

**Draft Agenda for the
Technical Conference on the Sanitation Performance Standard Regulation**

Wednesday, December 8, 1999

Regulatory Review segment:

8:00 Welcome - Mr. Tom Billy, Administrator; Dr. Mark Mina, Deputy Administrator of Field Operations; Dr. Paul Thompson, Director of TSC

8:30 [Review of the Sanitation Performance Regulation - Lee Puricelli, FSIS/OPPDE](#)

9:00 Q&As regarding the regulation

9:30 Break

10:00 Review of technical issues - Ron Eckel, FSIS/TSC

11:00 Q&As regarding technical issues

11:30 Lunch

1:00 [Overview of implementing the Sanitation Performance Standards Regulation - Ron Eckel, FSIS/TSC](#)

1:30 [Example scenario: Implementing the Sanitation Performance Standards Regulation - Jim Blank, Madison District Manager](#)

1:45 Example scenario - Implementing the Sanitation Performance Standards Regulation - Jan Behney, Philadelphia District Manager

2:00 Break

2:30 Q&As regarding implementing the Sanitation Performance Standards Regulation

Practical examples segment:

3:15 [Verification of the effectiveness of a sanitation program through records - Bob Savage, HACCP Consulting Group](#)

4:00 Q&As regarding verification of effectiveness of a sanitation program through records

4:30 Close for the day

Thursday, December 9, 1999

Practical examples segment (continued)

- 8:00 Opening and review
- 8:15 Equipment and facility design - Don Graham, Graham Sanitary Design Company
- 9:00 [Verification of the effectiveness of a sanitation program: microbiological testing - Kristen Bell, Cargill](#)
- 9:45 Break
- 10:15 Q&As on equipment/facility design and verification of the effectiveness of a sanitation program: microbiological testing
- 10:45 [Overview of regulatory changes related to the use of chemicals, non-food compounds, and proprietary substances - Lynvel Johnson, FSIS/TSC](#)
- 11:30 Lunch
- 1:00 Q&As on overview of regulatory changes related to the use of chemicals, non-food compounds, and proprietary substances
- 1:30 Open Q&A period - Panel of all speakers
- 2:15 Closing remarks
- 2:30 End of conference

Note: Speakers and times are proposed

SANITATION PERFORMANCE STANDARDS

December 1999

Background

This rule:

- Consolidates sanitation regulations for meat and poultry establishments.
- Eliminates unnecessary differences in sanitation requirements for meat and poultry establishments
- Converts prescriptive requirements to performance standards

Overview of 416

- 416.1 - General rules
- 416.2 - Grounds and facilities
- 416.3 - Equipment and utensils
- 416.4 - Sanitary Operation
- 416.5 - Employee Hygiene
- Custom operations

416.1 - General Rules

- 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 - General Rules

Definitions:

- Insanitary conditions
- Product adulteration

416.2 - Establishment grounds/facilities

- (a) Grounds/pest control
- (b) Construction
- (c) Light
- (d) Ventilation
- (e) Plumbing
- (f) Sewage disposal
- (g) Water supply
- (h) Dressing rooms/
& water/ice/solution reuse lavatories

416.2(a) - Grounds/pest control

- Grounds must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection.

416.2(b) - Construction

1. Buildings, structures, rooms, compartments must be of sound construction, kept in good repair, and 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.

416.2 (b) - Construction

2. Establishment walls, floors, and ceilings 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.

416.2 (b) - Construction

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.

416.2 (b) - Construction

4. Rooms or compartments where 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.

416.2 (c) - Lighting

- 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/locker rooms, and toilets.

416.2 (c) - Lighting

- Note: Lighting at inspector and reprocessing stations must meet regulatory requirements in sections 307.2 and 381.36.

416.2 (d) - Ventilation

- Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product or the creation of insanitary conditions must be provided.

416.2 (e) - Plumbing and Sewage

1. Plumbing and sewage must carry sufficient quantities of water to required locations throughout the establishment.

416.2 (e) - Plumbing and Sewage

2. Plumbing and sewage must properly convey sewage and liquid disposable wastes from the establishment.

416.2 (e) - Plumbing and Sewage

3. Plumbing and sewage must prevent the adulteration of product, water supplies, equipment, or utensils, and prevent the creation of insanitary conditions throughout the establishment.

416.2 (e) - Plumbing and Sewage

4. Plumbing and Sewage must provide adequate floor drainage in all areas where the floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

416.2 (f) - Plumbing and Sewage

- 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.

416.2 (f) - Plumbing and Sewage

- 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.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

1. A supply of running water that complies with National Primary Drinking Water regulations (40 CFR Part 141) at suitable temperature and under pressure as needed must be in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.).

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

1. (continued) 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.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

1. (continued) 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.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

2. Water, ice, or solutions 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 an acceptable level to prevent adulteration.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

3. Water use to wash or chill 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.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

3. (continued) Reuse water that has come into contact with raw product may not be used on ready to eat product.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

4. Reconditioned water that has never contained human waste and 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 this water meets criteria in (g)(1) of this section.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

4. (continued) 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 (g)(1) of this section.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

5. Any water that has never contained human waste and is free of pathogenic organisms may be used in edible/inedible product areas, provided it does not contact edible product. For example, reuse water may be used to move heavy solids, flush evisceration troughs, or wash antemortem areas and similar areas within the plant.

