United States Department of Agriculture
Farm Service Agency
Commodity Operations

Total Quality Systems Audit

Supplier Guidelines

Form #: TQ-005
Revision 002
Date: 10/01/01

(All previous forms and revisions are obsolete.
Please dispose and replace with this form.)

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Section 1

General Guidelines

1. General Information

A. Overview

(1) The Total Quality Systems Audit (TQSA) is a fee-for-service program open to the food industry. Participation in TQSA may be required as a condition of doing business with the United States Department of Agriculture/Commodity Credit Corporation (USDA/CCC). This requirement will be specified in the commodity purchase announcement/invitation or contract.

(2) TQSA does not excuse failure to comply with USDA/CCC contract requirements; Federal Food, Drug and Cosmetic Act (21 CFR); the Federal Acquisition Regulations (FAR); or other Federal, State, or local laws or regulations.

(3) Primary oversight and execution of TQSA is the responsibility of USDA, Farm Service Agency (FSA), Deputy Administrator of Commodity Operations (DACO). DACO divisions include the Kansas City Commodity Office (KCCO), and the Washington, DC offices of the Procurement and Donations and Warehouse and Inventory Divisions, FSA.

(4) TQSA is conducted in accordance with the Federal Acquisition Regulation (FAR) Part 9.1 (Contractor Qualifications) which outlines the policies, standards, and procedures for determining whether prospective contractors and subcontractors are responsible.

B. Confidentiality

All manuals and other data submitted under TQSA relevant to proposed or existing participation in the TQSA will be treated as proprietary information and will be held in the strictest confidence. Information gathered and/or reported by the auditors will also be treated as proprietary information and will be held in strictest confidence.

C. Applicability

(1) TQSA applies to all suppliers offering commodity for sale to USDA/CCC when TQSA is required by the purchase announcement/invitation or contract.

(2) Subcontractors utilized by a manufacturer or nonmanufacturer to provide contracted end products(s) are subject to TQSA.

D. Scope

(1) These guidelines are meant to assist a supplier (or auditee) in complying with TQSA. All attempts have been made to ensure the completeness and accuracy of these guidelines; however, they are subject to change.

(2) What these guidelines cover

(a) Initiation of services
(b) Types of services offered
(c) Requirements
(d) Definitions

(3) What these guidelines do NOT cover
   (a) Contract terms (refer to the purchase announcement/invitation)
   (b) Bidder status with KCCO
   (c) Bidder eligibility

E. Fees are to the account of the supplier and must be paid in full for all services rendered. A fee schedule can be found in Section 2 of these guidelines.

F. Inquiries and More Information
(1) Website: www.fsa.usda.gov/daco/TQSA/tqsa.htm
(2) General inquiries about TQSA should be directed to:
Procurement and Donations Division
USDA/FSA/PDD/Stop 0551
1400 Independence Ave, SW
Washington, DC 20250-0551
PH: (202)720-5074
FAX: (202)690-1809
(3) Inquiries about fees and services should be directed to:
Warehouse Licensing and Examination Division, Stop 9148
Kansas City Commodity Office
6501 Beacon Drive
Kansas City, Missouri 64133-6476
Ph: 816-926-6417
Fax: 816-926-1774
(4) Inquiries about procurement or contracting should be directed to:
   (a) Dairy and Domestic Operations Division, Stop 8718
   Kansas City Commodity Office
   6501 Beacon Drive
   Kansas City, Missouri 64133-6476
   Ph: (816)926-6124
   Fax: (816)823-4195
   (b) Export Operations Division, Stop 8738
   Kansas City Commodity Office
   6501 Beacon Drive
   Kansas City, Missouri 64133-6476
   Ph: (816)926-6707
   Fax: (816)823-1640

2. General Requirements

A. Compliance

(1) To fulfill the obligation of contracts that require TQSA, or where the supplier voluntarily agrees to participate in TQSA, suppliers must:

(a) comply with these guidelines, and any applicable supplemental documentation;

(b) respond in a timely manner to all Corrective Action Requests issued during a TQSA; and

(c) be current on payment for all services rendered.

(2) KCCO will be notified of any suppliers not in compliance with TQSA for review and appropriate action.

B. A TQSA is conducted on an individual plant basis. Each production facility will be rated independently of its parent company, affiliations, and/or subsidiaries.

C. Product samples may be taken during the course of any TQSA. Suppliers may be required to provide assistance in the collection of samples. Samples will be submitted to the appropriate testing facility for analysis and review to verify compliance with applicable standards. If samples are drawn, suppliers will be notified of the amount of product sampled, where it was sent, what analyses were performed, the results of those analyses, and related costs.

3. Types of Service

A. Baseline

A baseline TQSA is a full audit done for a new or potential TQSA participant.

Scope:	Entire quality system
Location:	Supplier's facilities Primary manufacturers must be in operation
Participants:	TQSA Team Supplier management, quality assurance/control personnel, plant employees directly involved in production or quality assurance

B. Full TQSA

A full TQSA is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Scope:	Entire quality system
Location:	Supplier's facilities Primary manufacturers must be in operation
Participants:	TQSA Team Supplier management, quality assurance/control personnel, plant employees directly involved in production or quality assurance

C. Surveillance

A surveillance TQSA is to confirm corrective actions have been completed and are successful, and to ensure continued conformance to the supplier's stated quality management system.

