

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

<h1 style="margin:0;">FSIS DIRECTIVE</h1>	7640.1 Amend. 1	10-30-97
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**INSPECTION DUTIES RELATED TO FACILITIES AND EQUIPMENT,
AND PLANT OPERATED QUALITY CONTROL PROGRAMS**

I. PURPOSE

This directive provides inspection program personnel with instructions for the performance of inspection verification tasks related to facilities and equipment, and plant operated quality control programs.

II. CANCELLATIONS

This directive cancels:
FSIS Directive 7630.1, Rev. 3, dated 2/03/94;
FSIS Notice 24-88 dated 5/25/88; and
MPI Bulletin 81-38 dated 8/27/81.

III. (RESERVED)

IV. REFERENCES

Sections 304.2, 308.5, 318.4(c), and 381.145 Meat and Poultry Inspection Regulations

FSIS Directive 5400.1, Rev. 2, "Inspection System Guide (ISG)";
FSIS Directive 5220.1, Rev. 1, "Granting, Refusing, Voluntary Suspension or Voluntary Withdrawal of Federal Inspection Service";
FSIS Directive 7220.1, Rev. 3, "Food Labeling Division Policy Memoranda";
FSIS Directive 8800.2, "Performance-Based Inspection System: Overview of Policies and Implementing Procedures"; and
FSIS Directive 8820.1, Rev. 1, "Corrective Action System".

V. FORMS AND ABBREVIATIONS

The following will appear as abbreviated in this directive:

IIC	Inspector-in-Charge
CS	Circuit Supervisor
DM	District Manager
OFO	Office of Field Operations

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

OPI: OPPDE

VI. INSPECTION RESPONSIBILITIES RELATING TO FACILITIES AND EQUIPMENT

A. The IIC should not maintain copies of blueprints, drawings and specifications and should return any copies to establishment management. The IIC should, however, request from establishment management written designation of the official premises' boundaries. This should be filed with the grant of inspection.

B. Inspection personnel verify through the performance of ISG tasks 1A01a1/a2 and 1B02a1/a2 that facility and/or equipment are not causing contamination or adulteration of products.

C. If a noncompliance is identified, inspection personnel classify and document the deficiency on a PDR and take other action as appropriate under Directives 8820.1, "Corrective Action System" and FSIS Directive 8830.1, "Progressive Enforcement Action (PEA)."

VII. INSPECTION RESPONSIBILITIES FOR QUALITY CONTROL PROGRAMS

A. Partial Quality Control (PQC) programs (now referred to as Quality Control (QC) Programs) and in-plant procedures are no longer prior approved by FSIS. Therefore, inspection personnel no longer have duties related to the prior approval of QC programs and in-plant procedures, EXCEPT Total Quality Control (TQC) systems and for the following:

1. Poultry Irradiation (381.149)
2. Poultry Slaughter Systems--NELS and NTIS (381.76)
3. Roast Beef (318.17)
4. Certain Canning Systems and Alternative Devices (318/381.307(b), 318/381.305(a), and 318/381.305(f))
5. Waste Water Treatment Systems/Water Reuses (308.3 and 381.50)

B. When TQC/QC program approvals are necessary, the IIC should:

1. upon receipt of the proposed TQC or QC program from the establishment, complete a Speed Memo (AD Form 311) and include the establishment name and number; recommendation for approval/disapproval with comments based on the review of the proposal, using the appropriate regulations; and a signature and date.

2. forward the completed Speed Memo attached to the original and two copies of the establishment's cover letter and proposal to the District Manager within 5 working days of receipt.

C. The IIC should not maintain QC programs, except for those listed above, on file and should return any copies to establishment management.

D. If establishments are operating a process or producing product under a QC program, inspection personnel verify that a written QC program is in the establishment's files and addresses raw material controls, process control, records control and corrective/preventive action. Data and information from the QC program must be made available to inspection personnel upon request.

E. Inspection personnel perform appropriate PBIS tasks to verify that the QC program is ensuring that the product/process meets regulatory requirements. If a labeling claim is more restrictive than the regulatory requirement, then the labeling claim becomes the regulatory standard that must be met.

F. Inspection personnel verify that limits prescribed in QC programs are met and, if not, corrective actions are taken. FSIS has developed limits for certain processes that establishments have used in their QC programs. Establishments may continue to use these limits or develop their own limits. If establishments fail to meet the criteria in paragraph D., establishments must meet the exact standards required by the regulations and inspection personnel perform the appropriate PBIS tasks to ensure compliance with the regulatory standard.

G. If a noncompliance is identified, inspection personnel classify and document deficiency on a PDR and take other action as appropriate under FSIS Directives 8820, "Corrective Action System" and FSIS Directive 8830.1, "Progressive Enforcement Action." Inspection personnel should not issue PDR's when there is deviation in a QC program standard more stringent than a regulatory standard, if such deviation does not exceed the regulatory standard.