416.2 (g) - Water Supply and Water, Ice, and Solution Reuse

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

416.2 (h) - Dressing Rooms/Lavatories

1. Dressing rooms, toilets and urinals need to be sufficient in number, ample in size, and conveniently located and maintained in a sanitary manner and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms/compartments where product is processed/stored/handled.

416.2 (h) - Dressing Rooms/Lavatories

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

416.2 (h) - Dressing Rooms/Lavatories

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

416.3 - Equipment & Utensils

- (a) Equipment and utensils used for processing or handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure product is not adulterated during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition.

416.3 - Equipment & Utensils

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

416.3 - Equipment & Utensils

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

416.4 - Sanitary Operation

- (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 or the adulteration of product.

416.4 - Sanitary Operation

- (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 or the adulteration of product.

416.4 - Sanitary Operations

- (c) 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.

416.4 - Sanitary Operation

(c) (continued) Documentation

substantiating the safety of chemical use in food processing environment must be available to FSIS inspection personnel for review.

416.4 - Sanitary Operation

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

416.5 - Employee Hygiene

- (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.

416.5 - Employee Hygiene

- (b) Clothing: Aprons, frocks, and outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned.

416.5 - Employee Hygiene

- (b) Clothing: (continued) 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.

416.5 - Employee Hygiene

(c) Disease control: Any person who has/appears to have an infections disease, open lesion, including boils, sores, 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.

Custom Exempt Operations

- Section 303.1(a)(2)(1)

If custom operations are conducted in an official establishment, all of the provisions of Part 416 applies.

Custom Exempt Operations

Section 303.1(a)(2)(1)

- 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) regarding water reuse, and any provisions of 416 relating to inspection or supervision by FSIS employees.

IMPLEMENTATION
of
Sanitation
Performance Standards

Implementation Strategy

- * District Office Meetings
- * Circuit Supervisor Work Unit Meetings
- * Supervisory Guidelines
- * FSIS Directive 11,000.1
Sanitation Performance Standards

Consolidation of the following ISP Codes:

06D01	Facilities and Equipment
06D02	Inspection Requirements
06D03	Condemned and Inedible Product
06E01	Sewage
06F01	Water Certification
06F02	Water Requirements
06G01	Pest and Rodent Control

... into ONE ISP procedure:

06D01

Sanitation Performance Standards

Sanitation Performance Standards:

- 416.2(a) Grounds and Pest Control**
- 416.2(b) Construction**
- 416.2(c) Lighting**
- 416.2(d) Ventilation**
- 416.2(e) Plumbing**
- 416.2(f) Sewage Disposal**
- 416.2(g) Water Supply and Water, Ice, and Solution Reuse**
- 416.2(h) Dressing Rooms, Lavatories, and Toilets**
- 416.3 Equipment and Utensils**
- 416.4 Sanitary Operations**
- 416.5 Employee Hygiene**

Inspectors will:

- * Perform ISP code 06D01 as scheduled through PBIS.
- * Randomly determine which sanitation performance standards to verify.
- * Goal is that over time all individual performance standards are verified.
- * Inspectors may make direct observations or review available records to verify compliance.

Example: Determining Compliance with Employee Hygiene -

Inspector will:

- * 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.

Noncompliance(s) Involving Direct Product Adulteration

For a Sanitation SOP noncompliance -

- * Follow the instructions found in FSIS Directive 5,000.1, Part Three, III.C.2.
- * Use appropriate ISP 01 procedure codes.

For a HACCP noncompliance -

- * Follow the instructions found in FSIS Directive 5,000.1, Part Two, III.C.2.
- * Use appropriate ISP 03 procedure codes.

Noncompliance(s) NOT Involving Direct Product Adulteration

If noncompliance is determined and direct product adulteration has not occurred, inspectors will need to determine the extent of the noncompliance before taking any action.

Inspectors actions will be dependent upon the severity of the noncompliance.

Three possible sets of actions could be taken:

Noncompliance(s) NOT Involving Direct Product Adulteration

[1] If there is an imminent probability that the noncompliance will result in product adulteration if not re-acted to immediately -

The Inspector will:

- * take regulatory control action.
- * document the finding on NR - fully describing the nature of the noncompliance and the performance standard not met.

EXAMPLE

While making a tour of the boning room, the inspector observes condensation dripping from an unclean surface near the boning table in area where gondolas containing trimmings are commonly pushed. It is determined that the plant has not identified nor is reacting to the insanitary condition.

Noncompliance(s) NOT Involving Direct Product Adulteration

[2] If the noncompliance does not need immediate attention [no control action is necessary] -

The Inspector will:

- * document the finding on a NR - fully describing the nature of the noncompliance and the performance standard not met.

EXAMPLE

While touring the frank peeling room, the inspector observed employees returning from break. Just after washing their hands and putting on plastic gloves, one employee was observed wiping their nose with one hand. Operations had not yet resumed and after observing the employee for several minutes, no attempt was made to remove the gloves, re-wash their hands and replace the gloves with clean ones.

Noncompliance(s) NOT Involving Direct Product Adulteration

[3] In situations where a condition exists that is less than perfect but not a noncompliance -

The Inspector will:

- * orally notify the establishment of the less than perfect condition.

