**CENTRIS CONSULTING**

# *Quality Control Manual*

# ISO 9001:2008

# Introduction

Centris Consulting developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Centris Consulting meets the requirements of the international standard ISO 9001:2008. This system addresses the design, development, and implementation of the company's services, including its deliverables herein referred to as the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of ISO 9001:2008. Each section begins with a policy statement expressing Centris Consulting's obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

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

David J. Nape

President & CEO

# Section 1: SCOPE

## 1.1 General

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard ISO 9001:2008

## 1.2 Application

Centris Consulting has determined that the following requirements are applicable and there are no exclusions.

# Section 2: NORMATIVE REFERENCES

## 2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- ▪ American National Standard ANSI/ISO/ASQ Q9000-2005, Quality Management Systems - Vocabulary.

- ▪ American National Standard ANSI/ISO/ASQ Q9001-2008, Quality Management Systems – Requirements

- ▪ American National Standard ANSI/ISO/ASQ Q9004-2000, Quality Management Systems – Guidelines for performance Improvements

## Section 3: DEFINITIONS

## 3.0 Quality Management System Definitions

This section is for definitions unique to Centris Consulting.

- ▪ Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.

- ▪ Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.

- ▪ Product – The end item result of meeting all contract terms and conditions. (eg: manufactured goods, merchandise, services etc.)

- ▪ Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable

# Section 4:  GENERAL REQUIREMENTS

## 4.1 General requirements

Centris Consulting has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS Centris Consulting has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them.

- Determined the sequence and interaction of these processes.

- Determined criteria and methods needed to ensure that the operation and control of the processes are effective.

- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes

- Established systems to monitor, measure and analyze these processes, and

- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

- Centris Consulting manages these processed in accordance with the requirements of ISO 9001:2008.

- Where Centris Consulting chooses to outsource any process that affects product conformity, Centris Consulting ensures control over such processes. Control of such processes is identified with the QMS.  *For purposes of this RFP, Centris hereby certifies that no process will be outsourced.*

## 4.2 Documentation Requirements

### 4.2.1 General

The QMS documentation includes:

- A documented Quality Policy and Quality Objectives

- This Quality Manual

- Documented Procedures

- Documents identified as needed for the effective planning, operation and control of our processes, and

- Quality Records

### 4.2.2 Quality manual

This Quality Manual has been prepared to describe Centris Consulting's QMS. The scope of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section.

### 4.2.3 Control of documents

All of the QMS documents are controlled according to the Document Control Procedure (AP-423). This procedure defines the process for:

- Approving documents for adequacy prior to issue

- Reviewing and updating as necessary and re-approving documents

- Ensuring that changes and current revision status of documents are identified

- Ensuring that relevant versions of applicable documents are available at points of use

- Ensuring that documents remain legible and readily identifiable

- Ensuring that documents of external origin are identified and their distribution controlled, and

- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose

### 4.2.4 Control of quality records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the Control of Quality Records Procedure (AP-424). This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

## Related Procedures

Document Control                 AP-423

Control of Quality Records     AP-424

# Section 5:  MANAGEMENT COMMITMENT

## 5.1 Management commitment

The Centris Senior Management Team has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct quarterly management reviews.
- Ensure the availability of resources.

## 5.2 Customer focus

Centris Consulting strives to identify current and future customer needs to meet customer requirements and exceed customer expectations.

Centris Senior Management Team ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization (SP-720).

## 5.3 Quality policy

Centris Senior Management Team ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is documented on A-500-001, Quality Policy.

## 5.4 Planning

### 5.4.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Objectives have been established for the Administrative Staff and for all Project Teams. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

### 5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

## 5.5 Responsibility, authority and communication

### 5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

### 5.5.2 Management representative

The QA/QC Coordinator has been appointed by Centris Consulting Senior Management Team as management representative. As management representative, they have the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

### 5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management

meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication.

