

W H I T E P A P E R

ISO 9001:2000 Deficiencies and CMII Solutions

(Rev C)

Purpose of This White Paper

Organizations with Quality Management Systems certified to ISO 9001 continue to operate in the corrective action mode and struggle with configuration management issues. This white paper is in response to their request for help.

- *ISO (International Organization for Standardization)*
- *History of ISO 9000 and the ISO 9001 Model*
- *Questionable Benefits of ISO 9001 Certification*
- *How Quality Relates to Configuration Management*
- *Seven Key Observations Regarding ISO 9001:2000*
- *Industry Specific Adaptations of ISO 9000/9001*
- *Definitions: ISO 9001:2000 Versus CMII*
- *Provisions for CM Within ISO 9001:2000*
- *ISO 10007 Quality Management — Guidance for CM*
- *Conclusions and Recommendations*

©2008 Vincent C. Guess



**CMII
Research
Institute**



**Institute of
Configuration
Management**

ISO (International Organization for Standardization)

ISO is the source of the ISO 9000 family of quality management standards and some 15,000 other international standards. ISO is a network of National Standards Institutes from over 140 countries working in partnership with international organizations, governments and industry. ISO technical committee ISO/TC 176 Quality Management and Quality Assurance is responsible for developing and maintaining the ISO 9000 family. The ISO Central Secretariat is located in Switzerland.

Of all the Standards, ISO 9001 "Quality Management System — Requirements" is the best known. It is a standard against which an organization's quality management system can be certified. It is estimated that a million ISO 9001 certifications have been issued in 170 countries.

ISO does not certify organizations. Many countries have formed accreditation bodies to authorize certification bodies. Certification is a written assurance by an independent body that your quality management system conforms to the ISO 9001 requirements. Registration means that the auditing body has recorded your certification in its client register.

History of ISO 9000 and the ISO 9001 Model

Pre ISO 9000 — British Standard, BS 5750 required factories to "document what they do and do what they document."

ISO 9000:1987 — was derived from BS 5750 and is comprised of three models, 9001, 9002 and 9003. The 9001 model encompassed all phases of a product's life cycle. The other two were for specific segments.

ISO 9000:1994 — emphasizes preventive actions.

ISO 9001:2000 — combined 9001, 9002 and 9003 into one and emphasizes process management. It requires involvement by upper executives and continual improvement driven by process performance metrics.

Questionable Benefits of ISO 9001 Certification

Organizations that have obtained ISO 9001 certification did it for various reasons. For some, it was an opportunity to learn what a quality management system is supposed to be and hopefully impress potential customers. Its real value was otherwise not clear.

Meeting the requirements for certification may or may not have made them more competitive. There are surveys that claim it did and others that claim it didn't. There are authors who claim the return on investment is good and others who claim it isn't.

We conducted our own surveys. Since 1987, over 6,000 configuration management (CM) professionals from various industries in over 30 countries have completed our 12-day CMII training and certification program. Many are from organizations certified to ISO 9001. Some are PMP certified. Some are Six Sigma black belts. Some work in organizations at CMMI Level 5. Some work with ITIL, some with SPICE. Many work with hardware, many with software. All organizational levels are represented. They learned from us and we learned from them.

How Quality Relates to Configuration Management

CM professionals define quality as conformance to requirements. An organization whose products consistently conform to the requirements is much more competitive than one that operates in the corrective action mode. To know the product will be right (and appealing to the customer) begins with knowing the requirements are right.

Therein lies the challenge because everything exists in a state of change. An organization that cannot accommodate change and keep their requirements clear, concise and valid has no choice but to operate in the corrective action mode.

Requirements must lead and physical items must conform. A document that has not been validated cannot be released. A document that has not been released cannot be used. Most organizations cannot endorse these rules because a fast and efficient change process is a prerequisite. Such a change process is not an ISO 9001 requirement.

Seven Key Observations Regarding ISO 9001:2000

Observation #1: Most organizations operate in the corrective action mode and spend a huge portion of their resources on intervention (to rescue quality and schedule). Certification to ISO 9001 has not enabled a single organization to escape the corrective action mode.

Observation #2: ISO 9001 authors are adamantly against CM's definition of quality (conformance to requirements). Instead, they define quality as a desirable characteristic (or whatever the customer likes).

