WHITE PAPER

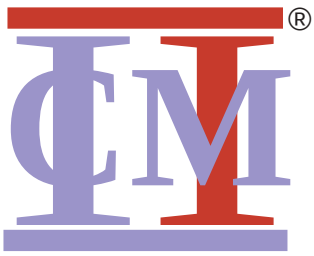
ISO 9001 and ISO 10007 Quality Management — Guidance for CM Relative to CMII

(Rev B)

SUMMARY — Provisions for controlling designs, documents and changes within ISO 9001 (2000) are unchanged from prior versions — except ISO 10007 is referenced as a guide for CM activities.

This guide, however, is limited to design definition and does not emphasize the ability to accommodate change. The viability of ISO 9001 is compromised accordingly.

ISO 9001 would be much more robust if its provisions for CM were upgraded per the CMII model.



Institute of Configuration Management

The Home of CMII

ISO 9001 QUALITY MANAGEMENT SYSTEMS & ISO 10007

Provisions for configuration management within ISO 9001 (2000) are highlighted within the following outline.

Paragraph 7.3.7 includes a note which references ISO 10007 (1995) *Quality Management — Guideline for CM*.

Provisions for CM Within ISO 9001 (2000)

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) ensure relevant versions available at points of use**
- **e) ensure documents are legible, identifiable and retrievable**
- **f) ensure control of external documents**
- **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

.3 outputs — **Design output documents shall be approved prior to release**

.5 verification — **Ensure the output meets the design or development inputs**

.6 validation — **Ensure that product meets requirements for intended use**

.7 control of changes — **Design changes shall be identified, documented and controlled**
Changes shall be approved before implementation
NOTE: See ISO 10007 for guidance

.5 Production and service operations

.2 Identification and traceability — **Identify the product by suitable means**
Identify its status with respect to measurement
Unique identification where traceability is required

8 Measurement, Analysis and Improvement

ISO 9001 (2000) replaces the 20-clause structure in ISO 9001 (1994) with eight sections that emphasize continuous process improvement.

Product realization (section 7) involves the interconnected processes required to start out with an idea and end up with a product.

Except for the reference to ISO 10007 (1995) within ISO 9001 (2000), provisions for CM are essentially unchanged from ISO 9001 (1994).

The content of ISO 10007 *Quality Management — Guideline for CM* is organized per the outline below.

Key points within the various sections that reveal the scope and emphasis of the configuration management process are highlighted.

ISO 10007 Quality Management — Guidance for CM

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

— approved baselines, plus approved changes, constitute the current approved configuration.

.3 CONFIGURATION CONTROL

— document and justify the change, evaluate the consequences of the change, 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 Procedures for Configuration Status Accounting

.6 Configuration Audit Procedures

.7 Configuration Management Plan — for a specific product or project.

8 Configuration Management System Audit

The primary objectives of CM, per ISO 10007, are 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.*

The CM process, per ISO 10007, is very similar to MIL-STD-973 *Configuration Management* (the traditional approach to CM).

ISO 10007 uses the same four basic functions — identification, configuration control, status accounting and audit — as the framework for CM activities.

Configuration Identification — *activities comprising determination of the product structure and selection of configuration items.*

Configuration Control — *after the initial release of configuration documents, all changes should be controlled.*

Configuration Status Accounting — *should provide information on all configuration identifications and all departures from the specified baselines.*

Configuration Audits — *performed before the acceptance of a configuration baseline to assure the product complies with its specified requirements and to assure the product is accurately reflected by its configuration documents.*

Structure of Configuration Management — *structure is normally project-related and adapted as necessary to meet the needs of the life cycle stages.*

It is noted that MIL-STD-973 evolved in a defense environment where the customer paid for development and took ownership of the design.

The change process therein was very formal and rigid and the scope was limited to design definition. Ability to accommodate change was not an objective.

With regard to CM, ISO 9001 (2000) and ISO 10007 (1995) have adopted the same scope and emphasis as found in MIL-STD-973 (1992).

The ideal CM process is that which can accommodate change and keep associated information clear, concise and valid. This emphasis is missing.

CM, AS REINVENTED, UNDER CMII

Configuration management is a multifaceted process with many elements. Those elements are often fragmented and may exist under various names.

