

*EPICOR, INCORPORATED
QUALITY ASSURANCE
MANUAL*

Revision: 6

Date 05/18/09

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Epicor, Incorporated

Corporate Quality Manual

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Epicor, Incorporated *Corporate Quality Manual*

Introduction:

This quality manual describes the policies and company-wide control system of Epicor, Incorporated (Epicor) quality management system. This quality management system addresses the requirements of the ISO (International Organization for Standardization) Quality Standards as defined in ISO-9001:2008 and ANSI/ASQ Q9002, the requirements of 10CFR50 Appendix B and the provisions of 10CFR Part 21. The Quality Assurance Procedures and Work Instructions of Epicor are proprietary. All unauthorized use is prohibited.

Approval:

This quality assurance manual has been approved in its entirety prior to issue by the executive management, signatures of which are listed below the quality policy. All subsequent revisions shall be approved by the same functions using their signature. Epicor reserves the right to make improvements of the quality assurance procedures and work instructions without necessarily revising the quality assurance manual. This manual will receive a general review on a semi-annual basis, and will be revised as needed.

The participation of all Epicor's employees in the development and approval of quality assurance procedures and work instructions is encouraged.

Quality Manual Control and Revision:

The quality transmittal log will issue the quality manual. The log will identify all copies issued, including controlled and uncontrolled copies. The log will be maintained by administration. Customers requesting a copy will have 15 working days to send an acknowledgment that they would like a controlled copy, otherwise the copy will be uncontrolled and revisions will not be sent.

The quality manual summary of revisions will be shown on page 4.

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Quality Manual Revision History

Date	Page #	Revision	Approvals
8/02/99	All	0	
11/04/99	1,3,4,17,33	1	
12/30/99	3,5,6,7,8,9,10,14,3 6	2	
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6/5/03	4,10,11,12-18, 24, 33, 34	4	
1/15/09	Manual incorporated into Software Program	5	
5/18/09	Manual revised to comply with ISO 9001:2008	6	F.M. Keough

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Quality Policy:

It is the policy of Epicor to assure customer satisfaction by providing the optimum product quality within the requested delivery schedule. Laboratory analyses are conducted and evaluated for the purpose of adhering to all regulatory and legal requirements and customer specifications. All records are properly filed and maintained. A safe working environment is maintained for all employees. The quality system is subject to periodic management review to ensure its effectiveness and continual improvement.

Rose M. Bussiculo

Epicor, Incorporated President

Fred M. Keough

**Epicor, Incorporated Quality Assurance
Coordinator**

Epicor, Incorporated

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Quality Objectives

Corporate:

- * To provide optimum product quality to the customer.
- * To meet all requested delivery schedules and ensuring customer satisfaction.

Executive Management:

- * To coordinate activities of all functions in the company
- * To provide all necessary capital equipment, personnel, and raw materials.
- * To provide effective training for all personnel.
- * To provide a safe working environment for all personnel.

Administraton:

- * To maintain appropriate records of all company activities.

Quality Assurance:

- * To monitor activities of all functions to ensure compliance with all policies, procedures and instructions.
- * To collect and analyze data from all appropriate functions.

Human Resources:

- * To maintain all appropriate employee records, including training records.

Purchasing/Shipping:

- * To arrange for the delivery of finished products to the customer.
- * To arrange for the delivery of raw materials to the company.

Production:

- * To manufacture all products in accordance with appropriate work instructions
- * To maintain sufficient quantity of finished product and raw materials to meet customer demand.
- * To properly operate and maintain all equipment in a safe manner.

Laboratory:

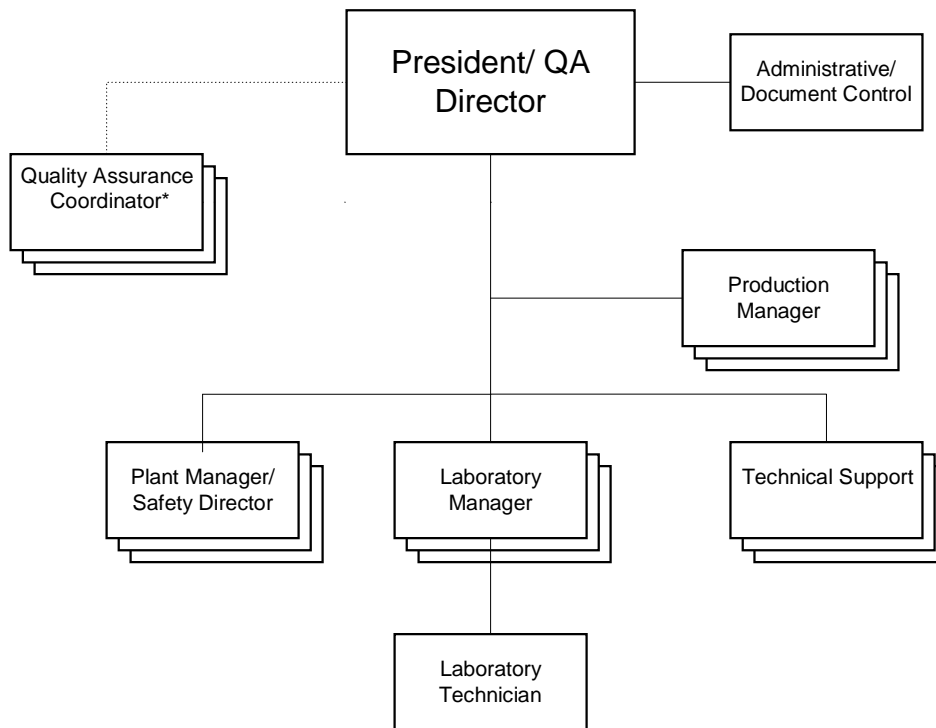
- * To assure all finished products meet Epicor and customer specifications.
- * To assure all raw materials meet Epicor specifications and are acceptable for use in production.

Technical Support:

- * Provide technical expertise to both in-house and customers as required.
- * Assists to insure customers' satisfaction.

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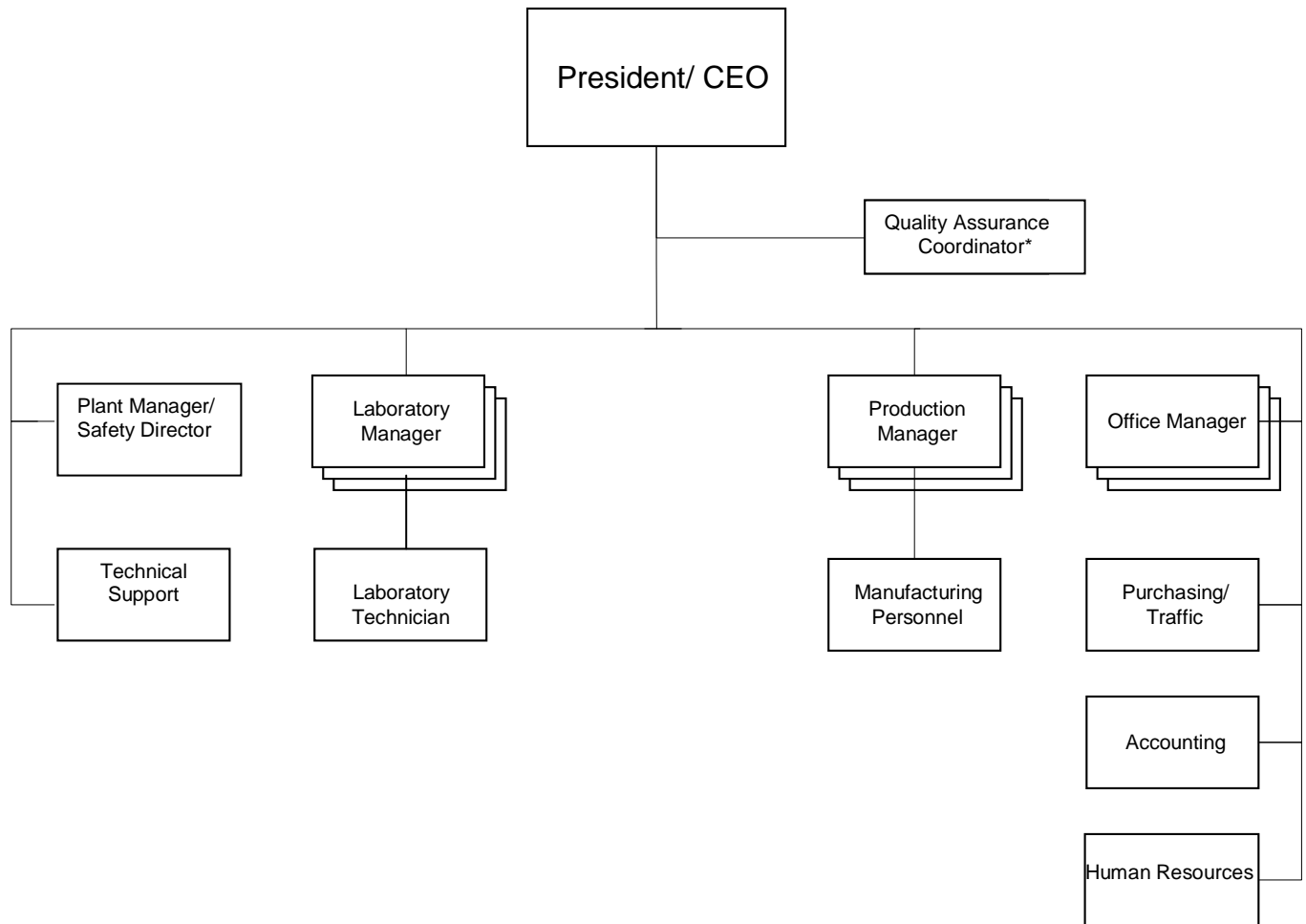
Quality Assurance Group Organizational Chart:



*** MANAGEMENT REPRESENTATIVE**

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Organizational Chart



*** MANAGEMENT REPRESENTATIVE**

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Scope:

This Quality Manual applies to all activities and personnel within Epicor.

This manual describes the Quality Assurance System, which will be used at Epicor to attain compliance with intent of the general quality requirements of ISO-9001:2008, the requirements of 10CFR50 Appendix B, and the provisions of 10CFR Part 21. The policy of Epicor is to apply this system to supplies, materials and services procured by Epicor as well as products produced by Epicor for end use by Epicor's customers.

This manual provides Epicor personnel and customers of Epicor with a general description of our Quality Assurance System, which has been planned and developed to assure all products and services conform to customer orders and contracts.

Written procedures for supplementing the system described herein shall be established and maintained.

Responsibility and Authority:

In all cases, the person verifying quality shall have sufficient authority and organizational freedom to perform the following:

- ◆ Initiate action to prevent the occurrence of any nonconformances relating to product, process and quality system.
- ◆ Identify and record any problems relating to the product, process and quality system.
- ◆ Initiate, recommend or provide solutions through designated channels.
- ◆ Verify the implementation of solutions.
- ◆ Control further processing, delivery or installation of nonconforming product until the deficiency has been corrected.

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4.1 Management Responsibility

4.1.1 Quality Policy

(Refer to Page 5 of the Quality Manual)

The executive management team shall ensure that the quality policy is documented, communicated, understood, implemented and maintained throughout all levels in the organization. The objective and goal of the quality policy is 100 percent Customer Satisfaction.

4.1.2 Quality Objectives

(Refer to Page 6 of the Quality Manual)

Quality objectives have been established for each function within the organization. These objectives are consistent with the Quality Policy and are measurable by laboratory analysis, frequent customer contact, executive management involvement in Epicor's quality program and internal quality audits.

4.1.3 Organization

(See Organization Charts on Pages 7&8 for Interrelationship)

4.1.3.1 Responsibility and Authority

The responsibility and authority of all personnel who manage, perform, and verify work affecting quality, are defined by Job Descriptions.

4.1.3.2 Resources

Executive Management will identify and provide the resources required to implement and maintain this Quality System including capital equipment, trained personnel, and raw material, and provide the means for continual improvement and customer satisfaction.

4.1.3.3 Management Representative:

The Quality Assurance Coordinator of Epicor is appointed as the management representative having the authority and responsibility for ensuring that the quality system is established, implemented, and maintained in accordance with the requirements of ISO-9001:2008, the requirements of 10CFR50 Appendix B, and the provisions of 10CFR Part 21.

The Quality Assurance Coordinator will report the performance review of the quality system to Epicor's management .

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4.1.3.4 Internal Communication Executive Management ensures that appropriate communication processes are established within the organization regarding the effectiveness of the Quality Management System. Quality Management System deviations are addressed immediately upon identification, resolved and documented. All such activities are discussed at frequent Quality Assurance Group meetings. In addition the Quality objectives are posted and reviewed at least annually with all employees.

4.1.4 Management Review Executive management shall review the quality system, including the Quality Policy semi-annually to ensure its continuing effectiveness in satisfying the requirements of ISO-9001:2008, the requirements of 10CFR50 Appendix B, the provisions of 10CFR Part 21 and the quality policy objectives and insure the Quality System is continually improving. Records of this review shall be maintained.

