. Submerged inlets are created when the outflow end of a potable water line is covered with water or other liquid. The other liquid may not be potable. Submerged inlets could be created by a hose lying in a pool or puddle of water on the floor. Once a cross-connection exists, any situation that causes a pressure differential with the potable line having the lower pressure can result in contamination of the entire water distribution system and potable water supply. This is called backflow and can be produced under a variety of circumstances as illustrated below:

** Backsiphonage is one form of backflow. It is caused by negative pressure in the delivery pipes of a potable water supply and results in fluid flow in the reverse direction. It may also be caused by atmospheric pressure exerted on a pollutant liquid source that forces the pollutant into a potable water supply system that is under vacuum. The action in this case is the common siphon phenomenon. The negative pressure differential that will begin the siphoning action is a potential occurrence in any supply line.*

** Differential pressure backflow refers to a reversed flow because of backpressure other than siphonic action. Any interconnected fluid systems in which the pressure in one exceeds the pressure of the other may cause flow from one to the other because of the differential. This type of backflow is of concern in buildings where two or more piping systems are maintained. The potable water supply is usually under pressure from the city water main. Occasionally, a booster pump is used. The auxiliary system often is pressurized by a centrifugal pump, although backpressure may be caused by gas or steam pressure from a boiler. A reversal in differential pressure may occur when pressure in the potable system drops below that in the system to which the potable water is connected. The best method of preventing this type of backflow is the complete separation of the two systems and/or an air gap. Other safety methods involve the installation of mechanical backflow prevention devices. All methods require regular scheduled inspection and maintenance to ensure ongoing effectiveness of installed devices.*

Some areas that should be considered in providing some form of protection from backflow and back siphonage include the following:

- * Water supply to pens for wash down or livestock watering.*
- * Water supply to compressor cooling systems, cooling towers, and boiler rooms.*

- * *Water supply to cleanup systems, clean in place (CIP) systems, etc.*
- * *Water supply to hose connections.*

Various mechanical antibackflow devices are available to prevent backflow into a potable water supply system. Generally, the selection of the type and number of fail-safe devices should be based upon the degree of hazard from contamination. Additional considerations include piping size, location, and the need to test periodically the backflow devices to ensure proper operation.

There are six basic types of devices that can be used to correct cross-connections:

- * *Air gap*
- * *Barometric loops*
- * *Vacuum breakers--both atmospheric and pressure type*
- * *Double check valves with intermediate atmosphere vent*
- * *Double check valve assemblies*
- * *Reduced pressure principal backflow preventers*
- * *Specific requirements concerning backflow can be found in local building and board of health codes.*

The following part covers I.e. above.

GENERAL PLUMBING FACILITIES - If the plumbing system is not properly installed, contamination of products can occur from flooding, back siphonage, stoppages and cross-connections with the potable water system.

1. Hose Connections and Hoses - There should be enough conveniently located hose connections with steam and water mixing valves or hot water connections provided throughout the establishment for cleaning purposes. Hose connections are important in promoting routine cleaning of the establishment. Consider the following guidelines when determining how many hose connections, location of hose connections, and storage of hoses:

- * *The number of hose connections depends on the number of drains.*
- * *If a shut-off nozzle is provided on the hose after the hot and cold water mixing valve, the vacuum breaker at the hose connection to the mixing valve will not work. Vacuum breakers should be installed on the hot and cold water supplies prior to the mixing valve to prevent such problems.*
- * *Hose connections should be provided with vacuum breakers to prevent back siphonage.*

2. Establishment Drainage System - There need to be efficient drainage and plumbing systems for the prompt removal of liquid and suspended solid wastes from the processing environment. Consider the following guidelines when designing or modifying your drainage system:

- * *All plumbing should be sized, installed and maintained in accordance with applicable state and local plumbing codes, ordinances, and regulations.*
- * *Drainage lines should be located so that if leakage occurs, it will not affect product or equipment.*

3. Floor Drains - All parts of floors where operations are conducted should be well drained. There are two basic types of drains: point drains and trench drains. Point drains, the most commonly used drain in most areas, are located in strategic points in the room with the floor sloped toward the drain. The wastewater flows over the surface of the floor until it reaches and is carried away by the drain. Trench drains involve a trough or trench that collects the waste from a larger area and directs the flow to a drain opening. The flooring is sloped toward the trench.

In a typical plant, one four-inch (10.16 cm) drainage inlet is provided for each 400 square feet (37.16 square meters) of floor space. A slope of about one-quarter inch per foot (2.08 cm per meter) to drainage inlets is generally adequate to ensure proper flow with no puddling. In dry production areas, where only a limited amount of water is discharged on to the floor, an adequate slope may be about one-eighth inch per foot (1.04 cm per meter). It is important that floors slope uniformly to drains with no low spots to collect liquid.

** The location of floor drains depends upon many factors such as the type of task conducted in the space, the geometric shape of the area drained, truck traffic patterns, and equipment locations.*

** There are special drainage considerations in areas where there is a high volume of water usage. The water in trench drains should flow in the opposite direction of the product flow, for example, from the poultry evisceration to the picking areas.*

** All parts of floors where wet operations or where floors are to be frequently hosed down should be pitched to floor or trench drains.*

** Floor drains should not be located under equipment because it makes them inaccessible cleaning.*

** Rooms without floor drains such as dry storage, large finished product coolers, and distribution warehouses may prefer to use mechanical cleaning machines instead of installing drains. Examples of such cleaning devices are floor scrubbers and dry/wet vacuum machines.*

4. Trap Seals - Each floor drain should be equipped with a deep seal trap and vented properly to the outside. The purpose of such traps is to seal off the drainage system so that foul odors (sewer gases) cannot enter the plant. Effectiveness of the trap depends upon enough water remaining to constitute a seal. As water flows through the trap and down the drainpipe, suction is created that will pull the water out of the trap and break the seal unless the suction is broken by venting the drainpipe on the effluent side of the trap to the outside air. The seal can also be broken by evaporation of trapped water. This is not a problem in frequently used drains, but does occur where drains are seldom used.

5. Drainage Lines - All drainage lines must comply with local code requirements. They should be installed and maintained to be leakproof. To prevent drainage lines from becoming entrances into the plant for pests, including rats and mice, all lines must be equipped with effective rodent screens. Secure drain covers, in addition to keeping out pests, also serve to prevent blockage of the traps and drainage lines with product scraps or other material too large to flow freely.

