UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	11,000.1	1-25-00

SANITATION PERFORMANCE STANDARDS

I. PURPOSE

The purpose of this directive is to provide instructions to you (inspection personnel) on how to verify sanitation in an establishment. **NOTE: DO NOT IMPLEMENT THE INSTRUCTIONS IN THIS DIRECTIVE UNTIL JANUARY 25, 2000.**

II. CANCELLATION

FSIS Notice 31-98--Condensation Policy
FSIS Directive 11,240.5—Plastic Cone Deboning Conveyors
FSIS Directive 11,100.3 Amend.2—Evaluating, Verifying, and Enforcing a Sanitation Standard Operating Procedure
FSIS Directive 11,520.4—Strip Doors in Official Establishments
FSIS Directive 11,540.1—Use of Certain Vehicles as Refrigeration or Dry Storage Facilities
MPI Bulletin 77-34—Chemical Disinfection in Lieu of 180 deg. F. Water
MPI Bulletin 77-129—Water Conservation and Sanitation
MPI Bulletin 79-68—Use of Iodine in Processing Water
MPI Bulletin 81-38—Equipment and Procedure Requirements for Processing Gizzards
MPI Bulletin 83-14—Monitoring Chlorine Concentration in Official Establishments
MPI Bulletin 83-16—Re-Use of Water or Brine Cooking Solution on Product Following a Heat Treatment
The Meat and Poultry Inspection Manual (Part 8)

III. [RESERVED]

IV. REFERENCES

9 CFR 416.1-416.6
FSIS Directive 5000.1
FSIS Directive 5400.5

V. A NOTE OF EXPLANATION

This is the first FSIS directive written in plain language and using a question and answer format. We are using plain language features in response to the Presidential Memorandum on Plain Language of June 1, 1998, which directs all Federal agencies to use plain language in government writing. Future directives and notices will incorporate plain language features.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD, Import Offices

OPI: OPPDE

VI. BACKGROUND

We (FSIS) are issuing this directive to make instructions about sanitation consistent with the Sanitation Requirements for Official Meat and Poultry Establishments Final Rule, which is effective January 25, 2000. (Attachment I includes the regulatory text). The rule consolidated the sanitation regulations into a single part applicable to both official meat and poultry establishments, and converted many of the highly prescriptive sanitation requirements to performance standards. Section 416.1 of the sanitation regulations states that "Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated."

It is important to note that establishments that met the relevant sanitation requirements before the promulgation of the rule do not have to do anything differently to continue to remain in compliance now that the rule has been published. The rule also did not affect establishments' obligation to comply with applicable Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and Occupational Safety and Health Administration (OSHA) regulations.

FSIS is using a new food safety strategy, moving away from a command and control methodology, toward a more flexible regulatory approach based on Hazard Analysis and Critical Control Point (HACCP) philosophy and performance standards. Performance standards set the results to be achieved but not the specific means used to achieve those results. Though establishments can use different and varying means to meet the performance standards—the required results must always be the same: establishments must prevent insanitary conditions that could lead to adulterated product. Performance standards are results-oriented. Performance standards provide flexibility allowing innovation and the discovery of new ways and technologies for achieving desired results. Further, performance standards more clearly differentiate between your responsibility and the establishment's. Performance standards neither lessen your authority nor weaken the statutory and regulatory requirements that official meat and poultry establishments must meet to maintain sanitary conditions.

VII. COMPLIANCE/NONCOMPLIANCE WITH THE SANITATION PERFORMANCE STANDARDS

We have consolidated Inspection System Procedure (ISP) codes 06D01, 06D02, 06D03, 06E01, 06F01, 06F02, and 06G01 into one ISP Code for Sanitation: 06DO1, "Sanitation Performance Standards." This change is necessary because the previous codes were based on former prescriptive regulations in sections 308 and 381 subpart H. We will amend FSIS Directive 5400.5 to reflect the changes to the ISP. (Attachment II is the new ISP code).

As scheduled by PBIS, you will perform ISP procedure 06DO1 to verify that establishments are operating in accordance with the sanitation performance standards (sections 416.2 – 416.6 of the Federal meat and poultry products inspection regulations). You may directly observe conditions in the establishment or review

records to verify that the establishment is complying with the sanitation performance standards. When the 06D01 procedure is scheduled by PBIS, you should perform verification activities for one or more of the sanitation performance standards regulations to verify establishment compliance. You should use your professional judgement as to which verification activities need to be performed. As a general rule, you should randomly determine which sanitation performance standard you will verify and try to vary the verification of performance standards. When you suspect any possible non-compliance with any of the sanitation performance standards, perform an unscheduled 06D01. (Note: establishments may incorporate their response to the performance standards into their Sanitation SOP's or their HACCP plans).

VIII. PERFORMANCE STANDARDS

A. Grounds and Pest Control

1. *What are the regulatory performance standards for grounds and pest control?*

Section 416.2 (a) states that "The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions."

2. *What do the performance standards mean?*

Proper maintenance of the grounds about an establishment is essential for ensuring good sanitation. You may request written designation of establishment boundaries to facilitate inspection of the establishment. However, establishments are responsible for preventing sources of adulteration of product even if the cause of the adulteration originates from conditions outside the designated boundaries of the establishment.

The pest management program does not have to be written.

