

CHANGE TRANSMITTAL SHEET

Verifying an Establishment's Food Safety System

5000.1
Revision 2
Amend. 1

7/18/06

This change transmittal issues FSIS Directive 5000.1, Revision 2, Amendment 1. This version includes Appendix A, Slaughter Process Verification Methodology, and Appendix B, Completing FSIS Form 5400-4, When More Than One Inspector Performs Sanitation ISP Procedures in Large Establishments 2006, which were inadvertently not included when FSIS posted the revised directive on June 1, 2006. In addition, this amendment:

1. clarifies the note on page 50;
2. corrects the first sentence of the note on page 28 by deleting the word "not;" and
3. changes "letter of information" to "letter" on page 86 under number 1.



Assistant Administrator
Office of Policy, Program, and Employee Development

APPENDIX A - SLAUGHTER PROCESS VERIFICATION METHODOLOGY

Hands-on verification of the pre-operational (pre-op) procedures component of a slaughter establishment's Sanitation SOP's will include utilization of a Pre-op Sanitation Inspection Plan. The development of a plan is necessary to provide uniformity in conducting pre-op sanitation inspection by identifying areas and units for random sampling. Plans will differ with the size of the establishment: Establishments that have 15 or more units will be subdivided into areas and have a certain time allotment as compared to establishments that have 14 or less units, which will not be divided into areas and thus will have a shorter time allotment.

Pre-op Sanitation Inspection Plans for Slaughter Establishments Having 15 Units or More

A. Pre-op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignments, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time for each assignment:

a. The pre-op start time will be determined by an inspection program employee based on the Inspection Units (IU's) selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

b. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate areas and identify units in each area:

a. An area is a major portion of an establishment designated in the Pre-op Sanitation Inspection Plan for hands-on pre-op sanitation inspection. Examples of an area include the picking area, the eviscerating area, or major equipment groupings or systems. The inspection program employee will determine the boundaries of each area. One to five areas will be covered during a pre-op inspection assignment.

b. Each area is divided into units. The size of an area may vary from 15 to 50 units. A unit is a numbered three-dimensional section within an area. Each unit must be sufficiently identified so that inspectors who rotate into a pre-op sanitation inspection assignment can easily identify each unit. A unit may have irregular boundaries that are

usually identified by landmarks such as an individual piece of equipment, utensils, associated floors, walls, drains, or other vertical structures and overhead structures. A hand-drawn schematic of the area will be used to identify units. The schematic will include major landmarks in the area such as walls, doors, and posts, and an outline of the principal equipment. The boundaries of the units will be drawn on the schematic and the units numbered. To the extent practical, units should be numbered in the order of product flow for each area. Large, complex equipment may be divided into smaller units. For example, a designated unit might be an individual piece of equipment, such as a picker, and the floor, gutter, drain, posts, walls, and overhead structures in the vicinity of that piece of equipment. The picker may also be divided down the middle and each half included in a different unit. Other examples of units include portions of the area with identifiable boundaries, such as the hide puller, including the floors, drains, walls, and overhead structures and a traffic lane through which products and personnel move.

c. Portable equipment and other equipment that is displaced during cleaning may not always be located entirely within a unit at the time of inspection. Such equipment will be inspected when it is within the boundaries of a unit.

d. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-op Sanitation Inspection Plan.

e. Inspection Units (IU's) will be randomly selected from units in an area:

(1) Upon receipt of the Procedure Schedule (i.e., the week before), an inspection program employee should select the random IU's for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but must be completed at least the day before hands-on verification is scheduled. This will allow determination of the lockout/tagout verification time based on the IU's selected. The selected IU's should remain under security. The amount of time for lockout/tagout verification should be communicated to the inspector(s) responsible for performing pre-op sanitation.

The number of IU's to be selected for area sampling is according to the following schedule:

<u>Units Per Area</u>	<u>Number of IU's</u>
15 to 30	3
31 to 40	4
41 to 50	5

(2) The Front-line Supervisor will authorize a method of randomly selecting IU's for inspection. The following method may be used:

(a) Number cardboard chips to correspond with the inspection unit numbers and place them in a container large enough to permit thorough mixing of the chips.

(b) Before each inspection, mix and then select the specified number of chips from the container.

(c) Write the IU numbers that have been selected for inspection on a piece of paper.

(d) Return the chips to the containers.

