Converting Your Systems Engineering Organization To ISO 9001 Compliance

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Abstract. Quality control is evolving from only being present during final inspection, into becoming an integral part of the systems engineering process. This evolution is being helped by the International Organization of Standards (ISO) 9000 series of standards that provides a checklist for documenting processes and assessing their performance. The standards do not apply to systems engineering at this time. They are however taking the place of similar Department of Defense (DoD) standards, so there is an excellent probability that they or an equivalent standard will apply to systems engineering in the future. This paper describes **one proposed way** to transform an organization toward compliance with the ISO 9001 Standard, and make an organization's systems engineering process more cost effective.

INTRODUCTION

In today's economic climate, the drive is toward cost effectiveness and the focus is on reduction of waste. One way of reducing waste is to perform tasks the same way each time the task is implemented (Taylor, 1911). This principle has since evolved into the concept of a >standardized process=. Since systems engineering has been defined as *"an iterative process of top down synthesis, development and operation of a real world system that satisfies in a near optimal manner, the full range of requirements for the system@* (Eisner, 1988), the concepts of standardized processes apply to organizations providing systems engineering services or performing systems engineering as part of a System Development Life Cycle (SDLC). Thus, the underlying reasons for a systems engineering organization to take the road to process standardization are as follows:

- Reduce waste by standardizing processes within the organization.
- Develop and communicate an understanding of the processes within the organization.

Be assured, if you don't go for standardization, the day will come when your customer will state "*if you don't understand your systems engineering processes, I can't trust you to develop my product in a cost effective manner"* (Kasser, 1995).

System engineering organizations can choose from several process standardization approaches, including:

- The International Council on Systems Engineering (INCOSE) System Engineering Capability Maturity Model (CMM) and other CMM=s (Sheard, 1997).
- The ISO 9001 Standard.

This paper focuses on achieving certification as being compliant with the ISO 9001 Standard. Such compliance requires:

- A documented process.
- Proof that the process is performed as documented.

The transition usually takes at least two years to complete (Hockman, Grenville, Jackson, 1994). This is because:

- It takes time to plan and implement the changes.
- The organization has to function in accordance with the new process for several months so that data can be collected to demonstrate compliance to the ISO 9001 Standard.

In-house personnel headed by someone with authority and credibility must implement transition. However, a consultant is often brought in to assist with reengineering the organization into an ISO 9001 Standard compliant mode. If such an external consultant is employed for this function, the consultant must be used as a guide and mentor, not as the implementor.

THE ISO 9000 SERIES OF STANDARDS

The ISO first published the 9000 Series Quality System Standards in 1987 and subsequently published revised versions in 1994. These standards have been adopted in the United States and issued as the American National Standards Institute/American Society for Quality Control (ANSI/ASQC) Q9000 series standards. As the ISO 9000 Standard states, the standards were developed because:

> ACustomer requirements are often incorporated in >specifications=. However, specifications may not in themselves guarantee that a customer's requirements will be met consistently, if there are any deficiencies in the organizational system to supply and support the product".

There are five basic standards:

- **ISO 9000 (ANSI/ASQC Q9000-1-1994).** Quality Management and Quality Assurance Standards Guidelines. ISO 9000 explains the philosophy behind the standards and provides a road map for their application.

- **ISO 9001 (ANSI/ASQC Q9001-1994).** Model for Quality Assurance in Design and Development, Production, Installation, and Servicing. **ISO 9001 is applicable when the contract specifically requires design efforts and the product requirements are stated principally in performance terms or they need to be established.**

- **ISO 9002 (ANSI/ASQC Q9002-1994).** Model for Quality Assurance in Production and Installation. ISO 9002 is applicable when the specified requirements for a product are stated in terms of an established design or specification.

- **ISO 9003 (ANSI/ASQC Q9003-1994).** Model for Quality Assurance in Final Inspection and Test. ISO 9003 is applicable in situations when the conformance of the product to specifications can be shown with adequate confidence providing that certain suppliers' capabilities for inspection and tests conducted on finished products can be satisfactorily demonstrated.
- **ISO 9004 (ANSI/ASQC Q9004-1-1994)**. Quality Management and Quality System Elements. ISO 9004 presents the philosophy behind the quality program elements and provides guidance on how to implement a quality program within an organization. ISO 9004 provides guidance on quality management and quality system elements.

Each standard in the ISO 9000 series deals with defining and documenting a product or service process. ISO 9001 and ISO 9002 are very similar; being contractual standards for use in a buyer-supplier relationship.

