Quality Management System Manual

ISO 9001-15

rde Connectors and Cables, Inc.
5277 NW 108th Ave
Sunrise, Florida, 33351-8070

Manual Content

SECTION 1
Introduction

1.1 Introduction

rde Connectors and Cables, Inc. has developed and implemented a Quality Management System (QMS) to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To implement this quality management system, rde has:

- Identified the processes required for the Quality Management System
- Ascertained the sequence and interaction of these processes
- Determined the criteria and methods required to verify the effective operation and control of these processes
- Verified the availability of information necessary to support the operation and the monitoring of these processes
- Measured, monitored and analyzed these processes and implemented action necessary to achieve planned results and continual improvement

rde Connectors and Cables, Inc. has committed to controlling products and processes to verify that they meet or exceed the contractual requirements. The extent of control will be as follows:

- The potential impact of the externally provided processes and products on rde's ability to consistently meet both the customer's and applicable statutory and regulatory requirements
- The degree to which the control of the process is shared
- The capability of achieving the control through **Paragraph 7.4**, **Communication**, in the Quality Manual

This manual is divided into thirteen sections. The first ten sections correlate to the Quality Management System sections of ISO 9001-15. Sections Eleven and Twelve contain additional information. Section Thirteen is the revision history for this document. Each section begins with a policy statement expressing rde's obligation to implement the basic requirements of the referenced Quality Management System section.

1.2 Objective of the Quality Manual

The Quality Manual specifies the requirements of the Quality Management System (QMS) to be applied when an organization:

1. Needs to demonstrate its ability to consistently provide products that meet both customer and applicable statutory and regulatory requirements
2. Aims to enhance customer satisfaction through the effective application of the Quality Management System, including processes for improvement of the QMS and the assurance of conformity to both customer and applicable statutory and regulatory requirements.
3. Intends to be certified per ISO 9001-15

All of the requirements of the Quality Manual are intended to be applicable to rde. This manual also provides a guideline to implement the QMS process in a systematic way. Where necessary, the generation of procedures can be important as an explanatory statement for each unit of operation on how to run the process.

This manual describes the Quality Management System and delineates authorities, interrelationships and obligations of the personnel responsible for performing within the Quality Management System. The Quality Manual also provides procedures or references for all activities comprising the Quality Management System used to verify compliance to the necessary requirements of the ISO Standard. This manual is used internally to guide the company's employees through the various requirements of the ISO Standard that must be met and maintained to verify customer satisfaction, ensure continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. It is also used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

1.3 Normative Reference

- **American National Standard ANSI/ISO/ASQ Q9000-2015, Fundamental and Vocabulary**

1.4 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015, additional QMS variations and the following apply:

Within this Standard, the term “manufacturer” is intentionally used to clearly delineate the relationship between the product creator and rde. The terms “external provider” and “original manufacturer” can be synonymous.

1.5 Vision Statement

To be identified in its field as a leading provider of best-in-class products and services within rde ’s chosen industrial markets.

1.6 Mission Statement

Striving for excellence in customer service and satisfaction in the field of interconnect device applications for industrial automation, through continuous innovation and improvement in rde’s products and processes.

1.7 Quality System Documentation Distribution

The Quality Manual and system documentation will be distributed as follows:

The Quality Manual and all system documentation will be distributed and maintained electronically on the company server. All employees have access to this information through the computer network. rde does not utilize a paper copy distribution system. The Document Coordinator (Office Assistant) will maintain, per Procedure P-750 Control of Documented Information, and a paper copy of initial document releases and all subsequent revisions until such time the registration company approves electronic record files.

SECTION 2
rde Connectors and Cables, Inc. Profile

rde developed and implemented a Quality Management System to document the company’s best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of rde meets the requirements of the International Standard ISO 9001 - 15. This system addresses the development, production and servicing of the company’s products.

SECTION 3
Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

SECTION 4
Description of the Quality System

4. Organizational Context (business environment)

4.1 Understanding the Organization and its Context (business environment) of rde Connectors and Cables, Inc.

The management of rde, utilizing **Procedure P-400**, **Organizational Context**, has determined external and internal concerns that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its Quality Management System. Resolution of these concerns has been demonstrated using risk analysis methods and documentation. Realization of risk analysis will be performed per the guidance documented in **Section 6.1**, **Risk Management**, in the Quality Manual.
rde monitors and reviews risk analysis documents to verify the prevention of negative impacts (risks) to the business and to verify that the consequences of these concerns will not jeopardize business opportunities.

- Concerns can include positive and negative factors or other conditions for consideration
- Understanding the external context (business environment) can be achieved by considering concerns arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local
- Understanding the internal context (business environment) can be achieved by considering concerns related to values, culture, knowledge and performance of the organization

Any changes in external and internal concerns that are relevant to the Quality Management System will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on rde's ability to consistently provide products that meet customer and applicable statutory and regulatory requirements, the Top Management of rde has determined:

1. The interested parties that are relevant to the Quality Management System implemented within rde
2. The requirements of these interested parties that are relevant to the Quality Management System. These includes the fulfillment of requirements to meet the product specification and compliance with applicable laws

The organization will monitor and review information about the needs of interested parties and their relevant requirements.
(Reference: Form F-400-03, Interested Parties)

4.3 Scope of the Quality Management System

The Top Management of rde has determined the limitations and applicability of the Quality Management System to establish its scope for certification. Consideration of the following points is important for the company before determining the scope of certification.

1. The external and internal concerns referred to in **Paragraph 4.1**, **Understanding the Organization and Its Context (business environment)**, of the ISO 9001-15 Standard
2. The requirements of relevant interested parties referred to in **Paragraph 4.2**, **Understanding the Needs and Expectations of Interested Parties**, of the ISO 9001-15 Standard
3. The products provided by rde

rde will apply all the requirements of ISO 9001-15 Standard as applicable within the determined scope of the Quality Management System.

By stating the above-mentioned scope, justification is also provided to determine any requirement of the ISO 9001-15 Standard that rde is not required to maintain

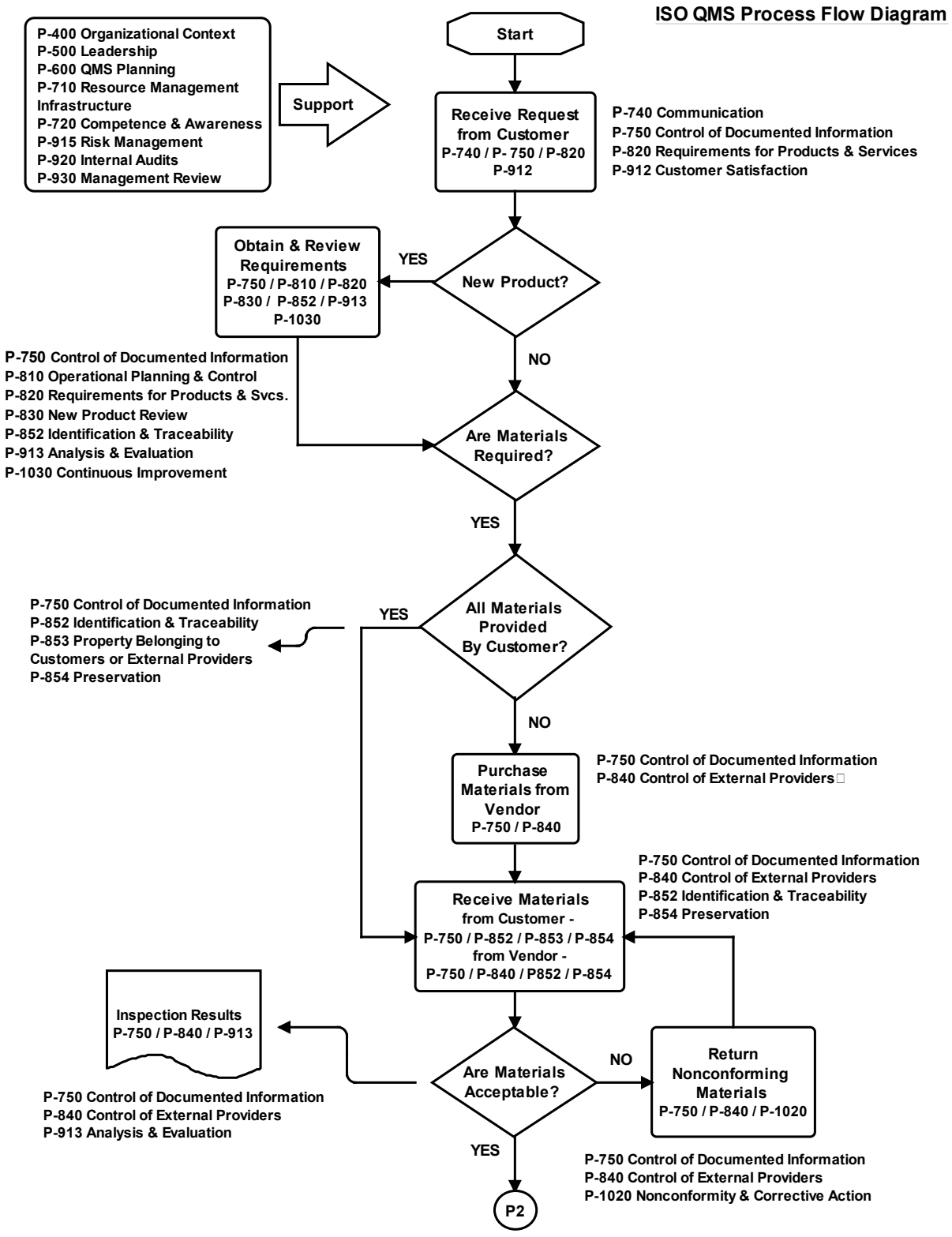
4.4 Quality Management System and Its Processes