6. *Cleanouts - Cleanouts should be installed in the drainage system to prevent sewer blockages. Consider the following guidelines when installing cleanouts:*

** Cleanouts should be located so they are readily accessible, and can be used without constituting a threat of contamination to edible products.*

** To help avoid water puddling, cleanouts should be located on the "high lines" of floor slopes and away from traffic patterns.*

ESTABLISHMENT SEWAGE TREATMENT - The design and construction of sewage treatment facilities must comply with local code requirements. An improperly designed sewage system can contaminate the ground and water supply.

1. Establishment Sewage Treatment – Sewage should never be allowed to come into contact with products, equipment, utensils, or any food contact surfaces. When installing an establishment sewage treatment facility, consider the following guidelines:

** The system should be large enough to handle the amount of sewage that the establishment produces and accommodate future increases.*

** If a private septic tank, pre-treatment, or treatment system is used, it should be designed and operated to prevent contamination of products.*

** The sewage facility should be located away from product operations and ingredient and packaging storage areas.*

** An area for cleaning solid waste containers with hot water, drains, and curbing should be located near any solid waste disposal facility.*

2. Grease Catch Basins or Interceptors - Grease catch basins can be a source of contamination of products if not properly designed and located. Consider the following guidelines when constructing a grease catch basin:

** Catch basins or interceptors for recovering grease should not be located in or near edible product departments or areas where edible products are shipped or received.*

** When a catch basin is located inside an establishment, it should be sealed with a gastite cover and located in a ventilated room.*

** Grease catch basins should be constructed so they can be completely emptied of their contents for cleaning.*

** The area surrounding an outside catch basin should be paved with impervious material, such as concrete, and drained.*

The following part covers 1.a., 1.c., and 1.f. above.

MEAT SLAUGHTER ESTABLISHMENTS - Although the flesh of healthy livestock is practically sterile, when the animal is killed many factors can contribute to contamination of the carcass including improperly designed and constructed slaughter facilities. Different species of livestock need different slaughter facilities.

Meat Slaughter--General Facilities Guidelines - The following guidelines apply to all establishments that slaughter cattle, calves, sheep, goats, hogs and equines. If you are building or modifying an establishment that slaughters these species, consider

these facilities guidelines to prevent contamination of carcasses during slaughter operations.

1. Livestock Pens - In addition to preventing contamination of the slaughter department and minimizing contaminates on the hides of the animals, proper design and construction of livestock pens prevent injury to the animals. Consider the following facilities guidelines when designing and constructing livestock pens:

** Livestock pens should be located outside the slaughter department to prevent contamination of products from dust, odors, and other contaminates. If possible, the livestock pens should be separated from the department by full-height partitions of impervious material.*

** Livestock pens, driveways, and ramps should be free from sharp or protruding objects which could cause injury or pain to the animals.*

** Floors of the pens, ramps, unloading chutes, and runways should be constructed to provide good footing for livestock. Waffled floor surfaces and cleated ramps are effective construction designs.*

** Floors of the pens, ramps, unloading chutes, and runways should be sloped for drainage and cleaning.*

** Pen enclosures (except gateways) should be high and sturdy enough to prevent livestock from escaping.*

** Gates, fences, and chutes should have smooth surfaces that are easily cleaned.*

** Man gates or, if the walls are concrete, toe holds formed in the walls should be present to allow people to escape from pen enclosures in an emergency.*

** To help prevent livestock from slipping and falling on floors covered with excess water, thereby further contaminating their hides, water troughs should be provided with overflows located above or adjacent to pen floor drains.*

** Hose connections should be provided for cleanups.*

** Covered pens should be provided to protect crippled or downer animals from adverse climatic conditions. If held overnight, the pens should be large enough to allow the animals to lie down and have facilities for feed and water. Pens and driveways should be arranged so that sharp corners and direction reversals of driven animals are minimized.*

** A "U.S. suspect" or "U.S. condemned" pen should be available at all times and designed to allow for complete separation, including the drainage system, from other livestock.*

2. Ante-mortem Inspection Areas - Ante-mortem inspection areas should be designed and constructed to facilitate inspection and to prevent animals from being injured.

Consider the following guidelines in designing and constructing these areas:

** To avoid delays in slaughter operations, pens for ante-mortem inspection should have the capacity for holding the maximum number of animals of the various species that will be slaughtered in a single day.*

** To facilitate the ante-mortem inspection of animals, a separate suspect pen with a squeeze chute should be provided, where the temperature of the animals may be taken.*

** At least 50 percent of the livestock pen, including the area where the suspect pen and squeeze chute are located, should be under a weather tight roof to provide an area for proper ante-mortem inspection in inclement weather.*

** Special consideration should be given to designing ante-mortem inspection facilities to allow for humane transporting of crippled or downer animals into the slaughtering department. Because crippled and downer animals have difficulty moving, special doorways and hoists to transport them to the stunning area should be provided.*

3. Slaughter Area - The slaughter area is one of the most difficult areas to keep sanitary because of the nature of slaughter operations. Consider the following guidelines in designing and constructing slaughter areas to minimize contamination of carcasses:

** The slaughter area should be separated from the outside by a full-height partition or wall made of impervious material.*

** Any doors to the outside of the slaughter area should be self closing to minimize the risk of contamination, including contamination by vermin.*

** Slaughter areas should have floor space arranged to facilitate the sanitary conduct of operations and efficient inspection. For example, to prevent contamination of carcasses, truckways through which products are conveyed from the slaughter area to rooms such as the offal cooler, should be located so that the material is not trucked beneath rails from which dressed carcasses and products are suspended. For the same reason, personnel traffic should not move through lines of carcasses.*

4. Stunning Areas Including Chutes and Alleys - Stunning areas, chutes and alleys, should be designed to prevent congestion, injury to animals, and minimize contamination of hides which can lead to contamination of the carcasses. Consider the following guidelines when designing these facilities:

** All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be large enough for the species being slaughtered.*

** All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be free from pain-producing restraining devices, sharp projections such as loose boards, exposed bolt ends, splintered or broken planking, protruding metal, and exposed wheels or gears.*

** All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be free of unnecessary holes and openings where the animals' feet or legs may be injured.*

** Overhead gates should be covered at the bottom edge to prevent injury to the animals.*

** Flooring should be constructed of roughened or cleated cement to reduce falls.*

** Stunning areas should be provided for confining animals for stunning before bleeding.*

** If ritualistic slaughter operations are conducted in the stunning area, shackles to confine the animals also should be provided.*

