

<i>CiDRA® Precision Services, LLC</i>	<b>Quality System Manual</b>	
		Rev. A
		Page 1 of 30

# **Quality System Manual**

## **CiDRA® Precision Services, LLC**

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**Revision A**

**January 2, 2008**

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>	
	<b>Section</b>	Table
	<b>Section Name</b>	Table of Contents
		Rev. A
		Page 2 of 30

Section	Section Title	Page No.
<b>Table</b>	<b>Table of Contents</b>	2
<b>1</b>	<b>Purpose</b>	3
<b>2</b>	<b>Scope</b>	4
<b>3</b>	<b>Logistics</b>	5
3.1	Approval Page	5
3.2	Manual Control	6
3.3	Distribution	6
<b>4</b>	<b>Quality Management System</b>	
4.1	General Requirements	7
4.2	Documentation Requirements	7
<b>5</b>	<b>Management Responsibility</b>	
5.1	Management Commitment	9
5.2	Customer Focus	9
5.3	Quality Policy	9
5.4	Planning	10
5.5	Responsibility, Authority and Communication	10
5.6	Management Review	15
<b>6</b>	<b>Resource Management</b>	
6.1	Provision of Resources	16
6.2	Human Resources	16
6.3	Infrastructure	16
6.4	Work Environment	17
<b>7</b>	<b>Product Realization</b>	
7.1	Planning of Product Realization	18
7.2	Customer Related Processes	18
7.3	Design and Development	19
7.4	Purchasing	20
7.5	Production and Service Provision	21
7.6	Control of Monitoring and Measuring Devices	23
<b>8</b>	<b>Measurement, Analysis and Improvement</b>	
8.1	General	25
8.2	Monitoring and Measurement	25
8.3	Control of Nonconforming Product	27
8.4	Analysis of Data	27
8.5	Improvement	28
App	Appendix A	
Revision	Revision History	

<i>CiDRA® Precision Services, LLC</i>	<b>Quality System Manual</b>	
	<b>Section</b>	1
	<b>Section Name</b>	Purpose
		Rev. Z
		Page 3 of 30

## **Purpose**

CiDRA® Precision Services, LLC developed and implemented a quality management system to better satisfy the needs of its customers and to improve management of the company. The quality system complies with the international standard ISO 9001:2000 and its technical equivalent, ANSI/ISO ASQ Q9001-2000. It covers the design, production, installation, and servicing of the company's products.

This manual is divided into 8 sections corresponding to quality system requirements of the ISO 9001 standard. Each section starts with a general policy statement expressing the commitment to the basic principles of the quality system element that is the subject of the section.

The purpose of this manual is to define and describe the quality system, and to define the authorities and responsibilities of the management personnel affected by the system.

Another purpose of this manual is to present our quality system to our customers and to inform them of the specific controls implemented to assure product quality.

<b><i>CiDRA® Precision Services, LLC</i></b>	<b>Quality System Manual</b>	
	<b>Section</b>	2
	<b>Section Name</b>	Scope
		Rev. Z
		Page 4 of 30

## **Scope**

ISO certification is applicable to CiDRA® Precision Services, LLC located at 50 Barnes Park North, Wallingford, Connecticut.

ISO 9001 certification applies to all products designed, manufactured, sold, and supported by CiDRA® Precision Services, LLC in Connecticut.


Exclusions: Due to customer design requirements, the CiDRA Precision Services (CPS) manufacture to print products will be excluded from section 7.3, Design and Development, of the Quality Management System.


## **Scope of Activity for Certificate**


CiDRA Precision Services, LLC produces high precision components and assemblies from difficult to machine materials.

CiDRA® Precision Services, LLC	<b>Quality System Manual</b>		
	Section	3	Rev. Z
	Section Name	Logistics	Page 5 of 30

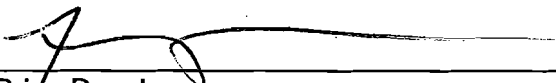
**3.1 Approvals:**


  
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 Marty Putnam  
 Vice President, Engineering

  
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 Brian Donahue  
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~~Bev Dwyer~~ Catherine Granucci  
 Manager, Business Administration Manager

  
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 Scott Utley  
 Production Supervisor

All signatures are kept on file.

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<b><i>CiDRA® Precision Services, LLC</i></b>	<b>Quality System Manual</b>	
	<b>Section</b>	3
	<b>Section Name</b>	Logistics
		Rev. Z
		Page 6 of 30

### 3.2 Manual Control

Manual Control Number

If a control number has been assigned to this document, this manual is a Controlled Copy. The holder of a Controlled Copy is responsible for maintaining the manual by inserting authorized changes.

The ISO Management Representative will distribute changes to all Controlled Copies. Changes may, or may not, be distributed to uncontrolled copies.