Scope:	Partial (will be identified at opening meeting)
Location:	Supplier's facilities or via other communication as needed
Participants:	TQSA Team or individual auditor Supplier management, quality assurance/control personnel, or person responsible for completing corrective action requests

D. Destination Reviews

Destination reviews are conducted at a point in the commodity distribution chain for the purpose of verifying product conformance to the applicable standards.

Scope:	Product review and analysis
Location:	Any point during distribution to end-user
Participants:	TQSA Team or individual auditor Personnel presently responsible for product protection and distribution

4. Structure and Reporting

A. Pre-Audit

(1) Supplier must make the following information available when an audit is scheduled:

(a) Contact person name and title

(b) Contact person phone number, fax number and E-mail address (if available)

(c) Person with signatory authority for TQSA records (if different from contact person)

(d) USDA/CCC products being produced and production schedule if awarded a recent contract

(e) Hours of operation

(f) Location and directions to facility

(g) Company safety policies, where applicable

(2) TQSA scheduler will:

(a) Schedule audit and coordinate with supplier

(b) Notify TQSA team members

(3) Auditor will:

(a) Contact company representative for audit confirmation during the week prior to an announced scheduled TQSA (surveillance and destination reviews may be unannounced)

(b) Provide and obtain any supplemental information needed

B. Audit

(1) Supplier must make pertinent quality system paperwork available, including, but not limited to:

(a) Quality Policy

(b) Quality Manual(s)

(c) Organizational chart

(d) Production/Process flow chart(s) for USDA product

(e) Procedures and work instructions not contained in the quality manual

(f) Quality Records

(g) Production Records

(h) Shipping Records

(i) In-Process and final testing procedures and results

(j) Sub-supplier certifications/records

(k) Proof of U.S. origin requirements

(l) All USDA/CCC contract documents (including current contracts under or pending production)

(m) All documentation and records relating to the organization's quality system not included in this list

(2) Supplier shall also make the following resources available:
   (a) Access to supplier's receiving, production (including laboratory) and distribution sites
   (b) Interview time with key personnel (will be identified from organizational chart)
   (c) Opportunity to talk with production level employees on site
   (d) Private working space for the TQSA team
   (e) Phone, copier, and fax machine access
   (f) Use of certified test equipment (e.g., weight scales)
   (g) Any required safety equipment (e.g., hardhats, bumpcaps, earplugs, or hairnets, as needed)
   (h) Personnel to accompany the auditors throughout their TQSA activities to provide guidance and assistance

(3) TQSA team will:
   (a) Present audit plan and schedule
   (b) Clarify audit procedures, guidelines, and requirements as needed
   (c) Conduct audit in professional manner
   (d) Where possible, ensure minimal disruption of supplier work environment
   (e) Communicate all findings to company representatives
   (f) Furnish a copy of completed TQSA report and corrective action requests (CARs)

(4) TQSA will consist of the following activities (not necessarily in this order):
   (a) Opening meeting
   (b) Plant walk-through (includes detailed facilities and equipment assessment, and review of production activities)
   (c) Interviews and observation of plant employees
   (d) Review of documentation and procedures
   (e) Review of records
   (f) TQSA team consultations
   (g) Preparation of TQSA report and corrective action requests
   (h) Closing meeting

(5) TQSA may also consist of product sampling as needed.

C. Post-Audit

TQSA team or auditors will:

(1) Furnish copy of TQSA Report, Summary, and CARs to KCCO, and TQSA management

(2) Ensure all corrective actions are followed-up and completed

5. Compliance

A. To be considered compliant with TQSA, suppliers must successfully conform to the following:
   (1) Current applicable commodity announcement/invitation requirements
   (2) Current Good Manufacturing Practices (GMPs) as amended (21 CFR Part 110)
   (3) Applicable Federal, State, and local food safety requirements
   (4) TQSA Report, Form TQ-003 contained in Section 4 of this guideline

B. Full compliance includes, but is not limited to: *documentation* of operating procedures, *consistent performance* of documented procedures, completion and retention of all applicable *records* (purchasing, analytical, processing, etc.), and adherence to contractual requirements.

C. All non-compliance observations and findings will be recorded by the TQSA team on Form TQ-003, TQSA Report. Evidence of major non-conformance or system failures will also be recorded on Form KC-03TQ, Corrective Action Request (CAR). The supplier will identify proposed corrective action plan on this form.

D. It is the responsibility of the suppliers to determine and make all necessary corrections in a timely manner. The suppliers will be given an opportunity after the TQSA to develop and implement a corrective action plan. The plan will state proposed course of action, or action taken, to remedy the problem and, where appropriate, expected time frame for completion. The plan or response must be submitted to the person indicated on the CAR within 10 working days. Auditors will follow-up to verify corrective action has been successfully made, and close the CAR.

E. The TQSA Report will be reviewed and scored prior to the closing meeting. Supplier will be able to review the report and dispute any findings at that time. Disputes may be settled by the presentation of additional information, or clarification of information. The report will be reviewed and necessary corrections made. All disputes will be settled at the closing meeting. The score presented at the end of the TQSA is final, and not subject to further review.

F. The TQSA Summary (Form KC-01TQ) and the CARs require the signature of the supplier's representative with the authority to sign or who has responsibility for plant operations. The contact person will be assumed to have this authority unless otherwise indicated by the supplier. Signature on the TQSA Summary constitutes agreement with the completed TQSA and all related records. Person with signatory authority must be present at the closing meeting.

G. TQSA Report, Summary, and CARs will be provided to KCCO. This information may be used in a determination of eligibility, awarding of contracts, or product acceptance or rejection.

