REVISIONS

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<td>19 Feb 2013</td>
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<td>B</td>
<td>Stage 1 Audit Updates</td>
<td>Dave Dufour</td>
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Introduction
Crew Training International, Inc. (CTI) adopted a process-based Quality Management System (QMS) in accordance with the International Organization for Standardization’s (ISO) International Standard 9001:2008, Quality Management Systems – Requirements. This approach emphasizes the importance of understanding and meeting requirements, the need to consider processes in terms of added value, obtaining results of process performance and effectiveness, and continual improvement of processes based on objective measurement.

CTI Quality Policy
Within CTI we are committed to provide products and services which meet the customers’ specified contractual requirements.

CTI recognizes that in order to provide and maintain consistently high quality work, an effective QMS is necessary to ensure proper communication, work control and accountable records are generated for all work undertaken. CTI is committed to setting and achieving quality standards that are capable of meeting the specified requirements and reasonable expectations of our customers.

It is the policy, therefore, of CTI to control and conduct its business of producing and implementing integrated management services by means of a formalized system of modern quality management. This quality management shall meet and exceed the quality system requirements as specified in ISO 9001:2008. Further, CTI is committed to the continual improvement of the implemented quality management system and will supply the resources necessary for improvement.

The Quality Manual (QM) defines CTI’s QMS which has been established and adopted as the means for achieving these declared objectives and which is detailed in the sections below.

All members of CTI staff are charged with promoting these aims and are required to familiarize themselves with the contents of this QM and to observe and implement the systems and procedures defined in the performance of their work.

The Quality Manager based at the CTI headquarters is the appointed management representative responsible for monitoring and ensuring the correct and effective implementation of CTI’s QMS as a whole.

Mission Statement
To deliver effective, evidence based management systems in accordance to the recommendations of ISO 9001:2008 and other industry standards.
# Quality Management System – Requirements

## 1. Scope and Exclusions

### 1.1. General

CTI complies with all applicable requirements of the ISO 9001:2008 International Standard for our training consulting services and products.

Purchasing (Section 7.4) – CTI does not purchase any items directly related to product realization. Purchases are related to infrastructure such as utilities, computers, software, etc., from distributors based on cost and availability. Additionally, CTI does not outsource any services or activities that affect product conformity to requirements.

Process Validation (Section 7.5.2) – CTI can verify product conformance through inspection.

Control of Devices (Section 7.6) – CTI does not presently utilize calibration equipment for the control of monitoring and measuring devices.

### 1.2. Application

All requirements stated in this quality manual are considered mandatory for all headquarters employees responsible for the definition, design, development, production, delivery, or support of training products specific to CTI.

## 2. Normative Reference


## 3. Terms and Definitions

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**ISO 9001 NO.** 422.000.000.000
**4. Quality Management System**

**4.1. General Requirements**

It is the policy of CTI to establish, document, implement, and maintain a QMS as a means of ensuring that its products and services conform to the specified requirements of the ISO 9001:2008 International Standard and to foster an environment of continual improvement. CTI determined the needed processes and their application throughout the organization. These included processes for management activities, provision of resources, product realization, measurement, analysis, and improvement.

The quality manual describes the sequence and interaction of our processes from introduction of product designs to product realization and delivery and includes all processes necessary for maintaining client satisfaction. In essence, they describe all the processes and actions necessary to achieve planned results and continual improvement of these processes.

The criteria and methods required to ensure the effective operation and control of these processes are defined and documented as necessary. The entire QMS documentation and other key information necessary to support the operation and monitoring of the CTI business processes are available to all employees on the quality assurance page of the company intranet.

Further, CTI ensures the following items are supported. Please refer to Figure 3, QMS Interaction Overview, in section 5.4.2 for more information:

- Availability of resources and information necessary to support the operation and monitoring of business processes
- Monitor, measure and analyze business processes
- Implement actions necessary to achieve planned results and continual improvement of business processes

**4.2. Documentation Requirements**

**4.2.1. CTI QMS Documentation**

The CTI QMS documentation includes:

- The quality policy and quality objectives
- This quality manual
- Documented procedures and records required by ISO 9001:2008 International Standards
- Documents, including records, determined by CTI to be necessary to ensure the effective planning, operation, and control of its processes (documented as procedures and work instructions)

This manual provides top level corporate guidance to meet ISO 9001:2008 requirements. The QMS utilizes a tiered approach and includes the quality policy, quality objectives, quality
metrics, this manual, procedures, work instructions, and records. Metrics are defined to support CTI quality objectives and are consistent with the quality policy.

