



**HOTSTART**®

5723 East Alki Avenue - Spokane, WA 99212

**ISO 9001-2008 Quality Manual**

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## 1.0 SCOPE

### 1.1                    OUR QUALITY COMMITMENT

This manual is Hotstart's description of our quality management system. It provides a description of the philosophy of quality and a structure from which all other actions and methods will be accomplished in regard to the quality of our products and services. This document alone does not guarantee an effective quality management system however, our people interacting with quality concepts and methods will provide a system of quality that is dynamic and founded on continually improving the way we do business.

The Management Team approves all concepts and principles in this manual. Assignments are made relative to ownership of specific sections of the quality system. Overall responsibility for effective implementation of the quality system is assigned to the Quality Assurance Manager.

This manual is widely distributed among our employees, customers and suppliers. The concepts contained herein are practical ideas and explanations of how Hotstart manages quality. The practical implementation is contained in our Level II and III procedures and instructions. The Quality Procedures Manual (Level II) is our proprietary approach to implementing the concepts of the Quality manual. The Quality Procedure titled: Quality Manual Deployment describes how each section of the Quality Manual is deployed throughout the organization. All documentation described herein is accessible on our corporate LAN system. Hotstart's Quality Management System is designed to comply with all sections of ISO 9001 version 2008.

Our approach to quality is summarized as follows:

**"Hotstart's policy toward quality is to continually make improvements so that we can fulfill and exceed our customer's expectations."**

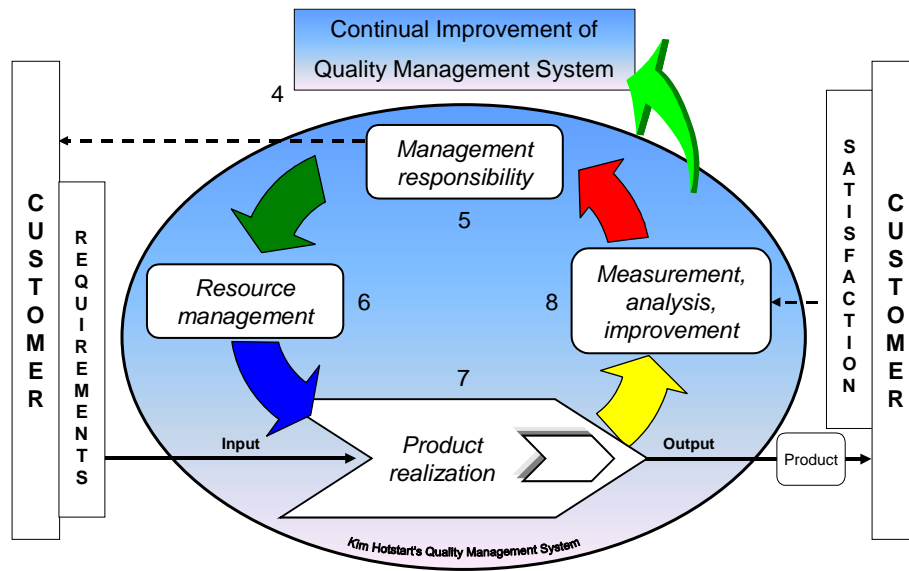
  
Rick Robinson, CEO

Date: 1/19/10

Note: This Quality Manual contains provisions, which through reference in this text constitute compliance to the International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, Hotstart management will investigate the possibility of applying the most recent edition of the International Standard.

## 1.2 HOTSTART' QMS MODEL

The following model is a representation of the 'closed loop' concept of Hotstart's Quality Management System. This model is part of the ISO 9001 Introduction and expands the Deming concepts of Plan-Do-Check-Act. It is provided here as a visual description of the model that Hotstart used to develop figure 2: Hotstart QMS Interrelationship Diagram.



