

Table 0: Revision History

Rev.	Date	DCN	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	03/08/2007	1073	Added Corrective Action Report and Corrective/ Preventive Action Report to Table 2. Changed Discrepant Material Report to Discrepancy Report. Changed AP-423 and AP-424 to QP-423 and QP-424.
F	05/04/2009	2551	Removed Machine Shop Manager from Org. Chart. Added Program Manager and Configuration Manager to Org. Chart. Added Personnel names. Changed references of MP-760 to QP-760. Added line e) to 7.1.
G	06/01/2010	3501	Changed ISO reference to 2001:2008. Changed distribution requirements. Removed names on org chart. Added Appendix 1 for process flow chart. Removed sign off in section 0.4, Changed "ECN" to "DCN"
H	07/20/2010	3564	Change distribution requirements to online only. Modified Appendix 1 to change name of processes. Added reference to process flow chart in section 4.1
J	03/30/2012	4996	Removed "Acronym" statement from 0.1. Removed 236291 from section 4.1, added individual Process Flow Chart Part Numbers. Corrected various grammatical and spelling errors. Moved "distribution" statement to page 1.
K	10/31/2014	7828	See DCR 01792. Updated document to current format. Changed nearly every section of the QMS to comply with the requirements of AS9100 revision C. Replaced Figure 1 with reference to form 251226.
L	11/11/2014	7867	See DCR 02002. 4.1: Deleted list of forms from second bullet.
M	01/06/2015	8004	See DCR 02117. 4.1: Changed "Process Flow Diagram (Appendix 1)" to "Process Flowchart 242428". Added bullet on controlling outsourced processes.

			<p>4.3: Added 242428. 5.6.3: Was 5.7 – corrected numbering. 7.4.1: Added bullet on documentation of control of outsourced processes. Appendix 1: Deleted.</p>
N	07/09/2015	8648	<p>See DCR 02689. 0.3: Changed “see form 251226” to “see LORD Corporation website”. 1.1: Added new first paragraph. 5.5.1: Changed “in Stellar Technology form 251226” to “on the LORD Corporation website”.</p>

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9.0 Appendix 1 – Process Flow DiagramError! Bookmark not defined.

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 AS9100, ISO 9001 and any applicable statutory and regulatory requirements. This system addresses the design, development, production, and servicing of the company's products.

This manual describes the QMS, and 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 and continuous improvement, and to 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. External copies are considered uncontrolled.

0.2 Distribution

The Quality Manual is available for viewing on Stellar Information System. A bill of material is part of QM-001 and lists each standard operation procedure that is part of the QMS. It can be accessed by any employee through Stellar Technology's ERP system and is available in production areas at supervisor terminals.

0.3 Organizational Chart

The Stellar Technology Organization Chart (see LORD Corporation website) 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.

0.4 Quality Policy

Stellar Technology 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, to use their training and experience to produce consistent results, and to always recommend improvements to the assembly process.

In Engineering: We remind each engineer to "plan their projects", "validate and verify their project results", and "execute and document the process". In addition, we remind them to be receptive to 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 relationships.

The Executive Management of Stellar Technology 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 Management System is applicable to design, manufacturing, and maintenance of pressure, load, force, torque, displacement, and temperature sensors, instrumentation, and specialty machining at Stellar Technology locations at 237 Commerce Drive, Amherst, New York, 14228 and 310 Creekside Drive, Amherst, New York, 14228.

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 AS9100, ISO 9001 and any applicable statutory and regulatory requirements.

1.2 Application

Stellar Technology has determined that there are exclusions from the AS9100 Standard:

Various part numbers or product families within the product line will be identified in the order entry process for which the requirements of the AS9100 QMS will be invoked and flagged through to shipping. TO THESE PRODUCTS ONLY will the requirements of AS9100 apply and be identified as such through the process.