H. Questions regarding limits developed by establishments or any other questions should be directed through supervisory channels to the Technical Center.

Deputy Administrator
Office of Policy, Program Development and Evaluation

Attachment 1	Background
Attachment 2	Modified ISG Task
Attachment 3	Deleted ISG Codes
Attachment 4	Elimination of PQC Program Requirements Found in Policy Memos

BACKGROUND

The final rule published on August 25, 1997, eliminates FSIS's requirement for prior approval of facilities, equipment, and certain Partial Quality Control(PQC) programs. This action is being taken to separate the roles of Government and the regulated industry, to remove unnecessary regulatory burdens on inspected meat and poultry establishments, to streamline and modernize the meat and poultry food safety regulation, and to encourage innovations that will improve food safety. The final rule represents an important shift away from FSIS's "command and control" regulatory approach and toward an approach consistent with the Agency's food safety mission. This is consistent with the new regulatory requirements for establishment operated sanitation SOP's and HACCP systems. FSIS believes adequate sanitation SOP's and HACCP systems will meet the same objectives as prior approval.

Beginning on the effective date of this final rule, establishment management will no longer be required to submit drawings and specifications of facilities for approval, before FSIS grants inspection or before establishments remodel facilities. The facilities must be capable of meeting the applicable processing requirements of a product, must be cleanable and must not become a source of hazards to the product. FSIS continues to expect establishment management to notify inspection personnel if changes to facilities or equipment may interfere with or require changes to inspection operations.

Additionally, establishment management will no longer be required to use FSIS- approved utensils and models of equipment. Equipment and utensils must continue to meet the general standards that they are of a material and construction that will facilitate thorough cleaning and cleanliness, will not contaminate product and will not interfere with or impede inspection procedures. It will be the responsibility of the establishment management to take action with respect to any equipment or facilities that may be causing a food safety hazard. However, FSIS will maintain its authority to prevent the use of equipment or facilities which poses a threat to public health or interferes with inspection.

The final rule also removes the requirement of prior approval for the majority of PQC programs. Pending further rulemaking, some PQC's will continue to be prior approved. Also, mandatory PQC programs related to food safety ultimately will be incorporated into establishment's HACCP systems.

Attachment 2

MODIFIED ISG TASKS

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<p>01B02 a1</p> <p>01B02a2</p>	<p>All product handling equipment and other equipment coming in contact with product are of a material and construction that facilitate thorough cleaning and cleanliness and must not interfere with or impede inspection procedures.</p>	<p>308.5 (a)</p> <p>381.53</p> <p>381.54</p> <p>QC Program</p>	<p>Evaluate available records to determine if the records are on file, accurate, complete, and, as applicable, indicate that the plant performs appropriate compliance task(s), including corrective and preventive actions when necessary.</p> <p>If results do not meet compliance standards, initiate appropriate action.</p> <p>Verify that: product handling equipment coming in contact with product is of a material and construction that facilitate thorough cleaning and cleanliness and does not interfere with or impede inspection procedures.</p>
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01B02a1- Eval avail plt records (prod handling/contact eqpt)

01B02a2 - Obsv equip sample for adequate maintenance program

FSIS DIRECTIVE 7640.1
Attachment 2

List of modifications to FSIS Directive 5400.1 Inspection System Guide (ISG)

Modify the following tasks by making the indicated pen and ink changes.

- 01C04 - Delete the word "Approved" where it appears
- 01C10 - Section task discussion. Delete PQC reg language
- 03A01 - Delete the word "Approved" where it appears
- 03I01 - Delete the word "Approved" where it appears
- 03E10 - Delete the word "Approved" where it appears
- 05A01c1 - Modify to state records are needed but not inventory log.
- 06B02 - Delete each lot ID, Green wt and word "Approved" where it appears 4th column
- 06B03 - 4th Column Delete the word "Approved" where it appears
- 06C01 - Delete the word "Approved" where it appears
- 06D05 - Delete the word "Approved" where it appears
- 06D06 - Delete the word "Approved" where it appears
- 06F01 - Delete the word "Approved" where it appears Add ref. 318.6
- 06F03 - Delete the word "Approved" where it appears Add ref. 318.6
- 06G01 - Delete the word "Approved" where it appears Column 1 and 2
- 06G02 - Delete the word "Approved" where it appears Column 1 and 2
- 06I03a - Delete the word "Approved" where it appears
- 06I03b - Delete the word "Approved" where it appears
- 06I04 - Delete the word "Approved" where it appears
- 06J05 - Delete the word "Approved" where it appears
- 06J07 - Delete the word "Approved" where it appears
- 06J09 - Delete the word "Approved" where it appears
- 06J11 - Delete the word "Approved" where it appears
- 06K03 - Delete according to QC Program and Add according to stated form.
- 06K05 - Delete the words "Approved Label" where they appears
- 06K17 - Delete the words "Approved Label" where they appears
- 06K18 - Add regulation site 317.4
- 06L02 - Delete the words "Approved PQC" where they appears
- 06L05 - Delete the word "Approved" where it appears
- 06M01 - Delete the word "Approved" where it appears
- 06N04 - Delete the word "Approved" where it appears
- 06N05 - Delete the word "Approved" where it appears
- 06N13n - Add equation for yield.
- 06Q03 - 04 and 05 Delete the word "Approved" where it appears