Quality procedures are defined to implement organizational processes for specific paragraphs of this manual. An additional tier of work instructions may be added as necessary to provide the necessary task details for employees. Quality records are maintained to provide evidence of conformity to requirements.

All documented procedures are established, implemented and maintained. The quality procedures describe criteria, methods, detailed activities, responsibilities and the quality assurance measures that are required to ensure the effective operation and control of CTI business processes. The CTI QMS also includes lower tier documents required by the organization to ensure the effective operation and control of CTI business processes. The degree of documentation is consistent with the size of the CTI business unit and the activities involved, methods used, complexity and interaction of the CTI business processes, and the competence required by CTI personnel involved in carrying out these activities. Refer to Figure 1, QMS Tiers.

![Figure 1. QMS Tiers](image.png)

Interactions between processes and extensive cross references are defined in the referenced procedures and work instructions.

The QMS is maintained, updated and continually improved as CTI incorporates new business practices. The system has been established and CTI employees are knowledgeable of which procedures apply to them, how to access those procedures, how to apply them to their job function, and how to report related results.

4.2.2. Quality Manual

CTI has established, documented, and maintains a quality system as a means of ensuring that its processes and products conform to specified requirements of the ISO 9001:2008. The quality manual (this document) includes the following:

- The scope of the QMS, including details of, and justification for, any exclusions;
Documented procedures or direct reference to them;
A description of the sequence and interaction between the processes of the QMS.

Quality Procedures and other lower tier documents referenced in the quality manual support the requirements of the quality manual and provide detailed requirements of the organization. This quality manual is a controlled document subject to the requirements of the Document Control Procedure (4.2.3).

4.2.3. Control of Documents

CTI ensures that pertinent issues of documents and data related to the requirements of the QMS and the ISO 9001:2008 standard are controlled. This control extends to documents of external origin, determined by CTI to be necessary for the planning and operation of the QMS, which are identified and their distribution controlled. The Document Control Procedure is established to define the processes necessary to control quality system documentation.

CTI recognizes that quality records are a special type of document and controls them as provided in section 4.2.4. CTI ensures that quality system documents remain legible and readily identifiable.

All documents and data related to the requirements of the QMS and the International Standard are reviewed and approved for suitability prior to release or use.

CTI QMS documents and their life-cycle (reviews, changes, and approvals) are maintained in the SharePoint database application. SharePoint uses a software feature to control reviews, changes, and approvals of controlled documents. SharePoint controls access privileges and records all changes to controlled documents. The master copy is published on the Quality Assurance (QA) page of the company intranet and is made available to all employees. Printed copies are for reference only and are uncontrolled. Employees utilize the electronic version of controlled documents distributed on the company intranet.

External documents are controlled (identified, verified, protected, and safeguarded) using a library electronic database located within SharePoint at each individual project site. All reference material used to develop products is available and controlled within the library. Employees will view or download all required Client/Government Furnished Information (C/GFI) from the site library. Employees will use the automated e-mail notification feature of the library application to receive automated notifications of changes. Printed copies of C/GFI are considered uncontrolled. Project Managers (PM) are responsible for the identification of C/GFI to be removed from the library at the conclusion of the project/contract. Refer to paragraph 7.5.4 for additional information on client property requirements.

Obsolete documents are maintained in a separate area of the database as reference documents for a minimum period of three years, or in accordance with statutory and regulatory requirements at the conclusion of the contract period of performance. Suitable identification will be applied to ensure obsolete documents are not erroneously used for product development and revision.

Referenced Procedure:
423.001.000.000 – Document Control Procedure
4.2.4. Control of Records

Records that provide evidence of conformity to requirements and the effective operation of the QMS are controlled. The Quality Records Procedure defines the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Quality records are maintained legible, readily identifiable and retrievable for a minimum period of three years in accordance with statutory and regulatory requirements after the conclusion of the contract period of regulatory requirements.

Referenced Procedure:
424.001.000.000 – Quality Records Procedure

5. Management Responsibility

5.1. Management Commitment

CTI is committed to the development, implementation and improvement of the QMS. Executive management continuously communicates the importance of the client focus and meeting client, statutory, and regulatory requirements at all levels. This is evident in the company’s dedication to the QMS, quality policy, quality objectives, management reviews, and by providing the resources to perform the activities described by the QMS. This is accomplished through annual planning, setting objectives, and budgeting.

5.2. Client Focus

CTI executive management ensures that client requirements are determined and fulfilled with the aim of enhancing client satisfaction. Evidence of the emphasis placed by CTI on client focus is embedded in the CTI corporate brief that every employee receives.

