

# Differences and Similarities between the Malcolm Baldrige Award (Ohio Partnership for Excellence Award) and the ISO 9001:2000 Standard

## Objective

- Brief Overview of the Malcolm Baldrige Award and ISO Standard
- Difference and Similarities Between Baldrige and ISO
- What Should We Pursue: Baldrige or ISO?

## Malcolm Baldrige Award Background

The Award was created by Public Law 100-107 (8/20/87). The U.S. Department of Commerce is responsible for the Baldrige National Quality Program and the Award. The National Institute of Standards and Technology (NIST) manage the Program.

The Board of Overseers advises the Department of Commerce on the Baldrige National Quality Program. The Board is appointed by the Secretary of Commerce and consists of distinguished leaders from all section of the U.S. economy. The Board evaluates all aspects of the Program, including the adequacy of the Criteria and processes for determining Award recipients.

The Board of Examiners evaluates Award applications and prepares feedback reports. The Panel of Judges, part of the Board of Examiners, makes Award recommendations to the Director of NIST. The Board consists of leading experts from US Businesses and Education, Healthcare and Nonprofit Organizations. NIST selects members through a competitive application process.

Award recipients are required to share information on their successful performance and quality strategies with other US organizations. Recipients are not required to share proprietary information, even if such information was part of their Award application.

## ISO Certification Background

ISO is the world's most respected quality management system. It began in 1946 when delegates from 25 countries met in London to "ensure the uniformity and harmonization of standards that had proliferated around the world." It became chartered the next year, and has now grown to 120 member countries. The ISO 9000 family of quality management standards was developed in 1987, and it has become the "gold standard" for manufacturing companies. The system is process-based and in essence is a process to ensure that all of the processes in an organization are defined, documented, interface with each other, and perform the way they were designed to perform. Many hospitals internationally are certified by ISO, and even though it is the international benchmark, American healthcare has been slow to embrace it.

The ANSI-ASQ National Accreditation Board (ANAB) is the U.S. accreditation body for management systems. ANAB accredits certification bodies for ISO 9001 quality management systems and ISO 14001 environmental management systems, as well as a number of industry-specific requirements documents based on ISO 9001.

A Certification Body or Registrar is the external auditor that would audit your business/quality management system to ensure it conforms to the ISO 9001:2000 Standard. In order for a Certifying Body to achieve Healthcare Certification, the Certifying Body would be required to assemble an audit team including a certified lead auditor with healthcare expertise. An industry specific checklist could be utilized; such as the Medicare/Medicaid Hospital Survey Report and the Life Safety Code. The certifying body must provide training to their auditors to ensure appropriate, on-going qualifications and must provide periodic evaluation of continued competence, including on-site witnessing of auditors (per IAF Guidance to Guide 62, G 2.2.10 and 2.2.11).

## Baldrige Award

The Baldrige Criteria for Performance Excellence are about winning. The Baldrige Award is a Competitive Annual National Award in which the organization must achieve business excellence results and be in top three of the applicants. Some State programs give recognition based on level of excellence (e.g. bronze, silver, gold & platinum). Baldrige sets tone of journey towards excellence, not destination of award. Some organizations have used the ISO 9001:2000 Standard as a foundation to begin aligning and implementing the Baldrige Criteria.

### Certification to the ISO 9001:2000 Standard

With ISO, the organization obtains certification to the ISO 9001:2000 Standard. The organization must maintain its certification by either having every six month or every year surveillance audits of its business management system. The organization’s entire business management system is audited every three years.

### Baldrige Criteria and Scoring

1. Leadership	120 points
2. Strategic Planning	85 points
3. Customer and Market Focus	85 points
4. Measurement, Analysis, and Knowledge Management	90 points
5. Human Resources Focus	85 points
6. Process Management	85 points
7. Results	450 points
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Total Points	1000 points

### ISO 9001:2000 Management Principles

The ISO Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

1. Customer Focus
2. Leadership
3. Involvement of People
4. Process Approach
5. Systems Approach to Management
6. Fact-based Decision Making
7. Mutually Beneficial Supplier Relationship

### Philosophy Similarities

Baldrige Criteria	ISO 9001:2000 Standard
Policy and Strategy	Quality Policy Quality Objectives
Customer & Market Focus Customer Satisfaction	Customer focus Customer related processes Customer Satisfaction
People Management	Human Resources Business Processes
Business Processes	QMS General Requirements Product Realization
Organization’s Business Results	Monitoring and Measurement of Processes Monitoring and Measurement of Product Analysis of Data

## Baldrige Award Costs

Award Category	Eligibility Fee	Application Fee	Site Visit
Healthcare - >500	\$150	\$5,000	\$20,000 - \$35,000
Healthcare - <500	\$150	\$2,000	\$10,000 - \$17,500

## ISO Standard Audit and Certification Costs

Depending on the number of employees and identified business processes (complexity of your organization), the below are estimated certification audit costs for medium-size community hospital:

- ◆ *Estimated Certification Audit* (16 man-days) = \$22,000 + travel expenses
- ◆ *Semi-Annual Surveillance Audits* (3 man-days) = \$4,500 + travel expenses or *Annual Surveillance Audits* (6 man-days) = \$9,000 + travel expenses

Note: This would be a medium complexity hospital with 900 employees.

