

QUALITY MANAGEMENT SYSTEM MANUAL

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1.0 SCOPE

1.1 Quality Policy

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

Company will:

- Be responsive to customers needs.
- Provide effective auction systems maintenance solutions.
- Provide reliable consultation and support.
- Ensure effective and efficient use of resources.
- Meet or exceed clients' requirements.
- Enhance customer/clients' satisfaction through a feedback process.
- Continually improve its products, services, and Quality Management System (QMS)
- Identify improvement opportunities.

1.2 Introduction

1.2.1 i-Naira Integrated Resources Ltd (i-Naira.com), developed and implemented a QMS to establish its ability to consistently provide auction services that meets customer and regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity.

1.2.2 This QMS complies with the international standard ISO 9001:2000.

1.2.3 The manual is divided into eight sections modeled on the sectional organization of the ISO 9001:2000 standard. Sections are further divided into several subsections representing main QMS processes. Each subsection defines general policies and basic principles for the pertinent quality system process; summarizes responsibilities and methods; and references relevant operational procedures and other documents.

1.2.4 The purpose of this manual is to:

- Define and describe the quality system
- Define authorities and responsibilities of the management personnel involved in the operation of the system
- Provide a general description of all processes comprising the QMS.
- Present and inform customers, clients, and other external interested parties of what specific controls are implemented at i-Naira.com to assure quality.

1.3 Application

1.3.1 The quality management system (QMS) defined in this manual applies to auction software infrastructure development, management/maintenance and troubleshooting services offered by i-naira.com before, during and after an auction event.

- 1.3.2 A specific “Quality Plan” will be written for a specific project when required by the customer or applicable government specification.
- 1.3.3 The procedures in this QMS will establish the management practices for customer satisfaction in the absence of specific references to quality procedures by the customer.
- 1.4 Exclusions**
- 1.4.1 The QMS 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 that do not apply are excluded from the scope of our quality system.
- 1.4.2 An ISO 9001 requirement may be excluded only when three conditions are met:
- The requirement must be within ISO 9001 Clause 7, Product Realization;
 - The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets specified requirements; and
 - The exclusion may not affect our ability to carry out corrective action.
- 1.4.3 Processes which are applicable, but which are performed by outside contractors, do not qualify for exclusion. They are accounted for in the QMS to ensure control over such outsourced processes. This is mostly applicable to valuers and technical partners who often work with i-naira.com at the pre-auction process level.
- 1.4.4 The QA Manager is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose to the top management that such requirements be excluded from the scope of the QMS.
- 1.4.5 Top management evaluates the proposed exclusions and determines whether they are appropriate. The evaluation and approval of exclusions are conducted within the framework of management reviews of the QMS (refer to Operational Procedure QOP-56-01, Management Review).
- 1.4.6 Any exclusions taken are documented in this section of the QMS 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.

CLAIMED EXCLUSIONS

No Exclusions taken

2.0 REFERENCE DOCUMENTS

2.1

3.0 TERMS AND DEFINITIONS

3.1

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

4.1.1 Quality Management System processes

4.1.1.1 The Quality Management System (QMS) is designed as a system of interrelated processes. All main activities of the system are defined as Quality System Processes (QSPs) and are grouped into the following four categories (refer to the Quality System Processes Map on next page):

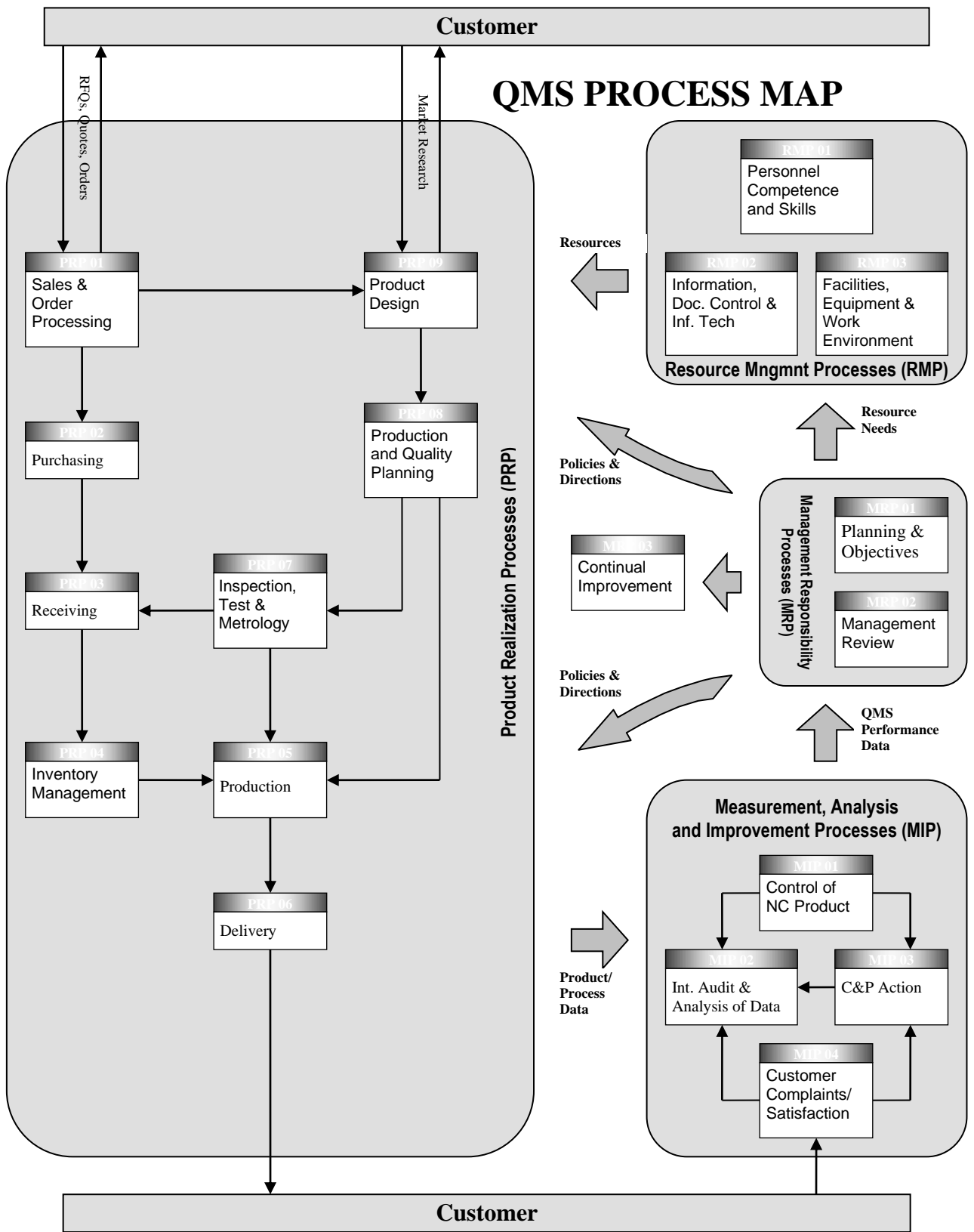
- Product Realization Processes (PRP),
- Measurement, Analysis and Improvement Processes (MIP),
- Management Responsibility Processes (MRP), and
- Resource Management Processes (RMP)

And are organized into a Plan-Do-Check-Act loop.

