QUALITY MANUAL

Reference: ISO 9001:2008, ISO 80079-34, and ATEX/IECEX Directive 94/9/EC

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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-01-0001 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.

Controlled Document

Approvals

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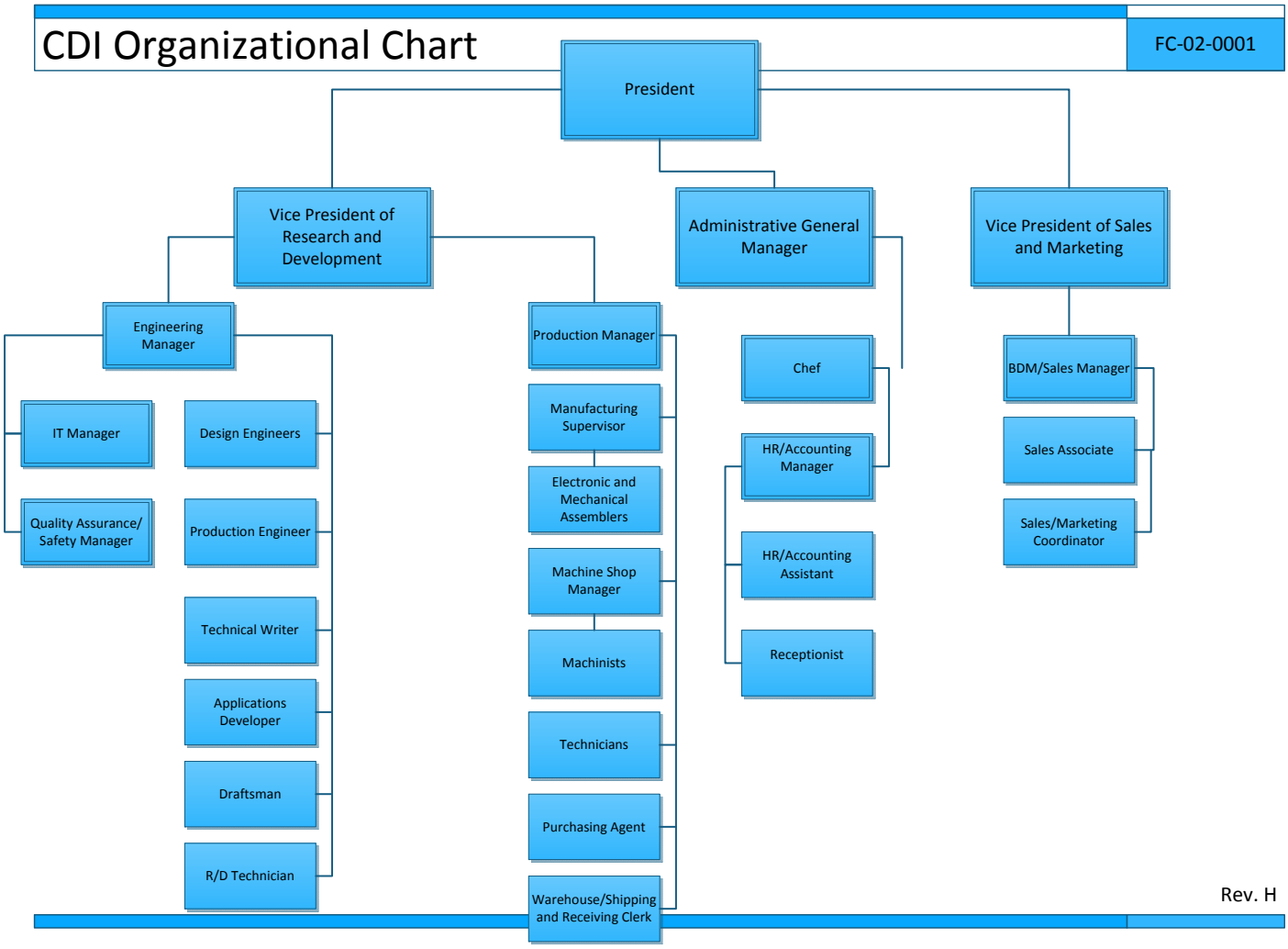

Figure 1: CDI Organizational Chart

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Figure 2: Table of Contents

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 (1-8) of this Quality Manual describe our organization's conformance to the requirements of the ISO 9001:2008 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 9001:2008, 80079-34-2011 and ATEX/IECEX Directive 94/9/EC.