Advantages of ISO compliance. The advantages of meeting the ISO 9000 Standards include (ISO 9000 Group, 1998) :

- Optimized company structure and operational integration.
- Improved awareness of company objectives.
- Improved communications and quality of information.
- Responsibilities and authorities clearly defined.
- Improved traceability to 'root causes' of quality problems.
- Improved utilization of time and materials.
- Formalized systems ensure consistent quality and punctual delivery.
- Documented systems provide useful references and training tools.
- Fewer rejects, therefore, less repeated work and warranty costs.
- Errors rectified at the earliest stage and not repeated.
- Improved relationships with customers and suppliers.
- Improved control during periods of change or growth.
- Use of a recognized logo on stationery and advertisements.
- Improved corporate quality image.
- Ability to bid for 'ISO 9000' contracts at home and abroad.
- Continuous quality assessment by experienced professionals.
- Reduced number of customer audits.
- Improved records in case of litigation.

A study commissioned by Lloyd's Register Quality Assurance, a United Kingdom-based certification body that assesses quality management systems, indicated that the benefits increase over time (Brecka, 1994). However, the standards do not deal with the effectiveness of the process. The hope seems to be that when the process is documented, it will also be analyzed and improved.

THE ELEMENTS OF THE ISO 9001 STANDARD

Section 4 of the ISO 9001 Standard contains 20 Quality System Elements, which provide a checklist or guide in the following areas:

- Process definition.
- Process control.
- Process measurement.
- Process improvement.
- Administrative support.

Consider each element of Section 4 of the ISO 9001 Standard in turn and a suggested way to comply with it (Kasser, 1995). The term *product* refers to the:

- System under development, to distinguish it from any systems used in the SDLC process.
- Service provided under the terms of a systems engineering support services contract.

Management Responsibility. The standard recognizes that the commitment to quality starts at the top of the organization and cannot be delegated. The documentation requirements of this section may be met by producing a Management Plan in the form of a System Engineering Management Plan (SEMP) for the quality program. The contents of this document must cover:

- **Quality Policy.** A statement of the objectives and commitment to Quality. The policy has to be understood and implemented at all levels in the organization. This is the basic element for developing and communicating the vision of quality within the organization.
- **Organization.** A description of the charter, organization, and interrelation of all personnel who manage, perform, and verify work affecting the quality of the product. This includes a description of their roles and responsibilities.
- **Verification Resources and Personnel.** A description of in-house activities to verify compliance to requirements, the resources allocated to those activities, and training.
- **Management Representative.** The name of the person who has the authority and responsibility for ensuring that the requirements of the standard are implemented and maintained. The road to ISO 9001 certification is a brand new path, so that person must be an effective person and must be given an adequate budget to do the job.
- **Management Reviews.** A description of when, and under what circumstances:
  - the quality program undergoes internal reviews at appropriate intervals to ensure the process is in control.
  - the records that must be made and how they are then to be made use of.

Quality System. To meet the requirements of this section, the supplier must show that procedures are documented, and more important, are implemented to ensure the product is produced to specifications. This is the standard SDLC methodology in which the:

- System Requirements Review (SRR) validates and provides consensus for the system level requirements.
- Preliminary Design Review (PDR) and Critical Design Review (CDR) verify the configuration items.

Demonstration of compliance to this section of the standard may be by means of:

- **Procedures or methodology manuals.** These manuals must describe the systems engineering methodologies used. They must also contain descriptions of the processes used within the methodology, such as the documentation preparation process, and the methodology for optimizing the effectiveness of a meeting.
- **Quality planning.** A written description of how the requirements for quality shall be met.

Contract Review. To meet the requirements of this section, the supplier must maintain procedures for contract review and for the coordination of these activities. In systems engineering, this section covers the parts of the SDLC methodology for:

- **Change control.** The change control process must be documented and shown to be followed.
- **The supplier's capability to perform.** The degree of expertise of the personnel performing the work. For example, the contractor must:
  - demonstrate there are sufficient senior personnel to guide the junior personnel in performing the systems engineering activities with a minimal amount of wasted effort.
  - show how skills needed on a part time basis by the project are made available.
- **Documentation of milestone reviews.** The documentation must include:
  - a description of the procedures to prepare and present each review.
  - the products to be produced and signed off at each review.

- the process for resolving the review item discrepancies and other outstanding issues.

