United States Department of Agriculture
Farm Service Agency
Commodity Operations
Quality Assurance

Product :	*			Contractor :	*
QA Rep :	*	Entity ID :	*	Plant Address :	*
Attachments :	No	Report No. :	*	Plant City :	*
Company :	*			Plant State :	*
				Plant Zip :	*
				Plant ZipPlus :	*
				Phone :	*
				E Mail :	*
				Contact :	*

Date : 4/17/2008

There are attachments.

No

1a. Has the organization's quality management system been established, documented, implemented, maintained and continually improved its effectiveness?

1b. Has the organization:
* identified the processes needed for the quality management system and their application throughout?
* determined the sequence and interaction of these processes?
*determined criteria and methods needed to ensure the effective operation and control of these processes?
* ensured the availability of resources and information necessary to support the operation and monitoring of these processes?
* measured, monitored, and analyzed these processes?
* implemented actions necessary to achieve planned results and continual improvement of these processes?

1c. Has the organization identified outsourced processes within its quality management system?
* ensured control over outsourced processes that affect product conformity with requirements?
* managed internal and external (outsourced) processes in accordance with a Quality Management System?

1d Does the organization's quality management system documentation include:
* a documented statement of a quality policy and quality objectives?
* a quality manual?
* documented procedures in the following areas?
Control of documents Control of records Internal audit Control of nonconforming product
Corrective action Preventive action Food Safety Program Good Manufacturing Practices
Good Lab Practices
* documents required to ensure the effective planning, operation and control of its processes (internal documents)?

1e. Has the organization established and maintained a quality manual that includes:
* the scope of the quality management system?
* the documented procedures established for the quality management system or reference to them?
* a description of the interaction between the processes of the quality management system?

1f. Has the organization established a documented procedure to define the controls needed to:
*approve documents for adequacy prior to issue?
* review and update as necessary and reapprove documents?
*ensure that changes and the current revision status of documents are identified?
*ensure that relevant versions of applicable documents are available at points of use?
*ensure that documents remain legible and readily identifiable?
*ensure that documents of external origin are identified and their distribution controlled?
*prevent the unintended use of obsolete documents?
*apply suitable identification to obsolete documents if they are retained for any purpose?

1g. Does the organization control documents required by the quality management system?

1h. Has the organization established and maintained records to provide evidence of:
* production or service conformity to requirements?
* effective operation of the quality management system?

1i. Are records legible, readily identifiable and readily retrievable?

1j. Has the organization established a documented procedure to define controls needed for records:
* identification?
* storage?
* protection?
* retrieval?

* retention time?
* disposition or disposal?

2a. Has top management provided evidence of organization's commitment to the development and implementation of the quality management system and continually improving its effectiveness by:
* communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements?
* establishing the quality policy?
* ensuring that quality objectives are established?
* conducting management reviews?
* ensuring the availability of resources?

2b. Has top management ensured that the responsibilities and authorities are defined and communicated within the organization?

2c. Has top management appointed a member of management as the Management Representative ,irrespective of other responsibilities, and does the representative have responsibility and authority that includes:
* ensuring that processes needed for the quality management system are established, implemented and maintained?
* reporting to top management on the performance of the quality management system and any need for improvement?
* ensuring the promotion of awareness of customer requirement throughout the organization?

2d. Has top management ensured that:
* appropriate communication processes are established within the organization?
* communication takes place regarding the quality management system?

2e. Does the organization's management review the quality management system including the quality policy at planned intervals, to ensure its continuing :
* suitability?
* adequacy?
* effectiveness?

2f. Does the organization's management review include assessing the need for changes to the quality management system, including the quality policy and objectives, and opportunities for improvement?

2g. Does the organization maintain records from the organization's management reviews?

2h. Do inputs to the management review include information on:
* result of audits?
* customer feedback?
* process performance and product conformity?
* status of preventive and corrective actions?
* follow-up actions from previous management reviews?
* changes that could affect the quality management system?
* recommendations for improvement?
* control of suppliers?
* food safety programs?

3a. Are personnel who perform work affecting product quality competent on the basis of appropriate:
* education?
* training?
* skills?
* experience?

