ISO 9001:2008 for Healthcare

Presented by Glenn Tanzman
May 26, 2010
ASQ Professional Development Meeting
Today’s Healthcare

- Ever increasing pressure on existing resources
  - Baby boomers aging population
  - New health reforms include more participants
- Challenges for improved quality and patient confidence
- Costs continue to escalate
- Technological enhances stress healthcare organizations
  - Required personal competencies proliferate
- No unifying system for certifying and accrediting healthcare exists—
  - JCAHO, HFAP, URAC, NCQA, or CAP
Universal Problems

Waste

Cost

Work-Arounds

Errors

Silos

Waiting

Staff Frustration
Current quality improvement initiatives are fragmented and not sustainable.

The Institute of Medicine estimates that medical errors cost the nation approximately $37.6 billion per year.

Approximately $17 billion of that amount are associated with preventable errors.

More than 44,000 deaths occur annually due to error, which could make medical errors the 8th leading cause of death.

An estimated 90,000 deaths per year, hospital acquired infections kill as many people in the U.S. as Aids, breast cancer, and car accidents combined.
Making Hospitals Work

- Purpose
- Process
- People

ISO Quality Management System

Patients

Staff & Providers

Healthcare Organization

Copywrite Tanzco Management Consulting 2010
ISO 9001:2008 in Healthcare

- Universally recognized standard and all ready in use by many international countries for healthcare
- A platform capable of supporting and coordinating the multiple elements and processes that healthcare services entail
- Provides an enhancement to the existing quality and business system of the healthcare organization
Benefits

- Provides a solid **basis for compliance** with all imposed requirements (JCAHO, etc.)
- Makes all other certification & accreditation processes **easier and less costly**
- Facilitates **improved understanding** of roles and responsibilities
- Improves **communication/coordination** between departments
- Improves **accountability** by requiring measurable improvement objectives
- Results in **improved systems, processes and outcomes**
Benefits of ISO 9001:2008 as a Quality Management System

- Systemic breakdowns are recognized and addressed
- Development of “Best practice” hospital-wide processes, with reference to supporting documentation
- Ensures conformance to and effectiveness of documented processes
- Focuses on Patient Care, Satisfaction, and Safety
- Reduce errors associated with ”hand-offs”
- Improve documentation and records
- Strengthen customer/community confidence and relationships
- Alignment of Hospital-wide, Departments, Individual objectives
- Foundation for on-going improvement initiatives
Clause 4 – QMS, Process Management, Documentation Requirements, Records Control

- Establish a quality manual; create a documented quality management system (QMS); and determine how the organizational structure, procedures and processes will satisfy quality objectives.
- Approved instructions for provision of patient care and support functions. The right documents must be available and indexed so they are readily accessible.
- Must have document control procedures and remove obsolete documents promptly.
Clause 5 – Management Responsibility, Customer/Patient Focus, Planning

- Provide the leadership, structure and resources, and establish the quality policy for the entire health care quality system.
- Quality planning suggests continuous improvement.
- ISO 9001 focuses on the fact that the patient understands and acknowledges ethical issues such as confidentiality, privacy, security, communications and orders (such as admission and discharge) and formally agrees with any contracts affecting his or her rights as a patient.
- Management Review
Structure of the ISO 9001:2008 Standard

- **Clause 6** – Resource Management Human Resources, Infrastructure, Work Environment
  - Ensures that employees have the *requisite skills* to do their jobs.
  - Further, *internal auditors must have quality training certificates on record*.
  - *All training must be documented*, and a central training records database must be preserved.
Clause 7 – Product / Service Realization, Customer Interface/ Communication, Design, Purchasing Management, Production/ Service Operations

- Defines the steps that must be taken by the hospital when new or additional services are created.
- Covers everything from subcontractors to medical equipment to pharmaceuticals.
- It is necessary that the QMS ensure the accurate and timely purchase of materials and supplies from approved vendors.
- Control of suitable process parameters and service conditions to clearly stated criteria for workmanship. (Quote)
- In health care settings, this clause has a special application. Patient records and patient activities are generally connected to a particular patient through the use of unique identification numbers.
Clause 8 – Internal Audits, Customer/Patient Satisfaction, Monitoring/Measurement, Handling Non-conformances, Corrective & Preventive Action, Continual Improvement

- Audits can be internal (first party), insurance underwriters (second party) or qualified health care registrars (third party). They could also be state licensure audits.
- All instruments and devices affecting quality health care have been properly calibrated.
- Requires verification that assessments, inspections and tests have been performed, and a patient's medical record shows what procedures, lab tests, results and assessments have been made.
- Nonconforming product also includes nonconforming service.
- The internal audit process, which identifies nonconformities, drives corrective and preventive action and reports corrective actions, processes and any quality trends to management review on a periodic basis. It is one of the strengths of an ISO 9001 QMS.
ISO 9001 only requires that, at a minimum, your QMS be rationalized and articulated by:

- A Quality Manual
- 6 Documented Procedures
  - Document Control
  - Record Control
  - Control of Non-Conforming Product (or Service)
  - Internal Audits
  - Corrective Action
  - Preventive Action
- At least 21 Records – [List of ISO 9001 required records](#)
Simply put, many lean hospitals describe their goals as follows:

- No waste
- No waiting
- Zero harm
Healthcare quality experts estimate that between 30 and 50% of all healthcare work activity can be categorized as "waste."

