



# **Corporate Quality Manual**

*For:*

**Regulatory Compliance Services**

*At:*

**1113 Busch Center Park  
Worthington, Ohio 43229-0469**

**Revised: August 2003**

## Table of Contents

	<u>Page</u>
<b>Introduction .....</b>	<b>1</b>
<b>Quality Manual Distribution .....</b>	<b>2</b>
<b>Company Organizational Chart.....</b>	<b>3</b>
<b>1.0 Scope .....</b>	<b>4</b>
1.1 General .....	4
1.2 Mission Statement.....	4
<b>2.0 Quality Management Systems References.....</b>	<b>5</b>
<b>3.0 Terms .....</b>	<b>6</b>
3.1 Quality.....	6
3.2 Definitions.....	6
<b>4.0 General Requirements .....</b>	<b>9</b>
4.1 General Requirements.....	9
4.2 Documentation Requirements.....	9
4.2.1 General.....	9
4.2.2 Quality Manual.....	9
4.2.3 Control of Documents .....	10
4.2.4 Control of Quality Records.....	10
4.3 Related Documents.....	10
Consulting Flow Diagrams .....	11
<b>5.0 Management Responsibility .....</b>	<b>13</b>
5.1 Management Commitment .....	13
5.2 Customer focus.....	13
5.3 Quality policy .....	13
5.4 Planning .....	14
5.4.1 Objectives .....	14
5.4.2 Corporate Quality Manual planning .....	14
5.5 Responsibility, authority, and communication.....	14
5.5.1 Responsibility and authority.....	14
5.5.2 Management responsibility .....	14
5.5.3 Internal communication .....	15
5.6 Management review .....	15
5.6.1 General.....	15
5.6.2 Review input.....	15
5.6.3 Review output.....	15
5.7 Related Documents.....	16

<b>6.0 Resource Management</b> .....	<b>17</b>
6.1 Provision of resources .....	17
6.2 Human Resources .....	17
6.2.1 General.....	17
6.2.2 Competence, awareness, and training.....	17
6.3 Infrastructure .....	17
6.4 Work Environment.....	17
6.5 Related Documents.....	18
<b>7.0 Product Realization</b> .....	<b>19</b>
7.1 Planning of Product Realization.....	19
7.2 Customer-related processes .....	19
7.2.1 Determination of customer requirements .....	19
7.2.2 Review of requirements related to the product .....	19
7.2.3 Customer communication.....	20
7.3 Production and service provisions .....	20
7.3.1 Control of production and service provisions.....	20
7.3.2 Validation of processes for production and service provisions .....	21
7.3.3 Identification and traceability.....	21
7.4 Control of monitoring and measuring .....	21
7.5 Related Documents.....	21
<b>8.0 Measurement, Analysis, and Improvement</b> .....	<b>22</b>
8.1 General .....	22
8.2 Monitoring and Measurement .....	22
8.2.1 Customer Satisfaction.....	22
8.2.1.1 Contract Fulfillment .....	22
8.2.2 Internal Audit .....	22
8.2.3 Monitoring and measurement of processes .....	23
8.2.4 Monitoring and measurement of records .....	23
8.3 Control of Non-Conformance .....	23
8.4 Analysis of Data.....	23
8.5 Improvement.....	24
8.5.1 Continual improvement .....	24
8.5.2 Corrective action.....	24
8.5.3 Preventive action.....	25
8.5.4 Related Documents .....	25



## Introduction

Regulatory Compliance Services, Inc. has developed and implemented a Corporate Quality Manual 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 manual is divided into seven sections. Each section begins with a policy statement expressing Regulatory Compliance Services, Inc.'s obligation to implement the basic requirements of the referenced Corporate Quality Manual 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 Corporate Quality Manual, 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 Corporate Quality Manual to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through various requirements 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 document is used externally to introduce our Corporate Quality Manual to 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 Corporate Quality Manual is maintained and focused on customer satisfaction and continuous improvement.

