| Revision Level | Reason for Revision | Originator | Date |
|---|---|---|---|
| 0 | Incorporated Quality Manual | R. Deptola | 10-16-03 |
| 1 | Changed format from date controlled to revision controlled | R. Deptola | 3-19-04 |
| 2 | Replaced SOP1008 with QM1 7.5.1 | R Deptola | 5/31/06 |
| 3 | Added reference to SOP 1315,<br>Added 7.5.3 (1) | J Lundeen | 2-26-07 |
| 4 | Added reference to SOP1002 to section 4.2.3<br>Removed sentence about “special processes” in section 7.5.2<br>Revised last paragraph in section 7.2.2<br>Revised Appendix B<br>Updated Org. Chart – Appendix A<br>Changed clause number from 8.2.5 to 8.3 Control of Non-Conforming Product | L Urman | 2-18-08 |
| **5** | Replaced Appendix C – QMS Flowchart with FAA Supplement<br>Added reference about FAA Supplement to section 3.0<br>Replaced Appendix B with .doc format<br>Deleted item 4.2.2 (c) Replaced reference to SOP 1526 with SOP 1311 in section 7.4.3 | L. Urman | 4/10/08 |
| **6** | Revised Quality Policy<br>Added Special Process definition in Section 7.5.2 | L. Urman | 4/30/08 |
| **7** | Revised Appendix A – Organizational Chart to show only position titles | L. Urman | 1/16/09 |
| **8** | Replaced ISO 9001:2000 with ISO 9001:2008 throughout the Manual, Revised section 1.0, revised Appendix C (FAA Supplement) to comply with the new requirements, inserted revised quality policy in section 5.3, deleted paragraph in Section 5.4.2, revised 5.6.1, Revised Appendix B & FAA supplement to reflect new Purchasing SOP #’s | L. Urman | 4/15/10 |
| **9** | Added 4.2.2 c and APPENDIX D | M.Auman | 05/19/10 |
| **10** | Revised “Appendix C” to reflect FAA Plain Language | M.Auman | 10/14/10 |
| **11** | Revised “Appendix C” to reflect FAA Atlanta MIDO recommendations | L. Urman | 12/13/10 |
| **12** | Revised Appendix C and updated signatures | S. Charlton | 03/28/11 |
| **13** | Revised Appendix C to Update cover sheet and add FAA revision level | M. Auman | 07/13/11 |
| **14** | Revised Appendix A,B,C,D, 4.2.4, Changed Policy Statement,5.6.1, | Ackerman | 3/1/13 |
| **15** | Updated manual to reflect the changes made to the ISO 9001:2008 standard that was missed in revision 8 and corrected language. | K.Ackerman | 7/05/13 |

## Section 1.0 - Table of Contents

## 1.0 Saft America Inc.-Valdese Quality Objectives

The objective of the Lithium Battery Division is to strengthen its position as world leader in its primary activity and ensure fast growth in its rechargeable activity. This involves satisfying its customers.

To attain these objectives, all the technical, industrial, commercial and administrative processes are reviewed regularly and objectively with the help of indicators and audits. The resulting action plans are aimed at swiftly increasing our levels of control over all the aspects of our activities, on a sustainable basis.

Our policy is built around five major themes:

- ⇨ Collecting and understanding customer requirements from the design stage onwards, for the products, the processes and the equipment, in order to supply customers with the products and services they expect.
- ⇨ Deployment of continuous improvement methodologies, making up the SAFT “World Class” program (PDCA, 5S, SMED, TPM, KAIZEN...).
- ⇨ Rigor in planning activities and flexibility in their execution to exceed the objective of delivering orders to the customer's desired date.
- ⇨ Development and involvement of the staff at all levels by encouraging initiative, responsibility and communication.
- ⇨ Control of all the environmental aspects throughout the cycle of product design, manufacture and delivery.

The Lithium Battery Division has adopted a Quality System based on the ISO 9001 latest revision.. All involved are responsible for applying its rules and complying with its principles.

The Quality Manager for the site is entrusted, together with their associates, with the task of ensuring the quality policy is correctly applied and reviewied periodically with the Departments and the Executive Committee.