Directors, PM’s, and supervisors continuously communicate the importance of meeting client, statutory, and regulatory requirements at all levels. The needs of our clients are determined through continual verbal and written communications as well as periodic meetings to better understand their individual requirements. All personnel who interface with clients are responsible to assess stated or implied needs and bring them to the attention of executive management so that they may be addressed.

All employees are chartered with ensuring our products and services meet client as well as statutory and regulatory requirements. CTI monitors, measures, and analyzes client satisfaction for continuous improvement.

5.3. Quality Policy

Executive management of CTI has defined and documented its quality policy and includes the organization’s commitment to comply with requirements and to continually improve the effectiveness of the QMS. The quality policy is relevant to organizational goals, expectations and needs of its clients. These concepts have been communicated to all employees within the scope of the QMS.
Quality concepts have been integrated into CTI company culture. CTI ensures that its quality policy is understood through training, communication, and the availability of company procedures and work instructions.

The quality policy is a controlled document subject to the requirements of document control (paragraph 4.2.3). The Policy is maintained through QMS audits, corrective and preventive action and is reviewed for continuing suitability through periodic management reviews.

Referenced Document: 530.001.000.000 – Quality Policy

5.4. Planning

5.4.1. Quality Objectives

Executive management has established quality objectives at appropriate functions and levels. Each objective is measured and evaluated by executive management for consistency with the quality policy.

CTI executive management establishes quality objectives at all relevant functions and levels within the organization. These objectives are derived from the CTI quality policy and are documented. Each quality objective is measurable and consistent with the quality policy and includes commitment to continual improvement.

The quality objectives identified in the opening paragraph include those needed to meet all contracted client requirements. In addition to management controls and performance objectives, the entire set of quality objectives also addresses client satisfaction, as well as applicable product and service delivery characteristics. The directorate level quality objectives are linked to the top level corporate objectives of CTI and are supported by all members of management.

5.4.2. Quality Management System Planning

CTI has identified and planned the resources needed to achieve its quality objectives. Quality planning addresses continual improvement of the QMS and assures that when changes to the QMS are necessary, the changes are implemented in a controlled manner to maintain the integrity of the QMS and the CTI service environment.

Quality planning is established through the quality manual, which identifies the business processes of the QMS and includes references to associated quality procedures.

Each activity has an owner who has the prime responsibility for ensuring that the process achieves its objectives and is under continual review for improvement. Evidence of CTI’s QMS planning is inherent in associated documentation of procedures, work instructions, and records and previously described in paragraph 4.2.2. Whenever changes are planned and implemented, management will ensure the integrity and effectiveness of the QMS.

Refer to figure 3 for the CTI approach to its QMS planning.
5.5. Responsibility, Authority, and Communication

5.5.1. Responsibility and Authority

CTI executive management is responsible for ensuring that authority and responsibilities are communicated throughout the organization. Functions and their interrelationships within the organization, including responsibilities and authorities, are defined and communicated in order to facilitate effective quality management. CTI ensures the responsibility, authority and interrelationship of personnel who manage, perform and verify work affecting quality is defined and documented, particularly for personnel who need the organizational freedom and authority to:

- Initiate action to prevent the occurrence of any nonconformance relating to CTI products, services, processes and QMS
- Identify and record any problems relating to CTI products, services, processes, and QMS
- Initiate, recommend or provide solutions through quality teams or through other designated channels
- Verify the implementation of solutions
- Control further processing, delivery or installation of nonconforming products until the deficiency or unsatisfactory condition has been corrected

The following organization chart is maintained to demonstrate the interrelationship of personnel.
Figure 4. CTI Executive Management Org Chart

The President/CEO, through the company’s top leadership, establishes the development of the quality policy, quality objectives, corporate quality planning, organizational structure, management review, and provides necessary resources. Other responsibilities and authorities are as follows:

General Counsel
- Legal Review of Requirements
- Legal Guidance

Operations Department Head
- Quality Assurance
- ISO Management Representative
- Contracting Authority
- Information Technology
- Facilities Security

Human Resources (HR)
- Defines company-wide training
- Maintains qualification and training records

Accounting and Finance
- Purchasing
  - Selects qualified supplies and vendors
  - Prepares and approves purchasing documents
  - Monitors and evaluates supplier performance
Chief Learning Officer
- Product Development

5.5.2. Management Representative
The President/CEO has appointed the Quality Manager as the ISO Management Representative, who has the responsibility and authority to:
- Ensure the processes needed for the QMS are established, implemented and maintained
- Report to executive management on the performance of the QMS and any need for improvement
- Ensure the promotion of awareness of customer requirements throughout the organization
- Act as the liaison between CTI and third parties on matters concerning the CTI QMS.