## 5.6 Management review

### 5.6.1 General

Top management reviews the QMS quarterly at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

### 5.6.2 Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement

### 5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibilities for required actions are assigned to members of the management review team.  Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

## Related Procedures:

| | |
|---|---|
| Customer Related Processes | SP-720 |
| Management Responsibility | AP-500 |
| Planning of Product Realization Processes | MP-710 |

# Section 6: RESOURCE MANAGEMENT

## 6.1 Provision of resources

Centris Consulting has implemented a Quality Management System that complies with the ISO 9000: 2008 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

## 6.2 Human resources

### 6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

### 6.2.2 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure. (AP-622)

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

## 6.3 Infrastructure

To meet quality objectives and product requirements Centris Consulting has determined the infrastructure needed (EP-630). The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventive maintenance plans
- Security plans

- Safety plans

## 6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

## Related Documents

| | |
|---|---|
| Competence, Awareness and Training | AP-622 |
| Infrastructure | EP-630 |

# Section 7: PRODUCT REALIZATION

## 7.1 Planning of product realization

Quality planning is required before new services, products or processes are implemented. The quality planning may take place as a design project, or according to the Planning of Product Realization procedure (MP-710). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,

- Processes, documentation and resources required

- Verification, validation, monitoring, inspection and test requirements, and

- Criteria for product acceptance

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

## 7.2 Customer-related processes

### 7.2.1 Determination of requirements related to the product

Centris Consulting determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer

- Required for delivery and post-delivery activities

- Not stated by the customer but necessary for specified use or known and intended use

- Statutory and regulatory requirements applicable to the product

- Additional requirements determined by Centris Consulting

Customer requirements are determined according to the Customer Related Processes Procedure. (SP-720)

### 7.2.2 Review of requirements related to the product

Centris Consulting has a process in place for the review of requirements related to the product (SP-720). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined

- Contract or order requirements differing from those previously expressed are resolved

- Centris Consulting has the ability to meet the defined requirements

- Records are maintained showing the results of the review and any actions arising from the review

- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance

- When product requirements are changed, Centris Consulting communicates changes to relevant personnel and amends relevant documents

### 7.2.3 Customer communication

Centris Consulting has implemented an effective procedure (SP-720) for communicating with customers in relation to:

- Product Information

- Enquiries, contracts and order handling, including amendments

- Customer Feedback, including customer complaints

## 7.3 Design and Development

### 7.3.1 Design and development planning

The design and development procedure (EP-730) outlines the process for controlling the design and development process. The Project Team plans design and development according to this procedure. The design plan includes:

- Design and development stages

- Required design reviews

- Verification and validation methods appropriate to each design and development stage

- Responsibilities and authorities for design and development

- Identification of the technical interfaces required for the project

- Updating of the design plan as the project progresses

### 7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (EP-730). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements

- Applicable statutory and regulatory requirements

- Where applicable, information derived from previous similar projects

- Other requirements essential for design and development

### 7.3.3 Design and development outputs

Outputs of design and development are documented according to the Design and Development Procedure (EP-730). They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements

- Provide appropriate information for purchasing, production and for service provision

- Contain or reference product acceptance criteria

- Specify the characteristics of the product that are essential for its safe and proper use.

### 7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements

- Identify any problems and propose necessary actions

- Include representatives of functions concerned with the design and development stage being reviewed

### 7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Design and Development procedure (EP-730).

### 7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

### 7.3.7 Control of design and development changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

## 7.4 Purchasing

### 7.4.1 Purchasing process

A documented procedure (AP-740) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

### 7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including where appropriate:

- Requirements for approval of product, processes and equipment

- Requirements for qualification of personnel

- Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

### 7.4.3 Verification of purchased product

The Purchasing procedure (AP-740) describes the process used to verify that purchased product meets specified purchase requirements. If Centris Consulting or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

## 7.5 Production and Service Provision

### 7.5.1 Control of production and service provision

Centris Consulting plans and carries out production and service provision under controlled conditions according to documented procedure (MP-750). Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product

- The availability of work instructions

- The use of suitable equipment

- The availability and use of monitoring and measuring devices

- The implementation of monitoring and measurement

- The implementation of release, delivery and post-delivery activities

### 7.5.2 Validation of processes for production and service provision

Centris Consulting validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent

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only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Centris Consulting has documented the process for validation including:

- Defined criteria for review and approval of the processes

- Approval of equipment and qualification of personnel

- Use of specific methods and procedures

- Requirements for records

- Revalidation

### 7.5.3 Identification and traceability

Centris Consulting identifies the product throughout product realization according to the Identification and Traceability procedure (MP-753). Product is identified with respect to monitoring and measurement requirements.