### 3.3 DISTRIBUTION

A read-only copy of this manual is available via the CiDRA® Precision Services, LLC intranet.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section</b>	4	Rev. A
	<b>Section Name</b>	Quality Management System	Page 7 of 30

## **4.1 General Policy and Requirements**

A Quality Management System is established, documented and maintained to ensure that products and services (subcontracted) conform to specified requirements. This quality system also measures and analyzes processes with the intention for continual improvements.

## **4.2 Documentation Requirements**

### **4.2.1 General Policy**

The purpose and scope of all quality system documents are defined. All quality documents are subject to review and approval prior to issue. The Quality Manual is issued and maintained by the Quality Manager and the Management Representative. Operational procedures are issued and maintained by the department in which they pertain. Product specifications, drawings and bills of material are issued and maintained by Engineering. The Engineering Manager coordinates document control-related activity. Obsolete documents are removed from active files. Documented quality system procedures and instructions are prepared to meet the requirements of ISO 9001 and CiDRA® Precision Services, LLC's stated Quality Policy. The documented quality system consists of the Quality Manual, operational procedures, product specifications, drawings, work instructions, and external documents. The quality system is then effectively implemented. Reference Procedures EP-05-01 through EP-05-03.

### **4.2.2 Quality Manual**

CiDRA's Quality Manual is the top-level document that contains the scope of the quality management system, including references to all pertinent documentation that supports each section. Some of those supporting documents are:

- Operational Procedures (Level II)
- Work Instructions (Level III)
- Product Drawings and Specifications
- Standards and Other Reference Materials
- Shop Routings

### **4.2.3 Control of Documents**

The purpose, scope and responsibility for controlling various types of documents are defined in Procedure EP-05-01, EP-05-03, EP-05-09 and EP-05-10. The document requirement may be initiated by anyone within the organization, but may only be issued by the responsible department. The responsible departments and the rules governing issue of documents are defined in Procedures EP-05-01,

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section</b>	4	Rev. A
	<b>Section Name</b>	Quality Management System	Page 8 of 30

Quality System Documentation, and EP-05-02, Document Control. Specific approval and issue procedures are defined within various element sections under heading of New Document Creation and Issue. Upon release, notice will be distributed to the appropriate individuals.

Document revision requests are reviewed by the cognizant department manager, delegated individual, and/or cross-functional team prior to revision of document. Once approved, the document is revised and a brief revision notice is issued to the appropriate individuals. Description of key differences is noted in the Revision History. Specific approval procedures are defined within various element sections under heading of Document Revisions. Obsolete quality documents are removed from circulation and use.

#### **4.2.4 Control of Records**

Quality records provide evidence that product designs meet their design input requirements, that finished products conform to the design output requirements, and that the quality system is operated in accordance with documented procedures. Quality record procedures are established and maintained by the originating department for creating, storing and disposing of quality records.

Quality records are created by personnel who are involved with a task, operation or activity whose results need to be recorded. Quality records identify the product, person or event to which they pertain, provide pertinent facts and data, and indicate originator and creation date of the record. The originating department establishes the format of quality records.

Quality records are indexed and grouped in such a way that they are readily retrievable. They can be stored in either hard copy or electronic format, depending upon the requirements of the responsible department. The locations and retention periods of all quality records are defined in Procedure QP-16-01, Control of Quality Records.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	5	Rev. A
	<b>Section Name:</b>	Management Responsibility	Page 9 of 30

## **5.1 Management Commitment**

In addition to meeting and/or exceeding our margin and cash plans by achieving quarter-over-quarter revenue and gross margin growth in all of our business segments and continually focusing on reducing costs and maximizing returns, the executive management of CiDRA® Precision Services, LLC is ultimately responsible for establishing, implementing, and maintaining the company's quality system. Specific responsibilities consist of formulating the quality policy, defining the organizational structure, assigning authorities and responsibilities, appointing the management representative, periodically reviewing the ISO 9001 quality system, and making available the resources and personnel necessary to maintain the system.

## **5.2 Customer Focus**

All contracts/orders are reviewed to assess if the customer's requirements are adequately defined and are understood, and if the company has the capacity to meet the contract requirements and achieve customer satisfaction.

The Client Services & Support Department is responsible for reviewing and processing all customer orders as outlines in procedure BP-03-01. The contract review verifies that the customer's requirements are defined and documented and that the company has the capacity to meet the contract requirements. Purchase orders are also reviewed and approved by representatives from Finance, Production Planning/Materials, Sales and Project Management. Any change orders are received and reviewed by the same functions that are responsible for the initial review of orders. Changes are communicated to all functions within the company that may be affected by the change of customer requirements.

## **5.3 Quality Policy**

CiDRA is committed to providing product quality and reliability in some of the most demanding and challenging industries and market applications. We are dedicated to continuous improvement, enhancing our leadership position in our chosen markets and to exceed our stakeholders' requirements in terms of quality, value and services.

