Systems Engineering and Management Applications of ISO 9001:2015 for Government

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The manufacturing segment of the business world is busy assessing the impact of ISO 9001:2015, and updating their management systems to meet the required compliance date. What does the new revision mean for government agencies that deliver large engineering projects rather than mass production? In fact, the standard, especially the new revision, can be used quite readily for government agencies, or applied to specific projects, once it is understood in terms of the similarities with systems engineering and project management. From there it can be extrapolated to "mission realization" systems, and a Quality Management System (QMS) is a logical result that can bring order to processes and systems that likely already exist in some fashion.

ISO 9001:2015 is less product-oriented than previous versions. It can be more broadly applied to public organizations as well as private; and to services (missions) as well as products. The emphasis on risk management in the revised standard provides the needed balance for weighing decisions with respect to cost, schedule, technical, safety, and regulatory compliance; so if this is not part of agency governance already, this is a good place to start, especially for large engineering projects. The Systems Engineering standard used for this analysis is from NASA's NPR 7123.1 *NASA Systems Engineering Processes and Requirements;* however, those who are more familiar with ISO/IEC 26702 *Systems Engineering-application and management of the systems engineering process,* or SAE/EIA 632 *Processes for Engineering a System* will also recognize the similarities. In reality, the QMS outlined by ISO 9001 reinforces the systems engineering processes, and serves to ensure that they are adequately implemented, although most of the ISO 9001 literature emphasizes the production and process aspects of the standard.

Rather than beginning with ISO 9001and getting lost in the vocabulary, it is useful to begin with the systems engineering lifecycle. Identification of stakeholder expectations, identifying solutions, creating specific product or service designs, production of the product or service, delivery to the public, and the associated management, planning, and control processes, are a familiar place to begin thinking of the overall system of identifying, designing, and competing a project or mission. Lining up this lifecycle with the ISO requirements (see Figure 1) illustrates how a quality management system is concerned with the same processes, and provides a governance and assurance function. If implemented properly, there are cost savings resulting from less rework, repair, reprocessing, failures, misplaced documents, and similar types of deficiencies[1]. Starting with an organization's systems engineering processes allows the organization to use their own terminology for a QMS plan, and tailor the plan to their own project or organization, so that it is more easily developed, understood, and implemented.

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[1] Stevens, Tim, Philip Crosby: Quality is Still Free, Industry Week, June 19, 1995, retrieved 2/16/2016 from http://www.industryweek.com/quality/philip-crosby-quality-still-free?page=1

A good example of this convergence of systems engineering and ISO 9001 is configuration management. The process of baselining configuration, tracking, and approving changes, are systems engineering processes, while ensuring as-built meets as-designed requirements, and identification of non-conformances, are generally understood as quality assurance functions. These two functions work together to ensure delivery of the correct design solution, which often has safety implications as well. Other examples of how the ISO standard can be demystified and understood to fit existing projects and processes include design controls, control of processes for products and services, and acceptance testing (validation).

SE PROCESS	ISO 9001:2015 REQUIREMENT
Stakeholder Expectations	Needs and Expectations of Interested Parties; Customer Focus; Customer Communication
Technical Requirements Definition	Requirements for Products and Services
Logical Decomposition	Design and Development Planning/Inputs
Design Solution Definition	Design and Development Outputs; Resources; Organizational Knowledge
Product Implementation	Design and Development Controls; Control of Production and Service Provision
Product Integration	Control of Externally Provided Processes, Products and Services
Product Verification	Design and Development Controls: Verification Activities
Product Validation	Design and Development Controls: Validation Activities
Product Transition	Release of Products and Services; Post Delivery Activities
Technical Planning	Operational and Planning Control
Requirements Management	Design and Development Planning/Inputs; Control of Externally Provided Processes, Products and Services
Interface Management	Control of Externally Provided Processes, Products and Services
Technical Risk Management	Actions to Address Risks and Opportunities
Configuration Management	Design and Development Changes; Changes to Requirements; Identification and Traceability; Control of Changes; Control of Nonconforming Outputs
Technical Data Management	Documented Information; Control of Documented Information; Control of Changes
Technical Assessment	Performance Evaluation; Monitoring, Measurement, analysis and Evaluation; Internal Audits
Decision Analysis	Measurement Review

