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**AN EXPLORATORY STUDY OF ISO 9001:2000 QUALITY
MANAGEMENT SYSTEMS USING THE ISO/IEC 15504
ARCHITECTURE**

by

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B.S. June 1983, University of Delaware


A Thesis Submitted to the Faculty of
Old Dominion University in Partial Fulfillment of the
Requirement for the Degree of


MASTER OF SCIENCE

ENGINEERING MANAGEMENT

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ABSTRACT

AN EXPLORATORY STUDY OF ISO 9001:2000 QUALITY MANAGEMENT SYSTEMS USING THE ISO/IEC 15504 ARCHITECTURE

Paul Richard Shimp
Old Dominion University, 2007
Director: Dr. Andres Sousa-Poza

The purpose of this paper is to provide an exploratory study on the implementation and issues regarding Quality Management Systems as defined by ISO 9001:2000 using the architecture of ISO/IEC 15504. The recently published ISO/IEC 15504 series of standards provides a framework to assess processes and determine levels of capability. With the use of this framework, the study will focus on the assessment and identification of problem areas requiring focus for continual improvement within an ISO 9001:2000 quality management system.

The structure of this paper is as follows: Section 1 provides a background discussion of ISO 9001:2000. The literature review conducted that resulted in the use of ISO/IEC 15504 during this study is discussed in section 2. Section 3 provides the methodology used for the research project. Sections 4 and 5 contain information regarding the development, deployment and analysis of the survey conducted. A discussion of the results obtained is provided in section 6. An overall summary of the study is provided in section 7 with concluding remarks in section 8.

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1 INTRODUCTION

With the growing need of international trade of goods and services following World War II, the International Organization of Standardization (IOS) was formed in 1947 consisting of countries wishing to participate. Headquartered in Geneva, Switzerland, the IOS was tasked to oversee the development of standard product and process standards. These standards would form the basis of international agreements called International Standards and would undergo review every five years to ensure the needs of participating countries were met. The Greek word ISO, meaning equal, was adopted by the IOS as the organizational acronym to avoid language translation difficulties.

During the early 1980's, an international standard on quality management systems was determined to be in need. Technical Committee 176 (TC176) was established by the IOS to facilitate the development and maintenance of quality systems standards. Using the British Standard BS5750 developed in 1979, ISO 9001 was developed and subsequently published in 1987 as the first international quality management systems standard. This document provided a minimum set of requirements for organizations to promote standard levels of product quality. To demonstrate compliance to the standard, the IOS established a structure allowing organizations to obtain certifications through third-party agencies. These agencies would be accredited by in-country government boards recognized by the IOS through International Memorandum of Agreements.

The 2nd edition published in 1994, contained minor updates with additional focus applied on customer complaints, preventive action, and the need for a quality manual describing the organization's quality management system. Following the 2nd edition, TC176 conducted extensive surveys in 1998 among the member nations and users to identify needed improvements to the standard. The survey identified seven top issues needing to be addressed (Tsim et al., 2002):

1. Simplicity, clarity, language terminology, less paper;
2. Integration into one management system;
3. Continuous improvement;
4. Process model, process orientation;
5. Compatibility with other management standards;
6. Customer satisfaction, and
7. Business orientation.

As a result of this survey, ISO 9001 was revised and the 3rd edition was released in December 2000, also known as ISO 9001:2000. The new standard was significantly restructured to address the top seven issues discussed above with focus on defining and measuring processes, continual improvement, and customer satisfaction. During development of the 3rd edition, eight Quality Management Principles were derived based on the experience and knowledge from members of the ISO Technical Committee ISO/TC 176, *Quality management and quality assurance*, which is responsible for developing and maintaining the ISO 9000 standards:

Principle 1 – Customer Focus: Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Principle 2 – Leadership: Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Principle 3 – Involvement of People: People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Principle 4 – Process Approach: A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5 – System Approach to Management: Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Principle 6 – Continual Improvement: Continual improvement of the organization's overall performance should be a permanent objective of the organization.

Principle 7 – Factual Approach to Decision Making: Effective decisions are based on the analysis of data and information.

Principle 8 – Mutual Beneficial Supplier Relationships: An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Structuring the quality management system in accordance with the ISO 9001:2000 results in a uniform set of documentation despite the type of organization, size and industry (Nelson, 2005). However, ISO 9001:2000 contains little guidance on how to assess the quality management systems to the new model. Companies would certify to the updated standard but are unsure on how to determine areas of priority and focus for continual improvement. ISO 9000:2005, the fundamentals and vocabulary document that supplements ISO 9001:2000 discusses the need for evaluating quality management systems for improvement. ISO 9004:2000 was developed by TC176 to supplement ISO 9001:2000 as guidance on a broader range of objectives for the continual improvement of the organization's overall performance, efficiency, and effectiveness (Cianfrani et al., 2001). However, when reviewing ISO 9004:2000, the document does not specifically provide the tools or techniques on how to determine or measure the effectiveness of the quality management system. Appendix A of ISO 9004:2000 does provide guidelines for self-assessing an organization for improvement. Five maturity levels with twenty seven questions are provided within the guidance; however appear to be directly tied to the basic requirements of ISO 9001:2000. The United States Technical Advisory Group, Product Support Initiative (PSI) 9004 Sub-team 6 conducted a survey regarding the use and issues of ISO 9004:2000. Responses were analyzed upon completion of the survey in January 2003. Of 354 individuals, 55% used it as a guide for implementing ISO 9001:2000 and 22% did not use it all. A low percentage of the group (8%) did indicate they used it as a self-assessment tool.

Overall, the results indicated the document was used more as a “how to guide” for implementing ISO 9001:2000 and not as an implementation aid for continual improvement as intended. (Russell, 2003; Yoo et al., 2004; Westcott, 2003)

As a result, this study was designed to identify a possible tool for use in assessing and determining areas of focus and priority for continual improvement within the ISO 9001:2000 defined Quality Management System, and it's potential for future use.

2 LITERATURE REVIEW

2.1 QUALITY MANAGEMENT SYSTEM ASSESSMENT METHODOLOGIES

As discussed during the Introduction within section 1, ISO 9001 was initially released in 1987. During this period, other well-known models were also in development and independent of each other, all focusing on business excellence; for example,

1. Malcolm Baldrige National Quality Award (MBNQA), created and signed into law on August 20, 1987, and established in 1988,
2. Software Process Maturity Framework released by the Software Engineering Institute (SEI) in 1987, later to become the Software Capability Maturity Model (CMM), and
3. European Foundation for Quality Management (EFQM) founded in 1989.

Recognizing the international status that ISO 9001 held and to retain the basic concepts of those specific models, many attempts were made mapping them to the 1994 revision of ISO 9001 (Achilleos and Ioannou, 2000; Seeples, 1994; Paulk, 1994; Mann and Voss, 2000). This pattern continued following the emergence of the 2000 revision of ISO 9001 (Tonk, 2000; Conca et al., 2004; Yoo et al., 2004). Each author attempted to show readers how ISO 9001 applied to their models, most which did not provide an assessment methodology that directly tied to the specific requirements of ISO 9001. It was also observed that others attempted to create and implement assessment methods of their own by integrating requirements of 1994 revision of ISO 9001 and other models (Russell, 1995) but were not adopted and recognized internationally.

In the mid-late 1990's, another model was emerging that consisted of the concepts of the Software Capability Maturity Model (CMM), titled ISO Software Process Improvement and Capability dEtermination (SPICE), later to become ISO/IEC 15504. This model intended to provide an internationally recognized method to assess and implement software process improvements within organizations. Upon gaining international standard recognition as ISO/IEC 15504, it was realized that the methodology could be used to assess various management systems, not those that are just software based thus was re-titled as Process Assessment. In reviewing ISO/IEC 15504-1:2004, section 4.1.4 states that the standard incorporates the intent of ISO 9001:2000 and that the framework could be used as a means to measure the quality of quality management system processes. This approach appeared to be a possible method for the assessment of an ISO 9001-based Quality Management System and would be explored within this study.

2.2 BACKGROUND OF ISO/IEC 15504

The ISO/IEC 15504 Process Assessment series of standards were developed and published in 2003-2004 from original work established by *ISO Software Process Improvement and Capability dEtermination (SPICE)* project, with the intent to provide a set of tools to assess and determine capability levels of processes employed by organizations. The standards contain four parts focused on process evaluation and improvement:

Part 1: Concepts and vocabulary (known as ISO/IEC 15504-1:2004)

Part 2: Performing an assessment (known as ISO/IEC 15504-2:2003)

Part 3: Guidance on performing an assessment (known as ISO/IEC 15504-3:2004)

Part 4: Guidance on use for process improvement and process capability determination (known as ISO/IEC 15504-4:2004)

Two additional parts are currently in development to provide process assessment models against which organizational assessments can be performed, referred to as Process Reference Models (PRMs). PRMs contain Process Categories reflecting the requirements within the associated models (e.g., ISO/IEC 12207:1995 and ISO/IEC 15288:2002).

Part 5: software lifecycle processes based on ISO/IEC 12207:1995/Amd.1:2002 and ISO/IEC 12207:1995/Amd.2:2004, and

Part 6: systems engineering processes based on ISO /IEC 15288:2002.

Other standards are also being considered for development as process assessment models (i.e., ISO 9001:2000).

Each Process Category defined within the PRM is assessed to determine its capability level. This is determined by defined Process Attributes for each level. ISO/IEC 15504-3:2003 defines six Process Capability Levels and nine associated Process Attributes (reference Tables 1 and 2). A Process Attribute Rating is determined based on the level of implementation and maturity for each Process Category (reference Table 3). The capability level is then determined for each Process Category based on the extent of implementation of each Process Attribute within the specific level (reference Table 4). An overall Process Profile is assembled to provide an overall summary of Process Category capabilities.

Table 1. Process Capability Levels

Level	Capability	Description
0	Incomplete	The process is not implemented, or fails to achieve its process purpose.
1	Performed	The implemented process achieves its process purpose.
2	Managed	The previously described Performed process is now implemented in a managed fashion (planned, monitored and adjusted) and its work products are appropriately established, controlled and maintained.
3	Established	The previously described Managed process is now implemented using a defined process capable of achieving its process outcomes.
4	Predictable	The previously described Established process now operates within defined limits to achieve its process outcomes.
5	Optimizing	The previously described Predictable process is continuously improved to meet relevant current and projected business goals.

Table 2. Process Attributes

Level	Process Attribute	Description
1	1.1 Process Performance	A measure of the extent to which the process purpose is achieved. As a result of full achievement of this attribute, the process achieves its defined outcomes.
2	2.1 Performance Management	A measure of the extent to which the performance of the process is managed. As a result of full achievement of this attribute: <ul style="list-style-type: none"> a) objectives for the performance of the process are identified; b) performance of the process is planned and monitored; c) performance of the process is adjusted to meet plans; d) responsibilities and authorities for performing the process are defined, assigned and communicated; e) resources and information necessary for performing the process are identified, made available, allocated and used; f) interfaces between the involved parties are managed to ensure both effective communication and also clear assignment of responsibility.

Table 2. Continued

Level	Process Attribute	Description
2	2.2 Work Product Management	<p>A measure of the extent to which the work products produced by the process are appropriately managed. As a result of full achievement of this attribute:</p> <ul style="list-style-type: none"> a) requirements for the work products of the process are defined; b) requirements for the documentation and control of the work products are defined; c) work products are appropriately identified, documented, and controlled; d) Work products are reviewed in accordance with planned arrangements and adjusted as necessary to meet requirements.
3	3.1 Process Definition	<p>A measure of the extent to which a standard process is maintained to support the deployment of the defined process. As a result of full achievement of this attribute:</p> <ul style="list-style-type: none"> a) a standard process, including appropriate tailoring guidelines, is defined that describe the fundamental elements that must be incorporated into a defined process; b) the sequence and interaction of the standard process with other processes is determined; c) required competencies and roles for performing a process are identified as part of the standard process; d) required infrastructure and work environment for performing a process are identified as part of the standard process; e) suitable methods for monitoring the effectiveness and suitability of the process are determined.
3	3.2 Process Deployment	<p>A measure of the extent to which the standard process is effectively deployed as a defined process to achieve its process outcomes. As a result of full achievement of this attribute:</p> <ul style="list-style-type: none"> a) a defined process is deployed based upon an appropriately selected and/or tailored standard process; b) required roles, responsibilities and authorities for performing the defined process are assigned and communicated; c) personnel performing the defined process are competent on the basis of appropriate education, training, and experience d) required resources and information necessary for performing the defined process are made available, allocated and used; e) required infrastructure and work environment for performing the defined process are made available, managed and maintained; f) appropriate data are collected and analyzed as a basis for understanding the behavior of .and to demonstrate the suitability and effectiveness of the process, and to evaluate where continuous improvement of the process can be made.

Table 2. Continued

Level	Process Attribute	Description
4	4.1 Process Measurement	<p>A measure of the extent to which measurement results are used to ensure that performance of the process supports the achievement of relevant process performance objectives in support of defined business goals. As a result of full achievement of this attribute:</p> <ul style="list-style-type: none"> a) process information needs in support of relevant defined business goal are established; b) process measurement objectives are derived from process information needs; c) quantitative objectives for process performance in support of relevant business goals are established; d) measures and frequency of measurement are identified and defined in line with process measurement objectives and quantitative objectives for process performance; e) results of measurement are collected, analyzed and reported in order to monitor the extent to which the quantitative objectives for process performance are met; f) measurement results are used to characterize process performance.
4	4.2 Process Control	<p>A measure of the extent to which the process is quantitatively managed to produce a process that is stable, capable, and predictable within defined limits. As a result of full achievement of this attribute:</p> <ul style="list-style-type: none"> a) analysis and control techniques are determined and applied where applicable; b) control limits of variation are established for normal process performance; c) measurement data are analyzed for special causes of variation; d) corrective actions are taken to address special causes of variation; e) control limits are re-established (as necessary) following corrective action.
5	5.1 Process Innovation	<p>A measure of the extent to which changes to the process are identified from analysis of common causes of variation in performance, and from investigations of innovative approaches to the definition and deployment of the process. As a result of full achievement of this attribute:</p> <ul style="list-style-type: none"> a) process improvement objectives for the process are defined that support the relevant business goals; b) appropriate data are analyzed to identify common causes of variations in process performance; c) appropriate data are analyzed to identify opportunities for best practice and innovation; d) improvement opportunities derived from new technologies and process concepts are identified; e) an implementation strategy is established to achieve the process improvement objectives.

Table 2. Continued

Level	Process Attribute	Description
5	5.2 Process Optimization	<p>A measure of the extent to which changes to the definition, management and performance of the process result in effective impact that achieves the relevant process improvement objectives. As a result of full achievement of this attribute:</p> <ul style="list-style-type: none"> a) impact of all proposed changes is assessed against the objectives of the defined process and standard process; b) implementation of all agreed changes is managed to ensure that any disruption to the process performance is understood and acted upon; c) effectiveness of process change on the basis of actual performance is evaluated against the defined product requirements and process objectives to determine whether results are due to common or special causes.

Table 3. Process Attribute Ratings

Rating	Achievement	Description
N Not achieved	0% to 15%	There is little or no evidence of achievement of the defined attribute in the assessed process.
P Partially achieved	>15% to 50%	There is evidence of an approach to, and some achievement of, the defined attribute in the assessed process. Some aspects of achievement of the attribute may be unpredictable.
L Largely achieved	>50% to 85%	There is evidence of a systematic approach to, and significant achievement of, the defined attribute in the assessed process. Some weakness related to this attribute may exist in the assessed process.
F Fully achieved	>85% to 100%	There is evidence of a complete and systematic approach to, and full achievement of, the defined attribute in the assessed process. No significant weaknesses related to this attribute exist in the assessed process.

Table 4. Capability Level Ratings

Level	Process Attribute	Process Attribute Rating
1	Process Performance	Largely or fully
2	Process Performance Performance Management Work Product Management	Fully Largely or fully Largely or fully
3	Process Performance Performance Management Work Product Management Process Definition Process Deployment	Fully Fully Fully Largely or fully Largely or fully
4	Process Performance Performance Management Work Product Management Process Definition Process Deployment Process Measurement Process Control	Fully Fully Fully Fully Fully Largely or fully Largely or fully
5	Process Performance Performance Management Work Product Management Process Definition Process Deployment Process Measurement Process Control Process Innovation Process Optimization	Fully Fully Fully Fully Fully Fully Fully Largely or fully Largely or fully

An example of how this would be used is as follows.