FSIS no longer requires the prior approval of pesticides because prior approval is contrary to the HACCP philosophy where establishments are responsible for identifying hazards and establishing critical controls. These performance standards establish that it is the establishment's responsibility for the safe and effective use and storage of pesticides.

The regulations require that documentation substantiating the safety of other chemicals, including pesticides, be made available for you to review (416.4 (c)). In most cases the document record will be the “Material Safety Data Sheet.”

3*. How do I verify compliance?*

Perform normal operational sanitation checks.

Observe to see if the grounds are maintained with no accumulation of trash, debris, or old equipment.

Observe whether pest control program is effective in preventing pests and vermin.

Observe to see that pesticides are properly stored, labeled, and applied in accordance with applicable label instructions.

Ask for and review supporting documentation i.e., EPA registration, label, and use instructions.

Ask the responsible party applying a pesticide about its proper use.

B. Construction

1*. What are the regulatory performance standards for construction?*

Section 416.2 (b) states:

“(1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.”

2. *What do these performance standards mean?*

The establishment buildings must be sound and kept in good repair to prevent insanitary conditions or the adulteration of product.

Establishments currently maintaining sanitary conditions will not be required to make changes to their construction or layout because of this performance standard.

Establishments can process, handle, or store edible and inedible product in the same room as long as they are separated by time or space, in a manner sufficient to prevent the adulteration of the edible product or the creation of insanitary conditions.

3*. How do I verify compliance?*

Observe the condition of the building, walls, ceilings, and floors to see whether they are sound and in good repair.

Observe that the walls, floors, and ceilings are made of durable materials impervious to moisture.

Observe that doors and windows close properly and prevent the entrance of vermin.

Check areas where both edible and inedible products are processed, handled, or stored to ensure that they are kept separate.

C. Light.

1*. What are the regulatory performance standards for lighting?*

Section 416.2 (c) states that “Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.”

2. *What do the performance standards mean?*

We have abolished the specific lighting requirements in the poultry regulations and have combined the separate meat and poultry lighting requirements into one performance standard.

While we are giving establishments flexibility in determining lighting requirements, lighting must be adequate in quality and well distributed to allow for the monitoring of sanitary conditions and processing conditions, and to examine product for evidence of adulteration.

3. *Is the Agency rescinding the lighting requirements for inspector and reprocessing stations?*

FSIS is not rescinding the lighting requirements for inspector and reprocessing stations (sections 307.2 and 381.36).

4. *How do I verify compliance?*

Observe whether the lighting is adequate to examine product and to monitor and maintain sanitary conditions throughout the establishment.

Check to see that lighting at the inspector and reprocessing stations meets regulatory requirements in sections 307.2 and 381.36.

D. Ventilation

1. *What are the regulatory performance standards for ventilation?*

Section 416.2 (d) states that “Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.”

2. *What does the performance standard mean?*

We do not expect that an establishment's ventilation will be able to completely eliminate all odors, vapors, and condensation but it must control them as far as necessary to prevent adulteration of product or the creation of insanitary conditions.

3*. How do I verify compliance?*

Verify that establishment can demonstrate that the proper air flow exist in the plant (e.g., observe ventilation systems, meet with plant management, review records).

E. Plumbing and Sewage

1. *What are the regulatory performance standards?*

a. Section 416.2 (e) states:

“Plumbing systems must be installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the establishment;

(2) Properly convey sewage and liquid disposable waste from the establishment;

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases."

b. Section 416.2 (f) states that "Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request."

2. *What do the performance standards mean*?

It is the responsibility of the establishment to ensure that plumbing and sewage systems provide an adequate supply of potable water and remove waste and sewage from the establishment without adulterating product or creating insanitary conditions.

3. How do I verify compliance?

Check that the water quantities are sufficient where needed in the establishment.

Check for cross-connection between potable and non-potable water.

Observe that the plumbing system is installed and maintained to prevent adulteration.

Check floors for proper drainage.

Ask appropriate employees about back-flow devices.

Check appropriate documentation if the sewage disposal system is a private system.

F. Water Supply and Water, Ice, and Solution Reuse

1. ***What are the regulatory performance standards for water supply and water, ice, and solution reuse?***

Section 416.2 (g) states:

"(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, or microbiological contamination so as to prevent contamination or adulteration of product. Reuse that has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced waste water treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions."

2. *What do the performance standards mean?*

The water performance standard makes transparent the current requirement that potable water comply with EPA's National Primary Drinking Water regulations. Certifications of water potability provided by the state or local governments or other responsible entities will show whether water meets the EPA requirements.

Some meat and poultry establishments use private wells for their water supply. EPA does not require testing for these water sources. Usually the state or local governments do not test the wells for potability. Most establishments can obtain the needed documentation from private laboratories. The regulations require that documentation certifying the potability of water from private systems be renewed at least semi-annually.

Establishments can reuse water in a manner that will neither adulterate product nor create insanitary conditions. FSIS permitted under the old regulations certain uses of nonpotable water. For example, an establishment recirculating water in a chill tank for raw poultry might add chlorine to the water to reduce the number of pathogens. An establishment reusing ice to chill raw poultry might bag the ice to prevent it from contacting product.

