CDI

QUALITY MANUAL

ISO 9001:2015, ISO 80079-34, UKEX and ATEX/IECEX Directive 2014/34/EU

QUALITY MANUAL

Reason for Revisions and Sections Affected:

INITIAL RELEASE Rev. A

Revision B / 6.24.2014 Added: PR-02-0005 to Procedure Table – Section: 2.0, Added: PR-02-0005 to Process Interaction Model – Section: 4.2.1.2, Added: ISO Authority Matrix (FM-03-0045) and Job Descriptions (FM-03-0022) – Section: 5.5.1, Added: Engineering Change Request Process (PR-02-0005) – Sections: 7.2.2, 7.3.1, 7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.3.7.

Revision C/ 9.29.2014 Added: Production Scheduler to Organizational Chart FC-02-0001 Rev. D

Revision D / 11.06.2014 Section 2.0: Added: Work Instructions to Figure: 3, Added 4.2.3.2: and Technical Publication/Documentation Work Instructions (WI-01-0001). Added 7.5.5: (WI-01-0002 Storage and Preservation of the CD-52 Bandit) Added 7.2.2 and 7.2.3: Absent Sales Representative – Critical Shipments (WI-01-0003)

Revision E / 11.19.2014 Section 2.0: Added: WI-01-0004 Control Plan Instructions to Figure 3 and 7.1.

Revision F / 1.28.2015 Added Sales Associates and deleted Domestic and International Sales from Organizational Chart FC-010001 Rev. E. Section 2.0: Added: WI-01-0005 Failure Modes and Effects Analysis to Figure 3 and 7.3.4.

Revision G / 3.02.2015 Updated FC-02-0001 Rev. F.

Revision H / 3.12.2015 Updated Figure 3 and 7.2.3 Added: Return Merchandise Authorization (WI-01-0006)

Revision I / 3.19.2015 Figure 1: Removed Rated Product Traceability Manager

Revision J / 3.26.2015 Added: WI-01-0007 Positive Material Identification to Figure 3 and 7.5.3.

Revision K / 7.06.2015 Added: WI-01-0008 CDI Drawing Guidelines to Figure 3 and 7.3.7.

Revision L / 7.24.2015 Updated Figure 1: FC-02-0001 Rev. H.

Revision M / 12.16.2016 Updated Manual to meet 9001:2015 requirements.
Revision N / 03.26.2018 Updated Organizational Chart.

Revision O / 09.30.2022 Added in Section 1.1 UKEX Equipment and Protective Systems Intended for Use in Potentially Atmospheres Regulation 2016, SI 2016:2017

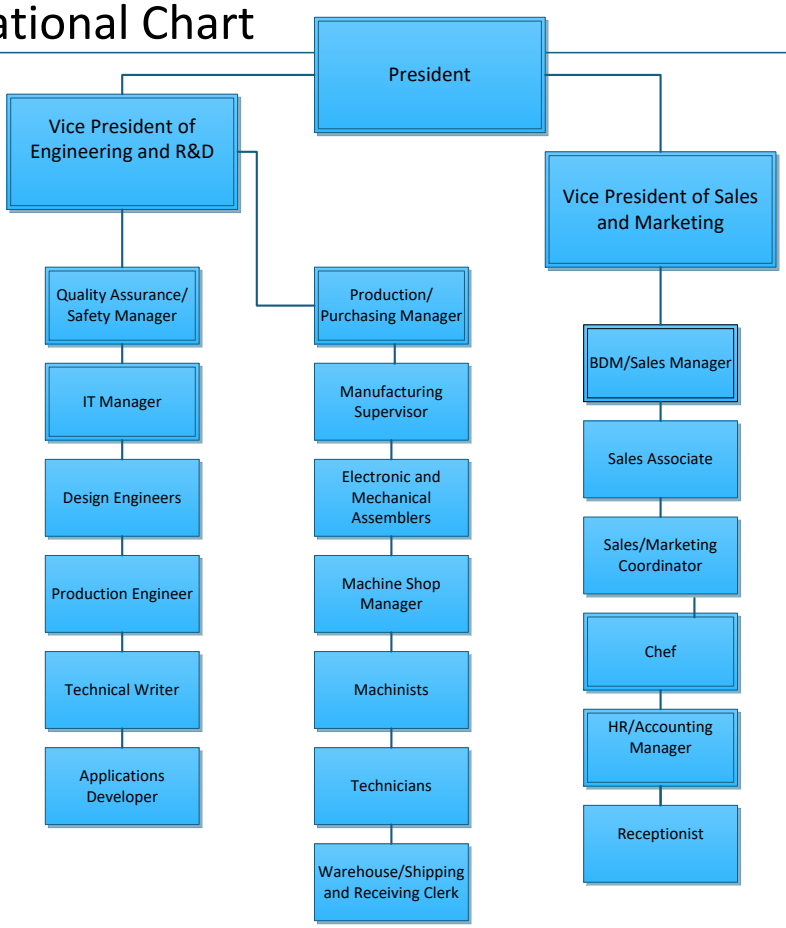
Approvals

Title	Signature	Date
Owner: Approval (Manager in affected area)	Jim Dashner	09.30.2022
Approval (Production) Production Manager	Jon Adams	09.30.2022
Approval (Quality Assurance) Quality Assurance Manager	Jim Dashner	09.30.2022
Approval (Management) Vice President	Jason Farque	09.30.2022