<i>CiDRA® Precision Services, LLC</i>	<b>Quality System Manual</b>		
	<b>Section:</b>	5	Rev. A
	<b>Section Name:</b>	Management Responsibility	Page 10 of 30

## 5.4 Planning

### 5.4.1 Quality Objectives

CiDRA® Precision Services, LLC's management will establish a company wide objectives program, leading to continuing improvement and performance. These objectives will be capable of being measured, with the goal of further enhancing CiDRA's overall business performance.

**Customer Satisfaction** – This will be monitored by a variety of means including, but not limited to, repeat customer metrics, customer returns, customer complaints, and on-time delivery metrics.

**Safety and Environment** – This program is constantly monitored to OSHA requirements and other regulatory agencies. The safety program is tracked using the OSHA Incident Rating system.

### 5.4.2 Quality Management System Planning

Quality planning is performed by the Executive Staff, department managers, or designees to fully meet specified requirements. Procedures and instructions for quality are kept current to conform to specified requirements. The Executive Staff, department managers, or designee gives consideration to activities as appropriate to meet the specified requirements for products, projects, or contracts. A flow chart describing the quality plan can be found in Appendix A of this manual. This flow chart is used to help monitor quality at each step in the process by relating the function to the procedures that establish the quality system.

## 5.5 Responsibility, Authority and Communication

Interrelation of CiDRA personnel who manage, perform, and verify work affecting quality is defined in the organization chart. Organization charts are kept on file and available upon request. The responsibilities and authorities for personnel who manage, perform, or verify work affecting quality, are described throughout the level two and three procedures of the quality system manual.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	5	Rev. A
	<b>Section Name:</b>	Management Responsibility	Page 11 of 30

### 5.5.1 Responsibility and Authority

#### **President**

- Formulates the quality policy.
- Provides the resources necessary to maintain the system.
- Conducts management reviews of the quality system.

#### **Engineering and Research & Development**

- Prepares product specifications from product briefs or customer-specified requirements.
- Design products.
- Initiates design reviews.
- Verifies and tests designs.
- Documents design outputs.
- Formulates preventive maintenance schedules and instruction.
- Collects and analyzes field performance and reliability data.
- Controls documentation and coordinates document control activities.

#### **Operations**

- Determines production personnel and equipment requirements.
- Administers continuous improvement programs.
- Controls and monitors processes.
- Defines workmanship standards.
- Maintains production equipment.
- Prepares quality plans.
- Plans and administers training requirements and programs.
- Maintains training records relative to the quality management system.
- Establishes and maintains the quality management system.
- Indicates requests for, and follows up on, corrective actions.
- Maintains and calibrates measuring and test equipment.
- Carries out quality surveys and audits.
- Performs inspections and testing in accordance with the quality plans.
- Handles non-conforming products.
- Maintains inspection records.
- Selects qualified suppliers and subcontractors.
- Prepares and approves purchasing documents.
- Verifies quality and quantity of received goods.
- Administers and assesses supplier performance.
- Provides resources to Engineering to ensure product is designed for manufacturability.
- Assists Engineering in providing tooling, fixtures, and process standards to Production.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	5	Rev. A
	<b>Section Name:</b>	Management Responsibility	Page 12 of 30

- Assists Engineering with the development of test specifications.
- Assists in the collection of product performance and reliability data and works with related departments for continued process and product improvement.
- Assists in carrying out supplier quality surveys and audits.

#### **Accounting and Law**

- Participation in the sales contract reviews.

#### **Sales & Marketing, Business Development**

- Conducts market research and analysis to establish the desired quality characteristics of products.
- Establishes functional specifications of products and associated services.
- Advertises and promotes company and products emphasizing their quality aspects.
- Monitors the quality of competitors.
- Provides pre-sales customer liaison and service.

#### **Client Services & Support Processes Servicing Orders**

- Performs servicing and applications support.
- Designs, coordinates, and implements training programs.
- Participates in design reviews.
- Provides resources to Engineering to ensure product is designed for serviceability.
- Provides post-sales customer liaison and service.
- Collects field performance and reliability data.
- Initiates requests for, and follows up on, corrective actions.
- Handles customer complaints.
- Controls returned material and customer supplied material.

#### **Human Resources**

- Assists department heads with respect to personnel qualification requirements.
- Recommends and helps implement measures to motivate personnel.
- Assists department heads in the development and coordination of training programs as necessary.

#### **Product Realization**

- Defines project scope and goals.
- Formulates project milestones.
- Formulates budget requirement.
- Tracks project schedule.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	5	Rev. A
	<b>Section Name:</b>	Management Responsibility	Page 13 of 30

- Tracks budget.
- Identifies areas of risk.
- Formulates risk mitigation paths.
- Reports project status to management.
- Tracks project phases through design reviews.

### 5.5.2 Management Representative

CiDRA® Precision Services, LLC has a dedicated Management Representative. This individual has the authority to create, implement and maintain the quality management system. This individual also ensures that the quality system is continuously improved, and promotes awareness of customer requirements throughout the organization.

### 5.5.3 Internal Communication

Each division head reports directly to the President, who is responsible for all aspects of CiDRA® Precision Services, LLC's operations, strategic management, and business policy formulation. Together they constitute the executive management.