2.0 Quality Management System References

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

- ANSI/ISO/ASQ Q9000-2008, Quality Management Systems – Vocabulary
- ISO 9001: 2008 International Organization for Standardization
- ANSI/ISO/ASQ Q9000-2008, Quality Management Systems – Requirements
- ANSI/ISO/ASQ Q9004-2009, Quality Management Systems - Managing for the Sustained Success of an Organization
- ANSI/NCSL Z540-1-1994, Calibration Laboratories and Measuring and Test Equipment – General Requirements
- Society of Automotive Engineers SAE AS9100C - Quality Management Systems – Requirements
- AS9102 - Aerospace First Article Inspection Requirement
- AS9103 - Variation Management of Key Characteristics
- IPC J-STD-001E-2010 - Requirements for Soldered Electrical and Electronic Assemblies
- ASME/ANSI Y14.5 - Dimensioning and Tolerance
- ANSI/NCSL Z-540 – Calibration Laboratories and Measuring Test Equipment – General Requirements

3.0 Quality Management System Definitions

3.1 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.
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.

Term	Definition
Document Change Notification (DCN)	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.
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
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 AS9100 and ISO 9001 standard are being met.
Product	The end item result of meeting all contract terms and conditions. (e.g., manufactured goods, merchandise, services, etc.)

Term	Definition
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; they 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.
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.

Term	Definition
Use-As-Is	A product disposition procedure used to dispose of nonconforming product containing one or more minor nonconformances 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 AS9100 and ISO 9001. 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 (CAPA), and management review.

To design and implement the QMS, Stellar Technology has:

- Addressed customer and applicable statutory and regulatory quality management system requirements.
- Identified the processes needed for the QMS and their application throughout the organization. They have been documented in the Process Flowchart 242428.
- Determined the sequence and interaction of these processes, and illustrated them on Process Flowchart 242428.
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective.
- 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.
- Ensured control over outsourced processes where such processes affect product conformity to requirements. The type and extent of control to be applied to these outsourced processes are as defined by contract as applicable.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in sections 4 through 8 of this QMS manual. Figure 1 shows that the customers of Stellar Technology play a significant role in defining requirements as inputs. Stellar Technology engages in the monitoring of customer satisfaction, which requires the evaluation of information relating to customer perception of whether or not Stellar Technology has met the customer requirements.