5.5.3. Internal Communication
CTI ensures that appropriate communication processes are established within the organization and communication takes place between its various levels and functions regarding the processes of the QMS and their effectiveness. This is accomplished through QMS training, meetings, quality bulletins, and the intranet. CTI has established open communication throughout the organization and emphasizes employee and client involvement in the QMS. Personnel are encouraged to provide suggestions through the Process Improvement Program Form to improve the effectiveness of the QMS. The effectiveness of our QMS is evident through internal audit results, corrective and preventive action, and performance measures.

5.6. Management Review

5.6.1. General
Executive management of CTI reviews the QMS at least annually to ensure its continuing suitability, adequacy and effectiveness in meeting internal needs of the ISO 9001:2008 requirements. The review includes assessment of opportunities for improvement and the need for changes to the organization’s QMS, including its quality policy and quality objectives.

Executive management reviews the QMS to assure continuous compliance to the ISO standard. Management may decide to hold reviews more frequently if the system is not functioning adequately, part of the system needs to be changed, or if client complaints or external audits reveal significant system failures. Results of management reviews are recorded and retained as quality records.

5.6.2. Management Review Input
Inputs to management review include current performance and improvement opportunities related to the following:
- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Changes that could affect the QMS
- Recommendations for improvement
5.6.3. Management Review Output

Outputs resulting from management review include any decisions or actions related to:

- Improvement of the effectiveness of the QMS and its processes
- Improvement of product related to customer requirements
- Resource needs

Referenced Procedure:
560.001.000.000 – Management Review Procedure

6. Resource Management

6.1. Provision of Resources

CTI executive management will determine and provide the resources needed to implement and maintain the QMS, continually improve its effectiveness, and to enhance client satisfaction by meeting client requirements. These resources are assessed and reviewed on a periodic basis consistent with business planning activities.

6.2. Human Resources

6.2.1. General

The SR VP HR will ensure personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. Specific activities are addressed in the Recruitment Procedure.

6.2.2. Recruitment

CTI determines the competence needs of its employees, where applicable, and provides training or other actions to achieve necessary competence.

CTI identifies the competence needed for each activity, assesses the competence of its employees to perform the activities, and develops training plans to provide the needed knowledge or skills.

Training is provided either on or off the job, internally or externally, as appropriate. The effectiveness of training is assessed though a continual evaluation of performance to determine if the training provided the desired skills. Effectiveness is assessed by the directors and/or supervisors who authorized the training to ensure that training objectives have been accomplished.

Qualifications and/or training records are maintained to document the employee’s demonstration of required skills. HR maintains employee folders detailing experience, skill, and other pertinent qualifications. Attendance sheets and certificates of proficiency and/or completion may be retained for employees as needed.

Additionally, CTI employees are made aware of quality system and client satisfaction responsibilities during introductory awareness training. QMS and client satisfaction responsibilities are reinforced during employee meetings.

Referenced Procedure:
622.001.000.000 – Recruitment Procedure
6.3. Infrastructure

6.3.1. General

CTI determines, provides and maintains the infrastructure needed to achieve the conformity of product requirements. This infrastructure includes facilities, workspace, associated utilities, process equipment (both hardware and software) and supporting services (transport, communication or information systems). HR coordinates activities with IT and Facility Management to ensure that required hardware, software and services are available for new employees.

6.3.2. Security

In the event that an employee requires a security clearance (Confidential, Secret, or Top Secret) HR will provide CTI’s Security Officer with the necessary information to begin the application process. In cases where clearance is granted the DSP-5 form will be maintained as a quality record of the clearance for a minimum of two years after expiration. The DSP-5 forms arrive from the government in a “locked” state preventing the addition of a QMS Number to the document, instead the 9-digit unique identifier issued by the government is used as the QMS Number for these records.

6.4. Work Environment

CTI manages and maintains a safe work environment needed to achieve conformity to product requirements and ensure that the work environment has a positive influence on motivation and performance of its employees. CTI considers the following factors to determine work environment requirements.

- Safety
- Ergonomics
- Social interaction
- Workplace location
- Creative work methods
- Heat, humidity, light, and airflow requirements
- Hygiene, cleanliness, noise, vibration, and pollution
- Protection and safeguarding of classified or competitively sensitive information
- Compliance with statutory and regulatory requirements

7. Product Realization

7.1. Planning of Product Realization

Upon receipt of new product requirements, CTI plans and develops processes needed for product realization. New processes supporting product realization are consistent to achieve interoperability with other processes identified within the QMS.