- a) Identify process categories to be assessed. An example would be Procurement consisting of processes used to identify, qualify, and manage suppliers providing products.
- b) The assessment team reviews each Process Attribute from 1.1 Process Performance through 5.2 Process Optimization for Procurement to determine how well the attribute has been implemented as defined per the description outlined in Table 2.

c) The assessment assigns ratings as defined in Table 3 for each Process Attribute based on the level of achievement obtained. For example,

Procurement may have been rated as follows:

1.1 Process Performance = P (partially)

2.1 Performance Management = F (fully)

2.2 Work Product Management = F (fully)

3.1 Process Definition = L (largely)

3.2 Process Deployment = L (largely)

4.1 Process Measurement = P (partially)

4.2 Process Control = P (partially)

5.1 Process Innovation = N (not achieved)

5.2 Process Optimization = N (not achieved)

d) Following the assessment, a Capability Level for Procurement would be determined based on the ratings received for the Process Attributes as defined within Table 4. Upon first glance, it would appear that Procurement may be Capability Level 3; however 1.1 Process Performance was only Partially Achieved and not Fully Achieved as required. Procurement does not meet all the requirements of Capability Level 3, nor Capability Level 2 but does meet Capability Level 1 therefore Procurement would be assigned Capability Level 1. The organization would need to focus on the Process Performance attribute to elevate the Capability Level Rating.

This same process would be performed for each process category assessed resulting in an overall profile for use by the organization.

3 RESEARCH METHODOLOGY

Using Grounded Theory, the study of the implementation of an ISO 9001:2000 Quality Management System and related issues would be explored based on the architecture of ISO/IEC 15504. The results of the study could be used to support the formulation of a future ISO/IEC 15504 Quality Management System Process Reference Model (PRM) defining the set of processes and expected outcomes based on ISO 9001:2000.

Using the Open Coding technique as outlined by Corbin and Strauss (1990) and Strauss and Corbin (1998), the study was administered through the use of a survey as shown in Figure 1.

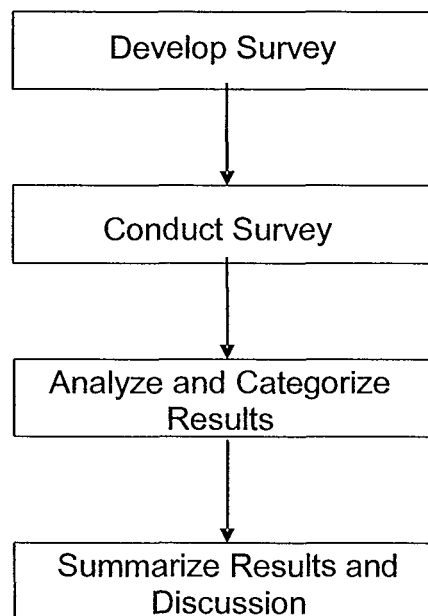


Figure 1. Information Gathering Flow

Develop Survey. Data collection may be conducted through the use of interviews and observations to develop grounded theory. A survey was designed to contain process categories of quality management systems, mapped to the clauses as defined within ISO 9001:2000 to facilitate data gathering. Using the Process Categories, individuals would specify and provide information on the ISO/IEC 15504 process attributes and ratings for each based on their assessments of the implemented quality management system. Questions would be open-ended, designed to help collect detailed information regarding difficulties encountered within each process category.

Conduct Survey. Sampling of information for grounded theory should not be in the form of specific groups, units, etc., but should be in terms of properties, dimensions, and variations. Companies that have implemented ISO 9001:2000 should have well established quality management systems. These companies would be selected to participate in the survey in order to determine the extent of their Process Capability. Targeting 10-15 companies to be sampled would range in size and complexity in order to provide a broad view of issues pertaining to the implementation of quality management systems. It would also be desirable that the companies selected are familiar with the Software Engineering Institute (SEI) Capability Maturity Model[®] Integration (CMMI) model, and associated maturity rating process to help facilitate this study. Subject matter experts selected from each company would receive a brief overview and instructions on how to complete the survey to assist consistency in the interpretation of each question.

Analyze and Categorize Results. In grounded theory, analysis should commence as soon as data becomes available. Each question would be reviewed for completeness once submitted and received from each company. Survey respondents would be contacted for clarification/confirmation for any question that appears to be incomplete or unique from answers submitted by others. Through Open Coding, individual responses would be compared to one another in order to identify similarities, differences, and dependencies. This analysis would be conducted to determine if initial trends or patterns emerge and would be an iterative process, continually exercised until all surveys were completed and received.

Summarize Results and Discussion. Categories and sub-categories containing the same observed phenomenon based on the data should be developed. The resultant survey data, information, and issues surrounding ISO 9001:2000 quality management systems would be summarized. Follow-on group and individual interviews would be conducted with the survey respondents to review the preliminary results and provide further understanding of patterns and issues that were observed during the analysis. Difficulties and recommendations of using the ISO/IEC 15504 architecture would be solicited and discussed with the survey respondents. Based on the comments and recommendations received from the follow-on interviews, additional analysis may be conducted. Data would be analyzed quantitatively to determine patterns or trends exist. Qualitative analysis would follow the data analysis to determine if other information regarding trends noted emerges based on inputs provided by the survey

respondents. Following the analysis and conclusion of the interview sessions, a final examination would be exercised to formulize conclusions for each category and sub-category identified. Following the conclusion of the survey and interview activity, theory regarding the results would be developed. Literature should be reviewed to determine if expected results were achieved. Following the conclusion of the survey and interview activity, theory regarding the results would be developed. A discussion would be provided to indicate how the theory developed was similar and dissimilar to other theories available regarding similar studies. Conclusions of the overall study would be finalized based on the comparison and discussion.

4 SURVEY

4.1 QUALITY MANAGEMENT SYSTEM PROCESS CATEGORIES

As discussed earlier, Process Assessment Models (PRMs) are available for software lifecycle and systems engineering processes but are not available for quality management systems based on ISO 9001:2000. In conducting research, it was determined that a set of quality management system process categories was non-existent therefore the process categories would need to be defined in order to properly use the ISO/IEC 15504 model. This was accomplished through the use of a series of inquiries with quality management system and survey subject matter experts (SMEs), each with a minimum of ten years experience in their respective field, as follows:

- Quality Management Systems (QMS) SMEs: 8
- RABQSA Certified QMS Auditors / Lead Auditors: 6
- ISO 9001 Registrars/Consultants: 4
- Certified Software Engineering Institute (SEI) CMMI Lead Assessor: 1
- Survey SME: 1

During initial discussions with the SMEs, the architecture defined within the ISO 9001:2000 model was reviewed to determine if it would be adequate as-is in defining the quality management system process categories. Within the ISO 9001:2000 model, five top level clauses are defined with many sub-tier clauses (reference Table 5):

- 4 Quality management system,
- 5 Management responsibility,

6 Resource management,

7 Product realization,

8 Measurement, analysis and improvement.

Four of these clauses are focused on organizational level processes (4, 5, 6, 8) and one is specific to product (7).

The SMEs concluded that the model itself would not clearly represent process categories without referencing various portions of major clauses along with various sub-tier clauses (e.g., Engineering, Production, and Purchasing sub-tiers to clause 7). The team agreed the best approach would be to define the process categories separately and map them into the specific clauses of ISO 9001:2000 (reference Table 5). In developing the process categories, it was essential that all clauses/sub-clauses and requirements of the ISO 9001:2000 standard be covered in order to ensure that all aspects of the quality management system model were covered.

Table 5. ISO 9001:2000 Clauses

4 Quality management system	7.3 Design and development
4.1 General requirements	7.3.1 Design and development planning
4.2 Documentation requirements	7.3.2 Design and development inputs
4.2.1 General	7.3.3 Design and development outputs
4.2.2 Quality manual	7.3.4 Design and development review
4.2.3 Control of documents	7.3.5 Design and development verification
4.2.4 Control of records	7.3.6 Design and development validation
5 Management responsibility	7.3.7 Control of design and development changes
5.1 Management commitment	7.4 Purchasing
5.2 Customer focus	7.4.1 Purchasing process
5.3 Quality policy	7.4.2 Purchasing information
5.4 Planning	7.4.3 Verification of purchased product
5.4.1 Quality objectives	7.5 Production and service provision
5.4.2 Quality management systems planning	7.5.1 Control of production and service provision
5.5 Responsibility, authority and communication	7.5.2 Validation of processes for production and service provision
5.5.1 Responsibility and authority	7.5.3 Identification and traceability
5.5.2 Management representative	7.5.4 Customer property
5.5.3 Internal communication	7.5.5 Preservation of product
5.6 Management review	7.6 Control of monitoring and measuring devices
5.6.1 General	8 Measurement, analysis and improvement
5.6.2 Review input	8.1 General
5.5.3 Review output	8.2 Monitoring and measurement
6 Resource management	8.2.1 Customer satisfaction
6.1 Provision of resources	8.2.2 Internal audit
6.2 Human resources	8.2.3 Monitoring and measurement of processes
6.2.1 General	8.2.4 Monitoring and measurement of product
6.2.2 Competence, awareness and training	8.3 Control of nonconforming product
6.3 Infrastructure	8.4 Analysis of data
6.4 Work environment	8.5 Improvement
7 Product realization	8.5.1 Continual improvement
7.1 Planning of product realization	8.5.2 Corrective action
7.2 Customer-related processes	8.5.2 Preventive action
7.2.1 Determination of requirements related to the product	
7.2.2 Review of requirements related to the product	
7.2.3 Customer communication	

Using an iterative process, the author drafted an initial list based on experience to start the dialogue with the SMEs as seen in Table 6. The recommended process categories were sent out for review through the use of e-mail due to extensive travel by many of the SMEs. The author contacted each SME for clarification on comments received and did incorporate any changes until feedback was received from all participants.

Table 6. Quality Management System Process Categories – Initial

Process Category	ISO 9001:2000 Clause(s)
Management	4.1, 5.1, 5.3, 5.5.3, 5.6
Human Resource Management	5.5.1, 5.5.2, 6.1, 6.2
Infrastructure and Environment	4.2, 6.3, 6.4
Customer Management	5.2, 7.2, 7.5.4, 8.2.1
Business Acquisition	7.1
Design and Development	7.3
Production	7.5.1, 7.5.2, 7.5.3, 7.6, 8.2.4
Purchasing	7.4
Materials Management	7.5.5, 8.3
Monitoring and Measurement	8.1, 8.2.2, 8.2.3,
Continual Improvement	5.4, 8.4, 8.5

Sixteen key comments were received from the SMEs as seen in Table 7. It was noted that the Survey SME did not have any suggestions at this time but liked the approach the team was taking.

Table 7. Initial Comments with Corrections

Comments - Rationale	Correction
1. Change Purchasing to Subcontract Management and Outsourcing - Purchasing itself does not include management of suppliers	Changed to Supplier Management
2. Add Program Management – key component to organizations	Added Program Management
3. Add Risk Management – key process to programs	Not added, key component of Program Management
4. Change Management to Business Management – Management itself is too broad	Changed
5. Add clause 5.4.1 to Management	Moved all of 5.4
6. Add clause 8.3 to Production – nonconforming material is key process for Production	Added clause
7. Add clause 7.5.5 to Production – missed clause	Added clause
8. Move clause 8.2.4 from Production to Monitoring and Measurement – 8.2.4 is part of Monitoring and Measurement	Product oriented measure, therefore added in lieu of moved
9. Clause 7.1 under Business Acquisition is weak but much needed	Comment only
10. Add Logistics under Production – customer support process is not covered	Added as Service with Production
11. Need to address retirement of product – new aspects of product lifecycle	Added as Disposal with Production and Service
12. Add Communications – Communications is key process across organizations	Added as Communications with clauses 5.1, 5.3, 5.5.1, 5.5.3, 7.2.3, 7.5.4
13. Delete Materials Management - not included within Service organizations	Deleted
14. Add Requirements Management with clauses 7.2.1 and 7.2.2	Not added, key component of Design and Development
15. Move clauses 5.5.1 and 5.5.2 from Human Resource Management to Management	Moved
16. Use terminology used in industry versus those in the ISO 9001 standard	Comment only

Based on the comments received, the process category list was updated as seen in Table 8 and sent out a 2nd round of reviews:

Table 8. Quality Management System Process Categories – 2nd Review

Process Category	ISO 9001:2000 Clause(s)
Business Management	4.1, 5.1, 5.3, 5.4, 5.5.1, 5.5.2, 5.6
Communications	5.5.1, 5.5.3
Human Resource Management	6.1, 6.2
Infrastructure and Environment	4.2, 6.3, 6.4
Business Acquisition	5.2, 7.1, 7.2
Customer Management	5.2, 7.2, 7.3.2, 7.5.4, 8.2.1, 8.5.2
Program Management	7.1, 7.3.4, 8.5.3
Supplier Management	7.4, 8.2.4, 8.5.2
Design and Development	7.3
Production, Service, and Disposal	7.1, 7.5.1, 7.5.2, 7.5.3, 7.5.5, 7.6, 8.2.4, 8.3
Monitoring and Measurement	8.2.2, 8.2.3, 8.2.4
Continual Improvement	5.4, 8.4, 8.5

Four key comments were received from the SMEs during the second review as seen in Table 9.

Table 9. Second Review Comments with Corrections

Comments- Rationale	Correction
1. Change Business Acquisition to Business Development – Business Development recognized term in Industry	Changed to Business Development
2. Add Configuration Management – critical activity in business	Added with Clauses 7.3 and 7.5.3
3. Add back in Materials Management – other areas could be excluded by design within Clause 7	Added back
4. Drop Disposal – term not recognized in Industry	Removed from Production and Service

After the comments were incorporated from the second review, the SMEs agreed upon fourteen process categories as seen in Table 10. Consistent with ISO/IEC 15504-2:2003, a process description was then defined for each Process Category to briefly describe each Process Category for use during the survey.

Table 10. Quality Management System Process Categories – Final

Process Category	Process Description	ISO 9001:2000 Clause(s)
1. Business Management	Processes that describe the development, implementation, and flow-down of an organizational structure, and business objectives and expectations.	4.1,4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6
2. Communications	Processes that describe how information is disseminated across and throughout the organization and within teams.	5.5.1, 5.5.3
3. Human Resource Management	Processes that describe how employment needs are identified and planned, and how employees are hired, developed, trained, deployed, motivated, and retained.	6.1, 6.2
4. Infrastructure and Work Environment	Processes that describe the make-up and inter-relationships within the organization required to effectively support and protect the workforce, business operations, and surrounding community.	6.3, 6.4
5. Business Development	Processes that describe how business opportunities are identified, captured, developed, and brought to market.	5.2, 7.1, 7.2
6. Customer Management	Processes that describe how customer requirements, expectations, and needs are identified, allocated, tracked, addressed, and communicated.	5.2, 7.2, 7.3.2, 7.5.4, 8.2.1, 8.5.2
7. Program Management	Processes that describe how programs are managed to ensure product quality, cost, schedule, and technical requirements and objectives are met.	7.1, 7.3.4, 8.2.3, 8.5.2, 8.5.3
8. Supplier Management	Processes that describe how suppliers are identified, evaluated, selected, monitored, and managed to ensure all product requirements are met.	7.4, 8.2.4, 8.5.2
9. Configuration Management	<i>Processes that describe how configuration items and changes thereto are determined, identified, tracked, communicated, controlled, verified, and managed to ensure contractual technical and functional requirements and product integrity are met.</i>	7.3, 7.5.3

Table 10. Continued

Process Category	Process Description	ISO 9001:2000 Clause(s)
10. Design and Development	Processes that describe how technical requirements are identified, captured, allocated, designed, verified, and validated to ensure that design quality and customer expectations are met.	7.2, 7.3
11. Production and Service	Processes that describe how production and service requirements are determined, planned, designed, validated, implemented and monitored to ensure product and process quality requirements are met.	7.1, 7.5.1, 7.5.2, 7.5.3, 7.5.5, 7.6, 8.2.4, 8.3
12. Materials Management	Processes that describe how product is handled, protected, preserved, stored, and delivered to ensure product quality and integrity.	7.5.5, 8.3
13. Monitoring and Measurement	Processes describing how the organization's key processes are assessed, measured, reported, and corrected.	8.2.1, 8.2.2, 8.2.3, 8.2.4, 8.5.2
14. <i>Continual Improvement</i>	<i>Processes that describe how data from processes and product at various levels of the organization are collected, reviewed and analyzed for required actions and improvement, and reported/monitored with and by Top Management.</i>	5.4, 5.6, 8.4, 8.5.1, 8.5.3

4.2 SURVEY DEVELOPMENT

Once the Quality Management System Process Category listing was completed, the Survey SME was consulted for guidance and lessons learned.

During the initial meeting with Survey SME, a top-level layout and approach was defined containing three sections:

1. Demographics, providing questions regarding the size and make-up of the company including any certifications held. This information allows for

categorization in support of the analysis to follow. The Survey SME recommended this section but cautioned to keep this section brief.

2. Process Capability Analysis, being the main body of the survey containing the fourteen process categories and information that would later result in a process capability rating. The survey SME recommended that the survey be limited in length to obtain participation; therefore each process category should be limited to contain no more than 3-4 questions each.
3. Follow-up Questions, containing questions to obtain information specific to the overall improvements of the companies' Quality Management System during the past five years. This section was suggested by the author, which the SME agreed may help in the analysis. Responses from the questions would allow for additional information in response to the capability level analysis.