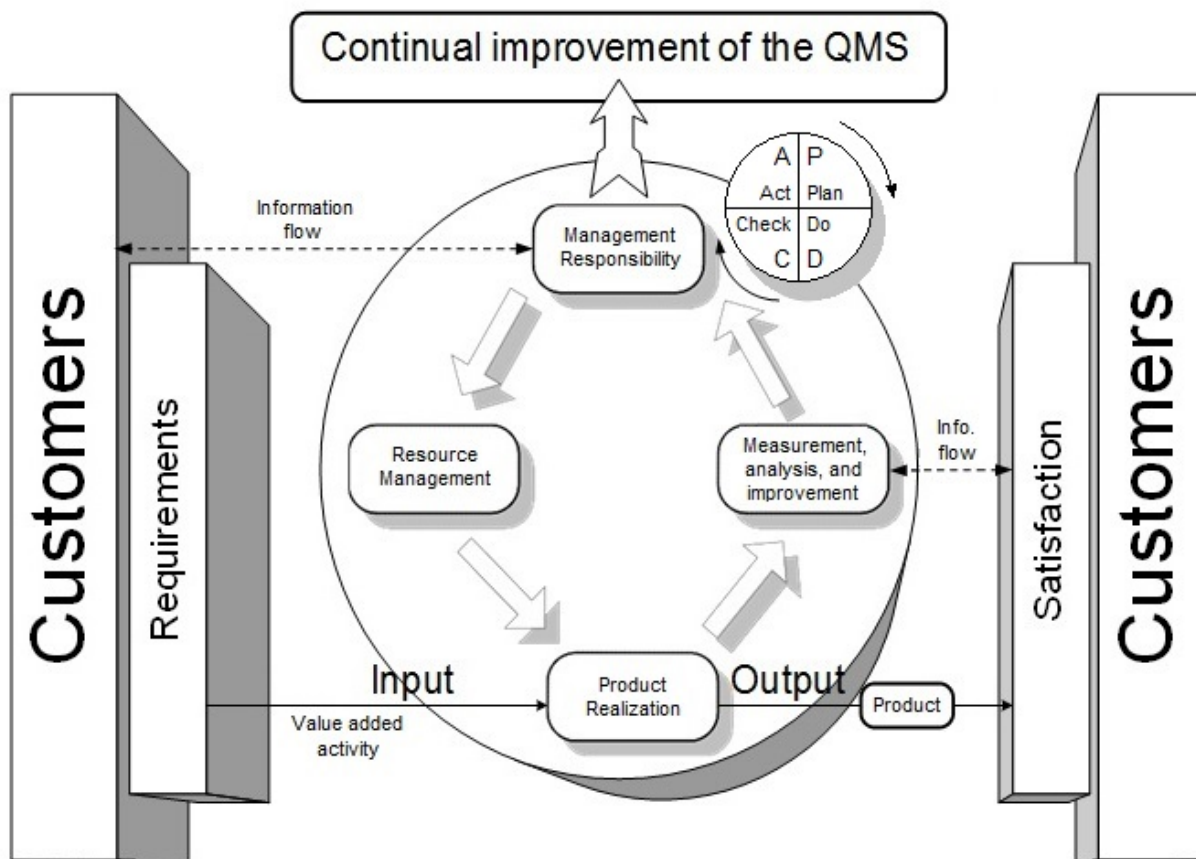


Figure 1: Model of a Process-Based Quality Management System

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.
- Access for all personnel so that the entire company is aware of relevant quality management system documentation and changes.
- Where the term “documented procedure” appears within the QMS, this means that the procedure is established, documented, implemented, and maintained. A single document may address the requirements for multiple procedures.
- Documentation may be in any form or type of medium.

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. These documents collectively define a quality system that complies with AS9100, ISO 9001 and any applicable statutory and regulatory requirements.

4.2.3 Control of Documents

All of the QMS documents are controlled according to the Document Control Procedure. Stellar Technology has established and maintains documented procedures to control all documents and data that relate to the requirements of AS9100 and ISO9001 and that are created by and/or retained by suppliers. This procedure shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes which define the processes for:

- Approving documents for adequacy prior to issue.
- Reviewing, 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 applying suitable identification to them if they are retained for any purpose.

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the QMS shall be controlled.

Stellar Technology shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

4.3 Related Procedures

- QP-423: Document Control
- QP-424: Control of Records
- 242428: Form, Process, Flowchart, Process Flow with Metrics

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 for 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 shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved. This will be reviewed and decided at the scheduled Management Review Meetings as per AP-500: Management Responsibility. Additionally, the 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 Stellar Technology's organization using Customer Related Processes.

5.3 Quality Policy

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

Executive Management reviews the Quality Policy at each management review meeting to determine the policy's appropriate to the purpose and its continuing suitability for Stellar Technology's organization. Management will also ensure that it includes a commitment to comply with requirements and continual improvement of the effectiveness of the QMS. Management uses the Quality Policy to provide the framework for establishing and reviewing Stellar Technology's quality objectives. 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 Stellar Technology's efforts in achieving our Quality Policy and reviewed annually for suitability. Objectives have been established at relevant functions and levels within Stellar Technology and are documented in Management Responsibility. Quality objectives are measurable, and reviewed at each management review meeting.

5.4.2 QMS Planning

The QMS has been planned and implemented to meet Stellar Technology's quality objectives and the requirements of section 4.1 of the AS9100 and ISO 9001 standards. Quality planning takes place as changes that affect the QMS are planned and implemented to ensure the integrity of the QMS.