Observation #3: ISO 9001 states that continual improvement includes implementing corrective actions. ISO 9001 does not promote seeking out and eliminating the root causes for continuous corrective action.

Observation #4: If you do not distinguish between corrective action and real improvements, then you cannot distinguish between cost avoidance and cost reduction.

Observation #5: ISO 9001 emphasizes a process approach for transforming inputs into outputs and identifies 19 types of processes. The list of 19 processes does not include a change process.

Observation #6: ISO 9001 simply states that changes shall be identified, documented, controlled and approved before implementation — and references ISO 10007 Quality Management — Guidance for CM.

Observation #7: ISO 10007 represents the traditional approach to CM (MIL-STD-973) and organizations that try to use it only go deeper into the corrective action mode.

Industry-Specific Adaptations of ISO 9000/ISO 9001

AS 9100 is the Aerospace version of ISO 9000. TL 9000 is the Telecommunication version of ISO 9000. PS 9000 is the Pharmaceutical Packaging Materials version of ISO 9000.

QS 9000 was the original automotive version of ISO 9000 which has been replaced by ISO/TS 16949:2002 as derived from ISO 9001:2000. ISO 13485:2003 is the Medical industry's version of ISO 9001:2000.

Definitions: ISO 9001:2000 Versus CMII

Term	ISO 9001:2000	CMII
Procedures	Procedures control processes.	Procedures provide the how-to for preparing documents and forms and performing other administrative tasks.
Processes	Processes transform inputs into outputs. Processes can be administrative, agricultural, chemical, mechanical, electrical, government and so on.	Processes (or process plans) provide (work) instructions for performing work on physical items. Process plans are not used to perform administrative tasks.
Quality	Quality is a desirable characteristic.	Quality is conformance to requirements.
Corrective Action	Corrective action is steps taken to remove the causes for a nonconformity or to make quality improvements.	Corrective action is any effort required to correct or compensate for something that should not be necessary.
Continual Improvement	Continual improvement includes implementing corrective actions.	Continual improvements are "real" improvements. Continuous corrective action is not continuous improvement.
Cost Avoidance Vs Cost Reduction	There is no distinction between cost avoidance and cost reduction.	Cost avoidance is to avoid corrective action. Cost reduction is to make processes that work, work better.
Documents	Five types of documents include specifications, quality manuals, quality plans, records and procedures.	Documents include various types of specifications, drawings, bills of material, process plans, administrative procedures and service manuals.
Infrastructure	Infrastructure includes buildings, work spaces, equipment, utilities, transportation, communication and so on.	(Business process) infrastructure is the integration of CM-related processes and IT tools for accommodating change, keeping requirements clear, concise and valid, and achieving consistent conformance and continuous improvement.
Quality Manual	A quality manual documents an organization's quality management system.	Provisions for ensuring quality are incorporated into the organization's strategic business plan, core business processes, operating standards, process plans and procedures. A quality manual would be redundant.

Provisions for CM Within ISO 9001:2000

ISO 9001:2000 is subdivided into 8 sections and its provisions for configuration management are highlighted in the outline shown below.

Paragraph 7.3.7 Control of Changes includes a reference to ISO 10007:1995 Quality Management — Guideline for CM.

ISO 9001:2000 — Eight Sections

- 1 Scope**
- 2 Normative reference**
- 3 Terms and Conditions**
- 4 Quality Management System**
- 5 Management Responsibility**
 - .5 Administration**
 - .6 Control of documents** — A documented procedure shall be established to:
 - a) approve documents for adequacy prior to use
 - b) review, update as necessary and re-approve
 - c) identify the current revision status
 - d) control versions available at points of use
 - e) ensure documents are legible and identifiable
 - f) ensure control of external documents and
 - g) prevent unintended use of obsolete documents
- 6 Resource Management**
- 7 Product Realization**
 - .2 Customer-related processes**
 - .1 Identify customer requirements**
 - .2 Review product requirements**
 - .3 Design and/or development** — Design documents shall be approved prior to release
 - .3 outputs** — Ensure the output meets the design inputs
 - .5 verification** — Ensure product meets requirements for intended use
 - .6 validation** — Changes shall be identified, documented and controlled
 - .7 control of changes** — Changes shall be approved before implementation
NOTE: See ISO 10007 for guidance
 - .5 Production and service operations**
 - Identify the product by suitable means
 - Identify its status with respect to measurement
 - Unique identification when traceability is required
 - .2 Identification and traceability**
- 8 Measurement, Analysis and Improvement**

Except for the reference to ISO 10007 within ISO 9001:2000, provisions for CM are essentially unchanged from ISO 9001:1994.

