Introduction

ISC ENGINEERING is a world leader specialized in custom molded cable assembly . ISC provides rapid prototype and preproduction and quick turn, low volume high mix assemblies to audio, automotive, electronics, industrial, instrumentation, marine, medical and the mil-spec industries.

ISC ENGINEERING developed and implemented a quality management system to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity. The quality system complies with the international standard ISO 9001 (2008).

The manual is divided into five sections modeled on the sectional organization of the ISO 9001 (2008) standard. Sections are further subdivided into several sub-sections representing main quality system elements or activities. Each sub-section starts with a general policy statement expressing the commitment to implement the basic principles of the pertinent quality system element or activity. The general policy statement is followed by more specific procedural policies outlining how the general policy is implemented, and referencing applicable operational procedures.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present the quality system to our customers and other external interested parties, and to inform them what specific controls are implemented at ISC ENGINEERING to assure quality.

President 

Index and Revision Status

GENERAL

Approved by: President	

Index and Revision Status

Exclusions

The quality management system shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this reason, those requirements of ISO 9001 (2008) that do not apply are excluded from the scope of our quality system. Following rules and criteria are used for excluding irrelevant requirements:

1. An ISO 9001 (2008) requirement may be excluded only when both of the following conditions are met:
   - The requirement must be within ISO 9001 Clause 7, Product Realization; and
   - The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets customer and applicable regulatory requirements.
2. Quality Assurance Manager is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.
3. Top executive management has the responsibility and authority for evaluating whether the proposed exclusions are appropriate, and for approving them. Evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system (refer to Procedure P-56-01, Management Review).
4. Any exclusion taken is documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

EXCLUSIONS

1. **Exclusion:** ISO 9001 (2008) Section 7.3, Design and/or Development, including all subsections

   Justification: ISC ENGINEERING does not design or develop products. All principal product characteristics are specified by the customers or their consultants. Our engineering activities are limited to developing tooling, methods and means of production, fabrication, or installation.
2. **Exclusion:** ISO 9001 (2008), Section 7.5.1/7.5.2 Exclusion of Post Delivery "**Control** and **Validation** of **Service** Provisions".

   Justification: ISC ENGINEERING does not provide any "Post Delivery Field Service

Exclusions

Activities”.

General Requirements

GENERAL POLICY

ISC ENGINEERING is committed to establish, document, implement and maintain a quality management system, and continually improve its effectiveness, in conformance with requirements of the ISO 9001 (2008) International Standard.

PROCEDURAL POLICIES

1. Quality system processes

1.1 Processes needed for the quality management system are identified in this quality manual and in associated procedures and work instructions. The documentation defines these quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

1.2 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

1.3 Procedure P-42-01, Quality System Documentation, explains in more detail how quality system processes are defined and documented.

2. Resources and information

2.1 President is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the top management. Top management is responsible for ensuring the availability of necessary resources and information. Section 6.1 of this quality manual, Provision of Resources, explains in more detail how resource requirements are identified and satisfied.

3. Monitoring and measurement

3.1 The performance of quality system processes is systematically monitored and/or measured. This is to ensure their effectiveness and identify opportunities for improvement.

3.2 The performance of product realization processes is usually monitored by measuring process parameters and/or product characteristics resulting from the process; and through the program of inspections and tests applied to the product. The performance of processes required for quality management is usually monitored through internal quality audits. The overall performance of the quality system is monitored by measuring customer satisfaction.

3.3 Monitoring and measuring activities are defined in Sections 8.1 and 8.2 of this quality manual, and in the corresponding operational procedures.

4. Conformance and continual improvement

4.1 The quality management system processes are regularly reviewed by the top management to identify any possible failures or breakdowns, as well as opportunities for their improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and management improvement projects. Sections 5.6 and 8.5 of this quality manual and the corresponding operational procedures define how management reviews and corrective/preventive actions are used to ensure conformance and improvement.

5. Outsourced or Sub-contracting processes

5.1 When processes that affect product conformity are outsourced ISC ENGINEERING is not absolved of the responsibility to provide conforming product to all customers. This is accomplished through special controls that are implemented to ensure that all processes meet the specified requirements. Such controls may include, as appropriate: evaluation and pre-qualification of suppliers; assessment of supplier realization processes and quality system; monitoring of supplier quality performance; requirements for inspection, testing or other records demonstrating product conformity; or containment and verification of the supplied product.

5.2 Section 7.4 of this quality manual and the corresponding procedures define such purchasing control system, the potential impact of any outsourcing, the degree to which the control for the process is shared and the capability of achieving the necessary control.

ASSOCIATED DOCUMENTS

- Quality Manual: All sections
- Procedure P-42-01: Quality System Documentation

Documentation and Records

GENERAL POLICY

Scope of the quality system documentation is defined. Establishment and revision of documents, and their distribution, is controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. A single document may include requirements for more than one procedure and requirements of one procedure may appear in more than one document. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval, and are stored in a suitable environment to minimize deterioration. Quality records are retained for a period of time at least equivalent to the industry standard or as directed by the customer.

PROCEDURAL POLICIES

1. Scope

1.1 ISC ENGINEERING quality system documentation comprises the following types of documents and records required by the International Standard:

- Quality manual (including a documented quality policy);
- Documented statements of quality objectives;
- Procedures: Second level documents defining the who, what, when and how the processes are carried out;
- Work instructions: (Third level documents detailing specific tasks);
- Standards and other technical reference materials;
- Customer provided documents of external origin determined by ISC ENGINEERING to be necessary for the planning and operation of the QMS;
- Product realization and control plans;
- Records required by the current ISO 9001 Standard;
- Customer satisfaction/perception documents;
- Training and H.R. records as applicable
- Documents, including records, determined by ISC ENGINEERING to be necessary to ensure effective planning, operations and control of processes, and

- Sub-contractor's documentation and records required to support the quality of the product or service.

The purpose, scope, and responsibility for controlling various types of documents are defined in Procedure P-42-01, Quality System Documentation.

2. Quality Manual

2.1 The top level document defining the overall quality management system is the Quality Manual. It includes:

- The scope of the quality system, including details of and justification for any exclusions (refer to Section 0.3);
- Documented procedures established for the QMS and references to them: and
- Description of quality system processes, their sequence, and interrelation.

3. Control of Documents

3.1 ISC ENGINEERING is gradually transitioning from paper to electronic documentation. As this transition progresses, new categories of documents are transferred form paper to electronic document control system. Both systems are currently used, and are defined in Procedure P-42-02, Control of Documents.

3.2 New documents and document changes may be initiated by anyone in the organization, but may only be issued by an authorized function. The authorized functions and the rules governing the issue of documents are defined in procedures P-42-01-, Quality System Documentation, and P-42-02, Control of Documents. All documents are reviewed and approved prior to issue.

3.3 A paper document is officially issued for use when it is approved by an authorizing function or department within the company. An electronic document is issued by being placed in a public directory accessible from the network.

3.4 Documents are distributed to personnel and locations where they are used and shall remain legible and identifiable. When appropriate and relevant, documents may display a distribution list. Electronic documents are available on the network and are accessible at relevant terminals and computers. Document placement is regulated by Procedure P-42-02, Control of Documents.

3.5 Documents of external origin that are determined to be necessary for the planning and operation of the QMS are identified and their distribution controlled.

3.6 Obsolete documents are removed from points of use when they no longer apply. Retained masters or copies of historical documents are properly marked and are kept

separate from active documents. Historical electronic documents are moved to an archive file and stored in directories that are accessible to authorized personnel only.

3.7 Document changes are reviewed and authorized by the same function that issued the original document. Revised documents are distributed with a change cover sheet summarizing the changes. For electronic documents this list is not necessary, as only the latest issue and revision of a documents is available on the network.

4. Control of quality records

4.1 Quality records are established and maintained to provide evidence that:

- Conformity to requirements and effective operation of the QMS is controlled;
- Materials, components, and production processes meet specified requirements;
- Finished product records conform to specifications, are identified, stored, protected, maintained, and are retrievable, retained and disposed of as required.
- The quality system is operated in accordance with documented procedures and that it is effective.

Where required, quality records also include traceability information.

4.2 Records are established by personnel performing the task, operation, or activity the results of which need to be recorded. Records are dated; and identify the product, person, or event to which they pertain and remain legible, readily identifiable and retrievable.

4.3 Records are indexed and grouped to facilitate their retrieval. Cabinets, binders, computer disks, and other storage media containing records are clearly labeled with identification of their content.

4.4 Records are normally stored by the same department that initially established the record. Records are stored in dry and clean areas, and electronic records are regularly backed up. Records shall remain legible, readily identifiable and retrievable and may not be stored in private desk drawers or other obscure locations.

4.5 Retention periods for quality records are retained for a minimum of 3 years active and 2 years inactive for a total of 5 years or as agreed in a contract or purchase order agreement.

4.6 All categories of quality records and their control, maintenance, storage, protection, retrieval, disposition and retention time by ISC ENGINEERING is provided in Procedure P-42-03, Control of Quality Records. The list identifies specific types of records for each category; their storage location; and retention period.

ASSOCIATED DOCUMENTS

- Procedure P-42-01: Quality System Documentation
- Procedure P-42-02: Control of Documents
- Procedure P-42-03: Control of Quality Records

Management Commitment

GENERAL POLICY

Top management is ultimately responsible for establishing, implementing, maintaining, and improving the quality system. Management commitment is demonstrated by communicating to the organization the importance of meeting requirements, establishing the quality policy and quality objectives, conducting management reviews of the quality system, and ensuring the availability of necessary resources.