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 9001:2008 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 9001:2008/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 9001:2008 scheme requirements (94/9/EC Annex IV and VII) 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 9001:2008 and ATEX/IECEX directive 94/9/EC.

Operating procedures (level 2 documentation) describe how Quality Management System processes are conducted in compliance with the stated policies and as required by ISO 9001:2008. 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-02-0019	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-02-0033	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-01-0006	Return Merchandise Authorization	Sales
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)

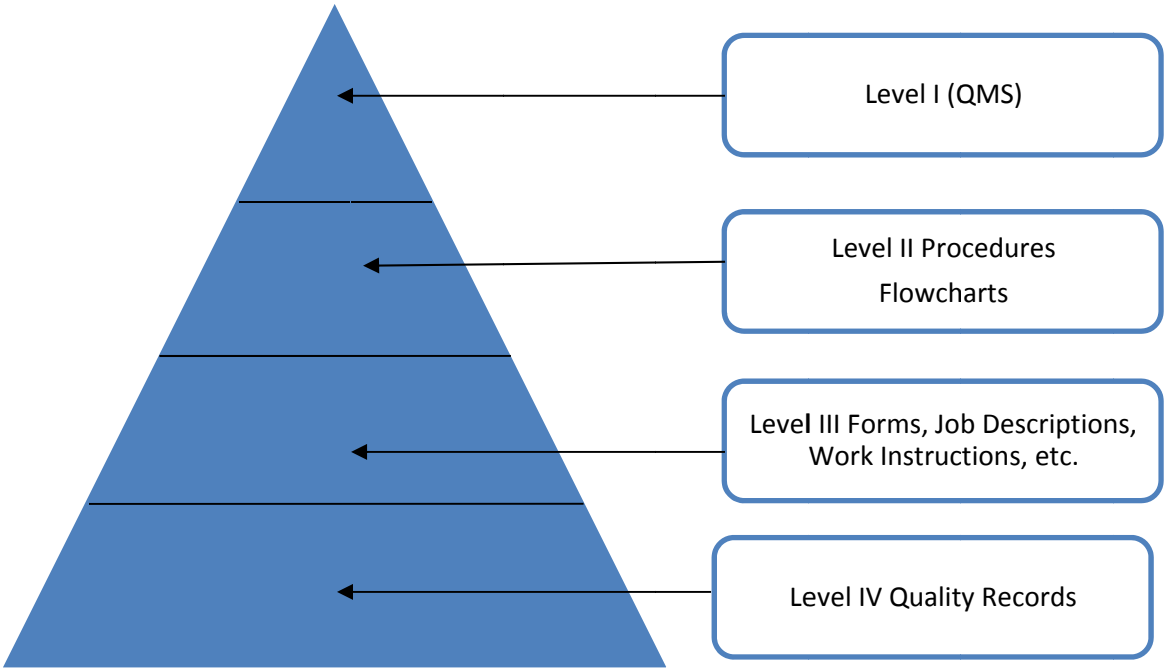

Figure 4: QMS Hierarchy

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 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

CDI shall establish, document, implement and maintain a Quality Management System and continually improve its effectiveness in accordance with the International Standard.
CDI Shall:

- Identify the processes needed for the Quality Management System and their application throughout the CDI organization.
- Determine the sequence and interaction of these processes.
- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- Monitor, measure where applicable, and analyze these processes, and
- Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by CDI in accordance with the requirements of the International Standard.

Where CDI chooses to outsource any process that affects product conformity to requirements, CDI shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be identified within the quality management system.

- Processes needed for the Quality Management System referred to above should include processes for management activities, provision for resources, product realization, measurement, analysis and improvement.
- An "outsourced process" is a process that the organization needs for its Quality Management System and which CDI chooses to have performed by an external party.
- Ensuring control over outsourced processes does not absolve CDI of the responsibility of conformity to all customer, statutory and regulatory requirements.
  The type and extent of control to be applied to outsourced process can be influenced by factors such as:
- The potential impact of the outsourced process on CDI's capability to provide product that conforms to requirements,
- The degree to which the process is shared,
- The capability of achieving the necessary control through the application of 7.4

4.2 Document Requirements

4.2.1 General

The Quality Management System shall include:

- Documented statements of a quality policy (see 4.2.1.1) and quality objectives (see 4.2.1.2)
- Quality Manual (This document QM-01-0001)
- Documented procedures and records required by the ISO 9001: 2008 International Standard and ATEX/IECEX (see 2.0), and

- Documents, including records, determined by CDI to be necessary to ensure effective planning, operation and control of its processes.