## 2.0 COMPANY BACKGROUND AND INFORMATION

The Saft America Inc. - Valdese facility started in 1989. The facility is in Valdese, North Carolina and is approximately 103,000 square feet. The plant began as a design and manufacturing facility for Lithium Sulfur Dioxide (LiSO2) batteries. When the Valdese facility started, the only customer was the United States military.
In the early 1990's, the Valdese facility began expanding the customer base to commercial and non-domestic military businesses. Throughout the 90's, the LiSO2 chemistry grew along with the introduction of various product lines. These new product lines included the design and manufacture of rechargeable lithium chemistries, and the facility also became the North American distributor for Lithium Thionyl Chloride and Lithium Ion batteries.
With the new millennium, Saft America Inc.-Valdese facility began design and manufacture of Manganese Dioxide (MnO2) batteries. Shortly thereafter, they became a manufacturer and distributor of Nickel Cadmium (NiCd) batteries. Saft-America Inc.-Valdese is currently the largest Lithium Sulfur Dioxide (LiSO2) battery manufacturer in the world.

## 3.0 - Scope of Quality Manual

The Scope includes: Design, Development, Manufacture and Distribution of Primary Lithium cells and batteries, nickel, cadmium batteries, lithium-ion rechargeable cells and batteries.

Servicing is excluded because servicing is not performed.

The Quality Management System described in and referenced by this manual applies to Saft America Inc.-Valdese and meets all requirements of the ISO 9001 latest revision. Specific requirements for the Federal Aviation Regulation CFR Title 14 Part 21 are found in Appendix C – FAA Supplement of this Manual.

All Saft America Inc.-Valdese personnel, directly or indirectly, have quality responsibilities and authorities as outlined in their job descriptions, relevant procedures, and work instructions. The Quality Manager serves as the ISO Management Representative, and as such, has direct responsibility and authority for ensuring an effective Quality Management System is in place and is compliant with the ISO 9001 latest revision.

## 4.0 General Requirements

### 4.1 Requirements

Saft America Inc.-Valdese has established, documented, implemented and maintains a quality management system (QMS) and continually improves its effectiveness in accordance with the requirements of the ISO 9001lastest revision.

Saft America Inc.-Valdese has:

a) Identified the processes needed for the QMS and their application throughout the organization.
b) Determined the sequence and interaction of these processes.
c) Determined criteria and methods needed to ensure that both the operation and control of these processes are effective.
d) Ensured the availability of resources and information necessary to support the operation and monitoring of these processes.
e) Monitors, measures where applicable and analyzes these processes.
f) Implements the actions necessary to achieve planned results and continual improvement of these processes.

Saft Operating Procedure (SOP) 1001 describes management responsibility and the provision of resources. Product realization and measurement are defined in documented procedures. (See Appendix B for a cross-reference of SOP's to ISO 9001 latest revision.)

The General Manager of Saft America Inc.-Valdese has ultimate responsibility for the QMS. The interrelationships between various departments within the Saft America Inc. – Valdese QMS are outlined in the QMS flowchart Figure 1. Specific QMS responsibilities are assigned to members of the Management Staff.

Where Saft America Inc.-Valdese chooses to outsource any process that affects product conformity to requirements, Saft America Inc.-Valdese ensures control over such processes. Control of outsourced processes is identified in Purchasing procedures, SOP's 2100 – 2199, and related Quality Assurance documentation.