*President:* \_\_\_\_\_



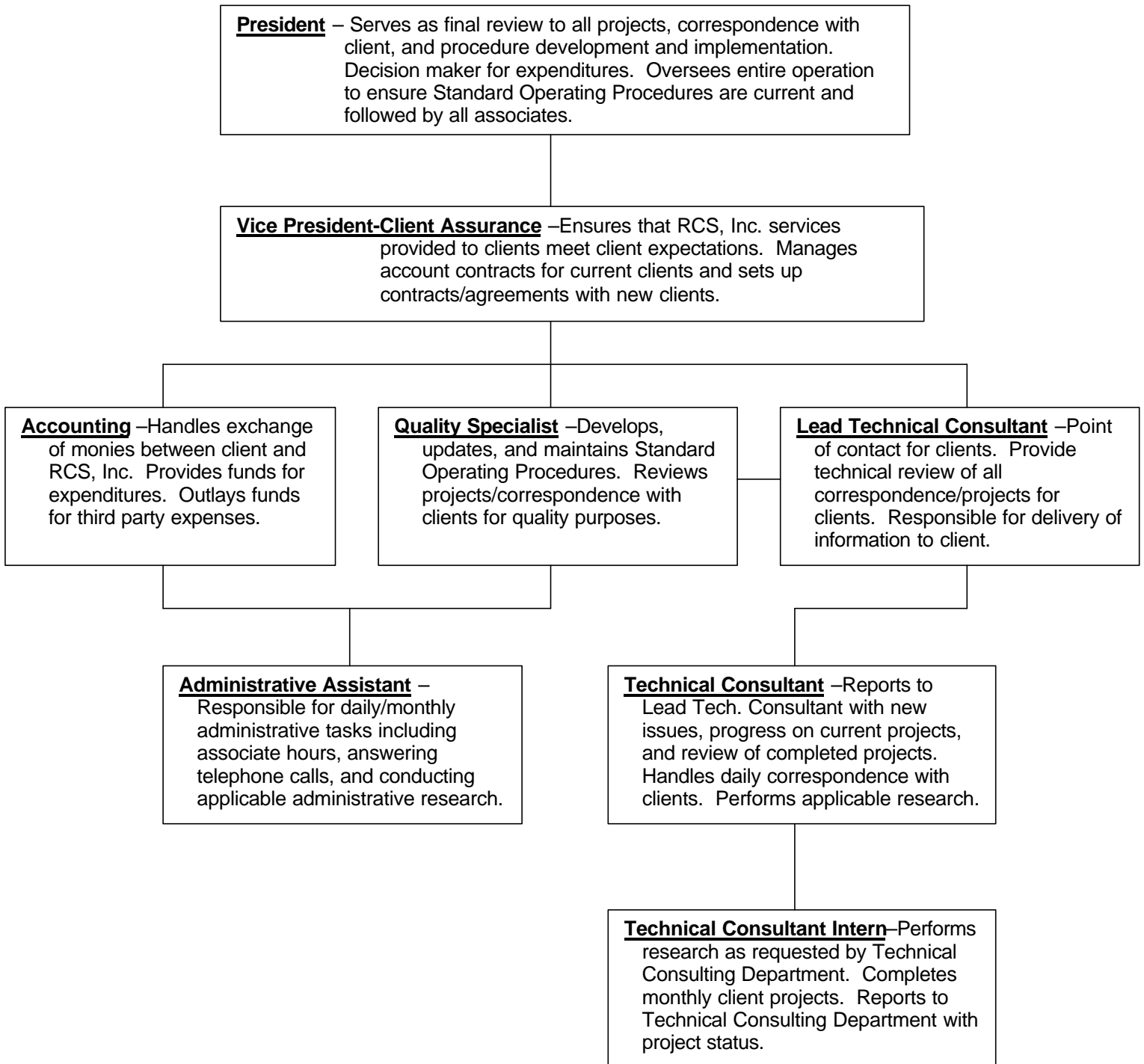
## Quality Manual Distribution

**This Quality Manual shall be distributed to the following:**

- President
- Vice President
- Customer Service
- Engineering Manager
- Finance
- Human Resources
- Management Representative
- Marketing Manager
- Operations
- Purchasing
- Quality Manager
- Sales Engineer



## Company Organizational Chart



# Section 1:

## Scope



## **1.0 Scope**

### **1.1 General**

The RCS, Inc. Quality Manual outlines the policies, procedures and requirements of the Corporate Quality Manual. These policies, procedures, and requirements apply to all aspects of business, including marketing, sales, consulting services, customer relations, accounting, and warehousing.