Reference

QAP 4.1 -- Management Responsibility

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4.2 Quality System:

4.2.1 General

Epicor shall establish, document, and maintain a formal quality system including a quality manual to ensure that products conform to specified requirements. The quality system is designed to meet ANSI/ASQCQ9002, the requirements of 10CFR50 Appendix B, and the provisions of 10CFR Part 21. The quality manual will be issued and controlled on page 4. The Quality Management System excludes all references to Design Control, use of Customer Supplied Product and Servicing, since Epicor does not engage in these activities.

4.2.1.1 Interaction between Processes

Epicor employs several processes to ensure compliance with the goals and objectives of the quality management system. These processes and their interaction are described as follows.

Executive Management

Executive management is responsible for ensuring that all aspects of the quality management system are adhered to and implemented as required. These include interactions internally with all aspects of company operation, and externally with suppliers, customers and various regulatory agencies.

This responsibility is carried out via various documented activities required by the Quality Assurance Manual such as:

- Frequent Quality Assurance meetings
- Compliance with all aspects of the quality assurance manual as demonstrated by annual internal audits of appropriate quality assurance procedures.

Ref: QAP 4.1, 4.2

Administration

The administrative area is responsible for maintaining and filing all appropriate documents normally associated with an administrative activity as well as filing and control of most quality assurance documents. The administrative area interfaces primarily with management. Compliance is reviewed annually via internal audits.

Ref QAP 4.5, 4.16

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Quality Assurance

The Quality Assurance Group conducts periodic internal audits and quality assurance meetings to measure the effectiveness of the Quality management system. These audits and meetings are documented, and cover all aspects of the quality management system on an annual basis. The Quality Assurance Group approves and audits external suppliers to ensure the quality of raw materials. The Quality Assurance Group interacts primarily with Executive Management, but monitors all aspects of the organization.

Ref: QAP 4.2, 4.14, 4.17, 4.20

Purchasing/Shipping

Purchasing/Shipping is responsible for receiving and processing all external customer purchase orders, as well as placing purchase orders to various Epicor suppliers. Purchasing interacts with Executive Management, external customers and suppliers and production. All Purchasing/Shipping activities are monitored by internal audits of the appropriate Quality Assurance Procedures.

Ref: QAP 4.3, 4.6, 4.15

Production

The production area is responsible for manufacturing products in compliance with internal and external specifications and requirements. The Production area interfaces with Purchasing/Shipping and the Laboratory. Compliance with the Quality Management System is documented via internal quality audits and laboratory analysis.

Ref: QAP 4.8, 4.9, 4.15

Laboratory

The laboratory is primarily responsible for ensuring that all raw materials and finished products meet the appropriate internal and external specifications. Additionally the laboratory must maintain "good laboratory practice" to ensure the laboratory operates within acceptable standards. The laboratory personnel interface primarily with the Quality Assurance Group and production personnel and technical personnel internally, and with customers and suppliers externally. Compliance with the quality management system is documented via internal quality audits.

Ref: QAP 4.10, 4.11, 4.12, 4.13, 4.20

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Technical Support Function

The Technical Support Function assists in ensuring customer satisfaction by customer contact via telephone or on site visits. The Technical Support Function interfaces with the laboratory and the quality assurance group internally, and with external customers and suppliers.

Ref QAP 4.3, 4.20

Human Resources

The human resources area is responsible for maintaining all records normally associated with human resources activities, including employee training records. Human resources interacts primarily with executive management. Compliance is reviewed annually via appropriate internal audits.