PROCEDURAL POLICIES

1. Top management

1.1 For the purpose of administrating the quality management system, top management is defined to include the President and management responsible for operations, engineering, sales, human resources, and quality assurance.

2. Customer requirements

2.1 Top management is committed to communicate the importance of meeting customer as well as statutory, regulatory and legal requirements. Management representatives are responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of management representative is stipulated in Section 5.5, Organization and Communication.

3. Quality policy and quality objectives

3.1 Top management establishes the quality policy, defines the purpose and objectives for the quality management system. They are documented and communicated in the form of organization and communication and quality objectives are defined in this manual in Section 5.3, Quality Policy, Section 5.4, Quality System Planning and 5.5, Organization and Communication and revisited in Section 8.2, Measuring and monitoring.

4. Management reviews

4.1 Top management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates current status and performance of the quality system and initiates actions for further improvement of the system. The process for conducting management reviews is defined in Section 5.6 of this manual and in Procedure P-56-01, Management Review.

5. Resources

5.1 Top management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. Section 6.1 of this manual defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

ASSOCIATED DOCUMENTS

- Quality Policy, Section 5.3; Quality Policy
- Quality Policy, Section 5.4; Quality System Planning
- Quality Policy, Section 5.5; Organization and Communication
- Quality Policy, Section 5.6; Management Review
- Quality Policy, Section 6.1; Provision of Resources
- Quality Policy, Section 8.2, Measuring and monitoring.
- Procedure P-56-01: Management Review

Customer Focus

GENERAL POLICY

The principal objective of the quality management system is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is a good understanding of customer requirements and a capability to consistently fulfill these requirements.

PROCEDURAL POLICIES

1. Determining customer requirements

1.1 Customer requirements are understood broadly to include all aspects of products and associated services that can influence customer satisfaction. When relevant, this may also include customer needs and expectations.

1.2 Customer requirements are determined and verified through the process of order review. This process is defined in operational procedures P-72-01 Order Processing.

2. Customer needs and expectations

2.1 When appropriate, customer needs and expectations are determined and are incorporated into product requirements. Sales and Quality are responsible for collecting and analyzing information on customer needs and expectations. The purpose is to gain understanding of:

- How well the customer likes the product?
- How well the product meets with customer's specifications and requirements?
- Do we continue to meet the growing needs of the customer?
- How well we meet our committed delivery dates?

2.2 Information about customer needs and expectations is collected and developed from various sources. These include:

- Trends in stated customer requirements and developments in pertinent legal and

regulatory requirements;

- Customer surveys and direct contacts with customers;
- Expressions of customer satisfaction and dissatisfaction, including customer complaints, and other customer feedback;
- Trade magazines, conferences, seminars, etc.

2.3 Information about customer needs and expectations is also extracted from customer feedback and complaints, and customer satisfaction data. Procedures P-72-03, Customer Feedback and Complaints, and P-82-01, Customer Satisfaction, define how this data is collected and used.

3. Fulfillment of customer requirements

3.1 The whole quality system is designed and implemented to ensure that customer requirements can be consistently fulfilled. Quality system processes that most directly contribute to achieving this objective are those related to the control of product realization processes and to monitoring and measuring those processes. Sections 7 and 8 of this manual define these processes.

3.2 Product conformity and on-time delivery performance are continually measured by top management during the customer order processing. If product conformity or a delivery schedule anomaly has been identified the customer is notified immediately, first by phone and then by fax or email.

ASSOCIATED DOCUMENTS

- Procedure P-72-01: Order Processing
- Procedure P-72-03: Customer Feedback and Complaints
- Procedure P-82-01: Customer Satisfaction

Quality Policy

QUALITY POLICY

ISC Engineering is committed to meeting customer requirements and increasing customer satisfaction through continual improvement of its products, services, and the quality management system.

PROCEDURAL POLICIES

1. Authority

1.1 Quality policy is established by the top management and is approved by the President and executive management. Any changes to the policy must be likewise approved by the President and top management.

2. Role of the policy

2.1 The main role of the quality policy is to communicate the company's commitments and aspirations with regard to quality, and to define principal objectives for the quality management system.

2.2 The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of quality policy in setting quality objectives is addressed in this manual in Section 5.4, Quality Planning. The use of the policy to facilitate continual improvement is explained in Procedure P-85-01, Continual Improvement.

3. Communication

3.1 The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.

3.2 The quality policy is also communicated to customers, consumers and other interested parties. For this purpose, it is displayed in the reception area and posted on ISC ENGINEERING Internet site.

Approved by: President	

4. Review

4.1 The quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in Procedure P-56-01, Management Review.

ASSOCIATED DOCUMENTS

- Procedure: P-56-01 Management Review
- Procedure: P-85-01 Continual Improvement

Quality System Planning

GENERAL POLICY

Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes (including any exclusions of ISO 9001 requirements); priorities for continual improvement; and resources needed to achieve quality objectives and to maintain and improve the quality system. Quality plans are periodically reviewed and updated to maintain the integrity of the quality system during organizational and other changes.

PROCEDURAL POLICIES

1. Quality objectives

1.1 Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance.

1.2 Quality objectives define the direction and priorities for continual improvement. Use of quality objectives for facilitating continual improvement is explained in Procedure P-85-01, Continual Improvement.

1.3 Quality objectives are classified into the following four categories:

- **Policy objectives:** These are principal, strategic objectives that apply to the whole organization. They are typically included in the quality policy itself, or may be communicated in memoranda's from the top management. Since ISC ENGINEERING's objective is to continue to better satisfy the customer, top management shall review the various information sources regarding customer satisfaction (see Section 8.2) and adjust or revise the policy objectives to promote continual improvement of the whole company in regards to the Quality Management Program. This shall be monitored within the framework of management reviews of the quality system, in accordance with Procedures P-56-01, Management Review.

- **Quality performance objectives:** These objectives set specific, measurable targets for improving operational performance to ensure product conformity and customer satisfaction. They apply to departments and functions having direct responsibility for activities like cost of quality for rework, machine set-up time, waste of labor and materials, excessive cost of non-quality issues, and excessive handling and storage. Performance objectives are established, documented, and monitored within the framework of management reviews of the quality system, in accordance with Procedures, P-56-01 Management Review.

- **Product quality objectives:** These objectives pertain to improvement of products and associated services. Top management may use various information derived from; customer complaints, expressions of customer satisfaction and other feedback, awards and recognitions from customers, customer satisfaction surveys, product returns, new and repeat customers and marketing due to product development.

- **Quality system objectives:** These objectives pertain to improvement of quality system processes and performance. The President/Sales and Quality, with input from Engineering Production and Customer Service assembles, integrates, and analyses all customer satisfaction data collected from various sources and pertaining to different aspects of company's Quality System. Customer satisfaction levels in all aspects are compared with results from previous periods of time and possible projections for the future. Quality system improvement objectives are then established, documented, and monitored and reported within the framework of management reviews of the quality system, in accordance with Procedure P-56-01, Management Review.

2. Quality system planning

2.1 Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

- To achieve the quality policy;
- To ensure and demonstrate our ability to provide consistent product that meets customer and regulatory requirements;
- To ensure high level of customer satisfaction;
- To facilitate continual improvement; and
- To comply with current requirements of ISO 9001.

Quality System Planning

2.2 The output of quality system planning is documented in this quality manual, in associated procedures, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

2.3 The integrity of the Quality Management System shall be maintained if and when any Quality Management System changes are implemented.

3. Product realization and verification planning

3.1 Planning of product realization, verification, and validation processes is addressed in Section 7.1 of this manual.

4. Continual improvement planning

4.1 Improvements of the quality system are planned within the framework of management reviews. The output of this planning is expressed in the form of quality system objectives, as defined above in Clause 1.3 of this section, and in Procedures P-85-01, Continual Improvement; and P-56-01, Management Review.

ASSOCIATED DOCUMENTS

- Procedure P-56-01: Management Review
- Procedure P-85-01: Continual Improvement
- Policy Manual: Section 7.1, Planning of Product Realization

Organization and Communication

GENERAL POLICY

Functions and their interrelation within the company are defined and communicated.

Top management appoints a management representative responsible for establishment and maintenance of the quality system, and for reporting to the top management on the performance of the system.

Issues regarding the quality system are communicated internally though distribution of pertinent documents, meetings, training and awareness programs, and management reviews.

PROCEDURAL POLICIES

1. Responsibility and authority

1.1 Departments, and functions within the company, and their interrelations, are defined in the organizational chart enclosed at the end of this section.

