

Quality

QUALITY MANUAL

Revision History

Table 0 : Revision History

REV	DATE	ECN	DESCRIPTION
A	10/8/2003	465	Initial release.
B	11/18/2003	482	Removed SP and SWI from Section 3.1; Updated terms in Section 3.2; Corrected typographical errors; Changed references of SP-720 to AP-720; Changed references of EP-630 to AP-630.
C	11/21/2003	486	Corrected Revision History Table to properly describe revision B changes.
D	01/02/2005	671	Remove Personnel names, Update quality policy.
E	3/8/2007	1073	Added Corrective Action Report and Corrective/ Preventive Action Report to Table 2. Changed Discrepant Material Report to Discrepancy Report. Changed AP-423 & AP-424 to QP-423 & QP-424.

Single sections or single pages of this document will not be revised. Hence, the entire document will be reissued as required. The authenticity of this document is only guaranteed when made available via a controlled distribution to individuals, directly from Stellar Technology Incorporated.

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0.0 Introduction**0.1 General**

Stellar Technology developed and implemented a Quality Management System (QMS) in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The QMS of Stellar Technology meets the requirements of the international standard ISO 9001:2000. This system addresses the design, development, production and servicing of the company's products.

The manual starts with a brief introductory section and the remainder is divided into eight sections that correlate to the QMS sections of ISO 9001:2000. Each section contains specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the QMS, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the QMS to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our QMS to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that

the integrity of the QMS is maintained and focused on customer satisfaction and continuous improvement.

The following acronyms are used throughout the QMS to assist with understanding the different content relationships”

0.2 Distribution

The Quality Manual shall be distributed to the following:

- Engineering Manager
- Machine Shop Manager
- Production Manager
- Purchasing Manager
- Quality Manager
- Sales Manager

Additional copies are distributed to employees as directed by department managers.

0.3 Organizational Chart

The Stellar Technology Organization Chart represents the top-tier management entries only. Any member of the Executive Management group may at any time function in any managerial position in order to accomplish its task.

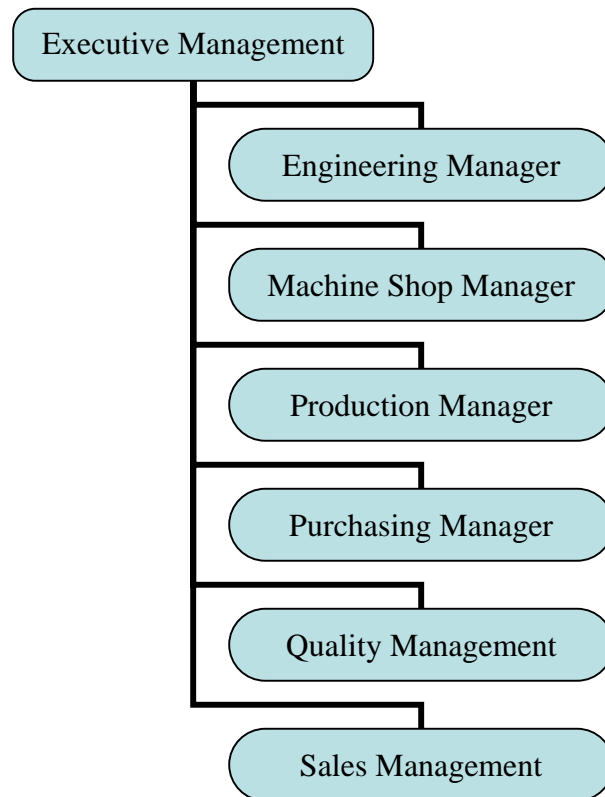


Figure 1: Stellar Technology Organizational Chart

0.4 Quality Policy

Stellar Technology Incorporated provides products and services for markets where safety, reliability and customer satisfaction are crucial. We are committed to improving our competitive position by developing products and services that our customers value, and creating systems and operations to deliver that value. Continuous improvement and variation reduction are our constant goals.

To promote a total company effort and commitment to our Quality Policy and Mission Statement our company has adopted the philosophy of “There is always time to do the job right!” in every area of the company.

In Assembly: We ask each employee to follow the work instructions and use their training experience to produce consistent results and in addition, to always recommend improvements to the assembly process.

In Engineering: We remind each engineer to “plan their projects” and “validate & verify their project results”, and in addition to “execute & document the process” and in addition, to be receptive of implementing recommendations from employees for improvements to processes.

In Sales: We ask employees to “confirm the customer’s requirements”, “be an effective communicator” and to listen and “encourage our customer’s feedback.” Keep in mind our first priority in the sales process is improving on our customer relation ships.