ISO certification will save your hospital not only money but also other resources such as time spent in redoing a task, or performing unnecessary or duplicate tasks. ISO is unique in that it relies on the individual organization to “establish, document, maintain and improve its processes. It is a quality management tool that can help organizations streamline processes and remove any unnecessary steps.

By defining your business management system and capturing any and all Federal, State and Local laws and rules, other accreditation standards and best practices; you essentially have positioned yourself to sustain performance improvements and adherence to any and all applicable laws.

## Baldrige Process for Award Application Submission

- Submit an application and if accepted, site visit scheduled
- Recognition levels in state programs (Bronze, Silver, Gold & Platinum)
- There may or may not be an Award Recipient
- Evaluation by trained volunteer team (6 to 10)
- Feedback must be consensus of the team
- Site visit may be 25-40 man-days
- Review time is hundreds of hours plus on-site time

## ISO 9001:2000 Process for Certification

After the healthcare organization obtains management commitment, a gap analysis should be performed. Many organizations that are accredited by the Joint Commission and correspondingly meet the Medicare Conditions of Participation and state laws and rules have many components of the ISO Standard in place. The organization must define the scope of its Business Management System (e.g. hospital, health system, physician office, and ambulatory surgery center). The organization would then develop the appropriate documentation (define and document its business processes and define their sequence and interaction). The organization would then implement its defined and documented business processes and monitor/measure them for effectiveness. Where processes do not achieve desired outcomes, actions are required to be implemented. Once an organization feels its system has been successfully implemented a pre-assessment (mock survey) would be conducted. If successful, the organization would invite the Registrar (external auditors) in for an audit. The Registrar would then assess the organization’s documented system to ensure adequacy, and then come on-site to audit the documented system for conformance and effectiveness.

- Evaluation by trained & paid auditors
- Initial audit is based upon system complexity and number of employees
- Document Review time may be 1 to 2 man-days
- On-going Surveillance audits review core elements and a portion of business processes

## Similarities and Differences for Successful Implementation

### Baldrige

- Driven by executive management
- Application summarizes existing processes and results
- Cross-functional input essential
- Requires analysis of results, trends and benchmarks
- Cycles of improvement required
- Harmonization of plans, processes, information, resource decision, actions, results and analyses to support key organization-wide goals.
- Current performance must be excellent for Application Submission
- Industry and benchmark leadership

### ISO 9001

- Organizations that are successful and demonstrate continual improvements are the ones in which ISO is driven by executive/top management.
- Cross-functional input required.
- System wide development & implementation required
- Requires analysis of results, trends and benchmarks
- Approximately 3+ months of records of implementation required for initial certification; for surveillance audits, evidence of improvement required
- All processes must be identified, defined with sequences and interactions recognized
- Measurements aligned with strategic goals
- Comprehensive metrics
- Data analyzed to become information
- Current performance is suitable, adequate and effective; if not, evidence of action required
- Results fully address customer, market, process and action plan requirements
- Excellent improvement trends/sustained excellent performance levels
- Industry and benchmark leadership

### Which Should we Implement?

- ISO is a fundamental Business Management System which requires analysis of data to drive process/system improvement.
- Baldrige is results-oriented.
- An effective Business Management System infrastructure is necessary to achieve sustainable results.
- By establishing an ISO based Business Management System, the organization can position itself effectively to achieve the Baldrige Award as well as sustain success and performance improvement.

*Innovative Quality Solutions Company is a full service training and consulting firm focused on total customer satisfaction, performance improvement and achievement of organizational objectives. Innovative Quality Solutions provides all aspect of support to organizations seeking certification and compliance to the ISO 9001, ISO 14001, AS 9100 and TS 16949 Standards. Since 1995, the firm has lead more than 250 organizations to successful first time certification. Innovative Quality Solutions is located in Akron, Youngstown, Cleveland and Columbus. Paula Sabo Fyda, President, may be contacted at 330-725-9927 or [paulaf@iqsconsulting.net](mailto:paulaf@iqsconsulting.net). Renee Mallett, VP of Healthcare Division, may be contacted at 614-855-0008 or [reneem@iqsconsulting.net](mailto:reneem@iqsconsulting.net). More information is located on Innovative Quality Solutions Company's website at [www.iqsconsulting.net](http://www.iqsconsulting.net).*