[A NR should not be documented in this case.]

EXAMPLE

While touring the dry spice mixing room, the inspector observed a small spider web in the far corner of the room.

OR

While touring the shipping dock area, the inspector noticed one of twelve fluorescent light fixtures not working.

Trend Determinations

The NR contains **four** trend indicators:

1. Lighting
2. Structural
3. Outside Premises
4. Product Based

Trend Determinations

If inspection personnel determine that establishments are repeatedly failing to meet sanitation performance standards and are not successfully implementing corrective and preventive measures, they may decide to **withhold the marks of inspection.**

Trend Determinations

- * There is no specific number
- * Can involve different types of noncompliances related to a single performance standard
- * All previous implemented corrective and preventive measures failed
- * Inspectors decision must be based on sound professional judgement and supported by NRs.

Trend Determinations

If the decision is made to withhold the marks of inspection, the inspector will contact the District Office and provide all the relevant information necessary to prepare a **“Notice Of Intended Enforcement Action”**

Appeal Rights

- * FSIS regulations [9 CFR 306.5 and 381.35] provide establishments the opportunity to appeal an inspection finding or decision made by any program employee.
- * Prior to appealing, the establishment may request that the program employee reconsider his or her finding or decision.
- * Appeals should be directed to the immediate supervisor having jurisdiction over the subject matter of the appeal.

Appeal Rights

The following outlines the chain-of-command for inspection decisions:

1. Program Employee, including IIC
2. Circuit Supervisor
3. District Manager
4. Assistant Deputy Administrator for District Inspection Operations
5. Deputy Administrator for Office of Field Operations

Appeal Rights

- * The appeal determination must be communicated orally or in writing.
- * The “**Inspection Appeals Tracking System**” (IATS) was set up to facilitate the efficient and effective resolution of appeals.
- * The appeal and the determination will become a matter of public record - anyone can obtain information concerning it through a **FOIA** request.

Implementation strategies taken by Food Safety and Inspection Service

FSIS is taking steps to ensure the consistency of inspection decisions related to the sanitation performance standard regulation.

Implementation strategies

(Continued)

- Circuit Supervisor meetings
- Work unit meetings
- Correlation reviews

In-Plant Scenario

- The inspector performs a 06D01 procedure to verify that the performance standards related to equipment and utensils have been met by the establishment. (Section 416.3)
- While performing this procedure, the inspector observes black grease on product contact surfaces.

In-Plant Scenario

(continued)

- System review reveals that the plant failed to control this finding, and that product may be adulterated.
- Inspector takes regulatory control action and documents finding on Noncompliance Record (NR) citing regulations 416.3 and 416.13.

Questions for plant management

- Has the insanitary condition resulted in adulterated product? If yes, has adulterated product been shipped?
- Have procedures to ensure appropriate disposition of adulterated product been taken?

Questions for plant management (continued)

- Has restoration of insanitary condition been accomplished? Is this a repetitive finding?
- Is there a design or implementation problem with the SSOP (i.e., qualitative assessment)?
- What effective preventive actions need to be taken?

Appeals

- Make timely appeals regarding disagreements with inspection decisions.
- Try resolve at the lowest possible level.
- Agency tracks all documented inspection decision appeals.



Sanitation Performance Standards Verification through Records

**Presented
By
Robert A. Savage
HACCP Consulting Group, L.L.C.
Fairfax, VA**

HACCP Consulting Group, L.L.C.

GOOD AFTERNOON EVERYONE.

**THANK THE COMMITTEE, DR THOMPSON FOR
THE INVITATION TO SPEAK AT THE
CONFERENCE AND RECOGNIZE MY FSIS
FRIENDS.**

**WE ‘VE HAD SOME INTERESTING
PRESENTATION THIS MORNING AND THIS
AFTERNOON FROM THE AGENCY NOW I FEEL
IT IS MY CHALLENGE IN THE LAST TALK OF
THE DAY TO TRY TELL EVERYONE HOW TO
STAY OUT OF TROUBLE WITH YOUR LOCAL
INSPECTOR AND THE AGENCY WHEN TRYING
TO COMPLY WITH THESE SANITATION
PERFORMANCE STANDARDS. THIS IS NO
SMALL TASK BUT I’LL TRY MY BEST.**



QUESTION # 1
**How Will You Verify
Compliance with the
Sanitation Performance
Standards?**

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**IN THIS PRESENTATION I'LL TRY TO ANSWER
TWO QUESTIONS.**

**HOW WILL WE VERIFY COMPLIANCE WITH
THE SANITATION PERFORMANCE STANDARDS?**

QUESTION # 2

What Can You Learn from Your Records to Ensure You Remain in Compliance with the Sanitation Performance Standards?

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AND SECONDLY, WHAT CAN WE LEARN FROM OUR RECORDS SO THAT WE REMAIN IN COMPLIANCE WITH THESE REQUIREMENTS SO WE CAN KEEP OUT OF TROUBLE WITH FOLKS LIKE JIM BLANK AND JAN BEHNEY (NO OFFENSE GUYS).