1.2 All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.

Following specific responsibilities and authorities are assigned:

President/ Sales

- Formulates the Quality Policy
- Establishes Quality Objectives
- Responsible to develop sound relationships between customers and the Company
- Keep company informed on competitive products and market direction
- Provides resources necessary to maintain and improve the quality system
- Conducts management reviews of the quality system
- Conducts market research to anticipate customer expectations
- Establishes specifications for new products (product briefs)
- Advertises and promotes company's products

Organization and Communication

Engineering / Tooling

- Review and establish manufacturing capabilities
- Resolve customer drawing and documentation anomalies
- Assists in product realization and verification planning
- Develop work instructions

Operations

- Schedules production
- Establish production work order package
- Plans production facilities, equipment, and processes
- Develops production processes consistent with work instructions
- Develops process operator and set-up instructions
- Controls and monitors processes
- Conducts in-process inspections
- Applies and maintains in-process product identification
- Maintains production equipment
- Provides training for its personnel

Purchasing

- Selects qualified supplies and subcontractors
- Prepares and approves purchasing documents
- Monitors and evaluates supplier performance

Receiving & Shipping

- Receives purchased & processed products
- Performs receiving inspection of non custom or complex product
- Verifies and applies product identification to purchased products
- Packages products for shipment
- Ships products to customers

- Operates the finished product stockroom
- Operates and maintains the raw material and parts stockroom

Customer Service/ Office Administration

- Provides customer liaison and service
- Provides product information
- Handles customer feedback and complaints
- Defines personnel qualification requirements
- Implements measures to motivate personnel
- Accounting and Finance

Quality Assurance and Quality Control

- Establishes and maintains the quality management system
- Audits implementation and effectiveness of the quality system
- Identifies opportunities for improvement of the quality system
- Develops quality plans and control plans
- Initiates corrective and preventive actions
- Responsible for the calibrated measuring and test equipment program
- Carries out subcontractor quality surveys and audits
- Performs Receiving/Shipping, In-Process & Final Inspections and testing
- Identifies the need for the use of statistical techniques
- Handles nonconforming products
- Coordinates the quality management program document control activities
- Maintains, or coordinates the maintenance of quality records
- Coordinates collection of quality performance data
- Provide required training for personnel

2. Management representative

2.1 ISC Engineering's top management has appointed the Quality Assurance Manager as the Quality Management Representative. The representative has the authority and responsibility to:

- Ensure that the quality management system is implemented, maintained and continually improved;
- Promote awareness of customer requirements throughout the organization;
- Report to the top management on the performance of the quality system, including needs for improvement; and
- Coordinate communication with external parties on matters relating to the quality system and ISO 9001 registration.

2.2 It is understood that the management representative maintains the organizational freedom and unrestricted access to top management to resolve all quality management issues.

3. Internal communication

3.1 Internal communication regarding the quality system flows two ways:

The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

3.2 Collectively the departments communicate to management information and data regarding customer needs and expectations, customer satisfaction, quality performance, the effectiveness of the quality system, and opportunities for improvement.

3.3 The information is communicated through manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.; and through training, on-the-job instruction, and meetings. Procedures P-42-01 , Quality System Documentation; P-42-02 , Control of Documents; and P-62-01, Training and Awareness, regulate these activities.

3.4 Management review meetings have a special role in ensuring proper communication between the top management and the organizations departments. The meeting provides the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate policies and directives to change and/or improve the quality system. This process is defined in ProcedureP-56-01, Management Review.

3.5 Quality Assurance Manager has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions within the organization, and that information and data about quality

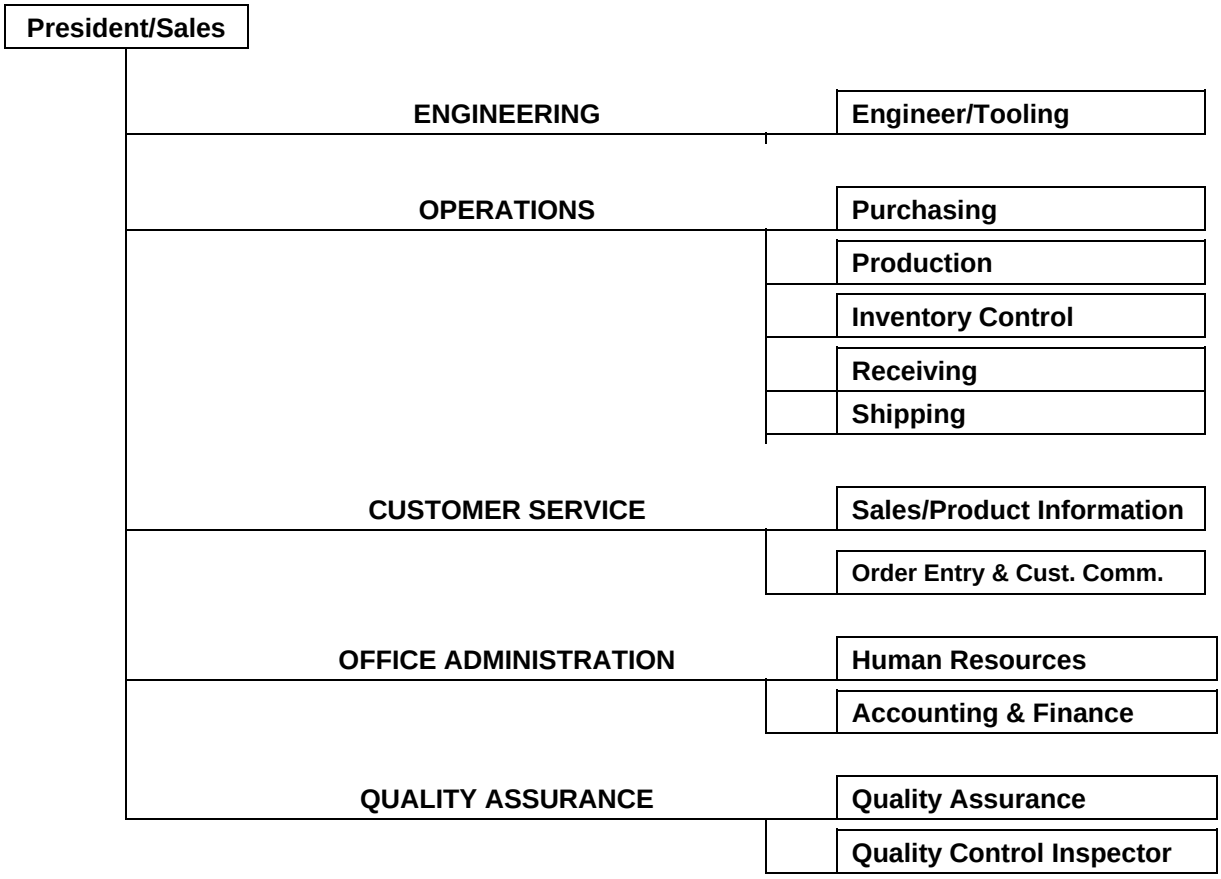
performance and the effectiveness of the quality system are reported to the top management.

ASSOCIATED DOCUMENTS

- Procedure P-56-01: Management Review
- Procedure P-62-01: Training and Awareness
- Procedure P-42-02 : Control of Documents
- Procedure P-42-01: Quality System Documentation

Organization and Communication

ISC ENGINEERING ORGANIZATIONAL CHART



Management Review

GENERAL POLICY

Top management conducts periodical reviews of the quality system. The review evaluates the suitability and effectiveness of the system, identifies opportunities for improvement, and considers the need for changes to the quality policy and quality objectives. Results of the review are documented.

PROCEDURAL POLICIES

1. General

1.1 The purpose of management reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives; and
- Identify opportunities for improvement of the quality system, processes and products.

1.2 Management reviews are chaired by the President and are attended by management representing the following departments: Operation/Production, Customer Service/Office Administration, Engineering/Tooling and Quality Assurance.

1.3 Management reviews are conducted at least three times a year. More frequent reviews are scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from the top management.

2. Review input

2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Results of audits,
- Customer feedback and complaints,

- Process performance and product conformance data,
- Status of preventive and corrective actions,
- Changes that could affect the quality system,
- Follow-up actions from earlier management reviews, and
- Recommendations for improvement.

Section 8.4 of this manual, Analysis of Data, and Procedure P-56-01, Management Review, define the scope, and method of presentation, of the input information and data.

3. Review output

3.1 Management reviews are concluded with actions related to improvement of the quality management system, setting and assigning quality objectives and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.

3.2 Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

ASSOCIATED DOCUMENTS

- Procedure P-56-01: Management Review

Provision of Resources

GENERAL POLICY

Top management is committed to provide adequate resources for the implementation and improvement of the quality system, and for addressing customer satisfaction.

PROCEDURAL POLICIES

1. General

1.1 Resources required for implementation and improvement of the quality system, and for addressing customer satisfaction, may include people, suppliers, information, infrastructure, work environment, and financial resources.

2. Determination of resource requirements

2.1 Quality Assurance and other management personnel involved in the quality system are responsible for determining resource requirements for the implementation and improvement of the system.

2.2 The President is responsible for determining resource requirements for addressing customer satisfaction. This is based on input from other management personnel responsible for activities relevant to particular aspects of customer satisfaction. Procedure P-82-01 explains how information about customer satisfaction is collected and analyzed.

2.3 The principal forum for determining and communicating resource requirements are management reviews of the quality system. Procedure P-56-01, Management Review, explains this process.

3. Provision of resources

3.1 Top management has the responsibility and authority for provision of resources.

3.2 Allocation of resources for particular activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

3.3 Allocation of resources may be documented in the quality manual, operational procedures, and minutes of meetings, memoranda, or any other form. Approvals of

resource allocations may be also communicated verbally.

3.4 Management review of the quality system is the principal forum for allocation of resources for the operation and improvement of the system. All actions initiated by the review are supported by allocation of specific resources necessary for their implementation. Procedure P-56-01, Management Review, defines this process.