6. Level Designations

A. Scores and Levels

(1) Scoring is done at the completion of baseline and full TQSAs. Scoring instructions can be found at the end of the TQSA Report, TQ-003 found in Section 4 of these guidelines.

(2) Scores will not be adjusted during surveillance visits, or destination reviews.

(3) Once a TQSA score has been calculated, a Frequency Level (FL) will be assigned. The FL does not impact bidder eligibility, but reflects the supplier's level of proficiency in the program.

(4) TQSA Scores and Corresponding FL

TQSA Score	Frequency Levels (FL)	Number of full audits during a 12-month cycle
90 - 100	I	1
80 - 89	II	2
Below 80	III	by suppliers request only

B. TQSA Frequency Levels

(1) Frequency Levels (FL) refer to a level of proficiency in the program, and determine the number of full TQSA during a 12 month cycle. This FL does not impact bidder eligibility, but is used to assess a supplier's ability to maintain the effectiveness of its quality management system. As a supplier's proficiency (as evidenced by score) increases, its FL (number of full audits during a 12 month cycle) decreases.

(2) All suppliers will be audited within 6 months of their baseline TQSA, regardless of TQSA score. This is to ensure the supplier has the ability to maintain the level assigned.

(3) **After baseline TQSA**, the following schedule applies:

TQSA Score	**Frequency Levels (FL)**	**Number of full audits during a 12-month cycle**
90 - 100	I	1
80 - 89	II	2
Below 80	III	by suppliers request only

(4) Suppliers are subject to 1-4 routine surveillance TQSA per year. Surveillance TQSA may be unannounced to the supplier.

(5) If a TQSA score is lower than the acceptable score for bidder eligibility, and the supplier has not previously been awarded a contract, the next full TQSA will be at the supplier's request. If the supplier has an outstanding contract to perform, appropriate FL for TQSA score will be applicable. Refer to purchase announcement/invitation or contract for more information.

(6) The FL does not preclude audits or reviews when deemed justified by KCCO and the TQSA review team. Reasons for additional audits or reviews include, but are not limited to, valid customer complaints, product non-conformances found during surveillance TQSA or destination reviews, or other contract non-conformances or non-fulfillment.

(7) Once a FL has been assigned, it can be changed according to the following parameters:

(a) FL Changes: When a supplier scores different than the last full TQSA, its FL will change to the corresponding FL immediately.

(b) No change: When a supplier scores within the same point bracket, its FL will not be changed.

7. Disclaimers

A. A TQSA is merely a "snap-shot" check of a supplier's quality management system, taken during a short, defined time period. It cannot find all defects in the supplier's system, but rather finds typical faults or trends. TQSA relies on sampling methods because the team members cannot check every detail during a TQSA. Non-discovery of a system failure does not absolve the supplier of its obligation and responsibility to comply with TQSA or any other contractual requirements and obligations.

B. TQSA does not excuse failure to comply with USDA/CCC contract requirements, Federal Food, Drug and Cosmetic Act (21 CFR), the Federal Acquisition Regulations (FAR), or other Federal, State, or local laws or regulations.

C. The ISO 9001 Quality Standards are used as a reference model of a comprehensive quality management system.

8. Civil Rights

The United States Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (such as Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202)720-2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 1400 Independence Ave., SW, Washington, DC 20250-9410 or call (202)720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.

Section 2

Fee Schedule

1. TQSA Fee Schedule

Audit Type	Administrative Fee	Per Auditor Hourly Rate	Minimum Number of Auditors	Estimated Time per Auditor
Baseline	NC	NC	2	20 hours
Full	$500.00	$94.00	2	18 hours
Surveillance	NC	as applicable*	1	4 hours
Destination	NC	as applicable*	1	<4 hours

NC = No charge

*The supplier is subject to the per auditor hourly rate of $94 if audit is conducted as a result of supplier noncompliance.

2. On full, surveillance, and destination reviews, actual costs may be billed for the following:
   A. sampling
   B. commodity analyses
   C. grade analysis

3. Invoices will be generated by Warehouse Licensing and Examination Division (WLED), KCCO. Hours billed will be taken from the TQSA Summary Report, Form KC-01TQ when received in office. Those suppliers requesting monthly billing will be billed at the end of the month.

4. Invoices are due upon receipt. If payment in full is not made within 30 days from date of invoice, late payment interest at the annual rate specified in the Prompt Payment Act will be applied to the amount on a daily basis accruing from the invoice date until payment in full is received.

5. Payment to be made by check payable to Commodity Credit Corporation and mailed to:
   DMD-DCB, Stop 8528
   Kansas City Finance Office
   P.O. Box 419205
   Kansas City, MO 64141-6205

6. Past Due Balances:
   A. WLED will notify the supplier if the balance is 30 days past due.
   B. WLED will notify the contracting officer(s) if the balance is delinquent.
      WLED will request that DMD-DCB begin collection actions.
   C. If an account is delinquent, suppliers may be considered not in compliance with TQSA.