REGARDING THE FIRST QUESTION, I THINK WE HAVE TO GO BACK TO THE BASICS FOR A FEW MINUTES AND TALK ABOUT WHAT ARE OUR STANDARDS IN THE PLANTS FOR ACHIEVING AND MAINTAINING SANITARY CONDITIONS AND HOW WE COMMUNICATE THESE STANDARDS TO OUR EMPLOYEES. AND YES, I AM GOING TO SPEND A FEW MINUTES TALKING ABOUT THE NEED AND IMPORTANCE OF HAVING WRITTEN STANDARD OPERATING PROCEDURES (SOPs) THAT WILL SPECIFICALLY ADDRESS THE NEW SANITATION PERFORMANCE STANDARDS.

I'M SURE THAT YOU HAVE ALL HEARD ABOUT SOPs OVER THE LAST FEW YEARS AS WE HAVE MOVED INTO HACCP AND HOPEFULLY THIS WILL BE OLD-HAT FOR MOST OF YOU BUT WITHOUT HAVING SOPs SO THAT EVERYONE IN YOUR ESTABLISHMENT KNOWS WHAT THE STANDARDS ARE, IT WILL BE EXTREMELY DIFFICULT TO MONITOR AND VERIFY YOUR COMPLIANCE WITH THIS RULE. IN A FEW MINUTES I'LL.....

Part 416 - Sanitation

- **Section 416.2 Establishment Grounds and Facilities**

- Grounds and pest control
- Construction
- Lighting
- Ventilation
- Plumbing
- Sewage disposal
- Water supply, ice and reuse
- Dressing rooms, lavatories, and toilets

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NOW EARLIER TODAY WE HEARD SOME GOOD PRESENTATIONS ABOUT THE SANITATION PERFORMANCE STANDARDS RULE BUT FOR THE PURPOSES OF DEVELOPING SOP I SEE AT LEAST 4 MAJOR SECTIONS OF THE RULE WHERE SOPs CAN BE DEVELOPED. ALSO, WITHIN EACH SECTION SEPARATE SOPs CAN ALSO BE DEVELOPED.

Part 416 - Sanitation

- **Section 416.3 Equipment and Utensils**
- **Section 416.4 Sanitary Operations**
- **Section 416.5 Employee Hygiene**

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Development of Standard Operating Procedures SOPs

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Development of Standard Operating Procedures (SOPs)

- **Not Mandatory but Necessary**
- **Use the FSIS Sanitation Performance Standards Compliance Guide {where applicable} and other References**
- **Use a Multidisciplinary Team**

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**STRESS HOW IMPORTANT SOPs ARE EVER
THOUGH THEY ARE NOT MANDATORY**

ADDRESS THE COMPLIANCE GUIDE

**IMPORTANCE OF A TEAM APPROACH LIKE
WAS DONE WITH HACCP**

BETTER PRODUCT

BUY-IN

Development of Standard Operating Procedures (SOPs)

- **Review the FSIS Sanitation Directive**
- **Review Past NRs/PDRs**
- **Make SOPs Clear and Simple**
- **Use SOPs as Training Tools**

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**STRESS THE IMPORTANCE OF THE CONTENT
OF THE SANITATION DIRECTIVE**

**REFERENCE THAT DURING OUR AUDITS OF
PLANTS WE REVIEW PAST NRs AND WHETHER
YOU AGREE WITH THEM OR NOT THERE ARE
STILL A LOT OF NRs THAT RELATE TO THE
AREAS WE ARE TALKING ABOUT IN THE NEW
SANITATION PERFORMACNE STANDARDS.**

**TRAINING, RELATE IT TO EMPLOYEE
TURNOVER AND THE HIGH EMPLOYEMENT
RATE.**


Development of Standard Operating Procedures (SOPs)

- SOP Format

- Purpose
- Background
- Scope
- Definitions
- Procedures
- Monitoring
- Documentation
- Corrective actions
- Verification
- References

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MANY WAYS OF DESIGNING SOPs AND MAYBE DURING OUR Q/A SESSION WE COULD TALK ABOUT SO OTHER APPROACHES YOU MIGHT HAVE TAKEN BUT THE APPROACH I'D LIKE TO SHARE WITH YOU TODAY COMES FROM ONE OUR CLIENTS BELIEVE IT OR NOT FROM AUSTRALIA



Our **GOAL** Should Be To
Make **EVERYONE** In The
Plant An **INSPECTOR** To
Find and Correct
Deficiencies **BEFORE** The
FSIS Inspector

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Development of SOP Monitoring Records

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Why Maintain SOP Records ?

- **Evidence that SOPs are being followed as written**
- **Provides documentation of compliance with the Sanitation Performance Standards**
 - **Plant Management**
 - **FSIS**

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Why Maintain SOP Records ?