FSIS is making final performance standards that will provide for the reuse of water in numerous processing contexts, provided that the establishment takes actions necessary to ensure that product is not adulterated by the water and that sanitation is not compromised.

In many cases establishments will document and monitor water reuse activities as part of their HACCP plans (See 417.2), because the water treatments or conditioning will eliminate or reduce hazards they have determined would be otherwise reasonably likely to occur.

The requirements that water be reused only "for the same purpose" refers to whether water is reused for processing ready-to-eat or not ready-to-eat products; it does not prohibit the reuse of water for different processes. For example, an establishment could reuse poultry chiller water in a scalding tank. An establishment could not, however, reuse poultry chiller water for cooking or cooling packaged ready-to-eat product.

3. *How do I verify compliance?*

Check documentation regarding the potability of the water supply or water/solution reuse.

Observe water supply for water sufficiency, hot water supply, and dead-end pipes.

Check to see how reconditioned water is used in processing areas.

Observe whether water and ice reuse is handled correctly.

Review records of backflow prevention device tests.

Check for cross-connections and identification if non-potable water is used.

G. Dressing room/lavatory.

1. *What are the regulatory performance standards for dressing rooms and lavatories?*

a. Section 416.2 (h) states:

“ (1) Dressing rooms, toilet rooms and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.”

2. *What do the performance standards mean?*

OSHA has always had standards for lavatories in their regulations (29 CFR 1910.141). These standards should be followed when establishments are constructed. FSIS will no longer dictate the number of lavatories required. Lavatory facilities need to be maintained by the establishment in good repair and in a sanitary manner.

3. *How do I verify compliance?*

Observe to see that dressing rooms and lavatories are maintained in a sanitary manner.

Check to see that lavatories have hot and cold running water, an adequate supply of soap, and towels for drying hands.

Observe whether receptacles are maintained in a sanitary manner.

H. Equipment – utensils.

1. *What are the regulatory performance standards for equipment and utensils?*

a. Section 416.3 states:

"(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment or utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses."

2*. What do the performance standards mean?*

Establishments have the flexibility to choose whatever method they want to clean utensils and equipment to ensure that they are maintained in sanitary condition so as not to adulterate product. We have eliminated the requirement that utensils and equipment used to dress diseased meat carcasses be cleaned with either 180 degree F. water or an approved disinfectant. FSIS no longer requires a specific method for the cleaning of utensils and equipment used to dress diseased meat carcasses, although they must still be maintained in a sanitary condition.

3. *How do I verify compliance?*

Check to ensure that equipment does not hinder efficient inspection.

Check equipment and utensils to ensure that they are sanitary and able to be cleaned.

Check to ensure that receptacles used for storing inedible product are properly and conspicuously marked.

I. Sanitary Operations

1. *What are the regulatory performance standards for sanitary operations?*

Section 416.4 states:

"(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." [In most cases the documentation will be "Material Safety Data Sheet." You do not keep these documents in your office files.]

(d) "Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments."

2. *What do the performance standards mean?*

Usually, an establishment cleans up its operations once a day; however, some establishments have for some time conducted chemical cleanup procedures less than once a day. Currently, establishments may use extended cleanup procedures without prior approval of FSIS. FSIS expects an establishment to incorporate extended cleanup procedures into its Sanitation SOP's (See 416.12).

To ensure that extended cleanup procedures prevent insanitation and the adulteration of product, most establishments will probably conduct microbiological and chemical sampling that evaluates the effectiveness of the extended cleanup. The establishment's Sanitation SOPs records would include the microbiological and

chemical data that distinguish acceptable sanitary conditions from marginal or unacceptable sanitary conditions. (See 416.14).

During the normal course of an establishment's operations meat and poultry products should not come in contact with non-food contact surfaces. Still if non-food contact surfaces are not properly cleaned and sanitized, insanitary conditions could result, leading to the potential adulteration of product.

We have discontinued approving all nonfood compounds and proprietary substances before use in official meat and poultry establishments. We are continuing to require that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary substances and nonfood compounds. [See Attachment IV for information on use of chemicals--non-food compounds and proprietary substances.]

Documentation substantiating the safety of a chemical's use in a food-processing environment must be available for your review. The documentation will vary with the nature and intended use of that chemical. For example, for a pesticide, an establishment should have documentation showing that the compound is registered with EPA and the label information for the pesticide. For a chemical sanitizer used on food contact surfaces, an establishment should have documentation showing that the compound complies with the relevant Food and Drug Administration regulations in 21 CFR 178.1010. (Sanitizers meeting this requirement are usually identified as "Food Grade.")

Meat and poultry establishments are responsible for ensuring that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately.

Establishments are free to choose whatever scientifically supportable method they find effective in limiting microbial growth in their operations.

3. *How do I verify compliance?*

Review any records associated with extended cleanup procedures.

Observe whether food-contact and nonfood-contact surfaces on equipment and utensils are being properly cleaned and sanitized.

Check to see if compounds are being used properly.

Check documentation attesting to the safety of the cleaning compounds in use.

Observe the storage, handling, and loading of product to see whether sanitary conditions are maintained.

J. Employee Hygiene

1. *What are the regulatory performance standards for employee hygiene?*

Section 416.5 states:

"(a) Cleanliness. All persons working in contact with product, food-contact surfaces and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected."