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Revision: 1/3/2000

FIGURE 1 ISO 9001 QMS MODEL

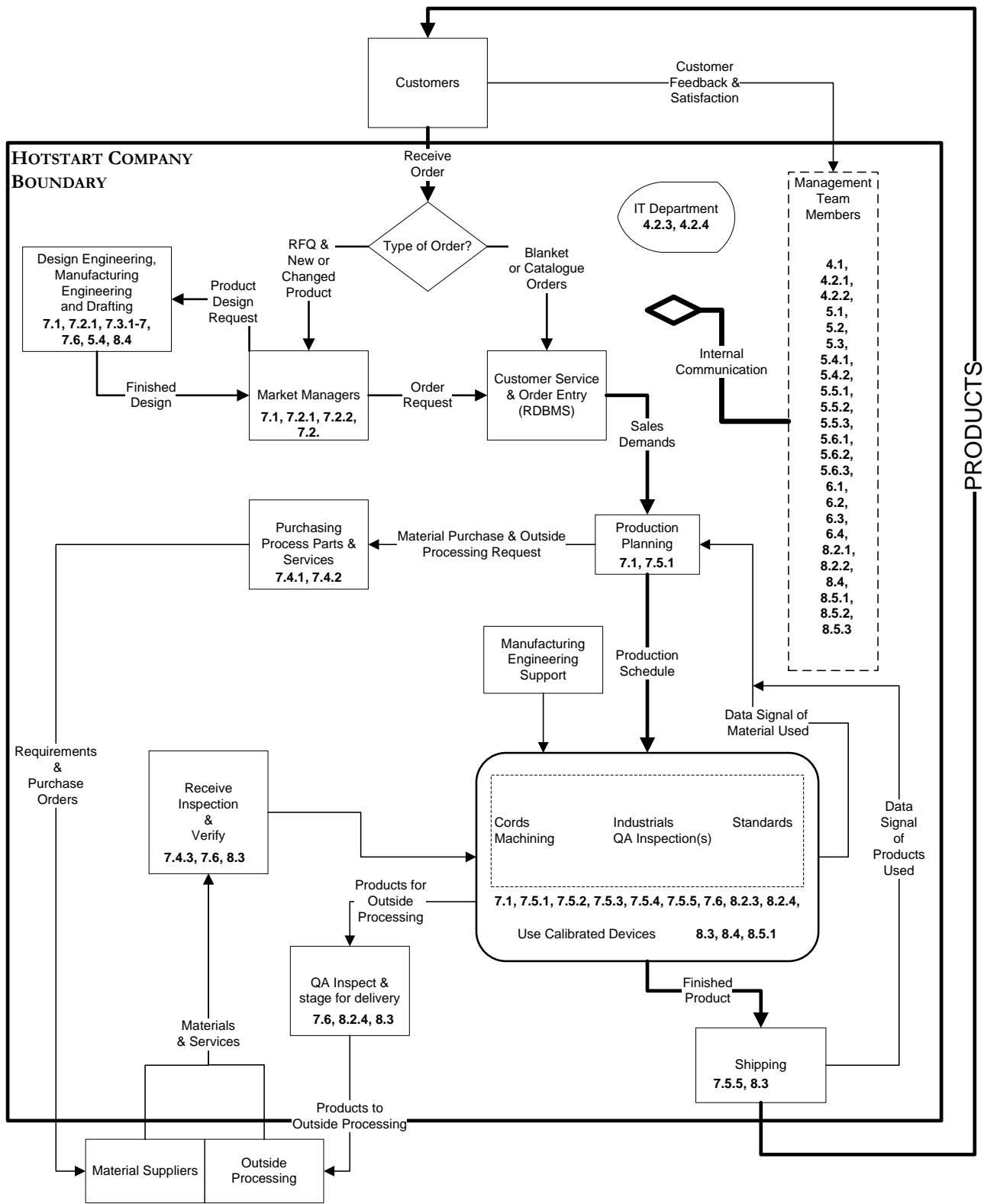


FIGURE 2 HOTSTART QMS INTERRELATIONSHIP DIAGRAM

## **1.3                    HOTSTART' BUSINESS DESCRIPTION.**

### ***History***

Hotstart holds an original patent for engine coolant heating and was established in 1942 under the ownership of Stanley Power. In 1956, Mr. Power passed away and passed ownership of the company to Loie Robinson and Colleen Randall with Hube Randall as General Manager.

The company has progressively grown and expanded to its present location of over 110,000 square feet of production and office space. This modern facility is located on over six acres in the industrial center of Spokane, WA.

Hotstart continues to be a privately held company owned by the Randall and Robinson families. Sales in 2008 were approximately \$35M with over 140 full time employees. In 1988, Jim Randall became Vice-President of Manufacturing and Rick Robinson was appointed Vice-President and General Manager. Rick Robinson assumed the role of CEO in 1990 after Hube Randall retired.

### ***Products***

Hotstart has been the industry leader in engine preheaters and accessories since, 1942. We successfully heat engines from as small as 100 CID (1.6 Liter) to approximately 75,000 CID (1200 Liter). Our products span the globe with electric heaters from 12 volt DC to 690 volt, single or three phase, 50 or 60 hertz.

### ***Mission***

It is the purpose of Hotstart to provide extended life, improved operations, and reduced emissions for internal combustion engines, primarily through engine heating. We also intend to use our technology for other applications within the scope of our manufacturing and marketing capabilities. Our customers are manufacturers and users in a worldwide marketplace.

We are committed to maintain the leadership position in our industry. This goal is achieved by exceeding our customers' expectations of quality, reliability and technical support.

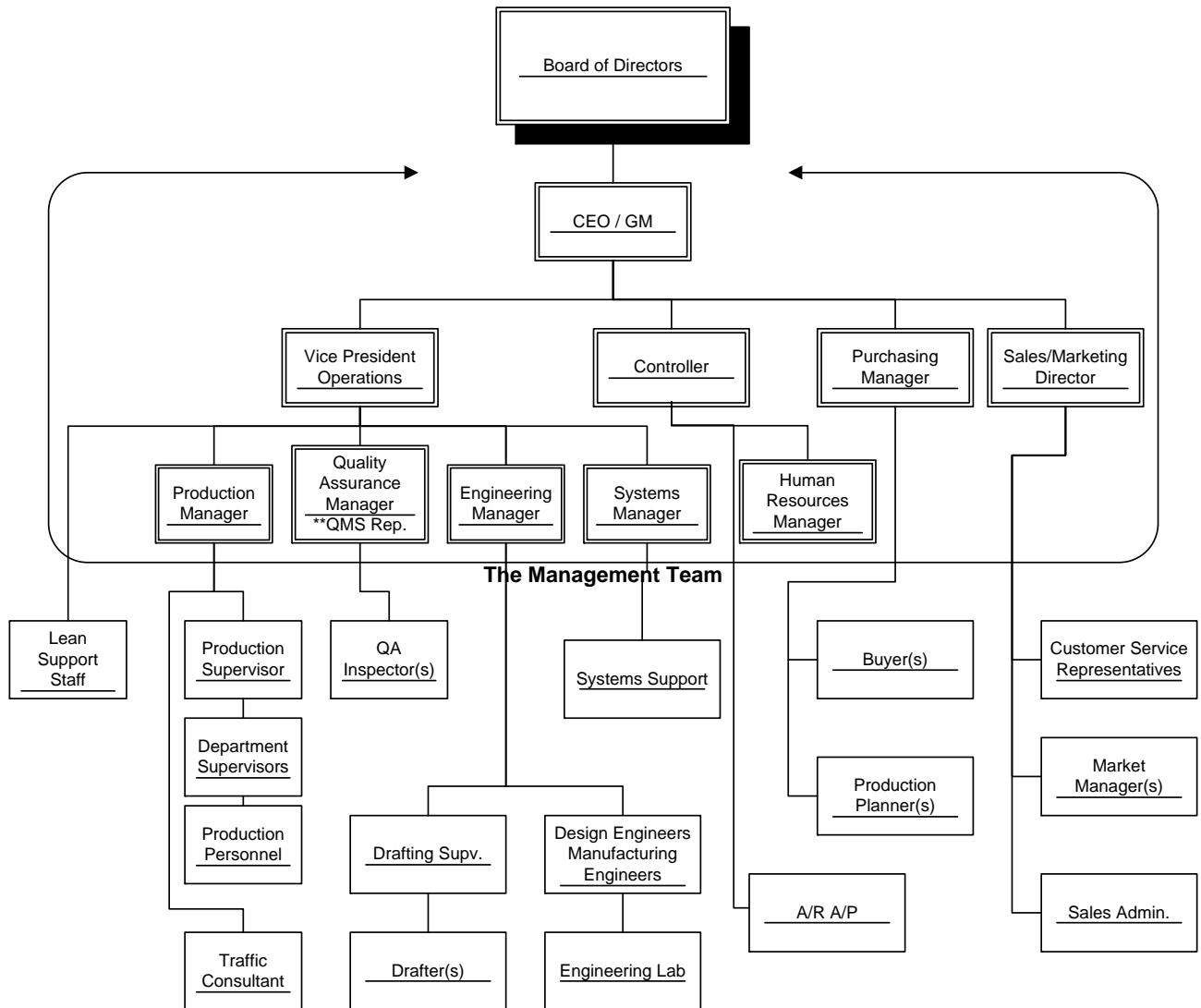
Our people are our greatest asset. Hotstart supports the personal and professional growth of each person. We attempt to create an environment of respect, freedom, creativity, personal growth and pride.