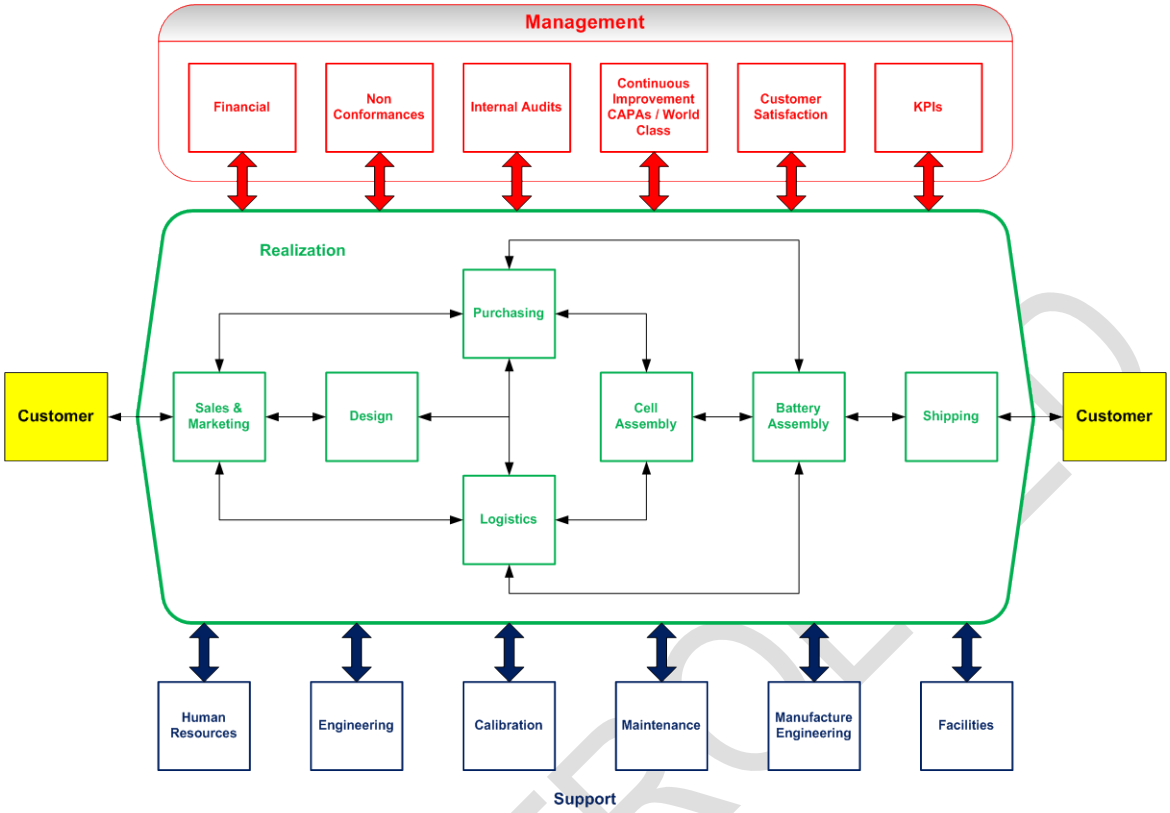


Figure 1

## 4.2 Documentation requirements

### 4.2.1 General

The QMS documentation includes:

a) Documented statements of a quality policy and quality objectives
   ⇒ Reference Section 1.0 of this manual.
b) this quality manual
c) Documented procedures and records required by the ISO 9001 latest revision
   ⇒ Reference Appendix B for a cross-reference of SOP's to ISO 9001: latest revision.
d) Documents, including records, determined by Saft America Inc.-Valdese to be necessary to ensure the effective planning, operation, and control of processes.

### 4.2.2 Quality Manual

Saft America Inc.-Valdese has established and maintains this quality manual that includes:

a) The scope of the QMS, including details of and justification for any exclusion.
b) Documented procedures established for the QMS, or reference to them, and .
   ⇒ Reference Appendix B
c) A description of the interaction between processes of the QMS.
   ⇒ Reference Appendix D

### 4.2.3 Control of Documents

Documents required by the QMS are controlled. Records are a special type of document and are controlled according to requirements defined in 4.2.4.
SOP's 1002 and 1403 have been established to define the controls needed

a) To approve documents for adequacy prior to issue.
b) To review and update as necessary and re-approve documents.
c) To ensure that changes and the current revision status of documents are identified.
d) To ensure that relevant versions of applicable documents are available at points of use.
e) To ensure that documents remain legible and readily identifiable.
f) To ensure that documents of external origin determined by SAFT Valdese to be necessary for the planning and operation of the QMS are identified and their distribution controlled, and;
g) To prevent the unintended use of obsolete documents, and to apply 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 are controlled. .

SOP's 1323 and1004 and Corporate Policy, Policy No. 2.35 defines the controls used for the identification, storage, protection, retrieval, retention time and disposition of records.

Records are legible, readily identifiable, and retrievable

## 5.0 Management Responsibility

### 5.1 Management Commitment

The General Manager provides evidence of his commitment to the development and implementation of the QMS and continually improves its effectiveness by

a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) Establishing the Quality Policy as described in Section 3.0 of this quality manual.
c) Ensuring that quality objectives are established,
d) Conducting management reviews,
e) Ensuring the availability of resources.
⇒ Reference SOP 1001 for Management Responsibility and commitment.

### 5.2 Customer focus

The General Manager ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction. SOP 1801 provides methods for ensuring customer requirements are determined and met. SOP 1408 and 1415 for Product Development ensures that customer requirements are communicated from Design through the manufacturing process.

