ISO 9001:2008
The Standard for World-Class Quality

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THE HAND THAT GUIDES…

Change Management Consulting specializes in providing ISO 9001/QS-9000 implementation and training services. Our ISO/QS Solution® is an affordable, innovative turnkey approach that provides all the documentation, guidance and training required for successful registration. We will focus your entire team on process improvements and help you improve your business performance. Our competitive advantage is our proven ability to help organizations find a faster, smoother route to improvement and success.

Our associates represent a broad range of industries and average over twenty-five years of practical experience. Numerous and diverse organizations have relied on our guidance to design and deploy cost-effective, profit-enhancing management systems. Our clients acknowledge that our ISO/QS Solution® is an efficient, comprehensive and practical approach to securing registration. We think you will find the cost vs. benefit most appealing. And we guarantee registration.

OUR APPROACH TO REGISTRATION

We create client partnerships that ensure meeting the requirements of the standard in the shortest time frame possible. Our flexible approach is designed to move an organization quickly down the path of continuous improvement. We customize the implementation plan and process to meet your operating requirements and management objectives. It results in a quality management system that is robust, proactive, and drives business results. Advantages of the ISO/QS Solution® include:

- Flat fee pricing
- Unique gap analysis (state of readiness)
- Ability to achieve strategic and operational goals
- Process streamlining and continuous improvement
- Efficient documentation development
- Customer satisfaction/loyalty measurement process
- Better staff understanding of what is expected
- Buy-in and ownership by entire staff
- Reduced operating costs
- Registrar coordination
- Guaranteed compliance
- Post project support

ISO 9000 OVERVIEW

ISO 9000 is an international family of generic quality standards, originally published by ISO (International Organization for Standardization) in 1987, and updated in 1994 and again in 2000 and 2008.

This international standard has currently been adopted by over one-hundred nations. It specifies elements necessary for the foundation of a quality management system, but does not specify how the requirements are to be implemented. It does not replace product safety and regulatory standards or requirements.

A quality management system refers to the activities you carry out within your organization to satisfy customers and to create customer loyalty. Complying with the ISO 9001 standard does not indicate that every product or service meets the customers' requirements—only that the quality management system in use is capable of meeting them. That is why you must regularly assess customer satisfaction and loyalty, and constantly improve business processes. Your effort must result in a culture of *continual improvement*.

THE ISO 9000 CORE STANDARDS

The key standards within the ISO 9000 family of standards (ISO 9001:1994, ISO 9002:1994, and ISO 9003:1994) have been merged into a single ISO standard—ISO 9001:2000.

There are four core standards. ISO 9001 is a requirement standard. ISO 9000, ISO 9004, and ISO 19011 are guidelines. ISO 9001 describes *what* must be done to develop a quality management system, not *how* to set it up. The core standards are:

- **ISO 9000:2008** provides quality management principles and fundamentals, describes what the series is about, and lists basic definitions of terms for use by any organization.
- **ISO 9001:2008** states requirements for quality management systems when it is necessary to demonstrate that an organization is capable of effectively meeting customer and regulatory requirements.
- **ISO 9004:2008** provides guidance for establishing a quality management system that goes beyond ISO 9001 requirements to meet and exceed customer expectations efficiently.
- **ISO 19011** provides guidance on planning and conducting quality audits.

ISO 9001:2008 includes five primary clauses that contain 23 sub-clauses. These requirements specify what your organization must do to conform to the standard. Many of these requirements must be documented and controlled.

WHAT ARE THE KEY FEATURES OF ISO 9001:2008?

The changes are largely interpretive, and focus on terminology clarifications. No "shalls" (requirements) were added or removed. Among the key features are:

- Easier adaptation to a wider range of organizations
- Focus on a process approach, including a process model
- More consistent terminology (e.g. outsourcing, design considerations)
- Reduction in the amount of required documentation
- Enhanced compatibility with ISO 14001:2004
- Linkage of quality management system to organizational processes
- Continual improvement of the quality management system
- Significant emphasis on achieving customer satisfaction
- More pervasive training throughout the organization

The Standard has a new process-oriented structure. It includes a process model based on the Plan-Do-Check-Act cycle—a four-step process for quality improvement. It provides the framework for the product and/or service cycle, including management review and control.