Attachment 2

- 06Q11 - Delete the word "Approved" where it appears
- 06Q12 - Delete the word "Approved" where it appears
- 06S03 - Delete the word "Approved" where it appears

- 06S04 - Delete the word "Approved" where it appears
- 06S05 - Delete the word "Approved" where it appears
- 06S07 - Delete the word "Approved" where it appears
- 06S08 - Delete the word "Approved" where it appears
- 06S09 - Delete the word "Approved" where it appears
- 06S11 - Delete the word "Approved" where it appears
- 06S12 - Delete the word "Approved" where it appears
- 06S16 - Delete the word "Approved" where it appears
- 06S18 - Delete the word "Approved" where it appears
- 06S21 - Delete the word "Approved" where it appears
- 06S22 - Delete the word "Approved" where it appears
- 06S23 - Delete the word "Approved" where it appears
- 06S24 - Delete the word "Approved" where it appears
- 06S25 - Delete the word "Approved" where it appears
- 06S26 - Delete the word "Approved" where it appears
- 06S27 - Delete the word "Approved" where it appears
- 06S29 - Delete the word "Approved" where it appears
- 06S30 - Delete the word "Approved" where it appears
- 06S31 - Delete the word "Approved" where it appears
- 06S32 - Delete the word "Approved" where it appears
- 06S33 - Delete the word "Approved" where it appears
- 06S34 - Delete the word "Approved" where it appears
- 06S35 - Delete the word "Approved" where it appears
- 06S36 - Delete the word "Approved" where it appears
- 06S37 - Delete the word "Approved" where it appears
- 06S39 - Delete the word "Approved" where it appears
- 07B02 - Delete the word "Approved" where it appears
- 07B05 - Delete required for PQC
- 07C03 - Delete the word "Approved" where it appears
- 07C04 - Delete the word "Approved" where it appears
- 08D02 - Delete the word "Approved" where it appears
- 08D03 - Delete 2nd sentence of standard
- 09A03 - Delete CS the word "Approved" where it appears
- 11Q01 - Delete QC statement
- 11U01 - Delete the word "Approved" where it appears

**FSIS DIRECTIVE 7640.1
Attachment 3**

DELETED ISG TASKS

The following is a list of deleted task codes:

Retired ISG Task codes

Task

01B01

01C07b1 and b2

01E

05B01b1

06B02

06B04

06B06

06B10

06C03

06N07

Attachment 4

ELIMINATION OF PQC PROGRAM REQUIREMENTS FOUND IN POLICY MEMOS

The following is a list of FSIS, Standards and Labeling Division/Food Labeling Division Policy Memoranda. The PQC requirements found in these memorandum are eliminated.

Policy Memorandums

- 044A: Raw Boneless Poultry containing Solutions
- 054: Quality Control Claims (9 CFR 318.145 (f))
- 057A: Labeling Turkey Ham Products Containing Added Water (9 CFR 381.171)
- 066C: Red Meat Products Containing Added Solutions
- 069: Labeling for Substitute Products
- 084A: Cooked Red Meat Products Containing Added Substances
- 108B: Water- Misted and Ice - Glazed Meat and Poultry Products
- 110: Perishable, Uncured Meat and Poultry Products in Hermetically Sealed Containers
- 121B: Labeling of Modified, Substitute Versions of Fresh (Species) Sausage, Hamburger, or Ground Beef Products with added Ingredients Used to Replace Fat Quality for Use of Certain Nutrient Content Claims Associated with a Reduction in Fat Content

**FSIS Directive 7640.1
Attachment 5**

ELIMINATION OF PQC PROGRAM REQUIREMENTS FOUND DIRECTIVES

The following is a list of FSIS Directives. The PQC requirements found in these directives are eliminated.

Directives

11,000.1 Sanitation Handbook
11,000.4, dated 11/24/96
11,100.1, dated 2/11/86
11,000.2, dated 4/28/87
11,140.1, dated 1/10/91
11,150.1 dated 10/22/92
11,220.1 dated 6/3/87
11,220.2, dated 2/23/89
11,550.1, dated 9/21/93