Figure 1: CDI Organizational Chart

CDI Organizational Chart

FC-02-0001



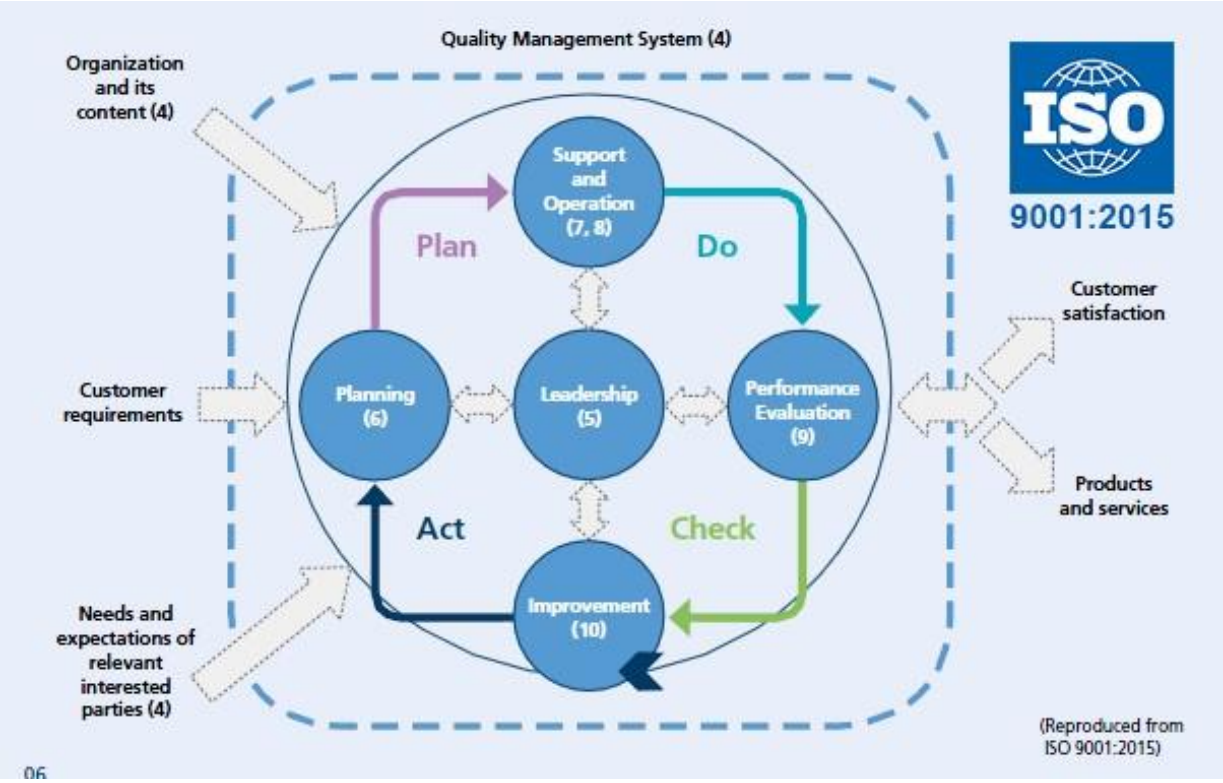


Figure 2: PDCA Process

1.0 SCOPE

1.1 Introduction

The objective of the quality management system is to provide CDI with methods to effectively determine customer requirements, create solutions to meet those requirements, and manufacture goods conforming to those requirements.

The following sections (1-10) of this Quality Manual describe our organization's conformance to the requirements of the ISO 9001:2015 and ISO/IEC 80079-34 standards. Each element reflects our organization's vision of quality as seen through the requirements of the standard, the needs of our customers, and our internally defined quality goals and objectives.

This Quality Manual is a controlled document and is intended to be part of the total quality system documentation. It has been prepared and is maintained by the Quality Assurance Manager. All suggestions for revisions to this document should be forwarded to the Quality Assurance Manager. In addition to any revision requests, this manual is reviewed yearly by the Quality Assurance Manager. Changes in requirements or context must be agreed to and approved by Senior Management.

This Quality Manual is based on and must be read in conjunction with ISO 9001:2015, 80079-34 and ATEX/IECEX Directive 2014/34/EU.

CDI's Quality Management System documentation ensures the effective operation and control of our business processes. Our Quality Management System documentation is designed to meet the requirements of ISO 9001:2015 as well as ATEX/IECEX certification and to be appropriate to our organization's size and type. It does not preclude the use of other quality systems that are compatible with the objectives of ISO 9001:2015/ATEX/IECEX and provides equivalent results. The purpose of this Standard is to establish requirements to ensure "good" manufacturing practices are applied that are appropriate for products intended for use in or associated with explosive atmospheres.
Manufacturers Quality Requirements are an integral part of most certification schemes and as such this Standard has been prepared with the ATEX/IECEX Equipment Certification Scheme requirements in mind and is intended to support the ATEX/IECEX and ISO 9001:2015 scheme requirements (2014/34/EU Annex X) for a manufacturers quality system and can be applied in other National or Regional Certifications Schemes that relate to the manufacture of explosion protected equipment.

The Quality Manual (level 1 documentation) contains not only the Quality Policy, but also all policies relating to the requirements of ISO 9001:2015 and ATEX/IECEX directive 2014/34/EU and UKEX Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016", SI 2016:1107 (as amended).

Operating procedures (level 2 documentation) describe how Quality Management System processes are conducted in compliance with the stated policies and as required by ISO 9001:2015. The majority of the level 2 and 3 documents are maintained on the CDI computer network.

Work Instructions, specifications and quality records (level 3 documentation) describe in detail how activities affecting quality are performed. The work instructions, drawings, as well as any forms used in conjunction with the Quality Management System are included in third level documentation.

The approval, issue and control of this Quality Manual, the Operating Procedures, the Quality Policy and all quality system documentation are detailed in the Document Control Procedure (PR-02-0006).