Design Control. To meet the requirements of this section, the supplier must establish and maintain procedures to control and verify the design of the product to ensure that the specified requirements are met. This section may be met by developing a SEMP for the project that must describe:

- Procedures to control and verify designs.
- The orderly transfer between stages in the SDLC.
- Plans that identify the responsibility for the design and development activity.
- Activities and the resources allocated to them.
- An Interface Control Document (ICD) between the different departments in the company defining their organizational and technical interfaces.
- The methodology for verifying the system requirements.
- The methodology for validating that the system meets the requirements.
- The procedure for identification, and appropriate review and approval of all changes and modifications.

Document and Data Control. To meet the requirements of this section, the supplier must establish, document and maintain procedures to control all documents and data that relate to the requirements of the standard. Complying with this section means having a documented process to:

- Ensure up-to-date SDLC documents are accessible as needed and where needed.
- Destroy obsolete SDLC documents and replace them by current versions, and notify all personnel of that fact.
- Review and approve SDLC documents.
- Incorporate the reason for changes in the SDLC documents.
- Circulate a master list of SDLC documents, with current revision status.
- Reissue SDLC documents after a number of changes have been made, as appropriate, instead of attaching change pages to the original.

Purchasing. To meet this section of the standard, the systems engineering contractor must establish, maintain, and follow documented procedures to:

- Select sub-contractors on their basis to meet the requirements of the sub-contract, and on their history of past performance.
- Establish and maintain a list of acceptable sub-contractors.
- Ensure that every sub-contractor has a quality system.
- Select Commercial-off-the-Shelf (COTS) component suppliers on their basis to meet the need in a timely manner, and on their past performance.
- Ensure that the purchasing documentation is clear, concise, correct, and communicates the need in an effective manner.
- Ensure that the purchasing process contains a feedback mechanism so that purchase orders and sub-contracts are reviewed before being placed.
- Verify the deliverables from a sub-contractor at source, namely an on-site acceptance test, prior to shipment.

Control of customer supplied product. To meet this section of the standard, the systems engineering contractor must have and follow procedures to verify, store, and maintain customer supplied products for incorporation into the product. In government contracts, this section deals with handling Government Furbished Equipment. These procedures must apply to software and hardware elements (i.e., integrated circuits, sub-assemblies and workstations).

Product Identification and Traceability. To meet this section of the standard, the systems engineering contractor must where appropriate, have and follow procedures to:

- Identify and trace requirements from applicable authorized sources.
- Set up and use a configuration control system.
- Retain manufacturing and test records.

These capabilities allow speedy assessment of the:

- Effect of proposed changes to requirements.
- Scope of rework or other damage control techniques in the event of problems occurring down schedule.

Process Control. To meet this section of the standard, the systems engineering contractor must where appropriate, have and follow procedures to deliver the product in a cost-effective manner, under controlled conditions, including:

- Monitoring and controlling to ensure the performance and appropriate tailoring of the SDLC methodology.
- Minimizing latent defects in the system. Latent defects in systems engineering tend to show up as bugs in the software, interface problems, and performance gaps after the system has been accepted and placed into operation.

Inspection and Testing. To meet this section of the standard, the systems engineering contractor must have and follow procedures to:

- Inspect purchased COTS products prior to integration in the system. This applies to software as well as microcomputers, disk drives and other hardware elements.
- Be able to process a waiver of receipt inspection in the event of urgent need.
- Develop a test plan for the product under development.
- Perform in-process inspection and testing at various checkpoints in the SDLC.
- Perform final acceptance test prior to handover to the customer.
- Determine the disposition in the event of non-conformance to a test.
- Maintain and make use of inspection and test records.

Inspection, Measuring and Test equipment. To meet this section of the standard, the systems engineering contractor must have and follow procedures to:

- Verify all hardware test equipment have the appropriate resolution to make the necessary measurements.
- Calibrate all test equipment used in measuring the performance of the system.
- Periodically check the calibration of the test equipment.
- Test software tools to verify they have the capability to make the measurement.
- Place the software tools used to test the system under configuration control.
- Maintain and make use of inspection and test records.

Inspection and Test Status. To meet this section of the standard, the systems engineering contractor must have and follow procedures to:

- Maintain configuration control over the product in each stage in the SDLC.
- Issue a Discrepancy Report (DR) when a problem is noted at a checkpoint in the SDLC.
- Maintain records to identify the person who approved a product at a checkpoint in the SDLC.

Control of Nonconforming Products. To meet this section of the standard, the systems engineering contractor must have and follow configuration control procedures to:

- Separate nonconforming products from conforming products.
- Track DRs and their resolution.