### **1.2 Mission Statement**

Regulatory Compliance Services, Inc. is a full-service regulatory / environmental, health and safety consulting firm. Our objective is to continuously improve the quality of all our services and processes to meet every clients requirements and exceed expectations, to minimize our costs and maximize our client's competitive position. Quality is recognized at Regulatory Compliance Services, Inc. as every associate's responsibility. It is designed into our services and inherent in our corporate culture.

# **Section 2:**

## **Quality Management System 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 Q9000-2000, Quality Management Systems - Vocabulary.
- American National Standard ANSI/ISO/ASQ Q9001-2000, Quality Management Systems – Requirements
- American National Standard ANSI/ISO/ASQ Q9004-2000, Quality Management Systems – Guidelines for performance Improvements
- Goetsch, David L and Davis, Stanley B. *Total Quality Handbook*, 2001, Columbus, Prentice Hall.
- Hughes, William, Total Quality Management. Course Notes and personal discussion, Winter 2003.
- Zuckerman, Amy, *ISO 9000 Made Easy: A Cost Saving Guide to Documentation and Registration*. New York, Amacom, 1995.

# Section 3: Terms

## 3.0 Terms

### 3.1 Quality

Quality is an ambiguous term that can not be defined by a single word, or even a group of words. It is a concept, a philosophy, and a way of life that defines one (as a person or a company) in terms of one's commitment to excellence. Quality is ultimately defined by the customer, which places a strong emphasis on customer satisfaction.

Quality uses many tools to reach the ultimate goal of satisfying the customer, every time. Continuous improvement, education, and training are essential to the quality philosophy. Standardization and consistency are critical; therefore, Standard Operating Procedures are at the core of quality. A quality program must utilize many scientific tools to track company progress in terms of quality.

If a quality program is going to be successful, it must be supported and implemented through the entire company, starting with management.

### 3.2 Definitions

- ANSI Z400- The American National Standard for preparing an MSDS that is complete with the basic information that complies with the OSHA Hazardous Communication Standard. Some information included in a MSDS consists of product name, chemical composition, first aid measures and, disposal considerations.
- Compliance audit- Identifies hazards that are regulated by the following agencies: OSHA, EPA, DOT, NFPA and local and federal government. Audits include employee training for safety.
- Contingency Plan- A document of guidelines issued by the DOT and EPA for the management and disposal of hazardous waste at a facility. Although the facility is responsible for the compliance with environmental regulations, RCS inc. provides guidance to the company in waste management activities and decisions. This document describes the hazardous waste management program at a facility by offering detailed procedures regarding handling, storage, labeling, and disposal requirements for hazardous waste.
- DPCC/DCR- Discharge Prevention, Containment and Countermeasure Plan/Discharge Cleanup and Removal Plan are reports that describe the storage, facility complex, maintenance procedures, training procedures, SOPs, and contact information in the event of an accident.

- Management Level HM-126F – Specific training is intended to teach the necessary knowledge, skills, and abilities for an individual that is involved in a specific job function. Although specific training will vary depending on the individuals involvement in the transportation cycle, the following are some potential training groups: shipping, handling/storage, clerical/driver, dispatch, sales, laboratory/research/development, training/safety department, administrative/management, mechanics, production, and purchasing.
- Process Safety Management – This plan ensures the safety of the facility’s employees. Standard operating procedures, operator training process, and hazard analysis are included in this plan that follows OSHA guidelines. PSM plans are reviewed on an annual basis.
- Risk Management- A plan of action taken by an operator at a facility that makes the supervisor responsible for enforcing the regulations and guidelines of their Risk Management Plan. This plan includes SOP’s, process safety information, operator training, and management of change. These regulations are intended to protect employees from harm in the workplace and the environment. RCS Inc. professionals develop Risk Management Plans that met or exceed EPA requirements. RMPs are reviewed on an annual basis.
- Safety Plans- Health and safety is the first concern in a workplace. The state and federal governments provide laws that require business to train and make hazards noticeable to employees. RCS assists in development of Safety Plans and in training and safety awareness. Safety plans follow OSHA regulations and provide guidance in recording accidents.
- Site Feasibility Studies - Phase I To assess environmental impacts that may affect a site. This report includes observes potential impacts to a site that may alter the sites ecology, environmental, functional use or economic value. This report is based on ASTM’s (American Society for Testing Methods) standard practices for environmental assessment process. RCS inc. performs a walk-through investigation to assess a site’s current operations. Visual observations include the site’s buildings and property as well as the adjacent property uses and conditions from public right of ways. Phase I also reviews state and federal agency database records.
- Site Feasibility Studies-Phase II- To assess environmental impacts that may affect a site. This report includes any observed potential impacts to the sites ecology, environment, functional use or economic value It documents visual observations and inquiry into public records only. This report is based on ASTM practice for the Phase II Report process and follows the guidelines established by ASTM. RCS inc. evaluates environmental concerns, evidence of hazardous disposal or release from