** When captive bolt stunners are used, the stunning areas should be designed and constructed to limit the free movements of animals so that the operator can locate the stunning blow with a high degree of accuracy.*

** When electrical stunning is used, the stunning area should be constructed so that any power-activated gates will not cause injury to the animals.*

5. Rail Arrangement and Truckways - To prevent contamination of carcasses, rails should be arranged to provide enough room for carcasses to move without touching equipment, walls, columns, other fixed parts of the building, and other carcasses. Consider the following guidelines when arranging rails in your establishment:

** Consideration should be given to the type of rail and the rail speed when determining how rails are to be arranged.*

** Trim rails should be arranged so that carcasses pass the final carcass inspection position after the final trim.*

** To prevent the carcass from becoming contaminated by debris on the floor and from splashes during cleanups, the cooler rails should provide for clearance from the lowest part of the carcass to the highest point of the floor.*

** A room or area for washing gambrels, hooks, and trolleys should be provided. The room or area should have an exhaust fan in an outside wall to dispense steam.*

6. Viscera Separation and Edible Byproducts Refrigeration - Because edible organs and parts (offal) are handled at temperatures conducive to bacterial growth, care must be taken in providing facilities for separation of viscera and for refrigeration of edible byproducts to prevent them from becoming contaminated. Consider the following guidelines for holding edible by products:

** Facilities, such as viscera trucks or pans, should be provided for separating and handling viscera of the various species of animals to prevent commingling.*

** To prevent cross contamination, a separate cooler or a separately drained part of a carcass cooler should be provided for holding edible organs and parts (offal) under refrigeration.*

** To convey the edible byproducts to a cooler, a truck with removable metal drip pans should be provided.*

** To prevent cross contamination, establishment and inspection personnel from the slaughter department should be able to access the edible byproduct cooler without passing through a line of carcasses or through a congested carcass cooler.*

7. Carcass Washing - Special facilities for washing inspected carcasses are needed to remove bone dust and other accidental contamination from the carcass. Consider the following guidelines when designing and constructing this area:

** A separately drained area or an area that is sloped to a floor drain should be provided where inspected carcasses are washed.*

** If the carcasses are washed manually by establishment personnel, a platform should be provided to allow establishment personnel to be able to reach all parts of the carcass.*

8. Retain Room/Compartment - A retain room, cage, compartment, or receptacle may be required by inspection. Depending on the needs of inspection, consider the following guidelines for designing and constructing this room:

** The retain room or compartment must be equipped for locking or sealing.*

** The room or compartment needs to be marked conspicuously "U.S. Retained."*

** If the retain compartment is located in the cooler, the compartment should be separated from the remainder of the cooler to prevent cross-contamination of inspected and passed carcasses. The separation can be accomplished by creating a compartment constructed of partitions of corrosion resistant wire screen or flat expanded metal.*

Cattle--Additional Facilities Guidelines - In addition to the guidelines (sections 1 through 8) for all establishments that slaughter livestock, the guidelines in the following sections 9 through 19 apply to establishments that slaughter cattle.

9. Cattle Dressing Layout - There are a number of different cattle dressing layouts that can be used in a cattle slaughtering operation. Depending on the number of animals slaughtered, rate of inspection, and number of inspectors, you should carefully consider your options for a layout for slaughter operations.

10. Rail Heights, Distances, and other Slaughter Area Dimensions - FSIS guidelines provide recommended distances, including rail heights, rail distances, and other cattle slaughter area dimensions.

11. Dry Landing Area -

A dry landing area large enough to accommodate stunned animals removed from the stunning pen should be provided adjacent to the stunning pen. Consider the following guidelines in designing and constructing this area:

** The area should allow enough room for the livestock.*

** The dry landing area should be located and drained separately from the bleeding area.*

** The dry landing area should be enclosed by a fence high enough and sturdy enough to prevent escape of inadequately stunned animals.*

12. Bleeding Area - To contain blood and prevent it from contaminating carcasses, a curbed bleeding area should be provided. Use the following guidelines in designing and constructing this area:

** The bleeding area should be located so that blood will not be splashed on stunned animals lying in the dry landing area or on carcasses being skinned on the cradle beds, if they are used.*

** The curb around the bleeding area should be located far enough from the dressing bed or cradle to allow room for the carcasses to be maneuvered into the bed or cradle.*

13. Facilities for Head Removal - To avoid contamination of the carcasses from rumen contents, facilities for head removal need to be carefully designed:

** Space should be provided for dehorning, flushing, washing, and inspecting heads; for storing heads on racks or trucks after removal from carcasses; and for head workup.*

** When a down hide puller is used, the head drop and head removal area should be curbed and drained.*

** A head wash cabinet should be provided.*

14. Facilities for Hide Removal - To limit contamination by hides, a hide chute should be provided near the point where hides are removed from carcasses. Consider the following guidelines when designing and constructing these facilities:

** The chute should have a hood of sturdy rust-resistant metal with a push-in door closely fitting a metal frame inclined so as to be self-closing. In order to evacuate airborne contaminants from hides such as scurf, dirt, spores, odors, and hairs, a vent pipe should extend from the hood vertically to a point above the roof.*

** Space needs to be provided between hide pulling and carcass evisceration to permit cervical inspection prior to viscera inspection.*

15. Facilities for Feet and Udders - Because of the high risk of contamination of carcasses from feet and udders that have been removed from carcasses, special facilities, such as a chute or slide, should be used for transferring these parts to containers. Consider the following guidelines for these facilities:

** A chute or slide should be used to avoid splashing of milk or other contaminants onto the carcasses, floor, equipment, and personnel.*

16. Foot Platforms - Foot platforms installed for establishment employees performing various carcass-dressing operations need to be carefully designed and installed to prevent contamination of carcasses. Consider the following guidelines:

** If elevated foot platforms are used, they should be located so they do not touch skinned portions of the carcass.*

** If stationary platforms are used, they should be set far enough away from the dressing rail to prevent contact with the forelegs of cattle.*

** To provide space for operations and to prevent cross contamination by carcasses, push fingers or rail stops on powered conveyor or gravity flow rails should be spaced far enough apart to prevent contact between carcasses.*

17. Viscera Trucks - In establishments with a limited rate of slaughter, viscera are usually placed in a specially designed handtruck for inspection. Consider the following guidelines for use of viscera trucks:

** For ease of cleaning, viscera trucks should be constructed of stainless or galvanized steel.*

** Viscera trucks should have an inspection pan and a lower viscera compartment.*

** When viscera trucks are used, a separately drained area should be available for washing and sterilizing such equipment.*