Hotstart is proud of the Spokane community and the lifestyle it supports. We believe in active participation in community affairs and encourage involvement by our people.

In order to maintain a posture of sustained growth, we depend on the continued vision and support of our stockholders. We must reward the risk and investment of the stockholders and maintain the future growth and development of the company. Hotstart will continue to support new ideas, research, change and investments in our people and facilities.

1.4

**HOTSTART ORGANIZATION**



## 2.0 QUALITY MANUAL – QMS FOUNDATION

The following table relates specific sections in this manual to documented procedures of HOTSTART QMS. This Quality Manual and supporting documentation will be revised as necessary.

Table 1

QM/ISO # Series	Document Name	Document #	Location
4.2.1	Quality Deployment Procedure	QP 4.2 a	Intranet
4.2.3	QMS Modification Procedure	QP 4.5 a	Intranet
4.2.3	Processing of Change Requests	QP 4.5 b	Intranet
4.2.3	Control of Externally Supplied Documents	QP 4.5 c	Intranet
4.2.3	Identification of Changed QMS Information	QP 4.5 d	Intranet
4.2.4	Control of Electronic Quality Records	QP 4.16 c	Intranet
4.2.4	Control of Quality Records not Stored On-line	QP 4.16 d	Intranet
5.6.1 5.6.2 5.6.3	Management Review Procedure	QP 4.1 a	Intranet
8.2.2	Internal Auditing Procedure	QP 4.17 a	Intranet
8.5.2	Corrective Action Procedure	QP 4.14 a	Intranet
8.5.3	Preventive Action Procedure	QP 4.14 b	Intranet
8.3	Control of Nonconforming Product Procedure	QP 4.13 a	Intranet

(Note: The above list is not inclusive but lists the minimum documented procedures available. Other Business Procedures and Processes are available on the company intranet.)

## 3.0 TERMS AND DEFINITIONS

Term	Definition
RDBMS	The <u>R</u> elational <u>D</u> ata <u>B</u> ase <u>M</u> anagement <u>S</u> ystem encompasses all data and records within our business manufacturing software. This excludes the Engineering CAD system and the Novell network.
Contract	Used within the sales department as a customer sales order placed to purchase Hotstart products
Inquiry	A request from a customer, or potential customer, for a quotation for a Hotstart product. A quotation will include, but is not limited to, price and delivery for a specified product.
Repetitive Manufacturing	Term used in our RDBMS for our process of manufacturing our standard product line. It is using the manufacturing philosophy of the Just-In-Time work-orderless, paperless production and used for product lines we build continuously. It allows us to handle all transactions on-line and adds support for timely delivery from our vendors to subassembly, to final assembly, through to shipping of our product.
Sub-contractor	An outside supplier to Hotstart, which supplies parts or services.

## **4.0 QUALITY SYSTEM REQUIREMENTS**

### **4.1 GENERAL REQUIREMENTS:**

HOTSTART has defined and manages processes necessary to ensure that products conform to customer requirements. As a means of implementing and demonstrating the defined processes, HOTSTART has established, documented, implemented, maintains and periodically improves the effectiveness of the QMS. The QMS is developed to comply with the requirements of ISO 9001 and is composed of the following:

- a) Determine list of processes needed for the quality management system and its application throughout the organization;
- b) Sequence and interaction of these processes is determined during product realization planning, quality management system review and product realization activities;
- c) Criteria and methods to ensure that both the operation and control of these processes are effective is determined during product realization planning, management review, product acceptance standards, internal audits;
- d) The management team ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) Process monitoring, measurement (where applicable) and analysis is performed as a part of product realization steps, management review, internal audits and product or process measurement and monitoring practices;
- f) The management team implements actions necessary to achieve planned results and for continual improvement of the quality management system processes.