ISO 10007 is also comprised of 8 sections (see page 7). The subparts under Sections 5 and 7 represent the traditional approach to CM.

The traditional approach to CM is also recognizable by the use of configuration Items, "fixed" baselines and deviations/waivers.

ISO 10007 Quality Management — Guidance for CM

The major activities of CM, per ISO 10007 are identification, change control, status accounting and audits. This traditional approach to CM was adopted from MIL-STD-973 Configuration Management (1992).

ISO 10007:1995 — 8 Sections

- 1 Scope** — may be tailored to suit individual projects.
- 2 Normative Reference**
- 3 Definitions**
- 4 Configuration Management System, Description and Objectives**
 - the main objective is to document and provide full visibility of the product's present configuration and the status of achievement of its physical and functional requirements — and that everyone working on the project at any time in its life cycle is using correct and accurate information
- 5 Configuration Management Process**
 - .2 CONFIGURATION IDENTIFICATION**
 - .1 Product Structure and Selection of Configuration Items**
 - .2 Documentation of Configuration Items**
 - .3 Numbering**
 - .4 Establishment of Configuration Baselines**
 - current approved configuration is approved baselines plus approved changes
 - .3 CONFIGURATION (CHANGE) CONTROL**
 - document and justify the change, evaluate its consequences, approve or disapprove the change, implement and verify the change, process deviations and waivers
 - .4 CONFIGURATION STATUS ACCOUNTING**
 - .5 CONFIGURATION AUDIT**
 - .2 Functional Configuration Audit**
 - .3 Physical Configuration Audit**
- 6 Organization of Configuration Management**
- 7 Configuration Management Procedures**
 - .2 Configuration Identification Procedures**
 - .3 Configuration Board**
 - .4 Configuration Control Procedure**
 - .5 Configuration Status Accounting Procedures**
 - .6 Configuration Audit Procedures**
 - .7 Configuration Management Plan** — tailored to the product or project.
- 8 Configuration Management System Audit**

Conclusions and Recommendations

A problem with quality is a problem with configuration management (CM). (Show me a quality problem and I will show you a CM problem). Fix CM and the quality problems go away.

The CM fix, however, must be the right fix. Traditional CM is not the right fix. The reference to ISO 10007 is a reference to traditional CM.

The right CM fix is CMII per the following definition:

CMII: A Highly Enhanced Version of Traditional CM

CM serves to manage products, facilities and processes by managing their requirements, including changes, and ensuring that results conform.

CMII expands the scope of CM to include all information that could impact safety, security, quality, schedule, cost, profit or the environment.

CMII also shifts the emphasis of CM and provides the how-to for:

- (1) accommodating change,
- (2) optimizing the reuse of standards and best practices,
- (3) ensuring that all requirements remain clear, concise and valid,
- (4) communicating (1), (2) and (3) to users promptly and precisely, and
- (5) achieving conformance to requirements in each case.

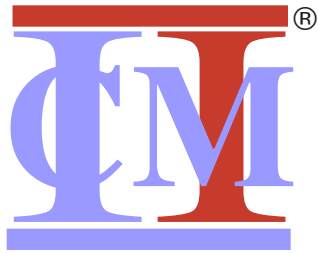
CMII promotes continuous improvement in (1) through (5).

The Institute of Configuration Management and the CMII Research Institute

It is concluded that the phenomenal growth of ISO 9000 since 1987 has been driven by hype and false hope. The deficiencies described in this white paper are real. What ISO 9001 needs is what CMII provides.

It is recommended that the deficiencies in ISO 9001:2000 not be carried forth into the ISO 9001:2008 upgrade. The Institute of Configuration Management and the CMII Research Institute are prepared to assist the ISO/TC 176 members ensure that ISO 9001:2008 is sound.

Our growing family of CMII grads have been making such improvements within their respective organizations for the past several years.



**Institute of
Configuration
Management**
www.icmhq.com



**CMII
Research
Institute**
www.cmiiresearch.com

by Vincent C. Guess
vince@cmiiresearch.com