4.2.1.1 Quality Policy Statement

It is the mission of CDI to manufacture the best and most modern pipeline pig tracking, locating, and communications equipment for our global customer base. Quality, durability, and safety are the focus of every member of our friendly and responsive staff.

CDI's emphasis on quality is met in the following ways:

1. By providing customers with high quality pipeline pig tracking and communications solutions and services which meet customer requirements and are fit for purpose.
2. By operating the business and its systems as required by ISO 9001: 2008.
3. By enhancing the skills of management and staff through regular review and by pursuing an on-going training program, the objective of which is to prepare staff to perform their work more effectively and safely.
4. By promoting a culture of continual quality improvements and through the philosophy of getting things done on time and "right the first time".
5. By promoting the quality management systems and ensuring implementation is achieved by regular internal auditing, management review, corrective and preventive actions.

CDI's Quality Objectives are:

1. 98% On Time Delivery
2. 95% Customer Satisfaction
3. 93% Employee Retention

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Control Devices, Incorporated

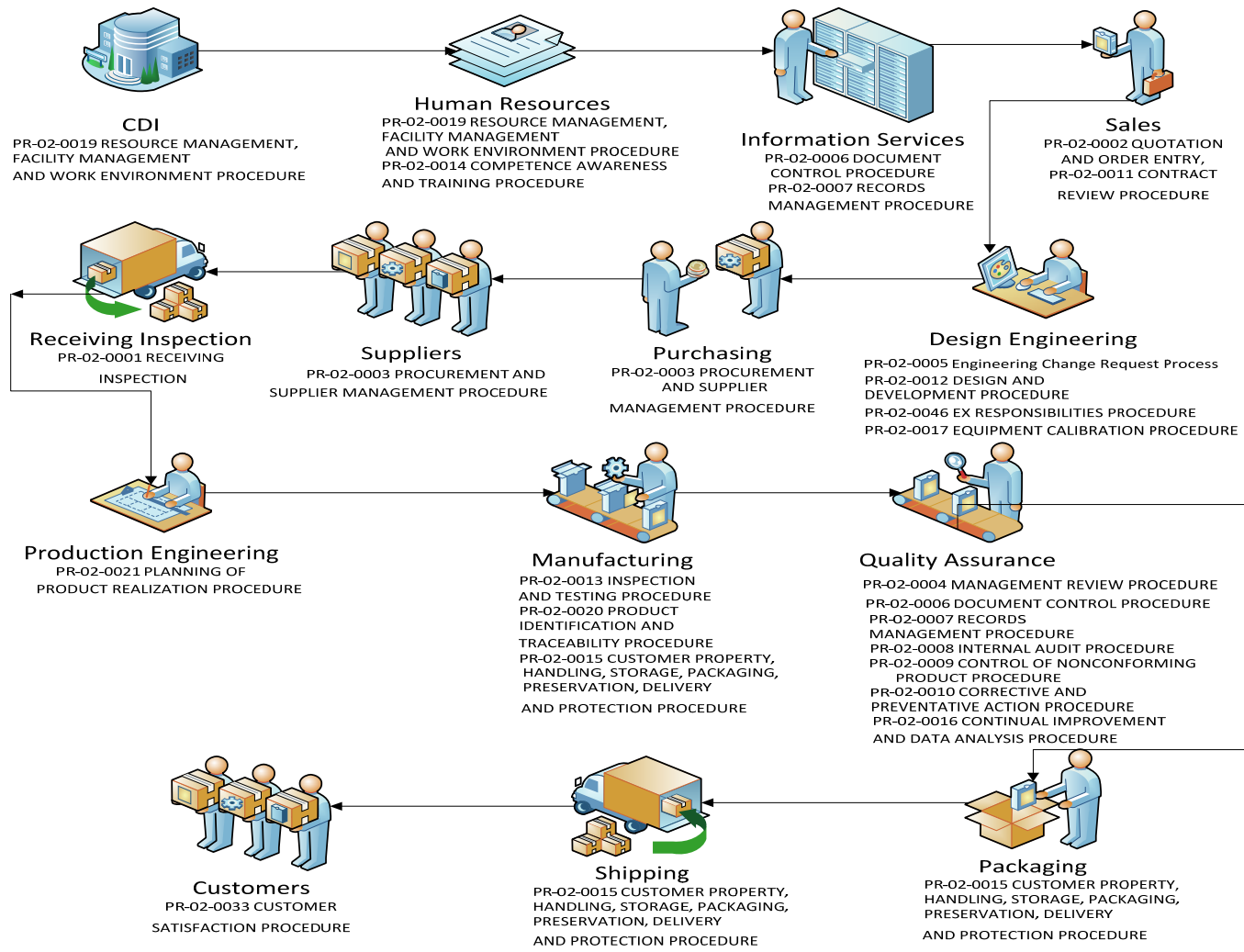
Quality objectives are derived from the Quality Policy. Quality objectives have been established to continually improve the Quality Management System (QMS) as a whole as well as each management process, extending to processes involved with meeting product requirements. Quality objectives are measurable, so that they can be analyzed during Management Review to determine the degree to which they are met.