or onto the property, evidence of environmental threats from adjacent properties, and recommendations for the abatement of any soil or water that's known to be contaminated. This report meets and exceeds ASTM standards. Testing of soil and visual observations are used to render technical opinion.

- Standard Operating Procedures (SOPs) – Controlled and documented processes that delineate the responsibilities and expected outcomes for each process that takes place at the RCS facility. SOPs must be approved by management and distributed to each associate, who must sign off to indicate understanding of the contents.
  
- Warehouse Level HM-126F – General awareness training programs associated with the transportation of hazardous materials. The DOT requires any worker involved with hazardous material transportation to have a general awareness and follow training procedures provided by the employer. This training program is to aid in meeting the initial requirement of hazmat awareness. Additional training may be required for some employees depending on their job function.

# **Section 4: General Requirements**

## **4.0 General Requirements**

### **4.1 General requirements**

Regulatory Compliance Services, Inc. has established, documented and implemented a Corporate Quality Manual (CQM) in accordance with company requirements. The Manual is maintained and continually improved using company objectives, data analysis, corrective and preventive action and routine Manual reviews.

To design and implement the Corporate Quality Manual, Regulatory Compliance Services, Inc. has:

- Reviewed all processes and procedures and documented them in Standard Operating Procedures.
- Provided sufficient training to ensure associates are knowledgeable of the SOPs and Quality Manual and capable of performing all tasks required as a condition of employment.
- Ensured the 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
- Established processes to identify deficiencies and improve processes to ensure continual compliance and process improvement.

### **4.2 Documentation Requirements**

#### **4.2.1 General**

The CQM documentation includes:

- A documented Quality Policy
- Quality Manual
- Documented Standard Operating Procedures
- Quality Records

#### **4.2.2 Quality Manual**

This Quality Manual has been prepared to describe RCS, Inc.'s Corporate Quality Policy. The scope and permissible exclusions of the CQP are described in Section One of this manual. Each section of the manual references documented procedures relating to the requirements outlined in that section. The Process Flow Diagram provides a description of the interaction between the processes of the Quality system

### **4.2.3 Control of documents**

All of the CQM documents are controlled according to the Q0301 - Document Control SOP. This procedure defines the process for:

- Document approval
- Document review and updates, and re-approval of revised documents
- Identification of changes and current revision status of documents
- Ensuring that current versions of applicable documents are available at workstations
- Ensuring that documents of external origin are identified and their distribution controlled
- Preventing the unintended use of obsolete documents and proper identification of obsolete documents if they are retained for any reason