The text of the standard is organized into four primary processes or clauses.

- Section 4. Quality management System
- Section 5. Management Responsibility
- Section 6. Resource Management
- Section 7. Product Realization
- Section 8. Measurement, Analysis, and Improvement

REQUIREMENTS AND FOCUS

The processes necessary to determine and meet customer requirements and to create a culture of continuous improvement—are to be planned, resourced, controlled, verified and improved. Our clients have always done it this way. The revised Standard emphasizes:

- **Greater Focus on the Customer**—organizations must determine customer needs and expectations and, as a new requirement, monitor customer satisfaction.

- **Measurable Objectives Must be Established**—increased emphasis is placed on the role of top management to develop and improve the system, integrate legal and regulatory requirements, and establish measurable objectives at appropriate levels.

- **Measurement and Continual Improvement is Required**—performance measurement and monitoring are new requirements. Data must be used to determine the performance of the quality system and to identify improvements.

- **Training Effectiveness Must be Evaluated**—evidence that training has been provided will not be enough. An evaluation of effectiveness is now required.

THE CMC 14-STEP ISO COMPLIANCE ROADMAP

The ISO/QS Solution® provides all the documentation, guidance, and training required for registration. Our process will speed you through the ISO journey—from start to finish—and in most cases have you ready for registration in 9 to 12 months. Mile markers include:

1. **Conduct Management Orientation (briefing)**
   Deliverable: Management Understanding of Registration Process and Commitment

2. **Perform Baseline Evaluation (gap analysis; includes documentation review)**
   Deliverable: Baseline Evaluation Report

3. **Facilitate Management Planning (assess resources and develop objectives)**
   Deliverable: Action Plan and Timeline

4. **Develop Responsibility Matrix (fixes accountability)**
   Deliverable: Responsibility Matrix (links the QMS element with the owner)

5. **Conduct ISO Awareness Training (for staff beginning with senior management)**
   Deliverable: Trained Staff With Clear Understanding of Their Personal Roles

6. **Develop Macro-Flowcharting (process mapping at organization level)**
   Deliverable: Macro-Flowchart of Company Operations

7. **Prepare Policy Documents (develop quality management system manual)**
   Deliverable: Draft Quality Manual

8. **Identify, Flowchart and Prepare System-Level Procedures (SLPs)**
   Deliverable: Flowcharts of Required SLPs and Completed Procedures

9. **Review and Recommend Changes to Work Instructions and Forms**
   Deliverable: Modified (streamlined) Work Instructions

10. **Coordinate Registrar Selection**
    Deliverable: Selected Registrar to Meet Your Organization's Requirements

11. **Support the Preparation of Audit procedures, Train Staff and Conduct Audits**
    Deliverable: Documented and Validated Internal Audit System

12. **Perform a Preassessment Evaluation**
    Deliverable: Audit Report Detailing Observations and Required Corrective Actions

13. **Take Corrective Action and Review Results**
    Deliverable: Corrective Action Review to Eliminate Nonconformities

14. **Provide Support During the Registration Audit**
    Deliverable: Continued Assistance Throughout the Registration Audit

THE REGISTRATION PROCESS

The ISO 9001 registration process is by facility—not by organization. Facilities become registered when their quality system is shown to meet the ISO 9001 standard in terms of documentation and performance.

Registration is carried out by accredited organizations (Registrars). There are three primary activities or services, both off- and on-site:

1. Stage 1 Audit: Review the facility's Level 1 & 2 documents, internal audit report and Management Review Minutes to ensure that these meet the Standard

2. Stage 2 Audit: Conduct a Registration Audit to verify compliance with the ISO 9001:2008 Standard

3. Conduct annual surveillance audits to ensure continued compliance

BENEFITS OF REGISTRATION

Our clients benefit from:

- A better understanding and consistency of all quality practices
- A trained workforce committed to continuous improvement
- Improved quality and operating efficiencies
- A streamlined set of processes (cost and cycle time reduction)
- Enhanced customer satisfaction and loyalty
- A more agile and competitive organization
- Increased market share and increased profits