Ref: QAP 4.18

Suppliers

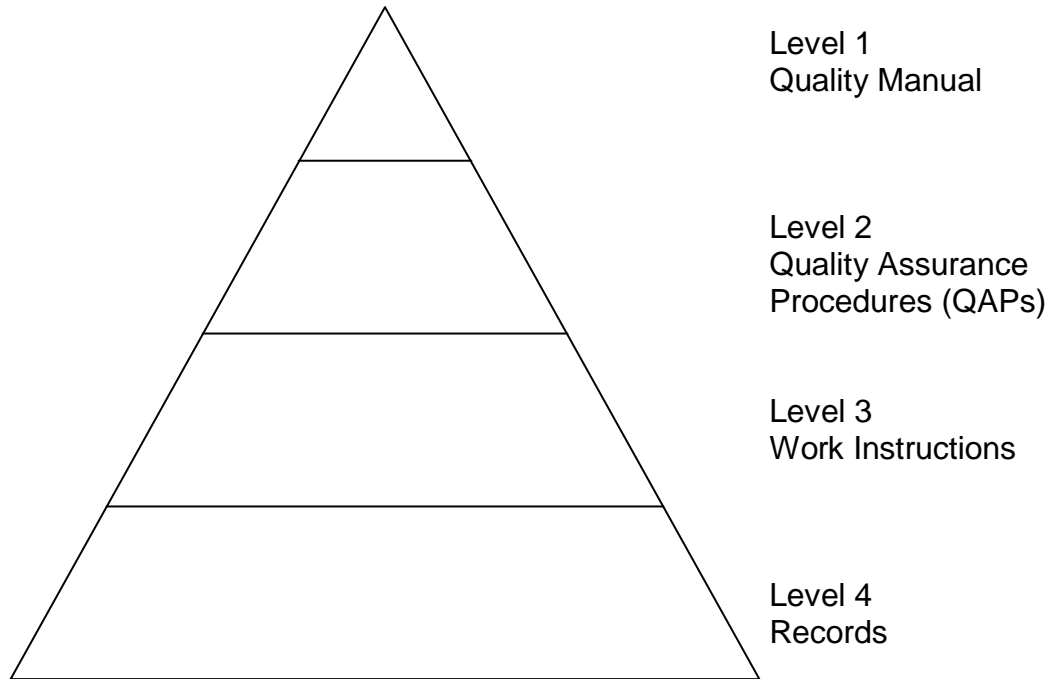
Epicor maintains a critical suppliers list. Suppliers on this list are audited on site periodically, or requested to submit documentation of their qualification via Epicor Form 06-1. Additionally, Epicor reviews critical suppliers performance at least annually via an internal rating system. Suppliers on site visits to Epicor are documented regarding the issues discussed. Suppliers interact with Executive Management, Quality Assurance, Laboratory, Purchasing/ Shipping and Production.

Customers

Epicor's Quality Management System ensures that all customer requirements are met, such as product quality (specifications), delivery and access to all internal resources to ensure customer satisfaction. In addition to frequent contact with the Epicor's staff, customers are requested to respond to an annual customer satisfaction survey. All customer correspondence is reviewed periodically by the Quality Assurance Group to identify areas for improvement. Customers interact primarily with Purchasing/Shipping and Technical Support.

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The quality system structure will be as follows:



References will be made to the quality assurance procedures in this manual.

4.2.2 Quality System Procedures

Procedures will be documented and will be consistent with ISO-9001:2008, the requirements of 10CFR 50 Appendix B, the provisions of 10CFR Part 21 and Epicor's quality policy. Effective implementation of the quality system and documented procedures is supported, analyzed and monitored by management. Epicor will implement actions needed to achieve planned results and continual improvement of these processes.

4.2.3 Quality Management System Planning

Epicor will document how requirements for quality will be met through the Quality Manual, Quality Assurance Procedures (QAP's), and Work Instructions (EP's). The Quality Plan will address the Quality system projects or certifications, objectives and goals of the quality policy, additional training needs, the audit plan and schedule, and give consideration to the following activities:

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The preparation of quality plans.

Identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality.

Ensuring the compatibility of the production process, inspection and test procedures and the applicable documentation.

The updating, as necessary, of quality control, inspection and testing techniques including the development of new instruments.

The identification of any measurement requirement involving capacity that exceeds the known state of the art, in sufficient time for the needed capability to be developed.

The identification of suitable verification at appropriate stages in the realization of product.

The clarification of standards of acceptability for all features and requirements, including those which contain a subjective element.

The identification and preparation of quality records.

The continual improvement of the Quality System.

Executive Management ensures that the Quality Management System is carried out to meet the requirements of this document, as well as company quality objectives via ongoing involvement in the daily company activities, frequent supplier and customer contact, and periodic, documented Quality Assurance Meetings.

Reference

QAP 4.2 -- Quality Systems and Planning

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4.3 Contract Review:

4.3.1 General

The contract review system of Epicor shall establish and maintain documented procedures for contract review and for the coordination of these activities.

4.3.2 Review

Before acceptance of a request for quote, order or contract, Epicor will review the contract to ensure that:

The requirements are adequately defined and documented.

Verbal order requirements are agreed to before their acceptance.

Any requirements differing from the quote or accepted order are resolved.

Epicor has the capability to meet the contractual requirements.

4.3.3 Amendments to Contract

Contract amendments are reviewed and approved and upon acceptance, all affected functions are advised.