Several process steps for product realization are outsourced. These process providers are selected and evaluated during product design (see 7.3). They are controlled according to practices determined by the Purchasing Department and Quality Assurance (see 7.4 and 8.2.3)

### **4.2 DOCUMENTATION REQUIREMENTS:**

#### **4.2.1 GENERAL REQUIREMENTS:**

The QMS documentation includes:

- a. Documented statements of quality policy and objectives;
- b. This Quality Manual;
- c. Documented procedures and records where required by ISO 9001 and the needs of the business (listed in table 1 of this manual) and;
- d. Documents, including records, determined to be necessary for effective planning, operation and control of processes, (listed on the company intranet site and QP 4.2a)

4.2.2

QUALITY MANUAL

The Management Team is responsible for preparation and maintenance of this quality manual. The Quality Management System is designed to comply with all sections of ISO 9001.

The quality manual includes:

- a. A description of the elements of the QMS and their interaction (section 1.2 Interrelationship Diagram);
- b. Hotstart Quality Policy;
- c. References to system level procedures (table 1 in section 2.0);
- d. Organizational Chart;
- e. Interrelationship Diagram.

4.2.3

CONTROL OF DOCUMENTS

HOTSTART has documented a system level procedure for controlling new and revised documents required for the operation of the QMS. The quality system procedure ensures that:

- a. Documents are approved for adequacy prior to release;
- b. Documents are reviewed, approved, updated and re-approved as necessary;
- c. The relevant versions of documents are available at all locations where activities essential to the effective functioning of the quality operating system and process are performed. Changes are identified within controlled documents;
- d. Obsolete documents are removed from all points of issue or use, or are otherwise controlled to prevent unintended use;
- e. Any obsolete documents retained for legal or knowledge preservation purposes are suitably identified.
- f. Applicable documents of external origin (determined by Hotstart to be necessary for the planning and operation of the QMS) are identified, controlled and recorded.

A Master list of all controlled documents is maintained. The list identifies current revision status of documents, and is used to preclude the use of invalid and/or obsolete documents.

Documentation is legible, readily identifiable, and readily retrievable.

NOTE: DOCUMENTATION IS IN THE FORM OF; PAPER, ELECTRONIC FILE (S), AND INDUSTRIAL PUBLICATIONS.

Quality records are documents specifically defined by HOTSTART. Quality records are established to demonstrate conformance to requirements and effective operation of the QMS.

HOTSTART has documented a system level procedure for record identification, collection, protection, indexing, accessing, filing, storage, retrieval, retention time and disposition.

## **5.0 MANAGEMENT RESPONSIBILITY**

### **5.1 GENERAL**

The processes covered in this section form a part of the network of inter-related processes within HOTSTART's Quality Management System (QMS). Customer focus, when managing processes, is an integral part of HOTSTART management responsibility.

The Management Team demonstrates, through its internal systems, that customer needs and expectations have been determined and translated into applicable customer requirements.

The Management Team demonstrates its commitment to meeting customer requirements for product through:

- a. Creating an environment for awareness and fulfillment of customer requirements as well as statutory and regulatory requirements;
- b. Establishing the HOTSTART quality policy and quality objectives;
- c. Establishing a QMS;
- d. Performing quarterly management reviews, and;
- e. Ensuring the availability of necessary resources.

### **5.2 CUSTOMER FOCUS**

The Management Team determines customer needs and requirements and converts them into the form of defined requirements with the goal of achieving customer confidence in HOTSTART products.

The Management Team ensures that defined requirements are fully understood and met.

### **5.3                      QUALITY POLICY**

The Management Team has established its **policy** for quality and ensures it:

- a. Is appropriate for the needs and requirements of HOTSTART, it's vendors and customers;
- b. Includes commitment to meeting requirements and continual improvement of the QMS;
- c. Provides a framework for establishing and reviewing quality objectives;
- d. Is communicated, understood and implemented throughout the organization;
- e. Is regularly reviewed for continuing suitability.

#### HOTSTART QUALITY POLICY

Our Quality Policy is to continually make improvements so that we can fulfill and exceed our customer expectations. Everyone at Hotstart is responsible for quality. The active participation and support of all of us is the key to our quality success. This focus on quality increases pride, satisfaction and opportunity for all our people. It will also enhance our relationships with our customers and suppliers.

### **5.4                      PLANNING**

#### 5.4.1                      QUALITY OBJECTIVES

HOTSTART has established corporate quality objectives, which have been deployed throughout the organization. The quality objectives are consistent with the quality policy and the commitment to continual improvement. Quality objectives include those needed to meet requirements of HOTSTART products and processes as well as customer requirements.

#### 5.4.2                      QMS PLANNING

HOTSTART has identified and defined the activities and resources needed to achieve quality objectives and to meet customer requirements. Planning is consistent with other requirements of the QMS and the results are documented.

Planning covers the following issues:

- a. The processes required in the QMS;
- b. The realization processes and resources needed, identifying quality characteristics at different stages, to achieve desired results;

- c. Verification activities, criteria for acceptability and the quality records needed.

Planning ensures that organizational change is conducted in a controlled manner and that the QMS is maintained during such change(s)

## **5.5                      QUALITY MANAGEMENT SYSTEM**

HOTSTART has established a QMS as a means of meeting its quality policy, achieving its quality objectives and ensuring that product conforms to customer requirements. The Quality Manual and Documented Procedures define the basis of the QMS.

### *5.5.1                      RESPONSIBILITY AND AUTHORITY*

Roles and their interrelationships, responsibilities and authorities are defined within an organizational chart, job descriptions, documented procedures and within processes to facilitate effective quality management and are communicated to relevant levels of the organization.