The opportunity with lean is to reduce costs by eliminating waste, not through traditional cost cutting, which often includes providing fewer services or reducing headcount.
ISO 9001:2008 Healthcare Quality Management System

Sample Quality Policy:

We will strive to be the leading provider of healthcare services in Southern Ohio. We will accomplish this through –

- Consistent compliance with all imposed requirements;
- Our focus on Patient Safety and Satisfaction; and
- Continual improvement of our products, services, and processes.
Recommended Approach for Developing a Healthcare Quality Management System

1. Obtain Management commitment to support, understanding, involvement, provision of resources
2. Educate Management & Staff about the ISO 9001:2008 Standard, Scope of Work, Organizational impact
3. Define Key Improvement Objectives
4. Identify and Map Organizational Processes, key as well as support. Address all imposed requirements.
6. Establish approach to document control and access.
7. Develop, review/revise, and incorporate all required support documentation (e.g. Department Policies/Procedures, forms)
Recommended Approach for Developing a Healthcare Quality Management System

8. Educate Staff on Quality Management System (QMS) documentation
9. Establish and implement monitoring/measurement for each process
11. Conduct a Management Review of the QMS.
12. Undergo a Pre-Assessment or “Mock Survey” to assess system implementation, readiness
13. Make required corrections
15. Undergo the Certification Audit
Process effectiveness: internal audits

- Audit all your documented processes at least twice a year.
- Train a sufficient amount of auditors to meet that internal audit goal.
- Establish measurements and monitors that will be reviewed by senior management at least twice a year.
Case Study

Results achieved at one hospital in Michigan during the implementation of ISO 9001

- Identified and defined best practices for all hospital wide patient care processes (outpatient, inpatient and emergency department) and support processes (e.g. maintenance, calibration, purchasing, receiving, contract management).
- Policy and Procedure Clean-up
- Forms and Document Clean-up – Index per Department and Hospital Wide
- All physician orders sets and protocols reviewed at least once a year.
- On-line Risk Occurrence Entry Implemented
- Centralized the Product Recall Process which includes medication, equipment, devices, food
- Capital Request – Reviewed process & policy, enhanced checklist
- Need for Unit Clerks identified and identified other needed resources
Case Study: St. Luke's Hospital in Maumee, OH

- ISO-certified since 2004
- Joint Commission- and DNV-accredited
- Cheryl Roush, CPHQ, organizational quality manager
- Certified hospital using existing staff
- Updated document control
  ◦ help keep forms current and cycle out older versions
  ◦ *Documents now posted on hospital’s intranet*
"Your document control is going to be a big [change]," says Roush. "Joint Commission requires that clinical processes are written, but a lot of other areas, like finance, didn't have documentation [requirements]."

"I recommend hospitals have one repository for documents," says Roush. "We have a procedure on document control; highlighting the approval process, the numbering system...everything is controlled on the intranet."
Additional Benefits of ISO 9001:2008 for Healthcare

- Improves Competitive Advantage
- Defined and documented Hospital/Health system-wide Processes
- Makes Operations/Processes Consistent
- Helps Establish a “Quality Culture” and a culture for “Patient Safety”
- Encourages Self-Assessment
- Establishes Internal Trust
- Improves Communication
More favorable impacts

- Consistency of services during times of change
- Patient/customer/physician satisfaction
- Accountability and Empowerment of employees
- Ability to evaluate effectiveness of processes through internal audits
- Compliance with regulations, contract requirements, codes
False Paradigm

- Hundreds of pages of text
- QMS EMS Manual
  - Purpose
  - Scope
  - Responsibility
  - Definitions
  - Procedure
  - Related Documents
- Procedures
- Work Instructions
  - For everything
  - Linked to a Procedure
- Forms/Records
  - Everything is a record
  - Linked to Work Instruction
- Must be a book (20-50 pages)
- Must address every shall
A Realistic and Practical Process-based Model

- Management Policies
  - Planning, Customer Focus, Objective Setting, Resource Allocation, etc.

- Core Processes
  - Sales/Contract Rev.
  - Design
  - Purchasing
  - Product Provision
  - Delivery/Installation
  - Service/Support

- Support Processes
  - Mgmt. Review, Doc/Rec Control, Internal Audits, CAPA, Training, etc.
Lean QMS Map/Quality Manual

Our organization plans for strategic and tactical Process Performance Measurement within every process.

Objectives Matrix
Strategic & Tactical
F-5410-01

QM-EMS Map (Quality Manual)

QMS/EMS Map (Quality Manual)

Effective Date: mm/dd/yyyy

QM-4220 Rev.: 0

Owner: Mgmt. Rep.

© 2005 Pinnacle Enterprise Group, LLC

Copywrite Tanzco Management Consulting 2010
Symbiosis ISO 9001 and Lean

Healthcare costs are rising too quickly and too many preventable errors occur in most hospitals around the world.

We strongly believe the "lean" methodology in combination with a strong QMS is our best hope for improving quality while truly reducing waste and excessive costs, thus increasing the value provided by our healthcare systems.
Making Hospital Work

ISO 9001:2008 will:

“Improve patient care while saving everyone’s time and hospitals’ resources”

Better patient care for less money, isn’t this a no-brainer.
Thank you!

Questions?