Section 3

Definitions

Audit (TQSA):	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Auditee:	An organization to be audited. In this guideline an auditee is considered to be one production facility, regardless of ownership status.
Auditor:	A person who has the qualifications and authorization to perform quality audits. A "lead auditor" is a person designated to manage a particular quality audit.
Baseline Audit:	A full TQSA done for a new or potential TQSA participant.
Commodity Credit Corporation (CCC):	Government-owned corporation which provides financing for farm programs, and for the purchase, storage and disposal of commodities in federal stocks. FSA employees are the administrative agents for the CCC.
Corrective Action Request (CAR):	Report showing major non-conformities found during an audit. Auditee is required to respond to the report by identifying root causes, short and long-term corrective actions, and measures to prevent recurrence of the problem. Refer to Form KC-03TQ (Section 5).
Destination Review:	Reviews conducted at a point in the commodity distribution chain for the purpose of verifying product conformance to the applicable standards or specifications.
Documentation:	The systematic, orderly, and understandable descriptions and records of those policies and procedures affecting product and service quality.
Frequency Level (FL):	Indicates a supplier's level of proficiency in the TQSA, and designates the number of full audits during a 12 month cycle.
Good Manufacturing Practices (GMPs):	Practices dictated by Food and Drug Administration as those to be used in common industry practice. Refer to the Code of Federal Register (CFR) Title 21 Part 110, as amended.
Inspection:	The activities, such as measuring, examining, testing, and gauging one or more characteristics of a product or service, and comparing these with specified requirements to determine quality.

ISO:	The International Organization for Standardization.
ISO 9001:	The body of standards pertaining to quality management; published by ISO.
KCCO:	The Kansas City Commodity Office.
KCCO:	The Kansas City Finance Office.
Nonconformance:	Deviation from applicable standards, requirements, or contract terms.
Nonconformity:	The nonfulfillment of specified requirements. Major non-conformities are those observations which occur in significant frequency, are severe in nature, or result in quality system breakdown. Minor non-conformities are merely observations or concerns, and do not usually indicate a system breakdown.
Objective Evidence:	Verifiable qualitative or quantitative information, records, or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement, or test and which can be verified.
Observation:	A statement of fact made during an audit and substantiated by objective evidence.
Operation:	The production of a product that is the same as, or similar to, the product being sold to USDA/CCC.
Procedures:	The documented practice(s) defining the who, what, and when of quality or production activities. Procedures are typically used at the departmental level, and may involve more than one department.
Procurement:	The acquisition of goods or services for use by the customer.
Quality:	The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs of the customer.
Quality Audit:	(see audit).
Quality Assurance:	All the planned and systematic activities implemented within a quality system that provide confidence that requirements for quality are being fulfilled.

Quality Control:	The operational techniques and activities used to fulfill the requirements of quality.
Quality Management:	The aspect of overall management function that determines and implements the quality policy.
Quality Manual:	The document stating the quality policy and describing the quality system of the organization. It should state the company's total commitment to quality.
Quality Plan:	A document setting out the specific quality practice, resources, and activities relevant to a particular product, process, service, contract, or project.
Quality Policy:	The overall intention and direction of an organization in regards to quality as formally expressed by top management.
Quality System:	The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
Random Sampling:	Sampling of finished product according to a statistical plan in order to attain a representative sample of a larger unit.
Record:	Document which furnishes objective evidence of activities performed or past results achieved.
Rework:	Action taken on a nonconforming product so that it will fulfill the specified requirements.
Specification:	The document that prescribes the requirements that the product or service has to meet.
Summary:	Form reporting audit dates, score, and total auditor hours. Refer to Form KC-01TQ in Section 4 of these guidelines.
Supplier:	Any primary manufacturer or nonmanufacturer who is doing business with USDA/CCC.
Surveillance audits:	Audits of the supplier's facility which may be unannounced and is intended to review only a portion of the supplier's quality system, confirm successful completion of corrective action requests, or to gather information requested by KCCO. May also include random sampling of finished product for analytical testing.

Testing:	A means of determining the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating actions and conditions.
Traceability:	The ability to trace the history, application, or location of an item or activity and like items or activities by means of recorded information.
Total Quality Management:	Management approach of an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction, and benefits to all members of the organization and to society.
TQSA (Total Quality Systems Audit):	(See audit.) TQSA is the method of supplier verification utilized by FSA to approve suppliers for some USDA/CCC food assistance programs.
TQSA Report:	Report generated upon completion of an audit which shows all observations, findings, and major and minor non-conformities found by the auditor(s). Refer to Form TQ-003 (Section 4).

Section 4

TQSA Summary, Form KC-01TQ
TQSA Report, Form TQ-003

☼KC-1TQ
(04-26-99)

U.S. DEPARTMENT OF AGRICULTURE
Farm Service Agency

TOTAL QUALITY SYSTEMS AUDIT - AUDIT SUMMARY

SECTION A - BUSINESS INFORMATION

1. TYPE OF AUDIT

2. CONTROL NO.	**3.** VENDOR/PLANT CODE	**4.** SMALL BUSINESS? ☐ YES ☐ NO

5. COMPANY NAME

6. PRODUCTS

7a. LOCATION OF MAIN OFFICE *(Complete mailing address, including ZIP code)*	**8a.** LOCATION OF PLANT *(Complete mailing address, including ZIP code)*
7b. PHONE NO. *(Include area code)* **7c.** FAX NO.	**8b.** PHONE NO. *(Include area code)* **8c.** FAX NO.
9a. CONTACT PERSON	**10.** HOURS OF OPERATION
9b. TITLE	

SECTION B - AUDIT INFORMATION

11. DATE(s) CONDUCTED	**12.** CARs ISSUED	**13.** DATE CARs DUE	**14.** TOTAL SCORE	**15.** FREQUENCY LEVEL

16. COMMENTS

17. AUDITORS	**18.** HOURS
19. **TOTAL HOURS BILLED**	

SECTION C - CERTIFICATION

I hereby certify that I agree with the results of the audit and the total hours billed.

