
FSIS DIRECTIVE

7610.2

10-5-94

Rev. 1

TOTAL QUALITY CONTROL FOR PROCESSING OPERATIONS

I. PURPOSE

This revised directive provides current FSIS policy and procedures with respect to submittal and routing for approval of new, revised, or amended TQC systems for processing operations. The inspector's checklist for TQC systems has been updated and is attached to this directive.

II. CANCELLATION

FSIS Directive 7610.2, dated 9/6/90

III. REASON FOR REISSUANCE

This directive has been rewritten in its entirety to:

- A. Provide FSIS employees guidance for processing and routing of establishment-submitted proposals for new, revised, or amended TQC systems;
- B. Update organizational references;
- C. Provide a new FSIS Form 7630-1 (see Attachment 1); and
- D. Update and attach the "Inspector's Checklist for TQC Systems" (see Attachment 2).

IV. REFERENCES

MPI Regulations, Sections 318.4 and 381.145

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

OPI: S&T/PPID

V. ABBREVIATION AND FORM

| | |
|-----|-------------------------|
| AS | Area Supervisor |
| IIC | Inspector in Charge |
| PQC | Partial Quality Control |
| QC | Quality Control |
| RD | Regional Director |
| S&T | Science and Technology |
| TQC | Total Quality Control |

FSIS Form 7630-1, TQC/PQC Program Submittal Cover Sheet, date 6/93

VI. DEFINITION

Approving Authority for TQC systems is the RD. When a section(s) of any proposed TQC system requires special expertise, that section(s) is routed to S&T, Headquarters, Washington, D.C., for review, evaluation, and approval and then returned to the RD who continues to be the "Approving Authority."

VII. GENERAL RESPONSIBILITIES

A. The Processed Products Inspection Division, S&T, will continue to issue new, revised, or amended TQC guidelines and policy statements, as needed, and to receive and address technical TQC policy concerns.

B. Inspection Operations will receive and address concerns about general operations and administrative responsibilities under a TQC system.

C. The RD will always be the "Approving Authority" for establishment-proposed new, revised, or amended TQC systems.

D. S&T will review, evaluate, and approve a pertinent section(s) of the proposal, when specific expertise is needed.

VIII. DEVELOPMENT OF PROPOSED TQC SYSTEM

A. Upon request by the establishment for information on TQC systems, the IIC will advise the establishment to contact the Regional QC Specialist. The QC Specialist will furnish the establishment with available TQC information which includes FSIS regulation requirements, policies, and other FSIS material.

B. Questions regarding TQC systems should be directed to the Regional QC Specialist.

C. All new or revised TQC systems should be accompanied by a cover letter that contains all the information listed below. The cover letter for an amendment to an already approved system must contain, at a minimum, items “1.,” “2.,” “3.,” and “7.” below.

1. Date of submission of documentation.
2. Name of company/establishment, address, telephone number, and establishment number.
3. Objective of the proposed new/revised/amended TQC system.
4. Length of time data generated by the establishment’s proposed or existing TQC system will be retained. Example: “All records generated by this TQC system will be retained a minimum of 1 year.”
5. Statement of establishment’s commitment to make all data, records, and information generated as a result of the proposed TQC system readily available to USDA officials.
6. Statement that an assigned, responsible establishment employee will be given authority to halt production and restrict shipment of product if standards established for the system are not met.
7. Original signature of establishment official responsible for quality control with printed name and title included.

D. Information in the establishment’s cover letter shall meet the requirements of MPI Regulations, §§ 318.4 and 381.145.

E. All pages and attachments (i.e., required labels, charts, forms, etc.) to the TQC system are to be numbered.

F. Establishment provides the original to the Regional Office and three copies to the IIC.

IX. APPROVAL PROCESS

A. The IIC will upon receipt of the proposal and direction from the RD:

1. Notify the Circuit Supervisor that a proposed TQC system has been received.
2. Review the proposed TQC system using the TQC checklist (see Attachment 2).

3. Initiate and forward FSIS Form 7630-1 to the AS (see Attachment 1). FSIS Form 7630-1 is used to obtain IIC and AS comments to aid the RD in approve/disapprove decisions on establishment-generated proposals for TQC systems. When completing FSIS Form 7630-1, assure the following steps are taken:
 - a. Review the proposal, using appropriate guidelines.
 - b. State, in the “comments” section, the capability of the establishment, including facilities and equipment, to comply with the provisions of the proposed new, revised, or amended TQC system.
 - c. Recommend approval or disapproval.
 - d. Sign
 - e. Forward the completed FSIS Form 7630-1 and three copies of the establishment’s cover letter and proposal to the AS within 5 working days of receipt.

B. The AS, upon receipt of FSIS Form 7630-1 will:

1. Review the proposal and the IIC’s comments.
2. Comment on the same FSIS Form 7630-1 that the IIC made comments on.
3. Sign.
4. Forward the completed FSIS Form 7630-1 and three copies of the establishment’s cover letter and proposal to the RD within 5 working days of receipt.