ASSOCIATED DOCUMENTS

- Procedure: P-56-01 Management Review
- Procedure: P-82-01 Customer Satisfaction

Competence, Awareness and Training

GENERAL POLICY

ISC ENGINEERING identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, experience, training, skills and experience. Product requirements may be affected directly or indirectly by personnel performing any task within the quality management system. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training are maintained.

PROCEDURAL POLICIES

1. Identification of training needs and awareness programs

1.1 Top management is responsible for identifying training needs and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

1.2 Managers are responsible for identifying training needs in their departments (competency and conformity to product requirements), and for establishing departmental training programs. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, using analytical and statistical techniques to ensure product integrity.

1.3 In addition, training needs are often identified in response to corrective or preventive action requests (NCR/CAR's), as nonconformities may be caused by inadequate training.

2. Awareness and training programs

2.1 ISC ENGINEERING provides, or supports, the following categories of company-wide and departmental training and awareness programs to ensure all personnel achieve and maintain the necessary competency:

- **General orientation and quality system awareness training** — Explains how the

product is used and how the quality system works to ensure product quality. Provided to all employees.

- **Safety training** — Instructs in safe working practices, use of personal protective equipment, first aid, etc. Provided to all employees.
- **Use of company-wide systems** — Explains interdepartmental systems, such as product identifying/numbering system, use of computers, etc. Provided to wide groups of employees.
- **External training** — External seminars, conferences, and courses. Provided to individual employees on as-needed basis.
- **Self-study** — Reading magazines, books, and reports. While all employees are encouraged to broaden their knowledge through reading, in some cases self-studying may be required as formal training.
- **Skill training in engineering, operations/tooling, and quality control** — departmental training in specific skills to achieve and maintain the necessary competency to ensure continual product integrity. Often provided as on-the-job training.

2.2 Procedure P-62-01, Training and Awareness, describes in detail the training and awareness programs provided by ISC ENGINEERING.

3. Effectiveness of training

3.1 Effectiveness/Competence training is evaluated using the following approaches:

- Follow-up performance evaluation of trained employees;
- Review of the overall performance in areas relevant to particular training programs;
- Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities; and
- A global review of all training and awareness programs, conducted within the framework of management reviews of the quality system.

Procedures P-62-01, Training and Awareness, and P-56-01, Management Review, prescribe more specific methods for evaluating particular categories of training and awareness programs.

4. Training records

4.1 Training records are established for all types of training. Records are normally

established and maintained by Quality. The Front Office also maintains the as-hired qualification records.

ASSOCIATED DOCUMENTS

- Procedure P-62-01: Training and Awareness
- Procedure P-56-01: Management Review

Infrastructure and Work Environment

GENERAL POLICY

Suitable infrastructure, facilities and work environment are provided as required to achieve product conformity. This includes planning, provision, and maintenance of employee facilities, workspaces, equipment, and associated services.

PROCEDURAL POLICIES

1. Infrastructure and Facilities

1.1 Planning of new, and/or modification of existing infrastructure and facilities are usually conducted in conjunction with product or process changes; capacity and/or work force expansions; and other such events. Facilities may also be expanded or modified to improve productivity and/or quality, or to improve the work environment.

1.2 Departmental managers are responsible for identifying the need and requirements for new, and/or modification of existing infrastructure and facilities in their departments. Requests for significant changes and/or expansions of facilities are submitted to the top management for review and approval.

1.3 When relevant, Quality Assurance reviews the proposed facilities or changes to ensure that they enhance the achievement of product conformity and quality.

2. Supporting services and maintenance of facilities

2.1 Maintenance of buildings and facilities is performed by ISC ENGINEERING. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, contracted landscaping, cleaning, telephone, information systems and electronic mail.

2.2 Repairs of buildings and other such facilities are contracted only when needed. The Engineering and Purchasing departments are responsible for coordinating and managing maintenance contracts.

2.3 Production equipment maintenance is addressed in Section 7.5 of this manual and

Procedure P-75-03, Equipment Maintenance.

3. Work environment

3.1 Departmental managers are responsible for ensuring suitable working environment for personnel. This is to include both human and physical factors. Some of the factors that may affect the product include the physical environments relating to; temperature, noise, humidity, ESD, lighting, and cleanliness of work stations.

3.2 Engineering, Production and Quality are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

ASSOCIATED DOCUMENTS

- Procedure P-75-03: Equipment Maintenance

Planning of Product Realization

GENERAL POLICY

Planning of product realization processes includes determination of quality objectives for products; development of required processes and process documentation; and establishment of product verification and validation programs. The plan also defines requirements for records necessary to demonstrate process and product conformity.

PROCEDURAL POLICIES

1. Product quality objectives

1.1 Quality objectives for product are defined in drawings and specifications contract documents, internal and external standards, product samples and workmanship standards, and applicable legal and regulatory requirements. These quality objectives are planned and managed from the onset through product realization in a structured and controlled way to meet acceptable risks for each order.

1.2 Operations, Engineering and Quality Assurance are responsible for identifying product quality objectives and requirements. This may be integrated with the process of determining customer and product requirements.

2. Product realization planning

2.1 Product realization planning includes, as applicable:

- Definition and evaluation of manufacturing operations and processes,
- Development of adequate and capable processes,
- Establishment and implementation of appropriate process control measures,
- Development of instructions and training for process operators, and
- Requirements for records necessary to demonstrate process conformity.

2.2 This Planning of Product Realization shall establish the processes, documents and

provide resources specific to the product as well as providing the required verification, monitoring and the measurement for product acceptance and the records to support the product requirements.

2.3 Product realization plans or otherwise known as “Production Work Order Packages” are established in collaboration between Operations, Engineering/Tooling, and Quality Assurance.

2.4 Product realization plans may incorporate “Risk Management Processes” dependent on ISC ENGINEERING”s ability to achieve applicable product and scheduling requirements that are appropriate to the company and the products provided. The plans may be in place for new technology requirements and shortened delivery schedules. Considerations for these may be defined in various types of production documents, production work order routers, control plans, instructions, inspection reports, etc.

2.5 Procedures related to Section 7.5, Operations, explain how outputs of product realization planning are used.

3. Product verification and validation planning

3.1 Product verification monitoring, measuring, and validation plans determine the inspection and testing program for a product acceptance, and for materials and components incorporated into the product. This includes:

- Identification of inspection and testing points,
- Inspection and testing scope, frequency, and method,
- Acceptance criteria, and
- Requirements for records necessary to demonstrate product conformity.

3.2 Operations, Quality Assurance and Engineering are responsible for development of product verification plans. The plans are defined in various types of documents, such as product drawings and specifications, production work order packages, purchasing documents, inspection and testing procedures, and so forth. Documents defining the inspection and testing program for a product are collectively referred to as control plans.

3.3 Procedures P-74-03, Verification of Purchased Product; P-82-04, In-process Inspections; and P-82-05, Final Inspection, explain how outputs of product verification and validation planning are used.

ASSOCIATED DOCUMENTS

- Procedure P-74-03: Verification of Purchased Product
- Procedure P-82-04: In-process Inspections
- Procedure P-82-05: Final Inspection

Customer-related Processes

GENERAL POLICY

Product requirements are determined to include customer requirements and legal, regulatory, and other necessary requirements that may not be specified by customers. Orders are reviewed to ensure that product and order requirements are defined and can be met, and to resolve any incomplete or conflicting requirements or no stated requirements. Verbal orders are confirmed before acceptance. Order amendments and changes are likewise reviewed and are communicated to all relevant functions. Order reviews are recorded.

Arrangements for communication with customers relating to product information, order handling, and customer feedback and complaints are defined and implemented. Where appropriate, operational procedures and instructions for these activities are established and implemented.

PROCEDURAL POLICIES

1. CUSTOMER AND PRODUCT REQUIREMENTS

1.1 Product requirements

1.1.1 The customer's product requirements including delivery and when required**,** post delivery activities (warranty provisions, contractual obligations, and statutory/legal requirements), or any additional requirements determined necessary are reviewed by Sales. This often involves input from Engineering, Operations, Purchasing, and Quality Assurance, depending on the nature and complexity of the order, and whether a similar order has been recently processed.

1.1.2 Product requirements are determined and reviewed with regard to requirements specified by the customer; other relevant product requirements not specified by the customer, and the company's capacity and capability to meet all applicable requirements.

1.2 No documentation or incomplete or conflicting requirements

1.2.1 No documentation or incomplete documentation or conflicting requirements are resolved with the customer before acceptance of the orders/contracts.

1.3 Verbal orders

1.3.1 Verbal orders are confirmed before acceptance. This may be by repeating the order requirements back to the customer and then sending and receiving a confirming fax or e-mail. Verbal orders may also be made a consideration for the President.

1.4 Amendments

1.4.1 Change orders are received and reviewed by the same functions that are responsible for the review of the initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements. Order Processing, P-72-01, Order Processing provides instructions on how to process change orders.

1.5 Record

1.5.1 Records of all customer orders, conflicting or ambiguous information, changes and amendments are maintained as a hard copy in the applicable customer purchase order file.

2. CUSTOMER COMMUNICATION

2.1 Product Information

2.1.1 The President/Sales and Engineering are responsible for developing the content and format for company's brochures, catalogs, internet site, and other forms of promotional and product information material. This is based on technical specifications developed by Engineering.