2.0 ASSOCIATED PROCEDURES and WORK INSTRUCTIONS

Procedure/Work Instruction Number	Procedure/Work Instruction	Department Owner
PR-02-0001	Receiving Inspection	Quality Assurance
PR-02-0002	Quotation, Contract Review and Order Entry	Sales
PR-02-0003	Procurement and Supplier Management	Purchasing
PR-02-0004	Management Review	Quality Assurance
PR-02-0005	Engineering Change Request Process	Engineering
PR-02-0006	Document Control	Quality Assurance
PR-02-0007	Records Management	Quality Assurance
PR-02-0008	Internal Audit	Quality Assurance
PR-02-0009	Control of Nonconforming Product	Quality Assurance
PR-02-0010	Corrective and Preventive Action	Quality Assurance
PR-02-0011	Contract Review	Sales
PR-02-0012	Design and Development	Engineering
PR-02-0013	Inspection and Testing	Quality Assurance
PR-02-0014	Competence Awareness and Training	Human Resources
PR-02-0015	Customer Property, Handling, Storage, Packaging, Preservation, Delivery and Protection	Distribution
PR-02-0016	Continual Improvement and Data Analysis	Quality Assurance
PR-02-0017	Equipment Calibration	Engineering
PR-02-0018	Return Merchandise Authorization	Sales
PR-02-0019	Resource Management, Facility Management and Work Environment	Engineering
PR-02-0020	Product Identification and Traceability	Manufacturing
PR-02-0021	Planning of Product Realization	Engineering
PR-02-0023	System Back-Up and Restore	IT
PR-02-0024	Risk Assessment	Quality Assurance
PR-02-0033	Customer Satisfaction	Sales
PR-02-0046	EX Responsibilities	Engineering

WI-01-0001	Technical Publication/Documentation Work Instructions	Engineering
WI-01-0002	Storage and Preservation of the CD-52 Bandit	Distribution
WI-01-0003	Absent Sales Representative / Critical Shipments	Sales
WI-01-0004	Control Plan Instructions	Engineering
WI-01-0005	Failure Modes and Effects Analysis	Engineering
WI-01-0007	Positive Material Identification	Quality Assurance
WI-01-0008	CDI Drawing Guidelines	Engineering

Figure 3: Procedure and Work Instruction Table

3.0 TERMS AND DEFINITIONS

3.1 Nomenclature

3.1.1 QM = Quality Manual, example: (QM-01-0001)
PR = Procedure, example: (PR-02-0001)
FC = Flow Chart, example: (FC-02-0001)
FM = Form, example: (FM-03-0001)
QP = Policy, example: (QP-01-0001)
WI = Work Instruction, example: (WI-01-0001)
CDI = Control of Devise Inc.
MR = Management Review

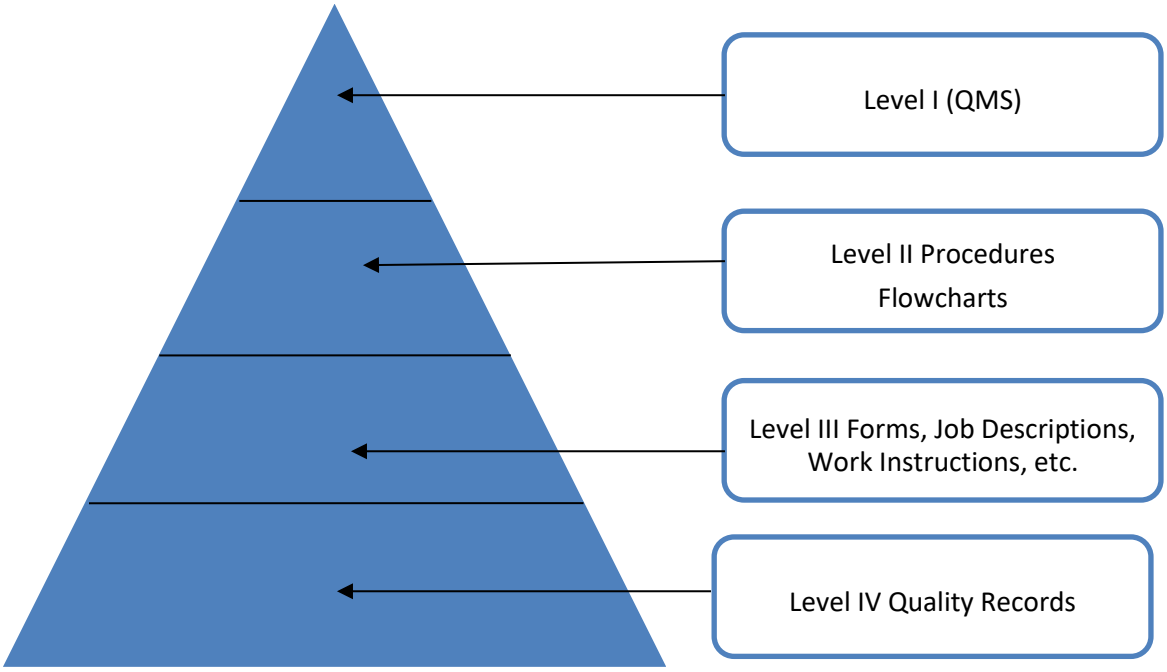


Figure 4: QMS Hierarchy

3.1.2 ATEX/IECEX component
Part of ATEX/IECEX equipment or a module marked with the ATEX/IECEX symbol, which is not intended to be used alone and requires additional consideration when incorporated into electrical equipment or systems for use in explosive atmospheres.

3.1.3 ATEX/IECEX or CSA/UL equipment
General term including machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material and which are capable of causing an explosion through their own potential sources of ignition.

3.1.4 ATEX/IECEX or CSA/UL certificate
This Document assures the conformity of a product and/or facility with specified requirements for explosive atmospheres.

3.1.5 Manufacturer
Organization, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection.

3.1.6 Contract
Requirements forming an agreement between a manufacturer and a customer and transmitted by any appropriate means.

3.1.7 Customer complaint
Any reported written or verbal allegation made by a customer who concerns the identity, quality, durability, safety, security, conformity or performance of any equipment or protective system or component as defined in the ATEX/IECEX or CSA/UL certificate or product documentation.

3.1.8 Product
The term “product” covers ATEX/IECEX and/or CSA/UL equipment, protective systems, safety devices, ATEX/IECEX and/or CSA/UL components and their combinations, as well as any other equipment that the company manufactures or software and service.