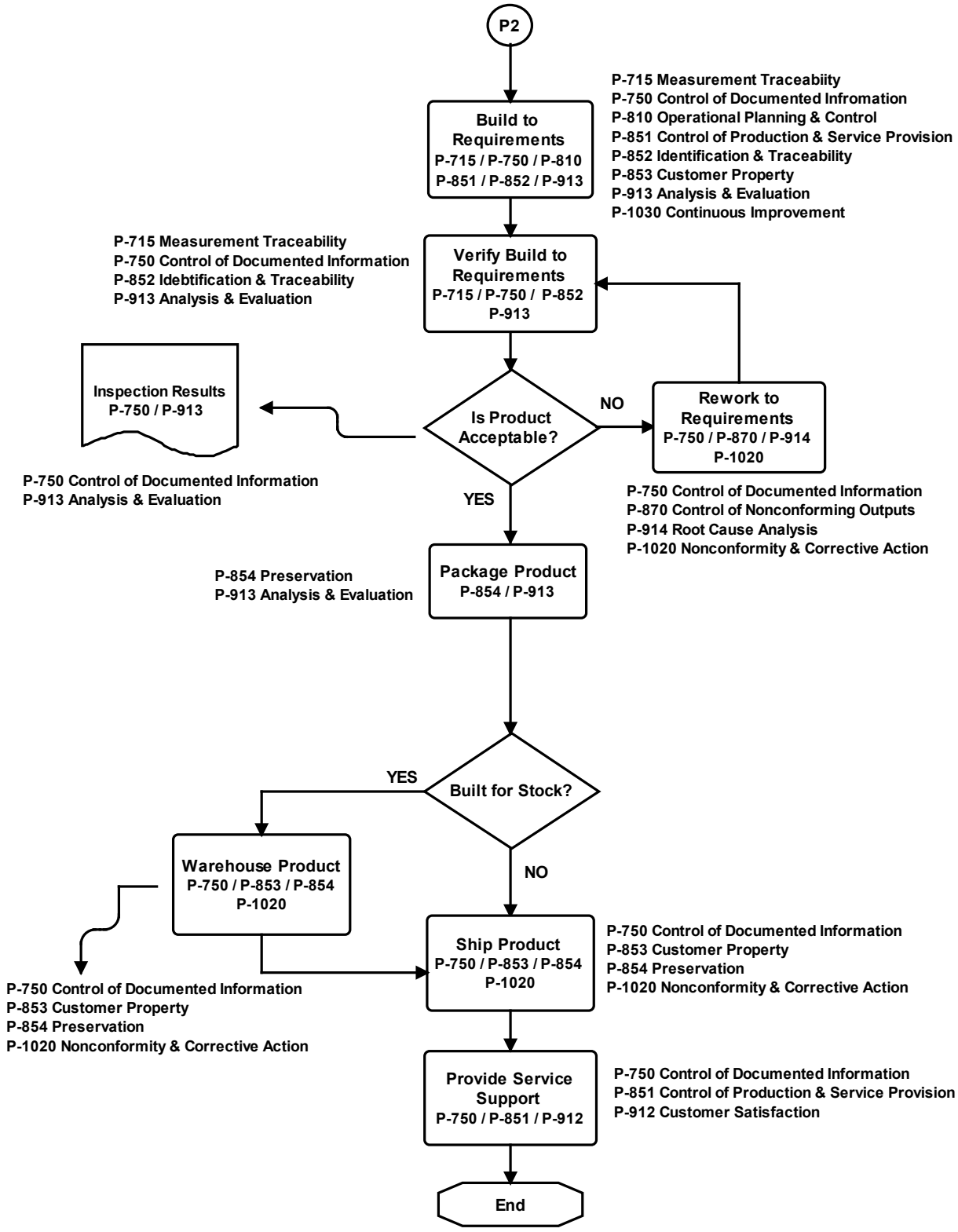
The Top Management of rde will establish, implement, maintain and continually improve the Quality Management System, including the processes required and their interactions in accordance with the requirements of ISO 9001- 15.
rde has determined the processes required for the Quality Management System and its application throughout the company. To design and implement the QMS, rde has:

- Determined the processes, including outsourced processes (and the necessary monitoring required for the QMS) and their application throughout the organization and has documented them on the ISO QMS Process Flow Diagram at the end of this section
- Determined the sequence and interaction of these processes and illustrated them on the ISO QMS Interaction of Processes (IOP) Diagram also at the end of this section

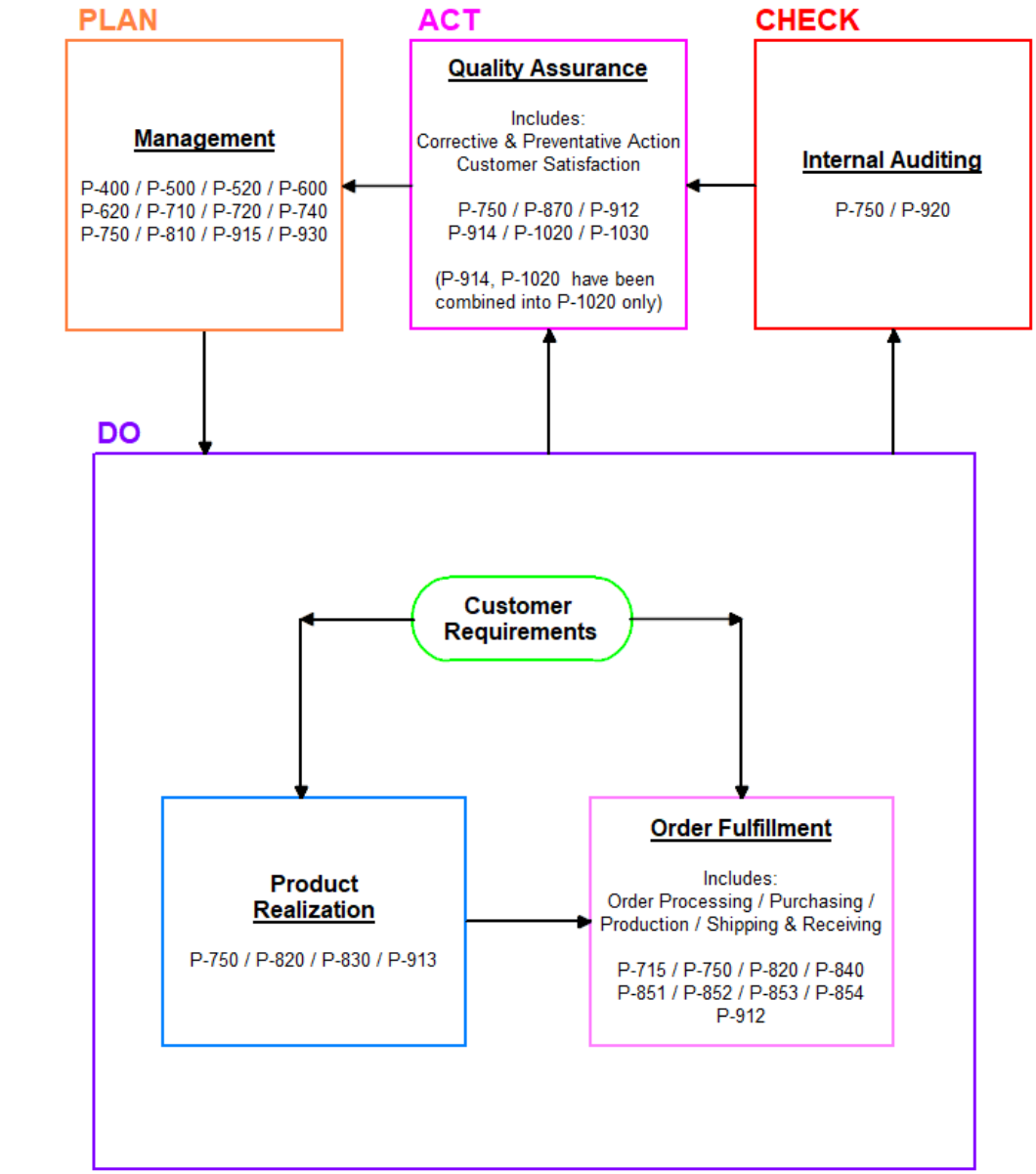
- Determined the criteria and methods required to verify that the operation and control of the processes are effective and has documented them in the quality plans and work instructions while utilizing the form **F-913-02**, **QMS – Monitoring**, **Measuring and Analysis Table**
- Verified the continuing availability of resources and information necessary to achieve planned results and the continual improvement of these processes
- Established systems to monitor, measure and analyze these processes
- Established processes to identify and implement the actions necessary to achieve planned results and the continual improvement of these processes

All documented information mentioned above will be maintained and controlled through **Procedure P-750**, **Control of Documented Information**.


ISO QMS Process Flow Diagram
P-400 Organizational Context
P-500 Leadership
P-600 QMS Planning
P-710 Resource Management
Infrastructure
P-720 Competence & Awareness
P-915 Risk Management
P-920 Internal Audits
P-930 Management Review
Support
Start
Receive Request from Customer
P-740 / P- 750 / P-820
P-912
P-740 Communication
P-750 Control of Documented Information
P-820 Requirements for Products & Services
P-912 Customer Satisfaction
New Product?
YES
Obtain & Review Requirements
P-750 / P-810 / P-820
P-830 / P-852 / P-913
P-1030
NO
P-750 Control of Documented Information
P-810 Operational Planning & Control
P-820 Requirements for Products & Svcs.
P-830 New Product Review
P-852 Identification & Traceability
P-913 Analysis & Evaluation
P-1030 Continuous Improvement
Are Materials Required?
YES
All Materials Provided By Customer?
YES
P-750 Control of Documented Information
P-852 Identification & Traceability
P-853 Property Belonging to Customers or External Providers
P-854 Preservation
NO
Purchase Materials from Vendor
P-750 / P-840
P-750 Control of Documented Information
P-840 Control of External Providers
Receive Materials from Customer -
P-750 / P-852 / P-853 / P-854
from Vendor -
P-750 / P-840 / P852 / P-854
P-750 Control of Documented Information
P-840 Control of External Providers
P-852 Identification & Traceability
P-854 Preservation
Inspection Results
P-750 / P-840 / P-913
Are Materials Acceptable?
NO
Return Nonconforming Materials
P-750 / P-840 / P-1020
P-750 Control of Documented Information
P-840 Control of External Providers
P-913 Analysis & Evaluation
YES
P-750 Control of Documented Information
P-840 Control of External Providers
P-1020 Nonconformity & Corrective Action
P2