2.1.2 Master copies and/or files of customer documents containing product information are controlled. They are reviewed and approved before release, and are identified by the part number or drawing number which correlates with the traveler.

2.1.3 Only the President and designated personnel from Customer Service, Office Administration and Engineering are authorized to communicate with customers regarding orders, scheduling or any other current product information.

2.2 Inquiries and order handling

2.2.1 Customer Service/Office Administration is generally responsible for receiving customer inquiries and orders. Orders for products are reviewed and further processed by the President and Engineering and may involve review by Operations; Purchasing, and Quality Assurance.

2.2.2 Handling of order amendments is controlled to the same extent as the handling of initial orders. Amendments are reviewed to verify that the new or modified requirements can be met, and a confirmation of acceptance is sent back to the customer.

2.2.3 Procedures P-72-01, Order Processing, instructs how to handle inquiries, orders, and amendments for products.

2.3 Customer feedback and complaints

2.3.1 Customer Service/Office Administration is also generally responsible for receiving and processing customer feedback and complaints. All received customer communication is recorded in the customer feedback and complaints log.

2.3.2 Customer feedback and complaints are classified into categories to allow for better tracking of trends and evaluating improvement in specific aspects. Every complaint is communicated to relevant functions within and outside the organization. The President, the responsible department, and Quality Assurance decide how to respond to the customer and, when appropriate, what corrective or preventive actions should be implemented internally or when applicable, externally.

2.3.3 Procedure P-72-03, Customer Feedback and Complaints, provides detailed instructions how to receive, process, and respond to customer feedback and complaints.

ASSOCIATED SECTIONS AND DOCUMENTS

- Procedure P-72-01: Order Processing
- Procedure P-72-03: Customer Feedback and Complaints
- Procedure P-82-05: Customer Feedback and Complaints

Purchasing

GENERAL POLICY

ISC Engineering evaluates its suppliers and purchases only from those that can satisfy quality requirements. Quality performance of suppliers is monitored and evaluated. Purchasing documents clearly and completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release. Purchased products are verified before they are incorporated into the product.

PROCEDURAL POLICIES

1. Supplier evaluation

1.1 All new suppliers are evaluated with regard to their quality and process capability. Purchasing and Quality Assurance, with the assistance of Engineering establish the criteria for selection of suppliers, and conduct supplier evaluation. Objective and reliable supplier data from external sources may be used for evaluation and selection.

1.2 Suppliers are rated APPROVED or NOT APPROVED. The approved suppliers are entered on the approved supplier list. Existing suppliers with a satisfactory quality performance history will be maintained as APPROVED as long as their performance remains satisfactory. Procedure P-74-01, Supplier Evaluation, governs supplier evaluation process.

2. Supplier quality performance monitoring

2.1 Quality performance (Product Quality, Documentation Expertise, and On Time Delivery) of suppliers is monitored. Suppliers showing inadequate performance are asked to implement corrective actions. If the requested corrective actions are not implemented and there is no improvement, the supplier is downgraded to the NOT APPROVED rating and is discontinued. Records of supplier's performance are maintained, including those directed by customers. The system for monitoring suppliers is defined in Procedure P-74-01, Supplier Evaluation.

3. Approved supplier list

3.1 Quality, in concert with Purchasing maintains a supplier list. Orders may only be placed with suppliers/vendors/processors that are identified as "Approved Suppliers"

on the list.

4. Purchasing information

4.1 Purchasing documents are prepared by the Purchasing department. The documents clearly and completely describe ordered products, including precise product identification and quality requirements. Purchase Orders for custom and complex product require additional review and approval prior to release.

4.2 The preparation, review, and approval of purchasing documents are explained in Procedure P-74-02, Purchasing.

5. Verification of purchased product

5.1 Purchased products are received and verified by a trained receiving clerk. (Identified on their training summary) This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all requested certificates and quality records are available. Designated products may be further inspected or tested by QC, as applicable.

5.2 QC inspection or testing may not be necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history.

5.3 When custom or complex product requires further verification and validation, (Beyond Requirements of 5.1 above) Quality Control is responsible for selecting appropriate methods for purchased product verification and acceptance. Procedure P-74-03, Verification of Purchased Product, sets forth detailed rules for selecting product verification methods and for performing receiving and QC inspections.

5.4 When verification of purchased product is to be performed at supplier's premises, purchasing documents specify the intended verification arrangements and method of product release.

ASSOCIATED DOCUMENTS

- Procedure P-74-01: Supplier Evaluation
- Procedure P-74-02: Purchasing
- Procedure P-74-03: Verification of Purchased Product

Operations

GENERAL POLICY

Product and process information and appropriate work instructions are established and are communicated to relevant personnel. Operations and production processes are monitored and controlled, and are validated where appropriate. Machines and equipment used in production and for monitoring and measurement activities are maintained. Methods for product release and delivery are defined.

Materials, components, parts, subassemblies, and finished products are identified. When required, traceability of materials and processes is recorded and maintained. Inspection and test status of product is identified to ensure that only product that has passed the required inspections is used, installed, or dispatched.

Customer-supplied products are normally controlled in the same manner as are purchased products. Customer property, including data, is marked to indicate ownership. Loss, damage, or unsuitability of a customer's product is recorded and reported to the customer.

Appropriate handling, storage and preservation methods are implemented to prevent product damage or deterioration. Receipt and dispatch to and from storage areas are controlled. The condition of products in stock is regularly assessed. Product packaging materials and methods are specified and controlled.

PROCEDURAL POLICIES

1. OPERATIONS CONTROL

1.1 Product and process specifications

1.1.1 Information specifying product characteristics is communicated to Operations in the form of drawings, specifications, samples, instructions, production work packages, and product-specific templates and other tooling, as required. This information is controlled in accordance with Procedure P-42-02, Control of Documents. Engineering, Production Planning and Quality Assurance determine the scope, form, and distribution of product specifications.

1.1.2 Product and process information required by process operators is communicated through the production work order package or may be included in work instructions. Where required for custom products, engineering drawings and specifications may be enclosed with the production work order package. Procedures P-75-01 Production Work Order Package, and P-75-02, Work Instructions, explain how to establish and use these documents.

1.2 Work instructions/workmanship standards

1.2.2 Work instructions and workmanship standards may be in the form of manuals, procedures, sheets, posted signs, or samples. They instruct on how to carry out a process or perform an operation or task. The need for work instructions is evaluated on the basis of criticality, importance and complexity of the process; the ability to verify results of the process; operator qualifications; and history of quality problems associated with the process. Workmanship standards are provided when acceptability of the process output can only be determined by comparison with a standard sample.

1.2.3 Procedure P-75-02, Work Instructions, specifies criteria for determining when work instructions are needed, and provides guidelines for issuing, authorizing and controlling work instructions.

1.3 Equipment maintenance

1.3.1 Key process equipment, machines and hardware are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment. Requirements for the maintenance of production equipment are specified in Procedure P-75-03, Equipment Maintenance.

1.4 Measuring and monitoring equipment

1.4.1 Requirements for measuring and monitoring equipment are determined by Operations, Engineering and Quality Assurance. This is in accordance with process control and product verification programs defined in product realization planning (refer to Section 7.1 of this manual).

1.4.2 Control system for measuring and monitoring equipment is defined in Procedure P-76-01, Measuring and Monitoring Equipment.

1.5 Process monitoring and control

1.5.1 Processes are monitored and controlled through variety of approaches, activities and techniques. The system is designed to control:

- Information, material and human (operator) input into the process;
- Technology, tools and equipment used;
- Process environment and performance; and
- Process output.

Process monitoring activities are further defined in Section 8.2 of this manual. Activities related to process control are defined in Operational Procedures P-75-01, Production Work Order; P-75-02, Work Instructions.

1.6 Product release and delivery and as applicable “post delivery activities”

1.6.1 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Procedure P-82-05 Final Inspection, define the system for final product verification and release.

1.6.2 Work transferred or processed by an outside vendor during normal or abnormal; (Power “Brown Outs”, Earth Quakes, or other environmental disasters) manufacturing conditions will be controlled by ISC ENGINEERING management. Included in this is the validation and verification, as applicable upon receipt to ensure the quality of the work accomplished at the outside vendor.

2. IDENTIFICATION AND TRACEABILITY

2.1 Product identification

2.1.1 Purchased products are identified with unique numbers, codes, or names. The identification is the same as, or is cross-referenced with, the designations used in drawings, specifications, bills of materials, parts lists, purchase orders, etc. Purchased products are identified by ISC ENGINEERING markings, labels, or tags on the products or their packaging and as necessary, identification of the area where the products are held.

2.1.2 During all stages of production, products are usually identified by the work order packages and other documents that accompany them through the production cycle. Parts and components may also be identified by labels or tags, or the containers in which they are held.

2.1.3 Final products are identified by their name and model number, which is labeled or marked on the products and/or is printed on the primary product packaging.

2.1.4 Rules and activities related to identification of products are governed by Procedure P-75-04, Product Identification and Traceability. Additional relevant procedures are P-75-01 Production Work Order Package; P-75-03, Verification of Purchased Product; P-82-05, Final Inspection; and P-75-08, Packaging, Labeling and Shipping.

2.2 Traceability

2.2.1 When required by contracts, laws and regulations, or voluntary standards traceability is implemented to the extent specified. Traceability may also be implemented for internal reasons, to facilitate corrective action.