4.1.1.2 The sequence and interrelation between the four groups and individual QSPs are illustrated in the QMS Processes Map diagram. Each QSP is further broken down into its sub-processes, as defined in the QMS Processes Matrix included after the diagram.

4.1.1.3 QSPs and their sub-processes are documented in this quality manual and in associated operational procedures and work instructions. This documentation defines the quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

4.1.1.4 QMS documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This 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.



QMS PROCESS MATRIX

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Product Realization Process 07 – Inspection, Test and Metrology	
Purpose	To verify conformity of products and to identify, maintain and calibrate monitoring and measuring devices.
Process Owners	QA and Production
Sub-Processes and Procedures	<ul style="list-style-type: none"> • Monitoring, measuring, and testing products - QOP-74-03, QOP-82-03 and QOP-82-04 • Applying and maintaining inspection status identification - QOP-75-04 • Releasing products - QOP-82-04 • Identifying nonconforming products - QOP-83-01 • Selecting monitoring and measuring equipment - QOP-76-01 • Calibrating monitoring and measuring equipment - QOP-76-01 • Controlling monitoring and measuring equipment - QOP-76-01

Product Realization Process 08 – Production and Quality Planning	
Purpose	To plan and develop processes needed for manufacturing and verification of product.
Process Owners	Engineering, Production and QA
Sub-Processes and Procedures	<ul style="list-style-type: none"> • Determining quality objectives and requirements for products - QOP-72-01 and QOP-73-01 • Developing, verifying and documenting production processes (process flowcharts, process sheets, equipment setup instructions, tooling specifications, operator instructions, etc.) - QOP-71-01, QOP-75-01 and QOP-75-03 • Establishing product acceptance criteria and product verification requirements (measuring, inspections, tests, etc) - QOP-71-01, QOP-73-01, QOP-74-03, QOP-82-03 and QOP-82-04

Product Realization Process 09 – Product Design	
Purpose	To design products meeting the design input requirements.
Process Owners	Engineering
Sub-Processes and Procedures	<ul style="list-style-type: none"> • Planning and scheduling design projects - QOP-73-01 • Reviewing and controlling design input - QOP-73-01 • Performing design activities - QOP-73-01 • Conducting design reviews - QOP-73-01 • Establishing design output documents - QOP-73-01, QOP-42-01 • Verifying and validating product designs - QOP-73-01 • Controlling design changes - QOP-73-01

Measurement and Improvement Process 01 – Control of Nonconforming Product	
Purpose	To identify, control and disposition nonconforming products.
Process Owners	QA and Production
Sub-Processes and Procedures	<ul style="list-style-type: none"> • Identifying, documenting and segregating (where applicable) nonconforming products - QOP-83-01 • Making nonconforming product disposition decisions - QOP-83-01 • Reworking and verifying nonconforming products - QOP-83-01

Measurement and Improvement Process 02 – Internal Audits and Analysis of Data	
Purpose	To verify conformity of the quality management system, and to evaluate its effectiveness and efficiency.
Process Owners	Management and QA
Sub-Processes and Procedures	<ul style="list-style-type: none"> • Conducting internal audits of the quality system - QOP-82-02 • Analyzing and evaluating results of internal, third-party and customer audits - QOP-56-01 • Collecting and analyzing quality performance data – QMS-08 Section 8.4

4.1.2 Resources and information

4.1.2.1 The Management Representative 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.

4.1.2.2 Top management is responsible for ensuring the availability of necessary resources and information.

4.1.2.3 *QMS-06 Section 6.1* explains in more detail how resource requirements are identified and satisfied.

4.1.3 Monitoring and measurement

4.1.3.1 Performance of QMS processes is systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.

4.1.3.2 Performance of QMS processes is monitored through internal quality audits (refer to *QMS-08 Section 8.2* and *QOP-82-02 Internal Quality Audits*). To help with the auditing, the Quality System Process Matrix defines for each process the areas to be audited and the reference clauses of ISO 9001.

4.1.3.3 The overall performance of the QMS is monitored by measuring customer satisfaction (refer to *QMS-08 Section 8.2* and *QOP-82-01 Customer Satisfaction*).

4.1.3.4 QMS processes are reviewed and analyzed by the management review of the quality system (refer to *QMS-05 Section 5.6* and *QOP-56-01 Management Review*).

4.1.4 Continual improvement

4.1.4.1 QMS processes are regularly reviewed by the top management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and through quality objectives.

4.1.4.2 *QMS-08 Section 8.5*, *QOP-56-01 Management Review* and *QOP-85-03 Corrective and Preventive Actions*, define how the quality management system itself ensures its own compliance and continual improvement.

4.1.5 Outsourced processes

4.1.5.1 When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls include, as applicable:

- Evaluation and pre-qualification of suppliers;
- Flow-down of customer (contract) requirements,
- Monitoring of supplier quality performance;
- Requirements for process control, inspection, testing and other such records demonstrating product conformity; and
- Receiving inspection of the supplied product.

4.1.5.2 *QMS-07 Section 7.4, QOP-74-01 Supplier Evaluation and Monitoring, QOP-74-02 Purchasing, and QOP-74-03 Verification of Purchased Product*, define these purchasing control processes.

4.1.5.3 Ensuring control over outsourced processes does not absolve COMPANY of the responsibility to conform to all customer and regulatory requirements.

4.2 Documentation and Records

4.2.1 Documentation

4.2.1.1 COMPANY QMS documentation comprises the following categories of documents:

- QMS manual, including a Quality Policy and objectives;
- Operational procedures, Work instructions, Forms;
- Product, labeling and packaging specifications;
- Manufacturing, installation and servicing specifications;
- Quality assurance/control procedures, specifications; records; and
- Standards and codes.

4.2.1.2 These categories are further defined in *QOP-42-01 Control of Documents*.

4.2.2 QMS Manual Requirements

4.2.2.1 COMPANY will establish and maintain this QMS manual that includes:

- The scope of the QMS, including details and justification for any exclusion.
- The documented procedures established for the QMS, or reference to them, and
- A description of the interaction between the processes of the QMS.

4.2.3 Control of Documents

4.2.3.1 COMPANY is gradually transitioning from paper to electronic documentation. As this transition progresses, new categories of documents are transferred from paper to electronic document control system. Both systems are currently used, and are defined in *QOP-42-01 Control of Documents*.

4.2.3.2 The document control system defined in *QOP-42-01 Control of Documents* ensures that:

- Documents are reviewed for adequacy and are approved prior to release;
- Documents are reviewed and updated as necessary, and revised documents are re-approved;

- Documents are identified, to include their current revision status and changes;
- Documents are distributed to, and are available at locations where they are used;
- Documents remain legible and readily identifiable;
- Document distribution is controlled; and
- Obsolete documents are withdrawn from points of use, and/or are clearly identified to prevent their unintended use.