### 5.3 Quality policy

The General Manager has established and ensures that the quality policy

a) Is appropriate to the purpose of the organization.
b) Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.
c) Provides a framework for establishing and reviewing quality objectives,
d) Is communicated and understood within the organization, and
e) Is reviewed for continuing suitability.

Management Review as described in SOP 1001 is the primary mechanism for reviewing the quality policy and ensuring its continued suitability and effectiveness. Training and new employee orientation as described in SOP 1936 ensures that the quality policy is communicated throughout the entire organization.

**Saft Valdese Quality Policy states:**

**Saft, Valdese is committed to achieve Total Quality through World Class Performance. World Class Performance is – Improvement, Execution and Innovation. We as individuals and teams strive to improve our products with flawless execution and in so doing; we add value to our customers and our business. We are dedicated to satisfying our customers with innovative solutions and products without error, on time, every time.**

## 5.4 Planning

### 5.4.1 Quality objectives

Through the Management Review Process, the General Manager and his Staff ensure that the quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within SAFT Valdese. The quality objectives are measurable and consistent with the quality policy.

### 5.4.2 Quality management system planning

The General Manager ensures that

a) The planning of the QMS is carried out in order to meet the requirements stated in section 4.1, as well as the quality objectives and,
b) The integrity of the QMS is maintained when changes to the QMS are planned and implemented.

Saft develops corporate goals and objectives to be met by the entire corporation. Saft Valdese develops plant-specific goals and objectives based on these corporate objectives. Departmental goals and objectives are defined based on the plant-specific goals and objectives.

Yearly plant goals and individual department goals tie back to the top level so that all Saft personnel understand their participation and impact on quality.

## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

The General Manager ensures that responsibilities and authorities are defined and communicated within SAFT Valdese.

### 5.5.2 Management Representative

The General Manager has appointed the Quality Manager who, irrespective of other responsibilities, has responsibility and authority that includes:

a) Ensuring that processes needed for the QMS are established, implemented, and maintained,
b) Reporting to the General Manager the performance of the QMS and any need for improvement,
c) Ensuring the promotion of awareness of customer requirements throughout the organization.

### 5.5.3 Internal communication

The General Manager ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS.

The Quality Manager communicates QMS matters to the General Manager on a monthly basis through monthly reports. All departments communicate QMS goals and results through monthly reports.

QMS matters are communicated to all personnel through Safety-Quality-Cost-Delivery (SQCD) boards posted in various areas throughout the facility. *The Echo* (Saft Valdese internal newsletter) also communicates various quality issues to all personnel.

Quality alerts also serve to communicate specifics to personnel who are directly involved with the respective quality issue.

## 5.6 Management Review

### 5.6.1 General

The General Manager and his Staff review Saft America Inc.-Valdese's QMS per the items in Section 5.6.2. At a minimum the reviews are held semi-annually or as needed to ensure its continuing suitability, adequacy and effectiveness. As defined in SOP 1001, this review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Records from management reviews are maintained.

### 5.6.2 Review Input

The Management Review procedure/agenda defines the items to be reviewed during Management Reviews and includes information on

a) Results of audits,
b) Customer feedback,
c) Process performance and product conformity,
d) Status of preventive and corrective actions,
e) Follow-up actions from previous management reviews,
f) Changes that could affect the QMS, and
g) Recommendations for improvement.

### 5.6.3 Review Output

The output from the Management Review includes any decisions and actions related to

a) Improvement of the effectiveness of the QMS and its processes,
b) Improvement of product related to customer requirements, and
c) Resource needs.

## 6.0 Resource Management

### 6.1 Provision of resources

The General Manager, along with the management staff, determines and provides the resources needed

a) To implement and maintain the QMS and continually improve its effectiveness, and
b) To enhance customer satisfaction by meeting customer requirements.

### 6.2 Human Resources

#### 6.2.1 General

Personnel performing work affecting conformity to product requirements have been determined competent on the basis of appropriate education, training, skills and experience.

#### 6.2.2 Competence, awareness, and training

SOP 1936 defines the procedure for

a) Determining the necessary competence for personnel performing work affecting product conformity to product requirements,
b) Where applicable, providing training or taking other actions to achieve the necessary competence,
c) Evaluating the effectiveness of the actions taken,
d) Ensuring that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) Maintaining appropriate records of education, training, skills and experience.