Following the initial meeting with the Survey SME, a draft survey was developed by the author using Microsoft Excel.

- Thirteen basic questions including size, certifications, and customers were developed for the demographics section.
- The Process Capability Analysis section was developed using the fourteen Process Categories and the ISO/IEC 15504 architecture. Again, with the assistance of the SMEs through several iterative inquiries, exploratory questions were designed to prompt individuals to consider the functionality while responding to each of the fourteen process categories. To assist in the development of these follow-on questions, the SMEs were requested

to use the eight Quality Management Principles used by TC176 in the development of ISO 9001:2000. These principles can be used by senior management as a framework to lead their organizations towards improved performance as defined within ISO 9000:2005.

During the first review of the draft survey with the Survey SME, the following observations and recommendations were made:

1. Surveys have better response when able to submit without documenting individual and company names; therefore recommended removal of specific questions of that type from the Demographics section.
2. The current approach for the Process Capability Analysis section would be confusing for those taking it. It was also noted that fourteen sections lengthy as within one as seen in Figure 2 would result in a very long survey. The SME recommended developing this section as a two-dimensional table and eliminate rating of the sub-elements of each Process Category to minimize the length of the survey. Training on how to complete this section would also be necessary and needs to be developed. It was also recommended to design questions specific for each Process Category to eliminate redundancy.
3. The Follow-up Questions section was too long with two sections and four open-ended questions. The SME recommended dropping this to one section and eliminate the open-ended questions which are already part of the Process Capability Analysis.

4. Use of a web-based tool versus Excel during deployment allows for an ergonomic appealing approach for those participating. The SME indicated there were several free tools available and recommended checking SurveyMonkey and Perseus SurveySolutions as possible vehicles to use in administering the survey.

Figure 2. Process Capability Analysis Survey Section - Initial Example

	Process Attributes									Reference ISO 9001:2000 Clause(s)
	1.1 Process Performance	2.1 Performance Management	2.2 Work Product Management	3.1 Process Definition	3.2 Process Deployment	4.1 Process Measurement	4.2 Process Control	5.1 Process Innovation	5.2 Process Optimization	
Attribute Rating Definitions										
Not achieved (0% to 15%) Little or no evidence of achievement										
Partially achieved (>15% to 50%) Evidence of a sound systematic approach to and achievement										
Largely achieved (>50% to 85%) Evidence of a sound systematic approach to and significant achievement										
Fully achieved (>85% to 100%) Evidence of a complete and systematic approach to and full achievement										
Process Category										
Business Management										
Strategic Planning & Direction										4.1, 5.4
Management Commitment (Quality, Customer, Improvement)										5.1, 5.2, 5.3
Organization Structure										5.5.1, 5.5.2
Management Review										5.6
How does the strategic plan and organizational objectives flow down to all functional areas of the structure?										
How does quality planning tie into strategic planning?										
How often are strategic plans reviewed along with quality objectives (e.g., management review)??										

Following the review of the initial draft survey with the SME, the demographics section was reduced from thirteen questions to nine. The Process Categories section was also restructured as suggested, significantly reducing the length of the survey. An example is seen in Figure 3. With the assistance of the Survey SME, ten questions were finalized within the Follow-Up Questions section and were designed to provide an indicator / level of satisfaction on how the company surveyed was progressing on process improvement, management commitment, and customer satisfaction.

1. <u>Business Management</u>: Processes that describe the development, implementation, and flow-down of an organizational structure, and business objectives and expectations. (ISO 9001 ref. 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6)					
	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance					
2.1 Performance Management					
2.2 Work Product Management					
3.1 Process Definition					
3.2 Process Deployment					
4.1 Process Measurement					
4.2 Process Control					
5.1 Process Innovation					
5.2 Process Optimization					
<p>1a. How does the strategic plan, business objectives, and functional objectives tie together and how are they flowed down through the organizational structure?</p> <p>1b. How is the organization structured? How are functional roles and responsibilities defined and communicated?</p> <p>1c. How are the organization's standard policies, processes and procedures managed and maintained? How are the organizational process interrelationships and dependencies defined, depicted, and viewed as a system of Quality Management?</p> <p>1d. <u>Process Category feedback and additional comments</u>: What weaknesses and improvements to your Quality Management System do you see needed for this process category based on your evaluation above?</p> <p>What changes to ISO 9001:2000 do you think need to be made in this area or do you think it is adequate as written?</p>					

Figure 3. Process Capability Analysis Survey Section – Final Example

At the recommendation of the Survey SME, both SurveyMonkey and Perseus SurveySolutions were assessed for possible use. Not being a very large survey, either one of these tools appeared to be potential solutions. Both tools were populated with the top level structure with some of the questions for experimentation. Even though more difficult to use, Perseus SurveySolutions

was selected over SurveyMonkey by having an unlimited number of questions and far better capability in data reporting and exportation. Table 11 summarizes the results of both tools. Following the selection process, the survey was populated into Perseus SurveySolutions.

Table 11. Survey Tool Results Comparison

	SurveyMonkey	Perseus SurveySolutions
Cost	Free with limited use; 10 questions and 100 response limit; upgrades available at a monthly fees	Free; no restrictions on number of questions
Accessibility	Supports for Internet Explorer and Firefox browsers	Does not support Firefox browser - therefore individuals would have to use IE to access surveys; survey is exportable to other media
Layout	Several background colors available; survey panel appears to be 3-dimensional and hard to read; individual pages allowed	Color background is limited but easy to read panels are flat and easy to read page and individual sections allowed
Design	Question design easy to use with many options; question numbering is automatic - can not define sub- numbers does no allow large/multiple matrices	Question desing not intuitive but great help panels available; Can define table and screen widths; can define indivivual and sub-group question numbers
Invite Notification	E-mail	E-mail
Security	Password protected	Password protected
Data Collection	Allows single to multiple entries by individuals; allows for pre-defined cut off date; allows authorized deletion of fictitious data; does not allow survey to be saved and completed later	Enforces single entry per person; allows authorized deletion of fictitious data; does not allow survey to be saved and completed later
Analysis Tools	Basic reports and tabulations; limited graphics; data exportable at additional cost	Reports, tables, and graphs available; data exportable to xml format and Excel but contain delimiters
Overall Rank	2	1

Following development of the survey (reference section 10.1), a training module was developed providing an overview of the ISO/IEC 15504 architecture. This module provided a quick overview of the survey objectives and structure (reference section 10.2).

4.3 SURVEY DEPLOYMENT

Once completed, fourteen companies ranging in size from 15 to over 5000 employees were requested to take the survey. Several of these companies also provide products and services to the commercial sector. Due to the sensitive nature of the survey, individual results were not disclosed. The survey was made available late-December 2005 through February 2006.

Initial inputs received from the first two companies after completing the survey indicated there was a problem attempting to complete the survey during one session without having the capability in saving the results. After consulting with the Survey SME, it was determined the best approach was to export the survey into Microsoft Word and allow the companies to have the option of completing it in this method. The survey was thus extended with final responses being received April 2006.

Of the fourteen companies surveyed, responses were received from eleven. Two of the companies elected not to respond due to concerns with specific competitors involved. One other company suffered a tragic loss during this survey period therefore was unable to participate.

Each completed survey was reviewed for completeness and specific trends upon receipt. Individual follow-on interviews were also conducted with

several participants to ensure understanding of the responses provided. Once complete, a capability level rating was awarded for each process category using the ISO/IEC 15504 Capability Level Ratings defined in Table 5 (reference sections 10.3 and 10.4 for data collected).

5 RESULTS

Individual responses were compared to one another in order to identify similarities, differences, and dependencies using the Open Coding technique. This analysis was conducted iteratively to determine trends or patterns until all surveys had been completed and received.

5.1 COMPANY DEMOGRAPHICS

Upon receipt of each survey, information was captured and categorized as shown in Table 12. The companies surveyed were assigned a number from 1 to 11 based on the size of the employee population.

Table 12. Company Demographics

Company	Number of employees	Skill Mix			ISO 9001 Certification	SEI CMMI Maturity Level
		Percent Engineering	Percent Manufacturing	Percent Support		
1	34	100	0	0	Yes	2
2	360	40	40	20	Yes	4
3	450	60	20	20	Yes	4
4	525	10	50	40	Yes	n/a
5	600	30	60	10	Yes	3
6	600	85	10	5	No	3
7	1800	70	15	15	Yes	5
8	2300	60	25	15	Yes	4
9	3000	40	20	40	Yes	n/a
10	3800	60	20	20	Yes	5
11	5000	40	40	30	Yes	3

As seen within Table 12, there were a few items that were immediately noted:

- Each company contained an Engineering discipline;
- One company did not have Manufacturing;

- Ten companies were ISO 9001:2000 certified, one declared compliance;
- Nine companies had implemented the SEI CMMI® model for software and systems engineering to some degree.

No other significant items were initially observed.

5.2 COMPANY PROCESS CAPABILITY ANALYSIS

In reviewing the information obtained from the Process Capability Analysis, Figure 4 shows that companies 3-5 have slightly higher mean and median capability levels than other companies. Table 12 shows that there was no specific pattern among these companies from a skill mix or SEI CMMI® levels but all three did contain less than 1000 employees. Table 12 also shows that companies 2 and 6 also had less than 1000 employees yet were extremely low in the mean and median capability levels. Follow-on interviews with these two companies revealed the following:

- Company 2 even though certified to ISO 9001:2000 had recently been divested from their parent company. As part of the acquisition, the company was undergoing significant changes in management, processes, and systems, thus the quality management system was undergoing a significant transformation and had not yet stabilized.
- Company 6 had not yet obtained certification to ISO 9001:2000 and was currently focusing their efforts on implementing the SEI CMMI® model. The Capability Maturity Model® Integration (CMMI) was designed to provide a process improvement approach for organizations. It can be used to guide process improvement across a project, function, or organization.

SEI CMMI[®] helps integrate separate organizational functions, establish process improvement goals and priorities, provides guidance on processes, and provides a reference point for appraising current processes. It should be noted that even though the company was pursuing the implementation of SEI CMMI[®], it was determined that the quality management system for this company was not yet fully implemented and institutionalized per ISO 9001:2000.

Based on the above circumstances, the data from companies 2 and 6 were set aside. The remainder of the study was conducted with the other companies that contained mature and functioning quality management systems. Each of the remaining companies indicated their initial certification to ISO 9001 was to the 1994 revision, later upgrading to the 2000 revision during recent years.

With the removal of companies 2 and 6, the average capability level rating was determined for each process category. As seen in Figure 5 and Table 13, the mean for each Process Category increased with the exclusion of these two companies. The overall mean and median levels jumped 25% from 2.0 to 2.5 with a drop in variation across all process categories.