4.2.1.2 Quality Manual

- CDI shall establish and maintain a Quality Manual including details and justification for any exclusion (QM-01-0001).
- References to procedures for the Quality Manual.

- Description of the interaction between processes.

Process Interaction Model



FC-02-0003 Rev. C

Figure 5: Process Interaction Model

4.2.3 Control of Documents

4.2.3.1 General

- CDI has developed all necessary documentation (a Quality Manual, quality policy, quality objectives, and operating procedures) to ensure the effective planning, operation, and control of its processes. Records are maintained as required by the Records Management Procedure (PR-02-0007).

- This Quality Manual contains a description of the scope of the Quality Management System. This manual references procedures that describe the sequence and interaction between the processes of the Quality Management System.

4.2.3.2 Equipment documents and manufacturer's documents shall be controlled by the Document Control Procedure (PR-02-0006) and Technical Publication/Documentation Work Instructions (WI-01-0001).

4.2.3.3 Documented procedures shall ensure that information contained within the manufacturer's documents is compatible with equipment documents. The manufacturer shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings.

4.2.3.4 The quality system shall ensure that no factor (type, characteristic, position etc.) defined within the ATEX/IECEX certificate and technical documentation (e.g. schedule drawings) is modified.

4.2.3.5 There is a documented system that refers all related drawings to the relevant schedule drawings. The drawing schedule is kept updated and is controlled by the engineering department.

4.2.3.6 Where there are common schedule drawings associated with more than one ATEX/IECEX certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings as described in Document Control Procedure (PR-02-0006).

4.2.3.7 CDI also has drawings for equipment not intended for use in potentially explosive atmospheres.

4.2.3.8 CDI documents contain responsibility for the quality system of each ATEX/IECEX certificate.

4.2.3.9 Where equipment documents or CDI's documents are passed to a Third party, they shall be provided in a way that is not misleading.

4.2.3.10 CDI management system and all important information sources are controlled by the Document and Data Control Procedure (PR-02-0006), which ensures that outdated or inaccurate information is not used and that appropriate information is available where it is needed. All documentation is reviewed and approved prior to use and changes to documentation are also reviewed, approved, and controlled. Such documents are maintained in such a manner as to ensure that they remain legible, readily identifiable and retrievable. Any such documents that become obsolete are disposed of or marked to prevent unintended use.

4.2.3.11 The Management Representative maintains a master file of all level one and level two documentation, as well as any forms. The most current version of any such document will be maintained in the master file, which will also indicate any further distribution of such documents. The Management Representative also maintains the electronic originals of such documentation as described in Document Control Procedure (PR-02-0006).

4.2.4 Control of Records

4.2.4.1 CDI maintains quality records in order to provide evidence of conformance to requirements as well as to provide evidence of the effective operation of the quality management system. Any records defined as quality records are controlled according to the Document Control Procedure (PR-02-0006), with use of Record Management Procedure (PR-02-0007). Such records are detailed on the Record Retention Log Form (FM-03-0061), which indicates the individual responsible for the records, storage locations, and periods of retention. Retention periods are specified to ensure that the records are being maintained to meet specific business, client, regulatory, and quality system requirements.

4.2.4.2 Examples of documents requiring control and retention are:

- Those arising from regulatory requirements
- Customer order
- Contract review
- Training records
- Inspection and test data
- Calibration data
- Sub-contractor or Supplier evaluation
- Delivery data (customer, delivery date and quantity, including serial numbers where available).

4.2.4.3 Quality Records are maintained and filed in a manner that ensures that they are readily available and protected from loss, damage, and deterioration as depicted in the Records Management Procedure (PR-02-0007).

Hard copy records are periodically reviewed and disposed of in accordance with internal and legal retention requirements. Records are only destroyed with the authorization of the Management Representative and the Vice-President of Engineering. Quality Records are retained in accordance with the Records Management Procedure (PR-02-0007).