P2
Build to Requirements
P-715 / P-750 / P-810
P-851 / P-852 / P-913
P-715 Measurement Traceabiity
P-750 Control of Documented Infromation
P-810 Operational Planning & Control
P-851 Control of Production & Service Provision
P-852 Identification & Traceability
P-853 Customer Property
P-913 Analysis & Evaluation
P-1030 Continuous Improvement
Verify Build to Requirements
P-715 / P-750 / P-852
P-913
P-715 Measurement Traceability
P-750 Control of Documented Information
P-852 Idebtification & Traceability
P-913 Analysis & Evaluation
Is Product Acceptable?
NO
Rework to Requirements
P-750 / P-870 / P-914
P-1020
Inspection Results
P-750 / P-913
P-750 Control of Documented Information
P-913 Analysis & Evaluation
P-750 Control of Documented Information
P-870 Control of Nonconforming Outputs
P-914 Root Cause Analysis
P-1020 Nonconformity & Corrective Action
YES
Package Product
P-854 / P-913
P-854 Preservation
P-913 Analysis & Evaluation
Built for Stock?
YES
NO
Warehouse Product
P-750 / P-853 / P-854
P-1020
P-750 Control of Documented Information
P-853 Customer Property
P-854 Preservation
P-1020 Nonconformity & Corrective Action
Ship Product
P-750 / P-853 / P-854
P-1020
P-750 Control of Documented Information
P-853 Customer Property
P-854 Preservation
P-1020 Nonconformity & Corrective Action
Provide Service Support
P-750 / P-851 / P-912
P-750 Control of Documented Information
P-851 Control of Production & Service Provision
P-912 Customer Satisfaction
End

INTERACTION of PROCESSES DIAGRAM



PROCESS TITLE (SEE: IOP Diagram for a List of Associated Processes)	PROCESS OWNER	RESPONSIBLE PARTIES	INPUTS	OUTPUTS	KEY PROCESS INDICATORS (KPI's)
Management	Company President	Company President	Quality Objectives	Business Planning	Profitability
		Top Management	Risk and Opportunities Evaluations	New Customers, Product Lines Diversification, Improved Efficiency	Employee Satisfaction
			Management Review Meetings	Continuous Improvement	
			Employee Reviews	Training, Goal Setting, Improved Work Environment	
			Customer Feedback	Quality Improvements	
			ISO Audit Results	QMS Process Improvements, and Plans	
Quality Assurance	Product Support Engineer	Corrective Action Team	CIAR Reports	Continuous Improvement	Non-conforming Product Returns
			RMA's	Corrective Actions and Root Cause Analysis	Product Rework and Scrap Rates
			Rework, and Scrap Reports	Process Improvements	
			Management Review Meetings	Need for Employee Training, Statistical Analysis Results of the QA System	
			ISO Audit Results	QMS, DCR's, and Process Improvements	
Internal Auditing	Lead Auditor	Audit Team Members	ISO Audits	Audit Reports	Conformance to ISO Requirements
				DCRs	
				Continuous Process Improvements	
				Successful External Audits	
Product Realization	Sales Manager	Sales Manager	Customer's Requirements	Assembly Drawings	Customer Requirements are Properly Captured and Documented
		Engineer		Bill of Materials	
				Product Specifications	
				Any Special Build or Test Requirements	
Order Fulfillment	Office Administrators	Sales Manager	Customer's Requirements	Finished Products	Product Delivery Times
		Engineer		Product Trackers	Vendor Performance
		Product Support Engineer	Product Specifications	Engineering Change Requests	Customer Satisfaction
		Production Staff	Sales Orders	Rework Reports	
		Shipping & Receiving Clerk	BOM's (Work Ticket)	Scrap Reports	
			Assembly Drawings		
			Product Trackers		
			Shipping Requirements		
			Invoices		

SECTION 5
Leadership and Commitment

Top Management of rde shall demonstrate leadership and commitment with respect to the Quality Management System through **Procedure P-500**, **Leadership**, and the following:

5.1 General Responsibilities

1. Accepting accountability for the effectiveness of the Quality Management System
2. Ensuring that the Quality Policy and Quality Objectives are established for the Quality Management System and are compatible with the context (business environment) and strategic direction of the organization
3. Ensuring the integration of the Quality Management System's requirements into the organization's business processes
4. Promoting the use of a process approach and risk-based thinking
5. Ensuring that the resources required for the Quality Management System are available
6. Communicating the importance of effective quality management and of conforming to the Quality Management System's requirements
7. Ensuring that the Quality Management System achieves its intended results
8. Engaging, directing and supporting persons to contribute to the effectiveness of the Quality Management System
9. Promoting improvement
10. Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

NOTE: Any reference to the term "business" in the International Standard should be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.2 Customer Focus

The Top Management of rde has demonstrated leadership and commitment with respect to customer focus by:

- Ensuring customer requirements are determined, understood and consistently met **(Reference: Paragraph 8.2**, **Requirement for Products in the Quality Manual)**
- Determining, understanding and consistently meeting applicable statutory and regulatory requirements **(Reference: Legal Register List and Evaluation / F-840-02 Approved Supplier List, F-840-03 Supplier Evaluation Form and F-840-04 Supplier Evaluation Summary Log,)**
- Mitigating the risks that can affect conformity of products (**Reference: Risk analysis documents, WI 600-01, Risk Analysis and Management, F-600-02, Risk and Opportunity Worksheet and F-600-03 Risk Management Analysis and Plan.)**
- Ensuring that the ability to enhance and maintain customer satisfaction is determined, and addressed. **(Reference: Paragraph 9.1.2**, **Customer Satisfaction, in the Quality Manual)**

5.2 Quality Policy

The Top Management of rde has established, implemented and maintained a quality policy that:

- Is appropriate to the purpose and context (business environment) of the organization and supports its strategic direction
- Provides a framework for setting quality objectives
- Includes a commitment to satisfy applicable requirements, statutes and regulations
- Includes a commitment for continual improvement of the Quality Management System

This quality policy shall be:

- Maintained as documented information and controlled through documented information as described in the Quality Manual
- Communicated, understood and applied within the organization
- Available to relevant interested parties as appropriate

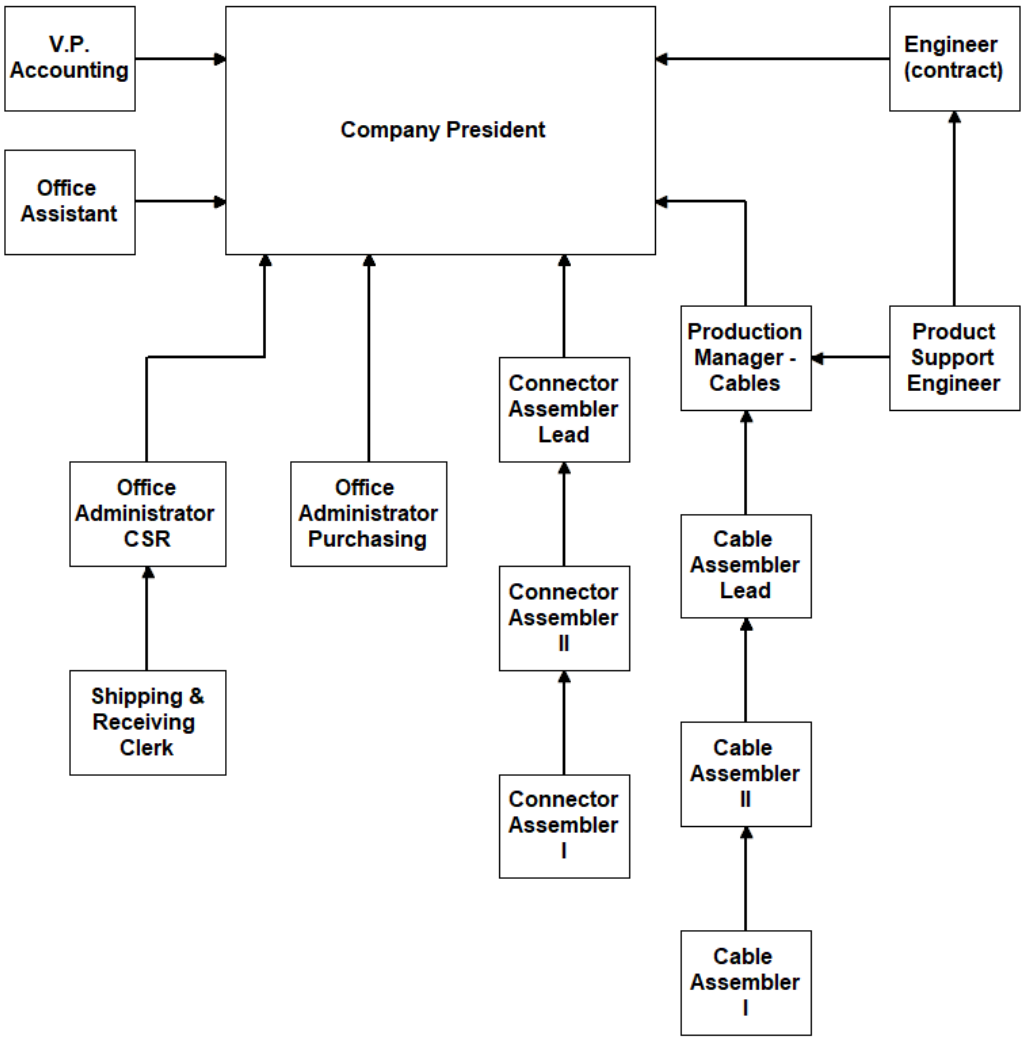
The Quality Policy is stated in **Procedure P-520**, **Quality Policy Statement**.

5.3 Organizational Roles, Responsibility and Authorities

The Top Management of rde verifies that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. The Top Management of rde assigns the responsibility and authority for executing the following tasks:

- Responsibility: ensuring that the Quality Management System conforms to the requirements of the ISO 9001-15 Standard and is achieved through:
    1. Internal Audits per **Paragraph 9.2**, **Internal Audit**, in the Quality Manual
    2. Management Reviews per **Paragraph 9.3**, **Management Review**, in the Quality Manual
    3. Awareness of every staff member through **Paragraph 7.3**, **Awareness**, in the Quality Manual
- Responsibility: ensuring that the processes are delivering their intended results (outputs) achieved through:
    1. Business Process Mapping
    2. **Paragraph 8.5.1**, **Production Control**, in the Quality Manual
- Responsibility: reporting on the performance of the Quality Management System achieved through Key Process Indicators (KPIs) and Management Reviews
- Responsibility: reporting all opportunities for improvement to Top Management of rde achieved through:
    1. **Paragraph 10.1**, **General (overview)**, in the Quality Manual
    2. **Paragraph 10.2**, **Nonconformity and Corrective Action**, in the Quality Manual
    3. **Paragraph 10.3**, **Continual Improvement**, in the Quality Manual
- Responsibility: ensuring the promotion of customer focus throughout rde achieved through:
    1. **Paragraph 5.1**, **General Responsibilities**, in the Quality Manual
    2. **Paragraph 7.3, Awareness**, in the Quality Manual
- Responsibility: ensuring that the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented. This is achieved through **Procedure P-750**, **Control of Documented Information**.