Corrective and Preventative Action. To meet this section of the standard, the systems engineering contractor must have and follow procedures to:

- Investigate the root cause of a DR and determine the corrective action to be taken to prevent recurrence.
- Detect and eliminate potential causes of non-conformance in the process and product.
- Review the effectiveness of the proposed corrective action.
- Maintain records of DRs and corrective actions.

Handling, Storage, Packaging, Preservation and Delivery. To meet this section of the standard, the systems engineering contractor must have and follow (as appropriate) procedures to:

- Handle, store and ship the system to the customer's location.
- Maintain the quality of the product after on-site inspection through the delivery and installation process at the customer's location.
- Restrict access to the product to authorized personnel during the SDLC.

Control of Quality Records. To meet this section of the standard, the systems engineering contractor must have and follow procedures to collect, maintain, and provide access to quality records. This requirement may be met by a configuration control system database.

Internal Quality Audits. To meet this section of the standard, the systems engineering contractor must have and follow procedures to verify the quality process, namely:

- A methodology for the conduction of internal audits to verify conformance to the ISO 9001 Standard.

- An independent evaluation of the audit results.
- A review of the audit results with the personnel responsible for the activity audited.
- Verification that the recommendations of the audit are carried out. The recommendations of one audit become additional metrics for a subsequent audit.

Training. To meet this section of the standard, the systems engineering contractor must have and follow procedures to:

- Identify training needs.
- Provide appropriate training.
- Identify appropriate qualifications for the personnel who will perform the training.
- Maintain records of which personnel received which training courses, and when the training took place.

Servicing. To meet this section of the standard, the systems engineering contractor must have (as appropriate) and follow procedures to:

- Resolve post-delivery problems including latent defects.
- Maintain records of post-delivery activities.

Statistical Techniques. To meet this section of the standard, the systems engineering contractor must have and follow procedures to:

- Identify adequate statistical techniques for verifying the acceptability of the process and product.
- Use statistical techniques for verifying the acceptability of the process and product.

THE ISO 9001 COMPLIANCE TRANSITION PROJECT

The ISO 9001 Compliance Transition Project begins when upper management makes and demonstrates their commitment to travel the road. This commitment is essential because of the resources that they will have to commit toward the effort. The decision must be an informed one, so, in systems engineering terminology, management must:

- Authorize the ISO 9001 Compliance Transition Project.
- Authorize a realistic budget.
- Appoint a project manager who is an experienced systems engineer with knowledge of the ISO standards and certification process.
- Allocate suitable resources in terms of knowledgeable personnel and equipment.
- Ensure the project personnel have a stake in the successful outcome of the project.

The ISO project implementation team will probably be working part time on this effort. This is not as bad as it seems, because the expanded time factor will assist in overcoming any potential resistance to the change.

This road contains a number of phases leading to intermediate milestones. The discussion that follows is a simplified description of one process an organization can follow to become ISO 9001 compliant.

In the spirit of applying lessons learned, statistics show (Hodlin, 1993):

- Seventy percent of all companies fail the assessment the first time around.
- Sixty percent of the problems are associated with the following five clauses of the standard:
  - Document control.
  - Design control.
  - Purchasing.
  - Inspection and test.
  - Process control.

Thus, the areas listed above represent the areas to concentrate on during the performance of the ISO 9001 Compliance Transition Project.

The terminology chosen for describing the project milestones is based on engineering language. This is because transforming an organization is a non-trivial project, and must be treated as such. This approach applies the project methodology for transitioning a legacy (computer based) system to the process of transforming an organization. The legacy system is non-ISO 9001 compliant, while the future system after the transition is ISO 9001 compliant.

The concept development phase. Once the project has been approved, the first phase is the preparation of an Operations Concept Review (OCR) for the process. This review must cover the road map, namely:

- The ISO 9001 Standard.

- The reason for making the commitment.
- The vision of how the organization will function once compliance with the ISO 9001 Standard is achieved.
- An initial assessment of the status of the organization
- An estimate of the resources that will be needed.
- The ISO 9001 Compliance Transition Project organization chart (authority and responsibilities).
- Which consultants will be brought in, why they are to be brought in, and what expertise they will supply.
- The initial transition plan (including any alternatives) showing in very broad terms how the changeover from the current way of doing business to the ISO 9001 Standard compliant way will be made.
- A preliminary schedule for the transition, which by the way started when the project was first authorized.

The review must be attended by all the managers in the organization including the Chief Executive Officer and their staff to demonstrate their commitment to the change (Hockman, et al., 1994). The review handout may serve as the System Operations Concept Document (SOCD) and initial version of the SEMP for the project. The decision to continue made at the end of the OCR must be visible throughout the organization.