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. The upper tier of the Organizational Chart is shown on the LORD Corporation website. Management will define the responsibilities and authorities of each of the positions on the Organizational Chart, which are reviewed and approved by Executive Management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

5.5.2 Management Representative

The Quality Systems Manager has been appointed by Executive Management as Management Representative. As Management Representative, the individual irrespective of other responsibilities has the following responsibilities 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.
- Have organizational freedom and unrestricted access to top management to resolve management issues.

5.5.3 Internal Communication

Executive Management will ensure 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, including the quality policy and quality objectives. 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.
- Changes that could affect the QMS.
- Recommendations for improvement.

5.6.3 Review Output

During the 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.

5.7 Related Procedures

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

6.0 Resource Management

6.1 Provision of Resources

Stellar Technology has implemented a QMS that complies with the AS9100 and ISO 9001 standards. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system while enhancing customer satisfaction by meeting customer requirements, 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, directly or indirectly, that affects product conformity to requirements. 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 when 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.

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 conformity of product requirements, Stellar Technology has determined the infrastructure needed and defined it in the Infrastructure procedure. 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 Processes procedure. During this planning, management or assigned personnel identify, as appropriate:

- The quality objectives and requirements for the product, which shall include:
 - Product and personal safety.
 - Reliability, availability, and maintainability.
 - Producibility and inspectability.
 - Suitability of parts and materials used in the product.
 - Selection and development of embedded software as applicable.
 - Recycling or final disposal of the product at the end of its life.
- Processes, documentation, and resources required.
- Verification, validation, monitoring, inspection, and test requirements.
- Criteria for product acceptance.
- Records needed to provide evidence that the realization processes and resulting product meet requirements.
- Resources to support the use and maintenance of the product.

The output of quality planning includes documented quality plans, processes, procedures, and design outputs. Configuration Management is established for control of all documents and processes associated with the product.

7.1.1 Project Management

As appropriate for Stellar Technology and the product, product realization shall be planned and managed in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

Stellar Technology shall establish, implement, and maintain a process for managing risk to achieve applicable requirements that includes, as appropriate to the organization and the product:

- Assignment of responsibilities for risk management.
- Definition of risk criteria (e.g., likelihood, consequences, risk acceptance).
- Identification, assessment, and communication of risks throughout product realization.
- Identification, implementation, and management actions to mitigate risks that exceed the defined risk acceptance criteria.
- Acceptance of risk remaining after implementation of mitigating action.

7.1.3 Configuration Management

Stellar Technology shall establish, implement and maintain a configuration management process that includes, as appropriate to the product:

- Configuration management planning.
- Configuration identification.
- Change control.
- Configuration status accounting.
- Configuration audit.

7.1.4 Control of Work Transfers

Stellar Technology shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of that work to requirements.

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. 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 intended use, where known.
- Statutory and regulatory requirements applicable to the product.
- Additional requirements determined by Stellar Technology.

Customer requirements, including special requirements, are determined according to the Customer Related Processes procedure.

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. The review will be conducted before Stellar Technology commits to supply the product to the customer. 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.
- Special requirements of the product are identified.
- Risks (e.g., new technology, short delivery time frame) have been identified.

In some situations, such as internet sales or direct sales, formal review is impractical for each order. Instead, the review can cover relevant product information such as catalogues or marketing material.

7.2.3 Customer Communication

Stellar Technology has implemented an effective procedure 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 outlines the process for controlling the design and development process. The Engineering Department plans design and development according to the Design and Development procedure. Where appropriate, Engineering will divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data, and planning constraints. The different design and

development tasks to be carried out are based on the safety and functional objectives of the product in accordance with customer, statutory, and regulatory requirements. The design and development 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.
- The ability to produce, inspect, test, and maintain the product.

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure. All inputs are reviewed for adequacy, and 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.

Requirements shall be complete, unambiguous, and not in conflict with each other. These requirements shall be reviewed for adequacy at the first stage of the process, during the Preliminary Design Review.