5.3 Company's Organization Chart



SECTION 6
Management of Risks and Quality Objectives

6.1 Risk Management

When planning for the QMS, rde has considered the concerns addressed in **Paragraph 4.1 of the ISO Standard** and the requirements addressed in **Paragraph 4.2 of the ISO Standard** 9001-15 and therefore utilizes **Procedure P-600**, **QMS Planning**. This activity correlates with the concerns described in **Paragraph 4.1**, **Understanding the Organization and its Context (business environment)** of rde where the internal and external concerns are addressed.

Therefore, determination of the risks and opportunities is required to:

1. Give assurance that the Quality Management System can achieve its intended results
2. Enhance desirable effects
3. Prevent, or reduce, undesired effects
4. Achieve improvement

The planning of risk management is concentrated on the following areas of concern:

a) Actions to address risks and opportunities and, how to:

b) Integrate and implement the actions into the QMS, according to **Paragraph 4.4 of the ISO Standard** 9001-15

c) Evaluate the effectiveness of the actions taken
(Reference: Paragraph 9.2.1 and 9.3.1 of the ISO Standard)

- Options to address risks can include avoiding risk, taking risks to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences of the risk, sharing the risk, or retaining risk by informed decision
- Opportunities can lead to the adoption of new practices, the launching of new products, the opening of new markets, the addressing of new customers, the building of partnerships, the use of new technologies and other desirable and viable possibilities to address the organizations or its customer's needs

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of the products.
In the context (business environment) of rde, risk management will concentrate on the following aspects:

1. Applicable legal compliance
2. Working environment

(Reference: **Paragraph 7.1.4**, **Environment for the Operation of Processes, in the Quality Manual)**
(Reference: Procedure P-915, Risk Management)

In conformance with **Paragraph 4.4**, **Quality Management System and Defined Processes**, in the Quality Manual, documented information regarding risk management will be established, implemented and maintained. The requirements of **P-750**, **Control of Documented Information**, will be followed. The effectiveness of actions taken to address risks and opportunities will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

6.2 Quality Objective:

rde's Statement of Quality Objectives can be found in the **Procedure P-620**, **Quality Objectives Statement**.

6.3 Planning of Changes

When rde determines the need for changes to the QMS, the changes will be carried out in a planned manner **(according to paragraph 4.4.1 and 4.4.2 of the ISO 9001-15 Standard)**.
When reviewing the need for changes, rde considers the following:

a) The purpose of the changes and their potential consequences
(Reference: Paragraph 6.1, **in the Quality Manual)**

b) The effects on the integrity of the Quality Management System
(Reference: Paragraph 7.5 in the Quality Manual)

c) The availability of resources to incorporate the change(s)
(Reference: Paragraph 7.1.1 in the Quality Manual)

Where the changes are applied, they will be performed per **Procedure P-750**, **Control of Documented Information**.

SECTION 7
Support

7.1 Resources

7.1.1 General

rde has determined and provided, or obtained, the resources required for the establishment, implementation, maintenance and continual improvement of the QMS. Determination of the resources required has taken into consideration **Procedure P-710**, **Resource Management Infrastructure** in addition to the following:

a) The capabilities of, and constraints on, existing internal resources

b) What resources must be obtained from external providers

The adequacy of resources outlined in **Paragraphs 7.1.2**, **People**, **7.1.3**, **Infrastructure**, **7.1.4**, **Environment for the Operation of Processes**, **7.1.5**, **Measurement Traceability** and **7.1.6**, **Organizational Knowledge**, will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**, **Management Review**, **in the Quality Manual.**

7.1.2 People

rde has determined and provided the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes. Determination of qualified personnel is addressed in **Paragraph 7.2, Competence**, in the Quality Manual.

7.1.3 Infrastructure

rde has determined, provided and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of its products. Determination of the Infrastructure within rde has taken into consideration the following:

a) Buildings and associated utilities equipment, including hardware and software

b) Transportation resources

c) Information and communication technology

All necessary infrastructure will be appropriately maintained to facilitate positive outcomes and to verify the adequacy of process control as is defined in **Paragraph 8.5.1.**, **Production Control**, in the Quality Manual.

(Reference: Procedure P-710, Resource Management - Infrastructure)

7.1.4 Environment for the Operation of Processes

rde has determined, provided and maintained the environment necessary for the operation of its processes and the conformity of its products. A suitable environment within rde can be a combination of human and physical factors, such as:

a) Social (e.g. non-discriminatory, calm, non-confrontational)

b) Psychological (e.g., stress-limited, burnout prevention, emotionally protective)

c) Physical (e.g., temperature, humidity, light, airflow, hygiene, noise)

These above-mentioned factors may be associated with the elements defined in **Section 6.1**, **Risk Management.**
The maintenance of the environment is also important to the efficiency of process control as is defined in **Paragraph 8.5.1**, **Production Control**, in the Quality Manual.

7.1.5 Measurement Traceability

rde has determined and provided the resources required to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products to requirements. Therefore, rde will confirm that the resources provided, as defined in **Procedure P-715**, **Measurement Traceability**, are:

a) Suitable for the specific type of monitoring and measuring activities being undertaken

b) Maintained to verify their continuing fitness for their purpose

Evidence of resource fitness for the purpose of monitoring and measuring will be retained as documented information and controlled according to the **Procedure P-750**, **Control of Documented Information**.

When measurement traceability is a requirement, or, is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment will be:

- Calibrated, verified, or both, at specified intervals against measurement standards traceable to international or national measurement standards. When no such standards exist, the basis used for calibration or verification will be retained as documented information
- Identified to determine their status
- Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results

Where the validity of previous measurement results may be adversely affected when measuring equipment is found to be unfit for its intended purpose, action must be taken in accordance with **Paragraph 8.7**, **Control of Nonconforming Outputs**, in the Quality Manual.

7.1.6 Organizational Knowledge

rde has determined the knowledge necessary for the operation of its processes and to achieve conformity of its products. This knowledge is maintained through documentation and will be made available to the extent necessary. When addressing changing needs and trends, the organization considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

Organizational knowledge is mandatory to demonstrate conformity to positive outcomes of rde's scope of certification as addressed in **Section 4.3**, **Scope of the Quality Management System**, in the Quality Manual.

Organizational knowledge gained by experience is used and shared to achieve the organization's objectives. Organizational knowledge can also be based on:

a) Internal sources (e.g., intellectual property, knowledge gained from experience, lessons learned from failed and successful endeavors, shared undocumented knowledge, experience and the results of improvements in processes and products

b) External sources (e.g., standards, academia, conferences and knowledge obtained from customers or external providers).

Management of organizational knowledge is addressed in **Paragraph 7.2**, **Competence**, in the Quality Manual.

7.2 Competence

7.2.1 Determination of Competence

rde will ensure competence through the use of **Procedure P-720**, **Competence and Awareness** and by the following documents:

a) Determine personnel competency based upon review of respective job descriptions, resumes and / or job applications. These documents detail the qualifications required and possessed for staff members doing the work under their control that affects the performance and effectiveness of the Quality Management System.

The competency of all personnel is mandated to ensure the efficiency of process control as it is defined in **Paragraph 8.5.1**, **Production Control**, in the Quality Manual.

Consideration of competency will associate the topics addressed in the Quality Manual through the following paragraphs:

a) **Paragraph 5.3**, **Organizational Roles**, **Responsibility and Authorities**

b) **Paragraph 7.1.2**, **People**

c) **Paragraph 7.1.6**, **Organizational Knowledge**

d) **Paragraph 7.3**, **Awareness**

Competency may need to be re-evaluated or determined when an issue is raised per **Procedure P-870**, **Control of Nonconforming Outputs**.

7.2.2 Competency

a) Job descriptions will detail the education, experience and the related skills required

b) Skills can be acquired from training and can be used to demonstrate appropriate expertise and to provide effectiveness of the QMS

c) Where training is applicable, a post evaluation of the training's effectiveness is measured

d) Documentation is updated as necessary

e) Appropriate documented information is retained in compliance with **Procedure P-750**, **Control of Documented Information**

7.3 Awareness

rde has verified that persons performing work under the organization's control are aware of the following:

a) rde's Quality Policy

b) rde's Quality Objectives

c) Their personal contribution to the effectiveness of the Quality Management System, including the benefits of improved performance

d) The implications of not conforming to the Quality Management System requirements

Where necessary, training will be conducted and the process shall be performed per **Section 7.2**, **Competence**, in the Quality Manual.

7.4 Communication

rde has determined the internal and external communications relevant to the Quality Management System through the information provided in **Procedure P-740**, **Communication**, including the following:

1. What will be communicated
2. When communication is to take place
3. Who will be included in the communication
4. How communication will be undertaken

5. Who will carry out the communication

7.4.1 Importance of Effective Communication

It is imperative for rde to consider internal and external communication input from interested parties and ensure that messages and information from them are managed in a professional and proper manner. Communication refers to all types of communications, both internal to, and external to, the organization.

- The ISO Standard requires organizations to establish and maintain processes for internal communications between the various levels and functions of the organization. Examples of internal communications may include:
    1. Communicating environmental objectives and targets to employees
    2. Raising awareness of environmental issues to employees
    3. Communicating the environmental policy to employees
    4. Advising of non-conformances to relevant departmental heads
    5. Reporting incidents arising from abnormal or emergency operation to Top Management
- External communication requirements may include suppliers and sub contract services and may be comprised of the following examples:
    1. Quality Policy
    2. Contracts
    3. Terms and conditions
    4. Service level agreements
    5. Order fulfilment
    6. Performance reporting

Maintenance of communication tools is performed per **Section 7.1.3**, **Infrastructure**, in the Quality Manual. Failed communication may cause the following situations to occur:

a) Complaint from customer or stakeholder

b) Output does not match the intended result(s) of the Quality Management System

c) The process is not delivering its intended product or service results

Where appropriate, problem-solving methods are performed per **Procedure P-870**, **Control of Nonconforming Outputs** and **Procedure P-1020**, **Nonconformity and Corrective Action**.

7.5 Documented Information

7.5.1 Top Management of rde will verify that the Quality Management System includes:

a) Documented information required by ISO 9001-15 Standard

b) Documented information determined by rde as being necessary for the effectiveness of the Quality Management System.

