

White Paper
CMII 815B

**How CMII Can Further
Enhance ISO 9001:2008**



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Revision Record

<i>Revision</i>	A	B	
<i>Released by</i>	WWG	WWG	
<i>Release date</i>	12/29/09	05/17/10	
<i>Authority</i>	063-WP	063A-WP	
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Purpose of This White Paper

Certification to ISO 9001 does not, in itself, enable an organization to become lean and agile. This white paper describes the reasons and how CMII provides the missing elements and required infrastructure.

OUTLINE

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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. 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.

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.

ISO 9001:2008 — amended to clarify points in the text and enhance compatibility with Environmental Standard ISO 14001:2004.

CMII and ISO 9000 – Driven By the Same Issues

The first CMII certifications were awarded in 1987, the same year that ISO 9000 was initially released. Both were driven by a need to solve ongoing quality problems, missed schedules and cost overruns.

ISO 9001:1987 focused on procedures. ISO 9001:2008 focuses on processes and emphasizes the achievement of conformity to customer and regulatory requirements. CMII shares the focus of ISO 9001:2008.

Insight to the ISO 9001:2008 Approach

- *ensure product meets customer and regulatory requirements (1.1a);*
 - *enhance customer satisfaction by improving the system (1.1b);*
 - *document the quality management system (4.2.1);*
 - *establish and maintain a quality manual (4.2.2);*
 - *control documents (4.2.3) and records (4.2.4);*
 - *define the product and regulatory requirements (7.2.1);*
 - *control design and development changes (7.2.7);*
 - *maintain identification and traceability (7.5.3);*
- (NOTE: In some industry sectors, this task is performed by configuration management)*
- *take corrective action (8.5.2) and preventive action (8.5.3)*

Insight to the CMII Approach

The differences are in the how-to's. The ISO 9001:2008 approach is very high level. CMII gets into the details of how information is managed and how work is performed. What prevents results from being right the first time? How much is being spent on corrective action?

CMII premise: When information used to perform a task is clear, concise and valid, conforming results are the norm. If less than accurate, results are unpredictable. Correct information is essential. Documents must be clear, concise and valid. Records and data must be accurate.

Other discoveries: To achieve a high level of integrity, each information set must be properly owned, validated and baselined. To maintain a high level of integrity, the change process must be fast and efficient. Nearly every organization is grossly deficient in both areas. Both are the responsibility of configuration management (CM).

Corrective vs Preventive Action per ISO 9001:2008

ISO 9001:2008 8.5.2 Corrective Action

The organization shall take action to eliminate the causes for nonconformances in order to prevent reoccurrence.

ISO 9001:2008 8.5.3 Preventive Action

The organization shall determine action to eliminate the causes of potential nonconformances in order to prevent their occurrence.

Cost Avoidance vs Real Improvements per CMII

Cost avoidance is to avoid waste. A reduction in the resources being spent on corrective action is a cost avoidance. It is more than fixing something that should not need to be fixed. It includes any time spent in a state of uncertainty about what to do or how to do it.

Continuous corrective action is not continuous improvement. ICM surveys reveal that most organizations (including those certified to ISO 9001) operate in the corrective action mode and spend over 40% of their resources on intervention. The goal of CMII is to achieve consistent conformance and drive intervention resources to zero.

As corrective action declines, resources can focus on real improvements. A real improvement is to take something that already conforms and make it better. As the resources being spent on intervention decline, the rate of real improvements may become increasingly robust.

ISO 9001:2008: Key CM Elements Are Missing

The major difference between CMII and ISO 9001:2008 is in how requirements are stated. A requirement to control change is different from a requirement to accommodate change. Requiring documents to be legible is not the same as requiring them to be clear, concise and valid.

These capabilities reside in the domain of CM — which is more than identification and traceability. CM provides the framework for a business process infrastructure that can achieve the CMII requirements. The very important role that CM must play is missing from ISO 9001:2008.

ISO 9000:2008 — Key Phrases and Emphasis

The quality management system shall be documented.

The quality system must

- provide products that meet customer requirements;*
- be continually improved to enhance customer satisfaction.*

Documented procedures shall be established to ensure that

- documents remain legible and readily identifiable;*
- changes and the current version of documents are identified;*
- correct versions of documents are available at points of use.*
- records remain legible, readily identifiable and retrievable.*

The organization shall provide the needed infrastructure which includes buildings, workspace, process equipment, utilities and services.

Design and development planning requirements:

- inputs shall be reviewed for adequacy;*
- outputs shall be reviewed prior to release;*
- changes shall be reviewed and approved.*

CMII — Key Phrases and Emphasis

Any information that could impact safety, security, quality, schedule, cost, profit or the environment must be controlled.

Properly structured baselines and a closely-coupled change process are the cornerstones to the business process infrastructure.

The entire organization shall use one common change process.

The change process shall be closed-loop and include a fast-track feature — which can accommodate 75 to 85% of all changes,

Each document must be co-owned by a creator and one or more users.

All work shall be authorized and controlled with forms.

Requirements must lead; physical items must conform.

Best Approach for Real Process Improvement

(1) Whether already ISO 9001 certified or not, measure the resources being spent on intervention and use the results as a guide.