20. COMPANY REPRESENTATIVE SIGNATURE	**21.** DATE

PRIVACY ACT AND PUBLIC BURDEN STATEMENTS

The following statements are made in accordance with the Privacy Act of 1974 (5 U.S.C. 552a). This data is being collected in performance of a Total System Quality Audit. Furnishing the data is voluntary; however, without it assistance cannot be provided. This information may be provided to other agencies, IRS, Department of Justice, or other State and Federal law enforcement agencies, and in response to a court magistrate or administrative tribunal.

Federal agencies may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Agriculture, Clearance Officer, OIRM (OMB No. 0560-XXXX), Stop 7630, Washington, D.C. 20250-7630.

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United States Department of Agriculture
Farm Service Agency
Commodity Operations

Total Quality Systems Audit

Report

Form #: TQ-003
Revision 004
Date: 10/01/01

(All previous forms and revisions are obsolete.
Please dispose and replace with this form.)

Company:
Location:
Control Number:
Audit Dates:
Total Score:

Element 4.1
Management Responsibility

QUESTION	ASSESSOR NOTES	RESULT
1. Is the quality policy communicated, understood, and maintained throughout the organization? (ISO 4.1.1)		
2. Are there clearly defined and documented responsibilities and authorities for all personnel affecting quality? (ISO 4.1.2)		
3. Is authority delegated to qualified personnel to: **-Prevent nonconformity reoccurrence?** **-Identify & record quality problems?** **-Initiate and verify corrective action?** **-Control further processing?** **(ISO 4.1.2)**		
4. Is there a periodic top management review of quality system effectiveness supported by appropriate records? (ISO 4.1.3)		
5. Are qualified personnel available for management, performance of work, and verification activities? (ISO 4.1.2.2)		
6. Is there a clearly identified management representative with authority & responsibility to ensure ISO 9001 compliance? (ISO 4.1.2.3)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.2
Quality System

QUESTION	ASSESSOR NOTES	RESULT
1. Is there a quality manual which meets ISO 9001 requirements for documentation of a comprehensive quality system, including the following elements: (ISO 4.2.1) **-Management responsibility** **-Quality policy** **-Organization** **-Quality planning** **-Contract review** **-Document & data control** **-Document changes** **-Purchasing** **-Subcontractor evaluation** **-Control of customer supplied product** **-Product identification and traceability** **-Process control** **-Process monitoring** **-Process capability/ performance** **-Process changes** **-Planned preventive maintenance** **-Inspection and testing** **-Appearance item testing (if applicable)** **-Lab accreditation (if required)** **-Inspection, measuring and test equipment** **-Measurement system analysis** **-Inspection and test status** **-Control of nonconforming product** **-Control of reworked product** **-Corrective and preventive actions** **-Handling, Storage, Packaging and Delivery** **-Control of quality records** **-Internal quality audits** **-Training** **-Statistical techniques** **-Continuous improvement** **-Customer specific requirements** **Adequacy of quality manual?**		

Element 4.2
Quality System (continued)

2. Is the quality planning process consistent with the elements of the quality system that addresses: **-Product program plan preparation?** **-Identification and acquisition of appropriate resources?** **-Updating & maintenance of all quality control and inspection methodology?** **-Identification of suitable verification at appropriate stages?** **-Review of standards and specifications?** **(ISO 4.2.3)**		
3. Are there adequate supporting procedures for each element of the quality manual? (ISO 4.2.2)		
4. Have special characteristics been identified and included in the quality plan? (ISO 4.2.3.a)		
SUMMARY QUESTION: **5. Is there a comprehensive (appropriate to the product or service produced) quality system established and implemented? (ISO 4.2.1)**		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.3
Contract Review

QUESTIONS	ASSESSOR NOTES	RESULTS
1. Are the contract review activities, adequately documented and maintained to ensure that order requirements are understood and are within the supplier's capability prior to order acceptance? (ISO 4.3.2)		
2. Are applicable domestic origin compliances verified? (ISO 4.3.2)		
3. Is there evidence of deployment of ISO-9001 and customer contract requirements into the quality system? (ISO 4.3.2)		
4. Are there provisions to document and deploy contract changes throughout the organization? (ISO 4.3.3)		
5. Are records of contract reviews maintained? (ISO 4.3.4)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.5
Document and Data Control

QUESTION	ASSESSOR NOTES	RESULT
1. Are new and revised documents reviewed and approved by authorized personnel prior to issue? (ISO 4.5.2)		
2. Is there a master list (or equivalent) identifying document revision status? (ISO 4.5.2)		
3. Is there timely review, distribution and implementation of customer standards/specs and changes? (ISO 4.5.2)		
4. Are all references documents available onsite? (ISO 4.5.1)		
5. Where documents or data are retained on software, are appropriate controls maintained for changes? (ISO 4.5.1 & 3)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.6
Purchasing

QUESTION	ASSESSOR NOTES	RESULTS
1. Are subcontractors evaluated and selected based on their ability to meet quality system and quality assurance requirements? (ISO 4.6.2.a)		
2. Does the supplier have a procedure to define the appropriate level of control over subcontractors? (ISO 4.6.2.b)		
3. Are quality records of subcontractors kept up to date and used to evaluate performance? (ISO 4.6.2.c)		
4. Do the purchasing documents contain data that clearly describe the product or service being ordered? (ISO 4.6.3)		
5. Where applicable, is there provision for the customer (or representative) to verify subcontractor quality onsite? (ISO 4.6.4.2)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.7
Control of Customer Supplied Product