Figure 1

In addition, the systems engineering lifecycle can be adapted to a mission realization life cycle for the overall government agency. All organizations, whether public, private, or non-profit, require input from stakeholders; a mission or definition of their purpose; a design solution to their planned product or service; implementation and delivery of the product or service; and

the necessary planning and control processes. Instead of "product realization," the concept of "mission realization" [2] was coined for government agencies. Once this mission realization lifecycle framework is understood, it can be effectively mapped to the provisions of the ISO standard and the quality management system readily falls into place as illustrated in Figures 2 and 3. This mapping works equally well for organizations as well as for specific projects. Those agencies with a regulatory focus can equate regulatory requirements with technical requirements, which are a significant aspect of the mission realization process, but not the entire QMS. Once the QMS is established, it then lends itself to process improvement and lean government activities, which will incrementally improve the organization's ability to deliver within cost and schedule constraints.

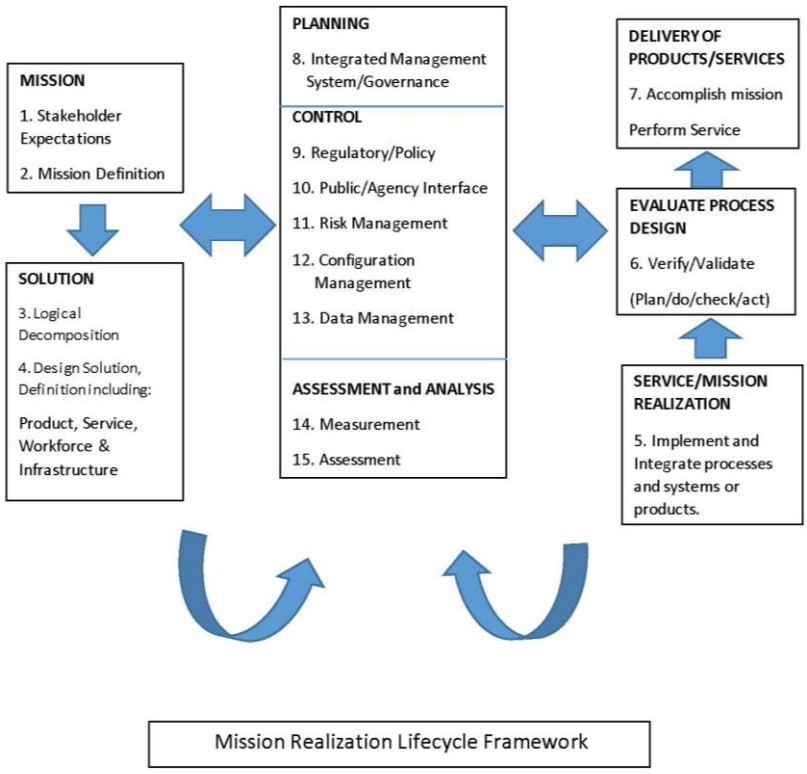

Figure 2

[2] Shepherd, Christena C., *A Framework for Government Agency Quality Management Systems*, ASQ Government Division Newsletter, March, 2016

Mission Realization Lifecycle Definitions

Stakeholder Expectations: General direction as identified by the executive and legislative branches of government, outlined in appropriations; expectations of the citizenry.

Mission Definition: Specifics of how the stakeholder expectations will be met, including types of programs, products and services. (Projects/Programs will follow their own lifecycle.)

Logical Decomposition: The mission definition is further "decomposed" (broken down) into contributing projects, products, and services.

Design Solution Definition: The programs, projects, products, and services are further defined in terms of infrastructure, processes, equipment, personnel, forms, and data.

Service/Mission Realization: Establishment and implementation of operations; integration of functions; performance of mission; acquisitions; processes.

Verify & Validate (V&V): Plan-Do-Check-Act; Design-Measure-Analyze-Implement-Control, Lean, Earned Value Management; is it the right service and is it being done correctly. (V&V as appropriate to the situation)

Accomplish the Mission: Complete the process of delivering on the agency's mission, vision, goals, products, services.

Integrated Management and Governance: Strategy, organization, communication.

Policy/Regulatory Management: Management of the agency's mission through compliance with applicable regulations, statutes, policies. These "technical requirements" inform the design of operations, products, and services, and guide decision making; are flowed down to suppliers, employees, and the public.

Interface Management: Implement, manage and control interface with other departments, agencies, and stakeholders.

Risk Management: Systematic identification of risks and their mitigations; taking action to eliminate, mitigate, or transfer risk; ensure that new initiatives are successful and that new risks for existing initiatives are identified in time.