7.3.3 Design and Development Outputs

Outputs of design and development are documented according to the Design and Development procedure. They are documented in a format that enables verification against the design and development inputs, and are approved prior to release. Outputs:

- Meet the input requirements for design and development.
- Provide appropriate information for purchasing, production, and service provisions.
- Contain or reference product acceptance criteria.
- Specify the characteristics of the product that are essential for its safe and proper use.
- Specify, as applicable, any critical items, including any key characteristics and specific actions to be taken for these items.

Upon completion of design and development, the data required to allow the product to be identified, manufactured, inspected, used, and

maintained shall be established. This shall include: drawings, parts list, and specifications necessary to define the configuration and the design features of the product. Also defined shall be the material, process manufacturing, and assembly data needed to ensure conformity of the product.

7.3.4 Design and Development Review

The design plan specifies suitable stages of the project to conduct design and development review. Systematic 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 and shall:

- 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.
- Authorize progression to the next stage/phase.

At each stage of review, the lead engineer shall maintain and distribute meeting minutes to summarize status and agreed-upon changes. The DCD will also be maintained and distributed accordingly. Impact on the project plan shall be integrated and distributed.

7.3.5 Design and Development Verification

Design and Development Verification shall be performed according to Design and Development procedure to ensure that the design and development outputs have met the design and development input requirements. Results shall be tabulated in a summary report. The verification requirements shall be itemized and detailed within the project plan.

7.3.6 Design and Development Validation

Design and development validation is performed according to the Design and Development procedure to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

Design and Development Validation shall be assessed from data representing the accuracies, repeatability, etc. of the equipment and processes used for product verification. Most of the validation will be assessed from the Quality System records supporting calibration,

measurement, and associated processes. When specialized test or measurement is required, a detailed plan shall be prepared to qualify the new methodology. Traceability to National Standards or physical phenomena shall be established.

7.3.6.1 Design and Development Verification and Validation Testing

Where tests are necessary for verification and validation, tests are planned, controlled, reviewed and documented to ensure and prove the following:

- Test plans or specifications identify the product being tested and the resources being used, and define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria.
- Test procedures describe the method of operation, the performance of the test, and the recording of the results.
- The correct configuration of the product is submitted for the test.
- The requirements of the test plan and the test procedures are observed.
- The acceptance criteria are met.

7.3.6.2 Design and Development Verification and Validation Documentation

At the completion of design and/or development, the summary report shall demonstrate compliance of the specification requirements to the final product definition or ICD for all identified operational conditions.

7.3.7 Control of Design and Development Changes

During the Design and Development process, changes are identified and all activities related to the identified changes are recorded according to the Design and Development procedure. The changes will be reviewed, verified and validated, as appropriate, and approved before implementation. The review of these changes will include evaluation of the effect of the changes on constituent parts and product already delivered. Design and Development changes are controlled in accordance to configuration management procedure(s).

7.4 Purchasing

7.4.1 Purchasing Process

The Purchasing procedure is followed to ensure that purchased product conforms to the specified purchase requirements. In addition, it ensures conformity of all products purchased from suppliers, including product from sources defined by the customer. 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 and includes as follows:

- Maintaining a register of suppliers that includes approval status (i.e., approved, conditional, disapproved) and the scope of the approval (i.e., product type, process family).
- Periodic reviews conducted of supplier performance where the results are used as a basis for establishing the level of controls to be implemented.
- Documented corrective and preventive actions (CAPAs) when dealing with suppliers that do not meet requirements.
- Where required, evidence that Stellar and all suppliers use customer-approved special process sources and document accordingly.
- Documented process defining responsibilities and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of suppliers depending on the supplier's approval status.
- Documented evidence for determining and managing the risk when selecting and using suppliers.
- Documentation of control of outsourced processes as required.