In planning new product realization, CTI determines quality objectives and requirements related to the product; the need to establish processes and documents, and to provide resources specific to the product; the 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.
The output of product planning is documented in a project specific Phase-In Plan and Quality Assurance Program Plan (QAPP).

The Phase-In Plan identifies the design and development stages and defines the processes needed for product realization. The Phase-In Plan is maintained as a quality record.

The QAPP summarizes the quality objectives and references requirements for the product. It also includes required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance. The QAPP is maintained as a quality record.

7.2. Client-Related Processes

7.2.1. Determination of Requirements Related to the Product.

Prior to accepting new work from clients, CTI determines requirements specified by the client and includes:

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

Product requirements are determined by several methods. Custom, innovative, and consulting products are defined by the commercial client during the contracting process through Client Requirements and Expectations (CREs). Products for the Department of Defense (DoD) are defined by Contract Data Requirements Lists (CDRLs), Contract Line Item Numbers (CLINs), System Specifications, Statements of Work.

Delivery, post-delivery, and acceptance criteria are documented on the applicable product CRE, CLIN, or CDRL documents. Necessary and additional requirements (including those that are not stated) are documented in the technical approach of the proposal. Legal reviews are conducted as appropriate to determine all applicable statutory and regulatory requirements. Any additional requirements determined after contract award are communicated through the PM to the client for resolution.

7.2.2. Review of Requirements Related to the Product.

The Operations Department Head, the Vice President of Business Development, the Chief Learning Officer, and the proposal manager are responsible for the review of requirements. A proposal manager forms and leads a matrix team of personnel to review proposals or contract changes. Before submission of a proposal or acceptance of a client requirement, the contract or order is reviewed by the Operations Department Head to ensure that:

- Product requirements are defined
- Differences between the contract requirements and those previously expressed are resolved.
- CTI has the ability to meet the defined requirements
If the client provides no documented statement of requirements, CTI takes precaution to adequately understand its client’s needs and expectations prior to commencement of services. CTI assesses its capabilities on a continuing basis.

**Amendment to a Contract**

When client requirements change, CTI ensures that relevant documentation is amended and that relevant personnel are made aware of the changed requirements.

The only CTI representative authorized to make changes to the contract is the Operations Department Head. Employees shall not implement any contractual changes unless authorized by the Operations Department Head or an official contract modification is issued. Employee discussions with the client are to enhance the mutual understanding of project requirements as defined by the contract. Final awarded contract documents (SOWs, CLINs, CDRLs, CREs, etc) and contract changes are maintained.

**7.2.3. Client Communication**

CTI is committed to client-focused service and support. Project managers, in cooperation with the client establish, maintain communication management plans documented as SOW’s.

CTI provides contact information for client feedback and complaints with our products as a feedback mechanism for the QMS. In cases of proposal submittal a CTI Executive will request a post-award conference with the procuring activity to assess performance.

**7.3. Design and Development**

CTI product design is normally determined by the client with specific requirements defined in the contractual documents. DoD contracts specify the standards to use for design and development and include detailed information regarding each product in the CLIN or CDRL. The product is further defined by a standardized DID listed as a reference on each applicable CDRL. Commercial contracts specify standards through CREs.

**7.3.1. Design and Development Planning**

CTI’s vast aviation experience is complemented by its expertise in the use of the Instructional Systems Design/Systems Approach to Training (ISD/SAT) process. The effective use of the full range of ISD/SAT processes sets CTI apart from other training-based companies.

The PM is responsible for managing the planning and scheduling of the project and are the interface between all organizations involved in product planning. The PM ensures that action items assigned during meetings are communicated to the appropriate directorate and monitors them until they are closed.

CTI documents the design and development of products through the use of an IMP that identifies all design and development stages. The contractual considerations for IMP development state that all work shall be identified by events, accomplishments, and criteria. Stages of product design and development derive from the appropriate events and sub-categories within the IMP. The review, verification, and validation that are appropriate to each design and development stage are identified in the project QAPP and controlled using the IMS.
7.3.2. Design and Development Inputs

Design input requirements shall be determined, documented, and reviewed for adequacy. They shall be complete, unambiguous, and not in conflict with each other. The design inputs shall include functional and performance requirements, applicable statutory and regulatory requirements, applicable information derived from previous similar designs, and any other requirements essential for design and development.

CTI specific product designs standards and instructions regarding each product are documented in the CRE or System Specifications.