- Shows DUE DILIGENCE (i.e., constant and earnest effort to accomplish what is undertaken)
- Identifies potential problem areas
- Provides a history of performance
- Documents actions taken to correct and prevent problems

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Development of SOP Monitoring Records


- **Correlate with the Standard Operating Procedure (SOP) and Sanitation Performance Standards**
- **Make Record Form Clear and Simple**

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Development of SOP Monitoring Records

- **Record Form should Include Corrective/Preventive Actions**
- **Monitoring Results should be Easily Tabulated in a Spreadsheet for Trend Analysis**

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Analysis, Evaluation and Utilization of Information on the SOP Monitoring Records

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Record Review Process

- **Same Process as for Sanitation Standard Operating Procedures (SSOP) Pre-operational and Operational Records**
- **Correlate with FSIS Noncompliance Record (NRs)**

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Record Review Process

- **Use Statistical Process Control Charts to TREND Data**
- **Compare Trend Data against Trend Data for NRs**
- **Use Results of Trend Analysis at Scheduled Staff Meetings**

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Filing of SOP Records

- **Consistent with SSOP and HACCP records**
- **Maintain in a central location**
- **Organize, Organize, Organize**

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Summary

- **Develop SOPs for the Sanitation Performance Standards**
- **Develop SOP Monitoring Records**
- **Utilize Records to Verify Compliance with the Performance Standards**
- **Utilize Records for Trend Analysis**

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Verification of the Effectiveness of a Sanitation Program through Microbiological Testing

Kristen Bell
Excel Corp.
A Cargill Foods Company

12/10/99

Ways to Evaluate the Effectiveness of a Sanitation Program

- ◆ Visually
- ◆ With ATP Bioluminescence
- ◆ With Protein Residue Kits
- ◆ Microbially

Recommended Analysis Option

- ◆ Aerobic Plate Count (APC)
 - ◆ Excellent indicator of sanitation program success
 - ◆ Simplest microbial test
 - ◆ Decent turn around time
 - ◆ Inexpensive

Factors that Affect Microbial Data

- ◆ Sampling technique
- ◆ Sampling methodology
 - ◆ Direct contact
 - ◆ Dilution
 - ◆ Sponge/Swab/Gauze
 - ◆ Rinse
- ◆ Size of area sampled

Factors that Affect Microbial Data (cont.)

- ◆ Plate incubation temperatures
- ◆ Plate incubation times
 - ◆ 72 hours at 25°C vs. 48 hours at 35°C
- ◆ Media used for growth
- ◆ Handling of sample during transport

Variability of Microbial Data within a Facility

- ◆ We're trying to eliminate something we can't see.
- ◆ Microorganisms are a biological entity...unpredictable.

Variability of Microbial Data amongst Facilities

- ◆ Physical facility
- ◆ Location
- ◆ Chemicals being used
 - ◆ Types
 - ◆ Proper training in preparation and use
- ◆ Time allotted for clean up
- ◆ Products being produced at facility

Variability of Microbial Data

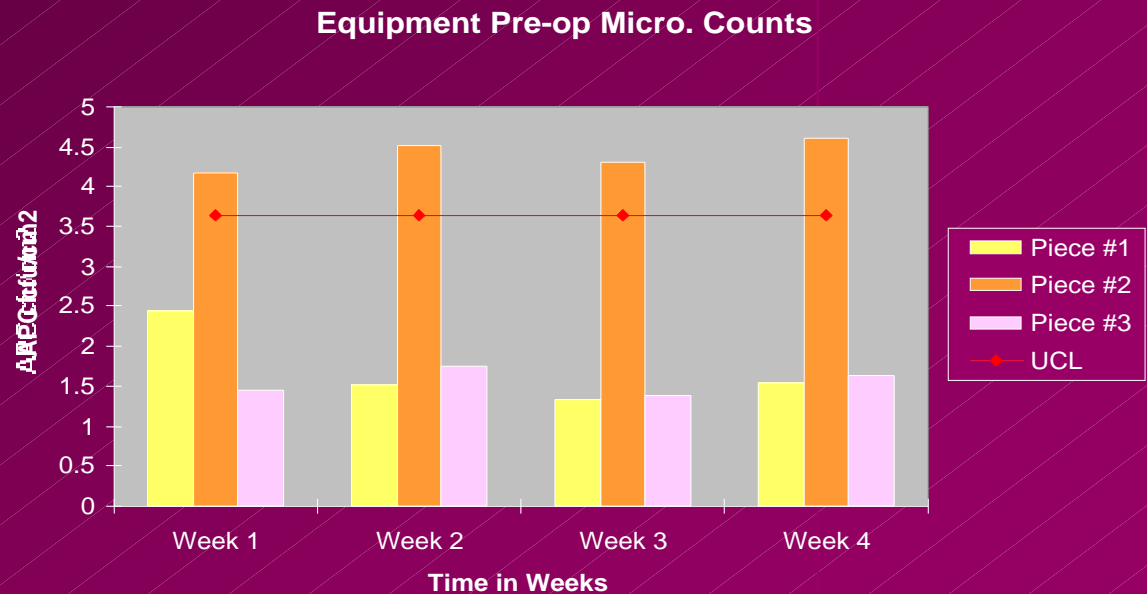
- ◆ To decrease effect of data extremes and avoid erroneous conclusions:
 - ◆ Use several data points
 - ◆ Sites within production areas (i.e. 2/area/day)
 - ◆ Use statistics