4.2.3 Control of records

4.2.4.1 Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS.

4.2.4.2 Records will remain legible, readily identifiable and retrievable.

4.2.4.2 Records are organized into the following categories:

- Project Deliverable documentation
- Annual Quality Assessments
- QMS Manual and Revisions thereto
- QMS Master Records
- Project files and their documentation
- Sub-contractor Quality Records

4.2.4.3 ***QOP-42-02 Control of Records*** defines more specifically what records are maintained in each category and designates their storage locations and retention periods. It also defines the process for ensuring that records are clearly identified, are stored in appropriate locations and conditions, are adequately protected, and are easily retrievable.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

5.1.2 Top management is committed to communicate the importance of meeting customer as well as statutory and regulatory requirements. Management Representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of Management Representative is defined in ***Section 5.5*** of this procedure.

5.1.3 Top management establishes the Quality Policy and ensures the objectives for the QMS are established. They are documented and communicated in the form of quality policy and quality objectives. Processes for establishing the quality policy and quality objectives are defined in ***Section 5.3*** and ***Section 5.4*** of this procedure, and are further detailed in ***QOP-56-01 Management Review***.

5.1.4 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 to further improve the system. The process for conducting management reviews is defined in ***QOP-56-01 Management Review***.

5.1.5 Top management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. ***QMS-06, Section 6.1*** defines processes for identifying resource requirements and allocation of resources for

specific activities and projects.

5.2 Customer Focus

- 5.2.1 The principal objective of the QMS is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is an accurate determination of customer requirements and an effective verification that the requirements are met.
- 5.2.2 Top management ensures that customer requirements are determined and are well understood. This is done through the process of order and contract review, as defined in this manual in *QMS-07, Section 7.2.1* and *Section 7.2.2*, and in associated operational procedures.
- 5.2.3 Top management ensures that customer requirements are met by inspecting and testing products at various stages of production and upon completion, as defined in this manual in *QMS-08, Section 8.2.4* and in associated operational procedures.
- 5.2.4 Top management ensures that customer satisfaction is systematically monitored as a measure of performance in determining and meeting customer requirements. This process is defined in this manual in *QMS-08, Section 8.2.1*, and in associated operational procedures.

5.3 Quality Policy

- 5.3.1 The “Quality Policy” is documented in *QMS-01, Section 1.1*.
- 5.3.2 The “Quality Policy” is established by the by the Chief Operating Officer (COO). In formulating the quality policy, the COO ensures that the policy is appropriate to the purpose of the company, and includes a commitment to comply with the requirements and continually improve the effectiveness of the QMS.
- 5.3.3 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 *Section 5.4.1 of this procedure* and in *QOP-56-01 Management Review*. The use of the policy to facilitate continual improvement is explained in *QOP-85-01 Continual Improvement*.
- 5.3.4 The “Quality Policy” is communicated throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.
- 5.3.5 The “Quality Policy” is periodically reviewed within the framework of management reviews of the QMS to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in *QOP-56-01 Management Review*.

5.4 Quality Management System Planning

5.4.1 Quality objectives

- 5.4.1.1 Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products (services) and processes, and to improve the QMS and quality performance.
- 5.4.1.2 Quality objectives are established at the management reviews of the quality system. Management reviews also initiate and monitor projects for achieving quality objectives. These processes for establishing, implementing and monitoring quality objectives are defined in *QOP-56-01 Management Review*.
- 5.4.1.3 Quality objectives define the direction and priorities for continual improvement. Use of

quality objectives for facilitating continual improvement is explained in *QOP-85-01 Continual Improvement*.

5.4.1.4 Quality objectives will be measurable and consistent with the quality policy.

5.4.2 Quality Management System planning

5.4.2.1 QMS 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 QMS is to:

- Achieve the quality objectives and ultimately the Quality Policy;
- Ensure and demonstrate our ability to provide Engineering Maintenance solutions that consistently meet customer requirements and applicable regulatory requirements;
- Ensure high level of customer satisfaction;
- Facilitate continual improvement; and
- Comply with requirements of the ISO 9001 standard and other applicable requirements for quality management systems.

5.4.2.2 The output of QMS planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all processes of the QMS (refer to *QMS-04, Section 4.1.1*).

5.4.2.3 Changes to the QMS are planned within the framework of management reviews (refer to *QOP-56-01 Management Review*). These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational changes; or to improve the effectiveness and efficiency of the QMS.

5.5 Organization and Communication

5.5.1 Responsibility and authority

5.5.1.1 Interrelation of all personnel who manage, perform and verify work affecting quality is identified in the Organizational Chart enclosed at the end of this *section 5.5.1*, and in operational procedures and other documents defining these activities. Top management ensures that the personnel have sufficient independence and authority to perform these tasks, in particular, internal auditors and personnel responsible for monitoring experience from the post-production stage and reporting adverse events.

5.5.1.2 The COO has the overall responsibility for the:

- Management of technical services in all areas of consulting engineering, engineering management and other operations support.
- Technical adequacy, planning, scheduling and execution of project activities

5.5.1.3 Program Managers are responsible for:

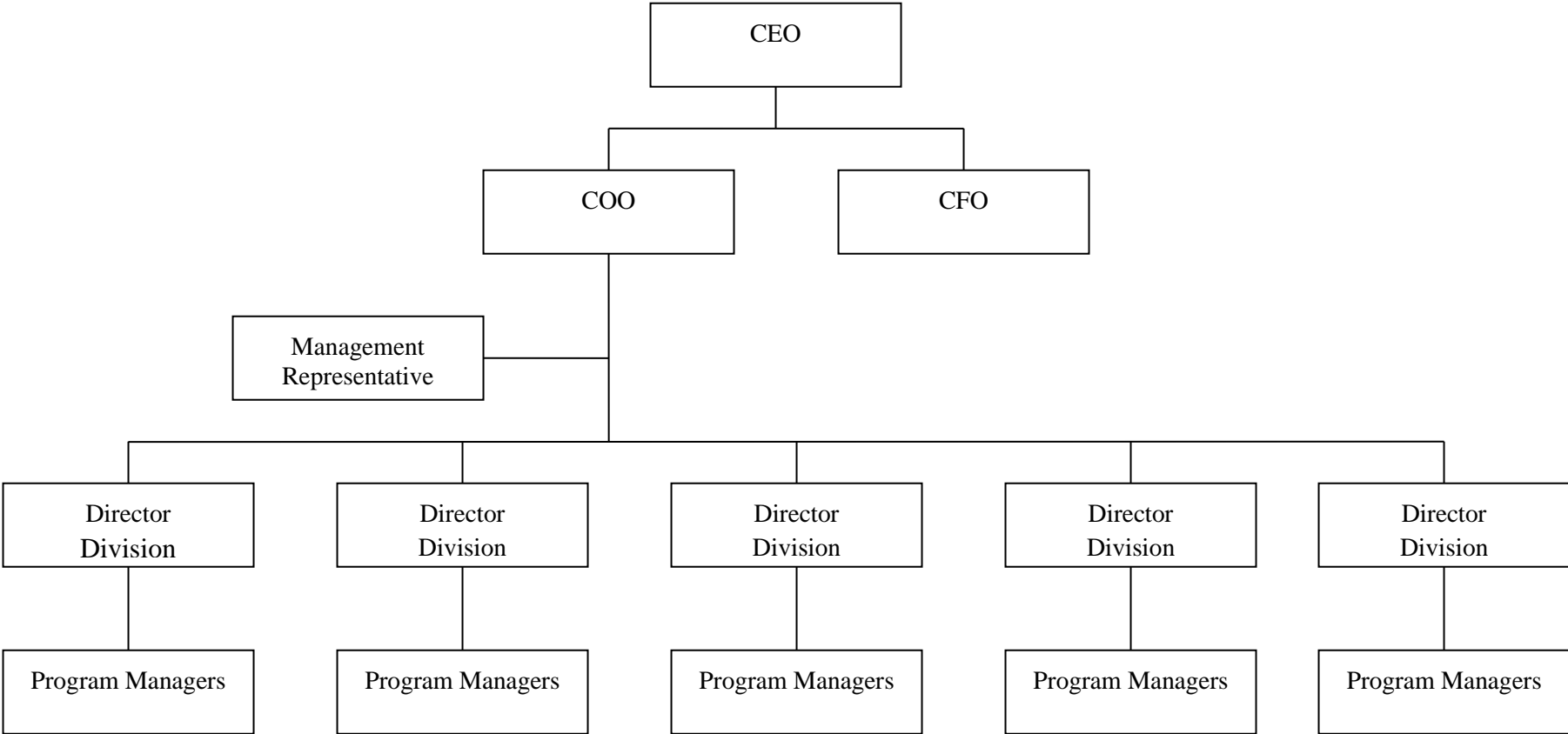
- The effective implementation and day-to-day management of the QMS process.
- Requesting assistance from their peers or from the Management Representative in performing quality reviews and audits within their areas of responsibilities.