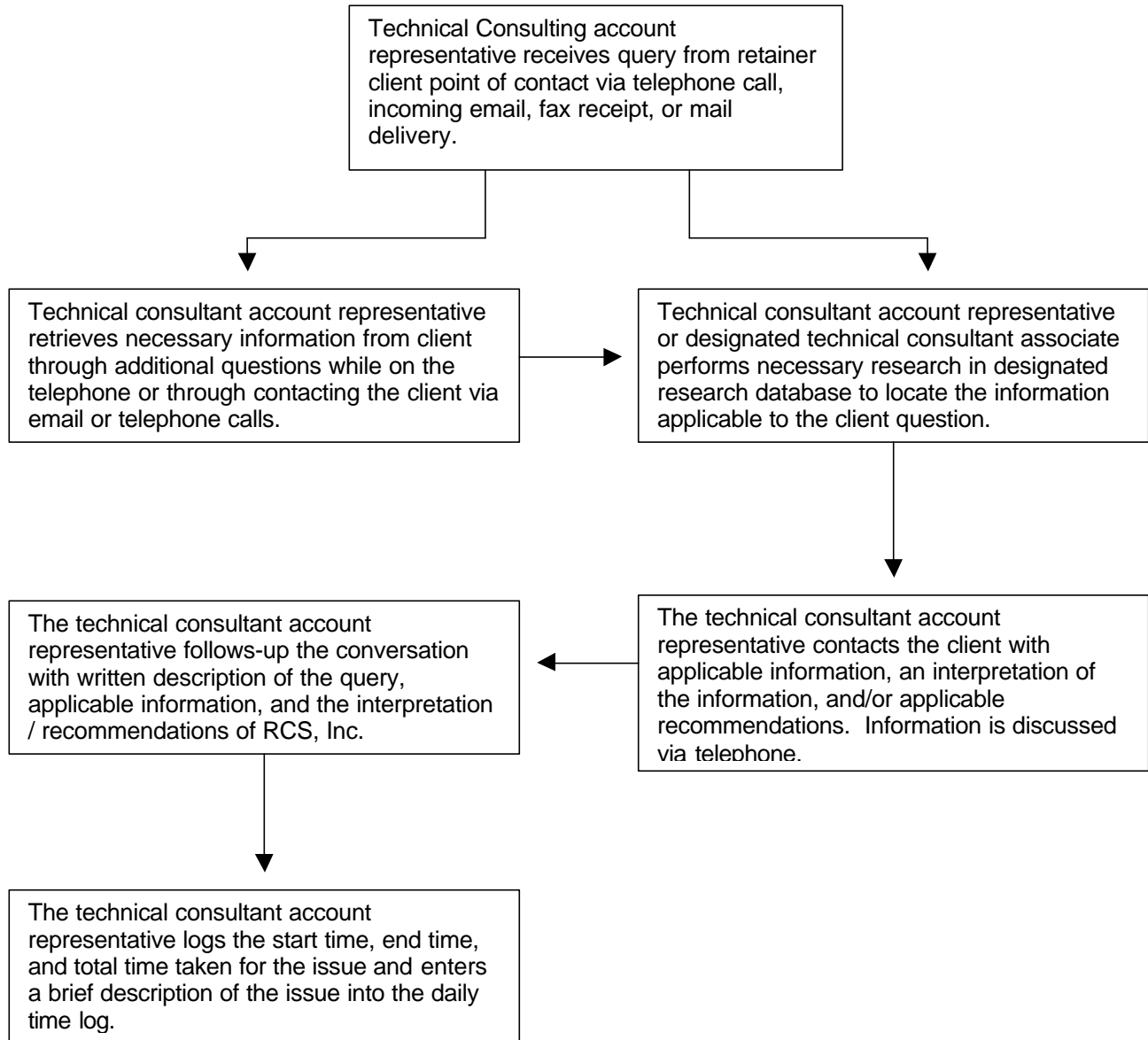
### **4.2.4 Control of quality records**

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the CQM. The records are maintained according to the Q0303 - Control of Quality Records SOP. 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.