Therefore, rde has determined the necessary documented information to be applied within the organization as follows:

7.5.2 Creating and Updating

When creating and updating documented information, rde shall ensure appropriate:

a) Identification and description (e.g., a title, date, author or reference number)

b) Formatting (e.g., language, software version, graphics)

c) Media (e.g., paper, electronic)

d) Reviews and approvals for suitability and adequacy

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the Quality Management System and by this International Standard will be controlled to ensure:

a) It is available and suitable for use, where and when it is needed

b) It is adequately protected (e.g., from loss of confidentiality, improper use or loss of integrity)

7.5.3.2 For the control of documented information, rde will address the following activities as applicable:

a) Distribution, access, retrieval and use

b) Storage and preservation, including preservation of legibility

c) Control of changes (e.g., revision control)

d) Retention and disposition

e) Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose

(Reference: Paragraph 5.6 of Procedure P-750, Control of Documented Information)

Documented information of external origin determined by rde to be necessary for the planning and operation of the Quality Management System will be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity will be maintained and protected from unintended alterations.

Documented information that provides evidence of product origin will be maintained and protected from unintended alterations.

When documented information is managed electronically, data protection processes will be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

Control of documented information will be performed per **Procedure P-750**, **Control of Documented Information**.

SECTION 8
Operations

8.1 Operational Planning

In order to meet the requirements for the provision and scope of which it is certified, rde plans, implements and controls its processes as defined in **Paragraph 4.4, Quality Management System and Its Processes** and by the following:

(Reference: Procedure P-810, Operational Planning and Control, Form F-810-01, Project Planning Worksheet and Form F-810-02, **Process Validation Worksheet)**

a). Determining the requirements for products

(Reference: Paragraph 8.2. in the Quality Manual, **Requirement for Products**)

b). Establishing criteria for the following:

1. The processes
2. The acceptance of products

c). Implementing control of the processes in accordance with the following criteria:

1. Business process mapping to overview the process criteria
2. **Paragraph 8.4**, **Control of Externally Provided Processes**, **Products and Services** in the Quality Manual. Pertains to purchasing activities and outsourced processes

3. **Paragraph 8.5.1**, **Production Control**, in the Quality Manual. Pertains to the control of operational processes
4. **Paragraph 8.6**, **Release of Products** in the Quality Manual. Pertains to the release of products to the customer

d). Determining the resources required to achieve conformity to the product and service requirements:

1. **Paragraph 7.1**, **Resources**, in the Quality Manual
2. **Paragraph 8.4**, **Control of Externally Provided Processes, Products and Services**, in the Quality Manual. Applies to outsourced processes or externally provided processes, if applicable.

e). Determining and keeping documented information to the extent necessary:

1. To have confidence that the processes have been carried out as planned
2. To demonstrate the conformity of products to their requirements, control of documented information will be per **Paragraph 7.5**, **Documented Information**, in the Quality Manual

All above-mentioned activity will be maintained to verify:

1. The output of planning activities remain suitable for rde's operations
2. The planning activities are adequately controlled and consequences of unintended changes can be reviewed so that action can be taken to mitigate any adverse effects

8.2. Requirement for Products

(Reference: Procedure P-820, Requirement for Products)

8.2.1 Customer Communication

Communication with customers will be performed per **Paragraph 7.4**, **Communication**, in the Quality Manual to verify the efficiency of the following processes:

a) The communicating of information relating to products during the quoting and bidding process

b) The handling of inquiries, contracts or orders including changes

c) The obtaining of customer feedback relating to products and that includes receiving complaints from the customers

d) The handling or controlling of customer property

e) The establishing of specific requirements for resolving unforeseen events

Solutions to any inadequacies will be based on **Procedure P-1020**, **Nonconformity and Corrective Action**.

(Reference: Paragraph 8.5.3, **Property Belonging to Customers or External Providers in the Quality Manual)**

8.2.2 Determining the Requirements Related to Products

When determining the requirements for the products offered to customers, the designated person will verify that:

a) The requirements for the products as defined in the contract document, include:

1) Any applicable statutory and regulatory requirements

2) Any requirements considered necessary by rde

b) The organization can meet the requirements for the products it offers as defined in the contract document

8.2.3 Reviewing the Requirements Related to Products

rde verifies that it can meet the requirements for products to be offered to its customers by conducting a review of the requirements before making any commitments.

All reviews will include the following requirements:

- Requirements specified by the customer including the requirements for delivery and post-delivery activities (per contract review)
- Requirements not stated by the customer but necessary for the specified or intended use, when known (includes legal, regulatory, industry standards and organizational standards)
- Requirements specified by rde per **Paragraph 8**, **Operation**, in the Quality Manual
- Statutory and regulatory requirements applicable to the products (per contract document and risk analysis)
- Contracts or order requirements differing from those previously expressed (contract document review and resolution)

  NOTE: A designated person will verify that contracts or order requirements, differing from those previously defined, are resolved prior to order acceptance.

The authorized person, before acceptance, will confirm the customer's requirements when the customer does not provide a documented statement of their requirements.

Documented information will be controlled per **Procedure P-750**, **Control of Documented Information**, as applicable when:

a) The information is based upon the results of new product reviews

b) The information is based upon any new requirements for the products

8.2.4 Changes to Requirements for Products

When the requirements for products are changed during the quote process or after order acceptance, rde verifies that relevant documented information is amended and that relevant persons are made aware of the changed requirement.

8.3 Development of Products

8.3.1 General

rde has established, implemented and maintains a new product development process that is appropriate to verify the subsequent provision of products.

(**Reference: Procedure P-830**, **New Product Review).**

8.3.2 New Product Planning

In determining the stages and controls for new product development, rde will consider:

- The nature, duration and complexity of the new product development activities
- The required process stages including, when applicable, new product reviews
- The required new product development verification and validation activities
- The responsibilities and authorities involved in the new product development process
- The internal and external resource needs for the development of the new product and or new service
- The need to control interfaces between persons involved in the new product development process
- The need for involvement of customers and users in the new product development process
- The requirements for the subsequent provision of new products
- The level of control expected for the new product development process by customers and other relevant interested parties

- The documented information required to demonstrate and verify that the new product development requirements have been met

8.3.3 New Product Development Inputs

rde has determined the requirements essential for the specific types of products to

be developed.

rde will consider:

- The functional and performance requirements
- Any information derived from previous similar new product development activities
- Any statutory and regulatory requirements
- Any standards or codes of practice that the organization has committed to implement
- The potential consequences of failure due to the nature of the products
- Whether the inputs will be adequate for new product development purposes

  NOTE: Incomplete, ambiguous or conflicting design and development inputs will be resolved
- The organization shall retain all documented information on new product development inputs

8.3.4 New Product Development Controls

rde will apply controls to the new product development process to verify that the results to be achieved are clearly defined:

- New product reviews are conducted to evaluate the ability of the new product development process to meet the requirements
- Verification activities are conducted to ensure that the new product development outputs meet the input requirements
- Validation activities are conducted to verify that the resulting products meet the requirements for the specified application and intended use
- Necessary actions are taken on any problems discovered during new product reviews and / or verification and validation activities
- Documented information of the new product development activities is retained

New product development reviews and the verification and validation activities have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products provided by rde.

8.3.5 New Product Development Outputs

rde will verify that new products development outputs:

- Meet the input requirements
- Are adequate for the subsequent processes for the provision of products
- Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria
- Specify the characteristics of the products that are essential for their intended purpose and their safe and proper provision

rde will retain documented information on new product development outputs

8.3.6 New Product Development Changes

rde identifies, reviews and controls changes made during, or after, the development of new products to the extent necessary to verify that there is no adverse impact on conformity to requirements.

The organization will retain documented information on:

- New product development changes
- The results of new product reviews
- The authorization of the changes
- The actions taken to prevent adverse effects

8.4 Control of Externally Provided Processes, Products and Services

rde verifies that externally provided processes, products and services, more commonly known as the purchasing process, conforms to requirements as stated in the ISO 9001-15 Standard.

(Reference: Procedure P-840, Control of External Providers)

NOTE: Scope of activity of externally provided processes has been explained in Annex A.8, Control of Externally Provided Processes, Products and Services of the ISO 9001-15 Standard.

Control of externally provided processes include:

a) Purchasing control which includes selection, evaluation, re-evaluation and monitoring of the external providers (suppliers)

b) Type and extent of control of the purchasing process

c) Effective communication with the external provider or supplier

For details regarding externally provided process control, refer to **Procedure P-840**, **Control of External Providers**.

Results of the performance of external providers will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

8.5 Production and Service Provision

8.5.1 Production Control

rde has implemented a production and service **Procedure P-851**, **Control of Production and Service Provision**, which maintains controlled conditions through the various processes.
Controlled conditions of the processes (process control) include the following:

a) The availability of documented information that defines:
   1. The characteristics of the products to be produced, to be provided or the activities to be performed
   2. The results to be achieved
b) The availability and use of suitable monitoring and measuring resources
c) The implementation of monitoring and measurement activities at appropriate process stages to verify that the criteria for the control of the processes and the criteria for the acceptance of the products has been met
d) The use of suitable infrastructure and environment for the process operations
e) The appointment of competent persons, including any required qualifications
f) The validation and periodic re-validation of the ability to achieve planned results by the processes of the production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement
g) The implementation of actions to prevent human error
h) The implementation of processes for the release of, delivery of and post-delivery of products

8.5.2 Identification and Traceability

rde uses suitable means to identify products (outputs) when it is necessary to verify the conformity of its products. This includes the control of the processes as defined in **Procedure P-852**, **Identification and Traceability** and the following:

Product Identification:

- Paperwork accompanies each lot of products through production. Product Trackers, Bills of Materials and Assembly Drawings are included in the paperwork
- Product Trackers identify the product and the Sales Order Number of the in-process items. Product Trackers are always kept with the lot of products either by posting at the workstation where the work is performed or by being placed in the container(s) with the product as it travels through production.

Identification of Measuring and Monitoring Status:

- Product Trackers identify the processes required, including test and inspection. Operators initial and date each step of the process and indicate a pass / fail condition for electrical testing (if required). All products that do not pass test and inspection are identified with a red, reject tag and handled per **Procedure P-870**, **Control of Nonconforming Outputs**.

Traceability:

- The Engineering Team members, with input from appropriate departments, determine traceability requirements
- Traceability requirements are documented in work instructions
- Traceability is maintained by documentation (a copy) of the Sales Order Number, the Bill of Material, the Assembly Drawing and the Product Tracker.