4.3.4 Customer Satisfaction

Epicor measures customer satisfaction via frequent customer contact by telephone or on site visits. All contacts are documented. Epicor also contacts customers at least annually with a request to fill out and return a customer satisfaction rating form. All customer contact is reviewed periodically by the Quality Assurance Group to identify areas for improvement.

4.3.5 Records

Records for contract reviews are maintained.

Reference

QAP 4.3 -- Contract Review

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4.5 Document and Data Control:

4.5.1 General

Epicor shall establish and maintain documented procedures to control all documents and data that relate to the requirements of ISO-9001:2008, the requirements of 10CFR 50 Appendix B and the provisions of 10CFR Part 21, including documents of external origin such as standards and customer drawings.

4.5.2 Document and Data Approval and Issue

Documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue.

A master list will be used to identify the current revision status of documents issued.

Appropriate documents shall be available at all locations where operations essential to the effective functioning of the Quality System are performed.

Obsolete documents are promptly removed from all points of issue and retained for knowledge purposes in a special file to prevent unintended use.

4.5.3 Document and Data Changes

Revisions to the Quality Management System cannot be implemented without the written approval of the President/Quality Assurance Director or a member of the Quality Assurance Group.

Reference

QAP 4.5 -- Document and Data Control

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4.6 Purchasing:

4.6.1 General

Epicor shall establish and maintain documented procedures to ensure that products and services obtained from outside suppliers conform to specified requirements.

4.6.2 Evaluation of Suppliers

All existing suppliers are approved and listed on the Approved Supplier List.

New suppliers are selected based on their ability to meet requirements including the Quality System and Quality Assurance requirements.

All suppliers shall be controlled, depending on the type of product and the impact on the quality of the final product. The control may consist of questionnaires, actual audits, supplier performance, and/or quality records.

4.6.3 Purchasing Data

Purchasing documents shall contain data clearly describing the products ordered, including where applicable:

Precise identification of product type, class or grade.

Specifications, Drawings, Process Requirements, or other relevant technical data, including approval, qualification of product, process, personnel, etc.

Identification of the quality system standard to be applied.

Purchasing documents are reviewed and approved prior to release.

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4.6.4 Verification of Purchased Product

Epicor reserves the right to verify purchased product at the suppliers facility when specified in the purchasing document. Where specified contractually, the customer may verify conformance to requirements at the supplier's facility and/or at Epicor' facility. Customer verification shall not absolve Epicor of the responsibility to provide acceptable product nor shall it preclude rejection by the customer.

Reference

QAP 4.6 – Purchasing

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4.8 Product Identification & Traceability:

4.8.1 General

Epicor shall establish and maintain documented procedures for identifying the product by suitable means from receipt, during all stages of production through delivery, where appropriate.

Where and to the extent that Traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches, which will be recorded.

Reference

QAP 4.8 -- Product Identification and Traceability

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4.9 Process Control:

4.9.1 General

Epicor's Executive Management consistently provides and maintains the infrastructure required to achieve its quality objectives. Such infrastructure includes buildings, utilities, process equipment, and support services as required.

Epicor shall identify and plan the production processes, which directly affect quality and shall ensure that these processes are carried out under controlled conditions.

Controlled conditions shall include the following:

Documented work instructions (EP's)

Use of suitable equipment and a suitable working environment. All existing equipment and the working environment are approved by executive management.

Compliance with references standards/codes and quality plans.

Monitoring and control of process parameters and product characteristics.

Approval of processes and equipment as appropriate.

Criteria for workmanship, which will be stipulated in the clearest possible manner.

Suitable maintenance of equipment to ensure continuing process capability.

Epicor does not have special processes.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate.

Reference

QAP 4.9 -- Process Control

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4.10 Inspection & Testing:

4.10.1 General

Epicor shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for product are met. The required inspection and testing, and the records to be established shall be detailed in the documented procedures.

4.10.2 Receiving Inspection and Testing

Epicor shall ensure that the incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements. Verification shall be per documented procedures.

In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the sub-contractor's premises and the recorded evidence of conformance provided.

Product is not released prior to verification.

4.10.3 In-Process Inspection and Testing

Epicor shall inspect and test in-process as required by documented procedures.

Material will not be moved to the next operation until all inspections are carried out in conformance with specified requirements.

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4.10.4 Final Inspection and Testing

Epicor shall carry out all final inspection and testing in accordance to documented procedures to complete the evidence of conformance to the specified requirements. The inspection shall require that all receiving and in-process inspection and testing have been carried out and that their results meet specified requirements. Outside laboratories may be employed if required.