Graphing Options

- ◆ Area comparisons
- ◆ Equipment comparisons
- ◆ Percent passing

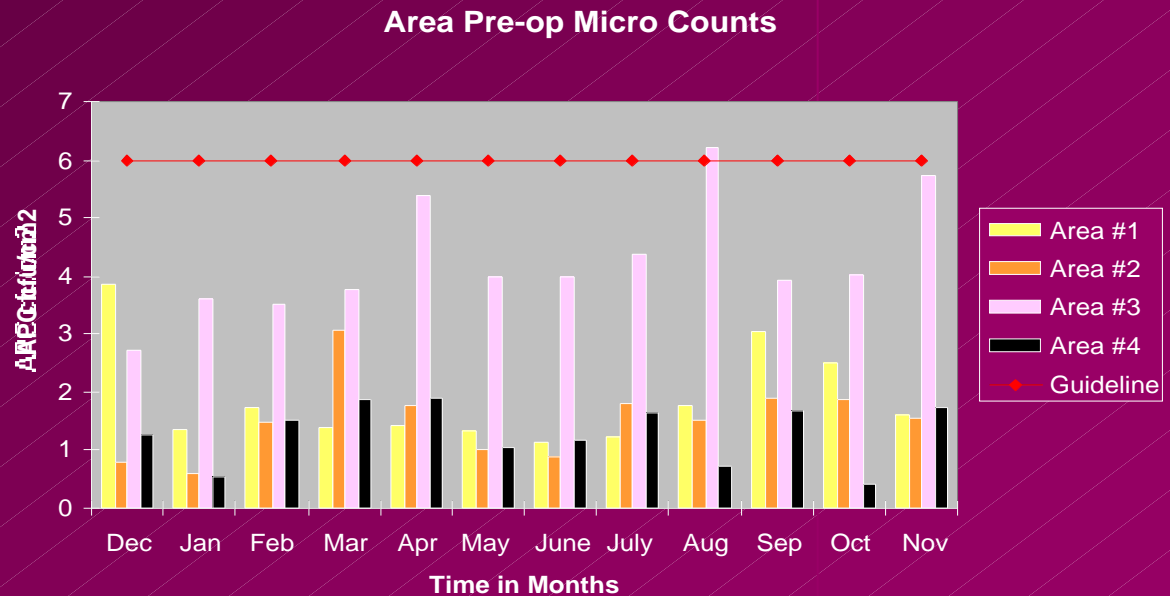
Graphing Options (cont.)

- ◆ 12 subgroups (3 pieces if equip. x 4 weeks)
- ◆ Subgroup size = 6 (6 day work week)
- ◆ 72 individual data points used in calculating UCL (12 x 6)



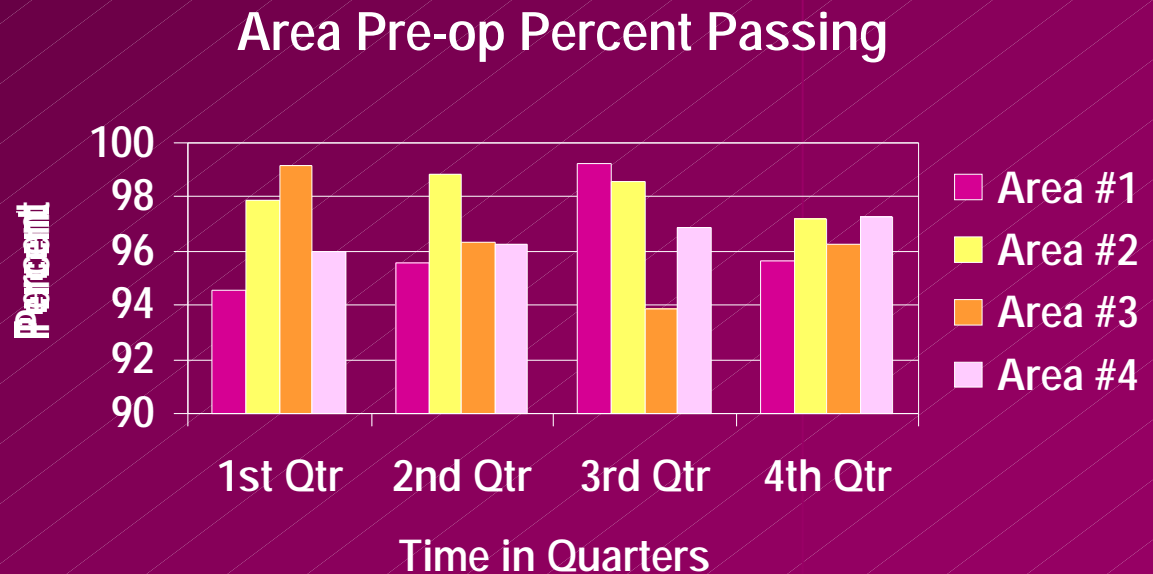
Graphing Options (cont.)

- ◆ Set a plant/company guideline and measure all results against that guideline

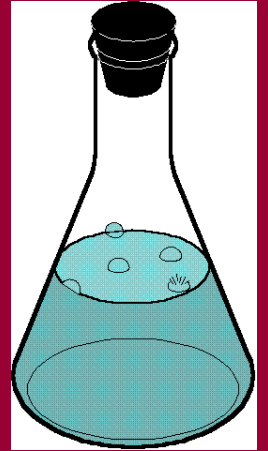


Graphing Options (cont.)