Principal Executive Manager

Quality Assurance Manager

The Executive Management of Stellar Technology Incorporated has formulated the Quality Policy. The policy is explained and discussed at the general orientation training given to all new employees and has been reviewed with all current employees. All employees are expected to know what the Quality Policy means to them as it affects their job or position within the company. The policy is posted in prominent locations throughout the facility.

1.0 Scope

1.1 General

The Quality Manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the international standard ISO 9001:2000.

1.2 Application

Stellar Technology has determined that there are no exclusions from the ISO 9001:2000 Standard.

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- ANSI/ISO/ASQ Q9000-2000, Quality Management Systems – Vocabulary
- ANSI/ISO/ASQ Q9000-2000, Quality Management Systems – Requirements
- ANSI/ISO/ASQ Q9004-2000, Quality Management Systems – Guidelines for Performance Improvements
- ANSI/NC SL Z540-1-1994, Calibration Laboratories and Measuring and Test Equipment – General Requirements

3.0 Quality Management System Definitions

3.1 QMS Prefixes

This section describes the QMS documentation prefixes, which are used to group related documents for easier navigation. Procedures relating to a specific department are prefixed with the first letter of the department, followed by the letter P, followed by a hyphen and the QMS section callout with decimals removed. The following is an example of an administrative procedure from section 6.2.2:

AP-622

Work instructions relating to a specific department are prefixed with the first letter of the department, followed by the letters WI, followed by a hyphen and the QMS section callout with decimals removed and finally, by a sequential index for the department section. The following is an example of an administrative work instruction from section 6.2.2:

AWI-622.1

Table 1: QMS Prefixes

Prefix	Definition
AP	Administrative Procedure
AWI	Administrative Work Instruction
EP	Engineering Procedure
EWI	Engineering Work Instruction
MP	Manufacturing Procedure
MWI	Manufacturing Work Instruction
QP	Quality Procedure
QWI	Quality Work Instruction

3.2 Company Specific Terms

This section describes definitions unique to Stellar Technology.

Table 2: Company Specific Terms

Term	Definition
Acceptance Tag	An identification label used to associate a part or assembly with acceptance test / inspection data.
Action Plan	A schedule, employee specific, that identifies training needs and a tentative time schedule to complete. At the completion of the action plan the employee will be fully qualified for a position.
Attachments	Documents used to further clarify or show examples of information described in the procedures and work instructions.
Audit Team	One or more auditors, and the Quality Assurance Manager or a member of the Executive Management.
Bill of Materials (BOM)	Document that lists components of an assembly
Calibration Records	An enumeration of transducer test results and error summary information.
CARB	Corrective Action Review Board consisting of The Quality Manager and Executive Management.
Corrective Action	Action taken to eliminate the cause of a detected nonconformance and prevent its recurrence.
Customer Owned Property	Any type of instrumentation, accessories, manuals or shipping containers that belong to a customer.
Customer Property	Property owned by the customer and provided for use in meeting the requirements of the contract. Customer property can include equipment, components, raw materials, assemblies and intellectual property.

Term	Definition
Customer Supplied Product	Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
Design Changes	Changes made to the inputs or plan during design and development activities.
Design Project	Planning of products, services or processes to transform a set of requirements into a product realization process.
Design Validation	Determination of the product's ability to meet user needs.
Design Verification	Determination that the product meets requirements.
Discrepancy Report (DR)	A quality management document used to report nonconforming product and the product's disposition.
Engineering Control Notification (ECN)	Document used to describe the issuance or revision of an item.
Engineering Project Database	A database containing design and development projects, associated tasks that have been completed and resources available for project use.
ESD	Electrostatic discharge.
Executive Management	Executive Management consists of all principals of Stellar Technology.
Forms	Documents used to make a record of completing all or part of the process described in procedures and work instructions.
IAW	In accordance with.
Infrastructure	Buildings, workspace, utilities, process equipment and supporting services.

Term	Definition
Inspection Router	A document that lists consecutive steps required to perform an inspection process.
Job Description	A form identifying the qualification requirements for each position within the company.
Key Product Realization Process (KPRP)	Product realization processes including customer related processes and quality management system processes that are considered most critical to meeting quality system objectives.
Labor Router	A document that lists consecutive steps required to perform a manufacturing process.
Manufacturing Procedures	Work instructions that detail specific manufacturing operations.
N.I.S.T.	National Institute of Standards and Testing.
Nonconforming/Discrepant/Defective	Is any departure from drawings, specifications, procedures or workmanship standards. The terms are synonymous and can be used interchangeably
PARB	Preventative Action Review Board consisting of the Quality Manager and Executive Management.
Pick-List	A fully exploded BOM that includes stock room locations of parts and quantities to be pulled from stock.
POC	Point of contact.
Preventative Action	Action taken to eliminate the cause of a potential nonconformance and prevent its occurrence.
Procedure	Document outlining specific work processes and how the requirements of the ISO 9001 standard are being met.