5.5.1.4 All departments and functions in the company are responsible for implementing, maintaining, and improving the QMS.

5.5.1.3 Authorities and responsibilities for specific processes of the QMS are defined:

- Throughout this quality manual and in every operational procedure where the specific quality system process or activity is documented; and
- In Quality System Process sheets in *QMS-04, Section 4.1* (as Process Owners).

Company Management



5.5.2 Top management

5.5.2.1 For the purpose of administrating the quality management system, top management includes the CEO, COO, CFO, Division Directors, and those personnel designated as Program Managers by the appropriate Division Director.

5.5.2.2 The Quality Assurance Manager located at Headquarters is appointed as the Management Representative and has the authority and responsibility to:

- Ensure that the QMS is implemented, maintained and continually improved;
- Promote awareness of regulatory and customer requirements throughout COMPANY;
- Report to the top management on the efficiency and performance of the QMS, and
- Coordinate communication with external parties on matters relating to the QMS, ISO 9001 and Technical Specification xxxx series.

5.5.3 Internal communication

5.5.3.1 Internal communication regarding the QMS flows two ways:

- Management will communicate 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 QMS.
- The organization communicates to the management information and data regarding quality performance, the effectiveness of the QMS, customer satisfaction, and opportunities for improvement.

5.5.3.2 Information is communicated through:

- Paper or electronic documents, such as manuals, procedures, instructions, drawings, specifications, quality records, reports, required reading, etc.;
- E-mails, memos, and meetings; and
- Training and awareness programs.

5.5.3.3 Any member of top management may issue stop work orders when significant conditions adverse to quality are identified or a violation of customer or applicable specified regulations warrant such actions.

5.5.3.4 *QOP-42-01 Control of Documents* and *QOP-62-01 Competence, Awareness and Training* define processes for distributing documents and for providing training and awareness programs.

5.5.3.5 Each Division QA representative has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the QMS are reported to the top management through the Management Representative.

5.6 Management Review

5.6.1 General

5.6.1.1 Management reviews of the QMS are conducted at least once a year. More frequent reviews are scheduled in periods when organizational, technological, product or other

changes require increased attention and input from the top management. The processes for initiating and conducting management reviews and for documenting their conclusions are defined in *QOP-56-01 Management Review*.

5.6.1.2 The purpose of management reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the QMS;
- Consider changes to the QMS, the quality policy or quality objectives; and
- Identify opportunities for improvement of the QMS, processes and products (services).

5.6.1.3 Management reviews are chaired by the CEO/COO and are attended by the Division Directors and Management Representative.

5.6.1.4 Additionally, the Management Representative will report to the CEO/COO on a monthly basis, preferably at the monthly management meeting, any significant deficiencies that require immediate process improvement.

5.6.1.5 The Management Representative and QMS Internal Auditors will meet as required to review any quality issues resulting from either internal audits or response to a nonconformance. Top management may attend this meeting for information or to provide any additional details.

5.6.2 Review input

5.6.2.1 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 conformity data, as applicable
- Status of preventive and corrective actions,
- Status of quality objectives,
- Changes that could affect the QMS,
- New or revised regulatory requirements,
- Follow-up actions from earlier management reviews, and
- Recommendations for improvement.

5.6.3 Review output

5.6.3.1 Management reviews are concluded with setting new quality objectives and initiating actions to improve the quality management system, processes, and products.

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

5.6.3.3 Improvements will be communicated to all COMPANY personnel per *section 5.5.3* of this procedure, and to specific customers as necessary.

5.6.3.4 Division Directors will hold annual meetings, documenting topics and attendance, with their respective Program Managers and affected personal following the management review meeting to:

- Communicate the importance of maintaining a quality process;
- Implement specific recommendations from the management review; and
- Assignment of action items.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

- 6.1.1 Resources required for implementing, maintaining and improving the QMS, and for addressing customer satisfaction, include personnel, infrastructure, work environment, process equipment, materials, information, and financial resources.
- 6.1.2 Determination of resource needs for specific 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.
- 6.1.3 Depending on the type and nature of the operation or activity, resource requirements are defined in:
- Quality manual, operational procedures and work instructions (*QOP-42-01 Document Control*);
 - Product and process drawings and specifications (*QOP-71-01 Planning of Product Realization and QOP-73-01 Design Control*);
 - Production plans (*QOP-75-01 Work Order and Production Records*);
 - Job descriptions, competence matrixes, and training programs (*QOP-62-01 Competence, Awareness and Training*);
 - Minutes of management reviews, quality objective records, and corrective and preventive action requests (*QOP-56-01 Management Review and QOP 85-04 Corrective and Preventive Action*).
- 6.1.4 Top management has the responsibility and authority for provision of resources.
- 6.1.5 Management reviews of the quality system are the principal forum for determining resource requirements and providing resources for maintaining and improving the quality system, and for enhancing customer satisfaction. *QOP-56-01 Management Review* defines this process.

6.2 Human Resources

6.2.1 General

- 6.2.1.1 Personnel performing work affecting product quality are competent. Competence is determined on the basis of appropriate education, training, skills and experience.
- 6.2.1.2 Human Resources department is responsible for training and awareness programs for company-wide participation (E.g. general orientation, company rules, regulations policies, etc.).
- 6.2.1.3 Division Directors are responsible for ensuring personnel understand the importance of QMS and Safety compliance and how they can affect customer relations.
- 6.2.1.4 Program Managers are responsible for identifying competency requirements and providing training in their divisions. Division/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, and other such skills as appropriate for particular positions and jobs.