### **Management Team & Job Descriptions**

**CEO/General Manager** - Responsible for the daily operations and strategic planning of the company. Reports to the Board of Directors and has final responsibility for the quality system of the company. Appoints the Quality Management Representative and Lead Quality System Internal Auditor. Shares Company strategic planning responsibility with the rest of the Management Team. ||

**Vice President, Operations** - Directly responsible for introducing and implementing Lean Management principles and activities throughout the company. Indirectly responsible for Production, Quality Assurance, Information Systems and Engineering report. Shares Company strategic planning responsibility with the rest of the Management Team. ||

**Controller** - Responsible to prepare and evaluate financial statements, taxes, budgets, and forecasts. Also, evaluate accounting, cost systems, benefits and insurance programs. The Controller is the personnel administrator. Shares Company strategic planning responsibility with the rest of the Management Team. ||

**Sales / Marketing Manager** - Responsible for planning, coordinating and directing the activities of the sales and marketing department to ensure continual sales growth while maintaining company profit margin goals. Shares product design direction with Engineering. Shares Company strategic planning responsibility with the rest of the Management Team. ||

**Production Manager** - Responsible for processing customer requests for product and maintaining product quality. Hires production personnel,

determines equipment, materials and supplies needed along with controls and processes. Shares Company strategic planning responsibility with the rest of the Management Team.

**Quality Assurance Manager** - Responsible for implementing and maintaining the quality system. Also, ensures that quality functions, referenced documents and procedures are implemented and maintained. Shares Company strategic planning responsibility with the rest of the Management Team.

**Purchasing Manager** - Responsible for the coordination of all purchases of raw material and supplies. Also, responsible for maintaining supplier relations to ensure quality of purchased materials. Shares Company strategic planning responsibility with the rest of the Management Team.

**Information Systems Manager** - Responsible for quality levels of stability, security, availability and vision regarding the information technology services with Hotstart. Shares Company strategic planning responsibility with the rest of the Management Team.

**Engineering Manager** - Responsible for Engineering and Drafting functions. Shares product design direction with Sales / Marketing. Shares Company strategic planning responsibility with the rest of the Management Team.

**Human Resource Manager** - Responsible for the Employee Handbook/Policies and Procedures, recruiting, compensation and benefits administration, personal transactions, prepare reports and recommendations to reduce turnover, compliance administration, facilitate effective and timely communication between all levels of employees, and budgetary responsibility for HR spending. Shares Company strategic planning responsibility with the rest of the Management Team.

All HOTSTART employees have the responsibility to ensure that our quality objectives are met. Their responsibility may include steps necessary to identify and record any quality problems, recommend solutions and verify implementation of solutions. Job Descriptions have been developed to describe skills and tasks for all positions affecting the quality of our products. Specific Level II procedures and applicable work instructions also identify responsibility for quality activities.

#### 5.5.2 MANAGEMENT REPRESENTATIVE

The CEO/GM appoints a member of the organization's management team as the Quality Management Representative. The Quality Management Representative, irrespective of other duties, has the authority and responsibility to insure the quality system conforms to the requirements of ISO Q9001 and that the quality system is established. The Quality Management Representative is responsible to provide an assessment to the management team on the performance of the quality system and ensures the promotion of awareness of customer

requirements throughout the organization. The management representative will serve a minimum of two years from the time of appointment. However, the appointment can be extended indefinitely

The Quality Assurance Manager is responsible to implement and maintain the quality system in accordance with the aforementioned standard.

5.5.3 INTERNAL COMMUNICATION

HOTSTART has established and maintains a process for internal communication between various levels and functions regarding the QMS and its effectiveness. Internal communication is currently ensured through systems and procedural interface requirements (formal methods of communication are: email, voice messages, company/employee meetings, company bulletin board, and company newsletter).

## **5.6                    MANAGEMENT REVIEW**

### *5.6.1                    GENERAL*

HOTSTART has established and maintains a process for Management Review. The Management Team, at specified intervals, reviews the QMS to ensure its continuing suitability, adequacy and effectiveness. The review includes evaluation of the need for changes to the QMS, including the quality policy and objectives.

### *5.6.2                    MANAGEMENT REVIEW INPUTS*

HOTSTART Management Reviews are conducted once per calendar quarter with the intent of determining current performance and improvement opportunities related to:

- a. Results of Audit reports;
- b. Customer feedback;
- c. Process performance and product conformance analyses;
- d. Status of preventive and corrective actions;
- e. Follow-up actions from earlier management reviews;
- f. Strategic Actions that could affect the QMS;
- g. Review of any recommendations for improvement;
- h. Review of quality goals and objectives;
- i. Management Representative's assessment.

### *5.6.3                    MANAGEMENT REVIEW OUTPUTS*

The outputs from Management Reviews include actions and decisions related to:

- a. Improvement of the QMS;
- b. Process and product analysis and/or improvement;
- c. Resource needs.

Records of Management Reviews are maintained.

## **6.0   RESOURCE MANAGEMENT**

### **6.1                    PROVISION OF RESOURCES.**

HOTSTART determines and provides, in a timely manner, resources needed to establish, maintain and improve the effectiveness of the QMS.

Such resources are applied to the managing of organizations, processes and projects to enhance customer satisfaction by meeting customer requirements.

## **6.2                    HUMAN RESOURCES**

### **6.2.1                    ASSIGNMENT OF PERSONNEL**

The Management Team selects and assigns personnel to ensure that those who have responsibilities defined in the QMS are competent on the basis of applicable education, training, skills and experience.

### **6.2.2                    COMPETENCE, TRAINING, QUALIFICATION AND AWARENESS**

HOTSTART has established and maintains a system level process to:

- a. Determine competency and training needs;
- b. Where applicable, provide training to address identified needs;
- c. Evaluate the effectiveness of training;
- d. Maintain appropriate records of education, training, skills and experience.

HOTSTART has established and maintains processes to make employees at each relevant function and level aware of:

- a. The importance of conformance with the quality policy, and with the requirements of the QMS;
- b. The significant impact of their work activities on quality, actual or potential;
- c. Their roles and responsibilities in achieving conformance with the quality policy and procedures and with the requirements of the QMS;
- d. The potential consequences of departure from specified procedures.