Term	Definition
Product	The end item result of meeting all contract terms and conditions. (i.e. manufactured goods, merchandise, services etc.)
Product Realization	Processes (from customer input through delivery and service) that lead to the creation of the final product or service.
Quality Records	Documentation of those activities wherein records of said activities must be maintained, will be specified in the procedure or work instruction level documents, as applicable.
Quarantine	A procedure used to segregate nonconforming material out of the normal flow of material for manufacture.
Records	Documents, Travelers, and Data Binders, etc. stating evidence of conformity achieved per requirements and/or providing evidence of the quality management system. Completed forms or information generated as a result of the process described in a document and retained as indicated in the Control of Records Procedure.
References	External documents or sources used in preparing documentation and completing work.
Re-Grade	A product disposition procedure used to dispose of nonconforming product that does not meet its specifications but meets the specifications of another grade.
Related Documents	Other documents that may need to be altered if the current document is revised or changed.

Term	Definition
Repair	A product disposition procedure used to reduce the effects of a nonconformance of a nonconforming product.
Return to Vendor	A product disposition procedure used to dispose of nonconforming product received from a supplier that is unusable for its intended purpose.
Rework	A product disposition procedure used to return nonconforming product to its original specifications.
Scrap	A product disposition procedure used to dispose of nonconforming product that is not usable for its intended purpose.
Shop Traveler	A transducer specific folder containing test results and calibration records.
Standard Process	Processes used in the realization of a standard product.
Templates	Electronic documents used to create quality system documentation.
Training Record	A form recording the details of a specific training class, job training or group training.
Use-As-Is	A product disposition procedure used to dispose of nonconforming product containing one or more minor non-conformances that is usable for its intended purpose.
Vault	A shared network folder that contains released documents. Access is restricted to certain individuals and is read-only. The Vault is maintained by the Network Administrator.
Work Instructions	Step by step directions on how a task should be done.

4.0 Quality Management System

4.1 General Requirements

Stellar Technology has established, documented and implemented a QMS in accordance with the requirements of ISO 9001:2000. The system is maintained and continually improved through the use of the Quality Policy, quality objectives, audit results, analysis of data, corrective and preventative action and management review.

To design and implement the QMS Stellar Technology has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual.
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram.
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
- Established systems to monitor, measure and analyze these processes.
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual.

- Documented procedures.
- Documents identified as needed for the effective planning, operation and control of our processes.
- Quality records.

4.2.2 Quality Manual

This Quality Manual has been prepared to describe Stellar Technology's QMS. The scope and permissible exclusions of the QMS are described in section 1.0 of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section.

4.2.3 Control of Documents

All of the QMS documents are controlled according to the Document Control Procedure (QP-423). This procedure defines the process for:

- Approving documents for adequacy prior to issue.
- Reviewing and updating as necessary and re-approving documents.
- Ensuring that changes and current revision status of documents are identified.
- Ensuring that relevant versions of applicable documents are available at points of use.
- Ensuring that documents remain legible and readily identifiable.
- Ensuring that documents of external origin are identified and their distribution controlled.
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

4.3 Related Procedures

- QP-423: Document Control
- QP-424: Control of Records

5.0 Management Responsibility

5.1 Management Commitment

Executive Management has been actively involved in implementing the QMS. It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the Quality Policy.

To continue to provide leadership and show commitment to the improvement of the QMS, Executive Management will do the following:

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives.
- Establish the Quality Policy.
- Conduct quarterly management reviews.
- Ensure the availability of resources.

5.2 Customer Focus

Stellar Technology strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Executive Management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements and communicated to the appropriate people in our organization using Customer Related Processes (AP-720).

5.3 Quality Policy

Executive Management ensures that the Quality Policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Executive Management reviews the Quality Policy at each management review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is documented in section 0.4 of this manual.

5.4 Planning

5.4.1 Quality Objectives

Quality objectives are established to support our organization's efforts in achieving our Quality Policy and reviewed annually for suitability. Objectives have been established for each department and are documented in the Management Responsibility Procedure (AP-500). Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

5.4.2 QMS Planning

The QMS has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001:2000 standard. Quality planning takes place as changes that affect the QMS are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the Organizational Chart. Job descriptions and the Organizational Chart are reviewed and approved by Executive Management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. The Organizational Chart is located in Figure 1 in this manual.