7.4.2 Purchasing Information

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

- Requirements for approval of product, processes, and equipment.
- Requirements for qualified personnel.
- QMS requirements.
- Identification and revision status of specification, drawings, process requirements, inspection/verification instructions, and other relevant technical data.
- Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the Stellar Technology, and (as applicable) critical items including key characteristics.
- Requirements for test specimens (production methods, number, storage conditions) for design approval, inspection/ verification, investigation, or auditing.
- Requirements regarding the need for the supplier to:
 - Notify the Stellar Technology of nonconforming product.
 - Obtain approval for nonconforming product disposition.
 - Notify the Stellar Technology of changes in product and/or process, changes of suppliers, and changes in manufacturing facility location, and (where required) obtain approval.

- Flow down to the supply chain the applicable requirements including customer requirements.
- Records retention requirements.
- Right of access by Stellar Technology, their customer, and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

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.

Verification activities may include:

- Objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records).
- Inspection and audit at the supplier's premises.
- Review of the required documentation.
- Inspection of products upon receipt.
- Delegation of verification to the supplier or supplier certification pending delegation requirements and addition to our supplier records.

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 Control of Production and Service Provision. –Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product, which may include drawings, material and process specifications, parts lists, and drawings.
- The availability of work instructions, which may include process flow charts, travelers/routers, work orders, and inspection documents.
- The use of suitable equipment, which may include product-specific tools and fixtures, and software programs.
- The availability and use of monitoring and measuring devices.

- The implementation of monitoring and measurement.
- The implementation of release, delivery, and post-delivery activities.
- Accountability for all product during production (parts quantities, split orders, nonconforming product).
- Evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized.
- Provision for the prevention, detection, and removal of foreign objects and debris (FOD).
- Monitoring and control of utilities and supplies (water, compressed air, electricity, chemical products) to the extent they effect conformity to product requirements.
- Criteria for workmanship, specified in the clearest practical way.

Planning considers, as appropriate:

- Establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified.
- Design, manufacture and use of tooling to measure variable data.
- Identification of in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization.
- Special processes.

7.5.1.1 Production Process Verification

Stellar Technology will use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process will be repeated when changes occur that invalidate the original results.

7.5.1.1.1 Production Process Documentation

Production operations shall be carried out in accordance with approved data. This data shall contain, as necessary, First Article Inspection as per the requirements of AS9102 or equivalent, which shall be performed as verification.

7.5.1.2 Control of Production Process Changes

- Process changes shall be identified to authorize and approve changes to production processes. They shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

- Changes affecting processes, production equipment, tools, and programs shall be documented. Procedures shall be available to control their implementation.
- The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

7.5.1.3 Control of Production Equipment, Tools and Numerically Controlled (NC) Programs

Production equipment, tools, and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to design data/specification.

Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.

7.5.1.4 Post Delivery Support

Post Delivery Support shall provide as applicable for the:

- Collection and analysis of in-service data.
- Actions to be taken, including investigations and reporting, when problems are detected after delivery.
- Control and updating of technical documentation.
- Approval, control, and use of repair schemes.
- Controls requirements for off-site work (work undertaken at the customer's facilities).

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

- Maintaining the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed-upon configuration.
- Establishing and documenting controls for media when acceptance authority media are used (e.g., stamps, electronic signatures, passwords).

Where traceability is a requirement, Stellar Technology shall control and record the unique identification of the product. According to the level of traceability required by a contract, regulatory, or other established requirement, Stellar Technology's system shall provide for:

- Identification to be maintained throughout the product life of all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced.
- Recording of the destination (delivery, scrap) of all products of the same batch for an assembly, as well as the identity of its components and those of the next higher assembly to be traced for a given product
- A sequential record of its production (manufacture, assembly, inspection) to be retrieved.

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, Customer Property, which 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 Preservation of Product. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

Preservation of the product also includes, where applicable, new product specifications, applicable statutory and regulatory requirements, and provisions for:

- Cleanliness.
- Prevention, detection, and removal of foreign objects.
- Special handling for sensitive products.
- Marking and labeling including safety warnings.
- Shelf life control and stock rotation.
- Special handling for hazardous materials.