Configuration Management: Ensure that configuration of products, processes, and infrastructure is identified and controlled to achieve consistent, fair, efficient, and effective results.

Data Management: Ensuring that the data collected from the public and for the service/product delivery is safeguarded, is accurate, and readily retrievable.

Assessment: Status and performance review of: programs, projects, products, services, infrastructure, fulfillment of strategy, and goals. Make necessary adjustments.

Decision Analysis: Management review of assessment data and subsequent decisions

Once the mission realization lifecycle definitions are understood, they can be extrapolated to the provisions of ISO 9001 as seen in Figure 3.

Mission Lifecycle	ISO 9001:2015 Requirement
Stakeholder Expectations	Needs and Expectations of Interested Parties; Customer Focus; Customer Communication
Mission Definition	Requirements for Products and Services
Logical Decomposition	Design and Development Planning/Inputs
Design Solution Definition	Design and Development Outputs; Resources; Organizational Knowledge
Service Implementation	Design and Development Controls; Control of Production and Service Provision
Service Integration	Control of Externally Provided Processes, Products and Services
Service Verification	Design and Development Controls (verification activities)
Service Validation	Design and Development Controls (validation activities)
Service Delivery	Release of Products and Services; Post Delivery Activities
Management and Governance	Operational and Planning Control; Leadership and Commitment; Policy; Planning; Understanding the Organization and its Context; Quality Management System
Regulatory & Policy Management; Acquisition	Design and Development Planning/Inputs; Control of Externally Provided Processes, Products and Services
Interface Management	Control of Externally Provided Processes, Products and Services
Risk Management	Actions to Address Risks and Opportunities
Configuration Management	Design and Development Changes; Changes to Requirements; Identification and Traceability; Control of Changes; Control of Nonconforming Outputs
Data Management	Documented Information; Control of Documented Information; Control of Changes
Assessment	Performance Evaluation; Monitoring, Measurement, Analysis and Evaluation; Internal Audits
Decision Analysis	Management Review

Figure 3

In many of the recent discussions and articles about the ISO 9001:2015 revision, the topic of risk is identified as the most significant change, although risk management is not new for systems engineering processes. ISO 9001 does not provide a specific process for risk management, nor does it require the implementation of ISO 36000[3], so if guidance on a risk management process is needed, ISO 36000 is a good place to begin. Risk management can be more broadly interpreted to organizational/institutional/mission risk management, and not limited to a specific engineering activity. If done properly, it will provide a disciplined, traceable process to explore the likelihood and consequences of possible undesirable events associated with policies, decisions, and even opportunities, as well as for technical risk. Cost and schedule are balanced against public safety, technical merits, and other factors as applicable, such as impact to the community. Examples of policy, management, and engineering decisions that have resulted from an underestimation of the likelihood and consequence of undesirable events are often in the news and will not be enumerated here, but can be easily recognized once the risk assessment and risk management processes are understood.

The release of ISO 9001:2015 is in reality a significant breakthrough for government agencies that are in need of improvements in efficiency, effectiveness, fairness, consistency, and value for the taxpayer, due to the broader appeal of the new provisions. Some translation and extrapolation are required; however, basic systems engineering and management principles can be correlated to the provisions of the standard.

For more information on ISO 9001:2015, visit ASQ Quality Management Standards and the ASQ Government Division.

[3] *ISO 31000:2009-11-15 International Standard*; *Risk management-Principles and guidelines*, Geneva, Switzerland: International Organization for Standardization, 2009.

References

ISO 9001, *Quality Management Systems-Requirements*; International Organization for Standardization; Geneva, Switzerland, 2015.

ISO 31000:2009-11-15 International Standard; *Risk management-Principles and guidelines;* Geneva, Switzerland: International Organization for Standardization, Geneva, Switzerland, 2009.

ISO/IEC 26702, *Systems engineering-Application and management of the systems engineering process;* International Organization for Standardization; Geneva, Switzerland, 2007

NPR 7123.1 *NASA Systems Engineering Processes and Requirements* http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=7123&s=1B

SAE/EIA 632 *Processes for Engineering a System,* SAE International, 2014, http://www.sae.org

Shepherd, Christena C.; *A Framework for Government Agency Quality Management Systems;* ASQ Government Division Newsletter, March 2016.

Stevens, Tim; *Philip Crosby: Quality is Still Free*, Industry Week, June 19, 1995, retrieved 2/16/2016 from http://www.industryweek.com/quality/philip-crosby-quality-still-free?page=1