2.2.2 As required, traceability may apply to materials, components, parts, production processes, environmental conditions, inspection and testing, and personnel responsible for processing and verification of products. The scope of traceability is documented in product manufacturing specifications or in the production work order package.

2.2.3 Activities related to establishment and maintenance of traceability are regulated by Procedures P-75-04, Product Identification and Traceability, and P-75-01, Production Work Order.

2.3 Inspection status identification

2.3.1 Following every inspection or test, products or the accompanying documentation is identified to indicate whether they have passed or failed the inspection. This is to prevent nonconforming product from being used or dispatched. Physical location of product can only be used as inspection status identification when the location is designated and contained, and in automated production transfer processes.

2.3.2 QC inspectors, receiving clerks, and production personnel authorized to carry out inspections and testing are responsible for identifying product inspection status. All personnel handling products are responsible for maintaining the identification.

2.3.3 Products that have passed the receiving inspection are identified as per paragraph 2.1.1 above and moved to the material stockroom or designated material staging areas in production. Where intermingling with other product is a possibility, the inspected items are also appropriately tagged or labeled.

2.3.4 The status of product is identified throughout the product realization process. The completion of an operation and/or inspection is usually identified by a sign-off or stamp in the work order router accompanying the product. The status may be also

identified by tagging or labeling, or holding products in designated containers.

2.3.5 Products that pass the final inspection are placed in the finished product area that is designated and used for this purpose.

2.3.6 Products that fail any inspections or tests are labeled with REJECTED sticker or tag, and are segregated and/or quarantined. Whenever a nonconforming product is identified, the nonconformity is documented using a product nonconformity report. Detailed instructions on how to identify conforming and nonconforming products are provided in Procedure P-75-05, Inspection and Test Status, and Procedure P-83-01, Control of Non-conformances.

3. CUSTOMER PROPERTY

3.1 Receiving

3.1.1 Customer-supplied products are received and inspected following the same procedure that applies to purchase products, i.e., Procedure P-74-03, Verification of Purchased Product. In the event the supplied products fail receiving inspection, or are not suitable for any other reason, the customer is contacted.

3.2 Marking, storage, and handling

3.2.1 Marking, storage, handling, and preservation of customer supplied products follow the same procedures that apply to purchase products. The applicable procedures are, P-75-04, Product Identification and Traceability; P-75-06, Product Handling and Preservation; and P-75-07, Storage Areas.

3.2.2 Customer-owned tooling and returnable packaging are permanently marked so that ownership of each item is visually apparent.

3.2.3 Customer’s software, documents, and other intellectual property and personal data are protected to the same extent as would internal documents of similar content, unless there are contractual requirements for special measure to protect customer’s intellectual property.

3.3 Special requirements

3.3.1 When specified in contracts or purchase orders, special handling instructions from customers will take precedent over the company's standard procedures.

3.4 Loss or damage

3.4.1 Customers are contacted and records maintained in the event of loss, damage, deterioration, or unsuitability of their products.

4. PRESERVATION OF PRODUCT

4.1 Product handling and preservation

4.1.1 Production is responsible for product handling and preservation in order to maintain conformity to requirements and may include ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage. Procedure P-75-06, Product Handling and Preservation, describes in detail how these policies are implemented.

4.2 Storage

4.2.1 Stockrooms and storage, staging and holding areas are controlled by the department that brings in new stock or uses the area. Only products that are properly identified and that have passed required inspections are authorized to enter and leave the stockrooms. Every year storage areas are inspected to assess the condition of stock.

4.2.2 When special storage conditions are specified (for example, temperature or humidity), products are stored in special rooms, boxes, or containers where the specified conditions can be continuously maintained. These special conditions are monitored to ensure that they are maintained without interruption and that the product is not compromised at ant time.

4.2.3 Products with limited shelf life are identified with expiration dates. These perishable products are also rotated in the stockroom to ensure that the oldest product is used first.

4.2.4 Material and finished product stockrooms are controlled using an inventory management system. The system can report available in stock quantities, product location, and turn-over times. The system is used to optimize and minimize inventory levels.

4.2.5 Procedure P-75-07, Storage Areas, governs the operation of stockrooms and storage, staging and holding areas.

4.3 Packaging and labeling

4.3.1 Primary packaging are cardboard boxes, crates, or other additional packaging intended to contain and protect products for shipping and transportation.

4.3.2 Primary packaging and labeling operations are controlled following the same policies and procedures that apply to production operations and processes. Product packaging and labeling are defined in drawings, specifications and artwork. These documents are issued and controlled in the same manner as other engineering documents. When appropriate, personnel involved with these processes are provided with work instructions and/or special training.

4.3.4 Shipping department is responsible for establishing specifications for secondary packaging and labeling. The specifications are compatible with requirements of commonly used carriers and for intended means of delivery (ground, sea, air). Packaging specifications are documented in drawings, written standards, and/or packaging instructions. Packaging specifications are maintained and controlled by Shipping.

4.3.5 Packaging and labeling activities are governed by Procedure P-75-08 Packaging, Labeling and Shipping.

4.4 Shipping and delivery

4.4.1 Shipping of finished products is initiated by the shipping order. The order identifies the shipping consignee address, shipping due date, products to be shipped, labeling requirements, and transportation mode or carrier. Before products are dispatched, the order is verified that the shipment contains the same products and quantities as specified in the sales order, and that packaging and labeling conform with customer and/or carrier requirements. Only orders that have been verified and signed off can be loaded for shipment.

4.4.2 Activities related to shipping and delivery operations are regulated by Procedure P-75-08, Packaging, Labeling and Shipping.

5. VALIDATION OF PROCESSES

5.1 Processes where the resulting output cannot be verified by subsequent monitoring and measuring and, as a consequence, deficiencies become apparent only after the product is in use or service has been delivered are designated as special processes.

5.2 Production and Quality Assurance are responsible for identifying, validating, and documenting special processes. Where applicable, Engineering may assist with establishing validation specifications and testing of samples.

5.3 Special processes are validated by use of approved criteria/method, approved equipment, and qualified personnel, maintaining records. In addition, revalidation such as; destructive testing of product samples and the use of work instructions and process procedures shall be used to demonstrate the ability of these processes to achieve planned results.

5.4 Production and Quality Assurance are responsible for selecting and implementing appropriate process validation and control measures for each special process. At a minimum, all special processes are documented in work instructions.

5.5 Special process records are established and maintained as appropriate. Depending on the control measures implemented, these records may include process qualification and validation reports, equipment qualification and maintenance records, first article inspections and tests, operator qualification and training records, and so forth.

ASSOCIATED DOCUMENTS

- Procedure P-42-02: Control of Documents
- Procedure P-74-03: Verification of Purchased Product
- Procedure P-75-01: Production Work Order Packages
- Procedure P-75-02: Work Instructions
- Procedure P-75-03: Equipment Maintenance
- Procedure P-75-04: Product Identification and Traceability
- Procedure P-75-05: Inspection and Test Status
- Procedure P-75-06: Product Handling and Preservation
- Procedure P-75-07: Storage Areas.
- Procedure P-75-08: Packaging, Labeling and Shipping
- Procedure P-76-01: Measuring and Monitoring Equipment
- Procedure P-82-05: Final Inspection
- Procedure P-83-01: Control of Non-conformances

Measuring and Monitoring Equipment

GENERAL POLICY

Appropriate measuring and monitoring instruments are maintained and selected to ensure that measurement capability is consistent with the measurement requirements. Equipment used for assuring product conformity is calibrated or verified, or both, using calibration standards traceable to the national standard. Calibration status of measuring equipment is identified with calibration stickers. Measuring equipment is properly maintained and its placement and use are controlled.

PROCEDURAL POLICIES

1. Controlled and uncontrolled equipment

1.1 The scope of the calibration control system extends to the measuring and test equipment, comparative reference hardware (such as gauges and templates), and test software used for:

- Setup and monitoring of production processes;
- Verification of product conformity; and
- Operations where defined accuracy of a measurement is required to assure product conformity.

1.2 Equipment used for other purposes may be exempted from calibration. Such equipment is labeled with stickers warning that it is not calibrated. Uncontrolled measuring equipment is prohibited for Quality Control inspections.

2. Measurement identification and selection of equipment

2.1 Identification of measurements to be made and the tolerance of the measured characteristics are documented in control plans and/or in product drawings and specifications.

2.2 Gauges, instruments, and other measuring and monitoring equipment are selected on the basis of their capability to provide the necessary accuracy of the measurement. Quality Assurance is responsible for selecting appropriate measuring and monitoring

equipment.

3. Equipment calibration and maintenance

3.1 Quality Assurance is responsible for calibrating and maintaining measuring and monitoring equipment. All active equipment is inventoried in a controlled list, indicating equipment calibration status and location.

3.2 Measuring equipment is calibrated using written instructions, unless calibration is simple and obvious. Only calibration instruments and standards having known relationship to the nationally recognized standards are used for calibrating measuring and test equipment.

3.3 Calibration is recorded in a calibration certificate and the calibrated equipment is labeled with a calibration sticker or has specific identification in order to determine its present calibration status. In addition to current calibration records, a record of validity of present and previous calibration results shall be maintained as well as those that were found not to conform.

3.4 Calibration-related activities are regulated by Procedure P-76-01, Measuring and Monitoring Equipment.

4. Validation of software

4.1 When in-house developed inspection, test, and/or monitoring software is created it is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or re-certified when conditions for which it was initially validated are materially changed.