### 6.3 Infrastructure

Saft America Inc.-Valdese has determined, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) Buildings, workspace and associated utilities,
b) Process equipment (both hardware and software), and
c) Supporting services (such as transport, communication or information systems).

### 6.4 Work environment

Saft America Inc.-Valdese has determined and manages the work environment needed to achieve conformity to product requirements.

The Management Responsibility and Training procedure addresses infrastructure and work environment as related to resource allocation in both manufacturing and administrative/support areas. SOP 1309, Process Control, and supporting Manufacturing, Maintenance and work instructions define the methods for managing the work environment.

## 7.0 Product Realization

### 7.1 Planning of Product Realization

Saft America Inc.-Valdese has planned and developed the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the QMS.

In planning product realization, Saft America Inc.-Valdese has determined the following, as appropriate:

a) quality objectives and requirements for the product

b) the need to establish processes and documents, and to provide resources specific to the product
c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance
records needed to provide evidence that the realization processes and resulting product meet requirements

SOP 1406, 1408 and 1415 defines the methods used to develop and communicate designs to the manufacturing area. SOP 1304 and 1309 define the methods used for controlling manufacturing processes. Work instructions and other supporting documentation provide guidance and methods to be used by manufacturing personnel to ensure the control of processes that affect quality.

### 7.2 Customer-related processes

#### 7.2.1 Determination of the requirements related to the product

SOP 1801 and 1802 define:

a) the requirements specified by the customer, including the requirements for delivery and post-delivery activities
b) requirements not stated by the customer but necessary for specified or intended use, where known
c) statutory and regulatory requirements applicable to the product, and
d) any additional requirements considered necessary by Saft America Inc.-Valdese.

#### 7.2.2 Review of requirements related to the product

SOP 1801 defines the method for the review of requirements related to the product. This review is conducted prior to Saft, Valdese commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) to ensure that:

a) product requirements are defined
b) contract or order requirements differing from those previously expressed are resolved, and
c) SAFT, Valdese has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained as defined by SOP 1323.

Saft America Inc.-Valdese does not provide customer requirements without a documented statement of those requirements by the customer.

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by Saft, Valdese before acceptance, see SOP 1410.

Changes to product requirements are allowed. Saft America Inc.-Valdese ensures that relevant documents are amended and relevant personnel are made aware of the changed requirements. SOP 1403, 1410 and SOP 1801 define the methods to carry out product changes, maintain the records associated with the changes and appropriate personnel are made aware of any change in product requirements.

#### 7.2.3 Customer communication

Effective arrangements are in place and implemented for communicating with customers in relation to

a) product information
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints

SOP 1410 defines communication with customers on product information and changes. Customer complaint and corrective action procedures SOP's 1329 and 1803 provides customer communication and feedback in regards to product issues.

### 7.3 Design and development

#### 7.3.1 Design and development planning

Saft America Inc.-Valdese plans and controls the design and development of product.

During the design and development planning, Saft America Inc.-Valdese determines

a) the design and development stages
the review, verification and validation that are appropriate to each design and development stage for which Saft America Inc.-Valdese is responsible
b) the responsibilities and authorities for design and development

Saft America Inc.-Valdese manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

#### 7.3.2 Design and development inputs

Design inputs relating to product requirements are determined and records maintained. Design inputs include:

a) functional and performance requirements
b) applicable statutory and regulatory requirements
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

Inputs are reviewed by Saft America Inc.-Valdese for adequacy per SOP's 1408 and 1415. Requirements are complete, unambiguous, and not in conflict with each other.

#### 7.3.3 Design and development outputs

Outputs of design and development are in a form suitable for verification against the design and development input and are approved prior to release, see SOP's 1408 and 1415.

Design and development outputs:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and service provision,
c) contain or reference product acceptance criteria, and
d) specifies the characteristics of the product that are essential for its safe and proper use.

#### 7.3.4 Design and development review

Systematic reviews of design and development are performed in accordance with planned arrangements as defined in SOP's 1408 and 1415:

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

These reviews include representatives from all functions concerned with the design and development stage being reviewed.. Records of the results of the reviews and any necessary actions are maintained.

