ISO-9001 WHITE PAPER

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ISO-9001 SUMMARY:[1]

The International Standard promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a quality management system, to enhance the customer's satisfaction by meeting customer's requirement …..

NOTE: In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

- ***PLAN:*** *Establish methods and methods necessary to deliver results in accordance with customer requirements and the organization policies".*
- ***DO:*** *Implement the process.*
- ***CHECK:*** *Monitor and measure the processes and product against policies, objectives, and requirements for the product and report the results.*
- ***ACT:*** *Take action to continuously improve process performance.*

SOFTWARE ENGINEERING CHALLENGE:

The easiest implementation of ISO9001 is in a Manufacturing company. In this case, virtually all of the PDCA steps are performed by employees of the company on company property. The proximity of the required activities to management facilitates the enforcement to the approved methods and processes.

The implementation of ISO9001 in a service-providing firm is considerably more difficult. In this case, most of the PDCA steps will be performed by company employees at the customer site. Good on-site supervision and the maintenance of an activity log will greatly facilitate the enforcement of the company's approved methods and processes.

The product of the Software Engineer is a special document defining a complex process to be performed by a computer at the customer site. In this case, most of the PDCA steps will be performed at the customer site without the presence of company employees. The company that develops a software product provides a service to the customer at the customer site without human intervention.

Can this "process-defining document" be compliant to the requirements of ISO9001?

PLAN:

In the Software Engineering world, the majority of the programming activity occurs in the PLAN step of the PDCA methodology. To this end, the Software Engineering team must develop the "process defining document" using standard methods and processes to the maximum degree possible.

The "What If We" programmable code generator (PCG) enables the use of enforceable standard methods and processes in the development of the "process defining document". Specifically, the PCG redefines the programming effort as a formal two-step process:

- The development of a library of "software parts".
- The use of this library in the development of product; i.e., the "process defining document".

This two step operation gives management and the software engineering staff greater control over the quality of the "process defining document".

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[1] ANSI/ISO/ASQ Q9001-2000

DO:

Unfortunately in the Software Engineering World, the large majority of this step is performed at the customer's site on the customer's machine. This often causes the customer to become an unwilling member of the software test team.

The Software Engineering team will usually perform one or more "dry-runs" with the "process defining document". Programmers will perform "check-out" runs on the programs that they are developing; and the Software Engineering organization may perform a formal test process to verify proper operation. Unfortunately, these efforts are not very effective relative to delivering a quality "process defining document".

There are well-established software engineering methods that improve the overall quality of the product and can render the "process defining document" to be more ISO-9001 compliant. There are coding methods that:

- Detect errors early in the development process. This capability can be greatly enhanced by a properly defined set of software parts.
- Detect errors early in the check-out process.
- Detect and properly respond to errors throughout the life of the product.
- Prepare an activity log for critical applications.

By defining the library of software parts using these more effective methods, their use in the development of product will be both facilitated and enforced.

CHECK

The goal of this step must always be to greatly reduce the required participation of the customer as a member of "test team". Problems and errors in the "process defining document" must be caught before its delivery. To this end, the processes used in any product must be evaluated relative to:

- Proper behavior relative to its definition.
- Detection and prevention of improper behavior during its use.
- Detection and prevention of improper use during the preparation of the "process defining document".

The "What If We" Programmable Monte-Carlo Test system (PMTS) was specifically developed to accomplish all of the above evaluation objectives. This system prepares, builds, and executes a test program for each of a randomly defined test sequence. The Software Unit Under Test can be an executable, a module such as a class or subroutine, or a software part thus supporting a very economical and effective "divide-and-conquer" test and evaluation strategy.

ACT

The ISO-9001 requirement to continuously improve the process performance must also be applied to the standard methods used in the delivered "process-defining documents". Unlike many of the UML development environments, neither the PCG nor PMTS define or restrict the methods deployed by the responsible organization. All of the defining files can easily be created or modified by a simple text editor such as the Windows Notepad utility by members of the responsible organization.