Figure 4. Company Capability Levels

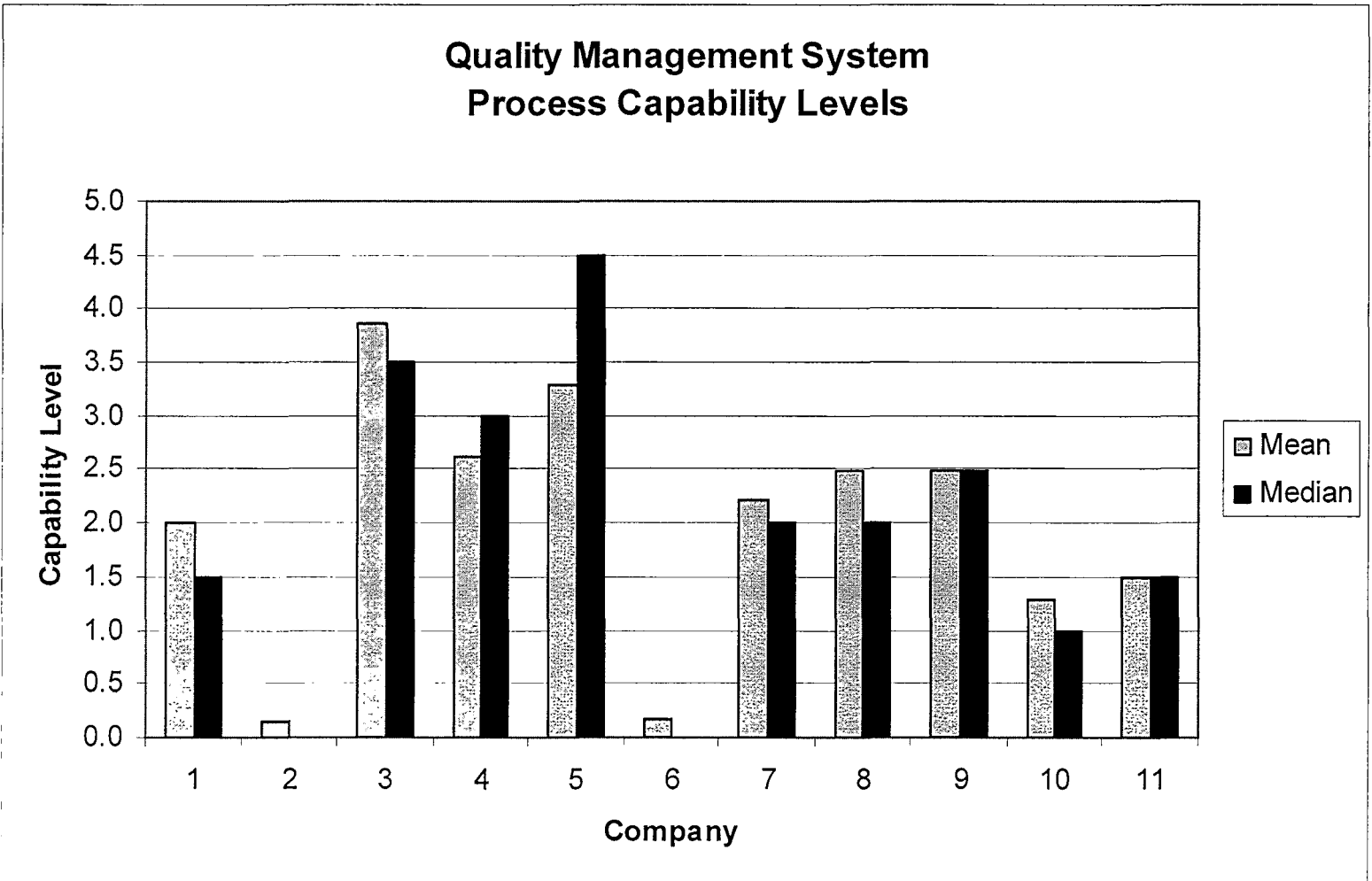


Figure 5. Company Capability Levels by Process Category

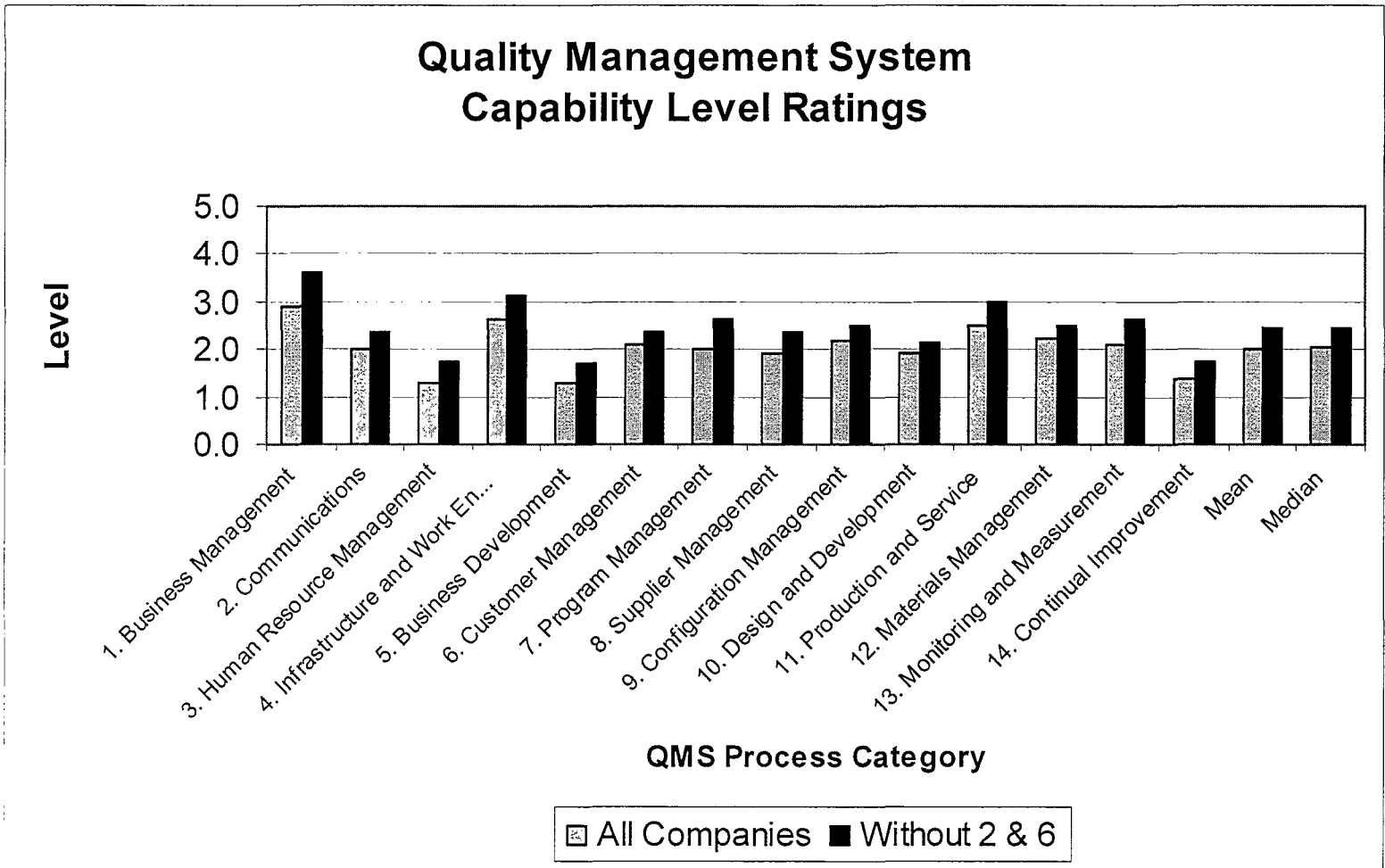


Table 13. Company Capability Levels Detail by Process Category

Process Category	All Companies		Without Companies 2 & 6		delta	
	All Companies	Std Deviation	Without 2 & 6	Std Deviation	Mean	Std Deviation
1. Business Management	2.9	1.6404	3.6	1.2360	0.7	-0.4044
2. Communications	2.0	1.2649	2.4	1.1180	0.4	-0.1469
3. Human Resource Management	1.3	1.1037	1.8	1.0138	0.5	-0.0899
4. Infrastructure and Work Environmer	2.6	1.7477	3.1	1.3017	0.5	-0.4460
5. Business Development	1.3	1.4181	1.7	1.4079	0.4	-0.0103
6. Customer Management	2.1	1.8684	2.4	1.7401	0.3	-0.1283
7. Program Management	2.0	1.7889	2.6	1.6667	0.6	-0.1222
8. Supplier Management	1.9	1.8529	2.4	1.7678	0.5	-0.0852
9. Configuration Management	2.2	1.8340	2.5	1.6583	0.3	-0.1757
10. Design and Development	1.9	1.5136	2.1	1.4814	0.2	-0.0322
11. Production and Service	2.5	2.0138	3.0	1.9221	0.5	-0.0917
12. Materials Management	2.2	1.6415	2.5	1.5119	0.3	-0.1296
13. Monitoring and Measurement	2.1	1.7581	2.6	1.7401	0.5	-0.0180
14. Continual Improvement	1.4	1.1201	1.8	1.0000	0.4	-0.1201
Mean	2.0	1.6272	2.5	1.5096	0.4	-0.1177
Median	2.0		2.5		0.4	

Upon further analysis, it was observed that 67% of the companies were rated Capability Level 1 for Continual Improvement whereas the remaining 33% were Level 3 out of a possible 5 (reference Figure 6).

The respondents indicated that Continual Improvement requirements were new to their organizations during the past five years as part of the update to ISO 9001:2000. Respondents that were capability level 1 indicated that they were still struggling with implementation with continual improvement programs and more guidance was needed. Other companies at level 3 had placed a more formal system in place gathering and implementing improvements from data and suggestions received from the workforce. Based on the inputs received, it was concluded that the results for this particular Process Category would have been low with the recent requirement imposed by ISO 9001:2000.

Human Resource Management and Business Development were also noted as having the lowest average levels at 1.6. Approximately 88% of the companies were rated between Capability Levels 1 and 2 for Business Development and 78% for Human Resource Management. Both of these areas had not matured over time. In discussing this with respondents, it was felt that Business Development as a process area was not specifically called out in ISO 9001:2000 therefore would lack direct focus during implementation and improvement to the QMS. The smallest company with 34 employees rated this area Level 5. Considerable focus was being applied by this company to business growth whereas the other companies were well established and focused on program performance.

However, Human Resource Management was addressed in all editions of ISO 9001 (1987, 1994, and 2000). Some of the respondents felt that the basic requirements were met within ISO 9001:2000 however maturity to higher levels did not evolve over time. This was thought that focus on improvement was being applied more to other areas directly supporting product development, build and delivery, and customer satisfaction as they all had done in the past.

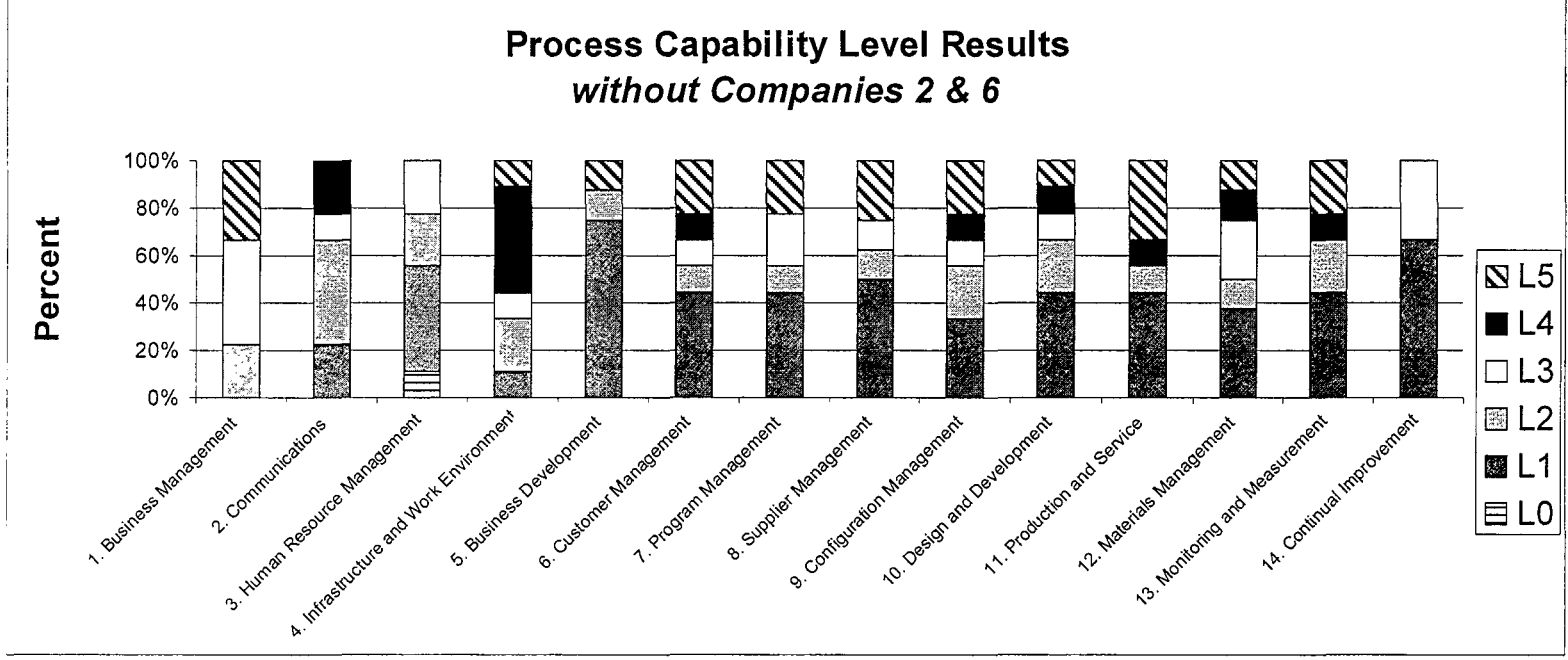
Finally, Business Management, and Infrastructure and Work Environment were noted as having the highest average ratings of 3.4 and 3.2 respectively.

The companies felt that Business Management has improved since the implementation of ISO 9001:2000 with the added requirements and focus on Top Management commitment, Quality Objectives, and customer satisfaction. As a result of the new requirements, many of the companies had better objectives programs tying in the Strategic Plans and flow down of expectations throughout the workforce.

Feedback from the participants indicated that Infrastructure and Work Environment rated high due to environmental, safety and health programs being well established and designed to assure state and federal regulations were being met. It was noted that eight of the remaining nine companies had implemented and were certified to the environmental management system standard ISO 14001:2004. Similar to ISO 9001:2000, ISO 14001:2004 requires monitoring, measuring, and improvement programs to environmental management, therefore this particular process area contained varying degrees of implementation and rated high on average as seen in Figure 6.

In addition, it was also noted that technology programs were in place at all companies to provide state-of-art computer equipment and software to the workforce, especially in the areas of engineering.

Figure 6. Process Capability Level Results without Companies 2 & 6



To determine if the process capability levels were dependent on company size, each was placed into a specific group based on employee population. Five groups were defined as follows: <500, 501-1000, 1001-2500, 2501-5000, and 5000+. Each grouping contained two companies with the exception the 5000+ group containing a single large company. In addition, the companies were also categorized into groups based on the SEI CMMI[®] Maturity Level. In reviewing Table 14, two observations were immediately made:

- a) the mean and median process capability levels went down for the larger employee population, and,
- b) the mean and median capability levels were not influenced by the SEI CMMI[®] Maturity Levels.

It was concluded that Quality Management Systems Capability Levels and SEI CMMI[®] Maturity Levels may not directly correspond due to differences in the scope and breadth of each standard taken within the companies; i.e., ISO 9001:2000 covers all aspects of the organization whereas SEI CMMI[®] focuses mostly on engineering and program management processes.

Table 14. Company Capability Levels by Employee Population

Category <i>by Employee Population</i>	Number Companies	Capability Levels	
		Mean	Median
<500	2	3.1	3.0
501-1000	2	2.9	3.0
1001-2500	2	2.4	2.0
2501-5000	2	1.9	1.8
>5000	1	1.5	1.5
<i>by SEI CMMI Maturity Level</i>			
N/A	2	2.5	2.5
2	1	2.0	1.5
3	2	2.4	3.0
4	2	3.2	3.0
5	2	1.8	1.5

To further analyze the patterns as discussed previously, the capability levels for each individual employee grouping were provided in Figure 7 and Table 15. As discussed previously all companies were experiencing problems with Continual Improvement and this is not company size dependent. This pattern also appears to be evident with Human Resource Management. However, looking at Figure 7 it can be seen that the smaller companies are more successful at Business Development and Supplier Management. As discussed earlier, the smaller companies depend on business growth to survive. Follow-on interviews also indicated that there was a smaller supplier base within the smaller companies than the larger companies, therefore were easier to manage. The process capability level appears to go down the larger the company (i.e., inversely proportional).

Finally, Table 15 provides the details for each process category based on company size. Those levels that were 3 or higher are highlighted in grey. Table 15 shows there are far more in grey within the smaller grouping than larger.

In addition, in referring to the Mean capability level column, those that were 3.0 or higher are highlighted in grey and anything lower than a 2 are in bold font. These areas are consistent with those previously discussed.

Figure 7. Company Process Capability Detail by Employee Population

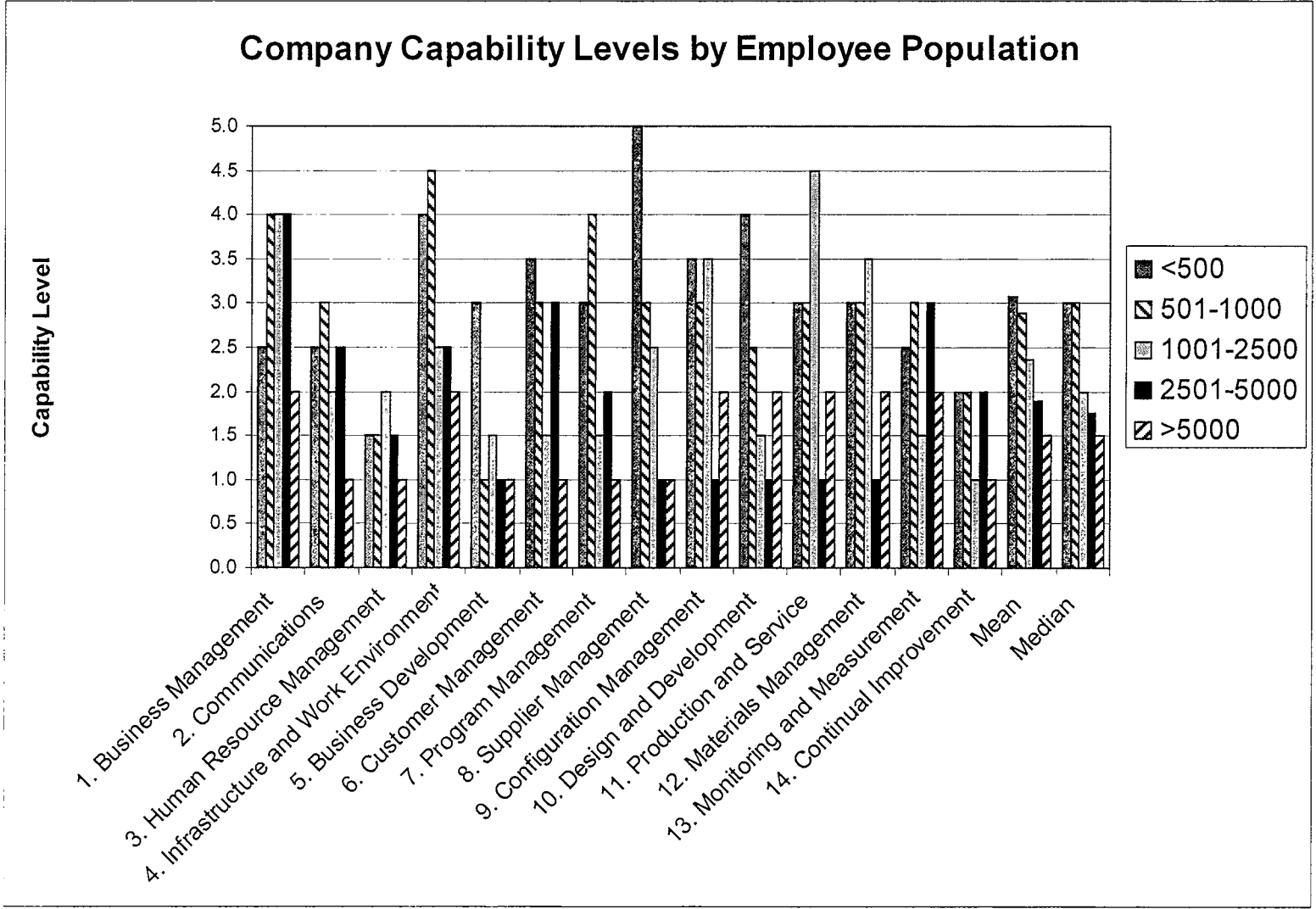


Table 15. Company Capability Levels by Employee Population Detail

Process Category	<500	501-1000	1001-2500	2501-5000	>5000	Mean	Median
1. Business Management	2.5	4.0	4.0	4.0	2.0	3.3	4.0
2. Communications	2.5	3.0	2.0	2.5	1.0	2.2	2.5
3. Human Resource Management	1.5	1.5	2.0	1.5	1.0	1.5	1.5
4. Infrastructure and Work Environment	4.0	4.5	2.5	2.5	2.0	3.1	2.5
5. Business Development	3.0	1.0	1.5	1.0	1.0	1.5	1.0
6. Customer Management	3.5	3.0	1.5	3.0	1.0	2.4	3.0
7. Program Management	3.0	4.0	1.5	2.0	1.0	2.3	2.0
8. Supplier Management	5.0	3.0	2.5	1.0	1.0	2.5	2.5
9. Configuration Management	3.5	3.0	3.5	1.0	2.0	2.6	3.0
10. Design and Development	4.0	2.5	1.5	1.0	2.0	2.2	2.0
11. Production and Service	3.0	3.0	4.5	1.0	2.0	2.7	3.0
12. Materials Management	3.0	3.0	3.5	1.0	2.0	2.5	3.0
13. Monitoring and Measurement	2.5	3.0	1.5	3.0	2.0	2.4	2.5
14. Continual Improvement	2.0	2.0	1.0	2.0	1.0	1.6	2.0
Mean	3.1	2.9	2.4	1.9	1.5	2.3	2.5
Median	3.0	3.0	2.0	1.8	1.5	2.4	2.5

=> Level 3
< Level 2

5.3 COMPANY QUALITATIVE ANALYSIS

To facilitate the qualitative analysis of responses received, comments provided were assembled in an Excel spreadsheet, by Process Category and question. Each Process Category was reviewed to determine if any general patterns or trends existed. In addition, the lowest and highest rated Process Categories were reviewed in detail to further understand weaknesses and strengths within each.