ASSOCIATED DOCUMENTS

- Procedure P-76-01: Measuring and Monitoring Equipment

Planning of Monitoring and Measurement

GENERAL POLICY

Measurement and monitoring activities required to assure product conformity, and to achieve improvement, are planned and defined. .

PROCEDURAL POLICIES

1. 1.Planning

1.1 Measurement and monitoring activities to assure and verify product conformity are defined in engineering specifications and drawings, production work packages, inspection and testing procedures, and process control procedures. These activities are further defined in this manual in Section 8.2, Measurement and Monitoring, and in several procedures referenced at the end of this section.

1.2 The effectiveness of the quality system is monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the top management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are further defined in this manual in Sections 8.2.

2.0 Statistical techniques

2.1 According to the nature of the product and the specified requirements Statistical techniques may be applied as an effective tool or per a customer's contract/purchase order to the following:

- Set up of process equipment;
- Process control;
- Product design experiments (customer directed);
- Validation of processes;
- Control of process stability and performance;

- Establishment of sampling plans for inspections;
- Evaluation of measurement systems;
- Failure mode and analysis of quality performance (company/customer directed) and
- Quality measuring and monitoring data.

2.2 Department managers, with the help of Quality are responsible for identifying the need for using statistical techniques during the manufacturing of product. Engineering may be called upon to assist in selecting and documenting specific statistical process analysis regarding non-conformances attributed to processes, product non-conformances and errors related to training deficiencies and supplier anomalies.

2. Statistical techniques

2.1 Statistical techniques are used to evaluate the quality of product (Matching sampling rate to the criticality of the product, when required or as an effective production tool) and using statistical data, such as customer complaints, supplier performance and company performance to determine required improvement activities for the Quality Management System.

ASSOCIATED DOCUMENTS

- Procedure P-74-03: Verification of Purchased Product
- Procedure P-82-01: Customer Satisfaction
- Procedure P-82-02: Internal Audit
- Procedure P-82-03: Statistical Process Control
- Procedure P-82-05: Final Inspection

Monitoring and Measurement

GENERAL POLICY

Customer satisfaction is the principal objective of the quality system, and the level of customer satisfaction is the most important measure of the effectiveness of the system. Customer satisfaction is measured by collecting and analyzing direct customer feedback, and by measuring secondary indicators of customer satisfaction. Customer satisfaction data is used by the top management to identify opportunities and priorities for improvement.

All activities and areas relevant to the quality system are audited at least once a year. Audits are scheduled on the basis of the status and importance of the activity. Internal auditors are independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and corrective actions are implemented in response to audit findings.

Quality system processes are monitored to ensure that they achieve planned results. Relevant product characteristics are measured through inspections, tests, and other product verification activities, as specified in control plans. Evidence of product conformity is recorded. Products are released for delivery only after all specified activities have been satisfactorily completed and verified.

PROCEDURAL POLICIES

1. CUSTOMER SATISFACTION

1.1 General

1.1.1 The President and Quality Assurance are responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

1.1.2 Information and data pertaining to customer satisfaction are collected from several sources. Specifically, these are:

- Customer feedback and surveys,
- Product returns and warranty claims,

- Delivered product quality
- Lost business analysis
- Compliments;
- Awards and recognitions, and
- Repeat customer rates

1.1.3 Procedure P-82-01, Customer Satisfaction, defines the system for collecting and analyzing the pertinent information and data, and for reporting results to the top management.

1.2 Customer feedback and surveys

1.2.1 Customer complaints, spontaneous expressions of satisfaction, and other unsolicited customer feedback are collected and processed by the Customer Service department. These activities are defined in Procedure P-72-03, Customer Feedback and Complaints. The resulting data is periodically analyzed by the Customer Service manager, and is presented and discussed at management review meetings.

1.2.2 Sales and Quality plan semiannual customer satisfaction surveys. Survey results are compiled and analyzed, and are combined with customer satisfaction data for compatible aspects of products and services. Conclusions are presented and discussed at management review meetings.

1.2.3 Awards and recognitions

1.2.4 ISC Engineering presents its products at conferences and for independent evaluations and assessments. It also encourages customers to rate its performance, and seeks to participate in customer's award and recognition programs. These recognitions and ratings are considered as an important input into determining customer satisfaction.

1.3 Product returns and warranty claims

1.3.1 Information about the rate of product returns and warranty claims is extracted from accounting, quality, and servicing records. Results and trends are reported and analyzed at management review meetings

1.4 Repeat customers

1.4.1 Sales records are periodically analyzed to identify repeat customers and track their ordering frequencies and patterns. The ratio of repeat customers is one of the most important indicators of customer satisfaction. Statistics on repeat customers frequencies and trends are presented and discussed at management reviews.

2. INTERNAL AUDIT

2.1 Planning and scheduling

2.1.1 Quality Assurance Manager establishes an internal audit plan and schedule in accordance with Procedure P-82-02, Internal Quality Audits. Every activity and area is audited at least once a year. Selected activities are audited more frequently, depending on their importance and quality performance history.

2.2 Audit team and preparation for audit

2.2.1 Only personnel independent of the audited activities are assigned to conduct internal audits. Normally, the Quality Assurance Manager leads the audit team except when QA activities are being audited. Audits of QA activities are usually conducted by Engineering.

2.2.2 Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists. Selection of auditors and preparation for the audit are explained in Procedure P-82-02, Internal Quality Audits.

2.3 Conducting the audit

2.3.1 Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO 9001, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

2.3.2 Nonconforming conditions are documented and recorded using the audit nonconformity report form. A model of the form and instructions on how to use it are provided in Procedure P-82-02.

2.3.3 Audits are conducted in a way that minimizes disruption of the audited activities.

2.4 Corrective action and follow up

2.4.1 When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to propose and implement necessary corrections and corrective actions without undue delay and to eliminate the detected nonconformities and their causes. Implementation and effectiveness of the action are verified by a follow-up audit. The NCR/CAR form (QF 8300) is used for monitoring and recording the implementation of the corrective actions.

2.5 Reporting

2.5.1 When the auditing cycle is completed, all associated records and results are maintained. All nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting.

3. MONITORING and MEASURING OF PROCESSES

3.1 Process monitoring

3.1.1 Quality system processes are monitored by variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

- Conducting internal audits to determine the effectiveness of the Quality Management System;
- Monitoring trends in corrective and preventive action requests;
- Analyzing product conformity and other quality performance data and trends, and
- Measuring and monitoring customer satisfaction.

3.2 Response Actions

3.2.1 When planned results are not achieved, correction and corrective action shall be taken, as appropriate. Consideration shall be taken for the appropriate measuring and monitoring of each process in relation to the impact on the conformity to product requirements and on the effectiveness of the quality management system. The Quality Assurance Manager may request the manager responsible for the process to provide correction and implement corrective action, in accordance with Procedure P-85-02, Corrective and Preventive Action.

4. MONITORING AND MEASUREMENT OF PRODUCT

4.1 Product verification

4.1.1 Inspection and testing program for a product is defined in various types of documents, such as product drawings and specifications, production work orders, purchasing documents, inspection and testing procedures, and so forth. Documents defining the inspection and testing program for a product are collectively referred to as control plans. Section 7.1 of this manual defines the process for establishing control plans.

4.1.2 **Verification of purchased product**: All purchased products are subjected to a visual inspection by the receiving clerk, and then some designated products are subjected to

a more detailed and technical QC inspection. Procedure P-74-03, Verification of Purchased Product, sets forward detailed rules for performing receiving and QC inspections.

4.1.3 **In-process inspections:** In-process inspections may be in the form of first article inspections, operator or QC inspections, and continuous product verification by automated inspection equipment. The focus is on defect prevention rather than detection. In-process inspection activities are regulated by Procedures P-82-04, In-Process Inspection.

4.1.4 **Final inspection**: Finished products are subjected to the final QC inspection. First, inspectors verify that all specified receiving and in-process inspections have been carried out satisfactorily. Then they perform the remaining inspections and tests necessary to complete the evidence of product conformity. Only products that pass the final inspection can be shipped. Procedure P-82-05, Final Inspection, regulates these activities.

4.2 Inspection, test and monitoring records

4.2.1 Results of inspections and tests are recorded. Rules for establishing records for specific types of inspections are defined in Procedures P-74-03, P-82-04, and P-82-05. Filing and maintenance of inspection records are regulated by Procedure P-42-03, Control of Quality Records.

4.3 Product release

4.3.1 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified unless otherwise approved by a relevant authority or by the customer. Records shall indicate the personnel performing final product inspections and tests and they shall have the authority to release products.

4.3.2 The identity of the person authorizing product release is recorded. The release of product shall not proceed until all the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, when applicable, by the customer. Also see, Procedure P-82-05, Final Inspection, defines specific methods for product release.

4.3.3 The evidence of conformity to process and product acceptance criteria is maintained as directed in Procedure, P-42-03 Control of Records.

ASSOCIATED DOCUMENTS

- Procedure P-42-03: Control of Records
- Procedure P-74-03: Verification of Purchased Product
- Procedure P-82-02: Internal Quality Audits
- Procedure P-82-04: In-process Inspections
- Procedure P-82-05: Final Inspection
- Procedure P-85-02, Corrective and Preventive Action.