### 7.3.5 Design and development verification

Verification is performed in accordance with planned arrangements as defined in SOP 1408, 1415 and 1318 to ensure that design and development outputs have met the defined design and development input requirements.. Records of the results of the verification and any necessary actions are maintained in accordance with SOP 1408, 1415 and 1323.

### 7.3.6 Design and development validation

Design and development validation is performed in accordance with planned arrangements as defined in SOP 1408, 1415 and 1318 to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Where practical, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained in accordance with SOP 1323.

### 7.3.7 Control of design and development changes

Design and development changes are identified and records maintained in accordance with SOP 1408 and 1415. The changes are reviewed, verified, and validated, as appropriate, and approved before implementation. The review of design and development changes includes the evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions are maintained.

## 7.4 Purchasing

### 7.4.1 Purchasing process

Purchasing procedures, SOP's 2100 – 2199; define the methods for ensuring that purchased products and services conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Saft America Inc.-Valdese Materials, Quality Assurance, and Engineering departments determine this and ensure that purchasing documents define these requirements.

Suppliers are evaluated and selected based on their ability to supply product/services in accordance with the specified requirements. The criteria for selection, evaluation and re-evaluation are established as defined in SOP 2117. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

### 7.4.2 Purchasing information:

The purchasing documentation describes the product to be purchased, including, where appropriate

a) Requirements for approval of product, procedures, processes, and equipment
b) Requirements for qualification of personnel, and
c) QMS requirements.

SAFT, Valdese ensures the adequacy of specified purchase requirements prior to their communication to the supplier per SOP's 1408, 1415 and 2104.

### 7.4.3 Verification of purchased product

SOP 1312 has established the inspection activities necessary for ensuring that purchased product meets specified purchase requirements.

Where Saft.-Valdese, or its customer, intends to perform verification at the supplier's premises, SOP 1311 states the intended verification arrangements and method of product release in the purchasing information.

## 7.5 Production and service provision

### 7.5.1 Control of production and service provision

SOP's 1009, 1309 and 1318 defines the controlled conditions under which production is planned and carried out. Controlled conditions include, as applicable:

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment
d) the availability and use of monitoring and measuring equipment,
e) the implementation of monitoring and measurement, and
f) the implementation of product release, delivery and post-delivery activities.

Saft America Inc.-Valdese has various work instructions and documentation as described in SOP's 1301, 1318, and 1002.

The following paragraph defines all of Saft America Inc.-Valdese involvement with Servicing.
Servicing is not applicable at Saft America, Lithium Battery Division. There are no specified requirements for Servicing and, due to nature of the product, Servicing has no relevancy.

### 7.5.2 Validation of processes for production

Saft, Valdese has validated all processes for production where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use.

Validation has demonstrated the ability of these processes to achieve planned results.

Saft, Valdese has established arrangements for these processes including, as applicable,

a) Defined criteria for review and approval of the processes,
b) Approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) Requirements for records (SOP 1323), and
e) Revalidation.

- Identified processes used in the fabrication system are: soldering and welding and shall be accomplished in accordance with approved data and controlled and inspected in accordance with:

a) USW-"n" Ultrasonic Weld Settings
b) ICW "n" Intercell Weld Settings
c) WTW-"n" Wire to Tab Weld Settings
d) ITP-0206-1 Weld Qualification Report

### 7.5.3 Identification and traceability

Where appropriate, product is identified by suitable means throughout product realization as defined by SOP 1332.

The product status is identified with respect to monitoring and measurement requirements as defined in SOP 1319.

1. If work instructions require formal inspection and acceptance before processing continues, such acceptance will be indicated by the presence of a Quality Assurance stamp. The Quality Assurance stamps will be controlled as defined in ITP-0723.

Where traceability is a requirement, Saft, Valdese issues a unique and controlled serial number for each product and maintains the records per SOP 1323.

### 7.5.4 Customer property

Saft America Inc.-Valdese exercises care with customer property while it is under Saft America Inc.-Valdese's control or being used by Saft America Inc.-Valdese. Saft America Inc.-Valdese identifies, verifies, protects, and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records are maintained. SOP 1410 and 1529 defines the procedures used for customer-supplied property.

### 7.5.5 Preservation of product

Saft America Inc.-Valdese preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements, as defined in SOP 1508 and SOP 1709. Where applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies the constituent parts of the product.

### 7.6 Control of monitoring and measuring equipment

Engineering determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements as defined in SOP 1318.