CiDRA® Precision Services, LLC's quality organization comprises eight primary divisions:

- Engineering and Research & Development, headed by the Vice President of Engineering, is responsible for product technology and assessing and integrating strategic technological advancements. Responsibilities also include interaction with Sales & Marketing and customers to assess market needs and requirements for product enhancements and new product opportunities.
- Operations, headed by the Vice President of Operations, is responsible for all manufacturing, procurement, quality, safety and related strategic programs and activities. Coordinates activities with Sales & Marketing relative to order and forecast inputs. Interacts with Engineering regarding concurrent engineering and design for manufacturing activities. Develops, executes and coordinates training programs and activities in manufacturing operations. As Management Representative, the Vice President of Operations has responsibility for the quality management system as defined in Section 5.5.2 of this manual.
- Sales and Marketing, headed by the President, is responsible for all worldwide sales and marketing activities and strategies, as well as the

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>	
	<b>Section:</b>	5
	<b>Section Name:</b>	Management Responsibility
		Rev. A
		Page 14 of 30

management of distribution channels. Coordinates activities with Operations relative to forecast input. Coordinates activities with Engineering with respect to defining customer needs, requirements, and new product opportunities. Directs Client Services & Support regarding training, installation and post installation activities and feedback from customers.

- Accounting and Finance, headed by the Office Manager is responsible for all finance and accounting. Coordinates with various division heads, budgets, and business planning activities. Analyzes and makes recommendations relative to the financial opportunity and risk of strategic business opportunities.
- Field Support, headed by the Vice President of Engineering is responsible for worldwide customer support activities, including: installation, training, communications, and technical support. Directs and coordinates strategic programs relating to the above responsibilities. Coordinates activities with engineering regarding new product development, and manufacturing regarding customer feedback.
- The Intellectual Property Department, headed by the President, is responsible for all matters related to patents, trademarks and copyrights, and all other Intellectual Property matters affecting the corporation.
- Human Resources, headed by the President, is responsible for all programs relating to human resource management. Coordinates with division and department heads to identify staffing needs and requirements. Administers programs relating to employee benefits and ensures compliance with federal, state, and local regulations as required.
- Product Realization, headed by the Vice President of Engineering, is responsible for the product development process. Responsibilities include interaction with CiDRA® Precision Services, LLC Sales & Marketing, Business Development and customers to help assess and translate needs and requirements into product features and specifications. Defines project scope and goals and formulates project milestones including all required test plans. Performs design reviews and maintains all appropriate records and minutes. Reports project status to management and coordinates activities with Sales & Marketing, Business Development, Operations and Client Services & Support on design for manufacture issues.

<b><i>CiDRA® Precision Services, LLC</i></b>	<b>Quality System Manual</b>	
	<b>Section:</b>	5
	<b>Section Name:</b>	Management Responsibility
		Rev. A
		Page 15 of 30

## **5.6 Management Review**

CiDRA's management reviews of the quality system are conducted at least once a year. The purpose of these reviews is to assess the effectiveness and continuing suitability of the quality system. The President is responsible for scheduling and conducting the reviews. Conclusions of the reviews are recorded. Details regarding the review inputs and review outputs, rules for scheduling, conducting, and recording the reviews are provided in Procedure QP-01-01, Management Review.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	6	Rev. Z
	<b>Section Name:</b>	Resource Management	Page 16 of 30

## 6.1 Provision of Resources

In order to achieve the company objectives, we will ensure that the essential resources are available. These resources will include the necessary personnel, equipment, facilities, and information for continuous improvement and to satisfy customer needs.

## 6.2 Human Resources

### 6.2.1 General

The company identifies the training needs of personnel and provides the required training. Personnel assigned to perform specific tasks are qualified on the basis of appropriate education, training, or experience. Records of personnel qualifications and training are maintained as described in procedure QP-18-01.

### 6.2.2 Competence, Awareness and Training

All employees will be assessed periodically to determine if their qualifications are adequate for their current responsibilities or if additional training is required.

Occurrences of product nonconformities and problems with operations and processes also provide data for determining employee training needs.

CiDRA® Precision Services, LLC provides employee orientation training to all new employees. This training includes an overview of the quality system.

Training in skills and knowledge required to perform specific tasks is provided directly to employees by their departments.

The Quality Programs Department maintains records of all internal and external training provided to employees.

## 6.3 Infrastructure

CiDRA® Precision Services, LLC shall identify, plan and implement the production, installation and servicing processes that affect quality and will ensure that these processes are carried out under controlled conditions. Reference procedures MP-09-01 and MP-09-04. Controlled conditions shall include the following:

- An appropriate working environment, as well as proper tools.
- Monitoring and inspection of process parameters and product specifications during production, where appropriate.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>	
	<b>Section:</b>	6 Rev. Z
	<b>Section Name:</b>	Resource Management Page 17 of 30

- Current assembly drawings, assembly instructions, visual aids, as well as any inspection and acceptance criteria required to produce a quality product.
- Equipment that is maintained as required ensuring continuing process capability and reliability.