3.1.9 Protective systems
Design units which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures.

3.1.10 Safety devices
Safety devices provide explosion protection by executing a safety function that works independent of the normal functions of the equipment under its control.

3.1.11 Schedule drawing
Drawing or document listed in the ATEX/IECEX and/or CSA/UL certificate

3.1.12 Related drawing
Drawing or document not listed in the ATEX/IECEX and/or CSA/UL certificate but linked to the schedule drawing and used for example, for detailed manufacture of component parts. E.g. General Arrangement with Bill of Materials, Cross Sections, Wiring Termination drawings, Work Instructions.

3.1.13 Equipment documentation
Documentation that enables the conformity of the product with the requirements of the Standard(s) to be assessed. It covers the design, manufacture and operation of the product and contains:

- A general description.
- Design and manufacturing drawings and layouts of components, sub-assemblies, circuits, work instructions, etc.
- Descriptions and explanations necessary for the understanding of drawings and layouts and the operation of the product.
- A list of the standards referred to in the ATEX/IECEX and/or CSA/UL certificate, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the Standards; • Results of design calculations made, examinations carried out, etc.
- Test reports.

3.1.14 CDI's documentation

Those documents required by CDI but not subject to assessment by a Certification Body when making an application for a Test Report or ATEX/IECEX and/or CSA/UL certificate. i.e., manufacturing instructions, related drawings, data sheets and sales literature.

3.1.15 Type of protection

Specific measures applied to ATEX/IECEX and/or CSA/UL equipment to avoid ignition of a surrounding explosive atmosphere.

3.1.16 Body responsible for verification

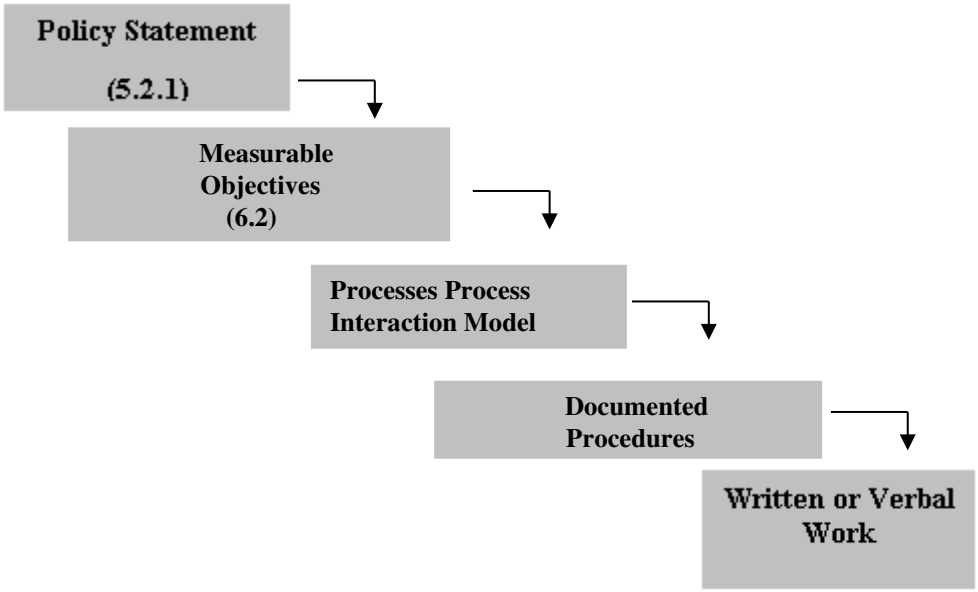
Body which conducts documentation review and periodical audit as appropriate. (E.g. CSA, UL, ATEX/IECEX, ISO).

4.0 Context of the Organization

4.1 Understanding the organization and its context

To fully understand the organization and its context, CDI has determined, monitor and review information the external and its strategic direction internal issues that are relevant and that affect the ability to achieve the intended results of the QMS.

CDI utilizes a QMS structured in the following sequence:



This manual includes:

- Quality Policy Statement (5.2.1)
- Scope of QMS (1.0)
- Measurable Objectives (6.2)
- QMS Process Interaction Model

Documented Quality Procedures are included in sections 2.0.

4.2 Understanding the needs and expectations of interested parties

To completely understand the needs and expectations of interested parties, CDI identifies the relevant interested parties, determines, monitors and reviews the requirements that are relevant to the QMS.

- The interested parties are identified by the Top Management. Their expectations and needs and the impact or potential impact on the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements are considered.
- Interested parties are customers, people in the organization and suppliers.

4.3 Determining the scope of the quality management system

To determine and establish the scope of the QMS, CDI has determined the boundaries and applicability of the QMS and considered the external and internal issues (4.1), the requirements of relevant interested parties (4.2), the requirements that can be applied, and the products and services of the company.

The scope is available and maintained as documented information stating the products and services covered by the QMS.

The scope of the QMS is as follows:

The scope of the Quality Management System includes the design, development and manufacturing of Modern Pipeline Pig Tracking Products industries at the Tulsa, OK location.

Conformity to ISO 9001:2015 may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

For any instance where a requirement cannot be applied, justification is documented.

CDI has determined that all requirements is applicable to the operations at the Tulsa, OK site. Customer and industry requirements have shown that conformity to product requirements is achieved with the initial specifications activities.