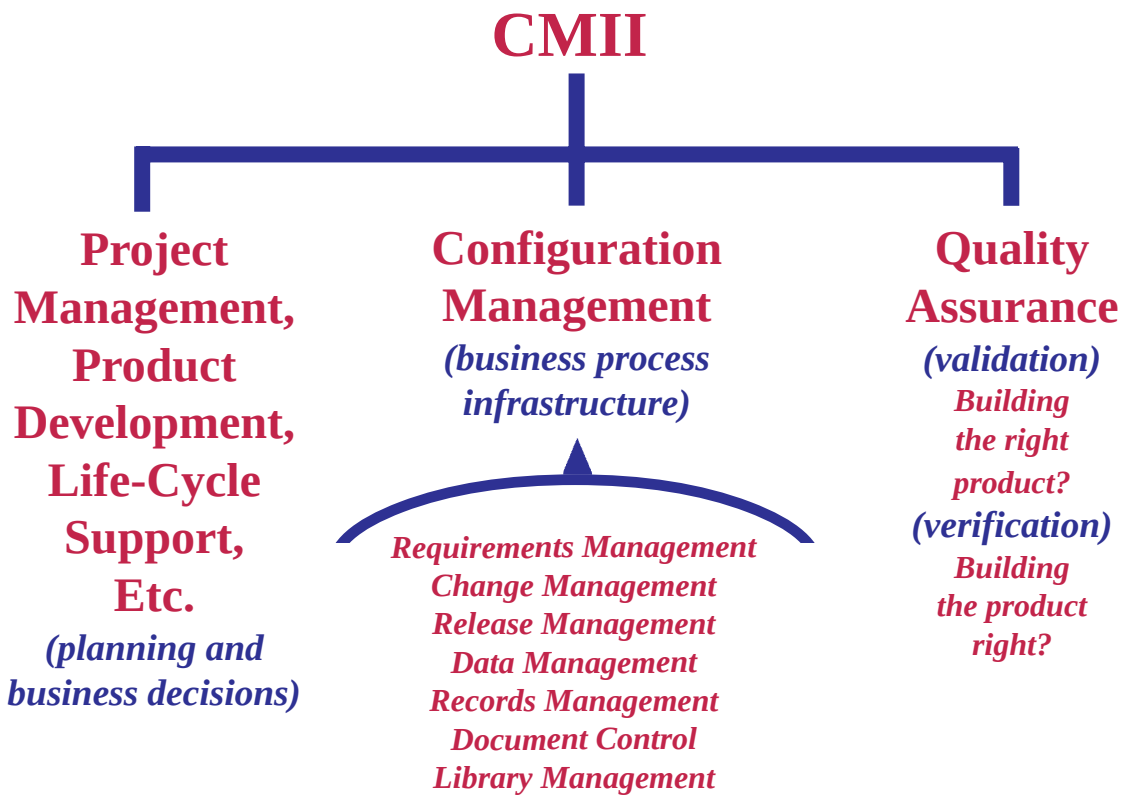
Each element is important in its own way. With CMII, they are brought together under one umbrella and integrated into one cohesive unit.

Overall effectiveness, before and after integration, is measured by the ability to accommodate change and keep released information clear, concise and valid.

As information integrity improves, the need for corrective action declines. As corrective action declines, real improvements become increasingly robust.

To "reinvent CM" is to provide a better *business process infrastructure* and thereby enable other core business processes to be more reliable and efficient.

The reinvented CM process provides an essential infrastructure that is missing in ISO 9001 (2000) and its referenced guide for CM, ISO 10007 (1995).



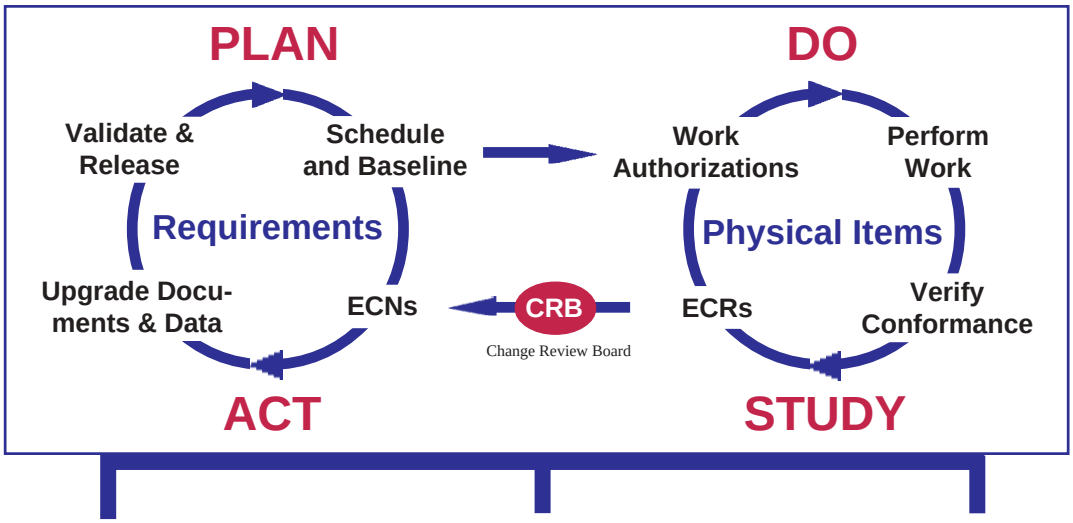
PROJECT MANAGEMENT: TWO CYCLES, NOT ONE

The project management cycle (plan, do, study and act) is ideal for demonstrating the proper role of CM and how key elements should be integrated.