Centris Consulting controls and records the unique identification of the product where ever traceability is a specified requirement

### 7.5.4 Customer property

Centris Consulting exercises care with customer property while it is under the organization's control or being used. A procedure (MP-754) outlines the Identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

### 7.5.5 Preservation of product

Centris Consulting preserves the conformity of product during internal processing and delivery to the intended destination per procedure (MP-755). This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

## 7.6 Control of monitoring and measuring equipment

Centris Consulting has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. A documented procedure (MP-760) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards

- Adjusted or re-adjusted as necessary;

- Identified to enable the calibration status to be determined;

- Safeguarded from adjustments that would invalidate the measurement result;

- Protected from damage and deterioration during handling, maintenance and storage.

In addition, Quality Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Centris Consulting takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

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

## Related Documents

Planning of Product Realization Processes MP-710

| | |
|---|---|
| Customer Related Processes | SP-720 |
| Design and Development | EP-730 |
| Purchasing | AP-740 |
| Control of Production and Service Provision | MP-750 |
| Identification and Traceability | MP-753 |
| Customer Property | MP-754 |
| Preservation of Product | MP-755 |
| Control of Monitoring and Measuring Equipment | MP-760 |

## Section 8: MEASUREMENT, ANALYSIS AND IMPROVEMENT

## 8.1 General

Centris Consulting has plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity of the product,

- To ensure conformity of the quality management system, and

- To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

## 8.2 Monitoring and Measurement

### 8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Centris Consulting monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Related Processes (SP-720) and the Management Responsibility procedures (AP-500).

### 8.2.2 Internal Audit

Centris Consulting conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization

- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (QP-822).

The management responsible for the area being audited is responsible for ensuring that any necessary corrections and corrective actions are taken without undue delay

to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

### 8.2.3 Monitoring and measurement of processes

Centris Consulting applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes (MP-824) and Management Responsibility procedures (AP-500).

### 8.2.4 Monitoring and measurement of product

Centris Consulting monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Monitoring, Measuring and Analysis of Product Realization Processes (MP-824).

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

## 8.3 Control of Nonconforming Product

Centris Consulting ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (QP-830).

## 8.4 Analysis of Data

Centris Consulting determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in the Management Responsibility procedure (AP-500). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

- Customer satisfaction

- Conformance to product requirements

- Characteristics and trends of processes and products including opportunities for preventive action

- Suppliers

## 8.5 Improvement

### 8.5.1 Continual improvement

Centris Consulting continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### 8.5.2 Corrective action

Centris Consulting takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QP-852) 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), and

- Reviewing the effectiveness of the corrective action taken.

### 8.5.3 Preventive action

Centris Consulting determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (QP-853) 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

- Reviewing the effectiveness of the preventive action taken

## Related Documents

| | |
|---|---|
| Management Responsibility | AP-500 |
| Customer Related Processes | SP-720 |
| Monitoring, Measuring and Analysis of Customer Satisfaction | AP-821 |
| Internal Audits | QP-822 |
| Monitoring and Measuring of Product and Realization Processes | MP-824 |
| Control of Nonconforming Product | QP-830 |
| Corrective Action | QP-852 |
| Preventive Action | QP-853 |

*Any revisions to this manual shall be documented and recorded below:*

## QUALITY SYSTEM MANUAL REVISIONS

| REV. | SECTION | SUB-SEC. | PARA. | CHANGE REQUEST # | DATE | AUTHORIZED BY |
|------|---------|----------|-------|------------------|------|---------------|
|      |         |          |       |                  |      |               |