(2) Develop a plan for reducing intervention resources and ramping up the rate of real improvements (first 2 of 8 steps as shown below).

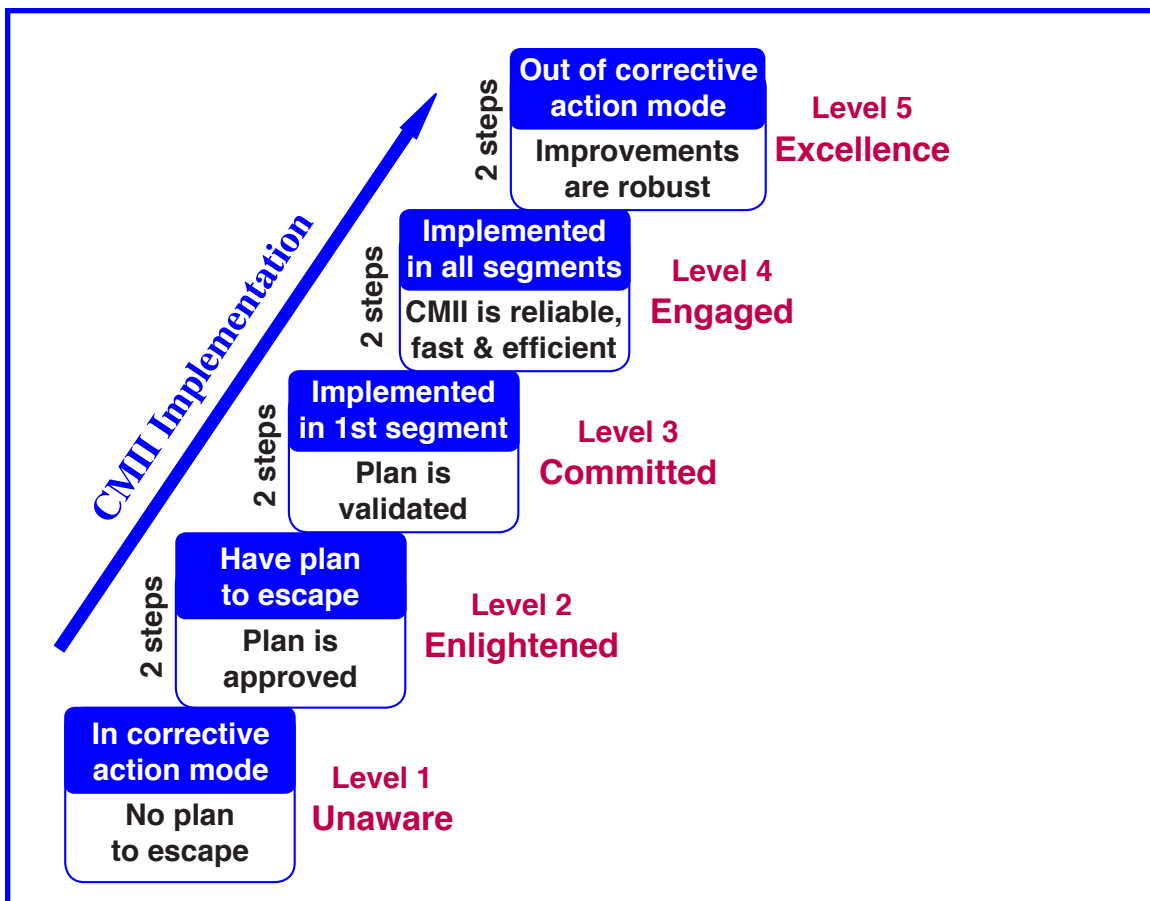
(2a) Define where you want to be;

(2b) Assess where you are relative to where you want to be;

(2c) Develop a transition plan;

(2d) Ensure that top management fully supports the plan.

You are now ready to make improvements that have real benefits.



Feedback from Our CMII Students

Since 1987, about 7,000 professionals representing every core discipline, from various industries and government agencies in over 30 countries, have achieved CMII certification. 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. Most organizational levels and life cycle phases are represented and we all learned from each other.

Students from the most advanced organizations often make the following observation. Except for CMII, we have expertise in all the above. CMII is what we are missing. Ability to accommodate change and keep requirements clear, concise and valid — that is where we need to improve.

Other Lessons Learned

When we seek out the root causes of quality problems, schedule problems or cost problems, we invariably find a CM problem. When we fix CM, the quality, schedule and cost problems invariably go away.

Process improvement must begin with CM. All routes to integrated process excellence go through the CMII-enhanced version of CM, not traditional CM. Traditional CM must be upgraded with CMII.

Conclusions and Recommendations

It is appropriate to think of ISO 9001:2008 as the requirement and CMII as the how-to. However, it is also necessary to expand the scope of the ISO 9001:2008 requirements.

The expanded scope of CMII (any information that can impact safety, security, quality, schedule, cost, profit or the environment) and the supporting business process infrastructure, provide the mechanism for achieving the ISO 9001:2008 requirements and/or objectives.

Organizations striving to comply with, or upgrade to, ISO 9001:2008 will have much greater success if their team includes CMII grads.