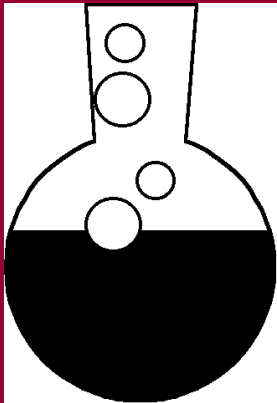
- ◆ Determine percent passing using UCL or established guideline



Chemicals



**Nonfood Compounds & Proprietary
Substances**



Chemical Compounds Under the New Sanitation Regulation

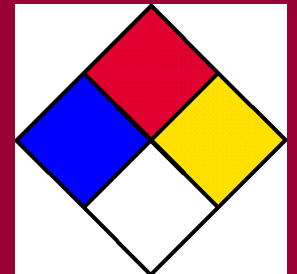
Chemical Compounds Under the New Sanitation Regulation

- The Agency has discontinued reviewing and approving chemical compounds for use in establishments.

Chemical Compounds Under the New Sanitation Regulation

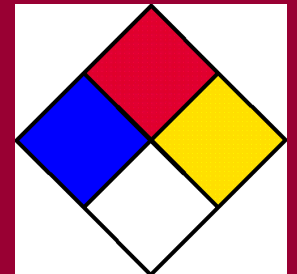
- The Agency has discontinued reviewing and approving chemical compounds for use in establishments.
- However, as is true today the compounds cannot adulterate or contaminate meat and poultry products.

Hazardous Substances



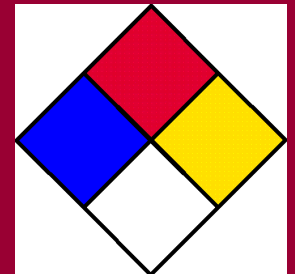
Hazardous Substances

- Materials classified as hazardous substances, extremely or super toxic, or containing heavy metals should not be allowed in the plant.



Hazardous Substances

- Materials classified as hazardous substances, extremely or super toxic, or containing heavy metals should not be allowed in the plant.
- If used the substance should not become a component of edible product according to 21 CFR 170.39



What is Required?

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- Documentation substantiating the safety of the chemical's use in a food processing environment.

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- In some cases other Federal Agencies have certain requirements that must be met.

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- Documentation substantiating the safety of the chemical's use in a food processing environment.
- In some cases other Federal Agencies have certain requirements that must be met.
- Previous approvals by FSIS are still acceptable providing that formulation and use has not changed since that approval.

What is Meant by Documentation?



What is Meant by Documentation?

- No requirement for any specific type of documentation



What is Meant by Documentation?

- No requirement for any specific type of documentation
- Use Directions

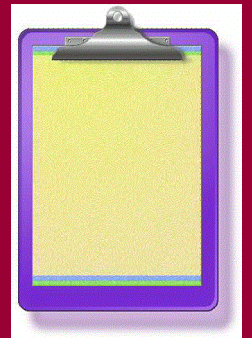


What is Meant by Documentation?

- No requirement for any specific type of documentation
- Use Directions
- Letters of guarantee

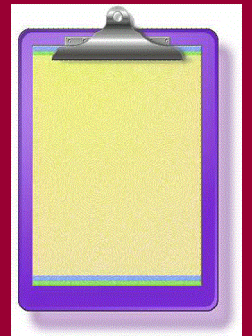


What is Meant by Documentation?



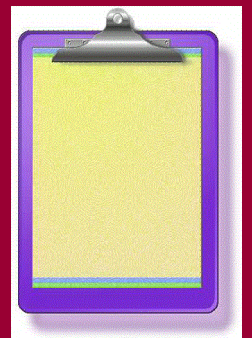
What is Meant by Documentation?

- Certification from other governmental agencies



What is Meant by Documentation?

- Certification from other governmental agencies
- Other material furnished by chemical manufactures and suppliers



Documentation substantiating the safety of the chemical varies with the nature and intended uses of the chemical.

What Should a Letter of Guarantee Contain?

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- **Statement specifying applicable limits under intended conditions of use**

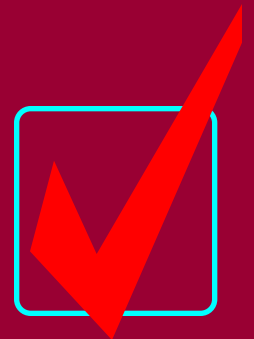
What Should a Letter of Guarantee Contain?

- **Name and address of supplier**
- **Brand name, code or other designation which uniquely identifies the compound**
- **Statement specifying applicable limits under intended conditions of use**
- **Statement that the material will be safe and effective under the intended use & will not adulterate food product**

What Should a Letter of Guarantee Contain?

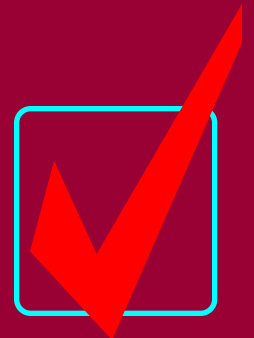
- **Name and address of supplier**
- **Brand name, code or other designation which uniquely identifies the compound**
- **Statement specifying applicable limits under intended conditions of use**
- **Statement that the material will be safe and effective under the intended use & will not adulterate food product**
- **Signature of an official of the supply firm.**

What is Meant by certification from Other Agencies?