Pre-op Sanitation Inspection Plans for Slaughter Establishments Having 14 Units or Less (small establishments)

Pre-op sanitation inspection in small establishments will differ from pre-op sanitation inspection in larger facilities. The Pre-op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignment, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time:

a. An inspection program employee will create a Pre-op Sanitation Inspection Plan. The plan will be filed in the inspector's office or in a file designated for the inspector's use in those establishments that are not required to maintain an inspection office.

b. The pre-op start time will be determined by an inspection program employee based on the IU's selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

c. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate units:

a. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-op Sanitation Inspection Plan.

- b. Small establishments will not be subdivided into areas.
- c. An inspection program employee will select 3 IU's at random for pre-op sanitation inspection as scheduled by the PBIS.
- d. An inspection program employee should select the random IU's upon receipt of the Procedure Schedule (i.e., the week before) for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but must be completed at least the day before hands-on verification is scheduled.

SUPPLEMENTARY INSTRUCTIONS REGARDING ENFORCEMENT ACTIONS

When noncompliance with regulatory requirement(s) is found, inspection program personnel will take action as outlined in FSIS Directive 5400.5 and FSIS Directive 5000.1, Revision 1, Chapter I, Sanitation, and consistent with applicable regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").

NOTE: Hands-on verification includes a records review component. Prior to performing the hands-on verification, the inspector will review the establishment's records for that day, if available at that time. Inspection program personnel will document findings on an NR. When determining if noncompliance exists, you must take into account what is known for a fact. Therefore, if an establishment's records for that day are available, there may be something in the records that would make a difference in determining whether the establishment has failed to comply with one or more regulatory requirements. If the establishment's records for that day are not available, findings written on the establishment's records later will not be known as a fact when a determination is made by the inspector during the hands-on verification.

The regulations on Sanitation SOP's require the establishment to implement procedures sufficient to prevent direct contamination or adulteration of product(s), and pre-op procedures in the Sanitation SOP's must address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils. Therefore, contaminated product and violative facilities, equipment, and utensils, in addition to requiring official control actions, will be considered Sanitation SOP failures. Official control action consists of retention of products and rejecting equipment, utensils, and rooms and/or areas to prevent their use in the production of products until a failure is remedied.

FSIS inspection program personnel will determine whether official control action is appropriate. When the Agency seeks to take further regulatory or administrative action, it must be able to rely on NR information. Therefore, documenting failure to comply with regulatory requirements as specified above is essential (whether or not official control action was taken).

APPENDIX B - COMPLETING FSIS FORM 5400-4 WHEN MORE THAN ONE INSPECTOR PERFORMS SANITATION ISP PROCEDURES IN LARGE ESTABLISHMENTS

When multiple inspectors perform an individual ISP procedure, that is 01B or 01C, each inspector will document individual findings. This can be accomplished by one inspector, as consulted on the local level, documenting on the NR, while the remaining inspection program personnel utilize an NR Continuation Sheet for documentation purposes. ALL noncompliance with regulatory requirements must be documented. The NR Continuation Sheet(s) should have the same number as the NR.

The NR should include a statement to indicate the number of the NR Continuation Sheets that are attached. The NR Continuation Sheets will be attached and all the documentation will be provided to the plant manager. It is essential that the failure to comply with regulatory requirement(s), whether documented on the NR or the NR Continuation Sheet, include all information related to the noncompliance. It is important that both are written in a manner to allow "visualization" of the noncompliance. Both the NR and NR Continuation Sheet need to contain the provision(s) of the regulation(s) with which the establishment failed to comply as well as the section or page of the establishment's Sanitation SOP procedures not followed. Previous noncompliance for the "same root cause" should be included in the documentation and, as instructed in FSIS Directive 5400.5, noncompliance trend information provided. Also, the failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration as documented previously should be included.

Because NR information will form the basis of further Agency actions, it will be essential for each person documenting noncompliance with one or more regulatory requirements to include all of the above information.

For example: There are three inspectors at Est. 38 who perform Pre-op verification. Two inspectors will document their findings on individual NR Continuation Sheets. One inspector documents failure to comply with regulatory requirement(s) on the NR. The NR and NR Continuation Sheets are put together, and the appropriate noncompliance and trend indicator blocks are marked on the NR and the Procedure Schedule. The NR will include a statement that there are two NR Continuation Sheets attached.

In the example, one of the inspectors documenting on an NR Continuation Sheet is responsible for pre-op verification on the slaughter floor. If this inspector finds repeated noncompliance for the same cause on the slaughter floor, he or she is responsible for including this information on the NR Continuation Sheet (including previous NR numbers and dates). This inspector should also include failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration, as previously documented, and any notification he or she has previously provided to the establishment pertaining to the repeated failure to comply with regulatory requirement(s).