** To prevent contamination of products, the washing facilities should be located at or near the point where condemned products are discharged from the trucks. When placed where splash might contaminate edible products, the truck washing area should have walls high enough to contain any splash.*

18. Moving-Top Inspection Tables - In some establishments, viscera are placed on a moving-top table for inspection. These tables have special considerations as follows:

** The table should be of a length that provides for evisceration, inspection, and viscera removal.*

** A continuous cleaning and sanitizing system should be available for the table.*

** To prevent contamination of products and the surrounding area, the viscera inspection table should have a drain under the table to prevent water from draining across the floor to other areas of the room.*

** To prevent contamination of carcasses, the foot platform, handwash sinks, hand tool disinfection unit (sterilizer), boot washing cabinet, and boot storage locker should be located alongside the loading end of the table.*

19. USDA Post-mortem Inspection Station and Retain Rail - Special facilities are needed for USDA post-mortem inspection for cattle. Consider the following provisions that must be met when designing these stations:

** An inspection station consisting of 5 feet (1.5 m) of unobstructed line space for each head or carcass inspector.*

** When viscera tables are used, there must be 8 feet (2.5 m) for each viscera inspector on the inspector's side of the table needs to be provided.*

** A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass.*

** A handwash sink (other than one that is hand operated), furnished with soap, towels, and hot and cold water, and located adjacent to the inspector's work area.*

** For each head and viscera inspector on cattle slaughter lines a sterilizer located adjacent to the inspector's work area.*

** For mechanized operations, a line control switch adjacent to each inspection station.*

** Facilities to position tally sheets or other recording devices, such as digital counters and facilities to contain USDA condemned brands.*

** Rail(s) for holding retained carcasses for final disposition along with platforms and handwash sinks. To prevent possible cross contamination, the retain rail must be long enough to prevent carcasses from touching.*

20. Calves, Sheep, and Goats—The guidelines provides a chart of the distances for used for rails and other facilities. When rails are involved in horizontal distance measurements, the distance is measured from the center of the rail. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

Hogs--Additional Facilities Guidelines - In addition to the general guidelines in sections 1 through 8, the following guidelines apply to those establishments that slaughter hogs. Consider these additional guidelines when building or modifying an establishment that slaughters hogs.

21. Livestock Pens - To prevent hogs from overheating, pens for hogs should have either a roof for shelter or a shower system to keep the animals cool in weather with temperatures greater than 70 deg.F (21 deg.C).

22. Location of Certain Operations - To prevent contamination, the following equipment and operations should be located in an area or areas separate from the carcass dressing area, except for the openings for access and passage of carcasses:

*** Hoisting, sticking, and bleeding.*

- ** Scalding vat.*
- ** Dehairing machine located within a curbed area having nonclogging drainage outlet.*
- ** Gambrelling table.*
- ** Singeing operations.*

23. *Rail Arrangements for Hogs - The guidelines provide a chart that provides the recommended distances for rails and other facilities for hog slaughter operations. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.*

24. *Scalding - To avoid contamination of the carcass, a scalding tank is used to remove hair and other contaminants. It is recommended that establishments install a mechanical exhaust fan above the scalding tank to disperse steam.*

25. *Shaving, Singeing, and Carcass Washing - A shaving rail (throw-out rail) should be provided prior to the head dropping operation, so that unclean hogs can be removed from the dressing line for cleaning. If a singer is used to remove hair, it should have an automatic cut off and starter switch to prevent the carcass from burning when the chain stops. If a polisher is used, water sprays to clean the carcass of hair should be provided. To remove hair from the hide which was missed by the scalding and dehairing process, a carcass washer should be located at a point after completion of shaving operations and before the head dropper's station.*

26. *Inspection Facilities - Special facilities are needed for USDA post-mortem inspection for swine. Consider the following guidelines when designing these stations:*

- * An inspection station consisting of 5 feet (1.5 m) of unobstructed line space for each head or carcass inspector must be provided.*

- * When viscera tables are used, there must be 8 feet (2.5 m) for each viscera inspector on the inspector's side of the table needs to be provided.*

- * A minimum of 50 foot-candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass must be provided.*

- * A handwash sink (other than one that is hand operated), furnished with soap, towels, and hot and cold water, must be provided adjacent to the inspector's work area.*

- * For each head inspector on swine slaughter lines, a sterilizer must be located adjacent to the inspector's work area.*

- * For mechanized operations, a line control switch must be provided adjacent to each inspection station.*

- * For swine slaughter lines requiring three or more inspectors, and for those one-and two-inspector configurations where the establishment installs a mirror, special facilities are needed. At the carcass inspection station one glass or plastic, distortion-free mirror, at least five by five feet (1.5 by 1.5 m), must be mounted at the carcass inspection station. The mirror should be mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet (90 cm) away, to allow any inspector standing at the carcass inspection station to readily view the back of the carcass.*

** Facilities to position tally sheets or other recording devices, such as digital counters and facilities to contain USDA condemned brands must be provided.*

The following part covers I.e. above.

ESTABLISHMENT WASTE DISPOSAL - Control and disposal of plant wastes are major concerns. Optimum use and reduction of waste are essential. From a plant sanitation standpoint, there are two vital concerns with waste disposal: (1) Plant waste contains most of the contaminants and disease-producing and product-spoiling microorganisms from the plant production processes; (2) plant wastes attract pests such as insects and rodents.

1. Organic Waste Disposal - When disposing of organic wastes such as feathers, viscera, blood, and manure, the following guidelines should be considered:

- * Waste materials should not be allowed to accumulate on or near the premises.*
- * Waste should be disposed of without creating insanitary or objectionable conditions.*
- * Waste should be removed daily.*
- * Holding bins should be cleaned before reuse and protected from insect and rodent harborage and infestations.*

2. Rubbish Removal - Rubbish, such as paper towels, cartons, office waste, and labeling materials, can become a sanitation problem. The following guidelines should be followed when removing rubbish:

- * Suitable containers should be conveniently located throughout the plant and emptied frequently.*
- * The accumulation of rubbish before its removal should not cause a nuisance.*
- * Plant refuse should be removed daily, or more often if necessary, to prevent a nuisance.*

Reference: Federal Register Vol. 62, No. 164, Monday August 25, 1997

Appendix A Guidelines for:

Location : Page 45027

Layout : Page 45028

Welfare facilities for Est. employees: Page 45029

Construction: Page 45030

Lighting, Ventilation, Refrigeration and Equipment: Page 45032

Water Supply: Page 45033

Plumbing: Page 45034

Establishment Sewage Treatment: Page 45034

Meat Slaughter Establishment: Page 45035

Plant waste Disposal: Page 45041

9 CFR Section 308.3

2. In approving blueprints for official establishments, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

Prior approval of blueprints for facilities and equipment is not required. However, the above guidelines (Appendix A, pages 45027-45041) will assist establishments in providing facilities and equipment that will provide a safe and wholesome food. In addition, every Chapter of the above guidelines has areas applicable to blueprints.