3b. Has the organization:
* determined the necessary competence for personnel performing work affecting product quality?
* provided training or taken other actions to satisfy needs?
* evaluated the effectiveness of the actions taken?
* ensured that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?
* maintained appropriate records of education, training, skills and experience?

3c. Has the organization determined, provided, and maintained the infrastructure needed to achieve conformity to product requirements?

3d. Does infrastructure include, as applicable:
* buildings, work space and associated utilities?
* process equipment (both hardware and software)?
* supporting services (such as transport or communication)?

3e. Does the organization identify and manage the work environment needed to achieve conformity to product requirement?

3f. Has the organization conducted security vulnerability assessment and established procedures that address:
* access for authorized personnel only?
* general security of the physical structures and grounds?
* emergency action planning?
* contact information for local authorities?
* contractors and visitors prior to gaining access to facility?

3g. Does the organization identify hazards and/or critical situations and is there a plan to control these situations? (HACCP, Food Safety Program)

3h. Are there sanitation policies and procedures in place to control the work environment and operating conditions that contribute to production of safe and wholesome products and are they followed?

3i. Are there Good Manufacturing Practices in place to control the work environment and operating conditions and are they followed?

3j. Is there a pest control program in place to control the work environment and operating conditions and are they followed?

4a. Does the organization plan and develop the processes needed for product realization and are the outputs of this planning in a form suitable for the organization's method of operation?

4b. In planning product realization, has the organization determined the following, as appropriate:
* quality objectives and requirements for the product?
* the need to establish processes, documents, and provide resources specific to the product?
* required verification, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance?
* records needed to provide evidence that the realization processes and resulting product meet requirements?

5a. Has the organization determined and reviewed requirements specified by the customer, including the requirements for delivery and post-delivery activities?

5b. Has the organization determined and reviewed requirements of food security, rail and truck inspections, seals on containers,cars and trailers?

5c. Has the organization determined and reviewed statutory, regulatory and contractual requirements related to the product?

5d. Has the organization determined and reviewed applicable domestic origin compliances?

5e. Has the organization determined and reviewed any additional requirements determined by the organization?

5f. Is a review conducted prior to the organization's commitment to supply a product, are records maintained and does the review ensure that:
* product requirements are defined?
* contract or order requirements differing from those previously expressed are resolved?
* the organization has the ability to meet the defined requirements?

5g. Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements?

5h. Does the organization determine and implement effective arrangements for communicating with customers in relation to:
* product information?
* enquiries, contracts, or order handling, including amendments?
* customer feedback, including customer complaints?

6a. Does the organization ensure that purchased product conforms to specified purchase requirements?

6b. Does the organization evaluate and select suppliers based on their ability to supply product in accordance with organization's requirements?

6c. Are the criteria for selection, evaluation, and reevaluation established and are records of evaluations and any necessary actions arising from the evaluation maintained?

6d. Has the organization identified and implemented the inspection or other activities necessary for ensuring that purchased (received) products meet specified purchase requirements and food security issues?

7a. Does the organization plan and carry out production and service provision under controlled conditions?

7b. Do these controlled conditions include, as applicable:
* availability of information that describes the characteristics of the product?
* availability of work instruction, as necessary?
* use of suitable equipment?
* availability and use of monitoring and measurement?
* implementation of monitoring and measurement?
* implementation of release, delivery and post-delivery activities?

7c. Where appropriate, does the organization identify the product by suitable means throughout production realization?

7d. Does the organization identify the product status with respect to monitoring and measurements requirements?

7e. Where traceability is a requirement, does the organization control and record the unique identification of the product?

7f. Does the organization have provisions to conduct routine internal mock recalls for:
* lot code backward?
* lot code forward?

7g. Are the results of these internal mock recalls documented and self-assessments performed at least annually?

7h. Does the organization maintain a recall and crisis response management system?

7i. Are documents of recall and crisis management activities on file?

7j. Does the organization exercise care with customer property while it is under organization's control or while using it and are records maintained?

7k. Does the organization preserve the conformity of product during internal processing and delivery to the intended destination and does this preservation include:
* identification?
* handling?
* packaging?
* storage?
* protection?

7l. Is there a security plan in place to insure the product and the constituent parts of a product are protected during handling and storage?