5.5.2 Management Representative

The Quality Manager has been appointed by Executive Management as Management Representative. As Management Representative, the individual has the following responsibility and authority:

- Ensure that processes needed for the QMS are established and implemented.
- Report to Executive Management on the performance of the QMS, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

5.5.3 Internal Communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, internal audit closing meetings, and other routine business communication.

5.6 Management Review

5.6.1 General

Executive Management reviews the QMS quarterly at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

5.6.2 Review Input

Assessment of the QMS is based on a review of information inputs to management. These inputs include the following:

- Results of audits.
- Customer feedback.

- Process performance and product conformity.
- Company level quality data.
- Status of preventative and corrective actions.
- Follow-up actions from previous management reviews.
- Planned changes that could affect the QMS.
- Recommendations for improvement.

5.7 Review Output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the QMS and its processes.
- Improvement of product related to customer requirements.
- Resources needed.

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

5.8 Related Procedures

- AP-720: Customer Related Processes
- AP-500: Management Responsibility

6.0 Resource Management

6.1 Provision of Resources

Stellar Technology has implemented a QMS that complies with the ISO 9001:2000 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

6.2 Human Resources

6.2.1 General

To ensure competence of our personnel, job descriptions are used to identify the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, Awareness and Training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Competence, Awareness, and Training Procedure (AP-622).

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

To meet quality objectives and product requirements Stellar Technology has determined the infrastructure needed (AP-630). The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventative maintenance plans.
- Sanitation plans.
- Building maintenance plans.

6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the QMS. The work environment is managed for continuing suitability. Data from the QMS is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventative or corrective action related to the work environment is required.

6.5 Related Documents

- AP-622: Competence, Awareness and Training
- AP-630: Infrastructure

7.0 Product Realization

7.1 Planning of Product Realization

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Planning of Product Realization procedure (MP-710). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product.
- Processes, documentation and resources required.
- Verification, validation, monitoring, inspection and test requirements.
- Criteria for product acceptance.

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Stellar Technology determines customer requirements before acceptance of an order. Customer requirements include those

- Requested by the customer.

- Required for delivery and post-delivery activities.
- Not stated by the customer but necessary for specified use or known and intended use.
- Statutory and regulatory requirements related to the product.
- Additional requirements determined by Stellar Technology.

Customer requirements are determined according to the Customer Related Processes procedure (AP-720).

7.2.2 Review of Requirements Related to the Product

Stellar Technology has a process in place for the review of requirements related to the product (AP-720). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined.
- Contract or order requirements differing from those previously expressed are resolved.
- Stellar Technology has the ability to meet the defined requirements.
- Records are maintained showing the results of the review and any actions arising from the review.
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance.
- When product requirements are changed, Stellar Technology communicates changes to relevant personnel and amends relevant documents.

7.2.3 Customer Communication

Stellar Technology has implemented an effective procedure (AP-720) for communicating with customers in relation to:

- Product information.
- Enquiries, contracts and order handling, including amendments.

- Customer feedback, including customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

The Design and Development procedure (EP-730) outlines the process for controlling the design and development process. The Engineering Department plans design and development according to this procedure. The design plan includes:

- Design and development stages.
- Required design reviews.
- Verification and validation methods appropriate to each design and development stage.
- Responsibilities and authorities for design and development.
- Identification of the technical interfaces required for the project.
- Updating of the design plan as the project progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (EP-730). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements.
- Applicable statutory and regulatory requirements.
- Where applicable, information derived from previous similar designs.
- Other requirements essential for design and development.

7.3.3 Design and Development Outputs

Outputs of design and development are documented according to the Design and Development procedure (EP-730). They are documented

in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements.
- Provide appropriate information for purchasing, production and for service provision.
- Contain or reference product acceptance criteria.
- Specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and Development Review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings, which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements.
- Identify any problems and propose necessary actions.
- Include representatives of functions concerned with the design and development stage being reviewed.

7.3.5 Design and Development Verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Design and Development procedure (EP-730)

7.3.6 Design and Development Validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever

practicable. Records of validation activities are maintained according to the Design and Development procedure.

7.3.7 Control of Design and Development Changes

The Design and Development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

7.4 Purchasing

7.4.1 Purchasing Process

The Purchasing procedure (AP-740) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate:

- Requirements for approval of product, processes and equipment.
- QMS requirements.