#### **6.4 Work Environment**

The company will maintain a work environment that has a positive influence on personnel. The work environment, which includes issues such as: safety, ergonomics, housekeeping, and air quality are all factors that contribute to enhancing performance within the company.

#### **Corporate Environmental Health & Safety Policy**

- The personal safety and health of each employee of CiDRA® Precision Services, LLC is of primary importance. The policy of this company will be to maintain a safe and healthy work environment at all times, and to comply with Occupational Safety and Health Administration (OSHA) regulations and state and local safety requirements. The prevention of occupationally induced injuries and illnesses will be treated as a priority by management and employees and will be given precedence in all operational matters. The company will not knowingly allow unsafe conditions to exist, or permit employees to participate in unsafe activities. The following philosophy statements support this policy:
- All injuries and accidents are preventable through the establishment of and compliance with safe work procedures.
- The prevention of bodily injury and safeguarding of health are the first consideration in all workplace actions and are the responsibility of every employee at every level.
- Written safety plans describing the safe work practices and procedures to be practiced in all workplace actions are an essential element of the overall workplace safety program.
- All employees at every level are responsible for knowing and following the safety practices described in the written safety plans.

<b>CiDRA® Precision Services, LLC</b>	<h1>Quality System Manual</h1>		
	<b>Section:</b>	7	Rev. A
	<b>Section Name:</b>	Product Realization	Page 18 of 30

## 7.1 Planning for Product Realization

CiDRA® Precision Services, LLC establishes and maintains procedures to control product design to ensure that specified requirements are met. The Product Realization Process encompasses six phases with distinct activities and deliverables that will promote successful program execution. The governing body for review of the deliverables and milestones is the Project Steering Team (PST). The sections below describe the major phases of the product realization phases and procedure EP-04-02 provides the details of the product realization process. NOTE: Not all the requirements listed in Section 7 - Product Realization will apply to all of our products. ***Catalog and customer designs (e.g. manufacture to print) will not require completion of the entire Product Realization Process, only a portion of this process may be necessary, i.e. Section 7.2.2. At present, CiDRA® Precision Services, LLC only productions customer designs.***

## 7.2 Customer Related Processes

### 7.2.1 Determination of Requirements Related to the Product

CiDRA® Precision Services, LLC will determine if all of the customer requirements have been specified, including statutory and regulatory requirements related to the product, along with delivery and post-delivery activities.

### 7.2.2 Review of Requirements Related to the Product

The technology realization phase consists of identifying technologies that offer viable production solutions, demonstrating bench top functionality, and developing first prototypes that facilitate customer feedback to further product definition. Technology realization can include devising or acquiring new technologies, leveraging technology platforms already existing within CiDRA, or appropriate combinations thereof. The technology realization phase also includes building the foundation for strong customer relationships, as well as developing a more detailed business opportunity case.

### 7.2.3 Customer Communication

The Client Services & Support is responsible for communicating, reviewing and processing all customer orders as outlined in procedure BP-03-01. The contract review verifies that the customer's requirements are defined and documented and that the company has the capacity to meet the contract requirements. Purchase orders are also reviewed and approved by representatives from Finance, Production Planning/Materials, Sales and Project Management.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	7	Rev. A
	<b>Section Name:</b>	Product Realization	Page 19 of 30

### **7.3 Design and Development**

#### **7.3.1 Design and Development Planning**

Once the PST has approved a project for a product realization activity, a core team is assigned and the Product Concept & Planning Phase is entered. The goal of this phase is to generate a plan for the product realization effort, which is detailed enough to allow review and approval of the project before the commitment of resources to staff the full project team. The PST reviews this plan and, if approved, resources and funding allocated for the project. Upon approval of the Product Concept Plan, the project would enter the Alpha Development Phase.

#### **7.3.2 Design and Development Inputs**

The purpose of the technology realization-planning phase is to establishing the initial inputs for product definition by working with the CiDRA® Precision Services, LLC marketing department and customers. This initial definition will include refining target optical, electrical, and mechanical specifications, as well as price targets. The planning phase includes technical brainstorming to establish potential technology solutions, developing the accompanying risk analyses, and establishing a detailed schedule.

#### **7.3.3 Design and Development Outputs**

The output information will comprise: acceptance criteria, process specifications, material specifications, test information, qualification testing etc. This information will enable the company to verify and validate to the planned requirements. Review of these outputs against inputs provide the evidence that the product and process have met the documented requirements.

#### **7.3.4 Design and Development Review**

This phase is primarily associated with Capability vs. Plan review activity. These include a review of product requirements as designed, and, first pass yield, quality, and safety issues. Documents all actions proposing change from initial design.