Identification and Traceability is maintained by retaining the documented information according to the **Procedure P-750**, **Control of Documented Information**.

8.5.3 Property Belonging to Customers or External Providers

rde exercises care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

rde identifies, verifies, protects and safeguards customer's or external provider's property provided for use or incorporation into the products.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the designated person shall report this to the customer or external provider and retain documented information on what has occurred.

Note: A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

rde preserves the conformity of products during internal processing, service provision and delivery to the intended destination to the extent necessary to verify conformity to requirements.

Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation and protection. Preservation also applies to the constituent parts of a product.

(Reference: Procedure P-854, **Preservation)**

8.5.5 Post-delivery Activities

rde will meet the requirements for post-delivery activities associated with its products.

In determining the extent of the required, post-delivery activities, rde has considered the following:

- Statutory and regulatory requirements
- The potential undesired consequences associated with the products
- The nature, use and intended lifetime of its products
- The customer's requirements
- Customer feedback

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of Changes

rde reviews and controls changes for the production and / or service provision to the extent necessary to verify continuing conformity with requirements. When changes are required, a documented change request is initiated.

rde will review the required changes and retain documented information describing the results of the review, the person(s) authorizing the change and any necessary actions arising from the review.

All changes to QMS processes, procedures or forms will be documented on **DCR Form, F-750-03**. An Engineering Change Notice (ECR) (currently in use is, **New Product Change Form, F-830-02**) is used for all product changes which are product orientated and technical in nature.

8.6 Release of Products

rde will implement planned arrangements, at appropriate stages, to verify product and service requirements have been met. The release of products to the customer will not proceed until the planned arrangements

have been satisfactorily completed in accordance with **Paragraph 8.5.1**, **Production Control** in the Quality Manual.

Any product or service that does not meet with customer requirements must be resolved through **Paragraph 8.7**, **Control of Nonconforming Product**, in the Quality Manual.

rde will retain documented information on the release of products. The documented information will include:

1. Evidence of conformity with the acceptance criteria
2. Traceability to the person(s) authorizing the release of the product and / or service

8.7 Control of Nonconforming Outputs

rde verifies that outputs (products) that do not conform to requirements are identified and controlled per **Procedure P-870**, **Control of Nonconforming Outputs**, to prevent their unintended use or delivery. rde takes appropriate action based on the nature of the non-conformity and its effect on the conformity of products. This action also applies to non-conforming products detected after the delivery of the products. The ways of dealing with non-conforming outputs must be per one or more of the following measures:

a) Correction (rework / replace)

b) Segregation, containment, return or suspension of provision of products

c) Informing the customer

d) Obtaining authorization for acceptance under concession. Conformity to the requirements will be verified when the non-conforming outputs are corrected

rde retains documented information that:

a) Describes the non-conformity

b) Describes the corrective actions taken

c) Describes any concessions obtained

d) Identifies the authority determining the resolution of the non-conformities

Information on nonconformities will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

SECTION 9
Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

1. rde determines:
   a) What criteria is to be monitored and measured
   b) The monitoring, measurement, analysis and evaluation methods required to verify rational results
   c) When the monitoring and measuring is to be performed
   d) When the results from monitoring and measurement will be analyzed and evaluated
2. rde evaluates the performance and the effectiveness of the Quality Management System
3. rde retains appropriate documented information as evidence of the results of the monitoring, measurement, analysis and evaluation methods according to **Procedure P-750**, **Control of Documented Information**.

9.1.2 Customer Satisfaction

rde monitors customer's perceptions through **Procedure P-912**, **Customer Satisfaction**, to the degree to which their needs and expectations have been fulfilled.

rde determines the methods for obtaining, monitoring and reviewing this information. Methods of evaluation should refer to **Paragraph 9.1.3**, **Analysis and Evaluation**, in the Quality Manual. Results of the monitoring activity will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

9.1.3 Analysis and Evaluation

rde analyzes and evaluates appropriate data through **Procedure P-913**, **Analysis and Evaluation**, and information arising from the monitoring and measurement methods in place. The results of the analysis and evaluation will be used in accordance with the following forms:

F-913-01, **Product / Service – Monitoring, Measuring and Analysis Table**

F-913-02, **QMS - Monitoring, Measurement and Analysis Table**

F-913-03, **Inspection Report**

9.2 Internal Audit

rde conducts internal audits (semi-annually) to provide information on whether the Quality Management System:

a) Conforms to the following:

1) rde's own requirements for its Quality Management System

2) The requirements of ISO 9001-15

b) Is effectively implemented and maintained

Execution of internal audits include:

c) Planning, establishing, implementing and maintaining an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which will take into consideration the importance of the processes concerned, any changes affecting the organization and the results of previous audits

d) Defining the audit criteria and scope for each audit (see: individual Internal Audit Checklists)

e) Selecting auditors and conducting audits, verifying objectivity and the impartiality of the audit process and verifying that the results of the audits are reported to relevant management staff

f) Taking appropriate corrective actions without undue delay

g) Retaining documented information as evidence of the implementation of the audit program and the audit results

Internal audit activities will be performed per **Procedure P-920**, **Internal Audits**. Results of internal audit activity will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**. **Management Review**, in the Quality Manual.

9.3 Management Review

9.3.1 General

The Top Management of rde reviews the organization's Quality Management System, at a minimum of once per year, to verify its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the company. rde may elect to review the Quality Management System on a more frequent basis as business conditions dictate. These reviews will be documented per **Procedure P-930**, **Management Review**.

9.3.2 Management Review Inputs

Top Management of rde plans and conducts Management Reviews taking into consideration the following:

Review Inputs:

1) The status of actions from previous management reviews
2) Any changes in external and internal concerns that are relevant to the Quality Management System
3) Information on the performance and effectiveness of the Quality Management System

This includes trends in:

a) Customer satisfaction and feedback from relevant interested parties
b) The extent to which quality objectives have been met
c) Process performance and conformity of products
d) Non-conformities and corrective actions
e) Monitoring and measurement results
f) Audit results
g) The performance of external providers
h) The adequacy of resources
i) The effectiveness of actions taken to address risks and opportunities
j) Opportunities for improvement

9.3.3 Management Review Outputs

The outputs of the Management Reviews include decisions and actions related to the following:

1) Any changes in external and internal concerns that are relevant to the Quality Management System
2) Information on the performance and effectiveness of the Quality Management System

This including trends in:

a) Customer satisfaction and feedback from relevant interested parties
b) The extent to which quality objectives have been met
c) Process performance and conformity of products
d) Non-conformities and corrective actions

e) Monitoring and measurement results

f) Audit results

g) The performance of external providers

h) The adequacy of resources

i) The effectiveness of actions taken to address risks and opportunities

j) Opportunities for improvement

Documented information of the Management Reviews will be retained as evidence of the results of Management Reviews.

SECTION 10
Improvement

10.1 General

rde determines and selects opportunities for improvement and implements all actions necessary to meet customer requirements and enhance customer satisfaction. These opportunities will include, at a minimum, the following:

a) Improving products to meet requirements as well as to address future needs and expectations

b) Correcting, preventing or reducing undesired effects

c) Improving the performance and effectiveness of the Quality Management System

The input of information used for improvement activities will be reviewed by the Top Management of rde as is required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

10.2 Nonconformity and Corrective Action

When a nonconformity occurs, including any arising from external complaints, designated personnel will review, plan and respond accordingly per **Procedure P-1020**, **Nonconformity and Corrective Action**. Response will be as follows:

a) React to the non-conformity and, as applicable:

1) Act to control and correct non-conformity

2) Mitigate the consequences through risk management techniques

b) Evaluate the need for action to eliminate the cause(s) of the non-conformity in order to prevent re-occurrence or occurrences elsewhere by:

1) Reviewing and analyzing the non-conformity

2) Determining the causes of the non-conformity (Root Cause Analysis)

3) Determining if similar non-conformities exist or could potentially occur within the organization

c) Implement any actions required to mitigate the situation

d) Review the effectiveness of any corrective action taken

e) Update risks and opportunities determined during planning, as required

f) Make changes to the Quality Management System, as required

Corrective actions must be appropriate to the effects of the non-conformities encountered. The company will retain documented information as evidence of the following:

a) The nature of the non-conformities and of any subsequent actions taken

b) The results of any corrective action

Detailed measures for acting on a non-conformity will be performed per **Procedure P-1020**, **Nonconformity and Corrective Action**, and its associated forms. Information on non-conformities, and corrective action, will be reviewed by the Corrective Action Team of rde as is required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

10.3 Continual Improvement

rde will continually improve the suitability, adequacy and effectiveness of the Quality Management System per **Procedure P-1030**, **Continuous Improvement**. Considerations regarding continuous improvement will be based on following inputs:

a) Results of analysis and evaluation as defined in **Paragraph 9.1.3**, **Analysis and Evaluation**, in the Quality Manual

b) The outputs from Management Reviews as defined in **Paragraph 9.3.3**, **Management Review Outputs**, in the Quality Manual

Based on the outputs from the Management Reviews, the Top Management of rde will determine if there are needs or opportunities that should be addressed as part of the continual improvement process.

NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

The ideas for the opportunities for improvement will be reviewed by the Top Management of rde as required by **Paragraph 9.3**, **Management Review**, in the Quality Manual.

Section 11

Business Management Principals

1. Focus on Customers and Interested Parties

To enhance corporate performance and achieve sustained success, organizations must focus on both their customers and their interested parties. Organizations can establish this focus by trying to understand the current and future requirements and expectations of both their customers and their interested parties and by constantly trying to meet these requirements and exceed these expectations.

2. Provide Leadership for Your Organization

To enhance corporate performance and achieve sustained success, organizations must verify that suitable leadership is provided at all levels. Suitable leadership is provided whenever leaders at all levels establish a unity of purpose and create an environment that encourages people to pursue a common direction and achieve a common set of objectives. By establishing a common purpose, leaders can verify that all strategies, policies, processes, and resources are aligned and are used to pursue a common direction and to achieve a common set of objectives.

3. Engage and Involve Your People

To enhance corporate performance and achieve sustained success, organizations must be able to create and deliver value. To do so, they must have people who are competent, they must enhance their knowledge and skills and they must manage them effectively by empowering them, by encouraging their involvement and engagement at all levels and by recognizing their achievements.