### **4.3 Related Procedures**

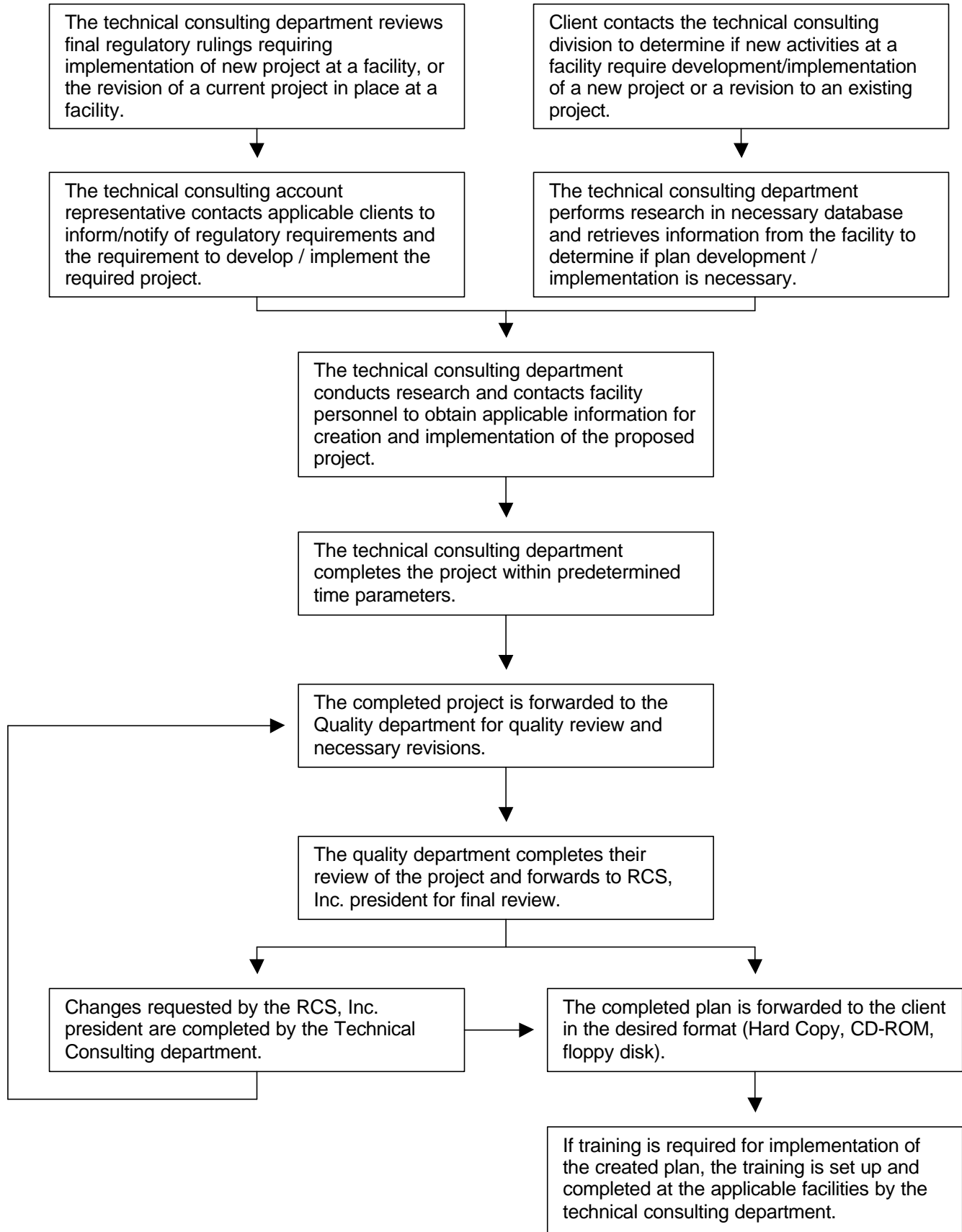
- Q0301 – Document Control
- Q0303 – Control of Quality Records

## RCS, Inc.-Ohio Consulting Flow Diagram – Retainer Client Queries





## RCS, Inc.-Ohio Consulting Flow Diagram – Project Completion



# **Section 5: Management Responsibility**

## **5.0 Management Responsibility**

### **5.1 Management commitment**

The quality aspect of the RCS business has been ingrained in the corporate philosophy since the beginning of the company. Management is aware that quality standards are going nowhere but UP in the upcoming years, and they are highly committed to raising the bar for everyone else.

RCS, Inc. management has been actively involved in development and implementation of the Corporate Quality Manual (CQM). They have provided the vision and strategic direction for the growth of the CQM, and established quality objectives and the quality policy.

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

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

### **5.2 Customer focus**

Regulatory Compliance Services, Inc. continuously strives to identify current and future customer needs, meet customer requirements and exceed customer expectations.

External as well as internal customers are at the center of all operations. Without satisfied external customers, RCS would not exist. Without satisfied internal customers, RCS would not function as needed to satisfy external customers and continually exceed their expectations.

RCS, Inc. management ensures that customer requirements are understood and met, by requiring compliance with all Standard Operating Procedures (SOPs). Through these SOPs, customer requirements are determined, converted into internal requirements, and communicated to the appropriate associates within the organization.

### **5.3 Quality policy**

RCS, Inc. management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the CQM.

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 Q0300 - Quality Policy.