Saft America Inc.-Valdese has established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, as defined in SOP 1307, measuring equipment has been:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded;
b) adjusted or re-adjusted as necessary;
c) identified in order to determine its calibration status;
d) safeguarded from adjustments that would invalidate the measurement result;
e) protected from damage and deterioration during handling, maintenance and storage.

Quality Assurance also assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements as defined in SOP 1307. Per SOP 1307 and 1313 appropriate action is taken on any equipment or product affected.

Records of the results of calibration and verification are maintained.

Any measurement-related software is controlled through the maintenance/calibration of the related hardware. This is undertaken prior to initial use and reconfirmed per the established calibration schedule.

## 8.0 Measurement, Analysis and Improvement

### 8.1 General

Saft America Inc.-Valdese, through policy deployment, has planned and implemented the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to product requirements,
b) to ensure conformity of the QMS, and
a) to continually improve the effectiveness of the QMS

This includes determination of applicable methods, including statistical techniques, and the extent of their use as defined in SOP 1320.

### 8.2 Monitoring and Measurement

#### 8.2.1 Customer satisfaction

Saft America Inc.-Valdese monitors information relating to customer perception as to whether the organization has met customer requirements through the use of corrective actions, customer complaints, and customer feedback.

Collection and analysis of customer satisfaction data per SOP 1806 ensures relevant information is available for management to review. The review of these measures during Management Review ensures that customer satisfaction is reviewed by the General Manager and his Staff.

#### 8.2.2 Internal audit

Internal audits are conducted at a minimum of once per year, to determine whether the QMS:

a) conforms to the planned arrangements for product realization, to the requirements of ISO 9001 latest revision, and to the QMS requirements established by Saft.-Valdese, and
b) is effectively implemented and maintained.

The audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods are defined in SOP 1314. Auditors are selected and conduct their audits to ensure objectivity and impartiality of the audit process. Auditors do not audit their own work or department.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, are defined in SOP 1314.

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Audit findings are addressed with corrective actions per SOP 1329. Follow-up activities include the verification of the actions taken and reporting of results from the verification.

#### 8.2.3 Monitoring and measurement of processes

Monitoring of the QMS processes occurs continuous for opportunities for improvement. Special focus occurs during the Internal Quality Audit process as defined in SOP 1314 and Management Reviews SOP 1001. These processes demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, per SOP 1329.

#### 8.2.4 Monitoring and measurement of the product

Saft America Inc.-Valdese monitors and measures the characteristics of the product to verify that the product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with planned

arrangements as defined in SOP 1318. Evidence of conformity with acceptance criteria is maintained through inspection and test records.

Certificates of Compliance indicate the person authorizing release of product for delivery to the customer per SOP 1325.

Release of product to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, by the customer and in accordance with SOP 1801 and 1318.

### 8.3 Control of nonconforming product

Saft, Valdese ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. SOP 1313 has been established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, Nonconforming product is dealt with by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
c) by taking action to preclude its original intended use or application,
d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained in accordance with SOP 1323.

### 8.4 Analysis of data

Saft America Inc.-Valdese has determined, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. SOP 1320 describes the use of these statistical techniques. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

a) customer satisfaction
b) conformity to product requirements
c) characteristics and trends of processes and products including opportunities for preventive action, and
d) suppliers.

### 8.5 Improvement

### 8.5.1 Continual improvement

The effectiveness of the QMS is continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### 8.5.2 Corrective action

Action is taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions to be appropriate to the effects of the nonconformities encountered.

SOP 1329 - Corrective Action procedure defines requirements for

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken, and
f) reviewing the effectiveness of the corrective action taken

### 8.5.3 Preventive action

Action also is taken to eliminate the causes of potential nonconformities. Preventive actions to be appropriate to the effects of the potential problems and are defined in SOP 1330.

SOP 1330 - Preventive Action procedure defines requirements for:

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken, and
e) reviewing the effectiveness of the preventive action taken.

All improvement activities, directly or indirectly, are considered as part of the Management Review activities.

| | |
|---|---|
| _____ | _____ |
| General Manager | Quality & World Class Manager |
| _____ | _____ |
| Financial Controller | HR Manager |
| _____ | _____ |
| Operations Manager | Battery Production Manager |
| _____ | _____ |
| Purchasing Manager | Technical Manager |