4. Use a Process Approach

To enhance corporate performance and achieve sustained success, organizations must use a process approach to manage their activities. The process approach is a management strategy.

When managers use this approach, it means that they manage and control their processes, the interactions between those processes and the inputs and outputs that tie those processes together. It also means that they manage all these interactions as a system.

When this approach is applied to quality management, it means that they manage their processes and their process interactions as a coherent Quality Management System.

5. Encourage Improvement

To enhance corporate performance and achieve sustained success, organizations must encourage and support improvement. If they wish to maintain current levels of performance, if they wish to respond to changing conditions and if they wish to identify, create, and exploit new opportunities, organizations must establish and sustain an ongoing focus on improvement.

6. Use Evidence to Make Decisions

To enhance corporate performance and achieve sustained success, organizations must establish an evidence-based decision-making process. Decision making is evidence-based whenever multiple types of input are gathered from multiple sources, whenever facts are identified, whenever data is analyzed objectively, whenever cause and effect relationships are examined, whenever potential unintended consequences are considered and whenever all of this is used to make corporate decisions.

7. Manage Your Corporate Relationships

To enhance corporate performance and achieve sustained success, organizations must manage their relationship with suppliers, partners, and other interested parties. Relationships must be carefully managed because suppliers, partners, and other interested parties can influence corporate performance and undermine corporate success.

Section 12
Quality Terms & Definitions

Audit - A systematic evidence gathering process. Audits must be independent and evidence must be evaluated objectively to determine how well Audit criteria are being met. There are three types of audits: First-party, Second-party, and Third-party. First-party audits are internal audits while second- and third-party audits are external audits.

Organizations use First-party audits to audit themselves. First-party audits are used to provide input for management review and for other internal purposes. They are also used to declare that an organization meets specified requirements (this is called a self-declaration).

Second-party audits are external audits. They are usually done by customers or by others on their behalf. However, they can also be done by regulators or any other external party that has an interest in an organization. Third-party audits are external audits as well. However, they are performed by independent organizations such as registrars (certification bodies) or regulators.

ISO also distinguishes between combined audits and joint audits. When two or more management systems of different disciplines are audited together at the same time, it's called a combined audit and when two or more auditing organizations cooperate to audit a single auditee organization, it's called a joint audit.

Audit Criteria - A reference point that includes policies, requirements, and other forms of documented information. Audit Criteria are compared against Audit Evidence to determine how well the Audit Criteria are being met. Audit Evidence is used to determine how well policies are being implemented and how well requirements are being followed.

Audit Evidence - Records, factual statements, and other verifiable information that is related to the Audit Criteria being used. Audit Criteria include policies, requirements, and other documented information.

Audit Findings - The results from a process that evaluates Audit Evidence and compares it against Audit Criteria. Audit Findings can show that Audit Criteria are being met (conformity) or that they are not being met (nonconformity). They can also identify best practices or improvement opportunities.

Audit Program - A set of one or more audits that are planned and carried out within a specific time frame and are intended to achieve a specific audit purpose.

Characteristic - A distinctive feature or property of something. Characteristics can be inherent or assigned and can be qualitative or quantitative. An inherent characteristic exists in something or is a permanent feature of something while an assigned characteristic is a feature that is attributed or attached to something.

Competence - Ability to apply knowledge and skill to achieve intended results. Being competent means having the knowledge and skill that you need and knowing how to apply it. Being Competent means that you are qualified to do the job.

Complaint - In the context (business environment) of ISO 9001-15, a complaint refers to an expression of dissatisfaction with a product or service and is filed by a customer and received by an organization. Whenever a customer lodges a complaint, a response is either explicitly or implicitly required.

Concession - A special approval that is granted to release a nonconforming product or service for use or delivery. Concessions are usually restricted to a specific use and limited by time and quantity and tend to specify that nonconforming characteristics may not violate specified limits.

Conformity - The "fulfillment of a requirement". To conform means to meet or comply with requirements and a requirement is a need, expectation, or obligation. There are many types of requirements including customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements and regulatory requirements.

Context (business environment) of the Organization - An organization's business environment. It includes all the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.

An organization's External Context (business environment) includes all the needs and expectations of interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment.

An organization's Internal Context (business environment) includes its values, culture, knowledge, and performance.

ISO 9001-15 expects you to consider your organization's internal and external context (business environment) when you define the scope of its QMS and when you plan its design and development.

Continual Improvement - A set of recurring activities that are carried out to enhance performance. Continual Improvements can be achieved by carrying out audits, self-assessments, and management reviews. Continual Improvements can also be realized by collecting data, analyzing information, setting objectives, and implementing corrective and preventive actions.

Contract - A binding agreement between two or more parties.

Correction - Any action that is taken to eliminate a nonconformity. However, Corrections do not address Root Causes. When applied to products, Corrections can include reworking products, reprocessing them, regrading them, assigning them to a different use, or simply destroying them.

Corrective Action - Planned steps that are taken to eliminate the causes of existing nonconformities to prevent recurrence. The Corrective Action Process attempts to make sure that existing nonconformities and potentially undesirable situations do not happen again.

Customer - Anyone who receives products or services (outputs) from a supplier. Customers can be either people or organizations and can be either external or internal to the supplier organization. Examples of customers include clients, consumers, users, guests, patients, purchasers, the organization's employees and beneficiaries.

Customer Satisfaction - A perception and a measure of degree. Customer Satisfaction can vary from high satisfaction to low satisfaction. If customers believe that you have met their requirements, they experience high satisfaction. If they believe that you have not met their requirements, they experience low satisfaction.

Since Customer Satisfaction is a perception, customers may not be satisfied even though you have met all contractual requirements. Just because you have not received any complaints does not mean that customers are satisfied.

There are many ways to monitor and measure Customer Satisfaction. You can use customer satisfaction and opinion surveys, you can collect product quality data (post-delivery), track warranty claims, examine dealer reports, study customer compliments and criticisms and analyze lost business opportunities.

Data - Any recorded or obtainable facts about an occurrence or object.

Defect - A type of nonconformity. Defects occurs when a product or service fails to meet specified or intended use requirements.

Product Development - A process (or a set of processes) that uses resources to transform general input requirements for an object into specific output requirements.

Determination - To find or to identify the value of a characteristic.

Documented Information - Recorded information that must be controlled and maintained, including its supporting medium. Documented Information can be in any format and on any medium and can come from any source.

In regards to ISO 9001-15, Documented Information includes information about the Quality Management System and related processes. It also includes all the information that organizations need to operate and all the information that they use to document the results that they achieve (aka records).

Effectiveness - The degree to which a planned effect is achieved. Planned activities and results are effective if the intended results are achieved.

Feedback - A comment or an opinion expressed about a product or service or an interest expressed in a product or a service. Feedback may also be used to refer to the customer complaints handling process itself.

Function - A role that is performed by an individual within an organization.

Improvement - A set of activities carried out to enhance performance (get better results). Improvement can be achieved by means of a single activity or by means of a recurring set of activities.

Information - Facts provided or learned about something or someone.

Information System - (In the context of this ISO 9001 Standard) a network of communication channels used within an organization.

Infrastructure - The entire system of facilities, equipment, and support services that organizations need to function (per **ISO 9001-15, Section 7.1.3**). The term infrastructure can include buildings, equipment, utilities, and technologies (both hardware and software).

Innovation - A process that results in a brand new or substantially changed object. An Object is any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures,

processes, plans, ideas, documents, records, methods, machines, tools, technologies, techniques, and resources.

Interested Party - Anyone who can affect, be affected by, or believe that they are affected by a decision or activity. An Interested Party is a person, group, or organization that has an interest or a stake in a decision or activity.

Involvement - Act or process of taking part in something and contributing to its achievement.

Knowledge - A collection of information and a justified belief that this information is true with a high level of certainty.

Management - Dealing with or controlling all of the activities that are used to coordinate, direct, and govern organizations. These activities include developing policies, setting objectives and establishing processes to achieve these objectives. In this context (business environment), the term management does not refer to people.

Management System - A set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are required to verify that policies are followed and objectives are achieved. These elements include structures, programs, procedures, practices, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

There are many types of management systems. Some of these include quality management systems, environmental management systems, financial management systems, information security management systems, business continuity management systems, emergency management systems, disaster management systems, food safety management systems, risk management systems, and occupational health and safety management systems.

The scope or focus of a management system could be restricted to a specific function or section of an organization or it could include the entire organization. It could even include a function that cuts across several organizations.

Measurement - A process that is used to determine a value. In most cases, this value will be a quantity.

Measuring Equipment - All entities required to carry out a measurement process. Accordingly, Measuring Equipment includes instruments and apparatuses as well as all the associated software, standards, and reference materials.

Monitoring - Determination of the status of an activity, process, or system at different stages or at different times. To determine the status, you need to continually check and critically observe the activity, process, or system that is being monitored.

Non-conformity - A nonfulfillment or failure to meet a requirement. A Requirement is a need, expectation, or obligation. Requirements can be stated or implied by an organization or interested parties.

Object - Any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures, processes, plans, ideas, documents, records, methods, tools, machines, technologies, techniques, and resources.

Objective - A result you intend to achieve; a goal. An Objective can be strategic, tactical, or operational and can apply to an organization or to a system, process, project, product, or service. An Objective may also be referred to as a target, an aim, a goal, or an intended outcome.

Quality Objectives are generally based on or derived from an organization's quality policy and must be consistent with it.

Objective Audit Evidence - Information that is verifiable and generally consists of records and / or other statements of fact that are relevant to the Audit Criteria being used.

Objective Evidence - Data that shows or proves that something exists or is true. Objective Evidence can be collected by performing observations, measurements, tests or by using other suitable methods.

Organization - A single person or a group that achieves objectives by using its own functions, responsibilities, authorities, and relationships. An organization can be a company, corporation, enterprise, firm, partnership, charity, association or institution. An organization can be either incorporated or unincorporated and be either privately or publicly owned. An organization can also be an operating unit that is part of a larger entity.

Output - The end result of a process. Outputs can be either tangible or intangible. The Output from one process is often the input for another process.

ISO 9001 lists four generic output categories: services, software, hardware, and processed materials. Outputs often combine several of these categories. For example, an automobile (an output) combines hardware (e.g., tires), software (e.g., engine control algorithms) and processed materials (e.g., lubricants).

Outsource - Agreed to arrangements with an outside organization to perform a part of a function or process. This is referred to as Outsourcing. To outsource means to ask an external organization to perform part of a function or process normally done in-house. While an outsourced organization is beyond the scope of your QMS, the outsourced process or function itself falls within your scope.