Control of Non-Conformances

GENERAL POLICY

Nonconforming product is identified, documented, evaluated, and prevented from being used or shipped. Reworked products are re-inspected and made conforming prior to release. Appropriate actions are taken when product nonconformity is identified after delivery. When appropriate, corrective and preventive actions are implemented to prevent recurrence of identified nonconformities. The Quality Management Program and associated programs that could affect product and customer satisfaction is subject to the same corrective and preventive control to ensure continuous improvement of the Quality Management Program.

PROCEDURAL POLICIES

1. Identification and documentation

1.1 ISC Engineering identifies and documents all product and system nonconformities, regardless of how insignificant they seem to be or how easily they can be reworked or replaced. Product and system nonconformity records are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented.

1.2 Non-Conformance and Corrective Action Reports are also issued for anomalies regarding the Quality Management System and relevant associated business and process management programs to ensure continual improve of the QMS.

1.3 Nonconforming products are documented using a Non-Conformance Report/ Corrective Action Report (NCR/CAR) QF 8300. It describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (re-inspection, concessions, corrective actions, etc.). The uses of the NCR/CAR for product and system anomalies are further explained in Procedure P-83-01, Control of Nonconforming Product.

1.4 To prevent nonconforming products from being used or shipped, the products are identified with a copy of the NCR/CAR and/or a rejection tag and are segregated.

2. Nonconformity review and disposition

2.1 Quality Assurance is responsible for reviewing the non-conformances and corrective actions for accuracy, issuing the NCR/CAR and for ensuring that timely disposition are obtained. Quality also reviews the disposition, verifying the satisfactory implementation and effectiveness of the corrective action, closure of the NCR/CAR and the maintenance of the Non Conformance log, (QF 8300).

2.2 The disposition decision may be: Rework to requirements of print/drawing or scrap. Accept As-Is, or Repairs (requires customer approval) depending on customer contract requirements and delegation of material review board authority.

2.3 Detailed rules for nonconformity review, for making the disposition decision, and for recording these activities are provided in Procedure P-83-01, Control of Non-conformances.

3. Re-verification of reworked product

3.2 Reworked products are re-inspected in accordance with applicable procedures and instructions (refer to Procedures P-74-03, Verification of Purchased Product; P-82-04, In-process Inspections; or P-82-05, Final Inspection, as applicable). Scrapped material is documented, reviewed for cause and corrective/preventive actions and then permanently marked, and positively controlled until it can be disposed of.

4. Product returns

4.1 When product nonconformity is detected by the customer after delivery or use has started, the customer is instructed to return the product, or a part. Quality Assurance evaluates returned products.

4.2 When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed what to do with the product. In situations when the nonconformity may create a safety or other hazard, the product may be recalled. Only the President of the company is authorized to make recall decisions.

ASSOCIATED DOCUMENTS

- Procedure P-83-01: Control of Nonconforming Product
- Procedure P-74-03,: Verification of Purchased Product
- Procedure P-82-04: In-process Inspections
- Procedure P-82-05: Final Inspection
- QF 8300: Non-Conformance Report/ Corrective Action Report (NCR/CAR)

Analysis of Data

GENERAL POLICY

ISC Engineering collects complies and analyzes information and data required for evaluating the suitability and effectiveness of the quality system and for identifying opportunities for continual improvement.

PROCEDURAL POLICIES

1. General

1.1 Data and information recorded in quality records are compiled and analyzed to identify non-conformances, their causes and preventive actions. This is accomplished periodically to determine trends in the performance and effectiveness of the quality system and to identify opportunities for improvement.

1.2 Quality Assurance is responsible for coordinating these activities, and for reporting conclusions and trends to the top management. This is usually done within the framework of management reviews of the quality system, in accordance with Procedure P-56-01, Management Review.

2. Scope

Following categories of information and data are recorded, compiled and analyzed:

2.1 Characteristics of processes and products:

- Process performance variation — recorded in process control charts (Procedure P-82-03) and evaluated by Production Engineering.

2.2 Conformance to customer requirements:

- Scrap, rework, repair rates (including cost) — recorded in product nonconformity reports (Procedure P-83-01) and reviewed for trends by QA.
- On-time delivery performance — recorded in delivery performance reports

(Procedure P-75-08) and evaluated for trends by executive management.

2.3 Suppliers

- Supplier quality performance — recorded in subcontractor quality performance files (Procedure P-74-01) and evaluated for trends by Purchasing and Quality Assurance.

2.4 Customer satisfaction and dissatisfaction:

- Customer satisfaction levels — recorded in customer satisfaction surveys and reports (Procedure P-82-01) and evaluated for trends by top management.
- Customer complaints — recorded in customer complaints log (Procedure P-72-03) and evaluated for trends by executive management.

2.5 Quality System:

- Effectiveness of training — recorded in training evaluation reports (Procedure P-62-01) and evaluated for trends by departmental managers.
- Effectiveness of quality system — recorded in internal audit reports (Procedure P-82-02) and evaluated for trends by executive management.

ASSOCIATED DOCUMENTS

- Procedure P-56-01, Management Review
- Procedure P-62-01, Competence, awareness and Training
- Procedure P-72-03, Customer Feedback and Complaint
- Procedure P-74-01 Supplier Evaluation
- Procedure P-75-08: Packaging, Labeling and Shipping
- Procedure P-82-01: Customer Satisfaction
- Procedure P-82-02: Internal Quality Audits
- Procedure P-83-01 Control of Non-Conformances

Continual Improvement

GENERAL POLICY

ISC Engineering deploys continual improvement philosophy throughout the entire company to eliminate the causes of non-conformities in order to prevent recurrence. The improvement effort is driven by goals defined in the quality policy and quality objectives. Improvement opportunities are identified by analyzing quality performance data and information. Improvement projects are defined and implemented through the system of corrective and preventive actions and management review actions.

Causes of identified nonconformities are investigated and, where appropriate, corrective actions are implemented to ensure that nonconformities do not recur. Preventive actions are implemented to eliminate the causes of potential nonconformities. Corrective and preventive actions taken are recorded and are followed up to ensure that they have been properly implemented and that they are effective.

PROCEDURAL POLICIES

1. CONTINUAL IMPROVEMENT

1.1 Opportunities for improvement

1.1.1 Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

1.1.2 Quality performance is determined by analyzing information about customer satisfaction, records of product and process nonconformity, results of internal audits, and other data and information relevant to quality performance. Section 8.4, Analysis of Data, defines the scope and system for collecting and analyzing such information.

1.1.3 Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

1.1.4 This process of facilitating continual improvement though the use of quality policy, objectives, and analysis of data, is defined in Procedures P-85-01, Continual Improvement, and P-56-01, Management Review.

1.1.5 In addition to management reviews, departmental managers identify improvement opportunities continually, based on daily feedback form their operations and other activities. Employees are also encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. These improvement opportunities are evaluated and prioritized by Quality Assurance and, where appropriate, are implemented though the system of corrective and preventive actions.

1.2 Implementation of improvement projects

1.2.1 Improvement projects are usually implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects may be also initiated by management directives, such as policy statements, announcements, memoranda, and so forth.

2. CORRECTIVE AND PREVENTIVE ACTION

2.1 Preventive versus corrective action

2.1.1 Preventive actions are requested and implemented when there are trends of decreasing quality capability and/or effectiveness of the quality system that create a risk for a potential nonconformity. Corrective actions are used when an actual nonconformity is identified.

2.1.2 Recognizing this difference, ISC Engineering has separate systems for identifying the need for corrective and preventive actions. However, once the need is identified, a common system is used to process both types of actions. Forms, logs and other documents and records for processing of corrective and preventive actions are the same.

2.2 Corrective actions

2.2.1 The need for corrective action is determined on the basis of identified actual nonconformities. Corrective action requests are typically triggered by such events as a failed inspection, customer complaint and/or product return, nonconforming

delivery from a supplier, or a quality system audit finding.

2.3 Preventive actions

2.3.1 The need for preventive action is determined on the basis of information and data regarding capability and performance of processes, product nonconformity rates, post-production experience feedback, service records, customer complaints, and quality system audit findings. Such information and data are collected and analyzed to detect unfavorable trends that, if not checked, will increase the risk of nonconformities. The system for collecting and analyzing quality performance information and data is defined in Section 8.4 of this manual.

2.4 Processing of corrective and preventive actions

2.4.1 Preventive and corrective actions are initiated, processed and followed up using a NCR/CAR (Non-Conformance/Corrective Action Request) form. The form documents the unsatisfactory condition and the corrective or preventive action to be taken, and is used to record the verification and closure of the action. Open NCR/CAR's are reviewed regularly to ensure that the actions are implemented and followed up in a timely manner. Procedure P-85-02, Corrective and Preventive Action, explains how to use the NCR/CAR system.

2.5 Continual improvement

2.5.1 Continual improvement actions are often defined as corrective and preventive actions. The effectiveness of the corrective and preventive action is examined to ensure the desired outputs were achieved. This is especially true for preventive actions. Procedures P-85-01, Continual Improvement, and P-56-01, Management Reviews, explain how the corrective and preventive action system is used for facilitating continual improvement.

ASSOCIATED SECTIONS AND DOCUMENTS

- NCR/CAR Form- QF 8300 NCR/CAR
- Procedure P-56-01: Management Reviews
- Procedure P-85-01: Continual Improvement
- Procedure P-85-02: Corrective and Preventive Action