Reference: Not applicable

3. In approving the facilities and equipment of official establishments, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

Prior approval of facilities and equipment is not required in official establishments. However, there are many factors that can control or prevent contamination of meat products. The most prominent guidelines for controlling and preventing contamination are listed in the Chapters on Layout, Welfare Facilities for Establishment Employees, and Meat Slaughter Establishments (Appendix A, pages 45027-45041), as explained above.

In addition, 9 CFR Section 308.3 provides the sanitary requirements needed for facilities and equipment to control and prevent contamination. It states that official establishments shall be maintained in sanitary condition, and to this end, the requirements of this section shall be complied with.

There shall be abundant light, of good quality and well distributed, and sufficient ventilation for all rooms and compartments to insure sanitary condition.

There shall be an efficient drainage and plumbing system for the establishment and premises, and all drains and gutters shall be properly installed with traps and vents approved by the circuit supervisor.

The water supply shall be ample, clean, and potable, with adequate facilities for its distribution in the establishment and protection against contamination and pollution. Every establishment shall make known and, whenever required by the circuit supervisor, shall afford opportunity for inspection of the source of its water supply, the storage facilities, and the distribution system. Equipment using potable water shall be so installed as to prevent back-siphonage into the potable water system. Nonpotable water is permitted only in those parts of official establishments where no edible product is handled or prepared, and then only for limited purposes such as on ammonia condensers not connected with the potable water supply, in vapor lines serving inedible product rendering tanks, in connection with equipment used for hashing and washing inedible products preparatory to tanking, and in sewer lines for moving heavy solids in the sewage. Nonpotable water is not permitted for washing floors, areas, or equipment

involved in trucking materials to and from edible product departments nor is it permitted in hog scalding vats, dehairing machines, or vapor lines serving edible product rendering equipment, or for cleanup of shackling pens, bleeding areas, or runways within the slaughtering department. In all cases, nonpotable waterlines shall be clearly identified and shall not be cross-connected with the potable water supply unless this is necessary for fire protection and such connection is of a type with an adequate break to assure against accidental contamination, and is approved by local authorities and by the circuit supervisor.

The circuit supervisor may permit the reuse of water in vapor lines leading from deodorizers used in the preparation of lard and similar edible product and in equipment where such water is used to thermally process canned product packed in hermetically sealed containers, provided:

The reuse is for the identical original purpose.

All pipelines, reservoirs, tanks, cooling towers, and like equipment employed in handling the reused water are so constructed and installed so they can be cleaned and drained, and are kept clean.

Approval for the reuse of water other than as specified in paragraph (d)(2) of this section or in section 318.305(h) shall be obtained from the Administrator in specific cases.

An ample supply of water at not less than 180 degrees F shall be furnished and used for the cleaning of inspection equipment and other equipment, floors, and walls which are subject to contamination by the dressing or handling of diseased carcasses, their viscera, and other parts. Whenever necessary to determine compliance with this requirement, conveniently located thermometers shall be installed by the operator of the official establishment to show the temperature of the water at the point of use.

Hot water for cleaning rooms and equipment other than those mentioned in paragraph (d)(4) of this section shall be delivered under pressure to sufficient convenient outlets and shall be of such temperature as to accomplish a thorough cleanup.

The floors, walls, ceilings, partitions, posts, doors, and other parts of all structures shall be of such materials, construction, and finish as will make them susceptible of being readily and thoroughly cleaned. The floors shall be kept watertight. The rooms and compartments used for edible product shall be separate and distinct from those used for inedible product.

Rails should be located and passageway space provided so that exposed product does not come in contact with posts, walls, and other fixed parts of the building, or with barrels, boxes, and other containers trafficked through holding and operating areas. Exposed product shall not be placed or stored beneath carcasses in coolers or holding areas.

The rooms and compartments in which any product is prepared or handled shall be free from dust and from odors from dressing and toilet rooms, catch basins, hide cellars, casing rooms, inedible tank and fertilizer rooms, and livestock pens.

Every practicable precaution shall be taken to exclude flies, rats, mice, and other vermin from official establishments. The use of poisons for any purpose in rooms or

compartments where any unpacked product is stored or handled is forbidden, except under such restrictions and precautions as are prescribed by the regulations in this part or by the circuit supervisor in specific cases. The use of insecticides, rodenticides, and similar pest control substances in hide cellars, inedible product departments, outbuildings, or similar places, or in storerooms containing canned or tierced products is not forbidden but only those approved by the Administrator may be used. So-called rat viruses shall not be used in any part of an establishment or the premises thereof.

Dogs and cats shall be excluded from the interior of official establishments; however, dogs may be permitted on the outer premises for guard purposes.

Reference: 9 CFR Section 308.3

4. In using construction and maintenance materials that are toxic free and have appropriate surface finishes, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

Prior approval for construction and maintenance materials is not longer required. However, the guidelines for such materials used in building meat establishments can be found in the chapter on Construction (page 45030), as explained above.

Reference: Not Applicable

5. In securing and maintaining potable water supplies, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

A supply of potable water is required for slaughter and processing facilities. To assist the establishment, the quality control guidelines for water (supply, quality, testing) used in a meat establishment are covered in the Chapter on Water Supply (page 45033), as explained above.