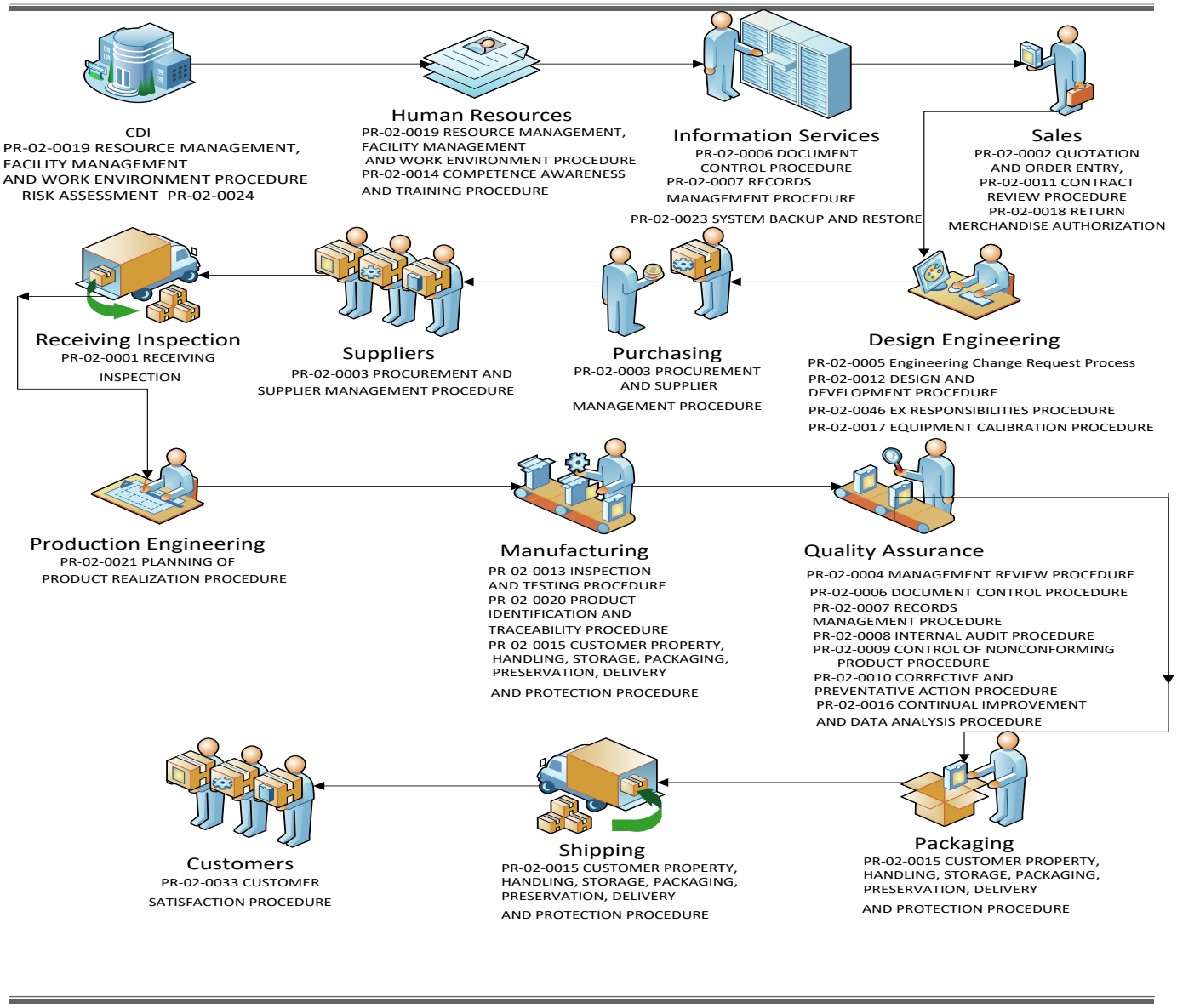
4.4 Quality management system and its processes

CDI QMS Processes are outlined below: These processes outline the work activities and interaction associated with CDI Quality Procedures.

The Quality System consists of the following:

a) Processes through Process Interaction Model that describe process flow throughout the organization and inputs required and the outputs expected from these process.
b) Sequence and interaction of processes is described in Process Interaction Model.
c) Criteria and methods to determine process effectiveness are specified by MR.
d) MR provides resources, information and the responsibilities and authorities needed to support process operation and monitoring.
e) Processes are monitored, measured, where applicable, and analyzed by MR.
f) Achievement of planned results and continual improvement of these processes is reviewed by MR.

Process Interaction Model



5. Leadership

5.1 Leadership and Commitment

5.1.1 General Requirements

CDI Top Management has established the QMS to continually improve the effectiveness and efficiency of the organization's performance by considering the business needs and customer satisfaction. CDI Top Management has outlined critical actions to be taken by CDI, in MR, to ensure an effective QMS is established, maintained and evaluated. CDI demonstrates leadership and commitment to the QMS by:

a) Taking accountability for the effectiveness of the QMS,

b) Ensuring that the quality policy and quality objectives are established and are compatible with the context of and strategic direction of the company,

c) Ensuring the integration of the QMS requirements into the company's business processes,

d) Promoting awareness of the process approach and risk-based thinking,

e) Ensuring that the resources needed for the QMS are available;

f) Communicating the importance of effective quality management and of conforming to the QMS requirements,

g) Ensuring that the QMS achieves its intended results,

h) Engaging, directing and supporting persons to contribute to the effectiveness of the QMS,

i) Promoting improvement,

j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

CDI Top Management emphasizes the prevention of problems, prevention of quality problems and demonstrates leadership and commitment to customer focus by ensuring that:

a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met,

b) The risks and opportunities that can impact conformity of products and services and the ability to enhance customer satisfaction are determined and addressed,

c) The focus on enhancing customer satisfaction is maintained (See PR-02-0033).

5.2 Policy

5.2.1 Establishing the Quality Policy

In support of the Vice President, the Top Management has established, implemented and maintained the quality policy that:

a) Is appropriate to the purpose and context of the organization and supports its strategic direction,

b) Provides a framework for setting quality objectives,

c) Includes a commitment to satisfy applicable requirements,

d) Includes a commitment to continual improvement of the QMS.

5.2.2 Communicating the quality policy

a) The Quality Policy is assigned control number QP - 01- 0001 and is approved by top management.

b) CDI posts the Quality Policy throughout the organization. Training Matrix and Records (FM-03-0015) explains and discusses the Quality Policy meaning to new employees.

c) CDI communicates and makes available, the Quality Policy to customers, people in the organization and suppliers in relevant interested parties. The Quality Policy is displayed throughout the organization.

