

The Eight Elements of Quality Management

By Gary C. Cseko

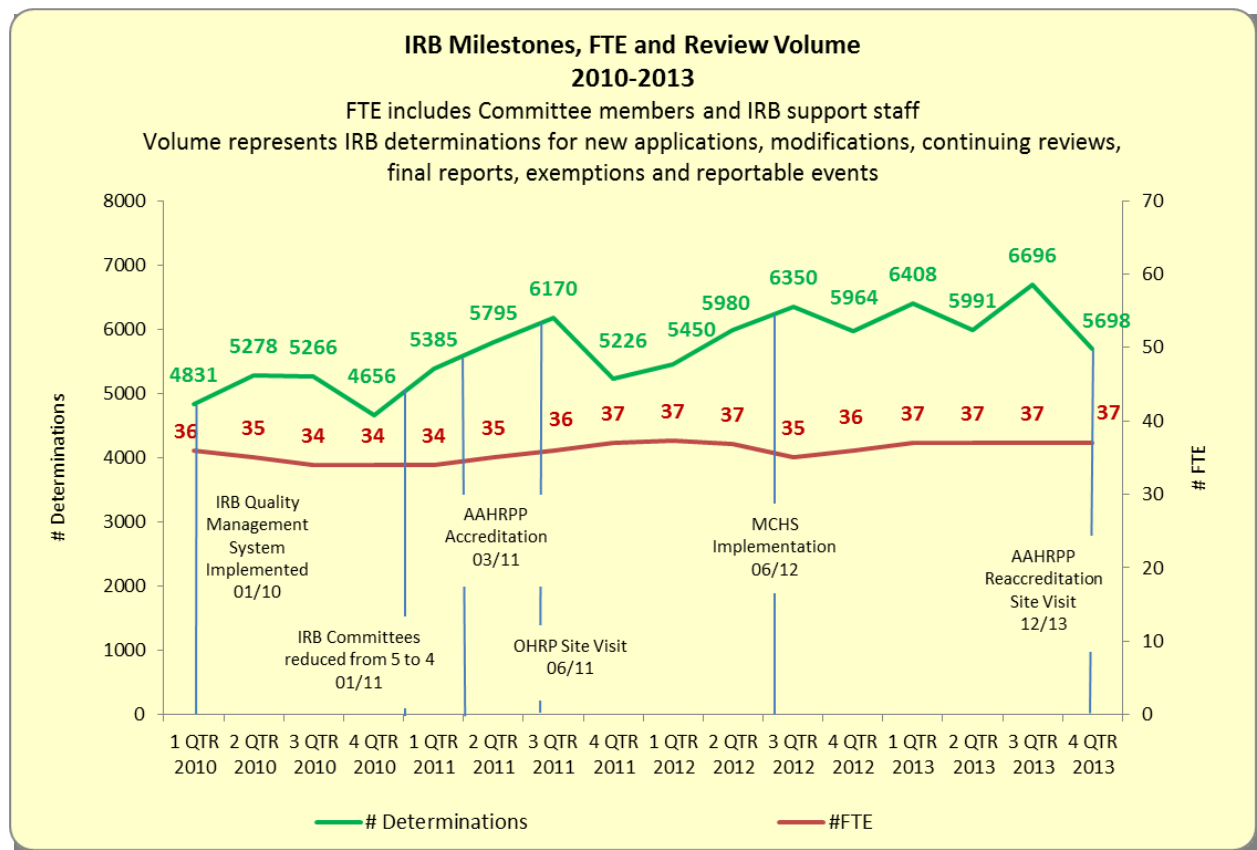
Most organizations want to provide high-quality products and services that meet or exceed the needs and expectations of their customers, albeit within the constraints of time and cost. Fortunately, processes that deliver high quality also often reduce timelines and cost.

ISO 9001-2008¹ provides a structured methodology for creating a quality management system (QMS) that can help organizations achieve consistently high levels of quality for products and services, as well as in internal processes, with shorter timelines and lower costs².

Mayo Clinic’s Comprehensive Research Management System (CRMS) employs a QMS framework based on ISO quality management principles, a quality manual template from 9000World.com, and the original concepts of Joseph M. Juran and W. Edwards Deming³.