Furthermore, 9 CFR Section 308.3 states that the water supply shall be ample, clean, and potable, with adequate facilities for its distribution in the plant and its protection against contamination and pollution. Every establishment shall make known and, whenever required by the circuit supervisor, shall afford opportunity for inspection of the source of its water supply, the storage facilities, and the distribution system. Equipment using potable water shall be so installed as to prevent back-siphonage into the potable water system. Nonpotable water is permitted only in those parts of official establishments where no edible product is handled or prepared, and then only for limited purposes such as on ammonia condensers not connected with the potable water supply, in vapor lines serving inedible product rendering tanks, in connection with equipment used for hashing and washing inedible products preparatory to tanking, and in sewer lines for moving heavy solids in the sewage. Nonpotable water is not permitted for washing floors, areas, or equipment involved in trucking materials to and from edible product departments nor

is it permitted in hog scalding vats, dehairing machines, or vapor lines serving edible product rendering equipment, or for cleanup of shackling pens, bleeding areas, or runways within the slaughtering department. In all cases, nonpotable waterlines shall be clearly identified and shall not be cross-connected with the potable water supply unless this is necessary for fire protection and such connection is of a type with an adequate break to assure against accidental contamination, and is approved by local authorities and by the circuit supervisor.

Reference: 9 CFR, Part 308.3(d)(1)

6. Within your pest control program(s) for insects and rodents, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

9 CFR Section 308.1 states that every practicable precaution shall be taken to exclude flies, rats, mice, and other vermin from official establishments. The use of poisons for any purpose in rooms or compartments where any unpacked product is stored or handled is forbidden, except under such restrictions and precautions as are prescribed by the regulations in this part or by the circuit supervisor in specific cases. The use of insecticides, rodenticides, and similar pest control substances in hide cellars, inedible product departments, outbuildings, or similar places, or in storerooms containing canned or tierced products is not forbidden but only those approved by the Administrator may be used.

Reference: 9 CFR, Section 308.3

7. When handling “ready-to-eat” products, what regulations, directives, and guidelines address the control and prevention of contamination and cross-contamination of these meat or poultry products? This information should include provisions to separate raw products from cooked products.

Cross contamination of ready-to-eat product by raw product may occur if the layout does not provide for the appropriate separation of these products. To prevent cross-contamination in the preparation of products the following guidelines on Layout (page 45028) are to be considered:

- a. Exposed cooked product should be physically separated from other areas of establishment. A non-pedestrian passage opening may be present for the transfer of products or supplies.*
- b. A ventilation system should be used to direct airflow from exposed cooked product areas.*
- c. Environmental control equipment such as fans and evaporators should not be located above the product.*
- d. Welfare rooms, dry storage, maintenance, box/carton make-up, packaging and palletizing areas should be separate but adjacent to the area.*

- e. Cooked product should be covered in rigid container to prevent contamination while in storage*
- f. Separate cooler or freezers should be available for exposed cooked product.*
- g. All cooking apparatuses for exposed product should have separate entry and exit portals*
- h. No cooked product wash or reconditioning sinks should be used.*

These guidelines would be used by establishments to develop Sanitation Standard Operating Procedures and a HACCP plan for RTE products (see Section C. of this questionnaire and Section J. of the Slaughter/Processing Questionnaire).

Reference: 9 CFR Parts 416 and 417

8. What requirements are there to prevent the contamination/adulteration of foods after processing? For example, are employees handling this product required to wash their hands with soap and hot water before entering the processing room?

The direction in and the means by-which product moves or flows within an establishment are important. From a product-flow standpoint, all meat ought to be considered microbiologically contaminated and handled accordingly. Thus the following guidelines (pages 45032-45034, as noted above) should be followed:

- a. Product being processed should flow progressively from highest potential exposure to contamination to the least potential exposure to contamination.*
- b. The flow of air and people should be the opposite of the product flow.*
- c. Product should move from raw to final cooked product areas to reduce the risk of contamination systematically along the way.*
- d. Locating trash dumpsters and receptacle so that they do not create risk of product contamination*
- e. Selecting room large enough to permit installation of all necessary equipment with space for establishment operations and inspection.*
- f. Locating people passageways to provide maximum clearance to products and production equipment*
- g. Keeping truck-ways unobstructed*

These guidelines are noted in Federal Register Vol. 62, No. 164, Monday August 25,1997 Rules and Regulations (Appendix A): Layout, Flow of operation (1) Page 45028

To prevent product contamination, other guidelines for lighting, ventilation, refrigeration, equipment, welfare facilities, plumbing and sewage disposal/treatment should also be considered. They are mentioned in Federal Register Vol. 62, No. 164, Monday August 25,1997 Rules and Regulations (Appendix A): Lighting, Ventilation,

Refrigeration and Equipment: Page 45032, Plumbing: Page 45034, and Establishment Sewage Treatment: Page 45034.

FSIS regulations require official establishments to have procedures in place to keep retorted and non-retorted containers separated. This can be accomplished by having complete physical separation or by placing dyes on the containers that change color after the heating process. For non-retorted processed products (e.g., cooked patties, cooked roast beef, cured product), establishments must have in place procedures specific to the type of processed product to prevent cross contamination. (9 CFR 318.17 and 318.23)

In addition, These guidelines would be used by establishments to develop Sanitation Standard Operating Procedures and a HACCP plan for RTE products (see Section C. of this questionnaire and Section J. of the Slaughter/Processing Questionnaire).

*Reference: 9 CFR Parts 416 and 417
9 CFR Sections 318.17 and 318.23*

9. What requirements are there to prevent contamination/adulteration of foods during the processing procedure, e.g., by temperature abuse, before the processing standard has been fully met?

FSIS Directives describe time/temperature controls that the inspectors rely upon to ensure that the procedure used by the establishment for processing will not cause or contribute to the adulteration of product. However, establishments may choose to use an alternative procedure to achieve the same goal. The directive also describes the cooling procedure of cooked product to prevent microbial growth.

9 CFR 318.301 establishes the procedures for the handling of processed product after filling and container closure to prevent adulteration.

*References: FSIS Directives 7110.3 and 5400.1
9 CFR Section 318.301*

C. Sanitation Standard Operating Procedures (SSOP)

1. What are the laws, regulations, and official directives that mandate that export establishments take responsibility for sanitation? Describe these requirements in detail.

The regulatory requirements pertaining to the development, implementation, and maintenance of written standard operating procedures for sanitation (SSOP) are found in 9 CFR, Part 416, Sanitation. In addition, FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations, dated 11-21-97; FSIS Directive 5400.5, Inspection System Activities, dated 11-21-97; and FSIS Directive 11,100.3 Amendment 2, Evaluating, Verifying, and Enforcing Sanitation Standard Operating Procedure Requirements, dated 7-24-97.