6.2.2 Competence, awareness and training

6.2.2.1 Processes for ensuring adequate competency and awareness of personnel are defined in *QOP-62-01 Competence, Awareness and Training* and address issues related to:

- Determining competency requirements,
- Identifying training needs,
- Providing training,
- Evaluating the effectiveness of training,
- Ensuring quality awareness, and
- Maintaining training records.

6.2.2.2 Files will be maintained on each technical individual, documenting their specific technical certifications as well as specific job related experience. Where customer contractual requirements specify a technical certification then evidence of that certification will become part of the customer project records.

6.2.2.3 Program Managers are responsible for:

- Assigning experienced and competent technical support to a project, including appointing qualified “Technical Inspectors” (TI).
- Quality of products and services within assign programs and projects.
- Management of project activities and to ensure that procedures and established QMS processes are implemented, technical activities affecting quality are documented, as appropriate, in drawings, specifications, reports and instructions.
- Collection, storage and maintenance of project records.
- Review of procurement requirements including contracts, purchase orders and referenced regulations within.
- Notifying the Management Representative when the Customer requirements dictate development of a specific QA Plan to meet specific customer requirements or appropriate regulations.
- Coordinating and scheduling project activities with the client and other organizations or offices.
- Identifying any certificates of conformance or related certifications when required by contract.
- Ensuring a formal review, check and approval of project documentation is performed prior to submittal to client.
- Prepare a written response to all discrepancies reported in review and audit reports. The response should address the discrepancy and corrective and preventive actions.
- Perform a documented annual review of the QMS process as it relates to his area of responsibility. Forward the results of this review and any corresponding nonconformance reports to the Management Representative.

- 6.2.4 Qualified Technical Inspectors (TI) provide the Program Manager with the resource to enhance the quality of services provided in the project. A TI's responsibilities include:
- Physical Inspection of parts and materials ordered and received for a particular project.
 - Testing and certifying materials and parts as having passed the designated tests, as applicable.
 - Witnessing any checkpoints, assembly stages, system operational tests, tolerance measurements and procedural steps requiring a witness or other certifying official.
 - Documentation of inspections, tests, certifications and related process activities.
- 6.2.5 Division Directors or Program Managers will designate Internal Auditors as necessary and ensure they receive appropriate training to perform their task.

6.2.6 **Training Opportunities**

- 6.2.6.1 Any management level may identify training opportunities.
- 6.2.6.2 Program Managers will identify training needs.
- 6.2.6.3 The Management Representative will identify quality related training opportunities and frequency.
- 6.2.7 Each division will maintain a personnel resume of past experience and a copy of all technical certifications earned by the employee. The Program Manager is responsible to ensure personnel maintain technical certifications at the required frequencies.

6.3 **Infrastructure**

6.3.1 **Buildings, workspace and associated utilities**

- 6.3.1.1 Infrastructure and facilities, such as buildings, workspaces and associated utilities, etc., are appropriate and are properly maintained for the technical staff. Maintenance and Installation services are performed on client premises.
- 6.3.1.2 The Information Technology (IT) department provides computer and online communication support for both staff and clients, as required.
- 6.3.1.3 Departmental managers are responsible for identifying the need and requirements for new, and/or modification or repair of existing infrastructure and facilities in their departments. Requests for changes and/or expansions of facilities are submitted to the top management for review and approval.
- 6.3.1.4 Maintenance of buildings and facilities is performed by external contractors. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning.

6.3.3 **Supporting services**

- 6.3.3.1 Supporting services required by COMPANY. include transportation, communication, and IT services:
- Transportation services are purchased from parcel delivery and courier services, and from trucking or other transportation companies or consolidators, as required. Transportation services are purchased in accordance with ***QOP-74-01 Supplier***

Evaluation and Monitoring, and *QOP-74-02 Purchasing*.

- Communication services are provided by various telephone, wireless, and internet access companies. Purchasing is responsible for administrating and coordinating these contracts.
- IT systems are designed and implemented by external consultants, while the day-to-day operating of the systems is the responsibility of the Information Technology (IT) Manager. The IT Manager is responsible for selecting IT consultants and for administrating IT contracts.

6.3.4 Equipment Maintenance

6.3.5 Equipment, machines, hardware, and software 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 *QOP-63-01 Equipment Maintenance*.

6.4 Work Environment

6.4.1 Human factors

6.4.1.1 Human Resources and Program Managers are responsible for ensuring suitable social and psychological conditions in the workplace. This is to include such aspects as interaction and communication between employees, employee harassment, conflict resolution, and so forth. Relevant workplace policies are implemented mainly through training and awareness programs and, where necessary, disciplinary actions. (Refer to *QOP-62-01 Competence, Awareness and Training*.)

6.4.2 Physical factors

6.4.2.1 Program Managers and Project Managers 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.

6.4.3 Health and safety

6.4.3.1 Health and safety management system is independent form the quality management system. It is is documented in the Health and Safety (H&S) manual.

7.0 PRODUCT REALIZATION

7.1 Product Realization Planning

7.1.1 COMPANY plans and develops processes needed to product realization. Planning of product realization is consistent with the requirements of the other QMS processes (*QMS-04*). These plans are specified by contract and in supporting documentation such as QA workbooks, engineering requirements, drawings, specifications and test requirements.

7.1.1.1 In planning product realization, COMPANY determines the following, as appropriate:

- Quality objectives and requirements for the product. (*QMS-05, section 5.4*)
- The need to establish processes documents and provide resources specific to the product (*QMS-05, section 5.4, QMS-06, section 6.1 and 6.2*).

- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance (*QMS-07, section 7.3, QMS-08, Section 8.2*).
- Records needed to provide evidence that the realization process and the resulting product meet requirements (*QMS-04, section 4.2.3*).

7.1.1.2 *QOP-71-01 Planning of Product Realization* assigns responsibilities and creates the framework for implementing the planning activities.

7.1.1.3 Results of production and quality planning are documented in the work order, as documented in *QOP-75-01 Work Order and Production Records*.

7.2 Customer-Related Processes

7.2.1 Determination of requirements related to the product

7.2.1.1 Any documentation from the customer that authorizes work is a customer's contract by definition for this section of the QMS.

7.2.1.2 Product requirements are determined, to include:

- Requirements specified by the customer, including requirements for delivery and post delivery activities,
- Requirements not stated by the customer, but necessary for specified or intended use, where known,
- Statutory and regulatory requirements related to the product, and
- Any additional requirements determined by COMPANY.

7.2.1.3 *QOP-72-01 Order Processing and Review* explains how product requirements are determined.

7.2.2 Review of requirements related to the product

7.2.2.1 Orders are reviewed prior to the commitment to supply a product to the customer to ensure that:

- Product requirements are defined;
- Contract or order requirements differing from those previously expressed are resolved, and
- COMPANY is able to meet customer requirements.