2. *What do the performance standards mean?*

Specific types of unhygienic practices have been removed from the regulations. You continue to have the authority to take action against any unhygienic practice that could result in insanitary conditions or adulterated product.

3. *How do I verify compliance?*

Observe whether employees engage in unhygienic practices.

Observe whether employees change dirty garments for clean ones when appropriate.

Observe whether employees have an infectious disease or condition.

K. Custom Exempt Facilities.

1. *What are the regulatory performance standards for custom exempt facilities?*

Section 303.1 (2) (i) states:

"Establishments that conduct custom operations must be maintained and operated in accordance with the provisions of §§ 416.1 through 416.6, except for

§ 416.2 (g) (2) through (6) of this chapter, regarding water reuse and any provisions of part 416 of this chapter relating to inspection or supervision of specified activities or other action by a Program employee. If custom operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter shall apply to those operations."

2*. What does the performance standard mean?*

Custom exempt facilities must comply with the sanitation performance standards except for sections 416.2 (g) paragraphs (1) through (6) about water reuse. The establishment conducting custom exempt/retail exempt activities should also operate in accordance with time/space separation and adequate procedures to ensure that product does not bear the mark of inspection.

3*. How do I verify compliance?*

Follow the verification instructions in FSIS Directive 5930.1.

IX. ENFORCEMENT ACTIONS

Sanitation Performance Non-compliances Involving Direct Product Contamination

If an establishment has not complied with a sanitation performance standard and product is directly contaminated, you will follow the instructions found in FSIS Directive 5000.1, Part Three, III. C. 2. (for Sanitation SOP non-compliance) or Part Two, III. C. 2 (for a HACCP non-compliance). Use the appropriate ISP 01 or 03 activity codes when you document such a noncompliance on the FSIS Form 5400-5, Noncompliance Record (NR). (**Note**: It is important in your description that you explain which performance standards you were verifying when you noticed the direct product contamination).

Sanitation Performance Non-compliances Not Involving Direct Product Contamination

1. If an establishment has not complied with a sanitation performance standard and product is not directly contaminated, you need to determine the extent of the non-compliance before taking any action.

a. If there is an imminent probability that the non-compliance will result in product adulteration if not addressed immediately, take a regulatory control action such as tagging product or rejecting equipment and complete a NR. Fully describe and detail the nature of the noncompliance and the performance standard not met.

b. If the noncompliance does not need immediate attention, first, notify the establishment management and then document the finding on a NR. Fully describe and detail the nature of the noncompliance and the performance standard not met.

c. In situations where a condition exists that is less than perfect but not a noncompliance notify the establishment but do not document the finding on an NR.

2. When you complete a NR, record the noncompliance under activity code 06D01 and mark the appropriate trend indicator. Provide the establishment management with a copy.

3. Review the establishment's response on the NR and verify by observation or reviewing documentation that the establishment implemented the appropriate corrective action and further planned action.

Trend Determinations

To determine whether there is a trend of performance standard noncompliances that warrant the withholding of inspection, you:

1. Compile all the NR's related to sanitation performance standards in question.

2. Verify that these NR's indicate that the establishment has repeatedly failed to meet sanitation performance standards and has not successfully implemented corrective and preventive measures.

Note: A trend of non-compliances can involve different types of noncompliances related to a single performance standard. It is important that you verify that all previous implemented corrective and preventive actions failed. Remember that there is no specific number of NRs needed to indicate a trend. Your decision must be based on your professional judgement and be supported by the NRs.

3. Inform the establishment management that you have identified a trend of non-compliances with the sanitation performance standards and they need to take corrective and further preventive action to address this situation or show why a trend does not exist. If after informing establishment management, they fail to address and adequately correct all related non-compliances, you may decide to withhold the marks of inspection. If you make the decision to withhold the marks of inspection, contact the District Office (DO) and provide all the relevant information for the DO to prepare a "Notice of Intent to Suspend Inspection." The Notice will:

1. Inform the establishment that the nature and scope of the noncompliances indicate that the establishment has repeated and recurring sanitation deficiencies;

2. state that FSIS intends to withhold the marks of inspection and suspend inspection;

3. explain the reason for the tentative determination;

4. reference each pertinent NR by number;

5. inform the establishment that it is being afforded the opportunity to demonstrate why inspection should not be withheld or suspended, or to demonstrate that it has achieved regulatory compliance; and

6. provide the establishment three business days from the date of the letter to provide its response to the DO.

Based on the establishment's response, the DO will determine further actions and notify you.

X. GUIDANCE

For technical guidance contact the Technical Service Center. For guidance related to regulatory activities refer questions through supervisory channels.

Deputy Administrator
Office of Policy, Program Development
and Evaluation

06D Sanitation Performance Standards

06D01	**Sanitation Performance Standards** Each official establishment must Be operated and maintained in a Manner sufficient to prevent the Creation of insanitary conditions and to ensure that product is not adulterated.	416.1-6 FSIS Dirs. 5000.1 5400.5 11,000.1	<u>Grounds and Pest Control</u> Do normal operational checks. Observe to see if the grounds are maintained with no accumulation of trash, debris, or old equipment. Observe whether pest control program is effective in preventing pests and vermin. Observe to see that pesticides are properly stored, labeled, and applied in accordance with applicable label instructions. Ask for and review supporting documentation, i.e., EPA registration, label and use instructions. Ask the responsible part applying a pesticide about its proper use. <u>Construction</u> Observe the condition of the building, walls, ceiling, and floors to see whether they are sound and in good repair. Observe that the walls, Floors, and ceiling are Made of durable materials impervious to moisture.