The requirements development phase. This is the phase in which:

- The ISO 9001 Standard is dissected.
- A requirement is developed for each process and product to be documented.
- The Requirements Traceability Matrix (RTM) is developed.
- Alternative ways of meeting the requirements may be proposed and analyzed.
- Internal audits take place to determine the exact current situation.
- The existing processes are documented. The people who perform each process must be involved in the documentation of their process.
- The documents are tested by auditing the processes.
- The Transition Plan is developed in more detail to show which elements will be firmed up in which order and by when. This plan is based on the resources that will be available.
- The Test Plan is also developed for demonstrating progress.

This phase terminates with a SRR. As before, the decision to continue made at the end of the SRR, must be visible throughout the organization.

The unit development phase. The next phase along the road maps into the unit development phase of the SDLC. During this phase:

- The Quality Manual is written.
- Each process in the system engineering methodology (or methodologies) is upgraded to conform to the requirements of the standard and documented accordingly. This is also a good time to make use of suggestions for process improvement by the employees who perform the process.
- Training takes place to make the new process known.
- The test team performs an audit to verify the change has taken place.
- Periodic management progress reviews take place and reports are published so that everybody involved can see the progress being made outside of the area in which they are working in. Certificates of Appreciation for any outstanding efforts should be presented at these review meetings.
- The third party registrar is chosen.

The pre-assessment review. The CDR must not take place until at least 90% of the processes have been upgraded and have been in operation for at least two months. In this instance, the CDR is a readiness review prior to performing the pre-assessment (quality language) or Integration Test (systems engineering language). The review covers:

- The status of the project.
- Customer feedback, what the customer thinks of the effort.
- Lessons learned during the process.
- An estimate of the cost savings due to process improvements already implemented.
- Internal audit results.
- Trend data collected by the test team (internal audit team) showing the rate of improvement.

The pre-assessment test. The remaining processes are upgraded and the upgraded system allowed to operate for at least two months. At the end of that time, the pre-assessment test is performed. This test is a dress rehearsal for the assessment (Acceptance Test). An outside auditor:

- Audits the processes, to ensure the procedures are followed.

- Compares the processes to the requirements in the Quality Manual to ensure that the system itself complies with its requirements.

The format of this test typically is:

- An opening meeting.
- The interview and investigation period.
- A closing meeting.

The result of the test is presented at the closing meeting. This pre-assessment may identify missing elements in the quality system that must be corrected before the assessment takes place. These are documented as DRs.

The operations phase. Any changes recommended as a result of the pre-assessment review are then made and the system allowed to operate for at least six months to collect data. By doing so, objective evidence (data) that the organization is in compliance with the requirements of the ISO standard will be available to the assessor.

The Assessment and its aftermath. The assessment is performed by the third party registrar and follows the same format as the pre-assessment. If the outcome of the assessment is a recommendation for registration, a certificate will be received within two months. If minor discrepancies are found, the organization will have two months or so to correct them.

Registration is just the beginning. The initial registration serves as a baseline for further process improvement. The system is now in its operational phase and changes (improvements) will occur. Each improvement lowers the cost of doing business increasing the competitive edge. Internal audits must continue to ensure the process and the documentation are synchronized. These audits will probably generate DRs which must be handled according to due process in a timely manner under configuration control. This process of improvement is a continuous loop without an exit.

SUMMARY

While the ISO 9000 series of standards have not yet been adopted in the systems engineering field, it is probable that the time will come when the standard or an equivalent will apply. ISO 9001 compliance provides an excellent starting point for institutionalizing quality when an organization begins the long trek down the road to cost effective systems engineering. It does however organize more than just the systems engineering and test departments because of the procurement and materials management aspects. This paper has suggested one approach to transitioning an organization to compliance with the ISO 9001 Standard.

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Dr. Kasser has more than 25 years of award winning experience in management and engineering. He teaches software design, software validation and verification, and software maintenance in the Graduate School of Management and Technology at the University of Maryland University College. He is a recipient of NASA=s Manned Space Flight Awareness (Silver Snoopy) Award for quality and technical excellence. He is a Certified Manager and a recipient of the Institute of Certified Professional Manager's 1993 Distinguished Service Award. He is the author of *Applying Total Quality Management to Systems Engineering* published by Artech House and more than 30 journal articles and conference papers. His current interests lie in the areas of applying systems engineering to organizations and using technology to improve the practice of management.

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