4.2.4.4 Record Type Retention

- Part Specifications, Assembly Drawings, Bills of Materials, Standard Operation Procedures, and Corrective Action Reports 10 years past last production date.
- All Documents regulated by an external Certifying Body including all documentation for UL, CSA, ATEX/IECEX and ISO 9001:2008 approved products 10 Years past last production date.
- Routing sheets, Vendor qualification sheets, Calibration documents, Training records 10 years past last production date.
- Inspection Reports, Non-Conforming Materials Reports, Engineering Change Orders 10 years past last production date.

Where agreed contractually or by regulations, quality records relating to a specific supplier, customer, or product are made available for evaluation by the customer, customer representative, or regulatory agency.

5.0 Management Responsibility

5.1 Management Commitment

Top management shall provide evidence of its commitment to the development and implementation of the Quality Management System and continually improving its effectiveness by:

- Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- Establishing the Quality Policy (see 5.3)
- Ensuring the quality objectives are established (see 4.2.1.2),
- Conducting management reviews, Management Review System (PR-02-0004), and
- Ensuring the availability of resources (see 6.0)

5.2 Customer Focus

- Top Management shall ensure that the customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3 Quality Policy

Top management shall ensure that the quality policy:

- Is appropriate to the purpose of the CDI organization,

- Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- Provides a framework for establishing and reviewing quality objectives,
- Is communicated and understood within the CDI organization, and
- Is reviewed for continuing suitability.

5.4 Quality Management Planning

5.4.2 Quality Management System Planning

Top management shall:

- Ensure QMS planning is carried out in order to meet clause 4.1 requirements as well as quality objectives
- The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
- Top management shall insure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the CDI organization. The quality objectives shall be measureable and consistent with the quality policy.

Change Control shall require:

- careful planning of the nature and timeline for the changes;
- determining the impact or outcome of such changes;
- ensuring adequate resources are available to implement the change;
- top management authorization
- change deployment and follow-up
- review of the QMS by top management after changes are effected.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management shall ensure that the responsibilities and authorities are defined and communicated within the CDI organization.

- CDI Organization Flow Chart (FC-02-0001)
- ISO Authority Matrix (FM-03-0045)
- Job Descriptions (FM-03-0022)
- Ex Authorized Person

EX Responsibilities Procedure (PR-02-0046)

5.5.2 Management Representative

Top management shall appoint a member of CDI's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- Ensuring that processes needed for the Quality Management System are established, implemented and maintained,
- Reporting to top management on the performance of the Quality Management System and any need for improvement, and
- Ensuring the promotion of awareness of customer requirements throughout the CDI organization.

5.5.3 Internal Communication

Top management shall ensure that the appropriate communication processes are established within the CDI organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

Top management shall review the CDI Quality Management System, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives, Management Review (PR-02-0004).

Records from management reviews shall be maintained (see 4.2.4)

5.6.2 Review Input

- The input for management review shall include information on:
- Results of Audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- The review shall include the overall effectiveness of the quality management system with respect to equipment intended for use in explosive atmospheres.
- Follow-up actions from previous management reviews
- Changes that could affect the Quality Management System and its processes
- Recommendations for improvement

5.6.3 Review Output

The output from management review shall include decisions and actions related to:

- Improvement of the effectiveness of the Quality Management System and its processes
- Improvement of product related to customer requirements, and
- Resource needs
  Management Review (PR-02-0004)

6.0 Resource Management

6.1 Provision of resources

CDI shall determine and provide the resources needed:

- To implement and maintain the Quality Management System and continually improve its effectiveness, and,
- to enhance customer satisfaction by meeting customer requirements.

Resource Management, Facility Management and Work Environment Procedure (PR-02-0019)

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training

CDI shall:

- Determine the necessary competence for personnel performing work affecting conformity to product requirements, Training and Competency Procedure (PR-02-0014),
- Where applicable, provide training or take other actions to achieve necessary competence,
- Evaluate the effectiveness of the actions taken,
- The manufacturer shall ensure that all persons having an impact on Ex compliance receive appropriate training.
- Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- Maintain appropriate records of education, training, skills and experience (see 4.2.4)

6.3 Infrastructure

CDI shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable:

- Buildings, workspace and associated utilities
- Process equipment (both hardware and software) and
- Supporting services (such as transport, communications and/or information systems.

Resource Management, Facility Management and Work Environment Procedure (PR-02-0019)

6.4 Work Environment

CDI shall determine and manage a safe work environment needed to achieve conformity to product requirements.