06D Sanitation Performance Standards

06D01

Construction (cont.)
Observe that doors and Windows close properly and prevent the entrance of vermin.

Check areas where both edible and inedible products are processed, handled, or stored to ensure that they are kept separate.

Light
Observe whether the lighting is adequate to examine product and to monitor and maintain sanitary conditions throughout the establishment.

Check to see that lighting at the inspector and reprocessing stations meets regulatory requirements in sections 307.2 and 381.36.

Ventilation
Verify that establishment can demonstrate that the proper air flow exist in the plant (e.g. observe ventilation systems, meet with plant management, review records).

Plumbing and Sewage
Check that the water quantities are sufficient where needed in the establishment.

6-5

INSPECTION SYSTEM PROCEDURE GUIDE
06 OTHER REQUIREMENTS

06D Sanitation Performance Standards

06D01

Plumbing and Sewage (Cont.)

Check for cross-connection between potable and non-potable water.

Observe that the plumbing system is installed and maintained to prevent adulteration.

Check floors for proper drainage.

Ask appropriate employees about back-flow devices.

Check appropriate documentation if the sewage disposal system is a private system.

Water Supply and Water. Ice. and Solution Reuse

Check documentation of water potability or water/solution reuse.

Observe water supply for water sufficiency, hot water supply, and dead-end pipes.

Check to see how reconditioned water is used in processing areas.

06D Sanitation Performance Standards

06D01

Water Supply and Water, Ice, and Solution Reuse (cont.)

Observe whether water and ice reuse is handled correctly.

Review records of backflow prevention device tests.

Check for cross-connections and identification if non-potable water is used.

Dressing room/lavatory

Observe to see that dressing rooms and lavortories are maintained in a sanitary manner.

Check to see that lavatories have hot and cold running water, adequate supply of soap, and towels for drying hands.

Observe whether receptacles are maintained in a sanitary manner.

Equipment - utensils

Check to ensure that equipment does not hinder efficient inspection.

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Equipment (cont.)

Check to ensure that receptacles used for storing inedible product are properly and conspicuously marked.

Sanitary Operations

Review any records associated with extended cleanup procedures.

Observe whether food-contact and nonfood-contact surfaces on equipment and utensils are being properly cleaned and sanitized.

Check to see if compounds are being used properly.

Check documentation attesting to the safety of the cleaning compounds in use.

Observe the storage, handling, and loading of product to see whether sanitary conditions are maintained.

Emplovee Hygiene

Observe whether employees engage in unhygienic practices.

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Employee Hvgiene (cont.)

Observe whether employees change dirty garments for clean ones when appropriate.

Observe whether employees have an infectious disease or condition.

Custom E;xempt Facilities

Follow the verification instructions in FSIS Directive 5930.1.

Make determination about compliance with regulatory requirements.

Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

Attachment III: Regulation Cross-reference Chart

SUBJECT	NEW REGULATION	OLD REGULATION(S)
General sanitation	§ 416.1	§§ 308.3(a),(g), 308.7, 381.45, 381.57, and all other provisions not listed below.
Establishment grounds and pest management	§ 416.2(a)	§§ 308.3 (h), 308.13, 381.49(b), 381.56(a), 381.59, and 381.60.
Establishment construction	§ 416.2(b)	§§ 308.3(e),(f),(h), 381.46, 381.47 and 381.48.
Light	§ 416.2(c)	§§ 308.3(b), 381.52(a) and (b).
Ventilation	§ 416.2(d)	§§ 308.3(b) and (g), 308.8(b), 381.52(a) and (c).
Plumbing	§ 416.2(e)	§§ 308.3(c), 381.47(b), 381.49(a),(b) and (c).
Sewage disposal	§ 416.2(f)	§§ 308.4(c) and 381.49(c)(4).
Water supply and water, ice, and solution reuse	§ 416.2(g)	§§ 308.3(d), 381.50 and 381.53(k) and FSIS policy.
Dressing rooms, lavatories, and toilets	§ 416.2(h)	§§ 308.4(a),(b),(d), 381.47(h), 381.51 and 381.53(c).
Equipment and utensils	§ 416.3	§§ 308.5(a), 308.6, 308.8(c), 308.16, 381.53(a)(1),(f),(g),(h),(i), (j),(k),(l), 381.54, 381.55 and 381.56(b).
Food-contact surface cleaning and sanitation	§ 416.4(a)	§§ 308.3(d)(4), 308.7, 308.8(a), 381.57 and 381.58.
Non-food-contact surface cleaning and sanitation	§ 416.4(b)	§§ 308.3(d)(4), 308.7, 308.8(a), 381.57 and 381.58.
Cleaning compounds and sanitizers	§ 416.4(c)	§ 381.60.
Operational sanitation	§ 416.4(d)	§§ 308.3(g), 308.7, 308.8(a), 308.9, 308.10, 308.11, 308.12, 381.47(e), 381.53(d),(e), and (g)(4).
Employee hygiene	§ 416.5(a)	§§ 308.8(c),(e), 381.47(i), 381.51(g), 381.61(b),(c), and (d).
Employee clothing	§ 416.5(b)	§§ 308.8(d) and 381.61(b).
Employee disease	§ 416.5(c)	§§ 308.14 and 381.61(a).
Tagging insanitary equipment, rooms, etc.	§ 416.6	§§ 308.15 and 381.99.