## **6.3                    INFRASTRUCTURE**

HOTSTART defines, provides and maintains the infrastructure needed to ensure the conformity of product through the planning process. Consideration of these factors is identified during the product and process planning stage.

These include:

- a. Work space and associated facilities/utilities;
- b. Equipment, hardware and software;
- c. Suitable maintenance;
- d. Supporting services such as shipping, transportation, communication or information systems.

## **6.4                    WORK ENVIRONMENT**

HOTSTART has defined and implemented those human and physical factors of the work environment needed to achieve conformity of product. Consideration of these factors is identified during the product and process planning stage.

This includes:

- a. Health and safety conditions;
- b. Work methods;
- c. Work ethics.

## **7.0   PRODUCTION PROCESS**

### **7.1                    PLANNING OF PRODUCT REALIZATION.**

Hotstart planning of product realization is consistent with other processes of the QMS. Product realization planning for new products is part of the Design Engineering Function. Customer requirements for quality plans are determined and implemented.

Product Realization Planning is managed by the design team for new products (refer to 7.3). Products realization is determined through application of defined work instructions, visual tools and product schedules.

During product realization planning the design team takes into consideration the following:

- a) quality objectives and requirements for the product based on customer specifications or industry standards;
- b) the need to establish processes, work instructions, training and resources specific to the product;
- c) methods of verification, validation, monitoring, measurement, inspection and test activities specific to produce the product as well as acceptance criteria;
- d) identification of records needed to provide evidence that the realization processes and resulting product fulfill stated requirements.

### **7.2                    CUSTOMER RELATED PROCESSES**

#### **7.2.1                    IDENTIFICATION OF CUSTOMER REQUIREMENTS**

HOTSTART has established and maintains a process for identifying customer requirements.

The process considers:

- a. The completeness of customer's product requirements;
- b. Requirements not specified by the customer but necessary for fitness for purpose;
- c. Obligations applicable to product, including regulatory and legal requirements;
- d. Customer requirements for availability, delivery and support of product.

7.2.2                      REVIEW OF CUSTOMER REQUIREMENTS

Customer requirements, including any requested changes, are reviewed before a commitment to supply a product is made to the customer (e.g. submission of a purchase order, acceptance of a contract or order) to ensure that:

- a. Identified customer requirements are clearly defined for production;
- b. Where the customer provides no written statement of requirement, the order requirements are confirmed before acceptance;
- c. Contract or order requirements differing from those previously expressed, e.g. in a purchase order or quotation, are resolved;
- d. HOTSTART has the ability to meet the customer requirements for the product.

The results of reviews and subsequent follow-up actions are recorded.

7.2.3                      CUSTOMER COMMUNICATION

HOTSTART has implemented effective liaison with customers, with the aim of meeting customer requirements.

HOTSTART has defined communication requirements relating to:

- a. Product information;
- b. Inquiry and order handling, including amendments;
- c. Customer complaints and actions relating to nonconforming product;
- d. Customer responses relating to performance of product.

## **7.3                      PRODUCT DESIGN AND DEVELOPMENT**

### **7.3.1                      PRODUCT DESIGN AND DEVELOPMENT PLANNING**

HOTSTART plans and controls the design process.

Product design & development plans include or reference, as a minimum:

- a. Stages of the product design and development process;
- b. Required review, verification and validation activities;
- c. Responsibilities and authorities for product design and development activities.

Interfaces between different groups involved in design and development are managed to ensure effective communication and clarity of responsibilities.

### **7.3.2                      PRODUCT DESIGN AND DEVELOPMENT INPUTS**

The requirements to be met by the product are defined and recorded and may include:

- a. Performance requirements from customer or markets;
- b. Applicable regulatory and legal requirements;
- c. Requirements derived from previous similar designs, and;
- d. Any other requirements essential for design and development.

The inputs are reviewed for adequacy and completeness. Incomplete, ambiguous or conflicting requirements are resolved.

### **7.3.3                      PRODUCT DESIGN AND DEVELOPMENT OUTPUTS**

The outputs of the product design and development process are recorded in a format that enables verification against input requirements.

Product design and development output:

- a. Meet the product design and development input requirements;
- b. Provide appropriate information for purchasing, production, service provision and can include details for the preservation of product.
- c. Contain or make reference to product design and development acceptance criteria,
- d. Defines the characteristics of the product that are essential to safe and proper use.

#### 7.3.4

#### PRODUCT DESIGN AND DEVELOPMENT REVIEWS

At suitable stages of the product design and development process, systematic reviews of the results are conducted to:

- a. Evaluate the capability to fulfill requirements for quality,
- b. Identify problems, if any, and propose development of solutions.

Participants in the design review process include representatives of functions concerned with the design stage being reviewed.

The results of design reviews and subsequent follow-up actions are recorded.

#### 7.3.5

#### PRODUCT DESIGN AND DEVELOPMENT VERIFICATION

Product design and development verification is planned and performed to ensure the output meets the input requirements.

The results of the verification and subsequent follow-up actions are recorded.

#### 7.3.6

#### PRODUCT DESIGN AND DEVELOPMENT VALIDATION

Product design and development validation is performed to confirm that resultant product is capable of meeting the particular requirements for a specific intended use. Wherever applicable, validation is defined, planned and completed prior to the delivery of the product. Where it is impossible to undertake full validation prior to delivery, partial validation of the design or development outputs are undertaken to the maximum extent practical.

The results of the validation and subsequent follow-up actions are recorded.

#### 7.3.7

#### CONTROL OF CHANGES

Product design and development changes or modifications are approved by authorized personnel and recorded before implementation. HOTSTART determines the effect of changes on:

- a. The interaction between the elements of the design and/or development;
- b. The interaction between the component parts of the resulting product;
- c. Existing products and upon post delivery service operation,

- d. The need for carrying out re-verification or re-validation for all or part of the design and/or development outputs.