#### **7.3.5 Design and Development Verification**

The purpose of this phase is to characterize the performance of the product based on the design input. This verification, is used to finalize of all specifications. All changes will be documented in accordance with CiDRA® Precision Services, LLC's QMS requirements.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>	
	<b>Section:</b>	7
	<b>Section Name:</b>	Product Realization
		Rev. A
		Page 20 of 30

### 7.3.6 Design and Development Validation

The development phase transitions the prototype to a production-intent design. Some examples of the validation are; product qualification, production line qualification, process capability studies, manufacturing documentation, operator training, supplier qualification, first article inspections, final packaging, and a pilot production run. Once these units have successfully passed qualification testing, the design and manufacturing processes are approved for production.

### 7.3.7 Control of Design and Development Changes

Document and Design revision requests are reviewed by the cognizant manager, delegated individual and/or cross-functional team prior to revision of a document. Once approved, the document is revised and a brief revision notice is issued to the appropriate individuals. Procedure EP-05-01 is utilized for the change process. Description of key differences is noted in the Revision History. Specific approval procedures are defined within various element sections under heading of Document Revisions. Obsolete quality documents are removed from circulation and use.

## 7.4 PURCHASING

### 7.4.1 Purchasing Process

CiDRA® Precision Services, LLC assesses its production suppliers and only purchases from those that can satisfy the company's requirements. Quality performance of suppliers is continuously monitored. It is our goal, through continuous monitoring and improvement, to achieve dependable "dock to stock" shipments from our suppliers. Purchasing documents clearly and completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release.

Quality capabilities and references of suppliers are assessed before orders for supply of materials, components, or services are placed. Quality performance of all suppliers is continuously monitored. Suppliers showing inadequate performance are asked to implement corrective action, and are discontinued if there is no improvement. The system for assessing and monitoring Suppliers is defined in Procedure PP-06-02.

Customer-supplied materials and equipment are handled in the same manner as other parts and equipment purchased for incorporation into CiDRA® Precision Services, LLC products. This handling encompasses acceptance, receiving, labeling, handling, storage, maintenance and shipping. Loss, damage, or unsuitability of a customer's materials is recorded and reported to the customer.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>	
	<b>Section:</b>	7
	<b>Section Name:</b>	Product Realization
		Rev. A
		Page 21 of 30

## 7.4.2 Purchasing Information

The Purchasing Department prepares purchasing documents. The documents clearly and completely describe ordered products, reference applicable standards, and state quality requirements. Rules applicable to the preparation, review and approval of purchasing documents are provided in Procedure PP-06-01.

## 7.4.3 Verification of Purchased Product

Purchased products with specified requirements will be inspected or verified in accordance with the quality plan or documented procedures. Non-conforming products are segregated and prevented from use in production. Procedure QP-10-01, Receiving Inspection, sets forward detailed rules for performing and recording receiving inspections. Our customers have the right to verify for themselves that the purchased products conform to specified requirements. Customer verification does not absolve us from responsibility to deliver a quality product. Customer-supplied parts, materials and equipment are received, inspected, and tested in the same manner as other purchased materials. Procedure BP-07-01, Customer-Supplied Materials, contains further instructions in this regard.

## 7.5 Production and Service Provisions

### 7.5.1 Control of Production and Service Provisions

The Manufacturing Department shall identify, plan and implement the production, installation and servicing processes that affect quality and will ensure that these processes are carried out under controlled conditions. Reference procedures MP-09-01 and MP-09-04. Controlled conditions shall include the following:

- Documented procedures defining the manner of production, installation, and servicing, where the absence of such procedures could adversely affect quality.
- An appropriate working environment, as well as proper tools.
- Monitoring and inspection of process parameters and product specifications during production, where appropriate.
- Current assembly drawings, assembly instructions, visual aids, as well as any inspection and acceptance criteria required to produce a quality product.
- Equipment that is maintained as required to ensure continuing process capability and reliability.

<b>CiDRA® Precision Services, LLC</b>	<h1>Quality System Manual</h1>		
	<b>Section:</b>	7	Rev. A
	<b>Section Name:</b>	Product Realization	Page 22 of 30

**7.5.2 Validation of Processes for Production and Service Provisions**

Production personnel normally perform inspection and testing of product, during the manufacturing process. Procedure QP-10-02, In-Process Inspection, will regulate all inspection activities. Final inspection and testing are performed in accordance with documented procedure QP-10-03. This procedure verifies that all preceding inspections and steps have been successfully completed and all data and documentation required to ship product is complete.

Final inspection and testing are performed in accordance with documented procedure QP-10-03. This procedure verifies that all preceding inspections and steps have been successfully completed and all data and documentation required to ship product is complete. In the event of any process nonconformances, reinspection/revalidation will be performed.

Some processes cannot be verified by inspection and/or testing. These will be referred to as “*special processes*.” Qualified personnel will perform these processes, and process parameters will be continuously monitored to ensure that specified requirements are met. Records shall be maintained for qualification of personnel, equipment and processes.