5.3.1 Business Management

Structures were well defined within the companies along with roles, responsibilities, business practices and processes. Organization structures were found to be mostly matrixed and working. Business processes were either maintained and improved upon by individual functional groups or integrated review boards. Strategic planning generally is performed with varied knowledge through the workforce and tied into personal objectives. Improvements recommended to the ISO 9001:2000 standard were the clarification of flow down of business objectives through the organization to eliminate confusion of those defined today as "Quality" objectives.

5.3.2 Communications

All companies reported having communication processes in place however varied from Newsletters, bulletin boards, All Hands Meetings, Company President Reviews, E-mail, Web postings, etc. Each company reported having regular meetings with executive management to review customer and supplier issues, results to annual objectives, staffing results, and process and product

performance. These reviews were either in the form of a single meeting or series of meetings however all were covering similar information. Most of the companies were happy with the current process employed but recommended adding requirements to the ISO 9001:2000 standard of communications with customer and suppliers.

5.3.3 Human Resource Management

Most companies have personal objectives defined for their employees and assess them annually. Some companies have employee recognition programs in place that vary from peer-to-peer to formal evening events. However, a couple of companies indicated their motivation programs are managed as part of the compensation received; i.e., annual pay increases are recognition of a good job done. Very few companies indicated that programs were in place for encouraging employees to bring forth improvement recommendations. All companies felt that human resource improvement programs were in need, including measurements on requisition filling and employee retention. Few companies felt ISO 9001:2000 was adequate as written for this specific area. Those that did recommend improvements felt employee motivation and recognition requirements as part of the quality management system were in need.

5.3.4 Infrastructure and Work Environment

All companies reported that facilities and tool needs are evaluated during proposal activities, and acquired mostly through capital investments. Long-term improvements and upgrades are included and planned as part of the strategic

planning by facilities and information technology groups. Most companies reported that environmental, safety and health programs are independent of their quality management systems. Audits, improvement programs, and management reviews were typically conducted separately. Those companies with ISO 14001:2004 registrations felt ISO 9001:2000 was adequately written but would like to see both management system standards integrated and combined.

5.3.5 Business Development

Most companies have business development plans but indicated they are disjoint from the strategic plans. The companies that responded in this manner also indicated that functional groups are not included during early on planning and development of proposals for potential business and capturing lessons learned. They all felt that ISO 9001:2000 was inadequate in addressing Business Development and Marketing requirements for the organization. This observation could contribute to the weakness within the quality management system of some of these companies by lacking specific oversight.

5.3.6 Customer Management

Customer requirements are typically captured during proposal phases of companies and during subsequent customer reviews. The larger companies indicated usage of requirements management tools to track, verify, and report compliance through delivery. Customer complaints on the other hand, were not captured and handled consistently, and a weakness in most companies (i.e., received and handled in ad hoc manner). This was found to be the case particularly in the larger companies containing several customers and individuals

interfacing with various levels of customer management; program management, contracts administration, quality assurance, engineering. Those responding felt this was an area needing immediate improvement. Companies also indicated a struggle initially to collectively capture customer satisfaction measures when ISO 9001:2000 was released. Many were now using annual surveys and identifying necessary actions to improve satisfaction levels. All companies reported usage of customer property and have adequate controls in place. All companies felt that ISO 9001:2000 was sufficiently written for this Process Category.

5.3.7 Program Management

Companies reported that they have company Program Management training programs in place. The training programs were defined and managed internally to the companies. All companies reported use of risk management practices and processes within the program management profession and programs. Some companies felt improvements were needed in this area, including more training with program managers and functional groups. Further interviews found that concerns in this area were the adequate identification and classification of risks within a given program. All companies did report that functional groups are included in the risk planning activities. Some companies felt that the ISO 9001:2000 standard should include requirements in risk and program management, similar to the SEI CMMI® maturity model.

5.3.8 Supplier Management

Companies reported having supplier management programs however were inconsistent on how the suppliers are included in future business planning

activities. Those that are included were those reported as being “team mates” in the planning and pursuit of new business opportunities in a partnership relationship. All companies responding did indicate that requirements flow down occurred within purchasing documents and were closely monitored by quality assurance and technical organizations. On-site assessments are usually performed prior to contract award to ensure capabilities exist to meet contractual and company requirements. All companies felt that ISO 9001:2000 was adequate as written in this specific area.

5.3.9 Configuration Management

All companies reported consistently as having configuration management practices and plans in place, some having designated groups in place to manage this specific area. Individual program practices are defined in configuration management planning documents. Requirements are managed closely through the use of configuration change boards. Product configurations are verified and confirmed through out the product lifecycle through the use of inspections and audits. All companies felt that there was no need of any changes to ISO 9001:2000 in this area.

5.3.10 Design and Development

All companies reported as having research and development programs in place. The smallest company also reported holding sessions with customers to review new technology pursuits for their awareness. Most of the companies also indicated invention recognition programs are in place for their employees. Training of engineers did vary among the companies. Many felt that there was

needed improvement in this area, tying back to Human Resource Management. The smallest company hiring needed skills as they emerge. The larger companies indicated that basic training programs are in place but improvements were needed in the area of emerging and future technologies in order to plan and meet new skill demands ahead of time. Program requirements are captured and managed closely by engineering organizations. Larger companies reported using automated tools in order to manage and track requirements through delivery. Design and development measurements were in place at all companies. Some companies reported having them were in the form of defect density, productivity, requirements stability, technical performance measures, schedule and cost. The measurements are reviewed during regular program reviews. Companies felt that ISO 9001:2000 was adequate as written in this area.

5.3.11 Production and Service

All companies with the exception of the smallest reported as having manufacturing organizations. The smallest company however did report being a provider of engineering services. All companies felt that Production and Service was adequately included during the proposal and strategic planning activities. Many companies reported using statistical process control methods and other measures to closely monitor manufacturing processes. Not all companies collected service data from customers and felt that this was an area for improvement needed within their respected companies, in data gathering, resources needed, and lessons learned. Follow-on interviews indicated that

service data is collected if contractually required, however typically determined to be a costly overhead expense by companies in other cases, therefore not performed. They all felt that ISO 9001:2000 was adequately written for the Process Category.

5.3.12 Materials Management

Companies responding to this specific area indicated use of receiving organizations and stock rooms to manage and control incoming material. Some reported as having shelf life items that are closely monitored for expiration dates. Electrostatic Discharge prevention programs were reported by some companies, which had training programs in place for employees handling product. Nonconforming material was reported as being identified in some fashion (tags, documents, etc.) and held to prevent co-mingling with good product. Companies reported that nonconforming customer property was managed consistent with internal procedures. No recommendations were identified to ISO 9001:2000.

5.3.13 Monitoring and Measurement

As discussed earlier under Customer Management, most companies reported using customer surveys to capture satisfaction levels. One company also indicated use of customer Award Fee and Contract Performance Assessment Review (CPAR) data as a mechanism to measure satisfaction. All companies struggled responding to how process and product performance measure tie into business objectives. Some companies indicated the measures are managed within specific functional groups however it was not evident the measurements are tied and trace into company business objectives. Two

companies reported the measurements as being functionally stove-piped and not well integrated. Audit programs were reported as being well established by all companies. Individuals are selected and trained to perform the audits. Audit priorities and direction did vary among the companies. Some reported direction was received by executive management whereas others are managed closely by quality assurance or ISO 9001 Management Representatives. All companies felt ISO 9001:2000 was adequately written in this area.

5.3.14 Continual Improvement

All companies responding indicated that significant improvement was needed in general in this Process Category. Many companies felt that root cause analysis of known reported problems was not well performed, many only performed by quality assurance personnel. Some companies during follow-on interviews have tried using Lessons Learned databases however were not consistently used by all personnel. Most companies also exhibited frustration in the area of data gathering and analysis. Analysis of data was found to be performed and contained within functional groups and/or programs but difficult to capture and perform at an organizational level. Specific items requiring improvement are identified and documented within quality improvement plans. Improvements identified the need of an integrated close-loop feedback program with the inclusion of measurements and improvements. Follow-on interviews determined most companies felt this Process Category needed the most work. ISO 9001:2000 introduced many new requirements in this area and were reported as being adequate as written.

5.4 QUALITY MANAGEMENT SYSTEM IMPROVEMENTS

As part of the follow-on questions within the survey, companies responded on how the companies improved in certain aspects of the quality management system during the past five years.

Overall, all eleven companies felt that that performance of their quality management systems maintained or improved during the past five years as seen in Figure 8. During subsequent discussions, they felt that this was due to the restructure of ISO 9001:2000 and the added requirements that help foster continual improvements within. It was especially noted that that business acquisition and growth increased during the period, which the respondents felt that the certification to the ISO 9001:2000 standard may have been a discriminator among the competition.

Finally, Company 6 was still in process of implementing ISO 9001:2000 and felt that progress was the same over the past five years whereas those that were certified felt that performance has improved.

Furthermore, in referring to Figure 9 which provides detailed responses, two responses did contain a worse rating by Company 2 in the area of Workforce Accountability and Training. The respondent felt these areas degraded due to transitioning into a new corporate structure.

Figure 8. Company Quality Management System Performance Improvement Satisfaction Levels

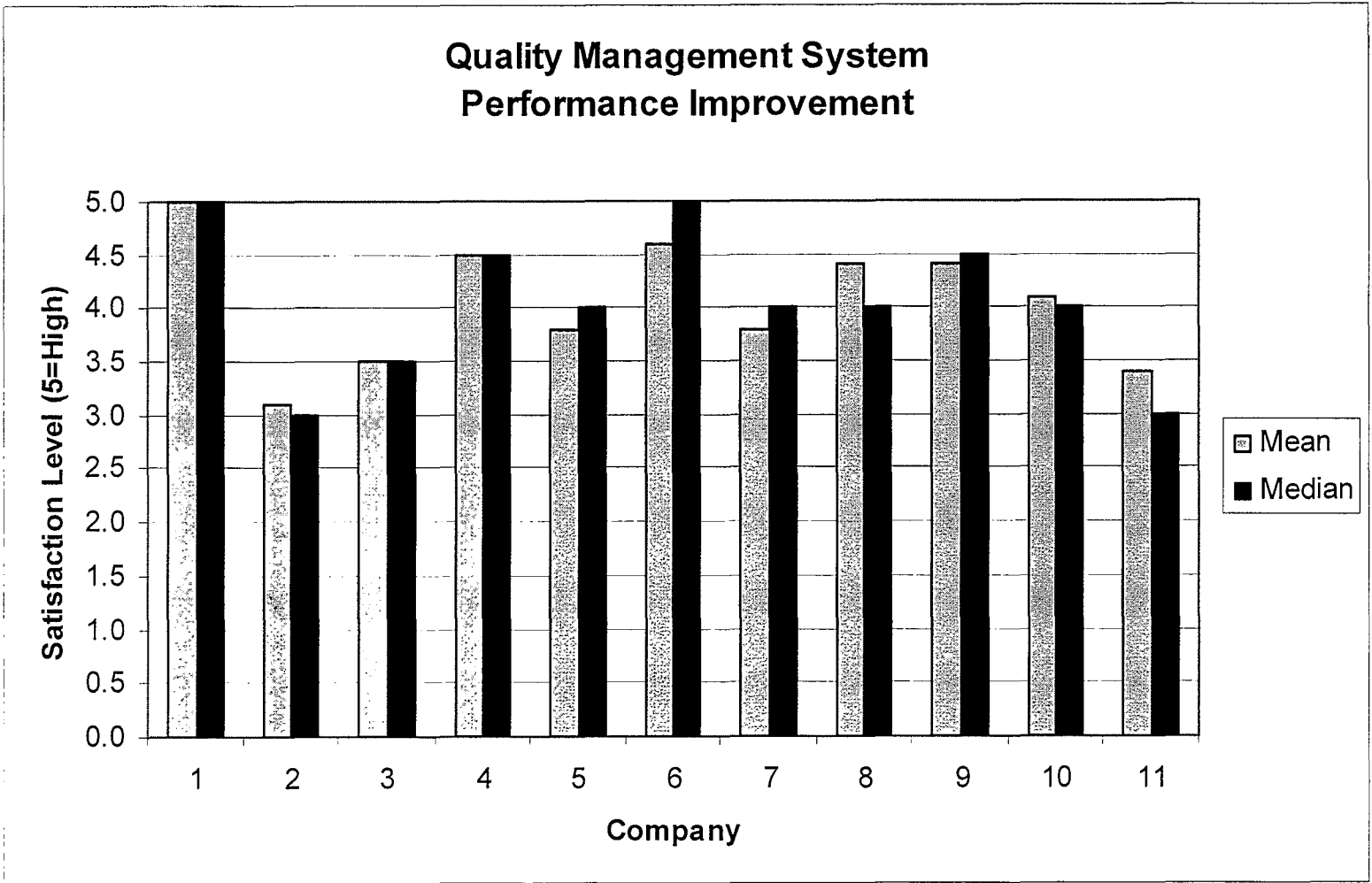
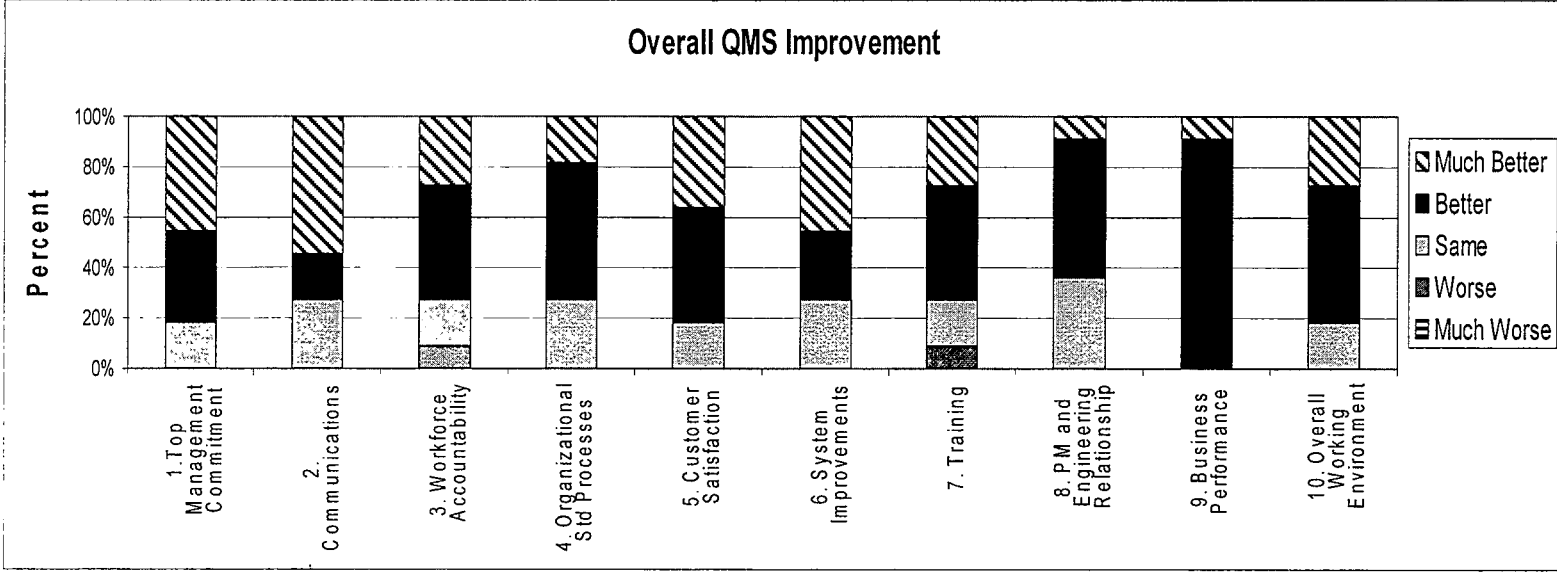


Figure 9. Overall Quality Management System Improvement Satisfaction Detail



6 DISCUSSION

Analysis of survey results found that the Human Resource Management, Business Development, and Continual Improvement process categories were of the lowest area of maturity.

With an average maturity level of 1.6 based on the ratings supplied by the companies, responses to questions relative to Human Resource Management indicate that training programs may be inadequate (see 5.3.10 Design and Development) and employee recognition/motivation programs are in need (see 5.3.3 Human Resource Management). This could contribute to employee acquisition and retention problems as expressed by several of the companies. Even though employee objectives are generally documented, it appears more focus needs to be applied in the area of measurements of employee satisfaction and skills development.