QUESTION	ASSESSOR NOTES	RESULTS
1. Is material examined upon receipt to check quantity, identity, and transit damage? (ISO 4.7)		
2. Is material periodically inspected to detect for signs of deterioration, proper conditions, & storage time limitations? (ISO 4.7)		
3. For any such product that is lost, damaged or otherwise unsuitable for use, are records maintained and reports provided to the customer? (ISO 4.7)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.8
Product Identification and Traceability

QUESTION	ASSESSOR NOTES	RESULTS
1. Is product identified, where appropriate, at all production stages? (ISO 4.8)		
2. Is traceability maintained and recorded when so required by the customer? (ISO 4.8)		
3. Is there a written recall procedure and has it been evaluated? (ISO 4.8, GMPs)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.9
Process Control

QUESTION	ASSESSOR NOTES	RESULTS
1. Have documented job instructions been developed that: (ISO 4.9) **-Are accessible at the work station?** **-Communicate requirements to all employees involved in this process?** **-Provide verification of job set-ups?** **-Specify monitoring of special characteristics?** **-List requirements for inspection, testing, gauging and recording results?** **-Provide sample size and frequency?** **-Establish approval and rejection criteria?** **-Specify monitoring of production and in-process gauging equipment?** **-Document the identification and handling of non-conforming material?** **-Specify appropriate notifications and corrective actions (including plans for unstable/non-capable processes)?** **-Specify application of statistical methods required by control plans?** **-Have appropriate approvals and date?** **-Have operation name and number?** **-Are keyed to process flow chart?** **-Have a revision date for instructions?**		

Element 4.9
Process Control (continued)

QUESTION	ASSESSOR NOTES	RESULTS
2. Do employees perform operations/inspections according to documented instructions? (ISO 4.9)		
3. Are process control requirements being met? (ISO 4.9)		
4. Is there an effective planned preventive maintenance system which includes: (ISO 4.9.g) **-A maintenance schedule with specific responsibilities assigned?** **-Maintenance evaluated for process capability improvement?** **-Evaluation for reduction of machine/process downtime?** **-Maintenance conducted at the prescribed frequencies for all equipment?** **-Availability of replacement parts for key equipment?** **-Predictive maintenance methods?**		
5. Does the supplier have a process to identify all applicable government safety and environmental regulations, including those concerning handling, recycling, eliminating, or disposing of hazardous materials? (ISO 4.9.b)		
6. Does the supplier have appropriate governmental certificates indicating compliance to the identified applicable regulations? (ISO 4.9.b)		
7. Is the work environment clean and well-organized? (ISO 4.9.b)		
8. Are internal Good Manufacturing Practices (GMP) policies established, communicated, and followed in accordance with applicable regulations? (ISO 4.9.c)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.10
Inspection and Testing

QUESTION	ASSESSOR NOTES	RESULTS
1. Incoming materials (ISO 4.10.2) **-Is purchased material controlled and verified per the selected system prior to release to production?** **-Are all contractually required testing/ analyses performed?** **-Is positive identification provided for material used in production but not verified?** **-Where specified as the control method, do suppliers submit statistical data as required?**		
2. In-process inspection and testing: (ISO 4.10.3) **Does the supplier:** **-Inspect and test product as required by the documented procedures?** **-Are all contractually required test/ analyses performed?** **-Hold product until the required inspections and tests have been completed?** **-Utilize defect prevention methods, such as statistical process control, error proofing, visual controls, rather than defect detection? (Methods should address all potential chemical, physical and microbiological defects.)**		

Element 4.10
Inspection and Testing (continued)

3. Final inspection and testing (ISO 4.10.4) **Does the supplier:** **-Conduct final inspection and testing in accordance with documented procedures?** **-Assure that no product is shipped until all activities specified in the documented procedures have been satisfactorily completed?** **-Are all contractually required test/analyses performed?**		
4. Does the supplier use accredited laboratory facilities when required by the customer? (ISO 4.10.1)		
5. Does the supplier maintain adequate records of all inspections and tests? (ISO 4.10.5)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.11
Inspection, Measuring, and Test Equipment

QUESTION	ASSESSOR NOTES	RESULTS
1. Has inspection, measuring, and test equipment (including software when appropriate) been provided that is capable of the required accuracy and precision? (ISO 4.11.2.a)		
2. Is the required accuracy/precision determined? (ISO 4.11.2.a)		
3. Is each item of inspection, measurement, and test equipment identified with a unique designation (including employee-owned equipment?) (ISO 4.11.3)		
4. Is each such piece of equipment calibrated at the prescribed intervals and in the correct environment (including employee-owned equipment?) (ISO 4.11.2.b)		
5. Are gauge condition and actual readings recorded prior to recalibration? (ISO 4.11.2.e)		
6. Are appropriate actions, including customer notification, taken on product and process when inspection, measurement, or test equipment is found to be out of calibration? (ISO 4.11.2.f)		
7. Are inspection, measurement, and test equipment properly handled, preserved, and stored to maintain calibration and fitness for use? (ISO 4.11.2.h)		
8. Are inspection, measurement, and test facilities (including software when applicable) safegaurded to insure that calibration is not disturbed? (ISO 4.11.2.i)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.12
Inspection and Test Status

QUESTION	ASSESSOR NOTES	RESULTS
1. Is inspection and/or test status suitably identified throughout the production process? (ISO 4.12)		
2. Is identification suitable to ensure non-conforming product is not released? (ISO 4.12)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.13
Control of nonconforming products