Resource Management, Facility Management and Work Environment Procedure (PR-02-0019)

7.0 Product Realization

7.1 Planning of Product Realization

CDI shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the Quality Management System (see 4.1).

In planning product realization CDI shall determine the following, as appropriate:

- Quality objectives and requirements for the product,
- The need to establish processes and documents, and to provide resources specific to the product,
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance,
- Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

A document specifying the process of the Quality Management System and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.
Planning of Product Realization Procedure (PR-02-0021), Control Plan Instructions (WI-01-0004)

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product.

The CDI organization shall determine:

- Requirement specified by the customer, including requirements for delivery and post-delivery activities,
- Requirements not stated by the customer but necessary for the specified or intended use, where known,
- Statutory and regulatory requirements applicable to the product, and
- Any additional requirements determined by CDI.
  Contract Review Procedure (PR-02-0011)

7.2.2 Review of requirements related to the product.

CDI shall review the requirements related to the product.
This review shall be conducted prior to the CDI's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

- Product requirements are defined,
- Contract or order requirements differing from previously expressed are resolved,
- CDI has the ability to meet the refined requirements per Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005).

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by CDI before acceptance.

Where the product requirements are changed, CDI shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements per Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005).

CDI shall ensure that any stated customer requirement is compatible with the Ex certificate e.g. equipment group, temperature class, type of protection, EPL and ambient temperature range.
Contract Review Procedure (PR-02-0011) Absent Sales Representative – Critical Shipments (WI-01-0003)

7.2.3 Customer Communication

CDI shall determine and implement effective arrangements for communicating with customers in relation to:

- Product information,
- Enquiries, contracts or order handling, including amendments, and
- Customer feedback, including customer complaints

Quotation and Order Entry Procedure (PR-02-0002)
Contract Review Procedure (PR-02-0011)
Customer Satisfaction Procedure (PR-02-0033)
Absent Sales Representative – Critical Shipments (WI-01-0003)
Return Merchandise Authorization (WI-01-0006)

7.3 Design and Development

7.3.1 Design and Development Planning

CDI shall plan and control the design and development of product.
During design and development planning, CDI shall determine:

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

Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005)

CDI shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Input

Input relating to product requirements shall be determined and records maintained (see 4.2.4).
These inputs shall include:

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

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

Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005)

7.3.3 Design and Development Output

The output of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

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

Information for production and service provision can include details for the preservation of product.

Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005)

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1).

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

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and necessary actions shall be maintained (see 4.2.4).

Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005) Failure Modes and Effects Analysis (WI-01-0005)

7.3.5 Design and Development Verification

Verification shall be performed in accordance with the planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.

Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005)

7.3.6 Design and Development Validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where know. Wherever practical, validation shall be completed prior to delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4). Design and Development Procedure (PR-02-0012) and Engineering Change Request Process (PR-02-0005)

7.3.7 Control of Design and Development Changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effects of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).Design and Development Procedure (PR-02-0012), Engineering Change Request Process (PR-02-0005), CDI Drawing Guidelines (WI-01-0008)

7.4 Purchasing

7.4.1 Purchasing Process

CDI shall ensure that the purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on the subsequent product realization or final product, Procurement and Supplier Management Procedure (PR-02-0003).

CDI shall evaluate and select suppliers based on their ability to supply product in accordance with CDI's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

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) supplier providing calibration services (including verification on measuring devices by comparison with calibrated equipment) shall be evaluated on their ability to meet stated requirements, in addition to 7.6;

3) 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.

c) suppliers not used for a period exceeding one year shall be re-evaluated in accordance with 7.4.1 b) prior to the placing of a contract or a purchase order;

d) requirements b) and c) are not mandatory for products, processes or services where CDI verifies conformance in accordance with 7.4.3;

e) the ongoing ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year;

f) CDI shall facilitate an arrangement whereby the body responsible for the verification of the Ex quality system may also verify aspects of any supplier's operation that affects the type of protection.

7.4.2 Purchasing Information

Purchasing information shall describe the product to be purchased, including where appropriate, Procurement and Supplier Management Procedure (PR-02-0003):

- Requirements for qualification of personnel, and
- Quality Management System 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.

7.4.3 Verification of Purchased Product

CDI shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, Receiving Inspection Procedure (PR-02-0001).
Where CDI or its customer intends to perform verification at the supplier's premises, CDI will state the intended verification arrangements and method of product release in the purchasing information .