The results of the review of changes and subsequent follow-up actions are recorded.

## **7.4                      PURCHASING**

### 7.4.1                      PURCHASING PROCESS.

HOTSTART controls its purchasing processes to ensure purchased product and/or services conform to HOTSTART' requirements. The type and extent of methods to control these processes is dependent on the effect of the purchased product and/or service upon final product.

HOTSTART evaluates and selects suppliers and/or service providers based upon their ability to supply product and/or services in accordance with HOTSTART' requirements. Evaluation, re-evaluation and selection criteria for suppliers and/or service providers are established. The results of evaluations and subsequent follow-up actions are recorded.

### 7.4.2                      PURCHASING INFORMATION

Purchasing documentation contains information clearly describing the product and/or service(s) ordered, including, but not limited to:

- a. Requirements for approval or qualification of product and/or service(s), procedures, processes, equipment and personnel;
- b. Any management system requirements.

HOTSTART reviews and approves purchasing documents for adequacy of the specification of requirements prior to release.

### 7.4.3                      VERIFICATION OF PURCHASED PRODUCT AND/OR SERVICE (S)

HOTSTART determines and implements the arrangements necessary for verification of purchased product and/or service(s).

Where HOTSTART intends to perform verification at our supplier's premises, such requirements will be designated in the purchasing information.

## **7.5                      PRODUCT OPERATIONS**

### **7.5.1                      CONTROL OF PRODUCTION**

HOTSTART plans and controls product through:

- a. The availability of specifications that define the characteristics of the product that is to be achieved,
- b. The availability of clearly understandable work specifications and/or instructions for those activities where they are necessary for the achievement of conformity of product;
- c. The use and maintenance of suitable production equipment;
- d. The provision of suitable working environment;
- e. The availability and use of suitable measuring and monitoring equipment;
- f. The implementation of suitable monitoring and verification activities;
- g. Suitable methods for release and delivery of product;
- h. Activities for return and customer claims.

### **7.5.2                      VALIDATION OF PROCESSES**

HOTSTART presently has several processes, which result in an output, which cannot be readily or economically verified by subsequent monitoring, inspection or testing. These processes include validation, which accomplish one or several of the following:

- a. Process(s) to be qualified prior to use;
- b. Qualification of equipment and/or personnel;
- c. Use of specific procedures or records,
- d. Re-validation.

Evidence of validated processes, equipment and personnel are maintained.

### **7.5.3                      IDENTIFICATION AND TRACEABILITY**

The Production Department has developed and maintains documented procedures to ensure the identification of parts, subassemblies, and products are maintained throughout our processes. Documented procedures also exist to identify product status in respect to monitoring and measurement requirements throughout product realization.

Part numbers are assigned to every purchased and manufactured subassembly or final assembly and are used to uniquely identify our products from receipt through production to delivery of the final product.

Records of this process are kept in the RDBMS. Each part will have the part number attached to it unless it is a batch lot then the container or stocking location will be labeled with the part number. Parts that are to be consumed immediately by the same operator or assembly team do not have to be labeled.

When HOTSTART or a customer requires traceability, it is done by the use of serial number or date code and at end product only. Records of this are maintained.

7.5.4                      CUSTOMER PROPERTY

HOTSTART does not currently inventory or manage customer-supplied product (raw materials or components) for incorporation into a finished product. Some customers return finished product for “re-configuration”. Such product is subject to documented process control procedures. Some customers return finished product for “restocking”. Such product is also subject to documented process control procedures. Some customers return finished product for “warranty consideration”. Such product is subject to documented process control procedures. Any customer owned items that are lost, damaged or become unsuitable for use while in the possession of HOTSTART, are recorded and reported to the customer and records are maintained.

7.5.5                      PRESERVATION OF PRODUCT

Product release does not proceed until all specified activities have been satisfactorily completed and the related documentation is available and authorized.

The Production Department has established and maintains documented procedures to ensure product is protected and handled correctly throughout all processes from receipt through manufacture to storage and shipment in order to prevent damage. All appropriate employees are trained in material handling methods and equipment use where required.

Materials and products are stored in designated areas and clearly identified. Receipts into and dispatch out of designated areas are tracked through our RDBMS. Cycle counts and full physical inventories are used to ensure the right quantities exist and the condition of the product is good.

Packaging shall meet HOTSTART and customer expectations. Packaging will meet or exceed regulatory requirements and can be tested for fragility, shock, vibration and transit drops. Temperature,

humidity, and shelf life for materials are included in determining storage and handling methods.

Delivery and scheduled delivery shall meet the customer's expectations. Only carriers on our approved list in our RDBMS system will be used.

## **7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT**

HOTSTART controls, calibrates, maintains, handles and stores applicable measuring and monitoring equipment used to demonstrate conformance of product to specified requirements.

HOTSTART provides methods of handling, preservation and storage that protect measuring equipment from damage or deterioration.

Measuring, inspection and test equipment is used in a manner, which ensures that measurement uncertainty, including accuracy and precision, is known and is consistent with the required measurement capability.

Software used for the monitoring and measurement of product requirements is confirmed as to its application prior to use.

HOTSTART:

- a. Calibrates or verifies, or both and adjusts measuring, inspection and test equipment at specified intervals or prior to use, against equipment traceable to international or national standards. Where no such standards exist, the basis used for calibration is recorded;
- b. Identifies measuring, inspection and test equipment with a suitable indicator or approved identification record to show calibration status;
- c. Determines the method for calibration of measuring and monitoring devices;
- d. Records the results of calibration and/or verification and maintains the results.
- e. Safeguards measuring, inspection and test equipment from adjustment, which would invalidate the calibration;
- f. Assess the validity of previous inspection and test results when equipment is found to be out of calibration and take appropriate actions.