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, Control of Monitoring and Measuring Devices, outlines the process used to ensure that monitoring and measurement is carried out in a manner that is consistent with the monitoring and measurement requirements.

Stellar Technology maintains a register of these monitoring and measuring devices, and defines the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method, and acceptance criteria.

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 ensures that environmental conditions are suitable for the calibration, inspection, measurement, and testing being carried out. The Quality department shall assess and record the validity of the previous measuring results when the equipment is found not conforming to requirements. Stellar Technology takes appropriate action regarding the equipment and any product affected and shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification. Records of all 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 is performed 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
- QP-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.

Note: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

- Design verification (reliability, maintainability, safety).
- Process Control:
 - Selection and inspection of key characteristics.
 - Process capability measurements.
 - Statistical process control.
 - Design of experiment.
 - Inspection.
 - Failure mode, effect and criticality analysis.

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 and Management Responsibility procedure.

The information is monitored and used for the evaluation of customer satisfaction which includes, but is not limited to, product conformity, on-time delivery performance, customer complaints, and corrective action requests. Stellar Technology develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assesses the effectiveness of the results.

8.2.2 Internal Audit

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

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

An audit program has been designed and implemented that 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.

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 and Management Responsibility procedure.

In the event of process nonconformity, Stellar Technology shall:

- Take appropriate action to correct the nonconforming process.

- Evaluate whether the process nonconformity has resulted in product nonconformity.
- Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or product.
- Identify and control any nonconforming product.

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.

Evidence of conformity with the acceptance criteria and/or rejection 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.

Additionally, Stellar Technology's inspection reports shall document measurement requirements for product acceptance, which include:

- Acceptance criteria and/or rejection.
- Where in the sequence measurement and testing operations are to be performed.
- Required records of the measurements results (at a minimum, indication of acceptance or rejection).
- Any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified, Stellar Technology ensures they are controlled and monitored by an established process:

- The First Article Inspection (FAI) process provides for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection.
- Where product is released for production use pending completion of all required measurement and monitoring activities, the product is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.
- Where required to demonstrate product qualification, Stellar Technology ensures that records provide evidence that the products meets the defined requirements.
- Stellar Technology ensures that all documents required to accompany the product are present at delivery.

8.3 Control of Nonconforming Product

Stellar Technology ensures that products that 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.

Note 1: The term “nonconforming product” includes nonconforming product returned by the customer.

Note 2: Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities.

Where applicable, Stellar Technology deals with nonconforming product by one or more of the following ways by:

- Taking action to eliminate the detected nonconformity.
- Authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer.
- Taking action to preclude its original intended use or application.
- Taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.
- Ensuring that the “nonconforming product control process” shall provide for timely reporting of delivered nonconforming product.

Stellar Technology's documented procedure defines the responsibilities and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions by taking action necessary to contain the effect of the nonconformity on other processes or product.

The procedure ensures that dispositions of USE AS IS or REPAIR shall only be used after approval by an authorized representative of the organization responsible for the design.

Note 3: Authorized representative includes personnel having delegated authority from the design engineering.

The Quality Department shall not use dispositions of USE AS IS or REPAIR, unless specifically authorized by the customer, and if the nonconformity results in a departure from the contract requirements.

Product that is dispositioned for SCRAP, shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

8.4 Analysis of Data

Stellar Technology determines, collects, and analyzes 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. 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 the Quality Policy, quality objectives, audit results, analysis of data, corrective and preventative actions (CAPAs), and management review. Stellar Technology monitors the implementation of improvement activities and evaluates the effectiveness of the results.

Note: Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.

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, Corrective and Preventive Action, 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 section 4.2.4).
- Reviewing corrective action taken.

- Flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,
- Specific action where timely and/or effective corrective actions are not achieved.
- Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

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, Corrective and Preventive Action, 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.

Note: Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.

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-850: Corrective and Preventive Action