## **5.4 Planning**

### **5.4.1 Quality Objectives**

Our goal for Regulatory Compliance Services, Inc. is to be regarded as the world leader in the quality of Hazardous Material Logistics, Environmental, Health / Safety, and Code management systems. To achieve this goal, we will supply our clients with the means to self-regulate and thus limit costly government involvement.

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. These quality objectives are measurable, and are reviewed against performance goals at each management review meeting.

### **5.4.2 Corporate Quality Manual planning**

The quality system has been planned and implemented to meet company quality objectives. Quality planning occurs whenever changes that affect the quality system are identified 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 management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located on the third page of this manual.

### **5.5.2 Management Representative**

The Quality Specialist has been appointed by RCS management as a management representative. As management representative, the Quality Specialist has the following responsibility and authority:

- Ensure that processes needed for the Corporate Quality Manual are established and implemented.
- Report to top management on the performance of the Corporate Quality Manual, 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 CQM.

### **5.5.3 Internal Communication**

Processes are established for communication within the organization. Methods of communicating the effectiveness of the CQM include weekly departmental meetings, distribution of meeting minutes to all interested parties, management review of proposed procedures and procedural changes, regular management meetings, and regular business correspondence.

## **5.6 Management review**

### **5.6.1 General**

RCS, Inc. management reviews the CQM regularly at management review meetings. This review assesses the continuing CQM 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 CQM is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the Corporate Quality Manual
- Recommendations for improvement

### **5.6.3 Review Output**

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

- Improvement of the effectiveness of the Corporate Quality Manual and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibility for required actions is 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.

### **5.7 Related Procedures**

- Q0305 – Management Responsibility

# **Section 6:**

# Resource Management

## **6.0 Resource Management**

### **6.1 Provision of resources**

Regulatory Compliance Services, Inc. has implemented this Corporate Quality Manual to comply with company requirements. Implementation was achieved with management commitment and sufficient resources. 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 personnel, job descriptions have been prepared to identify the qualifications required for each position that affects 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. Management maintains 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 Q0310 – Training.

### **6.3 Infrastructure**

To meet quality objectives and product requirements Regulatory Compliance Services, Inc. has determined and provided necessary infrastructure items, such as buildings, workspace, 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 on site, and include the following:

- Preventive maintenance plans
- Building maintenance 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 maintained to

ensure a safety. Continuous evaluation takes place to determine ongoing facility suitability.

### **6.5 Related Procedures**

- W0102 – Building Exterior and Grounds Maintenance
- W0107 – Housekeeping
- W0109 – Interior Building Maintenance
- Q0310 - Training



# **Section 7:** Product Realization

## **7.0 Product Realization**

### **7.1 Planning of product realization**

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to Q0309 - Planning of Product Realization. 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
- 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 customer requirements**

Regulatory Compliance Services, Inc. determines customer requirements before completion of a project proposal. 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 related to the product
- Additional requirements determined by Regulatory Compliance Services, Inc.

#### **7.2.2 Review of requirements related to the product**

Regulatory Compliance Services, Inc. conducts a review of project requirements prior to commencement of a project. This ensures that:

- Project requirements are defined
- Requirements differing from those previously expressed are resolved

- Regulatory Compliance Services, Inc. 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, Regulatory Compliance Services, Inc. communicates changes to relevant personnel and amends relevant documents

### **7.2.3 Customer communication**

Regulatory Compliance Services, Inc. is committed to maintaining open lines of communication between RCS, Inc. and its customers. All associates are responsible for providing a positive customer experience with each communication, however RCS Client Assurance Associates are dedicated to handling the following:

- Inquiries and contracts
- Project Management
- Customer Feedback, including customer complaints

## **7.3 Production and Service provision**

### **7.3.1 Control of production and service provision**

Regulatory Compliance Services, Inc. plans and carries out project completion under controlled conditions according to documented procedures. 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

### **7.3.2 Validation of processes for production and service provision**

Regulatory Compliance Services, Inc. validates any processes for project completion where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Regulatory Compliance Services, Inc. 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

### **7.3.3 Identification and traceability**

Regulatory Compliance Services, Inc. identifies the product throughout project completion according to project specifications. Each project is identified with a unique item number that is logged in the Master Document List.

## **7.4 Control of monitoring and measuring devices**

Regulatory Compliance Services, Inc. has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure (Q0308) 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.