5.3 Organizational roles, responsibilities and authorities

CDI Vice President ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood by:

a) Ensuring that the QMS meets the requirements of ISO 9001:2015,
b) Ensuring that the intended outputs of processes are delivered,
c) Reporting to top management on the performance of the QMS and on opportunities for improvement see 10.1.
d) Ensuring the promotion of customer focus within the company,
e) Ensuring that the integrity of the QMS is maintained when changes to it are planned and implemented.
In support of the Vice President, the Top management communicates the roles and authorities with the organization chart, FC-01-001 and Procedures where the functional departments and positions are identified.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, CDI has considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to (see PR-02-0024):

a) Give assurance that the quality management system can achieve its intended result(s);

b) Enhance desirable effects;

c) Prevent, or reduce, undesired effects;

d) Achieve improvement.

6.1.2 CDI has planned:

a) Actions to address these risks and opportunities;

b) How to:

1) Integrate and implement the actions into its quality management system processes (see 4.4);

2) Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services (Refer to: FM-03-0020 Safe Launch/Risk Management Assessment and PR-02-0024 Risk Assessment Procedure).

6.2 Quality objectives and planning to achieve them

6.2.1 CDI quality objectives are established by the Management and approved by Top Management at relevant functions, levels and processes needed for the quality management system.

The quality objectives are consistent with the quality policy, are measurable; take into account applicable requirements, are relevant to conformity of products and services and the enhancement of customer satisfaction; The objectives are monitored, communicated, and updated as required.

The quality objectives planning record QP - 01- 0001 is prepared by Top Management to detail the objectives. The documented information on the quality objectives is retained.

6.2.2 CDI quality objectives planning record QP - 01- 0001 and Management Review Output (Power Point) is used to plan quality objective projects and to outline details for what will be done, what resources will be required, who will be responsible, when it will be completed and how the results will be evaluated.

6.3 Planning of changes

Management determines the need for changes to the quality management system; the changes shall be carried out in a planned manner (see 4.4).

When changes to the QMS are needed, Top Management ensures that they are carried out in a planned and systematic manner with consideration is given to the purpose of the change and any of its consequences, the integrity of the QMS, the availability of resources, and the assignment of responsibilities.

7 Support

7.1 Resources

7.1.1 General

Management reviews the need and availability of resources with approval of Top Management. Resources are provided to implement the QMS and to continually improve the effectiveness of the QMS. Resources are provided to ensure customer satisfaction by meeting customer requirements (see PR-02-0019).

CDI considered:

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

b) What needs to be obtained from external providers.

7.1.2 People

CDI determines and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes based on their education, training or experience (see PR-02-0014).

7.1.3 Infrastructure

Management determines, provides and maintains infrastructure with approval by Top Management.

Infrastructure includes: Buildings, workspace and utilities. Process equipment including hardware and software is controlled by Top Management. Support services, such as transport, communication and information systems are also controlled by Top Management (see PR-02-0019).

7.1.4 Environment for the operation of processes

Management is responsible for determining and managing the work environment needed to achieve conformity to product requirements (see PR-02-0019).

7.1.5 Monitoring and measuring resources

7.1.5.1 General

CDI determines and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

CDI ensure that the resources provided:

a) Are suitable for the specific type of monitoring and measurement activities being undertaken;

b) Are maintained to ensure their continuing fitness for their purpose.

CDI retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources (see PR-02-0017 and Calibration Database).

7.1.5.2 Measurement traceability

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

a)calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; (see PR-02-0017 and Calibration Database).

b) Identified in order to determine their status;

c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

CDI determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6 Organizational knowledge

CDI determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, CDI consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

CDI has:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) Retain appropriate documented information as evidence of competence (see PR-02-0014 and Employee Competency Matrix FM-03-0013).

7.3 Awareness

CDI ensures that persons doing work under the organization's control are aware of:

a) The quality policy;

b) relevant quality objectives;

c) their 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 (see PR-02-0014, Employee Competency Matrix FM-03-0013 and Training Records FM-03-0015).

7.4 Communication

CDI has determined the internal and external communications relevant to the quality management system, utilizes multiple techniques (processes) to communicate QMS effectiveness throughout CDI including:

a) on what it will communicate

b) when to communicate

c) with whom to communicate

d) how to communicate

e) Who communicates

7.5 Documented information- Addressed in PR-02-0006 and PR-02-0007

7.5.1 General – Addressed in PR-02-0006
7.5.2 Creating and Updating – Addressed in PR-02-0006
7.5.3 Control of Documented Information – Addressed in PR-02-0006 and PR-02-0007

8 Operation

8.1 Operational Planning and Control

Quality planning is an integral part of process and product development for CDI to meet the requirements for the provision of products and services. Quality objectives are planned to ensure product quality requirements are met, QMS Process Interaction Model. The need for processes, documents, and resources to produce product, including facilities is planned, including processes QMS Process Interaction Model. Quality Assurance provides planning to identify the need for activities related to verification, validation, monitoring, measurement and inspection/test needed for product acceptance. Inspection and testing is performed to demonstrate the ability of the processes to achieve the planned results. Inspection and testing include raw materials used in the manufacture of products, in-process testing during manufacturing and final testing of finished products. Manufacturing has records available needed to provide evidence that processes are effective and meet product requirements. Quality records are monitored by Quality Assurance. Outputs from planning are reported to MR; QMS Process Interaction Model.

CDI ensure that outsourced processes are controlled (see 8.4).

8.2 Requirements for products and services

8.2.1 Customer communication

CDI top management ensures that information relating to products and services and customer requirements are met to enhance customer satisfaction. Improvements identified by Management are made with approval of Top Management. Vice President of sales are the first contact with CDI customers or potential customer enquiries (see PR-02-0002 Quotation and PR-02-0011 Contract Review). Information about CDI products, capabilities, order handling, amendments are provided to customers by Sales. Customer satisfaction, customer feedback and customer complaint records are kept by Sales and Quality (see PR-02-0033 Customer Satisfaction) and handling customer property (see PR-02-0015).