First, it must be recognized that project management is two cycles, not one. A requirements cycle coexists with a physical item cycle.

The physical item cycle is driven by the requirements cycle. Quality assurance activities (validation and verification) have their proper place in each cycle.

Requirements must lead and physical items must conform. A fast and efficient change process is a prerequisite.



Project Management, Product Development, Life-Cycle Support, Etc.
(planning and business decisions)

Configuration Management
(business process infrastructure)

Requirements Management
Change Management
Release Management
Data Management
Records Management
Document Control
Library Management

Quality Assurance
(validation)
Building the right product?
(verification)
Building the product right?

KEYS TO CM AND INFORMATION MANAGEMENT

Again, a change process cannot be fast and efficient change if the information being changed is not properly identified, structured, linked and owned.

Baselines are the ideal place to maintain and display the structure for each model and the linkages from each item at each level to its supporting documents.

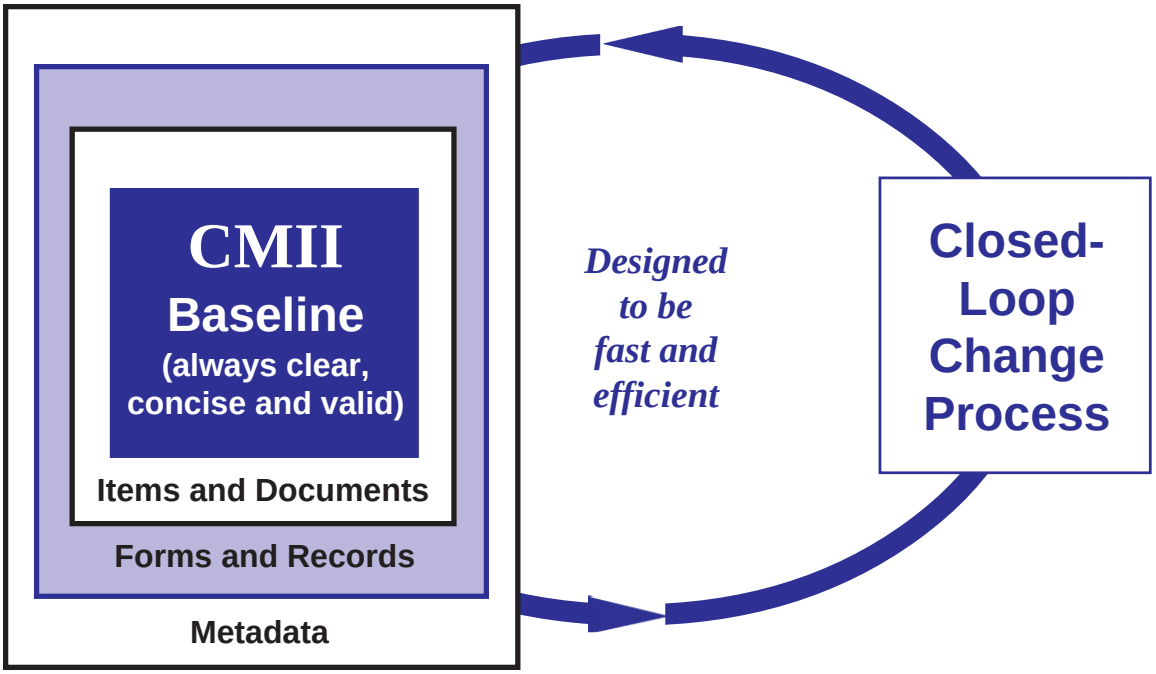
Physical item hierarchies provide the ideal framework for dividing huge amounts of design and process information into manageable increments.

Once baselines and their content are properly established, it is then possible to design the change process in a manner that optimizes speed and integrity.

The appropriate change process is closed-loop (to enhance integrity) and includes a fast-track feature (to enhance speed).

Speed and integrity are further optimized by ensuring that each information set is co-owned by its assigned creator and one or more designated users.

The potential benefits of ISO 9001 will remain compromised until its CM component is upgraded accordingly.



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