The weakness noted in Human Resource Management is consistent with survey conducted with 277 organizations by the US Technical Advisory Group (TAG) to ISO/TC 176 on implementing ISO 9001:2000 (Liebesman, 2002). The 227 organizations identified sub-clause 6.2.2 Competence, awareness and training second to sub-clause 8.2.1 Customer satisfaction as the most difficult to develop and implement as a process. The 2000 revision of ISO 9001 does place more focus on the area of resource management (Bendell and Boulter, 2004) yet organizations continue to struggle with this specific area.

In reviewing the responses to questions regarding Business Development, many companies felt that the business development plans were disjoint from company strategic plans, and that ISO 9001:2000 is generally inadequate in this area. Business development had also not been found as a quality management systems area of concern within literature. This particular area is not mapped directly into the ISO 9001:2000 standard as expressed in company feedback, therefore could be at risk of being overlooked in most implemented programs.

Finally, analysis of the responses indicate that companies struggle in capturing and analyzing data at the organizational level and conducting lessons learned, including those from customer deployed product (see 5.3.11 Production and Service) and customer complaints/satisfaction (see 5.3.6 Customer Management), all forming part of Continual Improvement. Being a new formal requirement of ISO 9001:2000, it appears and would be expected that companies would struggle with this area. Continual Improvement and Customer Satisfaction were also identified in the US Tag Survey (Liebesman, 2002) as being difficult processes to define and implement as seen with this study.

Overall, most companies responded that their overall Business Performance improved during the past five years. Even though this survey sampled a smaller number of companies, many studies have determined that most companies have experienced an increase in overall sales following certification to the ISO 9001:2000 standard (Chow-Chua et al., 2003). This was especially noted for those that are small-medium size. The results of this survey indicated that smaller companies fair better than larger ones in process capability

levels. This is consistent with making the 2000 revision of ISO 9001 more user friendly for smaller organizations by reducing the number of required procedures from eighteen to six (West, 2001). With less procedures required, the smaller organizations may be able to apply more focus on process structure and business growth. Other studies performed have also concluded that the structured and organized framework of ISO 9001:2000 implemented within smaller organizations does provide the element necessary to facilitate further business growth (Bendell and Boulter, 2004).

As discussed earlier, more focus has typically been applied to those areas directly affecting product (e.g., Design and Development, Production and Service, Materials Management). It must be noted that other areas do indirectly affect overall company efficiencies (productivity, learning, etc.) therefore require the same level of attention and improvement. It is recommended future studies should be performed to explore this area to determine underlying causes and difficulties within organizations, especially those that are large in size and complexity. With the concerns consistent across companies in this area, it is questionable to what ISO 9001 Registrars are assessing and determining to be adequate for certification and could be concluded that more focus and assistance may be required in this area.

6.1 LIMITATIONS OF STUDY

This study involved responses received from eleven of fourteen companies selected. Each company selected had some level of involvement with the SEI CMMI[®] model yet two of the companies lacked mature quality

management systems in accordance with ISO 9001:2000, therefore were excluded from the analysis for consistency. This resulted in a detailed analysis of only nine companies. It was noted that a larger sample size would have been desirable, including more companies that are small in size, to further validate the observations made in the area of Human Resource Management, Business Development, and Continual Improvement. Using companies that have implemented SEI CMMI[®] may have also biased the resulting data in the area of Design and Development processes.

If done differently, a larger number of companies would have been selected with the possible assistance and recommendations from established ISO 9001 Registrars. More time would have also been spent on evaluating and acquiring a better suited web-based survey tool that would allow for incremental saving and update by respondents while taking the survey. The tool would also need to include enhanced functionality to facilitate exporting and analyzing data.

Future expanded research is recommended using the ISO/IEC 15504 architecture in quality management systems, and may support needed changes for companies of all sizes to the upcoming revision to ISO 9001 and ISO 9004 currently scheduled in 2009.

7 SUMMARY

In summary, a survey was developed with the assistance of industry subject matter experts (SMEs) using the ISO/IEC 15504 architecture to assess and determine areas of improvement within ISO 9001:2000 defined quality management systems. The SMEs assisted in the development of fourteen quality management system process categories in support of the ISO 9001:2000 model to base the survey on. The survey was designed to provide information regarding the maturity of each of the fourteen quality management process categories and exploratory questions to assist in the identification of areas in need of improvement. An experienced Customer Survey SME was utilized to help develop the survey in order to meet the objectives of this exploratory study, and ensure consistent data gathering and maximum participation by respondents.

Fourteen companies were selected to participate in a survey. The companies were selected based on their experiences with the ISO 9001:2000 model in designing and implementing their quality management systems and basic awareness of SEI CMMI[®]. Of the fourteen companies selected, eleven participated in the survey. Of the eleven respondents, two were found to have unstable quality management systems due to the lack of complete implementation and recent transition to another company due to a recent acquisition.

Each of the participating companies provided information for each process category based on their analyses and observations. Follow-on interviews were

performed with several companies to clarify responses provided and to ensure consistency. Resultant data were analyzed for trend based on demographics, company size, maturity ratings of process categories, and responses to exploratory questions.

During the analysis, it was determined that Human Resource Management, Business Development, and Continual Improvement were consistently noted as being less mature than the other eleven process categories reviewed. Continual Improvement, as a process is new to the ISO 9001:2000 model, whereas Human Resource Management had been defined since the initial release of ISO 9001 in 1987. Follow-on analysis indicated that more focus needs to be applied internally in this area and that companies feel that ISO 9001:2000 is adequate as written. Business Development, on the other hand is not clearly defined within ISO 9001:2000 therefore maybe a weakness within the model itself.

Overall, using ISO/IEC 15504 as a framework to analyze quality management systems defined by ISO 9001:2000 was found to be beneficial by the participating companies to help identify and prioritize areas for improvement and focus.

8 CONCLUSIONS

Using the ISO/IEC 15504 architecture as a tool for assessing quality management systems was found to be beneficial to use supplementing the ISO 9001:2000 standard in determining the process capability levels and identifying areas requiring focus and further improvement. As a result of this study, weaknesses to the quality management systems were consistently found to be in the areas of Human Resource Management, Business Development, Customer Management, Continual Improvement as found in prior studies and surveys. Using ISO 9001:2000 as a stand alone model or ISO 9004:2000 to assess quality management systems may not have identified these specific groups as being areas requiring focus, especially the Business Development process category.

Other observations made were that smaller companies appear to have been more successful in implementing quality management systems with an elevated focus on business development and growth than larger companies, mostly in part for survival. Quality management systems as defined by ISO 9001:2000 are more difficult to manage for the larger companies without adequate tools to assist in the prioritization and targeting of process categories for improvement.

It is therefore recommended that future research be conducted to understand if and how smaller companies have been more successful in the implementation of ISO 9001:2000, and what improvements could be made in the

area of Human Resource Management and Business Development within quality management systems.

In conclusion, it is recommended that a set of quality management processes be defined that are agreeable to the international community allowing full utilization of the existing ISO /IEC 15504 model to supplement ISO 9001:2000 to identify, prioritize, and drive continual improvements throughout the organization, and be a possible replacement for ISO 9004:2000.

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10 APPENDICES

10.1 SURVEY INSTRUMENT

Demographics

The following questions are to be used only for top level analysis and for follow-up questions, if needed

1. What is your name?

2. What type of industry are you in?

	Defense Contract	Consultant	Engineer Services	Commercial Systems Integrator	Auditing/Certification Provider	Academic	other
Please check all that apply	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Who are your primary customers?

	ARMY	FAA	HUD	NAVY	USAF	USMC	Commercial	Gov't Agency	other
Please check all that apply	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. What percent (roughly) is your company/location in the following areas as it pertains to your current Quality Management System and/or scope of ISO 9001 Certification? (should equal to 100%)

Engineering	<input type="text"/>
Manufacturing	<input type="text"/>
Support	<input type="text"/>

The following section pertains to the Process Capability (Maturity) of each process category of the Quality Management System. There are fourteen (14) process categories. Please rate each category as defined in the ISO/IEC 15504 tables that follow and using the questions that immediately follow each category.

If a particular section does not apply to your organization by design, please respond N/A for all questions in that section.

Attribute Ratings and Process Attribute Descriptions are provided for reference below.

Attribute Rating Definitions are as follows:

Not achieved (0% to 15%): Little or no evidence of achievement

Partially achieved (>15% to 50%): Evidence of a sound systematic approach to and achievement

Largely achieved (>50% to 85%): Evidence of a sound systematic approach to and significant achievement

Fully achieved (>85% to 100%): Evidence of a complete and systematic approach to and full achievement

Process Attribute Description

1.1 Process Performance: Process purpose is achieved

2.1 Performance Management: Performance of the process is managed.

2.2 Work Product Management: Work products produced by the process are appropriately managed.

3.1 Process Definition: Standard process is maintained to support the deployment of the defined process.

3.2 Process Deployment: Standard process is effectively deployed as a defined process to achieve its process outcomes.

4.1 Process Measurement: Measurement results are used to ensure that performance of the process supports the achievement of relevant process performance objectives in support of defined business goals.

4.2 Process Control: Process is quantitatively managed to produce a process that is stable, capable, and predictable within defined limits.

5.1 Process Innovation: Changes to the process are identified from analysis of common causes of variation in performance, and from investigations of innovative approaches to the definition and deployment of the process.

5.2 Process Optimization: Changes to the definition, management and performance of the process result in effective impact that achieves the relevant process improvement objectives.

1. Business Management: Processes that describe the development, implementation, and flow-down of an organizational structure, and business objectives and expectations.
(ISO 9001 ref. 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1a. How does the strategic plan, business objectives, and functional objectives tie together and how are they flowed down through the organizational structure? How often are they reviewed and communicated with the workforce?

1b. How is the organization structured? How are functional roles and responsibilities defined and communicated?

1c. How are the organization's standard policies, processes and procedures managed and maintained? How are the organizational process interrelationships and dependencies defined, depicted, and viewed as a system of Quality Management?

2. Communications: Processes that describe how information is disseminated across and throughout the organization and within teams.
(ISO 9001 ref. 5.5.1, 5.5.3)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2a. How is the status of the quality management system (including business performance, successes, initiatives, items of importance, company news) communicated to the organization and stakeholders?

2b. How are process performance, product quality, and employee, supplier, and customer related issues communicated and reviewed with top management and affected functional groups?

2c. How and what type of communications are provided to suppliers and customers regarding the status and performance of the organization's Quality Management System?

3. Human Resource Management: Processes that describe how employment needs are identified and planned, and how employees are hired, developed, trained, deployed, motivated, and retained.
(ISO 9001 ref. 6.1, 6.2)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3a. How does the organization determine, plan, track, acquire, and ensure resources needed to achieve current and future organizational and program needs?

3b. How is competence determined for individual job assignments? How are job expectations communicated and measured with the workforce?

3c. How does the organization identify training needs consistent with current and future business needs? How are training modules measured and/or determined to ensure they are effective once conducted?

3d. How is the workforce motivated and recognized for their efforts in achieving process and product quality? How are they encouraged to identify and bring forth process improvements?

4. Infrastructure and Work Environment: Processes that describe the make-up and inter-relationships within the organization required to effectively support and protect the workforce, business operations, and surrounding community. (ISO 9001 ref. 6.3, 6.4)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4a. How are facilities and utilities maintenance organizations involved, considered, and planned for during program and organizational planning activity?

4b. How are organizational and employee tool needs and technologies determined, planned, and acquired? How do they tie into the organization's strategic plan?

4c. How does the environmental, safety, and health program tie into the Quality Management System (e.g., audits, reviews, etc.)? How does the organization ensure regulations are being met and being communicated to the affected workforce?

5. Business Development: Processes that describe how business opportunities and identified, captured, developed, and brought to market.
(ISO 9001 ref. 5.2, 7.1, 7.2)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5a. How is the business acquisition plan developed and how is ensured to be consistent with the strategic plan and business/stakeholder objectives?

5b. How does the organization's research and development programs tie into the business development and capture plans?

5c. How does the business capture team tie in the affected functions of the organization during proposal development and submission?

6. Customer Management: Processes that describe how customer requirements, expectations, and needs are identified, allocated, tracked, addressed, and communicated.

(ISO 9001 ref. 5.2, 7.2, 7.3.2, 7.5.4, 8.2.1, 8.5.2)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6a. How are customers needs, expectations, and requirements captured and reviewed?
How are changes to contractual requirements communicated and verified among affected functional groups and teams?

6b. How are customer complaints, issues, and inquiries handled, managed, communicated, measured, reported, and tracked to closure?

6c. How is intellectual property and customer property handled and accounted for?

7. Program Management: Processes that describe how programs are managed to ensure product quality, cost, schedule, and technical requirements and objectives are met.

(ISO 9001 ref. 7.1, 7.3.4, 8.2.3, 8.5.2, 8.5.3)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7a. How is training and qualifications determined and provided for Program Managers? How does the training tie in and meet the needs of evolving technologies and customer needs?

7b. How does Program Management ensure all risks are captured, monitored, mitigated/contained, communicated, and managed? How are affected functional groups involved and included with the risk management process?

7c. How are functional teams included in the planning and execution of programs? How do Program Managers monitor and document activity status reviews with the functional groups and how do they report program status to top management?

7d. How does Program Management ensure customer requirements and satisfaction are being met? How and what methods do they interface with their customers to receive continual feedback?

8. Supplier Management: Processes that describe how suppliers are identified, evaluated, selected, monitored, and managed to ensure all product requirements are met.

(ISO 9001 ref. 7.4, 8.2.4, 8.5.2)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8a. How are suppliers involved and included in current and future business plans? How are teaming arrangements determined and established?

8b. How are supplier capabilities determined and evaluated prior to contract award and what functional groups are involved with this activity?

8c. How are suppliers monitored and measured to determine program requirements are being met and who performs this activity? How are suppliers managed when they are not meeting contractual obligations?

9. Configuration Management: Processes that describe how configuration items and changes thereto are determined, identified, tracked, communicated, controlled, verified, and managed to ensure contractual technical and functional requirements and product integrity are met.
(ISO 9001 ref. 7.3, 7.5.3)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9a. How are configuration items determined, documented, and managed from the system level down to the allocated components?

9b. How are changes to technical and functional requirements tracked and verified within the design process (change boards, etc.)? How are affected product for mandatory changes captured and corrected to the latest configuration requirements?

9c. How does the organization/program ensure and verify that products within the product life cycle are of current configuration (e.g., documents, hardware, software)?

10. Design and Development: Processes that describe how technical requirements are identified, captured, allocated, designed, verified, and validated to ensure that design quality and customer expectations are met. (ISO 9001 ref. 7.2, 7.3)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10a. How are new technologies and design techniques planned, developed, and inserted into the organization's engineering practices? How does the organization promote and recognize individuals to bring forth patents and inventions?

10b. How does the organization identify, plan, and provide new skills needed for engineers on new programs and technologies? How are engineers skills kept up-to-date with the latest technologies and design techniques?

10c. How are requirements identified, allocated, communicated, verified, and managed among responsible functional groups and product teams? How is scope creep handled and contained?

10d. How and what types of standard measurements and reviews are determined and established to ensure design and development objectives are being met?

11. Production and Service: Processes that describe how production and service requirements are determined, planned, designed, validated, implemented and monitored to ensure product and process quality requirements are met. (ISO 9001 ref. 7.1, 7.5.1, 7.5.2, 7.5.3, 7.5.5, 7.6, 8.2.4, 8.3)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11a. How does the organization determine and implement new production processes and tools? How does the organization determine production and test readiness for transition from development?

11b. How are production processes measured and monitored to ensure product quality and productivity objectives and being met? How are measurement results and actions communicated to management and production employees?

11c. How is service and field performance data collected and fed back into the production and design processes for improvement?

12. Materials Management: Processes that describe how product is handled, protected, preserved, stored, and delivered to ensure product quality and integrity. (ISO 9001 ref. 7.5.5, 8.3)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12a. How are raw materials identified, verified, managed, and disposed of to meet special handling requirements (e.g., shelf life, hazardous material, certificate of conformance verification)? How is stock verified and managed (e.g., audits, first-in/first-out)?

12b. How are product handling techniques identified and ensured (e.g., ESD, Fibre optics, containers, designated holding areas)? How are individuals handling product trained/certified for special handling?

12c. How is nonconforming material identified, controlled, and ensured it is not commingled with good product? How is defective customer owned material handled (both in possession and upon receipt)?

13. Monitoring and Measurement: Processes describing how the organization's key processes are assessed, measured, reported, and corrected. (ISO 9001 ref. 8.2.1, 8.2.2, 8.2.3, 8.2.4, 8.5.2)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13a. How is customer satisfaction determined and measured? How are results and planned actions for improving customer satisfaction communicated with the workforce, and affected suppliers and customers?

13b. How are process performance and product quality measurements tied into business performance goals and customer expectations and needs? How are goals determined for these measurements, and progress monitored and reviewed with management?