7.2.2.2 Records of the results of the review and any associated actions are maintained. (*QMS-04 sect.4.2.4*)

7.2.2.3 When the customer provides no documented statement of requirements (as with verbal orders), the customer requirements are confirmed before acceptance.

7.2.2.4 Change orders and amendments are processed and reviewed using the same procedures that apply to the processing of initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements.

7.2.2.5 Processes for handling and reviewing orders and change orders are defined in Operational Procedure *QOP-72-01 Order Processing and Review*.

7.2.3 Customer communication

7.2.3.1 COMPANY will determine and implement effective arrangements for communication with customers in relation to product information, inquiries, contracts, order handling, amendments, customer feedback and complaints.

7.2.3.4 Arrangements for communicating with customers regarding inquiries and order handling are defined in Operational Procedure *QOP-72-01 Order Processing and Review*.

7.2.3.5 Arrangements for communicating with customers regarding customer feedback and complaints are defined in Operational Procedures *QOP-82-01 Customer Satisfaction* and *QOP-85-02 Customer Feedback and Complaints*.

7.3 Design and Development

7.3.1 Design and development planning

7.3.1.1 COMPANY will plan and control the design and development of product.

7.3.1.2 During the design and development phase, COMPANY will determine

- The design and development stages,
- The review, verification and validation that are appropriate to each design and development stage, and
- The responsibilities and authorities for design and development.

7.3.1.3 COMPANY will manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

7.3.1.4 Planning output will be updated, as appropriate, as the design and development progresses.

7.3.1.5 COMPANY designs customer-specified products and modifications when required by contract. The quality control system for design is defined in *QOP-73-01 Design Control*.

7.3.1.6 The Program Manager is responsible for scheduling the project; assignment of qualified personnel; and control of organizational and technical interfaces. The design project plan is documented in Form *QF-73-01-1, Design Project Plan*.

7.3.1.7 The assigned Design Project Manager is responsible for the planning of design projects, including the identification of design, review, verification and validation activities

7.3.2 Design and Development Inputs

7.3.2.1 Inputs relating to product requirements will be determined and records maintained (*QMS-04, sect. 4.2.4*). These inputs shall include

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

7.3.2.2 The inputs will be reviewed for adequacy. Requirements will be complete, unambiguous and not in conflict with each other.

7.3.2.3 Design input requirements are developed by Design Project Manager from product concepts, such as product briefs, sketches, models, rough prototypes, etc. Design inputs are reviewed and approved before they are used in design.

7.3.2.4 Engineering design and design modification documents include manufacture, layout, assembly, piping/isometric, installation drawings and wiring/cabling diagrams (point to point).

7.3.2.5 In-house developed software for the purposes of design or critical calculations will be reviewed and approved prior to use in design

7.3.3 Design and Development Outputs

7.3.3.1 The output of design and development will be provided in a form that enables verification against the design and development input and will be approved prior to release.

7.3.3.2 Design and development outputs will:

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

7.3.4.1 Design output consists of documents, samples, models, math data, software, etc., that specify the product and its manufacturing, packaging, labeling, installation and servicing; as well as product (service) acceptance criteria, as applicable.

7.3.4.2 In a limited fashion, COMPANY provides review procedures to holders of COMPANY software when the client is having severe problems operating the software. It is likely that the general area of design and development review will expand as COMPANY expands its own capabilities, services and products.

7.3.4.3 Design output documents are checked and approved before they are released for production. Design output documents are maintained and controlled in accordance with Operational Procedures *QOP-42-01 Document Control*.

7.3.4 Design and Development Reviews

7.3.4.1 At suitable stages, systematic reviews of design and development will be performed in accordance with planned arrangements (see *section 7.3.1* of this procedure) to:

- Evaluate the ability of the results of design and development to meet requirements, and
- To identify any problems and propose necessary actions.

7.3.4.2 Participants in design reviews will include representatives of functions concerned with the design and development stage being reviewed. Records of the results of the reviews and any necessary actions will be maintained. (*QMS-04, sect. 4.2.4*)

7.3.5 Design Verification and Validation

7.3.5.1 Verification will be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions will be maintained. (*QMS-04, sect. 4.2.4*).

7.3.6 Design and Development Validation

7.3.6.1 Design and development validation will be performed in accordance with planned arrangements (see *Section 7.3.1* of this procedure) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.

7.3.6.2 Wherever practical, validation will be completed prior to the delivery or implementation of the product. Records of the results of the verification and any necessary actions will be maintained. (*QMS-04, sect. 4.2.4*).

7.3.7 Control of design and development changes

7.3.7.1 Design and development changes will be identified and records maintained. The changes will be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes will include evaluation of the effect of the changes on constituent parts and product already delivered.

7.4 Purchasing

7.4.1 Purchasing Process

7.4.1.1 COMPANY will ensure that product conforms to the specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

7.4.1.2 COMPANY will evaluate and select suppliers based on their ability to supply product in accordance with COMPANY's requirements. Criteria for selection, evaluation and reevaluation are established based on specifications, client request and/or contract requirements.

7.4.1.3 COMPANY employees will follow the purchasing procedures established in reference 2.11, COMPANY Procedure Manual for Purchases.

7.4.1.4 Records of the results of the evaluations and any necessary actions resulting from the evaluations will be maintained. (*QMS-04, sect. 4.2.4*).

7.4.1.5 The CEO, COO, CFO and properly designated personnel (such as Contracts Manager) of COMPANY are authorized to execute contracts. Only the Purchasing Agent is authorized to sign the contract.

7.4.1.6 In the absence of a Purchasing Agent, the Office Director will designate an acting Purchasing Agent.

7.4.3.1 Purchasing maintains an Approved Supplier List. Orders for materials, components and subcontracted services may only be placed with vendors that are on the list.

7.4.2 Purchasing information

7.4.2.1 Purchasing Information shall describe the product to be purchased, including where appropriate

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

7.4.2.2 COMPANY will ensure the adequacy of the specified purchase requirements prior to their communication to the supplier.

7.4.4.1 Purchasing documents are prepared by the Purchasing Agents within each division/department. The documents clearly and completely describe ordered products, including precise product identification and quality requirements. Purchasing documents are reviewed and approved prior to release. The processes for the preparation, review and approval of purchasing documents are defined in Operational Procedure *QOP-74-02 Purchasing*.

7.4.4.2 Purchasing requirements of a service are based on the qualifications of the individual needed to perform the service.

7.4.4.3 For general office supplies, including computing materials, the normal competitive process will be used.

7.4.4.4 For job-related materials, the QMS contractually applied to COMPANY will also be applied by COMPANY to its suppliers.

7.4.3 Verification of purchased product

7.4.3.1 COMPANY will establish and implement the inspection or other activities necessary for ensuring that the purchased product meets specified purchase requirements.

7.4.3.2 Where COMPANY or its customer intends to perform verification at the suppliers premises, COMPANY will state the intended verification arrangements and method of product release in the purchasing information.