Attachment IV: Use of Chemicals (Nonfood Compounds and Proprietary Substances)

As discussed in the Directive, we have discontinued the practice of reviewing and approving nonfood compounds and proprietary substances before they are used in official meat and poultry establishments. However, we are continuing to require that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary substances and nonfood compounds. One of the ways you can verify this is by observing the use of the chemical in the establishment. In this Appendix, we have listed the typical and appropriate uses of the various types of chemicals, as well as the safety concerns regarding each chemical use.

Another way you can verify that chemicals are being used correctly is to review the documentation substantiating that the chemical in question can be used in a food processing environment. We require that establishments have such documentation available for your review (9 CFR 416.4(c)). The documentation will vary with the nature and intended use of that chemical.

In some cases, other Federal Agencies require that chemicals meet their regulatory requirements. For example, EPA requires that pesticides be registered with EPA, labeled as such, and used only in accordance with approved instructions. An establishment should have documentation indicating that they meet these requirements. Also, many chemicals, such as food contact surface sanitizers and lubricants used in food processing areas must meet FDA requirements. Again, the establishment must have documentation demonstrating this. Often, the statement “Food Grade” on the label of these and other chemicals indicates that they meet FDA requirements.

Many chemical uses (anti-slip compounds, laundry soaps, etc.) are not approved for use by any Federal agency. An establishment will likely have labels, instructions, or letters of guarantee form the manufacturer to substantiate the safety of these chemicals in a food processing environment. In some cases, documentation will state that the chemical use was previously approved by USDA or FSIS and that the formulation and use has not changed since that approval. You may take this into account as evidence that the chemical and its use is safe and acceptable.

Cleaners

What are examples of cleaners?

Compounds for use as general cleaning agents on all surfaces, or for use with steam or mechanical cleaning devices in all departments. (formerly “A1”).

Compounds for use only in soak tanks or with steam or mechanical cleaning devices in all departments. (formerly “A2”).

Acid cleaners for use in all departments. (formerly "A3").

Floor and wall cleaners for use in all departments. (formerly "A4").

Floor and wall cleaners for subfreezing temperatures. (formerly "A5").

Scouring cleaners. (formerly "A6").

Degreasers or carbon removers for food cooking or smoking equipment, utensils, or other associated surfaces. (formerly "A8").

Cleaning and/or degreasing solvents for use in nonprocessing areas. (formerly "K1").

What standards should cleaners meet?

Cleaners should leave no visible residue after rinsing. Further, cleaners should be able to remove odors.

Hazardous Substances

When are cleaners containing hazardous substances permitted for use?

Materials that are: known human carcinogens; mutagens or teratogens classified as hazardous substances; heavy metals; or hazardous compounds classified as extremely or super toxic, should not be allowed in the plants unless it is established that the substance will not become a component of edible product according to the levels exempted under the threshold of regulation process indicated in Title 21 CFR Section 170.39.

How are cleaners containing hazardous substances to be used?

Use of special purpose cleaners classified as hazardous materials should be limited to the amount and frequency only sufficient for the required effect. Personnel protection provisions and precautions to prevent food and food contact surfaces from contamination and residuals should be specified; use should be in accordance with manufacturer's labeling instructions and precautions.

Use of hazardous substances containing fluorine compounds, such as hydrofluoric acid, hydrofluosilic acid, or ammonium bifluoride, to remove siliceous scale deposits or for similar cleaning purposes should be in accordance with provisions for the special purpose cleaners classified as hazardous materials. Each use should be documented and the substance should not be stored within the plant. Hydrofluoric acid is extremely irritating and corrosive to the skin and mucous membranes. The acid and its salts are highly toxic and may cause death or permanent injury after limited exposure to small quantities.

How should cleaners consisting of hydrocarbons, chlorinated hydrocarbons, etc. be used?

Cleaners consisting primarily of hydrocarbon, chlorinated hydrocarbon or other water immiscible solvents should be limited to use in non-processing areas. Treated food processing equipment and utensils should be washed and thoroughly rinsed with potable water before being returned to a processing area.

How should cleaners with very low freezing points be used?

Cleaners formulated to provide very low freezing points such as alcohol or glycol based compounds are appropriate for use on surfaces that do not contact food in areas with subfreezing temperatures. The cleaning solution and solubilized soil should be effectively removed by wiping, wet vacuuming, or other appropriate means.

Laundry compounds

What standards should laundry compounds meet?

Labeling of laundry compounds should include appropriate use directions. The rinsing instructions should be sufficient to prevent food contamination or inspection interference, and ensure effective removal of laundry agents from food contact articles, e.g. carcass shrouds.

Hand Care Treatments

What are examples of hand care treatments?

Handwashing compounds for use in all departments. (formerly “E1”).

Handwashing and sanitizing compounds. (formerly “E2”).

Hand sanitizing compounds. (formerly “E3”).