13c. How are auditors identified and qualified to assess the organization's processes? How is the audit program measured and monitored to determine if it is effective in identifying issues of significance affecting organizational performance and objectives?

13d. How does Top Management utilize, support, direct, and monitor the internal audit program? How are organizational processes to be audited identified, scheduled, tracked, and reported to the organization's management team?

14. Continual Improvement: Processes that describe how data from processes and product at various levels of the organization are collected, reviewed and analyzed for required actions and improvement, and reported/monitored with and by Top Management.

(ISO 9001 ref. 5.4, 5.6, 8.4, 8.5.1, 8.5.3)

	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved	N/A
1.1 Process Performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.1 Performance Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Work Product Management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1 Process Definition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Process Deployment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1 Process Measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Process Control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1 Process Innovation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Process Optimization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14a. How is causal analysis techniques rolled out to the organization and in what form does training take (class room, CBT)? How is causal analysis invoked and documented (e.g., Lean Sigma Programs, corrective/preventive actions, Statistical Process/Quality Controls)?

14b. How are data consolidated and analyzed, and at what levels of the organization level (who) determines areas of concern and needed improvement? How are trends and significant areas of importance identified and tie into the quality improvement program and plans?

14c. How are quality improvement plans and Quality Objectives determined, developed, managed, and relate to one another? How are improvement suggestions captured, reviewed, and communicated back to the workforce?

Follow-Up Questions

1. Think of your Quality Management System five years ago versus today. Evaluate whether the performance in each of the following areas has changed.

	Much Better	Better	Same	Worse	Much Worse
Top management involvement and commitment (audits, reviews, objectives, and improvement)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Communication by management and others (accessibility, active listening, openness, trust)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Workforce accountability (commitment to objectives, dependability, taking initiative to improve, tenacity/morale)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Organizational standard processes (well defined, interrelated, value-added, communicated, followed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Customer satisfaction (good measures, proactively sought upon and improved)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improvements (enhanced processes, tools, measurements)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training (available, effective, funded)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Program Management and Engineering Relationships (sought for guidance and assistance, ability to influence when needed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Business performance (new contracts, new customers, new products)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Overall Working Environment (exciting, innovative, improving)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. What recommendations would you make to the ISO 9001:2000 standard structure to enhance the requirements, implementation, and effectiveness of the Quality Management System?

3. Do you feel using the ISO/IEC 15504 framework would be a beneficial assessment and improvement tool for Quality Management Systems (attribute ratings, etc.)? What changes would you make?

4. Any other items of interest or concern that you would like to share regarding the implementation and/or effectiveness of your Quality Management System?

Quality Management Systems Survey 2005/2006 Overview

Paul Shimp

Purpose

Provide an exploratory study on the implementation and issues regarding quality management systems (QMS) as defined by ISO 9001:2000

- ISO/IEC 15504 series of standards provides a framework to assess processes within various models and determine levels of capability
- Using this framework, the study will focus on the primary areas requiring focus for continual improvement within a quality management system

Approach

- Survey developed to assist in analysis to determine
 - Demographic issues and dependencies
 - Degree of and issues surrounding QMS implementation
 - Areas for improvement
- ISO/IEC 15504 framework used as a basis of measurement

ISO/IEC 15504 Overview

- Series of Process Assessment Standards published 2003-2004
- Originated from ISO SPICE (Software Process Improvement and Capability dEtermination)
- Matured as a process to us with models of all types (i.e., Software dropped)
- Core documents
 - Part 1: Concepts and Vocabulary
 - Part 2: Performing an Assessment
 - Part 3: Guidance on Performing an Assessment
 - Part 4: Guidance on Use for Process Improvement and Process Capability Determination
 - Part 5: An exemplar process assessment model (based on ISO/IEC 12207)

Source: ISO Spice Website (http://www.isospice.typepad.com/isospice_home/)

ISO/IEC 15504, continued

■ Assessment Process Concept & Structure

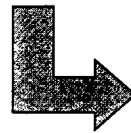
- Process Dimension defines a set of process categories for the model under assessment
- Capability Dimension define the possible levels of capability (maturity) for each process category within the Process Dimension under assessment
 - Process Attributes are defined within each capability level describing the level of capability expected
- Attribute Ratings define the percentage range and level of implementation for each Process Attribute

Source: ISO/IEC 15504-2

ISO /IEC 15504, continued

■ Process Dimension

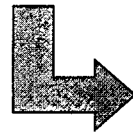
- Defined set of Process Categories from the model (standard) under assessment;
e.g., ISO/IEC 12207



Process Category	Description
Acquisition	Processes performed by the customer, in order to acquire a product and/or a service.
Supply	Processes performed by the supplier in order to propose and deliver a product and/or a service.
Engineering	Processes that directly elicit and manage the customer's requirements, specify, implement, and/or maintain the software product and its relation to the system.
Operation	Processes performed in order to provide for the correct operation and use of the software product and/or service.
Supporting	Processes which may be employed, by any other processes at various points in the software life cycle.
Management	Processes that contain practices that may be used by anyone who manages any type of project or process within a software life cycle.
Process Improvement	Processes performed in order to define, deploy, assess and improve the processes performed in the organizational unit.
Resource and Infrastructure	Processes performed in order to provide adequate human resources and necessary infrastructure as required by any other process performed by the organizational unit.
Reuse	Processes performed in order to systematically exploit reuse opportunities in organization's reuse programmers.

ISO/IEC 15504, continued

- Capability Dimension
 - Six potential levels of capability possible
 - Similar to SEI CMM and CMMI



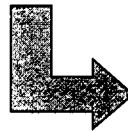
Level	Level	Description
0	Incomplete	The process is not implemented, or fails to achieve its process purpose.
1	Performed	The implemented process achieves its process purpose..
2	Managed	The previously described Performed process is now implemented in a managed fashion (planned, monitored and adjusted) and its work products are appropriately established, controlled and maintained.
3	Established	The previously described Managed process is now implemented using a defined process that is capable of achieving its process outcomes.
4	Predictable	The previously described Established process now operates within defined limits to achieve its process outcomes.
5	Optimizing	The previously described Predictable process is continuously improved to meet relevant current and projected business goals.

Source: ISO/IEC 15504-2, section 5

ISO/IEC 15504, continued

■ Process Attributes

- Nine process attributes within Capability Levels 0 thru 5

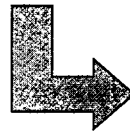


Level	Process Attribute	Description
1	1.1 Process Performance	A measure of the extent to which the process purpose is achieved
2	2.1 Performance Management	A measure of the extent to which the performance of the process is managed.
2	2.2 Work Product Management	A measure of the extent to which the work products produced by the process are appropriately managed.
3	3.1 Process Definition	A measure of the extent to which a standard process is maintained to support the deployment of the defined process.
3	3.2 Process Deployment	A measure of the extent to which the standard process is effectively deployed as a defined process to achieve its process outcomes.
4	4.1 Process Measurement	A measure of the extent to which measurement results are used to ensure that performance of the process supports the achievement of relevant process performance objectives in support of defined business goals.
4	4.2 Process Control	A measure of the extent to which the process is quantitatively managed to produce a process that is stable, capable, and predictable within defined limits.
5	5.1 Process Innovation	A measure of the extent to which changes to the process are identified from analysis of common causes of variation in performance, and from investigations of innovative approaches to the definition and deployment of the process.
5	5.2 Process Optimization	A measure of the extent to which changes to the definition, management and performance of the process result in effective impact that achieves the relevant process improvement objectives.

Source: ISO/IEC 15504-2, section 5

ISO/IEC 15504, continued

- Attribute Rating
 - Rating awarded based on level of implementation for each Process Attribute



Rating	Percentage	Description
N Not achieved	0% to 15%	There is little or no evidence of achievement of the defined attribute in the assessed process.
P Partially achieved	>15% to 50%	There is evidence of a sound systematic approach to and achievement of the defined attribute in the assessed process.
L Largely achieved	>50% to 85%	There is evidence of a sound systematic approach to and significant achievement of the defined attribute in the assessed process.
F Fully achieved	>85% to 100%	There is evidence of a complete and systematic approach to and full achievement of the defined attribute in the assessed process.

Source: ISO/IEC 15504-2, section 5

ISO/IEC 15504, continued

■ Assessment Process

1. Each process category is assessed to determine level of implementation for each of the nine Process Attributes
2. Attribute Rating is awarded based on level of implementation for each Attribute; e.g.,
Engineering for attribute 5.1 Process Innovation = 75% achieved (estimated)
 - L (Largely achieved)

Source: ISO/IEC 15504-2, section 5

ISO/IEC 15504, continued

- Assessment Process, continued

3. Process Profile assembled to award overall Capability Level for each Process Category

Level	Process Attribute	Process Attribute Rating
1	Process Performance	Largely or fully
2	Process Performance Performance Management Work Product Management	Fully Largely or fully Largely or fully
3	Process Performance Performance Management Work Product Management Process Definition Process Deployment	Fully Fully Fully Largely or fully Largely or fully
4	Process Performance Performance Management Work Product Management Process Definition Process Deployment Process Measurement Process Control	Fully Fully Fully Fully Fully Largely or fully Largely or fully
5	Process Performance Performance Management Work Product Management Process Definition Process Deployment Process Measurement Process Control Process Innovation Process Optimization	Fully Fully Fully Fully Fully Fully Fully Largely or fully Largely or fully

Source: ISO/IEC 15504-2, section 6

QMS Survey

■ Survey Structure

1. Demographics (e.g., type of industry, customers, no. employees and sites, registrar used, certification dates, skill mix)
2. Process Capability Analysis
 - ✓ Assessment of 14 QMS Process Categories
 - ✓ Attribute ratings to be obtained within each Process Category for each company
 - ✓ Open-ended Exploratory questions following each Process Category
3. Follow-on questions (satisfaction levels and improvements to ISO model)

■ Survey Instrument

- Web-based Survey developed using Perseus SurveySolutions Express application (ref: <http://express.perseus.com/>)

QMS Survey, continued

- QMS Process Dimension
 - Research indicates that a Process Dimension listing process categories for Quality Management Systems as defined by ISO 9001:2000 are not defined or available
 - ✓ ISO/IEC 15504 development team aware and possible future planned effort
 - Survey conducted by P. Shimp
 - With 20 subject matter experts (SMEs) across industry (defense contractors, ISO registrars, US TAG TC176 consultants, CMMI and ISO Certified Lead Assessors)
 - Resulted in recommendation and determination of 14 Process Categories covering all elements of ISO 9001:2000 model
 - SMEs and eight Quality Management Principles used to develop exploratory questions on implementation and functionality

QMS Survey, continued

■ QMS Process Categories (Process Dimension)

1. **Business Management**: Processes that describe the development, implementation, and flow-down of an organizational structure, and business objectives and expectations.
2. **Communications**: Processes that describe how information is disseminated across and throughout the organization and within teams.
3. **Human Resource Management**: Processes that describe how employment needs are identified and planned, and how employees are hired, developed, trained, deployed, motivated, and retained.
4. **Infrastructure and Work Environment**: Processes that describe the make-up and inter-relationships within the organization required to effectively support and protect the workforce, business operations, and surrounding community.
5. **Business Development**: Processes that describe how business opportunities and identified, captured, developed, and brought to market.
6. **Customer Management**: Processes that describe how customer requirements, expectations, and needs are identified, allocated, tracked, addressed, and communicated.
7. **Program Management**: Processes that describe how programs are managed to ensure product quality, cost, schedule, and technical requirements and objectives are met.

QMS Survey, continued

■ QMS Process Categories (Process Dimension)

8. **Supplier Management**: Processes that describe how suppliers are identified, evaluated, selected, monitored, and managed to ensure all product requirements are met.
9. **Configuration Management**: Processes that describe how configuration items and changes thereto are determined, identified, tracked, communicated, controlled, verified, and managed to ensure contractual technical and functional requirements and product integrity are met.
10. **Design and Development**: Processes that describe how technical requirements are identified, captured, allocated, designed, verified, and validated to ensure that design quality and customer expectations are met.
11. **Production and Service**: Processes that describe how production and service requirements are determined, planned, designed, validated, implemented and monitored to ensure product and process quality requirements are met.
12. **Materials Management**: Processes that describe how product is handled, protected, preserved, stored, and delivered to ensure product quality and integrity.
13. **Monitoring and Measurement**: Processes describing how the organization's key processes are assessed, measured, reported, and corrected.
14. **Continual Improvement**: Processes that describe how data from processes and product at various levels of the organization are collected, reviewed and analyzed for required actions and improvement, and reported/monitored with and by Top Management.

QMS Survey, continued

■ Survey Process Capability example

Process Category 1: Business Management				
	Not Achieved	Partially Achieved	Largely Achieved	Fully Achieved
1.1 Process Performance	✓	✓	✓	✓
2.1 Performance Management	✓	✓	✓	✓
2.2 Work Product Management	✓	✓	✓	✓
3.1 Process Definition	✓	✓	✓	✓
3.2 Process Deployment	✓	✓	✓	✓
4.1 Process Measurement	✓	✓	✓	✓
4.2 Process Control	✓	✓	✓	✓
5.1 Process Innovation	✓	✓	✓	✓
5.2 Process Optimization	✓	✓	✓	✓

Q1. How do business objective, the strategic plan, and organizational objectives tie together and how are they flowed down through the organizational structure?
--

QMS Survey, continued

■ Example: Human Resource Management

Processes that describe how employment needs are identified and planned, and how employees are hired, developed, trained, deployed, motivated, and retained.

1.1 Process Performance: A measure of the extent to which the process purpose is achieved

- ✓ Are resource needs identified, planned and acquired to meet business needs?

2.1 Performance Management: A measure of the extent to which the performance of the process is managed

- ✓ Are resource and training needs being monitored and resolved timely?

2.2 Work Product Management: A measure of the extent to which the work products produced by the process are appropriately managed.

- ✓ Are the documents and goals associated with HR activities identified and under control?

3.1 Process Definition: A measure of the extent to which a standard process is maintained to support the deployment of the defined process.

- ✓ Is a process owner identified and is the process standardized, documented, and assessed regularly for updates?

3.2 Process Deployment: A measure of the extent to which the standard process is effectively deployed as a defined process to achieve its process outcomes.

- ✓ Are controls in place to monitor and ensure that the standard HR process is deployed and compliant?

QMS Survey, continued

■ Example: Human Resource Management, continued

4.1 Process Measurement: A measure of the extent to which measurement results are used to ensure that performance of the process supports the achievement of relevant process performance objectives in support of defined business goals.

- ✓ Are resource and training goals needs are determined and planned ahead of time?
- ✓ Are measurements established to meet those goals?

4.2 Process Control: A measure of the extent to which the process is quantitatively managed to produce a process that is stable, capable, and predictable within defined limits.

- ✓ Are the measurements used to manage the HR Process to make decisions?
- ✓ Is the HR Process under statistical control?

5.1 Process Innovation: A measure of the extent to which changes to the process are identified from analysis of common causes of variation in performance, and from investigations of innovative approaches to the definition and deployment of the process.

- ✓ Is analysis conducted based on the performance of the HR Process?
- ✓ Are other HR methods investigated and benchmarked?

5.2 Process Optimization: A measure of the extent to which changes to the definition, management and performance of the process result in effective impact that achieves the relevant process improvement objectives.

- ✓ Are changes to the HR process measured and determined to meet the desired impact and capability improvement?

Survey Schedule

- Complete Survey February 2006
- Analyze Results/Provide Feedback April 2006

Contact Information

- Paul Shimp
 - pshimp1@adelphia.net



Questions?



*Thank You for Your
Time and Input!!*

Back-up

QMS Process Categories

1. Business Management

ISO 9001:2000 References: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6

- Items to Consider: Strategic planning and direction, Management Commitment (Quality, Customer Satisfaction, Continual Improvement), organizational structure, roles and responsibilities, process, document and records management, Management Review and involvement

Description

Processes that describe the development, implementation, and flow-down of an organizational structure, and business objectives and expectations.

- Q1. How does the strategic plan, business objectives, and functional objectives tie together and how are they flowed down through the organizational structure? How often are they reviewed and communicated with the workforce?
- Q2. How is the organization structured? How are roles and responsibilities communicated?
- Q3. How are the organization's standard policies, processes and procedures managed and maintained? How are the organizational process interrelationships defined, depicted, and viewed as a system of Quality Management?

QMS Process Categories, continued

2. Communications

ISO 9001:2000 References: 5.5.1, 5.5.3

- Items to consider: Organizational, team, and Intra-department communication

Description

Processes that describe how information is disseminated across and throughout the organization and within teams.

- Q1. How is the status of the quality management system (including business performance, successes, initiatives, items of importance) communicated to the organization and stakeholders?
- Q2. How are program performance and issues communicated to top management and affected functional groups?
- Q3. How and what type of communications are provided to suppliers and customers regarding the status and performance of the organization's Quality Management System?