7.4.5.1 Purchased products are verified prior to use in production and/or dispatch to customers. Quality Assurance is responsible for selecting appropriate methods for purchased product verification and acceptance. *QOP-74-03 Verification of Purchased Product* defines the processes for verifying, identifying and releasing purchased products.

7.4.5.2 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.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

7.5.1.1 Product installation and provision of associated services are carried out under controlled conditions. The controlled conditions include the control of, as applicable:

- The availability of information that describes the characteristics of the product,

- The availability of work instructions, as necessary,
- The use of suitable equipment,
- The availability of monitoring and measuring devices,
- The implementation of monitoring and measuring devices, and
- The implementation of release, delivery and post delivery activities.

7.5.2 Validation of processes for production and service provision

7.5.2.1 COMPANY will validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

7.5.2.2 Validation will demonstrate the ability of the processes to achieve planned results.

7.5.2.3 COMPANY will make arrangements for these processes including, as applicable:

- Defined criteria for review and approval of the processes,
- Approval of equipment and qualification of personnel,
- Use of specific methods and procedures, requirements for records (*QMS-04, sect. 4.2.4*), and
- Revalidation

7.5.3 Identification and traceability

7.5.3.1 Where appropriate, COMPANY will identify the product by suitable means throughout product realization.

7.5.3.2 COMPANY will identify the product status with respect to monitoring and measurement requirements.

7.5.3.3 Where traceability is a requirement, COMPANY will control and record the unique identification of the product. (*QMS-04, sect. 4.2.4*)

7.5.4 Customer property

7.5.4.1 COMPANY will exercise care with customer property while it is under COMPANY's control or being used by COMPANY. COMPANY will identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer product is lost, damaged, stolen or otherwise found to be unsuitable for use, this will be reported to the customer and records maintained. (*QMS-04, sect. 4.2.4*)

7.5.4.1 Customer-supplied products are received and inspected following the same procedure that applies to the purchased products, i.e., *QOP-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.

7.5.4.4 Customer's software, documents, and other intellectual property are protected to the same extent, as would COMPANY's internal documents of similar content, unless there are contractual requirements for special measures to protect customer's intellectual property.

- 7.5.4.5 When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures.
- 7.5.4.6 Customers are immediately informed in the event of loss, damage, deterioration, or unsuitability of their products.

7.5.5 Preservation of product

7.5.5.1 COMPANY will preserve the conformity of the product during internal processing and delivery to the intended destination. The preservation will include identification, handling, packaging, storage and protection. Preservation will also apply to the constituent parts of the product.

7.6 Control of Monitoring and Measurement Devices

7.6.1 General

7.6.1.1 COMPANY will determine the monitoring and measurement devices to be undertaken and the monitoring and measure devices needed to provide evidence of conformity of product to determined requirements. (see *Section 7.2.1* of this procedure)

7.6.1.2 COMPANY will establish processes to ensure monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

7.6.1.3 Where necessary to ensure valid results, measuring equipment will be:

- Calibrated and verified at specific intervals, or prior to use, against measurement standards traceable to international or national standards; where no such standard exist, the basis used for calibration or verification shall be recorded;
- Adjusted and re-adjusted as necessary;
- Identified to enable the calibration status to be determined;
- Safeguarded from adjustments that would invalidate the measurement result;
- Protected from damage and deterioration during handling, maintenance and storage.

7.6.1.4 COMPANY will assess and record the validity of the previous measuring results when the equipment is not found to conform to requirements. The organization will take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained. (*QMS-04, sect. 4.2.4*)

7.6.1.5 When used in monitoring and measurement of specified requirements, the ability of software to satisfy the intended application will be confirmed. This will be undertaken prior to initial use and reconfirmed as necessary.

7.6.1.1 Appropriate measuring and monitoring devices are selected to ensure that measurement capability is consistent with the measurement requirements. Devices used for ensuring and verifying product conformity are calibrated. *QOP-76-01 Measuring and Monitoring Equipment* defines the calibration and control system.

7.6.2 Measuring and monitoring devices calibration and maintenance

7.6.2.1 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;
- Monitoring of environmental conditions;
- Verification of product conformity; and
- Operations where defined accuracy of a measurement is required to assure product conformity.

7.6.2.2 Quality Assurance is responsible for calibrating and maintaining measuring and monitoring devices. All active devices are inventoried in a controlled list, indicating their calibration status and location.

7.6.2.3 Measuring devices are checked, adjusted and re-adjusted as necessary; and are calibrated at specified intervals (or prior to use) against measurement standards traceable to international or national measurement standards.

7.6.2.4 Calibration is recorded in a calibration log and the calibrated devices are labeled with a calibration sticker to identify their calibration status.

7.6.2.5 Measuring and monitoring devices are safeguarded from adjustments that would invalidate the measurement result.

7.6.2.6 Measuring and monitoring devices are protected from damage and deterioration during handling, maintenance and storage.

7.6.3 Validity of measurements made with nonconforming measuring equipment

7.6.3.1 When measuring equipment is found not to conform to requirements, previous measuring results are reassessed, and appropriate action is taken on the equipment and any product affected.

7.6.4 Validation of software

7.6.4.1 In-house developed inspection, test, and monitoring software is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

8.1.1 COMPANY will plan and implement the monitoring, measurement, analysis and improvement processes needed to:

8.1.1.1 Demonstrate conformity of the product,

8.1.1.2 Ensure conformity of the QMS, and

8.1.1.3 Continually improve the effectiveness of the QMS.

8.1.2 This will include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer satisfaction

8.2.1.1 COMPANY will monitor information relating to customer perception as to whether COMPANY has met customer requirements. COMPANY will determine the methods

for obtaining and using this information.

8.2.1.1 Information related to customer satisfaction is collected and compiled from the following sources:

- Customer complaints,
- Spontaneous expressions of customer satisfaction and other feedback,
- Awards and recognitions from customers, associations and consumer groups,
- Customer satisfaction surveys
- Warranty claims,
- Repeat customers, and

8.2.1.2 *QOP-82-01 Customer Satisfaction* defines the responsibilities and methods for collecting the information.

8.2.1.3 Marketing is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

8.2.1.4 Customer satisfaction is used as one of the measurements of the performance of the quality management system. For this purpose, customer satisfaction information is reported to, and evaluated by the management review of the quality system, as defined in *QOP-56-01 Management Review*.

8.2.2 Internal audit

8.2.2.1 COMPANY will conduct internal audits at planned intervals to determine whether the QMS:

- Conforms to the planned arrangements (see *Section 7.1* of this procedure), to the requirements of the ISO 9001:2000 standard and to the QMS requirements established by COMPANY, and
- Is effectively implemented and maintained.

8.2.2.1 Quality Assurance is responsible for conducting internal audits of the quality management system to determine whether the quality system:

- Conforms to quality plans, to management system requirements as defined in this quality manual and operational procedures, and to the requirements of the ISO 9001 standard,
- Is effectively implemented and maintained.

8.2.2.2 Internal audits are conducted in accordance with a planned program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of the previous audits. The audit criteria, scope, frequency and methods will be defined.