Employing QMS, the Mayo Institutional Review Board (IRB) achieved a 24% increase in workload, while meeting turnaround time targets, enhancing quality, and holding employee numbers (FTEs) nearly flat (Figure 1).

Figure 1. Mayo IRB Workload vs. Staffing Levels



QMS benefits included the following:

- Increased efficiencies
- Improved financial performance
- Better employee morale
- Factual approach to decision-making
- Controlled and documented work processes
- More satisfied customers
- Culture of continuous improvement

Mayo Clinic's QMS is based on the eight ISO elements, all of which are required to realize its full potential (Figure 2):

Figure 2. Elements of Mayo's QMS Model
(based on information from 9000World.com)



1. Management Commitment

Organizational leaders must be active and visible champions of the QMS. They must ensure that all employees buy into the QMS concept, goals and objectives for processes throughout the organization.

2. Culture

Quality management, as a way of thinking about obstacles and achieving objectives, must become ingrained in the organizational psyche. The staff must become comfortable with the notion that mistakes are opportunities for improvement, not failures to be hidden from management. Accordingly, leadership must provide an environment in which staff can discuss problems openly and collaborate to enhance operational performance.

3. QMS Administration

An effective QMS requires business processes of its own. It thus needs a vision, strategic goals, operational objectives, and metrics, along with the leadership and resources to function properly.

4. Documentation System

Consistent high quality and continuous improvement require documenting core business processes with standard operating procedures (SOPs). SOPs must be easily accessible. The QMS must support periodic reviews, so SOPs can be updated as processes improve and the environment changes.

5. Competence, Awareness and Training

SOPs are useless until staff members receive the necessary training and education. There should be clear job descriptions, congruent delegations of responsibility and authority, and effective performance management that includes frequent feedback on performance.

With a QMS, the primary focus is not on whether an individual employee is doing a good or bad job. Instead, the focus is on whether the organization provides the processes and procedures that enable that employee to deliver high-quality results. When a performance issue occurs, management first looks to the processes and procedures to ensure they are not the root cause of the problem, then to the sufficiency of the training provided, and then to the clarity of the employee's goals, responsibilities and supervision, before reaching any conclusions about the competency or attitude of the employee.

6. Measurement and Analysis

It is difficult to manage, much less improve, business processes without measurement. Key performance indicators (KPIs), with associated targets, can measure work volumes, staffing requirements, cycle times, defects, etc. Identifying and analyzing errors and other non-conforming events to determine their root cause makes it possible to accurately identify opportunities for improvement and then track progress.

7. Customer Service & Satisfaction

Every business process has customers, whether internal or external. The concept of quality is important only to the extent that it improves customer satisfaction. Business process owners thus must understand the needs and expectations of their customers.

8. Continuous Improvement

A fundamental principle of quality management is that there is always room for improvement. Achieving a goal means creating a new goal, or dealing with a change in the environment that creates a new problem to be solved. Sometimes, processes can be improved in a major way, but most process improvement occurs in continuous, incremental steps. All employees should always be looking for ways to make operations more efficient and better meet their customers' needs and expectations.

Quality Management Systems help organizations apply methodologies like Six Sigma, Malcolm Baldrige National Quality Award criteria, and lean techniques to process improvement⁴, and ensure that improvements will be sustained. Using this approach gives an organization a simple, well-defined, and straightforward framework for consistently achieving high levels of quality, i.e., delivering what the customers want. Most importantly, a QMS helps create a culture of quality, service and continuous improvement. Achieving high levels of quality and service does not "just happen"; it takes a system.

References

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4. Cochran, C.(2008). *ISO 9001 in Plain English*. Chico, CA: Paton Professional.

Acknowledgement

I would like to thank Darren Gronseth, Manager of the Mayo Clinic Office of Research Quality Management Services, for his vision, teaching and mentoring, which have greatly influenced my thinking on quality management. I would also like to thank him for his review and comments on this article.

Author

Gary C. Cseko is Division Chair, Research at Mayo Clinic. Contact him at cseko.gary@mayo.edu.