7.3.3. Design and Development Outputs

The output of design and development provides appropriate information for production. Design outputs meet the input requirements for design and development, provide appropriate information for production, contain or reference product acceptance criteria, and, if applicable, specify the characteristics of the product that are essential for its safe and proper use.

CTI utilizes CDRLs and CLINs, provided by the client as the output of design and development for DoD contracts. On commercial contracts, CTI utilizes the client’s product specification (CRE document, SOW or contract).

CTI documents the output of the design and development planning in a product review checklist to enable verification against the design and development input. Design output records are available to all employees involved with product realization.

When additional design output details are required to provide appropriate information for production, a PM may authorize additional design outputs in the form of a product design style guide. The style guide provides production information and references the design inputs and outputs. The style guide may also contain or reference the product acceptance criteria and may include required front matter, templates, formatting requirements, required acronyms, technical specification, or drawings. Approved product design style guides are maintained as a quality record.

7.3.4. Design and Development Review

CTI conducts systematic reviews of design and development efforts at suitable stages in accordance with planned arrangements. Reviews are performed to evaluate the ability of the results of design and development to meet requirements, identify any problems and proposed necessary actions.

A key to our client-focused strategy includes involvement of our client in the review of design and development. CTI allows our client to perform formal client reviews and seeks draft product acceptance during appropriate stages of product realization to ensure that client requirements are met. Student Critiques are performed post course delivery as a method of gathering feedback on courseware and courseware delivery. PMs will assess scope impacts, perform change control to ensure client design inputs and changes are incorporated into the product, and ensure client inputs (Student Critiques) are maintained as quality records in SharePoint.
7.3.5. **Design and Development Verification**

CTI performs design and development verification IAW planned arrangements and ensures that the design and development outputs have met the design and development input requirements. The PM verifies product checklists are complete and requirements are met prior to product release activities. The PM verification checklist is maintained as a quality record within SharePoint.

7.3.6. **Design and Development Validation**

Our clients perform final validation in accordance with planned arrangements after delivery. CTI’s strategic consulting, studies, and analysis products are utilized by our clients to make decisions regarding their product realization. CTI normally provides various options based on client resource availability and future plans. Our clients may utilize some or all of our recommendations in the implementation of their product realization (funding constraints and other restrictions may prevent our clients from adopting all options included in our products).

CTI conducts a final product review prior to delivery utilizing SharePoint to ensure that the products content and format meet prescribed expectations and that approved processes are followed to develop the product. Product leads, Directors, PMs, and management review and approve products prior to delivery. Automated records are maintained within SharePoint.

Final validation is accomplished by the client after delivery and monitored through feedback. CTI uses various feedback methods and monitors various indicators that include overall client satisfaction, repeat business, client referrals, and client acceptance of products. Appropriate records are maintained.

7.3.7. **Control of Design and Development Changes**

CTI will identify and maintain a record of all design and development changes. Contract changes follow the contract amendment processes described in paragraph 7.2.2.

CTI identifies, controls, reviews, and approves internal changes utilizing the SharePoint change management software. All changes are reviewed, verified, and validated as appropriate prior to implementation. PMs will coordinate with the Chief Learning Officer on scope verification issues and ensure approved client design inputs and changes are incorporated into the product (see paragraphs 7.3.4 and 7.3.5). All design and development changes impacting products already delivered are evaluated for effect by executive management who determine appropriate action.

Control of design and development changes are automatically recorded using the inherent change management features of SharePoint. Product release baselines are maintained for historic reference.

**Referenced Procedure:**
730.001.000.000 – Design and Development Procedure

7.4. **Purchasing**

This section is excluded. CTI does not presently purchase any items directly related to product realization. Additionally, CTI does not outsource any services or activities that affect product conformity to requirements.
7.5. Production and Service Provision

7.5.1. Control and Production and Service Provision

CTI identifies and plans production and service activities that directly affect quality to ensure that these activities are carried out under controlled conditions. Controlled conditions include, as applicable:

- Availability of information that specifies product characteristics
- Use of documented work instructions where the absence of such instructions could adversely affect quality
- Use of suitable production equipment or software
- Compliance with reference standards, handbooks, master plans and/or documented procedures and work instruction
- Monitoring and control of suitable product characteristics and processes
- Implementation of defined processes for release, delivery and applicable post-delivery activities

Subsequent to a successful review of new or changed client requirements, requirements are passed to impacted CTI directors (see 7.1). The PM will coordinate changes to the IMP, IMS, and QAPP with impacted directors as required. The PM ensures these plans are executed and the product is delivered under controlled conditions.