8a. Does the organization determine:
* the monitoring and measurement to be undertaken, establish processes to ensure they are carried out and is it consistent with the requirements?
* the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements?

8b. Where necessary to ensure valid results, is measuring equipment:
* calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards? Where no such standard exists, is the basis used for calibration or verification recorded?
* adjusted or readjusted as necessary?
* identified to enable the calibration status to be determined?
* safeguarded from adjustments that would invalidate the measurement result?
* protected from damage and deterioration during handling, maintenance and storage?

8c. Does the organization maintain records of the results of calibration and verification?

8d. Is the confirmation of computer software undertaken prior to initial use and reconfirmed as necessary?

9a. Does the organization plan and implement the monitoring, measurement, analysis, and improvement processes needed to:
* demonstrate conformity of the product?

* ensure conformity of the quality management system?
* continually improve the effectiveness of the quality management system?

9b. Does this include the determination of applicable methods, including statistical techniques and the extent of their use?

10a. As a measurement of the performance of the quality management systems, does the organization obtain, monitor, and use information relating to customer satisfaction?

10b. Does the organization conduct internal audits at planned intervals to determine whether the quality management system:
* meets the established quality management system requirements?
* is effectively implemented and maintained?

10c. Has the organization planned and defined the audit:
* criteria?
* scope?
* frequency?
* methods?
* the status and importance of the processes and areas to be audited?
* the results of previous audits?

10d. Does the organization ensure objectivity and impartiality of the audit process?

10e. Has the organization documented a procedure defining the responsibilities and requirements for:
* planning and conducting audits?
* reporting results?
* maintaining records?

10f. Does management, responsible for the area being audited, ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes including follow-up and verification and documentation of the actions taken?

10g. Does the organization
* apply suitable methods for monitoring and measurement of the quality management system processes?
* demonstrate the ability of the processes to achieve planned results?
* take corrective actions when the planned results are not achieved to ensure product conformity?

10h. Does the organization monitor and measure the characteristics of the product to verify that product requirements are met?

10i. Is monitoring and measuring of the product characteristics carried out at appropriate stages of the product realization process in accordance with planned arrangements?

10j. Does organization records indicate the person(s) authorizing release of product?

10k. Does the organization ensure that product release and service delivery does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by customer?

11a. Does the organization ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use and delivery?

11b. Does the organization have a documented procedure which defines controls and related responsibilities and authorities for dealing with nonconforming products?

11c. Does the organization deal with nonconforming product in one or more of the following ways:
* by taking action to eliminate the detected nonconformity?
* by authorizing its use , release, or acceptance under concession by a relevant authority and, where applicable by customer?
* by taking action to preclude its original intended use or application?

11d. Are records maintained of the nature of nonconformities and any subsequent actions taken, including concessions obtained?

11e. When nonconforming product is corrected, does the organization subject it to re-verification to demonstrate conformity to the requirements?

11f. Does the organization take appropriate action when nonconforming product is detected after delivery or use of the product has started?

12a. Does the organization determine, collect, and analyze data to demonstrate the suitability and effectiveness of the quality management system and provide information relating to:
* customer satisfaction ?
* conformance to product requirements ?
* characteristics and trends of processes and products, including opportunities for preventive action?
* suppliers?

12b. Does the organization continually improve the effectiveness of the quality management system through the use of:
* a quality policy?
* quality objectives?
* audit results?
* analysis of data?
* corrective and preventive actions?
* management review?

12c. Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?

12d. Is corrective action(s) appropriate for the nonconformities encountered?

12e. Does the organization have a documented procedure which defines requirements for:
* reviewing nonconformities (including customer complaints)?
* determining the causes of nonconformities?
* evaluating the need for action to ensure that nonconformities do not reoccur?
* determining and implementing action needed?
* records of results of corrective action taken ?
* reviewing corrective action taken?

12f. Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence?

12g. Are preventive actions taken appropriate to the effects of the potential problems?

12h. Does the organization have a documented procedure which defines requirements for:
* determining potential nonconformities and their causes?
* evaluating the need for action to prevent occurrence of nonconformities?
* determining and implementing action needed?
* records of results of preventive action taken?
* reviewing preventive action taken?

Summary