8.2.2.3 Selection of auditors and conduct of audits will ensure objectivity and impartiality of the audit process. Auditors will not audit their own work.

8.2.2.3 Appropriate corrective actions are taken by management personnel responsible for the areas where nonconforming processes and/or practices are identified by the audit. Auditors follow up to ensure that the actions taken are fully implemented and are effective.

- 8.2.2.4 ***QOP-82-02 Internal Quality Audits*** defines the responsibilities and requirements for planning and conducting audits, and reporting and maintaining records (*QMS-04, Section 4.2.4*).
- 8.2.2.5 The Management responsible for the area being audited will ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up actions will include the verification of the actions taken and the reporting of verification results. (see 8.5.2)
- 8.2.3 Monitoring and measurement of processes**
- 8.2.3.1 Quality management system processes are monitored by a variety of approaches and techniques, as appropriate for a particular process and its importance. These include:
- Conducting internal audits of the quality system (*QOP-82-02 Internal Quality Audits*);
 - Monitoring trends in corrective and preventive action requests (*QOP-85-03 Corrective and Preventive Actions*);
 - Measuring product conformity and monitoring other quality performance data and trends (*QOP-74-03 Verification of Purchased product, QOP-82-03 In-process Inspections*, and *QOP-82-04 Final Inspection*); and
 - Measuring and monitoring customer satisfaction (*QOP-82-01 Customer Satisfaction*).
- 8.2.3.2 When a quality system process does not conform to requirements, Quality Assurance initiates a corrective action request to address the problem. The process for requesting and implementing corrective actions is defined in *QOP-85-03 Corrective and Preventive Action*.
- 8.2.4 Monitoring and measurement of product**
- 8.2.4.1 The monitoring and measurement program for products is defined in drawings and specifications, production work orders, purchasing documents, and in inspection and testing procedures. Documents defining the inspection and testing program are collectively referred to as control plans.
- 8.2.4.2 **Verification of purchased product:** All purchased products are subjected to a visual inspection by the receiving clerk. Some designated products are also subjected to a more detailed and technical QC inspection. Processes for performing these inspections are defined in *QOP-74-03 Verification of Purchased Product*.
- 8.2.4.3 **In-process inspections:** In-process inspections are in the form of first article inspections, operator and QC inspections, continuous product verification by automated inspection equipment, and statistical process control (SPC). The focus is on defect prevention rather than detection. Systems for performing in-process inspections are defined in *QOP-82-03 In-process Inspections*.
- 8.2.4.4 **Final acceptance 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 packaged and shipped *QOP-82-04 Final Inspection* defines these activities.

- 8.2.4.5 Results of inspections and tests are recorded. Instructions for establishing records for specific types of inspections are defined in inspection procedures and work instructions. Filing and maintenance of inspection records are regulated by *QOP-75-01 Work Order and Production Records* and *QOP-42-02 Control of Records*.
- 8.2.4.6 Products are released for packaging and shipping only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products. The identity of the person authorizing product release is recorded. *QOP-82-04 Final Inspection* defines specific methods for product release.

8.3 Control of Non-Conforming Product

8.3.1 Identification and documentation

- 8.3.1.1 Nonconforming products are documented in the Product Nonconformity Report (PNR). The report describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (re-inspection, concessions, corrective actions, etc.). The use of the PNR and its processing are explained in *QOP-83-01 Control of Nonconforming Product*.
- 8.3.1.2 When nonconforming product is detected after delivery or use has started, the effects, or potential effects of the nonconformity are evaluated by Quality Assurance, and appropriate action is taken.
- 8.3.1.3 To prevent nonconforming products from being used or shipped, the products are marked with a REJECTED label or tag, and are segregated.

8.3.2 Nonconformity review and disposition

- 8.3.2.1 Quality Assurance is responsible for reviewing nonconformities and deciding on the disposition of nonconforming products. In simple and routine cases this responsibility is delegated to production supervisors.
- 8.3.2.2 The disposition decision may be to rework, repair, accept as-is, regrade or scrap.
- 8.3.2.3 Processes for reviewing product nonconformities, for making disposition decisions, and for recording these activities are provided in *QOP-83-01 Control of Nonconforming Product*.

8.3.3 Verification of reworked products

- 8.3.3.1 Reworked products are re-inspected to demonstrate conformity to the original requirements. Repaired and regraded products are also inspected to verify that they meet the modified (downgraded) specification. These verification activities are carried out in accordance with applicable inspection instructions and procedures (refer to *QOP-82-03 In-process Inspections* and *QOP-82-04 Final Inspection*).

8.4 Analysis of Data

8.4.1 General

- 8.4.1.1 Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance and effectiveness of the quality system and to identify opportunities for improvement.
- 8.4.1.2 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 Operational Procedure *QOP-56-01 Management Review*.

8.4.2 Scope

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

8.4.2.1 Characteristics of processes and products:

- Process performance variation
- Cycle times
- Unscheduled machine downtime.

8.4.2.2 Conformity to product and customer requirements:

- Scrap, rework, repair rates
- On-time delivery performance

8.4.2.3 Suppliers:

- Supplier quality performance

8.4.2.4 Customer satisfaction and dissatisfaction:

- Customer satisfaction
- Customer complaints

8.4.2.5 Quality System:

- Effectiveness of training
- Results of Internal Audits

8.5 Improvement

8.5.1 Continual improvement

8.5.1.1 COMPANY Inc. continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. *QOP-85-01 Continual Improvement* defines this process.

8.5.1.2 Internal audit results and quality performance data are analyzed by management review to assess the effectiveness of the quality system and current organizational performance. Opportunities and priorities for improvement are identified by comparing present quality performance to goals and aspirations defined in the quality policy. This process is defined in *QOP-56-01 Management Review*.

8.5.1.3 Improvement projects are defined either as corrective and preventive actions or as quality objectives. These processes are defined in *QOP-85-03 Corrective and Preventive Actions*, and *QOP-56-01 Management Review*, respectively.

8.5.2 Corrective action

8.5.2.1 Customer complaints

8.5.2.1.1 Customer complaints that allege deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product are logged and documented.

8.5.2.1.2 Complaints that involve a possible failure of a product, labeling, or packaging to meet any of its specifications are always investigated, and the results of the investigation are documented.

8.5.2.1.3 The system for receiving, logging, investigating and responding to customer complaints is defined in *QOP-85-02 Customer Feedback and Complaints*.

8.5.2.2 Corrective and preventive action

8.5.2.2.1 Corrective actions are taken to eliminate causes of actual nonconformities in order to prevent their recurrence.

8.5.2.2.2 Preventive actions are implemented to eliminate causes of potential nonconformities in order to prevent their occurrence.

8.5.2.2.3 The process for taking corrective and preventive actions includes requirements for:

- Reviewing nonconformities and potential nonconformities,
- Determining causes for actual and potential nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur and that potential nonconformities are prevented,
- Determining and implementing actions needed, including, if appropriate, updating documentation,
- Recording the results of any investigations and of actions taken, and
- Reviewing the corrective or preventive action taken and its effectiveness.

This process is defined in *QOP-85-03 Corrective and Preventive Action*.