Quality Control assesses and records the validity of the previous results, and takes appropriate action to adjust measurement methods when necessary.

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.

## **7.5 Related Documents**

- Q0308 – Measuring, Monitoring, and Analysis
- Q0309 – Planning of Product Realization

# **Section 8:** Measurement, Analysis, and Improvement

## **8.0 Measurement, Analysis and Improvement**

### **8.1 General**

Regulatory Compliance Services, Inc. plans and implements monitoring, measurement, analysis and improvement processes as needed

- To ensure conformity of the Corporate Quality Manual
- To continually improve the effectiveness of the Corporate Quality Manual

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 Corporate Quality Manual, Regulatory Compliance Services, Inc. monitors information relating to customer perception as to whether the organization has fulfilled customer requirements.

##### **8.2.1.1 Contract Fulfillment**

On a quarterly basis, each contract is reviewed by the Quality Department to ensure all compliance to contractual obligations. If any contractual obligations are found to be outstanding, correspondence is initiated with the client to determine the status and need for fulfillment of such obligations.

#### **8.2.2 Internal Audit**

Regulatory Compliance Services, Inc. conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements 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 Q0307 – Internal Audits.

Management in charge of the area being audited is responsible for ensuring that 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.

In the case of a process failure, a CPAR (Corrective / Preventive Action Request) is submitted according to Q0304 and Q0306, Corrective and Preventive Action procedures. The failures are thoroughly investigated, and the results are forwarded to management for review. As a result of investigative findings, process are changed as necessary.

### **8.2.3 Monitoring and measurement of processes**

Regulatory Compliance Services, Inc. applies methods for monitoring and measurement, where applicable, of the Corporate Quality Manual processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure compliance with the quality policy. The process for identifying and carrying out the required monitoring and measuring of processes is documented in Q0308 – Monitoring, Measuring and Analysis, and Q0305 - Management Responsibility procedures.

### **8.2.4 Monitoring and Measurement Records**

Evidence of conformity with the acceptance criteria is maintained. Records are maintained to indicate the person(s) 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 deemed applicable by the customer.

## **8.3 Control of Non-conformance**

Regulatory Compliance Services, Inc. is an organization that has dedicated itself to providing expert consulting services to customers in need of regulatory assistance. As such, non-conformity is not acceptable. All projects are reviewed by management before being released to the next department involved in the project. If non-conformity is discovered at any time during the process, the project is immediately returned to the responsible department for correction. The non-conforming product is destroyed or identified and controlled to prevent its unintended use or delivery.

## **8.4 Analysis of Data**

Regulatory Compliance Services, Inc. determines, collects and analyzes 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 Q0305 – Management Responsibility. 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**

Continual improvement is emphasized, in regards to documentation as well as associate education and training.

Documents are reviewed on a regular basis to ensure they are kept current. Any changes to a procedure result in issuance of a revised Standard Operating Procedure. Training on the new procedure is completed if necessary. Associates are always encouraged to submit recommendations that will result in more efficient or cost effective task completion.

### **8.5.2 Corrective action**

Regulatory Compliance Services, Inc. takes action to eliminate any problems and non-conformities to prevent recurrence. Corrective actions are implemented as necessary when a non-conformance has been identified, by either a customer or an internal associate.

RCS SOP Q0304 – Corrective Actions defines requirements for

- Reviewing non-conformities (including customer complaints)
- Determining the causes of non-conformities
- Evaluating the need for action to ensure that non-conformities do not recur
- Determining and implementing action needed
- Records of the results of action taken

- Reviewing corrective action taken

### **8.5.3 Preventive action**

Regulatory Compliance Services, Inc. takes steps to eliminate the causes of potential non-conformities in order to prevent their occurrence.

RCS SOP Q0306 – Preventive Actions defines requirements for

- Determining potential non-conformities and their causes
- Evaluating the need for action to prevent occurrence of non-conformities
- Determining and implementing necessary actions
- Records of results of action taken
- Reviewing preventive action taken

### **8.6 Related Documents**

- Q0304 – Corrective Action
- Q0305 – Management Responsibility
- Q0306 – Preventive Action
- Q0307 – Internal Audits
- Q0308 – Measuring, Monitoring, and Analysis