C. The RD, as “Approving Authority,” will, upon receipt of the proposal:

1. Retain the original cover letter and documentation in the Regional Office.
2. Review current FSIS guidelines to determine whether any section(s) of the proposal need to be reviewed, evaluated, and approved by S&T, Headquarters. Examples of proposals that call for specific S&T expertise/approval that must be provided in written form to the RD:
 - a. Processing shelf stable canned product or perishable, uncured products in hermetically sealed containers. The Processed

Products Inspection Division, S&T, will evaluate, and provide written comments/approval to the RD;

- b. Water re-use. The Facilities, Equipment, and Sanitation Division, S&T, will review, evaluate, and provide written comments/approval to the RD;
- c. Poultry chilling, moisture control, and other similar meat and poultry activities. The Slaughter Inspection Standards and Procedures Division, S&T, will review, evaluate, and provide written comments/approval to the RD.

- 3. Forward the section(s) of the TQC proposal to the appropriate S&T division along with any comments provided on FSIS Form 7630-1.
- 4. Obtain a compliance history and review and evaluation summary of the establishment from Regulatory Programs (for new TQC systems only).

D. S&T, Headquarters, when asked to review, evaluate, and approve a section(s) of the establishment's proposed system will:

- 1. Review and evaluate the section(s) forwarded by the RD, taking into account all information provided by the RD; MPI Regulations, §§ 318.4 and 381.145; and other guidelines.
- 2. Provide comments and /or approval to the RD.

E. The RD, as "Approving Authority," will evaluate the proposal, any written comments/approval from S&T, comments on FSIS Form 7630-1, and the Checklist. The RD will then:

- 1. Approve any proposal **without revisions**, where possible. Stamp each page of the proposed new, revised, or amended TQC system with the word "APPROVED" and the date of approval.
 - a. Prepare and send a letter to establishment management stating that the proposal has been approved. Attach a copy of the proposal with the stamp of approval and date of approval on every page.
 - b. Retain the original submittal in the Regional Office as the complete record and forward copies of the complete record to the AS and the IIC. Additionally, forward one copy of the approval letter **only** to the Circuit Supervisor. All copies of the complete record should be filled in the Regional, Area, and IIC's offices in chronological (date) order.

NOTE: The complete record referred to in IX.E.1.b. consists of the original incoming cover letter from the establishment; the original of the proposal stamped on every page with the word, "APPROVED," and with the date of approval; and a copy of the notification of approval.

- c. Contact establishment management for agreement on start-up date for new system(s).
2. Approve any proposal with **minor changes**, when possible:
 - a. Contact the IIC and/or establishment management directly to discuss needed changes.
 - b. Ensure that the establishment provides copies of corrected pages for the proposal, through the IIC, unless otherwise directed.
 - c. Make judicious use of pen and ink changes, if agreed on by establishment management.
 - d. Continue with the approval process as described above in Paragraph IX.D.1.
 3. Deny any proposal that needs **extensive revision** and provide formal notification to the applicant:
 - a. Detail the basis for denial, as required by MPI Regulations, §§ 318.4 and 381.145.
 - b. State that the establishment must submit any revisions directly to the RD, as "Approving Authority," and provide the name and address of the person to whom the revisions will be sent.
 - c. Attach and return the original to the establishment with copies of the letter to the AS and the IIC.

NOTE: Proposed TQC systems being either approved or denied should **not** be returned to the establishment management by any level except the "Approving Authority."

- F. Upon receipt of the approval for the proposed TQC system, the IIC will:
 1. Create a TQC system file.
 2. Insert the IIC copy of the approval letter and approved system into the file.
- G. Upon receipt of an approved amendment or revision, the IIC will:

1. Insert the IIC copy of the approval letter and approved pages into the file.
2. Remove superseded pages from the file.

H. **The RD, the AS and the IIC should be careful** when inserting approved revised pages in all existing copies of a proposal or of an already approved system.

1. Insert pages with changed wording. Check continuity of text from prior pages. Destroy voided pages.
2. Ensure:
 - a. Accuracy of the original/copies;
 - b. Maintenance of confidentiality of establishment data;
 - c. Uniformity of file contents; i.e., the files contain the complete “package” and are filed in chronological (date) order; and
 - d. Approval information is entered in the RD’s QCSYSTEM database and, once in the regional system, is transmitted to the Headquarters QCSYSTEM database.

X. TERMINATION OF A TQC SYSTEM

An approved TQC system may be terminated at any time by the owner or operator of the establishment upon written notice to the RD. The RD shall respond in writing to the establishment official and provide copies of the rescindment letter to the IIC and AS.

*/s/ Margaret O’K. Glavin
for*

Administrator

Attachments

- 1 – FSIS Form 7630-1
- 2 – Inspector’s Checklist for TQC Systems