Performance - A measurable result, either good or bad (per ISO). Performance refers to the measurable results that activities, processes, products, services, systems and organizations achieve. Performing well, good Performance, means that acceptable results are being achieved. Bad Performance of poorly performing means that unacceptable results are being produced.

Performance Indicator - A characteristic (metric) that is used to measure customer satisfaction and the organization's performance.

Policy - A general commitment, direction or intention and is formally stated by Top Management. A Quality Policy Statement should express Top Management's commitment to the implementation and improvement of its Quality Management System and allow managers to set Quality Objectives.

Process - A set of activities that are interrelated or that interact with one another. A Process uses resources to transform inputs into outputs. Processes are inter-connected because the output from one process often becomes the input for another process.

While a Process usually transform inputs into outputs, this is not always the case. Sometimes inputs become outputs without transformation.

Organizational processes should be planned and carried out under controlled conditions. An effective Process is one that realizes planned activities and achieves planned results.

Process Approach - A strategy that manages and controls the processes that make up an organization. When managers use a process approach, it means that they manage and control the interaction between processes and the inputs and outputs that tie these processes together.

Process-based Quality Management System - A process approach to manage and control how the Quality Policy is implemented and how the Quality Objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes.

Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single integrated process-based QMS.

Product - A tangible or intangible output that is the result of a process.

Products can be tangible or intangible. Per a note to this definition, there are three generic product categories: hardware, processed materials, and software. Many products combine several of these categories. For example, an automobile (a product) combines hardware (e.g., tires), software (e.g., engine control algorithms), and processed materials (e.g., lubricants).

Provider - A person or an organization that supplies or provides products or services. Providers can be either internal or external to the organization. Internal providers supply products or services to people within their own organization while external providers supply products or services to other organizations.

Quality - The inherent characteristics of an object as measured or compared against the inherent characteristics of other objects of a similar kind; the degree of excellence of an object.

The adjective Quality applies to objects and refers to the degree to which a set of inherent characteristics fulfills a set of requirements. An object is any entity that is either conceivable or perceivable and an inherent characteristic is a feature that exists in an object.

The Quality of an object can be determined by comparing a set of inherent characteristics against a set of requirements. If those characteristics meet all requirements, high or excellent Quality is achieved but if those characteristics do not meet all requirements, a low or poor level of Quality is achieved.

The Quality of an object depends on a set of characteristics and a set of requirements and how well the former complies with the latter.

Quality Management - All activities that organizations use to direct, control, and coordinate quality. These activities include formulating a Quality Policy and establishing Quality Objectives. Also included are quality planning, quality control, quality assurance, and quality improvement.

Quality Management System (QMS) - A set of interrelated or interacting elements that organizations use to formulate quality policies and quality objectives and to establish the processes that are required to verify that policies are followed and objectives are achieved. These elements include structures, programs, practices, procedures, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

Quality Objective - A method used by companies to focus the goals from the Quality Policy into plans for improvement; Improvements, relating to quality, that the organization plans, implements and intends to achieve.

Quality Objectives are based on or derived from an organization’s quality policy and must be consistent with it. They are usually formulated at all relevant levels within the organization and for all relevant functions.

The adjective quality applies to objects and refers to the degree to which a set of inherent characteristics fulfills a set of requirements. An object is any entity that is either conceivable or perceivable. Therefore, a quality objective can be set for any kind of object.

Quality Policy - An organization’s expressed commitment to the Quality Management System (QMS) that allows managers to set Quality Objectives. The Quality Policy should be based on ISO’s quality management principles, should be compatible with your organization’s other policies and should be consistent with its vision and mission.

ISO's quality management principles ask you to focus on customers and interested parties, to provide leadership, to engage and involve people, to use a process approach, to encourage improvement, to use evidence to make decisions, and to manage corporate relationships.

Regulatory Requirement - An obligation that is specified by an authority that gets its mandate from a legislative body.

Release - To grant permission to proceed to the next stage of a process. The term release is also used to refer to a version of software or documented information.

Requirement - A need, expectation, or obligation. A Requirement can be specified or implied by an organization, a customer or other interested parties.

A Specified Requirement is one that has been stated (in a document for example), whereas an Implied Requirement is a need, expectation or obligation that is common practice or customary.

There are many types of requirements. Some of these include customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements and regulatory requirements.

Review - A formal assessment or examination of something with the possibility or intention of instituting change if necessary.

A Review is an activity. Its purpose is to determine how well the subject / object being reviewed can achieve established objectives. Reviews ask the following question: is the subject (or object) of the Review a suitable, adequate, effective and efficient way of achieving established objectives.

There are many kinds of reviews. Some of these include management reviews, design and development reviews, customer requirement reviews, nonconformity reviews, and peer reviews.

Per ISO 9000, a Review determines the effect of uncertainty on an expected result and an effect is a positive or negative deviation from what is expected. The following two paragraphs will better explain what this means.

This definition recognizes that all of us operate in an uncertain world. Whenever we try to achieve something, there is always the chance that things will not go as planned. Sometimes, we get positive results, sometimes we get negative results and occasionally, we get both. Because of this, we need to reduce uncertainty as much as possible.

Uncertainty (or lack of certainty) is a state or condition that involves a deficiency of information and leads to inadequate or incomplete knowledge or understanding. In the context (business environment) of management, uncertainty exists whenever the knowledge or understanding of an event, consequence, or likelihood is inadequate or incomplete.

Risk-based Thinking - A coordinated set of activities and methods that organizations use to manage and control the many risks that affect the ability to achieve objectives. Risk-based thinking replaces what the old standard used to call “Preventive Action”.

While Risk-based Thinking is now an essential part of the new Standard, it does not actually expect you to implement a formal risk management process nor does it expect you to document your organization’s risk-based approach.

Root Cause Analysis - A method of problem solving used for identifying the true causes of errors or problems. An element is considered a root cause if its removal from the problem prevents the final undesirable event from recurring.

Service - An intangible output that is the result of a process that includes at least one activity and that is agreed upon and conducted between the supplier (provider) and the customer.

Service provision can take many forms. Service can be provided to support an organization's own products (e.g., warranty service or the serving of meals). Conversely, it can be provided for a product supplied by a customer (e.g., a repair service or a delivery service). It can also involve the provision of an intangible item to a customer (e.g., entertainment, ambience, transportation or advice).

Statutory Requirement - A statutory obligation that is defined by a legislative body.

Strategy - A plan for achieving an objective.

Supplier - A person or an organization that provides products and /or services.

Suppliers can be either internal or external to an organization. Internal Suppliers provide products or services to people within their own organization while External Suppliers provide products or services to other organizations.

Examples of suppliers include organizations and individuals who produce, distribute, or market products, provide services or publish information. While ISO still includes a definition for this term, the new ISO 9001 - 15 Standard no longer actually uses it. It prefers instead to use the term "External Provider".

System - A set of interrelated or interacting elements.

A Management System is one type of system. It is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are required to verify that policies are followed and objectives are achieved.

Top Management - The employees at the top levels of an organization.

Top Management refers to those people who provide resources, delegate authority and who coordinate, direct, and control the operations of an organization. However, if the scope of a management system covers only part of an organization, then the term Top Management refers instead to the people who direct and control that part of the organization.

Traceability - The ability to identify and track the history, distribution, location and application of products, parts, materials, and services. A traceability system records and follows the trail as products, parts, materials, and services are received from suppliers, are processed and ultimately distributed as final products and services.

Validation - The process of declaring something legally or officially acceptable.

Validation is a process that uses objective evidence to confirm (validate) that the requirements, which define an intended use or application, have been met. Whenever all requirements have been met, a validated status is established. Validation can be carried out under realistic use conditions or within a simulated use environment.

There are several ways to confirm that the requirements, which define an intended use or application, have been met. For example, you could do tests, you could carry out alternative calculations or you could examine documents before you issue them.

Verification - The process of establishing the validity or accuracy of something.

Verification is a process that uses objective evidence to confirm (verify) that specified requirements, which define an intended use or application, have been met. Whenever specified requirements have been met and verified, a verified status is achieved.

There are many ways to verify that requirements have been met. For example, you could inspect something, you could do tests, you could carry out alternative calculations or you could examine documents before you issue them.

Section 13
Revision History

Revision A

Revision Date: 02.06.2019

1. Initial release of the Quality Manual, QM-01

Revision B

Revision Date: 04.26.2019

1. All references to the word "Design" have been removed since the Company only "Develops" products using existing parts, or customer's designs
2. IOP Diagram revised to clarify processes
3. IOP Table added

Revision C

Revision Date: 05.16.2019

1. IOP Table revised to list the following:

a. Support Processes
b. Process Owners
c. Responsible Parties
d. Inputs / Outputs /KPIs

Revision D

Revision Date: 04.29.2020

1. All references to the word "Services" have been removed since the Company provides only products, no services
2. List of KPI's revised to include only those that are able to be monitored and measured, but are also key to customer satisfaction

Revision E

Revision Date: 04.26.2021

1. Number of active KPIs reduced, and refined

Revision F

Revision Date: 11.09.2021

1. Procedure P-914, and procedure P-1020 have been combined

   Explanation: Due to overlapping requirements in procedure P-914, Root Cause Analysis, and procedure P-1020, Non-conformity and Corrective Action, and due to the fact that section 9.4.1 is not an ISO requirement in the 9001-15 Standard, procedure P-914 and procedure P-1020 have been combined to include all steps required by ISO for the corrective action process including Root Cause Analysis.

Revision G

Revision Date: 03.17.2020

1. The IOP Diagram has been revised, with its original 8-processes now consolidated into 5- processes

   Explanation: Previously, Order Processing, Purchasing, Production, and Shipping and Receiving were listed on the IOP Diagram as individual processes. Since RDE's business model is that of an order fulfillment center, it was decided to combine these four processes into one, entitled Order Fulfillment.

2. The KPI Table has been revised to match the new IOP Diagram

   Explanation: The KPI's remain as before, but some have been reworded slightly for clarity, and have been consolidated under each appropriate process to match the reduced number of processes now listed on the IOP Diagram.

   The Organizational Chart has been revised to reflect staffing changes that have occurred since the initial release of this document

3. Revision dates, for each revision of this document, QM-01, have been added to the Revision History, and the Revision History has been reformatted with additional information added for clarity, and improved access of the information contained therein