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, non metallic parts, resins and similar), a specific analysis certificate or declaration shall be supplied.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

CDI shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- The availability of information that describes the characteristics of the product,
- The availability of work instructions, as necessary,
- The use of suitable equipment,
- The availability and use of monitoring and measuring equipment,
- The implementation of monitoring and measurement, and
- The implementation of product release, delivery and post-delivery activities.

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.

7.5.2 Validation of Processes for Production and Service Provision

CDI shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use. Validation shall demonstrate the abilities of these processes to achieve planned results. CDI shall establish arrangements for these processes including, as applicable:

- Defined criteria for review and approval of the processes,
- Approval of equipment and qualification of personnel,
- Use of specific methods and procedures,
- Requirements for records (see 4.2.4), and
- Revalidation

Where a process can affect the integrity of a type of protection, and where the resulting integrity cannot be verified after manufacture (e.g. the environmental conditions required for curing an encapsulant), that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters.
Inspection and Testing Procedure (PR-02-0013)

7.5.3 Identification and Traceability

Where appropriate, CDI shall identify the product by suitable means throughout production realization, Product Identification and Traceability Procedure (PR-02-0020).

CDI shall identify the product status with respect to monitoring and measurement requirements throughout product realization.
Where traceability is a requirement, CDI shall control the unique identification of the product and maintain records (see 4.2.4).

CDI shall establish and maintain procedures for product identification during all stages of production, testing, final inspection and placing on the market; traceability is required with respect to the final product and its significant parts for Ex certification.
Traceability can be achieved using serial number, batch or other acceptable method.
(WI-01-0007) Positive Material Identification

7.5.4 Customer Property - RMA (Return Material Authorization)

CDI shall exercise care with customer property while it is under CDI's control or being used by CDI. CDI shall identify, verify, protect and safeguard customer property provided for use or incorporated into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, CDI shall report this to the customer and maintain records (see 4.2.4).

It is the responsibility of CDI to verify the compatibility of the customer supplied product with the requirements of the Ex certificate.
(PR-02-0015 Customer Property, Handling, Storage, Packaging, Preservation, Delivery and Protection Procedure)

7.5.5 Preservation of Product

CDI shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

CDI shall provide customers with instructions prepared in accordance with the relevant standards or statutory and regulatory requirements.
(PR-02-0015 Customer Property, Handling, Storage, Packaging, Preservation, Delivery and Protection Procedure)(WI-01-0002 Storage and Preservation of the CD-52 Bandit)

7.6 Control of Monitoring and Measuring Equipment

7.6.1 CDI shall determine the monitoring and measurement to be undertaken and the monitoring and measurement equipment needed to provide evidence of conformity of product to determine requirements, Equipment Calibration Procedure (PR-02-0017).

CDI shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measuring requirements, Inspection and Testing Procedure (PR-02-0013).
Where necessary to ensure valid results, measuring equipment shall:

- Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standard exists, the basis used for calibration or verification shall be recorded (see 4.2.4).
- Be adjusted or re-adjusted as necessary,
- Have identification in order to determine its calibration status,
- Be safeguarded from adjustments that would invalidate the measurement results,
- Be protected from damage and deterioration during handling, maintenance and storage.

In addition, CDI shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. CDI shall take appropriate action on the equipment and any product affected.
Records of the results of calibration and verification shall be maintained (see 4.2.4).

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

8.0 Measurement, Analysis and Improvement

8.1 General

CDI shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- To demonstrate conformity to product requirements,
- To ensure conformity of the Quality Management System, and
- To continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques and the extent of their use. Inspection and Testing Procedure (PR-02-0013)

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, CDI shall monitor information relating to customer perception as to whether CDI has met customer requirements. The methods for obtaining and using this information shall be determined. Customer Satisfaction Procedure (PR-02-0033)

8.2.2 Internal Audit

CDI shall conduct internal audits at planned intervals to determine whether the Quality Management System should be evaluated:

- Conforms to the arrangements (see 7.1), of the requirements of the International Standard and to the Quality Management System requirements established by CDI, and
- Is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the process and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. This selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

The audit program shall address the effectiveness of the elements of the quality system as described in this standard to ensure that the products are in conformity with the Ex certificate. The maximum period between audits should normally be 12 months and shall not exceed 14 months.
Internal Audit Procedure (PR-02-0008)

8.2.3 Monitoring and Measuring of Processes
CDI shall apply suitable methods for monitoring and. Where applicable, measurement of the Quality Management System processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken as appropriate. Inspection and Testing Procedure (PR-02-0013)

8.2.4 Monitoring and Measurement of Product
CDI shall monitor and measure the characteristics of the product to verify that the product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of the product for delivery to the customer (see 4.2.4). The release of the product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily complete, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Where routine tests are required by the Ex certificate and by the technical documentation, these tests shall be performed as specified. Unless specifically permitted by the Ex certificate and the technical documentation, statistical methods shall not be used.