8.2.2 Determining the requirements for products and services

Requirements specified by the customer, including delivery and post-delivery activity are considered in Sales. Requirements necessary for product intended use and not stated by the customer are considered in Sales and Engineering. Statutory and regulatory requirements applicable to product are determined in Sales and Engineering. Additional requirements identified by CDI, to determine product requirements, are considered in Sales and Engineering (see PR-02-0011 Contract Review).

8.2.3 Review of the requirements for products and services

Sales and Engineering review requirements prior to an agreement to supply product to ensure product requirements are defined. Requirements differing from previous contracts are resolved. Review includes CDI capability to meet requirements. Records of customer requirement activities are maintained by Sales. Where the customer provides no documented statement of requirements, Sales and Engineering confirms customer requirements before acceptance of the contract (see PR-02-0011 Contract Review).

8.2.4 Changes to requirements for products and services

When product requirements are changed, Sales and Engineering makes changes to documents and informs Purchasing, Manufacturing and Quality Assurance.

8.3 Design and Development of product and services Addressed in PR-02-0012 (Design and Development Procedure).

8.3.1 General (Address in PR-02-0012)

8.3.2 Design and Development Planning (Address in PR-02-0012)

8.3.3 Design and development inputs (Address in PR-02-0012)

8.3.4 Design and development controls (Address in PR-02-0012)

8.3.5 Design and development outputs (Address in PR-02-0012)

8.3.6 Design and development changes (Address in PR-02-0012)

8.4 Control of externally provided processes, products and services

8.4.1 General

Product and services are purchased from approved suppliers. Raw material is inspected by Receiving Inspection (see PR-02-0001). Suppliers are selected, evaluated and re-evaluated by Purchasing and Quality based on previous effects on final product. Suppliers are selected on their ability to supply product and services as specified by CDI (see PR-02-0003 Procurement and Supplier Management Procedure).

CDI shall follow:

a) while manufacture, testing and final inspection may be sub-contracted, the responsibility for ensuring conformance with the Ex certificate shall not be subcontracted;

b) suppliers that provide a product, process or service that can affect the product's compliance with the Ex certificate, shall only be selected after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements:

1) Documented objective evidence that the supplier can provide a product, process or service that is fit for its purpose shall be made by one or more of the following methods:

- the supplier has an acceptable Ex quality system,
- the supplier has a quality system certificate in accordance to the appropriate standard and with an acceptable scope,
- a documented site assessment to ensure that all relevant controls are available, documented, understood and effective.

2) Where the features affecting the type of protection cannot be verified at a later stage, e.g. Encapsulated intrinsically safe circuits, then the product, process or service shall only be accepted by one of the following methods:

- CDI can demonstrate that the control process implemented by the subcontractor ensures Ex compliance.

3) The body responsible for the verification of the quality system performs periodic audits at the sub-contractors.

4) Where the features affecting the type of protection cannot be verified at a later stage, e.g. Encapsulated intrinsically safe circuits, then the product, process or service shall only be accepted by one of the following methods:

- CDI can demonstrate that the control process implemented by the subcontractor ensures Ex compliance,
- The body responsible for the verification of the quality system performs periodic audits at the sub-contractors.

8.4.2 Type and Extent of Control

FM-03-0011 Supplier Evaluation Form and QM-01-0002 Supplier Quality Manual specifies CDI criteria for supplier selection, evaluation and monitoring. Supplier selection and evaluation records are kept by Quality. Written Purchase Orders describe requirements for acquiring the associated product, procedure, process, equipment or service; requirements for personnel qualifications; and QMS requirements.

CDI shall follow:

a) The purchasing documents shall clearly describe the specific requirements pertaining to subcontracted product set out in the Ex certificate and the technical documentation (e.g. For process control, testing or inspection);

b) for items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item;

c) CDI shall define the method by which documents, e.g. technical specifications, stated in a particular purchase order remain traceable to the order;

d) Where CDI does not provide such documents with subsequent orders, then CDI shall have procedures for ensuring that suppliers have current copies of documents and that their integrity be maintained.

8.4.3 Information for external providers

Purchasing ensures purchasing requirements are adequate prior to communication to supplier(s). Receiving Inspection receives purchased products and performs visual inspection and quantity count when received. Top management reviews information for External Providers. CDI does perform verification at the supplier's premises (if applicable). CDI gives special attention and care to customer property when it is used or under CDI control. Customer property is identified, verified, protected, and safeguarded. Customer property that is lost, damaged, or unsuitable for use is reported to the customer and records are maintained by Quality and Sales (see PR-02-0015).

CDI shall follow:

a) for purchased products that can compromise the type of protection CDI shall determine and implement verification arrangements which demonstrate the product's compliance with the Ex certificate, taking into account the nature of the product and the nature of the supplier;

b) When deciding what type of verification is required for a particular purchased product, CDI shall consider the nature of the purchased product, the supplier and how critical it is to the type of protection.

c) where the supplier has been evaluated, and documented objective evidence has been obtained to demonstrate that the supplier is fully capable of producing and verifying the product or

service, no further verification of the product or service is required, provided a declaration of conformity according to ISO/IEC 17050-1 is supplied with each batch or product;

d) where the Ex certificate specifies routine tests or inspections, these shall be carried out on each product. They may be carried out by either the supplier or CDI. When carried out by the supplier, this shall be specified on the purchasing documents, e.g. by a quality plan, and confirmed by the supplier, e.g. by a declaration of conformity according to ISO/IEC 17050-1 including test results, if required;

e) where verification of a purchased product cannot be carried out after manufacture, e.g. the internal parts of encapsulated intrinsically safe circuits, then the product shall only be accepted if supplied with a declaration of conformity according to ISO/IEC 17050-1. This shall specifically state compliance to the purchase documents, e.g. a quality plan that lists the factors that together demonstrate conformity of the product;

f) where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch;

g) where either the supplier or CDI requires training or specialist skills or knowledge to carry out a verification, then the training material, specialist skill, knowledge or background shall be documented and training records maintained;

h) where CDI chooses not to carry out inspections and tests on his own premises, then inspections and tests shall be performed on the supplier's premises under the responsibility of CDI;

i) where a supplier provides product with evidence of conformity applicable to use in an explosive atmosphere (e.g. Ex certificate), then further verification is not required unless CDI considers it necessary;

j) where verification of a purchased product relates to the material (metals, alloys, nonmetallic parts, resins and similar), a specific analysis certificate or declaration shall be supplied.