Hand creams, lotions, and cleaners. (formerly “E4”).

What is the status of hand care products formulated with chlorhexidene gluconate?

Hand care products formulated with chlorhexidene gluconate and intended to be used as an antimicrobial hand cleaner or hand sanitizer/dip in food handling and processing are considered a “drug” and possibly “new drugs” under the Federal Food, Drug, and Cosmetic Act (FFDCA). These products are subject to registration by the Food and Drug Administration (FDA), Over The Counter Drug Compliance Branch, before they can be marketed and used. Establishments should keep registrations on file for review by FSIS inspection personnel.

What is the status of hand care treatments intended to protect skin from exposure to toxic chemicals or pathogens?

Hand care treatments intended for use as a “barrier” or “shield” to prevent or mitigate human disease by protecting skin from exposure to toxic chemicals and/or pathogenic microorganisms are considered “drugs” and “new drugs,” under the FFDCA. These products are subject to registration by the FDA before they can be marketed and used. Establishments should keep registrations on file for review by FSIS inspection personnel.

What standard should hand care treatments intended to remain on the hands of food handlers meet?

Hand treatments intended to remain on the hands of food handlers should be formulated in compliance with appropriate food additive regulations, Title 21 of the Code of Federal Regulations (CFR) Section 178.1010, or appropriate GRAS materials.

What precautions should establishments take with hand care stations?

Precautions should be taken to ensure hand care stations do not cause direct or indirect contamination of food or food contact surfaces with hand care substances. Therefore, FSIS recommends that only liquid hand cleaners and sanitizers be used in areas where food and food contact surfaces are exposed.

What should be done when using hand treatments not formulated in compliance with appropriate food additive regulations?

Hand treatments not formulated in compliance with appropriate food additive regulations should be:

a. thoroughly removed from the hands by rinsing in clean potable water, or

b. separated from contact with food by the use of gloves that are an effective barrier to migration of the nonfood substance to edible product.

Sanitizers and Disinfectants

What are examples of sanitizers and disinfectants?

Antimicrobial agents always requiring a rinse. (formerly “D1”).

Sanitizers for all surfaces not always requiring a rinse. (formerly “D2”).

What standards should chemicals used to sanitize food contact surfaces meet?

a. Chemical sanitizers and other chemical antimicrobials used on food contact surfaces must comply with the 21, CFR Section 178.1010 or appropriate food additive regulations.

b. Chemicals used to sanitize food contact surfaces and utensils must comply with 21 CFR 178.1010.

c. Sanitizers should only be applied to cleaned surfaces. Sanitized food contact equipment and utensils must be adequately drained, in accordance with 21 CFR 178.1010(a), sufficient to prevent food adulteration.

What is required of EPA registered antimicrobials?

EPA registered antimicrobials must include labeling instructions stating that they are appropriate for use in food establishments. Establishments should keep registration documentation on file for review by FSIS inspection personnel.

How are chemical germicides to be used?

Chemical germicides established as meeting efficacy requirements of EPA as both a hospital level disinfectant and a tuberculocide are appropriate for use to decontaminate implements provided:

a. Food contact surfaces are subsequently washed and rinsed.

b. Appropriate preventative actions are taken to protect edible products and food packaging materials.

c. Directions on the label specify minimum contact time required to meet both registered kill levels.

Insecticides, Rodenticides, and similar Pesticides

What are examples of insecticides, rodenticides, and similar pesticides?

Nonresidual pesticides. (formerly “F1”).

Residual pesticides. (formerly “F2”).

Rodenticides for controlled use only. (formerly “F3”).

Fumigants for controlled use only. (formerly “F4” and “F5”).

What standards should pesticides meet?

These products are toxic by design, in varying degrees, and should be applied and stored in such a manner as to prevent adulteration of food product, and contamination of food contact equipment and packaging material. All containers used to store, dilute, dispense, or transport pesticides should be clearly labeled. Re-use of containers for other purposes are prevented by destruction of container or other means sufficient to render containers unfit for reuse.

Pesticides must be EPA registered with labeling instructions and precautions pertinent to its use.

How are pesticides to be used?

Pesticides must be used only in accordance with specific registered label uses and precautions and should not be applied during establishment production hours.

How are restricted-use pesticides to be used?

Restricted-use pesticides must be used only under the control of certified applicators (as defined in 7 USC 136 (e)).

How are dry bait rodenticides to be used?

Dry bait rodenticides should be secured in tamper-resistant stations.

What standard should powdered or granular insecticides meet?

Powdered or granular insecticides should be colored distinctly (traditionally, blue or green) to distinguish the pesticide from edible substances, unless provided in labeled dispenser containers.

What standard should liquid baits and dry baits meet?

To minimize the possibility of undetected contamination of food products, all liquid baits, and dry baits in which the inert ingredients consist mainly of meal or flour, should be distinctly colored. Where inert ingredients consist mainly of whole or cracked grain, or flour or meal pressed into cakes or pellets that do not have characteristics of food products, no addition of color is necessary.

Should pesticidal tracking materials be used in establishments?

Pesticidal tracking materials should not be used in a food establishment. The concern here is that product contact surfaces, utensils, linens, and direct contact packaging materials may become contaminated through transfer of tracking material from pests.