**7.5.3 Identification and Traceability**

CiDRA® Precision Services, LLC has established and maintained documented product identification procedures from receipt of goods to installation of finished product. If special requirements for traceability are received by Contracts, CiDRA® Precision Services, LLC will adhere to these requirements. Identification and traceability of appropriate material is the responsibility of the Engineering and Planning Departments respectively. Procedure MP-08-01 details the labeling of incoming material, as well as the serialization of finished goods. The Manufacturing Department maintains serialization records.

**7.5.4 Customer Property**

Customer-supplied materials and equipment are handled in the same manner as other parts and equipment purchased for incorporation into CiDRA® Precision Services, LLC products. This handling encompasses acceptance, receiving, labeling, handling, storage, maintenance and shipping. Loss, damage, or unsuitability of a customer’s materials is recorded and reported to the customer. The Client Services Department is responsible for coordinating with the customer for the receipt of customer-supplied parts, materials and equipment. Customers are contacted in the event of loss, damage, deterioration, or unsuitability of their

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>	
	<b>Section:</b>	7
	<b>Section Name:</b>	Product Realization
		Rev. A
		Page 23 of 30

materials. Verification by CiDRA® Precision Services, LLC does not absolve the customer of the responsibility to provide acceptable materials.

### **7.5.5 Preservation of Product**

Procedures are established and maintained for handling and preservation of components and products to prevent damage. Storage areas are controlled. Packaging is specified and controlled.

The Manufacturing Management is responsible for product handling and preservation during production, storage, and delivery. Where contractually specified, this shall be extended to include delivery to destination. Reference Procedure PP-15-03.

The stockroom and its operation are the responsibility of the Manager of Procurement. Only products that have proper documentation are authorized to enter and leave the stockroom. Reference Procedure PP-15-02.

Packaging is specified by Manufacturing Engineering, freight consultants, or by customer specifications for top level equipment only. The specifications are communicated to shipping personnel in the form of drawings and/or work instructions. Computers and miscellaneous spare parts are packaged to protect products during handling. Reference Procedure PP-15-01.

### **7.6 Control of Monitoring and Measuring Devices**

Procedures are established and maintained by the Manufacturing Department for the control, calibration, and maintenance of inspection and test equipment used by CiDRA® Precision Services, LLC to verify conformance of product to requirements.

Manufacturing, as appropriate, will identify all inspection, measuring and test equipment that may have a material effect on product quality and ensure that such equipment is calibrated at regular intervals to nationally recognized standards. Where appropriate, the calibration of software is included in this program. This equipment has calibration labels.

All other measuring and test equipment not referenced in the above paragraph is exempt from the calibration requirement. Such equipment does not have calibration labels.

Manufacturing identifies measurements to be made and accuracy required.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>	
	<b>Section:</b>	7
	<b>Section Name:</b>	Product Realization
		Rev. A
		Page 24 of 30

Manufacturing also works with internal customers and external suppliers to define the process through which inspection, measuring, and test equipment is calibrated, including frequency of calibration, calibration method, acceptance criteria, and actions to be taken when results are unsatisfactory.

Manufacturing is responsible for calibrating and maintaining the appropriate measuring and test equipment. All active equipment is entered on a controlled list, indicating the calibration status and the equipment locations. Calibration is recorded in a calibration certificate and calibrated equipment is labeled with a calibration sticker.

All calibration-related activities are regulated by Procedure QP-11-01, Inspection, Measuring, and Test Equipment.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	8	Rev. A
	<b>Section Name:</b>	Measurement, Analysis, and Improvement	Page 25 of 30

## **8.1 General**

Measurement data is utilized by management for making fact based decisions and system improvements. The following paragraphs describe what is currently implemented and utilized to demonstrate quality system and product conformity. Continuous improvement methods are based on the use of internal audits, corrective actions, preventive actions, and management review.

## **8.2 Monitoring and Measuring**

### **8.2.1 Customer Satisfaction**

CiDRA® Precision Services, LLC's customers are provided with product support through the Field Support Group. Reference procedure FP-19-01.

The Client Services & Support Group is responsible for customer satisfaction assessment and communicating the information received to the appropriate functional groups.

Members of the Client Services & Support group will provide customer support to customers. The various engineering disciplines within CiDRA® Precision Services, LLC will provide the expertise to address questions and problems with CiDRA® Precision Services, LLC products.

The Client Services & Support Group will administer warranties for the commercial product line.

The Client Services & Support Group will manage product returns in accordance with procedure QP-13-02 Customer Return Procedure.

Product upgrades may include changes to the software or hardware that affect the performance or data output from a system. The Client Services & Support Group will coordinate all upgrades to existing systems.

### **8.2.2 Internal Audit**

Internal quality audits examine the performance and effectiveness of the quality system. They comprehensively test the quality system for compliance with the policies, objectives, and procedures stated in the Quality System Manual. The results of internal quality audits form an integral part of management review activities and can include recommendations for amendments to existing policies or procedures pertinent to the continued effective performance of the quality system.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	8	Rev. A
	<b>Section Name:</b>	Measurement, Analysis, and Improvement	Page 26 of 30

An internal quality audit plan and implementation schedule are established and maintained by the Lead Auditor in compliance with Quality Procedure QP-17-01. Each element of the Quality Manual is periodically audited by trained personnel who are independent of personnel having direct responsibility for the activity being audited. Audits are scheduled on the basis of the status and importance of the activity to be audited.