QMS Process Categories, continued

3. Human Resource Management

ISO 9001:2000 References: 6.1, 6.2

- Items to consider: Provision of Resources, Training

Description

Processes that describe how employment needs are identified and planned, and how employees are hired, developed, trained, deployed, motivated, and retained.

- Q1. How does the organization determine, plan, track, acquire, and ensure resources needed to achieve current and future organizational and program needs?
- Q2. How is competence determined for individual job assignments? How are job expectations communicated and measured with the workforce?
- Q3. How does the organization identify training needs consistent with current and future business needs? How are training modules measured and/or determined to ensure they are effective once conducted?
- Q4. How is the workforce motivated and recognized for their efforts in achieving process and product quality? How are they encouraged to identify and bring forth process improvements?

QMS Process Categories, continued

4. Infrastructure and Work Environment

ISO 9001:2000 References: 6.3, 6.4

- Items to consider: Business Continuity Planning (Disaster Recovery), Business Management Information Systems, workstations and software tools, Environmental and Safety Programs, Facilities and Maintenance Program

Description

Processes that describe the make-up and inter-relationships within the organization required to effectively support and protect the workforce, business operations, and surrounding community.

- Q1. How are facilities and environmental, safety and health programs involved and considered during program and organizational planning and support?
- Q2. How are organizational and employee tool needs and technologies determined and planned? How do they tie into the organization's strategic plan?
- Q3. How does the environmental, safety, and health program tie into the Quality Management System (audits, reviews, etc.)? How does the organization ensure state and federal regulations are being met?

QMS Process Categories, continued

5. Business Development

ISO 9001:2000 References: 5.2, 7.1, 7.2

- Items to consider: Business Development (Marketing, Opportunity Identification), Proposal Development, Win and Capture Plan

Description

Processes that describe how business opportunities are identified, captured, developed, and brought to market.

- Q1. How is the business acquisition plan developed and how is ensured to be consistent with the strategic plan and business/stakeholder objectives?
- Q2. How do the organization's research and development programs tie into the business development and capture plans?
- Q3. How does the business capture team tie into the affected functions of the organization during proposal development and submission?

QMS Process Categories, continued

6. Customer Management

ISO 9001:2000 References: 5.2, 7.2, 7.3.2, 7.5.4, 8.2.1, 8.5.2

- Items to consider: Contract Requirements Management, Customer Communication, Correspondence and Tracking, Customer Property Management, Customer Satisfaction

Description

Processes that describe how customer requirements, expectations, and needs are identified, allocated, tracked, addressed, and communicated.

- Q1. How are customer needs and expectations captured along with customer requirements? How are changes to contractual requirements communicated and verified among affected functional groups and teams?
- Q2. How is intellectual property handled? How does the organization promote patents and inventions from the workforce?
- Q3. How are customer complaints handled, managed, communicated, measured, reported, and tracked to closure?

QMS Process Categories, continued

7. Program Management

ISO 9001: 2000 References: 7.1, 7.3.4, 8.2.3, 8.5.2, 8.5.3

- Items to consider: Program Planning, Program Organization, Risk Management, Program Monitoring and Control

Description

Processes that describe how programs are managed to ensure product quality, cost, schedule, and technical requirements and objectives are met.

- Q1. How is training and qualifications determined and provided for Program Managers? How does the training tie in and meet the needs of evolving technologies and customer needs?
- Q2. How does Program Management ensure all risks are captured, monitored, mitigated/contained, communicated, and managed?
- Q3. How do Program Managers monitor status with the functional groups and how do they report status to top management? How are functional teams included in the program planning, execution, and associated reviews?

QMS Process Categories, continued

8. Supplier Management

ISO 9001:2000 References: 7.4, 8.2.4, 8.5.2

- Item to consider: Supplier Evaluation and Control, Purchasing and Supplier Product Requirements, Supplier Product Acceptance (Source/Receiving Inspection), Supplier Performance Monitoring and Reporting

Description

Processes that describe how suppliers are identified, evaluated, selected, monitored, and managed to ensure all product requirements are met.

- Q1. How are suppliers involved and included in current and future business plans?
How are teaming arrangements determined?
- Q2. How are supplier capabilities determined prior to contract award? What functional groups are involved with this determination?
- Q3. How are suppliers monitored and measured to determine program requirements are being met? How are suppliers managed when not meeting contractual obligations?

QMS Process Categories, continued

9. Configuration Management

ISO 9001:2000 References: 7.3, 7.5.3

- Items to consider: configuration management planning, identification, configuration tracking, audits, status reporting and communication, change requests, and measurements

Description

Processes that describe how configuration items and changes thereto are determined, identified, tracked, communicated, controlled, verified, and managed to ensure contractual technical and functional requirements and product integrity are met.

- Q1. How are configuration items determined and managed from the system level down to the allocated components?
- Q2. How are changes to technical and functional requirements tracked and verified within the design process (change boards, etc.)? How are affected product for mandatory changes captured and corrected to the latest configuration requirements?
- Q3. How does the organization/program ensure and verify that products within the build and test cycle are of current configuration (hardware and software)?

QMS Process Categories, continued

10. Design and Development

ISO 9001:2000 References: 7.2, 7.3

- Items to consider: Planning, Requirements Management (allocation, traceability, verification), Verification and Validation, Configuration Management

Description

Processes that describe how technical requirements are identified, captured, allocated, designed, verified, and validated to ensure that design quality and customer expectations are met.

- Q1. How are requirements identified, allocate and verified among responsible functional groups/teams? How is scope creep handled and contained?
- Q2. How and what types of standard measurements are determined and established to ensure design and development objectives are met?
- Q3. How is program development status communicated to top management and how frequent are reviews held?

QMS Process Categories, continued

11. Production and Service

ISO 9001: 2000 References: 7.1, 7.5.1, 7.5.2, 7.5.3, 7.5.5, 7.6, 8.2.4, 8.3

- Items to consider: Production Planning and Readiness, Process and Tool Qualification/Validation, Product Identification and Traceability, Fabrication, Manufacturing, Assembly, and Service Controls, Inspection and Test, Product handling,
- Nonconforming Material Control, Calibration Program

Description

Processes that describe how production and service requirements are determined, planned, designed, validated, implemented and monitored to ensure product and process quality requirements are met.

- Q1. How does the organization determine and implement new production processes and tools? How does the organization determine production readiness and transition from development?
- Q2. How are production processes measured and monitored to ensure product quality and productivity. How are measurement results and actions communicated to management and employees?
- Q3. How is service/field data collected and fed back into the production and design processes for improvement?

QMS Process Categories, continued

12. Materials Management

ISO 9001:2000 References: 7.5.5, 8.3

- Items to consider: Shelf life, first in-first out, special handling qualifications, special/customer packaging requirements

Description

Processes that describe how product is handled, protected, preserved, stored, and delivered to ensure product quality and integrity.

- Q1. How are materials identified, verified, and disposed to meet special handling requirements (e.g., shelf life, hazardous material, certificate of conformance)?
- Q2. How are product handling techniques identified and ensured (e.g., ESD, Fibre optics, containers, designated holding areas)? How are individuals handling product trained/certified for special handling?
- Q3. How is stock verified and managed (e.g., audits, first in-first out)?

QMS Process Categories, continued

13. Monitoring and Measurement

ISO 9001:2000 References: 8.2.1, 8.2.2, 8.2.3, 8.2.4, 8.5.2

- Items to consider: Customer Satisfaction, Internal Audits, Monitoring of Processes, Monitoring of Product, Corrective Action

Description

Processes describing how the organization's key processes are assessed, measured, reported, and corrected.

- Q1. How does the internal audit program assess the organization's processes and ensure business objectives are being met?
- Q2. How are process performance and product quality measurements tied into business performance goals and customer expectations and needs? How are goals determined for these measurements and progress reviewed with management?
- Q3. How is customer satisfaction determined and measured? How are results and planned actions for improving customer satisfaction communicated with the workforce and customer set?

QMS Process Categories, continued

14. Continual Improvement

ISO 9001:2000 References: 5.4, 5.6, 8.4, 8.5.1, 8.5.3

- Items to consider: Data and Causal Analysis, Preventive Action, Quality Improvement Planning and Implementation

Description

Processes that describe how data from processes and product at various levels of the organization are collected, reviewed and analyzed for required actions and improvement, and reported/monitored with and by Top Management.

- Q1. How are data consolidated and analyzed at the organizational level to determine improvement areas? How are the reviews conducted, in what type of forum and by whom?
- Q2. How is causal analysis rolled out to the organization and in what form does training take (class room, CBT)?
- Q3. How are Quality Improvement Plans determined and developed? How are improvement suggestions captured, reviewed, and communicated to the workforce?

Quality Management Principles

- Developed by Technical Committee 176 (TC176)
 - Based on extensive customer research
 - Overwhelming approval by member countries

“A quality management principle is a comprehensive and fundamental rule or belief, for leading and operating an organization, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all other stakeholders.”

*Source: International Organization for Standardization
(<http://www.iso.org/iso/en/iso9000-14000/understand/qmp.html>)*

Quality Management Principles

Principle 1 - Customer-Focused Organization

Organizations depend on their customers and therefore should understand current and future customer needs, meet customer requirements and strive to exceed customer expectations.

Key benefits:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.

Applying the principle of customer focus typically leads to:

- Researching and understanding customer needs and expectations.
- Ensuring that the objectives of the organization are linked to customer needs and expectations.
- Communicating customer needs and expectations throughout the organization.
- Measuring customer satisfaction and acting on the results.
- Systematically managing customer relationships.
- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

Quality Management Principles

Principle 2 - Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Key benefits:

- People will understand and be motivated towards the organization's goals and objectives.
- Activities are evaluated, aligned and implemented in a unified way.
- Miscommunication between levels of an organization will be minimized.

Applying the principle of leadership typically leads to:

- Considering the needs of all interested parties including customers, owners, employees, suppliers, financiers, local communities and society as a whole.
- Establishing a clear vision of the organization's future.
- Setting challenging goals and targets.
- Creating and sustaining shared values, fairness and ethical role models at all levels of the organization.
- Establishing trust and eliminating fear.
- Providing people with the required resources, training and freedom to act with responsibility and accountability.
- Inspiring, encouraging and recognizing people's contributions.

Quality Management Principles

Principle 3 - Involvement of People

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Key benefits:

- Motivated, committed and involved people within the organization.
- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.

Applying the principle of involvement of people typically leads to:

- People understanding the importance of their contribution and role in the organization.
- People identifying constraints to their performance.
- People accepting ownership of problems and their responsibility for solving them.
- People evaluating their performance against their personal goals and objectives.
- People actively seeking opportunities to enhance their competence, knowledge and experience.
- People freely sharing knowledge and experience.
- People openly discussing problems and issues.

Quality Management Principles

Principle 4 - Process Approach

A desired result is achieved more efficiently when related resources and activities are managed as a process.

Key benefits:

- Lower costs and shorter cycle times through effective use of resources.
- Improved, consistent and predictable results.
- Focused and prioritized improvement opportunities.

Applying the principle of process approach typically leads to:

- Systematically defining the activities necessary to obtain a desired result.
- Establishing clear responsibility and accountability for managing key activities.
- Analysing and measuring of the capability of key activities.
- Identifying the interfaces of key activities within and between the functions of the organization.
- Focusing on the factors such as resources, methods, and materials that will improve key activities of the organization.
- Evaluating risks, consequences and impacts of activities on customers, suppliers and other interested parties.

Quality Management Principles

Principle 5 - System Approach to Management

Identifying, understanding and managing a system of interrelated processes for a given objective improves the organization's effectiveness and efficiency.

Key benefits:

- Integration and alignment of the processes that will best achieve the desired results.
- Ability to focus effort on the key processes.
- Providing confidence to interested parties as to the consistency, effectiveness and efficiency of the organization.

Applying the principle of system approach to management typically leads to:

- Structuring a system to achieve the organization's objectives in the most effective and efficient way.
- Understanding the interdependencies between the processes of the system.
- Structured approaches that harmonize and integrate processes.
- Providing a better understanding of the roles and responsibilities necessary for achieving common objectives and thereby reducing cross-functional barriers.
- Understanding organizational capabilities and establishing resource constraints prior to action.
- Targeting and defining how specific activities within a system should operate.
- Continually improving the system through measurement and evaluation.

Quality Management Principles

Principle 6 - Continual Improvement

Continual improvement should be a permanent objective of the organization.

Key benefits:

- Performance advantage through improved organizational capabilities.
- Alignment of improvement activities at all levels to an organization's strategic intent.
- Flexibility to react quickly to opportunities.

Applying the principle of continual improvement typically leads to:

- Employing a consistent organization-wide approach to continual improvement of the organization's performance.
- Providing people with training in the methods and tools of continual improvement.
- Making continual improvement of products, processes and systems an objective for every individual in the organization.
- Establishing goals to guide, and measures to track, continual improvement.
- Recognizing and acknowledging improvements.

Quality Management Principles

Principle 7 - Factual Approach to Decision Making

Effective decisions are based on the analysis of data and information.

Key benefits:

- Informed decisions.
- An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.
- Increased ability to review, challenge and change opinions and decisions.

Applying the principle of factual approach to decision making typically leads to:

- Ensuring that data and information are sufficiently accurate and reliable.
- Making data accessible to those who need it.
- Analysing data and information using valid methods.
- Making decisions and taking action based on factual analysis, balanced with experience and intuition.

Quality Management Principles

Principle 8 - Mutually Beneficial Supplier Relationships

An organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

Key benefits:

- Increased ability to create value for both parties.
- Flexibility and speed of joint responses to changing market or customer needs and expectations.
- Optimization of costs and resources.

Applying the principles of mutually beneficial supplier relationships typically leads to:

- Establishing relationships that balance short-term gains with long-term considerations.
- Pooling of expertise and resources with partners.
- Identifying and selecting key suppliers.
- Clear and open communication.
- Sharing information and future plans.
- Establishing joint development and improvement activities.
- Inspiring, encouraging and recognizing improvements and achievements by suppliers.

10.3 COMPANY PROCESS LEVEL RATINGS

Process Category	Company										
	1	2	3	4	5	6	7	8	9	10	11
<i>Mean Capability Level</i>	2.0	0.1	3.9	2.6	3.3	0.2	2.2	2.5	2.5	1.3	1.5
<i>Median Capability Level</i>	1.5	0.0	3.5	3.0	4.5	0.0	2.0	2.0	2.5	1.0	1.5
1. Business Management	2	0	3	3	5	1	3	5	3	5	2
2. Communications	2	1	3	4	2	0	2	2	4	1	1
3. Human Resource Management	0	0	3	2	1	0	3	1	2	1	1
4. Infrastructure and Work Environment	4	0	4	4	5	0	2	3	4	1	2
5. Business Development	1	0	5	N/A	1	0	2	1	1	1	1
6. Customer Management	4	0	3	5	1	0	2	1	5	1	1
7. Program Management	1	0	5	3	5	0	2	1	3	1	1
8. Supplier Management	N/A	0	5	1	5	0	2	3	1	1	1
9. Configuration Management	4	0	3	1	5	0	2	5	1	1	2
10. Design and Development	3	1	5	1	4	0	2	1	1	1	2
11. Production and Service	1	0	5	1	5	N/A	4	5	1	1	2
12. Materials Management	N/A	0	3	1	5	N/A	3	4	1	1	2
13. Monitoring and Measurement	1	0	4	5	1	1	1	2	5	1	2
14. Continual Improvement	1	0	3	3	1	0	1	1	3	1	1

10.4 COMPANY QMS IMPROVEMENTS

QMS Improvements	Company										
	1	2	3	4	5	6	7	8	9	10	11
<i>Mean Response</i>	5.0	3.1	3.5	4.5	3.8	4.6	3.8	4.4	4.4	4.1	3.4
<i>Median Response</i>	5.0	3.0	3.5	4.5	4.0	5.0	4.0	4.0	4.5	4.0	3.0
1. Top Management Commitment	5	4	3	5	4	5	4	5	5	4	3
2. Communications	5	3	3	5	5	5	3	5	5	4	4
3. Workforce Accountability	5	2	3	4	3	5	4	4	4	5	4
4. Organizational Std Processes	5	3	3	4	4	5	4	4	4	4	3
5. Customer Satisfaction	5	4	4	4	4	5	5	5	3	4	3
6. System Improvements	5	3	4	5	3	5	4	5	5	4	3
7. Training	5	2	4	5	4	4	3	4	5	4	3
8. PM and Engineering Relationship	5	3	4	4	3	4	3	4	4	4	3
9. Business Performance	5	4	4	4	4	4	4	4	4	4	4
10. Overall Working Environment	5	3	3	5	4	4	4	4	5	4	4

Legend	
Much Better	5
Better	4
Same	3
Worse	2
Much Worse	1

11 VITA

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