Only establishments that have a grant of inspection from the federal government can export product to a foreign country. All official establishments must show responsibility for Sanitation. Section 304.3 (a) of 9 CFR states that an establishment must have a written SSOP before being granted Federal inspection. Section 416.11 states that each official establishment must develop, implement, and maintain a written SSOP, as mandated in Part 416 of the regulations. FSIS Directive 5000.1 states that SSOP requirements apply to all official establishments and are essential to operating and maintaining an establishment with sanitary practices that prevent the distribution of adulterated and contaminated product. FSIS Directive 5400.5 states that establishments that export product must meet all foreign requirements.

Establishments that wish to export product to a specified foreign country must meet the specific requirements of that country and are approved by inspection personnel as eligible before exporting can take place, as stated in FSIS Directive 9080.1, Special Export Requirements, page 2. FSIS requires and verifies that establishments meet foreign product and export requirements, as per the Inspection System Procedure Guide in FSIS Directive 5400.5. FSIS Directive 9020.1 (page 2) states that establishment management must provide sanitary equipment, sanitizing of facilities, and other sanitary conditions before inspection can be performed for export certification. . In addition, export certificates are not issued by inspection personnel unless the product is inspected and passed and the requirements of the foreign government are met, as per CFR 322.2 and FSIS Directive 9060.4 (page 1 and 2).

*References: FSIS Directives 5000.1, 9060.4, and 5400.5
FSIS Directives 11,100.3, 9020.1, and 9080.1
9 CFR Part 416 and Sections 304.3 and 322.2*

2. What are the laws, regulations, and official directives that mandate that export establishments determine those aspects of establishment sanitation that pose a risk of causing direct product contamination. The government documents, in the form of a written SSOP or the equivalent, must describe and mandate:

- a) **the process whereby establishments identify areas of risk of direct product contamination.**
- b) **the process whereby establishments identify cleaning procedures, including frequency and accountability for cleaning.**
- c) **the process whereby establishments identify corrective actions to be taken.**

The laws, regulations, and directives that mandate the identification of sanitary risks are noted below.

a) Section 416.12 of 9 CFR; FSIS Directive 5000.1, pages 43-44; and FSIS Directive 5400.5, state that the written SSOP developed by the establishment must describe all the

procedures that an establishment will conduct on a daily basis. These sanitation procedures must be sufficient to prevent the direct contamination or adulteration of food product(s). Establishment management must signify its intent to implement and maintain the SSOP by signing and dating the SSOP document. The procedures must address, at a minimum, the cleaning of all food contact surfaces of facilities, equipment, and utensils. In addition, the mandated HACCP plan developed by establishments is required to identify all food safety hazards and develop the corresponding corrective action(s) (see 417.2 and 417.3).

b) Section 416.12 of 9 CFR; FSIS Directive 5000.1, pages 43-44; and FSIS Directive 5400.5, state that the establishment-developed SSOP must identify pre-operational and operational sanitation procedures, identify and establish the frequency of conducting each sanitation procedure conducted during operations, and identify the responsible establishment employee(s). Accountability of cleaning procedures is accomplished by the following actions. Section 416.14 of 9 CFR states that the establishment must routinely evaluate the effectiveness of the SSOP and its procedures in preventing product contamination and adulteration. The establishment must revise the SSOP and its procedures, where applicable, in response to the above evaluation and to changes in facilities, equipment, utensils, operations, or personnel.

c) Section 416.15 of 9 CFR states that each official establishment must take appropriate corrective action(s) when either the establishment or FSIS determines that the SSOP and/or its procedures have failed to prevent direct product contamination or adulteration.

*References: FSIS Directive 5000.1
9 CFR Part 416*

3. What are the laws, regulations, and official directives that mandate that establishments take corrective actions and that the inspection program takes enforcement actions and has an effective enforcement program? The program documents must describe and mandate that:

- a) establishments take action to prevent product contamination and take corrective actions when insanitary conditions or contaminated products are found.**
- b) the foreign inspection system takes effective enforcement action, including the suspension and withdrawal of inspection of those establishments that fail to prevent product contamination or take corrective actions.**

Enforcement actions and policy are found in FSIS Directives 11,100.3, 11,040.1, 5400.5, 5000.1, 8830.1*, and 8820.1* and 9 CFR sections 416.13, 416.14, 416.15, 416.16, and 416.17. Also see Slaughter/Processing Questionnaire under Control of Non-compliant Product, question number one.*

a) *The implementation and maintenance of the SSOP are mandated in sections 416.13 and 416.14. The regulations require that each official establishment monitor sanitation procedures daily and routinely evaluate the effectiveness of the SSOP and its procedures. The SSOP and its procedures are thereby revised in keeping with the above findings regarding facilities, equipment, utensils, operations, and personnel.*

Developing appropriate corrective actions and maintaining the documentation of the monitoring of sanitation procedures and any corrective actions that are initiated are mandated in sections 416.5 and 416.6 (see also FSIS Directive 5000.1). Each official establishment is required to take appropriate corrective action to any SSOP or procedural failure to prevent product contamination or adulteration. The corrective actions must ensure the appropriate disposition of the product, the restoration of sanitary conditions, and prevent the recurrence of the failure. In addition, each establishment must maintain daily records sufficient to monitor the sanitation procedures SSOP and the corrective actions taken. A responsible establishment official is required to initial and date the records, ensuring FSIS that the records are authentic. These records will be used to make changes and improvements in the SSOP and its procedures.

b) *Section 9 CFR 416.17 (see also FSIS Directives 5000.1, page 45 and 11,100.3*, pages 1-5) states that the Agency must verify the adequacy and effectiveness of the SSOP and its procedures by determining that the establishment meets the requirements of Part 416. The verification could include a review of the SSOP, a review of the daily records, direct observations of the SSOP, its procedures, and the corrective actions, and/or direct observation or testing of sanitary conditions. FSIS Directive 5400.5 assigns specific tasks to government inspectors regarding the above reviews and observations.*

FSIS Directive 5000.1 (pages 21, 22, 25, 26, and 63-67) and FSIS Directive 11,100.3 (pages 2-3 and 5-17) specify how inspectors are to properly review sanitary procedures and conditions. The Directives state the specific action that inspector is to take if a noncompliance occurs or the establishment fails to prevent product contamination or take corrective actions. Specifically, inspection program officials are authorized and required to refuse to allow applicable products to be labeled, marked, stamped, or tagged as “inspected and passed” or “inspected for wholesomeness” and to place a retain or rejected tag on the product or equipment/room/utensil/compartment, respectively. Inspection officials will advise establishment management and the District Office. If immediate corrective action is not initiated by the establishment, the District Office will notify a Compliance Officer. The Compliance Officer will conduct an investigation at the applicable establishment, collect evidence, obtain signed statements from management and FSIS officials, and initiate/document an official case file. When FSIS documentation (Noncompliance Reports, etc.) indicates repeated failures of the SSOP program, inspection program personnel are authorized to withhold inspection from the establishment and take control of the product. Inspection personnel are required to advise the establishment and to review and verify establishment documentation.*