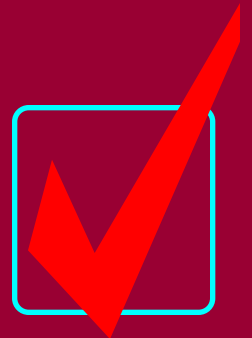
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- In some cases , other Federal Agencies require that chemicals meet their regulatory requirements, and be used in accordance with approved instructions.



What is Meant by certification from Other Agencies?

- In some cases , other Federal Agencies require that chemicals meet their regulatory requirements, and be used in accordance with approved instructions.
- An establishment should have documentation indicating that they meet these requirements.



**Specific Examples of
Compounds Requiring
Approval from Other Agencies.**

Specific Examples of Compounds Requiring Approval from Other Agencies.

- **Pesticides**

- Under the the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency(EPA) reviews pesticide formulations, intended use, and other information.

Pesticides



Pesticides



- All pesticides used in the US are registered with EPA.

Pesticides



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- EPA prescribes labeled and use.

Pesticides



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- EPA prescribes labeled and use.
- Pesticide must be used only in accordance with approved instructions.
- Establishments using pesticides must follow the FIFRA

Sanitizers and Disinfectants

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- Chemical sanitizers and chemicals used on food contact surfaces must comply with 21 Code of Federal Regulations (CFR) 178.1010 or appropriate food additive regulations

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- Chemical sanitizers and chemicals used on food contact surfaces must comply with 21 Code of Federal Regulations (CFR) 178.1010 or appropriate food additive regulations
- EPA regulated antimicrobials must include documentation stating that they are appropriate for use in food establishments.

**Hand Care Products
Containing Chlorhexidene
Gluconate**

Hand Care Products Containing Chlorhexidene Gluconate

- Used as an antimicrobial hand cleaners or hand sanitizers.

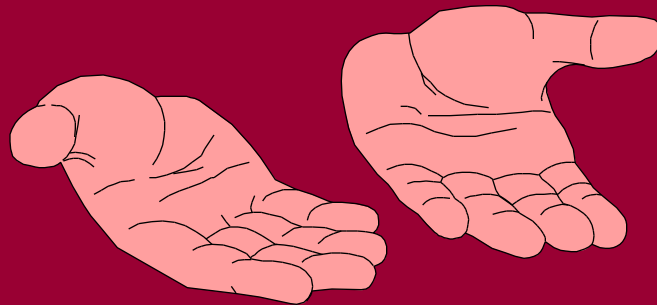
Hand Care Products Containing Chlorhexidene Gluconate

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- Considered a “drug” and possibly a “new drug” under the Federal, Food, Drug, and Cosmetic Act (FFDCA).

Hand Care Products Containing Chlorhexidene Gluconate

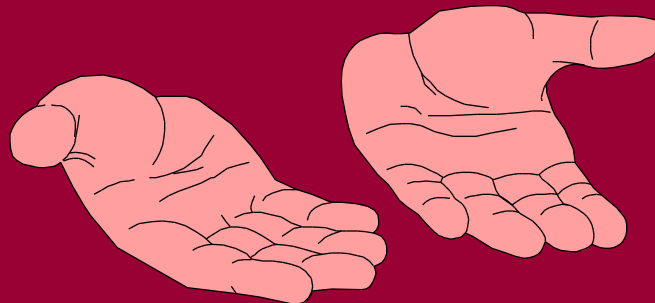
- Used as an antimicrobial hand cleaners or hand sanitizers.
- Considered a “drug” and possibly a “new drug” under the Federal, Food, Drug, and Cosmetic Act (FFDCA).
- Must be registered with FDA.

Hand Care Products Intended to Remain on Hands



Hand Care Products Intended to Remain on Hands

- Formulated in compliance with appropriate food additive regulations 21 CFR 178.1010, or appropriate GRAS.



Lubricants

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

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- Lubricants used on food contact surfaces should have appropriate food additive status.

Will Guidance be Available?

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- Agency is developing guidelines for compliance with the sanitation performance standards

Will Guidance be Available?

- Agency is developing guidelines for compliance with the sanitation performance standards
- Guidance material will explicitly address the appropriate formulation and safe use of nonfood compounds and proprietary substances.

**What will the the guidance
material be based upon?**

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- Criteria previously used by the Agency.

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- Requirements of other Federal Agencies.
- Criteria previously used by the Agency.
- Guidance material can be found on the FSIS web sight. www.fsis.usda.gov/

How will the Inspector Verify Compliance?

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- Direct observation of establishment operations

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- Inspection of an establishment's premises and product.

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- Direct observation of establishment operations
- Inspection of an establishment's premises and product.
- Sampling of product for chemical residues (**If Necessary**).
- Review of establishment records.

Does the Establishment Need to
Obtain New Documentation by
January, 25, 2000.

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- **No**

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- Theme of Conference: Nothing needs to be changed.

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- Theme of Conference: Nothing needs to be changed.
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- Then they will meet the requirements on Jan. 25.

Does the Establishment Need to Obtain New Documentation by January, 25, 2000.

- **No**
- Theme of Conference: Nothing needs to be changed.
- If chemicals are approved and meeting requirements today,
- Then they will meet the requirements on Jan. 25.
- If nothing has changed, e.g. formulation of chemical.