Directors are responsible for the preparation of updated Product Design Style Guides, product review checklists, (as required) and providing information for inclusion into the planning documents (IMP, IMS, & QAPP). The information should describe requirements, description of work processes, references to required procedures/specifications, software applications used, inspection checklists, and the identification of persons performing inspection or verification.

CTI provides all employees access to information that describes the product characteristics, requirements, and work instructions via the company’s intranet page and the SharePoint application. SharePoint change management software provides monitoring and measuring capabilities and controls for product release, delivery, and post-delivery activities.

7.5.2. Validation of Processes for Production and Service Provision

This section is excluded. CTI can verify product conformance through inspection.

7.5.3. Identification and Traceability (Configuration Management)

CTI ensures that activities are identified by suitable means throughout the production, review, approval, and release processes. Product identification is provided by using the company’s file naming convention (or part numbering system) to assign unique identification to all products.

CTI controls and records unique identifiers of the products for traceability. CTI provides for traceability and configuration management using SharePoint change management software. Nonconforming or obsolete products will be marked as “rejected” within the database.

Products and/or services activities are uniquely identified and traceable through all stages by means of change document (work order) numbers, IMP/IMS identification numbers (or Work Breakdown Structure), form numbers, time sheets, signatures, etc.
CTI identifies the status of work activities with respect to measurement and monitoring requirements. Identification of inspection and test status is maintained throughout a project to ensure that only products and services that have passed required inspections and tests are delivered or used. Suitable means of identification are in place throughout the process. CTI identifies product life cycle status and revision level using SharePoint database.

7.5.4. Client Property
CTI will exercise care with client property while it is under its control or being used by CTI. CTI will identify, verify, protect, and safeguard property provided for use or incorporation into the product. If any client property is lost, damaged, or otherwise found to be unsuitable for use, the PM will report it to the client and ensure records are maintained. Records of these situations (letters or e-mail to the client) will be maintained within the SharePoint project site library (within the C/GFI folder).

7.5.5. Preservation of Product
CTI utilizes the configuration management process to preserve the conformity of product during internal processing and delivery to the intended destination. The product baseline preserves identified products, related checklists, transmittal information, revision, status, names of reviewers, approvers, and provides for storage and protection. This preservation also applies to the source files (constituent parts) of the product. Routine backup of electronic files and databases is accomplished.

7.6. Control of Monitoring and Measuring Devices
This section is excluded. CTI does not presently utilize calibrated measurement devices.

8. Measurement Analysis, and Improvement

8.1. General
Monitoring, measurement, analysis, and improvement processes are planned and implemented to demonstrate conformity of products, to ensure conformity of the QMS, and to continually improve the effectiveness of the QMS. CTI defines, plans, and implements the monitoring, measurement, analysis and improvement of the processes.

CTI uses statistical techniques, where appropriate, to economically establish conformance to specifications. Statistical techniques are also used to determine process capabilities and identify potential quality improvements. Depending on applicable circumstances, sampling, charts, diagrams, and metrics may be used to convert data to presentable information for decision-making.

8.2. Monitoring and Measurement

8.2.1. Client Satisfaction
CTI monitors information on client satisfaction and dissatisfaction as measurements of performance of the QMS. This information is used to evaluate client perceptions as to whether CTI is fulfilling their expectations. CTI obtains this information from various sources such as client surveys, data on delivered product quality, user opinion surveys, etc.

8.2.2 Internal Audit
CTI conducts periodic internal audits to determine whether its QMS:
- Conforms to the planned arrangements (see 7.10), to the requirements of the ISO 9001:2008 International Standard and the CTI QMS
- Has been effectively implemented and maintained

The responsibilities and requirements for planning and conduction audits, establishing records and reporting results are documented in the Internal Audit Procedure.

Internal quality audits are planned and scheduled on the basis of the status and importance of the processes and areas to be audited, as well as the results of previous audits. As a minimum, the schedule is such that the complete QMS is audited annually. The audit criteria, scope, frequency and methods are defined. Personnel assigned to perform internal audits are qualified by education and experience. Training is provided as required. Auditors performing each audit are independent of those having direct responsibility for the activity being audited.

The results of internal audits are documented and brought to the attention of the director having responsibility for the area audited. Management personnel responsible for the area make timely corrective action on any nonconformities and their causes found during the audit.

Audit results are analyzed to determine if modifications to the QMS are needed. The Quality Manager is responsible for communicating the results of the audit to executive management. Functional area directors are responsible for identifying and documenting root causes, corrective action, and preventive action for any area/items found deficient.