Where practicable, the label bearing the marking data shall not be affixed until the final inspection and testing has been satisfactorily completed.
Inspection and Testing Procedure (PR-02-0013)

8.2.5 Calibration of Measuring and Production Equipment and Tooling
All equipment used in the production of products shall be properly calibrated and/or maintained. All production related equipment is maintained in the main quality system database. Each record includes:

- Tracking Number. This tracking number is also on the equipment.
- Equipment Description, type, Manufacturer and Model
- Location - Calibration requirements
- Calibration interval with justification for the interval
- Calibration Procedure (As applicable)
- Calibration History
- Calibration Due

The database shows all due and past-due calibration requirements. Each piece of equipment is due for calibration based on the lead-time defined for the instrument. Each piece of equipment should be serviced based on the service description. The records are maintained by the Engineering department. Any equipment that is past the calibration due date must be pulled from production and kept in a secure area until it is calibrated. Equipment Calibration Procedure (PR-02-0017)

8.3 Control of Nonconforming Product
CDI shall ensure that the product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, CDI shall deal with nonconforming product by one or more of the following ways:

- By taking action to eliminate the detected nonconformity,
- By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
- By taking action to preclude its original intended use or application,

- By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

a) CDI shall maintain a system such that in the event of the product not complying with the Ex certificate, and having been supplied, then the CDI's customer can be identified;

b) CDI shall take action, appropriate to the degree of risk, where a nonconforming product has been supplied to a customer;

c) where an unsafe nonconforming product has been supplied to a customer, CDI shall inform the customer, in writing as well as the body responsible for the verification of the quality system, and the issuer of the Ex certificate;

d) where it is not possible to trace the unsafe, nonconforming product (e.g. product supplied via a distributor, or for high volume products such as cable glands) then a notice shall be placed in appropriate publications providing recommended action to be taken;

e) for all nonconforming product that has been supplied to a customer, CDI shall maintain, for a minimum period of 10 years, records of:
- serial numbers or identification of products supplied;
- the customer who received the product;
- the action taken to inform customers and the body responsible for the verification of the quality system in the case of unsafe nonconforming product;
- the action taken to implement corrective and preventative action;

f) concessions for the product that take it outside the design, as defined in the Ex certificate and technical documentation, are not permitted.
Control of Nonconforming Product (PR-02-0009)

8.4 Analysis of Data

CDI shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement of the effectiveness of the Quality Management System can be made. This shall include data generated as a result of monitoring and measurement and from other relative sources. The analysis of data shall provide information relating to:

- Customer satisfaction (see 8.2.1)
- Conformity to product requirements (see 8.2.4),
- Characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- Suppliers (see 7.4).

Continual Improvement and Data Analysis Procedure (PR-02-0016)

8.5 Improvement

8.5.1 Continual Improvement

CDI shall continually improve the effectiveness of the Quality Management System through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review.
Continual Improvement and Data Analysis Procedure (PR-02-0016)

8.5.2 Corrective Action

CDI shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.
A documented procedure shall be established to define requirements for:

- Reviewing nonconformities.
- Determining the causes of nonconformities.
- Evaluating the need for action to ensure that nonconformities do not recur.
- Determining and implementing action needed
- Records of the results of actions taken (see 4.2.4), and
- Reviewing the effectiveness of the corrective action taken
  Control of Nonconforming Product (PR-02-0009)
  Corrective and Preventative Action Procedure (PR-02-0010)

8.5.3 Preventive Action

CDI shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of potential problems.

A documented procedure shall be established to define requirements for:

- Determining potential nonconformities and their causes,
- Evaluating the need for action to prevent occurrence of nonconformities.
- Determining and implementing action needed.
- Records of results of actions taken (see 4.2.4),
- Reviewing the effectiveness of preventive action take
  Control of Nonconforming Product (PR-02-0009)
  Corrective and Preventive Action Procedure (PR-020010)

9.0 REVISION HISTORY

Revision/Date	Description of Change	9.0
Revision A / 6.03.2014	Initial Release	
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-01-0001 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.	