In addition, Section 310.25 (b) (3) (iii), of 9 CFR, states that failure to maintain sanitary conditions would result in the suspension of inspection services. Enforcement actions are

identified in FSIS Directive 11,100.3, Section VII, H for repetitive SSOP failures. FSIS Pre-HACCP Sanitation Standard Operating Procedures (SSOP) Reference Material – 1997 indicates that the withholding, suspension and/or withdrawal of inspection are enforcement processes that will not occur for individual deficiencies, but may follow from a determination that the SSOP has failed.*

Sanitation deficiencies are only a part of a large number of possible noncompliance problems that may occur in an establishment. The following enforcement procedures apply to all noncompliances. FSIS Directive 8820.1 Rev. 2 dated October 22, 1996 states that when corrective actions are not properly taken and result in a recurring noncompliance, inspection personnel will implement Progressive Enforcement Action (PEA) as outlined in FSIS Directive 8830.1* dated January 4, 1995. The three stages of PEA (where each stage intensifies the inspection effort, involving progressively higher ranking inspection personnel) may be bypassed when significant violations affect the protection of the public health or economic welfare. In these instances, other compliance actions may occur, including criminal sanctions. FSIS Directive 5400.5 dated August 24, 1998 states that it is the responsibility of establishment management to prevent contamination and adulteration and to take actions that correct the immediate situation and prevent a recurrence of the problem. Actions that do not accomplish these tasks are inadequate. As stated above and in FSIS Directive 11,040.1 Rev 2 dated November 7, 1996, recurring noncompliances may initiate PEA in the establishment.*

In non-HACCP establishments, establishments must have an SSOP and are responsible for maintaining a sanitary environment. In this case FSIS enforces sanitation requirements (see FSIS Directive 8830.1) by undertaking enforcement actions (PEA) when corrective actions are not properly taken by the establishment, resulting in recurring sanitation problems. The Directive (8830.1*) also states that failure of the establishment to comply with provisions of the FMIA and/or PPIA and the regulations, including SSOP requirements, can result in a refusal, suspension, or withdrawal of inspection services and/or imposition of criminal or civil sanctions.*

In HACCP establishments, as stated in FSIS Directive 5000.1, a noncompliance with the Salmonella standard or a failure by the establishment to meet the standard may constitute a failure to maintain sanitary conditions and/or failure to maintain an adequate HACCP plan. In accordance with 9 CFR Part 417, this may cause FSIS to suspend inspection service.

** It should be noted that, according to FSIS Directive 5400.5, only establishments that do not have a HACCP system are subject to FSIS Directives 5400.1, 5400.2, 8800.1, 8800.3, 8810.1, 6350.1, 6540.1, 7310.4, 8820.1, 8821.1, 8830.1, and 11,100.3.*

*References: FSIS Directives 11,100.3, 11,040.1, and 5400.5
FSIS Directives 5000.1, 8830.1, and 8820.1
9 CFR Sections 416.13, 416.14, 416.15, 416.16, and 416.17*

D. Other Procedures

- 1. In maintaining sanitation during fabrication, further processing, and other operations, what are the procedures for the detection and control of contamination of meat and poultry products?**

FSIS regulations (9 CFR 308, 381-Subpart H, and 416) state that all official establishments must maintain sanitary conditions to prevent the contamination and adulteration of meat and poultry products. FSIS regulations (9 CFR 416.11) state each official establishment shall develop and maintain written standard operating procedures for sanitation (SSOP) describing all procedures that will be conducted before and during operations, sufficient to detect and prevent direct contamination and adulteration of products.

FSIS regulation (9 CFR 416.15) requires all official establishments to take appropriate corrective action(s) when either the establishment or FSIS determines that the SSOP may have failed to prevent direct contamination or adulteration of products. Correction actions include implementing procedures to ensure appropriate disposition of product that may be contaminated, restoring sanitary conditions, and preventing the recurrence of direct contamination or adulteration of product, including appropriate reevaluation and modification of SSOP and related procedures.

References: 9 CFR Parts 308 and 416

- 2. When product is shipped from one official establishment to another, what are the procedures for the detection and control of contamination of meat and poultry products?**

FSIS regulations (9 CFR 302.3 and 318.1) require all products entering any official establishment to have been previously inspected and passed in an official establishment or imported from a country approved by FSIS and subsequently inspected and passed by FSIS upon entering the United States. All products are subject to FSIS examination to assure that they are free of contamination and are not adulterated. In addition, all establishments shall develop and implement a HACCP (9 CFR 417) plan designed to control food safety hazards that may occur before, during, and after entry into the establishment.

*References: 9 CFR Sections 302.3 and 318.1
9 CFR Part 417*

- 3. In monitoring and controlling product temperature and condition during the preparation, storage, and shipment of product destined for export to Country-X, what are the procedures for the detection and control of contamination of meat and poultry products?**

FSIS regulations (9 CFR 416 and 417) require official establishments to operate under

SSOP and a HACCP plan. Accordingly, the SSOP shall identify the procedures during the preparation and storage of product sufficient to prevent contamination or adulteration of product due to temperature abuse. A HACCP plan shall identify the critical control points established to detect and prevent temperature abuse and contamination of product during preparation, storage, and shipment of product. Official establishments shall maintain daily records sufficient to document the implementation and monitoring of SSOP and critical control points. These records must be readily available to any FSIS employee. In addition, compliance officers conduct random and planned reviews at warehouses, freezers, and other facilities to ensure that products are sound, wholesome, and properly labeled.

References: 9 CFR Parts 416 and 417

- 4. During maintenance work, product may be exposed to environmental contaminants (such as a paint solvent or styrene monomer floor topping). During maintenance work, what are the procedures for the detection and control of contamination of meat and poultry products?**

FSIS sanitation regulations (9 CFR 308 and 416) require official establishments to describe their daily procedures to detect and prevent the contamination of product. This includes contamination due to exposure to environmental contaminants.

References: 9 CFR 308 and 416

Remember: Cite the section in your regulations or other reference material that governs your response(s) to each question or request. In addition, provide examples of any forms, charts, or other documents applicable to each question or comment.