QUESTION	ASSESSOR NOTES	RESULTS
1. Is there identification, documentation, segregation (where possible) to a designated area, and disposition of nonconforming and suspect product? (ISO 4.13.1)		
2. Are there clear definitions for responsibilities for review and disposition of nonconforming and suspect product? (ISO 4.13.2)		
3. Are nonconforming and suspect products reviewed according to the defined procedures? (ISO 4.13.2)		
4. Are nonconforming and suspect products: **-reviewed to specified requirements?** **-accepted with customer approved concessions?** **-reworked to approved specifications?** **-regraded for alternative applications?** **-rejected or scrapped?** **(ISO 4.13.2)**		
5. Are there provisions in the process that only material that has passed the inspections and /or tests can be provided to the customer? (ISO 4.13.2)		
6. Are reworked products reinspected and/or tested according to defined procedures? (ISO 4.13.2)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.14
Corrective and Preventive Action

QUESTION	ASSESSOR NOTES	RESULTS
1. Are appropriate corrective actions developed to eliminate the causes of the nonconformances? (ISO 4.14.2.c)		
2. Are the customer complaints and reports of nonconformances handled effectively? (ISO 4.14.2.a)		
3. Are the causes of nonconformances investigated and the results documented? (ISO 4.14.2.b)		
4. Is the effectiveness of the corrective action verified? (ISO 4.14.2.d)		
5. Are nonconformance reports (eg. Product quality, deviation, audit result, quality records, etc) used to develop preventive actions? (ISO 4.14.3.a)		
6. Is the relevant information on actions taken (including changes to procedures) submitted to management for review? (ISO 4.14.3.d)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.15
Handling, Storage, Packaging, Preservation and Delivery

QUESTION	ASSESSOR NOTES	RESULTS
1. Do the supplier's material handling methods prevent product damage and deterioration? (ISO 4.15.2)		
2. Are storage areas appropriate for preventing damage or deterioration of the product? (ISO 4.15.3)		
3. When required by the nature of the product, is the condition of product in stock checked at intervals to detect deterioration? (ISO 4.15.3)		
4. Does the supplier control the packing, packaging, and marking processes to the extent necessary to ensure product conformance to specification? (ISO 4.15.4)		
5. Are applicable customer packaging standards available? (ISO 4.15.4)		
6. Are applicable customer packaging standards complied with? (ISO 4.15.4)		
7. Are methods appropriate for the product used for preservation and segregation? (ISO 4.15.5)		
8. When contractually required, does the supplier arrange for the protection of product quality during delivery to the destination? (ISO 4.15.6) **-Does this include trailer/railcar cleaning, inspection and preparation?**		
9. Is there an inventory management system to optimize inventory turns and stock rotation? (ISO 4.15.3)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.16
Control of Quality Records

QUESTION	ASSESSOR NOTES	RESULTS
1. Are there records that show effective operation of the quality system, including pertinent subcontractor quality records? (ISO 4.16)		
2. Are all quality records legible and readily retrievable? (ISO 4.16)		
3. Are these records (hardcopy or electronic) stored in a suitable environment to prevent deterioration, damage, or loss? (ISO 4.16)		
4. Are there procedures established for the retention and disposal of quality records (including retention and disposal schedules)? (ISO 4.16)		
5. Are quality records retained per established procedures and for the specified periods? (ISO 4.16) **Typical records include:** **Certificate of Conformance** **Certificate of Analysis** **Control Charts** **Internal Quality Audits** **Inspections records** **Contract specified records**		
6. Are these records available to the customer for evaluation upon request? (ISO 4.16)		
7. Has the supplier fulfilled responsibilities for retention control and timely disposal of records? (ISO 4.16)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.17
Internal Quality Audits

QUESTION	ASSESSOR NOTES	RESULTS
1. Does the supplier carry out internal quality system audits as planned? (ISO 4.17)		
2. Are personnel conducting the audit independent of the function being audited? (ISO 4.17)		
3. Are the audits scheduled on the basis of the status and importance of the activity? (ISO 4.17)		
4. Are the results documented and brought to the attention of the responsible personnel? (ISO 4.17)		
5. Are corrective actions timely, recorded, and evaluated for effectiveness? (ISO 4.17)		
6. Does the audit include work environment, and general housekeeping? (ISO 4.17)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.18
Training

QUESTION	ASSESSOR NOTES	RESULTS
1. Have the training needs for all personnel performing activities affecting quality been met? (ISO 4.18)		
2. Do qualifications for jobs affecting quality include identification of appropriate education, training needs, and experience? (ISO 4.18)		
3. Are records of training maintained? (ISO 4.18)		
4. Is training effectiveness periodically evaluated? (ISO 4.18)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.20
Statistical Techniques

QUESTION	ASSESSOR NOTES	RESULTS
1. Has the supplier identified the need for statistical techniques for establishing, controlling, and verifying the capability of process parameters and product characteristics? (ISO 4.20.1)		
2. Are there procedures established and maintained to implement and control the application of statistical techniques? (ISO 4.20.2)		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

Element 4.21
Customer Satisfaction

Questions	Assessors Notes	Results
1. Does the supplier have a procedure for conducting customer satisfaction surveys? (ISO 8.2.1)		
2. Is there a written procedure for compiling, analyzing, and acting upon information contained in customer feedback data, reflecting the level of customer satisfaction? (ISO 7.2.1)		
3. Does the supplier incorporate customer satisfaction measures into continual improvement efforts? (ISO 8.4)		
4. Does the supplier have a procedure to gather information from end users where their product is used as a component of a product or when the end user is not the purchasing agent? (ISO 8.2.1)		
5. Is there a procedure for retrieving, analyzing, and acting on customer feedback and customer complaint data? (ISO 7.2.)		
6. Are there effective arrangements for communicating with customers in relation to: **a) product information;** **b) inquires, contracts, or order handling; including amendments; and** **c) customer feedback, including customer complaints? (ISO 7.2.3)**		
ANY ADDITIONAL SUPPLIER QUALITY SYSTEM REQUIREMENTS TO BE VERIFIED ONSITE		

NOTE: Customer Satisfaction - To make certain that all the efforts of the vendor actually results in satisfied customers. This will require the vendor to search out and put to use information that reflects the degree of satisfaction being experienced by their customer. This element emphasizes the need to measure customer satisfaction as an indicator of overall system performance.