What standards should nonpesticidal tracking materials meet?

Nonpesticidal tracking materials should have a distinct color (traditionally blue or green) to distinguish it from edible substances, and may not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

What should be done after areas are treated with pesticides?

Treated areas should be sufficiently ventilated. Facilities, equipment, utensils, etc. should be thoroughly washed after pesticide application.

Pest control programs and treatments should be recorded with details sufficient to document compliance with appropriate requirements and provide for trace back in the event of accidental contamination.

What are examples of water treatments?

General potable water treatment compounds. (formerly “G1”).

Phosphate potable water treatment compounds. (formerly “G2”).

Silicate potable water treatment compounds. (formerly “G3”).

Chlorine potable water treatment compounds. (formerly “G4”).

Cooling and retort water treatment compounds. (formerly “G5”).

Compounds for treating boilers, steam lines, where the steam produced may contact edible products and/ or cooling systems where the treated water may not contact edible products. (formerly “G6”).

Compounds for treating boilers, steam lines, and/or cooling systems where neither the treated water nor the steam produced may contact edible products. This does not include compounds added to water used to cook and cool containers of meat and poultry products. (formerly “G7”).

What standard should boiler water treatments meet?

Boiler water treatments where the steam may contact food must be formulated in compliance with 21 CFR, Section 173.310.

What standard should ion-exchange resins used in water purification meet?

Ion-exchange resins used for water purification must be formulated in compliance with 21 CFR, Section 173.25.

What standards should additives used in water meet?

Additives used in water in which fruits and vegetables are washed must be formulated in compliance with CFR 21, Section 173.315 and defoamers found in 21 CFR, Section 173.340(a)(2).

Additives used in water for preflushing of animal casings must be GRAS.

What standards should processing additives meet?

Processing additives are appropriate for use provided that the quantities of these compounds are controlled, monitored and limited to the amount sufficient for the purpose of such use.

Processing additives for potable water treatments should be composed of appropriate substances which are prior sanctioned by FDA or GRAS and limited to the following:

a. In potable water, phosphate should not exceed 10ppm, silicate should not exceed 10ppm, and chlorine should not exceed 5ppm.

b. In other processing applications, chlorine should not exceed 50ppm in carcass wash and 20ppm on trimmed or reprocessed poultry carcasses.

What standard should compounds containing sodium or potassium salts meet?

Compounds containing the sodium or potassium salts of nitrate, sulfite, bisulfite or metabisulfite should be decharacterized so their effect on the heme pigments in meat products is prevented. Decharacterization may be achieved by the addition of colorant to prevent mishandling or by other means such as creation of a basic environment to prevent the formation of acid species of these additives.

What standard should additives containing nitrate, borate, and nitrate meet?

Additives containing nitrite, borate, and nitrate containing treatments for nonprocessing water should be colored distinctly (traditionally, blue or green) to avoid accidental misuse.

Lubricants

What are examples of lubricants?

Lubricants with incidental contact. (formerly “H1”).

Lubricants with no contact. (formerly “H2”).

Soluble oils. (formerly “H3”).

What standards should lubricants meet?

Lubricants intended for incidental food contact must comply with 21 CFR, Section 178.3570.

Lubricants used on food contact surfaces should have appropriate food additive status:

a. formulated from an edible oil (for example: an over the counter food grade oil such as corn oil, olive oil, or canola oil to name a few).

b. mineral oil complying with 21 CFR, Section 172.878

c. or substances which are GRAS.

Lubricants should be limited to the amount sufficient for the technical purpose.

How should lubricants be applied to food contact equipment?

Lubricants should be applied to food contact equipment, which requires lubrication, in a manner that does not contaminate food contact surfaces.

Anti-Slip Compounds

What is an example of an anti-slip compound?

Absorbents or antislip agents for spot application to floors. (formerly “J1”).

What standards should anti-slip compounds meet?

Anti-slip compounds are intended for spot application to floors and are limited to the floor area where the hazard exists. They may be used provided their use does not result in dusting, tracking, or other objectionable conditions. These compounds should not be used as a substitute for good sanitation and should be removed as part of the routine floor cleaning operation in accordance with the plants SSOP.

Anti-slip compounds should be adequate to correct temporary hazardous conditions; should not promote microbial growth or attract or harbor pests; should be composed of inert material so that any contact with food results only in surface contamination that is easily identified and removable.

Letters of Guarantee

What should a letter of guarantee contain?

Documentation substantiating compound safety and efficacy, such as letters of guarantee, are appropriate, but not required, for all chemical compounds that are used

in the areas of food processing, handling, and storage, and that do not otherwise require declaration on food labeling under Title 7 (part 59) and Title 9 (parts 317 and 381). A letter of guarantee should normally contain the following:

1. Name and address of supplier.

2. Brand name, code or other designation which uniquely identifies the compound. Identification should ensure that the specific chemical ingredients of the compound are traceable in the event of food contamination.

3. A statement that the material will be safe and effective under the intended conditions of use and will not adulterate food product.

4. A statement specifying the applicable limits, if appropriate, under intended conditions of use.

5. Signature of an official of the supplying firm.

A supplier's letter of guarantee may be limited to a specific shipment, in which case it would be attached to the invoice, or it may be a continuing letter of guarantee that need not accompany each shipment.