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of Purchased Product

The Purchasing procedure describes the process used to verify that purchased product meets specified purchase requirements. If Stellar Technology or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Stellar Technology plans and carries out production and service provision under controlled conditions according to documented procedure (MP-750). Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product.
- The availability of work instructions.
- The use of suitable equipment.
- The availability and use of monitoring and measuring devices.
- The implementation of monitoring and measurement.
- The implementation of release, delivery and post-delivery activities.

7.5.2 Validation of Processes for Production and Service Provision

Stellar Technology validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Stellar Technology has documented the process for validation including:

- Defined criteria for review and approval of the processes.
- Approval of equipment and qualification of personnel.

- Use of specific methods and procedures.
- Requirements for records.
- Revalidation.

7.5.3 Identification and Traceability

Stellar Technology identifies the product throughout product realization according to the Identification and Traceability procedure (MP-753).

Product is identified with respect to monitoring and measurement requirements. Stellar Technology controls and records the unique identification of the product wherever traceability is a specified requirement.

7.5.4 Customer Property

Stellar Technology exercises care with customer property while it is under the organization's control or being used. A procedure (MP-754) outlines the identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

7.5.5 Preservation of Product

Stellar Technology preserves the conformity of product during internal processing and delivery to the intended destination per procedure (MP-755). This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Devices

Stellar Technology has determined it is necessary to maintain well-controlled monitoring and measurement devices in order to provide evidence of conformity of product to requirements. A documented procedure (MP-760) outlines the process used to ensure that monitoring and measurement to be

carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.
- Adjusted or re-adjusted 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.

In addition, the Quality department assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Stellar Technology takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed.

This shall be undertaken prior to initial use and reconfirmed as necessary.

7.7 Related Documents

- MP-710: Planning of Product Realization Processes
- AP-720: Customer Related Processes
- EP-730: Design and Development
- AP-740: Purchasing
- MP-750: Control of Production and Service Provision
- MP-753: Identification and Traceability
- MP-754: Customer Property
- MP-755: Preservation of Product
- MP-760: Control of Monitoring and Measuring Devices

8.0 Measurement, Analysis and Improvement

8.1 General

Stellar Technology has plans and implements the monitoring, measurement, analysis and improvement processes as needed:

- To demonstrate conformity of the product.
- To ensure conformity of the QMS.
- To continually improve the effectiveness of the QMS.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the QMS, Stellar Technology monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in Customer Related Processes (AP-720) and Management Responsibility procedure (AP-500).

8.2.2 Internal Audit

Stellar Technology conducts internal audits at planned intervals to determine whether the QMS:

- Conforms to the planned arrangements (see 7.1), to the requirements of the International Standard and to the QMS requirements established by the organization.
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and

conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (QP-822).

The manager responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and Measurement of Processes

Stellar Technology applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the process. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes (MP-824) and Management Responsibility procedure (AP-500).

8.2.4 Monitoring and Measurement of Product

Stellar Technology monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Monitoring, Measuring and Analysis of Product Realization Processes (MP-824).

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of the product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.3 Control of Nonconforming Product

Stellar Technology ensures that products, which do not conform to customer requirements, are identified and controlled to prevent their unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming products are defined in the Control of Nonconforming Product procedure (QP-830).

8.4 Analysis of Data

Stellar Technology determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made. The process for determining, collecting and analyzing this data is defined in the Management Responsibility procedure (AP-500). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends to processes and products including opportunities for preventive action
- Suppliers

8.5 Improvement

8.5.1 Continual Improvement

Stellar Technology continually improves the effectiveness of the QMS through the use of Quality Policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review.

8.5.2 Corrective Action

Stellar Technology takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QP-852) defines requirements for:

- Reviewing nonconformities (including customer complaints).
- Determining the causes of nonconformities.
- Evaluating the need for action to ensure that nonconformities do not recur.
- Determining and implementing action needed.
- Records of the results of action taken (see 4.2.4).
- Reviewing corrective action taken.

8.5.3 Preventative Action

Stellar Technology determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventative actions are appropriate to the effects of the potential problems.

A documented procedure (QP-853) 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 action taken.
- Reviewing preventative action taken.

8.6 Related Documents

- AP-500: Management Responsibility
- AP-720: Customer Related Processes
- AP-821: Monitoring, Measuring and Analysis of Customer Satisfaction
- QP-822: Internal Audits
- QP-824: Monitoring, Measuring and Analysis of Product Realization Processes

- QP-830: Control of Nonconforming Product
- QP-852: Corrective Action
- QP-853: Preventative Action