8.5 Production and service provision

8.5.1 Control of production and service provision

CDI plans and carries out Manufacturing and Engineering to produce products under controlled conditions including: Information is available that describes the characteristics of the product, equipment is selected and maintained by production and is suitable for producing product, monitoring and measuring equipment are selected, maintained, and calibrated, monitoring and measurement of product quality is performed. Release, delivery and post-delivery of products are performed.

CDI validates special processes for production by performing the following control requirements: daily validation and approval of criteria for production and service processes, daily validation of equipment used and personnel qualifications, daily review of specific methods and procedures to control processes and continuing process revalidation.

To provide evidence of conformity of product to determined requirements, monitoring and measurement is performed with equipment needed, Manufacturing. Manufacturing processes ensure monitoring and measurement can be carried out consistent with monitoring and measurement requirements. Measuring equipment requiring calibration is: adjusted or re-adjusted as needed, identified to enable the calibration status to be determined and safeguarded from adjustments that would invalidate results. Measuring equipment is protected from damage and deterioration during handling, maintenance, and storage. When equipment does not conform to requirements, the validity of the previous measuring results are assessed and recorded. Appropriate action is taken on the equipment and product affected. Records of the results of calibration and verification are maintained by Manufacturing and Quality Assurance.

CDI shall provide procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the product with the type as described in the Ex certificate.

8.5.2 Identification and traceability

Product is identified throughout manufacturing (see PR-02-0020 Identification and Traceability). Product test status is identified by Manufacturing. As per customer requirements, products are labeled or marked by manufacturing (see PR-02-0020 Identification and Traceability & PR-02-0015 Customer Property) to ensure the items can be identified and traced. Customer required traceability records are maintained by Manufacturing and Quality.

8.5.3 Property belonging to customers or external providers. Addressed in PR-02-0015 (Customer Property, Handling, Storage, Packaging, Preservation, Delivery and Protection Procedure).

8.5.4 Preservation of product. Addressed in PR-02-0015 (Customer Property, Handling, Storage, Packaging, Preservation, Delivery and Protection Procedure).

8.5.5 Post Delivery Activities. Addressed in PR-02-0015 (Customer Property, Handling, Storage, Packaging, Preservation, Delivery and Protection Procedure).

8.5.6 Control of changes

When product requirements are changed, Engineering makes changes to documents and informs Quality and Manufacturing.

8.6 Release of products and services

Products and services are not released until customer requirements are satisfactorily completed, unless approved by relevant authority or by the customer. See PR-01-0013 Inspection and Testing Procedure, for final inspection records indicating the person authorizing release of product.

8.7 Control of nonconforming outputs

8.7.1 – Addressed in PR-02-0009
8.7.2 – Addressed in PR-02-0009

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

CDI plans and implements monitoring, measurement, analysis and improvement processes needed to: Demonstrate product requirements, ensure conformity of the QMS and continually improve the QMS. Methods for monitoring and measuring processes are applied using process interaction including processes QMS Process Interaction Model or by Management. Planned results are reviewed by Management. When planned results are not achieved, corrections and corrective actions are made, as appropriate, by Top Management to ensure processes are resulting in conformity of the product. Products are not released until customer requirements are satisfactorily completed, unless approved by relevant authority or by the customer. See Manufacturing, for final inspection records indicating the person authorizing release of product. Products are monitored and measured throughout manufacturing to meet acceptance criteria, and inspection records are kept. Quality maintains evidence of non-conformity (RMAs, and NCR Reports).

9.1.1 General. Address in PR-02-0017 in Equipment Calibration Procedure).

9.1.2 Customer satisfaction. Addressed in PR-02-0033 (Customer satisfaction Procedure).

9.1.3 Analysis and evaluation

QMS data is recorded analyzed and used to determine the suitability, effectiveness, and opportunities for improvement of the QMS. Data is recorded from monitoring and measurement, and from other relevant sources. Information is provided relating to: Customer perception and satisfaction, conformance to product requirements, characteristics and trends of process and products including opportunities for preventive actions. Opportunities for preventive action are also reviewed and evaluated by the Management. Supplier information needed is determined, collected and analyzed by Quality and Purchasing.

9.2 Internal audit. Addressed in PR-02-0008 (Internal Audit Procedure).

9.3 Management review

9.3.1 General

Top Management and Management reviews the QMS to ensure continuing suitability, adequacy, effectiveness and alignment with the strategic direction of CDI. The reviews include QMS status assessment, opportunities for improvement and changes needed for the QMS, Quality Policy and quality objectives are included in reviews. MR records are maintained by Quality (Management Review Power Point).

9.3.2 Management review inputs. Addressed in PR-02-0004 (Management Review Procedure).

9.3.3 Management review outputs. Addressed in PR-02-0004 (Management Review Procedure).

10 Improvement

10.1 General

CDI has determined and selected opportunities for improvement and implemented any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

a) improving products and services 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.

10.2 Nonconformity and corrective action. Addressed in PR-02-0009 (Control of nonconforming outputs) and PR-02-0010 (Corrective Action Procedure).

10.3 Continual improvement. Addressed in PR-02-0016 (Continual Improvement and Analysis Data).