The Internal Quality Audit Team consists of a cross-functional representation of the quality organization or an independent, qualified auditor and is directed by a Lead Auditor who is responsible for maintaining the team's training, preparedness, independence, and integrity in compliance with Procedure QP-17-01.

The scope of internal quality audits includes gathering evidence, recording deficiencies, issuing corrective action, and specifications for reporting in accordance with Procedure QP-17-01. The results of internal quality audits are recorded and discussed with the management responsible for the area being audited.

Follow-up audits verify the implementation, effectiveness, and timeliness of corrective actions taken in compliance with Procedure QP-17-01.

### **8.2.3 Monitoring and Measurement of Process**

Where and when appropriate, statistical techniques are employed to control and verify the acceptability of process capability and product characteristics. The Product Delivery identifies the need for the use of statistical techniques. The Product Delivery establishes and maintains documented procedures to implement and control the application of the recommended statistical techniques. Reference Procedure QP-20-01.

### **8.2.4 Monitoring and Measurement of Product**

Inspection and testing procedures are established and maintained by the Quality Assurance and Manufacturing Departments. The objective of inspections and testing is to verify that details, components, subassemblies and finished products perform to the specified requirements. Records of inspection and testing are maintained as evidence of product conformance.

Final inspection and testing are performed in accordance with documented procedure QP-10-03. This procedure verifies that all preceding inspections and steps have been successfully completed and all data and documentation required to ship product is complete. Inspection and test records show clearly whether the product has passed or failed all phases of production, up to and

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	8	Rev. A
	<b>Section Name:</b>	Measurement, Analysis, and Improvement	Page 27 of 30

including final inspection and test. Where the product fails to pass any inspection and/or test, the procedure for control of nonconforming product QP-13-01 shall apply. Manufacturing will file and maintain inspection and test records in accordance with QP-10-04 Inspection and Test Records.

**8.3 Control of Nonconforming Product**

Nonconforming product is controlled to ensure that it is prevented from unintended use or installation. Nonconforming product is defined as product that does not meet or exceed CiDRA® Precision Services, LLC’s specified requirements. The procedures provide for the identification, documentation, evaluation, segregation, and disposition of non-conforming product, and for notifying the functions concerned.

The responsibility for review and authority for the disposition of nonconforming product may be assigned to Advanced Manufacturing, Engineering, Client Services & Support, Quality Assurance, or Purchasing. The Material Review Board Core Team can consist of representatives from Engineering, Manufacturing and Quality Assurance.

Disposition of non-conforming product may be:

- Rework in house
- Return to supplier for rework
- Return to supplier for replacement
- Return to supplier for credit
- Scrap
- Use “as is”

Any nonconforming product that is declared to be “use as is” will be documented accordingly as described in Procedure QP-13-01 and disclosed to the customer as required by contract.

Any nonconforming product returned from a customer will be handled in accordance with Procedure QP-13-02.

**8.4 Analysis of Data**

Throughout the system, management continuously monitors, analyzes and collects data to effectively evaluate the company’s overall performance against plan and objectives. Conformance to product requirements, process trends, supplier performance, and customer satisfaction are currently reviewed and analyzed for potential improvements.

<b>CiDRA® Precision Services, LLC</b>	<b>Quality System Manual</b>		
	<b>Section:</b>	8	Rev. A
	<b>Section Name:</b>	Measurement, Analysis, and Improvement	Page 28 of 30

## **8.5 Improvement**

### **8.5.1 Continual Improvement**

Along with the continuous improvement activities from the management review process: audit results, data analysis, corrective and preventive action, CiDRA® Precision Services, LLC management has created a culture that allows individuals to actively participate in the continual improvement process throughout the quality management system.

### **8.5.2 Corrective Action**

Quality Department establishes and maintains procedures for initiating, implementing, and ensuring effective preventive and corrective actions as described in procedure QP-14-01.

The procedures, forms, or flow charts for corrective action detail the following:

- The effective handling of customer complaints and internal reports of non-conformities. Investigating the cause of non-conformities relating to the final product, production process, or the quality system, and recording the results of the investigation.
- Determining the corrective action needed to eliminate the cause of nonconformities.
- Applying the controls to ensure that corrective action is taken and that it is effective.

### **8.5.3 Preventive Action**

The procedures, forms, or flowcharts for preventive action detail the following actions:

- Using appropriate sources of information such as, but not limited to, processes, work operations, audit results, inspection and test reports, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of non-conformity.
- Determining the steps needed to deal with any problem requiring preventive action.
- Initiating preventive action and applying controls to ensure that it is effective.
- Steps to effectively eliminate the causes.

# APPENDIX A