Effective Date of Element 4.21, Customer Satisfaction, is October 1, 2002.

Audit Report Summary

ELEMENT	CONFORMS	NONCONFORMITIES		POINTS
		Minor	Major*	
4.1 Management Responsibility				
4.2 Quality System				
4.3 Contract Review				
4.5 Document and Data Control				
4.6 Purchasing				
4.7 Control of Customer Supplied Product				
4.8 Product Identification and Traceability				
4.9 Process Control				
4.10 Inspection and Testing				
4.11 Inspection, Measuring and Test Equipment				
4.12 Inspection and Test Status				
4.13 Control of Nonconforming Product				
4.14 Corrective and Preventive Action				
4.15 Handling, Storage, Packaging, Preservation and Delivery				
4.16 Control of Quality Records				
4.17 Internal Quality Audits				
4.18 Training				
4.20 Statistical Techniques				
4.21 Customer Satisfaction				
Other Customer Requirements				
TOTALS:				

(* All major nonconformities require a Corrective Action Report (CAR) to be completed and filed with audit report.)

Target date for correction of all nonconformities: _____

TOTAL SCORE: _____

(NOTE: Effective Date of Element 4.21, Customer Satisfaction, is October 2, 2002)

Scoring Guidelines

Question Scoring

Within each element, the result for each question is in marked in the right hand column as follows:

0 = No, this requirement is not met at all, or there are major inconsistencies in implementation.

M = Yes, this requirement is met, but there are minor inconsistencies in implementation.

C = Yes, this requirement is met, and effectively implemented.

Element Scoring

0* = One (or more) questions with a result of "0", or four or more questions with a result of "M"

1 = One to three questions with a result of "M"

2 = No "0" or "M" results

***Special Note: A result of "0" in any element of Form TQ-003 would preclude participation in commodity purchase programs until such time corrective action is determined, implemented, and verified as effective. (Element scoring: 0 = one (or more) questions with a result of "0," or four or more questions with a result of "M".)**

Final Scoring

The final score is calculated by dividing the sum of the element scores by the number of applicable elements answered and multiplying the result by 50. Total score will be between 0 and 100 points.

Reporting of Assessment Findings

Notes regarding nonconformities on the auditor checklist should contain detailed information about the findings and evidence. The report summary page should include a tally of the question results and the point values for each element. The target date for correction of all nonconformities should also be noted on the report summary page.

All major nonconformities should have a Corrective Action Report (CAR) completed, containing detailed information, company proposed corrective action, and targeted completion date. CAR(s) should be signed by the auditor(s) and company representative(s) and accompany the assessment report.

Section 5

Corrective Action Request, Form KC-03TQ

See reverse side for Privacy Act, Public Burden and Nondiscrimination Statements. **Form Approved - OMB No. 0560-XXXX**

☼KC-3TQ
(4-9-99)

U.S. DEPARTMENT OF AGRICULTURE
Farm Service Agency

TOTAL QUALITY SYSTEMS AUDIT - CORRECTIVE ACTION REQUEST (CAR)

1. COMPANY NAME		2. CAR NO. of
3. PLANT LOCATION		4. AUDIT DATE
5. CONTROL NO.	6. VENDOR/PLANT CODE	7. PRODUCT

OBSERVATIONS MADE BY AUDITOR

8. AREA OF OBSERVATION

9. OBSERVATION MADE

10. NOTED BY

Signature below constitutes receipt and acknowledgment of the CAR only.

11. AUDITOR	12. DATE	13. COMPANY REPRESENTATIVE	14. DATE

COMPANY'S CORRECTIVE ACTION

15. Actions to be taken must be reported below. Return this form within 10 working days to the office shown:

USDA-FSA
Kansas City Commodity Office
Attn: WLED-EB-TQSA
P.O. Box 419205
Kansas City, MO 64141-6205

Phone: 816-926-6585
FAX: 816-926-1774

16. The following actions have been proposed or completed to correct this occurrence and to prevent recurrence.

17. ASSIGNED TO	18. DEPARTMENT
19. TARGET COMPLETION DATE	20. ACTUAL COMPLETION DATE

PRIVACY ACT AND PUBLIC BURDEN STATEMENTS

The following statements are made in accordance with the Privacy Act of 1974 (5 U.S.C. 552a). This data is being collected in performance of a Total System Quality Audit. Furnishing the data is voluntary; however, without it assistance cannot be provided. This information may be provided to other agencies, IRS, Department of Justice, or other State and Federal law enforcement agencies, and in response to a court magistrate or administrative tribunal.

Federal agencies may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Agriculture, Clearance Officer, OIRM (OMB No. 0560-XXXX), Stop 7630, Washington, D.C. 20250-7630.

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