Follow up activities verify and record the implementation of the corrective action, report and verification results, and close out the audit (see 8.5.2). Subsequent action verifies the effectiveness of the corrective action taken.

Results of internal audits, in summary form, are submitted for management review. Records of the audit results and associated corrective actions are retained.

Referenced Procedure:
822.001.000.000 – Internal Audit Procedure

8.2.3. Monitoring and Measurement of Processes
CTI applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective actions are taken, as appropriate.

Each director is responsible for implementing and then monitoring the effectiveness of the processes under their control. CTI utilizes a process improvement program to identify, review, and approve procedure and work instruction changes in accordance with the Document Control Procedure.

8.2.4. Monitoring and Measurement of Product
CTI measures and monitors the characteristics of product or service activities to verify the requirements are met. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements (see 7.1). Evidence of conformity with the acceptance
criteria is maintained as a quality record titled “Contract Tracker”. Records indicate the authority responsible for release of deliverables.

CTI carries out all final inspection in accordance with the IMP, IMS, and QAPP and/or documented procedures to complete the evidence of conformance of the finished product/service to specified requirements. Evidence of conformity with the acceptance criteria and records of the persons authorizing the release of the product will be maintained within SharePoint. Product release and delivery will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by executive management and, where applicable, by the client.

Automated records (change documents, version history, and item history) clearly show whether the product has passed or failed the inspection or tests according to defined acceptance criteria. Where the product or service fails to pass any inspection, the procedure for the Control of Nonconforming Product is applied (see 8.3).

8.3. Control of Nonconforming Product

CTI will ensure that products which do not conform to product requirements are identified and controlled to prevent unintended delivery to the client. Nonconforming products will be controlled and identified using features of the SharePoint application. All products identified as “rejected” will be electronically segregated from the product release baseline. The product baseline will also ensure the correct version/revision is included with the product release.

These activities are defined and documented in the procedure “Control of Nonconforming Product”. This procedure includes provisions for identification, documentation, evaluation, segregation (where practical), disposition of nonconformity, and for notification of the functions concerned, and assigning responsibility for the review and the authority for disposition of the nonconformity.

Where applicable, CTI deals with nonconformities in 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 the client; or by a relevant authority
- 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

CTI will take action to eliminate the detected nonconformity, maintain automated records, and re-verify that the product demonstrates conformity to the requirements. When non-conformities are corrected, the corresponding products are reprocessed and subjected to re-verification after correction to demonstrate conformity.

On the rare occasion when the detected nonconformity cannot be eliminated, executive management (and the client as applicable) may authorize its use, release, or acceptance under concession. CTI may also take action to preclude the product’s original intended use or application.
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained within the inherent features of the SharePoint application (see 4.2.4). The SharePoint database is used to store and analyze nonconformity trends.

Referenced Procedure:
830.001.000.000 – Control of Nonconforming Product Procedure

8.4. Analysis of Data
CTI determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement can be made. This includes data generated by measuring and monitoring activities and other relevant sources. The analysis of data provides information relating to:

- Client satisfaction (8.2.1)
- Conformity to product requirements (see 8.2.4)
- Characteristics and trends of processes and products, including opportunities for preventative action (see 8.2.3 and 8.2.4)

8.5. Improvement

8.5.1. Continual Improvement
CTI plans and manages the processes necessary for continual improvement of the QMS. CTI facilitates the continual improvement of the QMS through the use of quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review.

8.5.2. Corrective Action
The QM is responsible for managing the corrective action program as defined in the corrective action procedure. All personnel are responsible for taking action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. The corrective action procedure defines requirements for:

- Reviewing nonconformities (including customer complaints)
- 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 action taken (see 4.2.4)
- Reviewing the effectiveness of the corrective action taken

Referenced Procedure:
852.001.000.000 – Corrective Action Procedure

8.5.3. Preventive Action
CTI determines the action to eliminate the cause of potential nonconformities in order to prevent their occurrence. Appropriate sources of information such as results from processes and work operations which affect product quality, concessions, audit results, quality records, service reports and client complaints are analyzed to detect preventive action possibilities.
The Quality Manager is responsible for managing the preventive action program as defined in the Preventive Action Procedure. All personnel are responsible for taking action to eliminate the causes of potential nonconformities. Preventive actions will be appropriate to the effects of the potential problems.

The Preventative Action Procedure defines 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 action taken (see 4.2.4)
- Reviewing the effectiveness of the preventive action taken

Referenced Procedure:
853.001.000.000 – Preventive Action Procedure