## **8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 GENERAL REQUIREMENTS**

HOTSTART has defined, planned and implemented measurement, monitoring, analysis and improvement processes to ensure that the QMS, processes and products conform to requirements.

The type, location, timing and frequency of measurements and the requirements for records are defined.

The effectiveness of measures implemented is periodically evaluated. HOTSTART identifies and uses appropriate statistical tools. The results of data analysis and improvement activities are inputs into the management review process.

### **8.2 MONITORING AND MEASUREMENT**

#### **8.2.1 CUSTOMER SATISFACTION**

HOTSTART has determined and established processes for measurement of quality management system performance. Customer satisfaction is used as one measure of system output and internal audits are used as a tool for evaluating ongoing system compliance.

HOTSTART monitors information and data on customer satisfaction and dissatisfaction. The methods and measures for obtaining customer satisfaction information and data and the nature and the frequency of reviews are defined.

#### **8.2.2 INTERNAL AUDITS**

HOTSTART has established a documented procedure for performing objective audits in order to determine if the QMS has been effectively implemented and maintained and conforms to HOTSTART QMS requirements. In addition, the organization may carry out additional audits to identify potential opportunities for improvement.

HOTSTART audit process, including the schedule, is based on the status and importance of the activities, areas or items to be audited, and the results of previous audits.

The system level documented procedure for internal audit covers the audit scope, frequency and methodologies, as well as the responsibilities, requirements for conducting audits, recording and reporting results to management. Follow-up activities include

verification of corrective actions taken and the reporting of verification results. 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.

Personnel other than those who performed the work being audited perform audits. HOTSTART may choose to have internal audits performed by a subcontractor. In such cases, the subcontractor will abide by the HOTSTART documented audit procedure. Records of the audits and their results are maintained.

#### 8.2.3                      MONITORING AND MEASUREMENT OF PROCESSES

HOTSTART applies suitable methods for measurement and monitoring of processes necessary to meet customer requirements and to demonstrate the process's continuing ability to satisfy its intended purpose. Measurement results are used to maintain and improve those processes.

When planned results are not achieved, corrective action is taken to ensure conformity of the product.

#### 8.2.4                      MONITORING AND MEASUREMENT OF PRODUCT

HOTSTART applies suitable methods for measurement and monitoring of the characteristics of the product to verify that requirements for the product are met. Evidence of implementation of required measurement and monitoring and conformance with the acceptance criteria are recorded and maintained. Records indicate the authority responsible for release of product.

Product does not proceed or is not released for shipment to the customer until all specified activities have been satisfactorily completed and the related documentation is available and authorized.

### **8.3                      CONTROL OF NONCONFORMITY**

#### 8.3.1                      GENERAL REQUIREMENTS

HOTSTART ensures product that does not conform to requirements is controlled to prevent unintended use or delivery.

HOTSTART provides for identification, recording and reviewing the nature and extent of the nonconformity encountered.

The HOTSTART system level documented procedure defines controls, related responsibilities and authorities for nonconforming product.

8.3.2

NONCONFORMITY REVIEW AND DISPOSITION

Where applicable, HOTSTART reviews nonconformities and determines action(s) to be taken. These nonconformities are:

- a. Reworked to conform to requirements, or
- b. Accepted “as is”, with or without correction or adjustment, (with customer concession as applicable),
- c. Scrapped or “Returned to Vendor”.
- d. Addressed by taking appropriate actions when nonconforming product is detected after delivery or use has started.

Where it is necessary to repair or rework product, verification requirements are determined and implemented.

Responsibility and authority for reviewing and resolving nonconformities are defined. When required by contract, the proposed use or repair of nonconforming product is reported for approval to the customer (if applicable). The description of any rework, adjustment, accepted nonconformity, product repair or modification is recorded and maintained.

**8.4**

**ANALYSIS OF DATA FOR IMPROVEMENT**

A process for the analysis of applicable data is followed as one means of determining the effectiveness of the QMS and for identifying where improvements can be made. HOTSTART collects data generated by measuring and monitoring activities and other relevant sources.

HOTSTART analyzes applicable data to provide information on:

- a. Customer satisfaction and dissatisfaction;
- b. Conformance to product requirements;
- c. Characteristics and trends of processes and products, including opportunities for preventive action;
- d. Supplier performance.

## **8.5                      IMPROVEMENT**

### 8.5.1                      CONTINUAL IMPROVEMENT

HOTSTART continually improves the QMS by evaluating the use of the quality policy, objectives, internal audit results, analysis of data, corrective and preventive action and management review.

### 8.5.2                      CORRECTIVE ACTION

HOTSTART has established a documented procedure for reducing or eliminating the causes of nonconformity in order to prevent recurrence.

The system level procedure for the corrective action process defines requirements for:

- a. Review of nonconformities (including customer complaints);
- b. Determination of causes of nonconformities;
- c. Evaluation of the need for actions to ensure that nonconformities do not recur;
- d. Implementation of any actions determined necessary to ensure that nonconformities do not recur,
- e. Recording results of actions taken;
- f. Follow-up to ensure corrective action taken is effective and recorded.

### 8.5.3                      PREVENTIVE ACTION

HOTSTART has established a documented procedure for eliminating the causes of potential nonconformities to prevent occurrence. QMS records and results from the analysis of data are used as inputs for preventive action, as applicable.

The system level preventive action procedure addresses:

- a. Identification of potential nonconformities;
- b. Determination of the causes of identified potential nonconformities and recording the results,
- c. Determination of preventive action needed to eliminate causes of potential nonconformities,
- d. Implementation of preventive action;
- e. Review to ensure preventive action taken is effective and recorded.