No product shall be dispatched until all the activities specified in the documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

4.10.5 Inspection and Test Records

Epicor shall establish and maintain records, which provide evidence that the product has been inspected and/or tested. These records shall clearly show whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

10.4.6 Monitoring and Measuring of Processes

Epicor has in place an effective monitoring and measuring system to monitor the effectiveness of the quality management system. The details of the monitoring and management systems are contained within the quality assurance procedures.

Reference

QAP 4.10 -- Inspection and Testing

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4.11 Control of Inspection, Measuring & Test Equipment:

4.11.1 General

Epicor shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by Epicor to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation, or servicing, and shall be rechecked at prescribed intervals. Epicor shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

Where the availability of technical data pertaining to the measurement equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the measuring equipment is functionally adequate.

4.11.2 Control Procedure

Epicor shall:

Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision.

Identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust equipment at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented.

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Define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, and location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory.

Identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status.

Maintain calibration records for inspection, measuring and test equipment (see 4.16).

Assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration.

Ensure that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out.

Ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained.

Safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustment, which would invalidate the calibration setting.

Reference

QAP 4.11 – Control of Inspection, Measuring and Test Equipment

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4.12 Inspection & Test Status:

4.12.1 General

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2, page 28)] is dispatched, used or installed.

Reference

QAP 4.12 – Inspection and test Status

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4.13 Control of Nonconforming Product:

4.13.1 General

Epicor shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is kept from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and notification of the functions concerned.

4.13.2 Review and Disposition of Nonconforming Product

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be:

Reworked to meet the specified requirements

Accepted with or without repair by concession

Regraded for alternative applications

Rejected or scrapped.

Where required by the contract, the proposed use or repair of a product which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.14).

Repaired and/or reworked product shall be reinspected in accordance with the quality plan and/or documented procedures.

Reference

QAP 4.13 – Nonconforming Material Control

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4.14 Corrective and Preventive Action:

4.14.1 General

Epicor shall establish and maintain documented procedures for implementing corrective and preventive action.

Documented procedures will be changed and recorded based on corrective or preventive action.

4.14.2 Corrective Action

Corrective action procedures shall include:

Effective handling of customer complaints.

Supplier nonconformances, as needed

Internal nonconformances will be reviewed in preventive actions.

Root cause(s) determination, corrective actions to control problem, and verification that corrective action was effective.

4.14.3 Preventive Action

Preventive action procedures shall include:

Reports and analysis are used to determine significant problems that need preventive actions. The reports may come from customer complaints, internal nonconformances, supplier nonconformances, internal audits, and quality system reviews.

Root cause(s) determination, preventive action(s) to control problem(s), verification that preventive action(s) were effective.

Information on actions taken is submitted for management review.

Frequent customer contact.

Reference

QAP 4.14 – Corrective and Preventive Action

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4.15 Handling, Storage, Packaging, Preservation & Delivery

4.15.1 General

Epicor shall establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.

4.15.2 Handling

Epicor shall provide methods of handling product that prevent damage or deterioration.

4.15.3 Storage

Epicor shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

Stock shall be assessed annually to determine the condition of the product.

4.15.4 Packaging

Epicor shall control packing, packaging, and marking processes including material used to the extent necessary to ensure conformance to specified requirements.

4.15.5 Preservation

Epicor shall apply methods for preservation and segregation of product when under Epicor's control.

4.15.6 Delivery

Epicor shall arrange for the protection of the quality of product after inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

Reference

QAP 4.15 – Handling, Storage, Packaging, Packaging, and Delivery

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4.16 Control of Quality Records:

4.16.1 General

Epicor shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, retention, and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation for the quality system including records from suppliers.

Records shall be readily retrievable and placed in an environment suitable for preventing damage or loss.

Where agreed contractual records shall be made available for evaluation by the customer.

Reference

QAP 4.16 – Quality Record Control

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4.17 Internal Quality Audits:

4.17.1 General

Epicor shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the Quality System.

Internal quality audits shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results shall be recorded and brought to the attention of the personnel who have direct responsibility for the area being audited and who will take timely corrective action to correct deficiencies found.

Follow up activities shall verify and record the implementation and effectiveness of the corrective action taken.

Executive management shall review the internal audits.

Reference

QAP 4.17 – Internal Quality Audits

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4.18 Training:

4.18.1 General

Epicor shall establish and maintain documented procedures for identifying training needs and providing for the training of all personnel performing activities affecting quality.

Executive management ensures a competent work force by establishing job descriptions for the various activities performed by personnel affecting product quality.

Training is provided for new employees as required or for existing employees to upgrade their skills. Education, previous experience and skills are considered in evaluating the need for training. Training regarding quality objectives is provided to all employees at least annually. All new employees receive safety training. Competency of such training is judged by the employees manager or by written examinations.

Records of training and other skills are maintained in employee files located in the Human Resources Office.

Reference

QAP 4.18 – Training

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4.20 Statistical Techniques:

4.20.1 Identification of Need

Epicor shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

4.20.2 Procedures

Epicor determines, collects and analyzes all appropriate data to ensure the suitability and effectiveness of the quality management system and identify areas where continual improvement of the system can be implemented. This shall include data generated from monitoring and measuring and from other relevant sources such as customer satisfaction reports and supplier performance.

Data analysis shall include product conformance to all related requirements, customer satisfaction, review of process and product trends, including opportunities for preventive action and correction of same if required. Supplier performance will be reviewed at least annually.

Reference

QAP 4.20 – Statistical Techniques

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Term	Definition
<i>ASL</i>	Approved Supplier's List
<i>Approved</i>	The status given to an entity when it has been demonstrated to be capable of fulfilling requirements.
<i>Conformity</i>	The fulfillment of specified requirements.
<i>Corrective Action Plan</i>	A plan for correcting a process or part quality issue.
<i>Critical Supplier</i>	A supplier which provides goods or services that are essential to the quality of the product.
<i>Customer</i>	The recipient of a product provided by the supplier.
<i>Environment</i>	All of the conditions surrounding and affecting manufacture and quality of a part or product.
<i>Functional Verification</i>	Testing to ensure the part conforms to all customer and supplier engineering performance and material requirements.
<i>Inspection</i>	An activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic.
<i>Nonconformance</i>	Product or material which does not conform to the customer requirements of specifications.
<i>Objective Evidence</i>	Information which can be proved true based on facts obtained through observation, measurement, test or other means.
<i>Organization</i>	A company, corporation, firm, enterprise or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

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Glossary

Term	Definition
<i>Procedure</i>	A specified way to perform an activity. A documented procedure usually contains: the purpose and scope of an activity; what shall be done by whom; when, where and how it shall be done; what materials, equipment and documents shall be used; and how it shall be controlled and recorded.
<i>Process</i>	A set of interrelated resources and activities which transform input into output.
<i>Work Instruction</i>	Epicor Procedure – EP
<i>QAP</i>	Quality Assurance Procedures.
<i>Quality</i>	The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.
<i>Quality Manual</i>	(Also known as the Quality System Plan) A document that describes the elements of the quality system used to assure customer requirements, needs and expectations are met.
<i>Quality Policy</i>	The overall intentions and direction of an organization with regard to quality, as formally expressed by top management.

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Glossary

Term	Definition
<i>Quality Record</i>	A document which provides objective evidence of the extent of the fulfillment of the requirements for quality or the effectiveness of the operation of a quality system element.
<i>Repair</i>	The action taken on a nonconforming product so that it will fulfill the intended usage requirements although it may not conform to originally specified requirements.
<i>Rework</i>	The action taken on nonconforming product so that it will fulfill the specified requirements.
<i>Service</i>	The results generated by activities at the interface between the supplier and the customer and by supplier internal activities, to meet customer needs.
<i>Statistical Process Control</i>	The use of statistical techniques such as control charts to analyze a process or its output so as to take appropriate action, which achieve and maintain a state of statistical control and improve the capability of the process.
<i>Supplier</i>	Providers of materials, parts or services to an organization.
<i>Validation</i>	Confirmation by examination and provision of objective evidence that the particular requirements for a specified intended use are fulfilled.
<i>Verification</i>	Confirmation by examination and provision of objective evidence that the specified requirements have been met.

Epicor, Incorporated Corporate Quality Manual

Bibliography

<u>Document</u>	<u>Title</u>	<u>Author</u>
ANSI 8402	ANSI 8402 -- Quality Vocabulary	ANSI
ANSI/ASQ Q10011	ANSI/ASQ Q10011 -- Quality System Auditing	ANSI
ANSI/ASQ Q9002	ANSI/ASQ Q9002 -- Model for quality assurance in production and installation	ANSI
10CFR 50 Appendix B	Domestic Licensing of Production and Utilization Facilities	NRC
10CFR Part 21	Reporting Defects and Noncompliance	NRC