WHAT IS ISO 9001-2000?

- A series of minimum requirements for development of a quality management system
- A standard developed by the ISO (International Organization for Standardization)
- The American National Standard (ANSI) for Quality Management Systems
- Requirements specify what must be achieved (a set of end results), not how to achieve requirements
- Specifies a platform for consistency, continuity, and continuous improvement
WHY IS ISO 9001-2000 A GOOD FIT?

- The “glue” that keeps systems alive and running regardless of changes in structure, management, personnel
- Seamless system to manage, evaluate and continuously improve core processes
- Vehicle to comply with multiple standards and imposed regulatory requirements
- Effectively control process consistency and quality of service
ISO 9001-2000 provides:

- A mechanism to identify, analyze and improve systemic breakdowns and close gaps and holes.
- A systematic framework to improve organizational performance.
- A method to facilitate compliance with internal and external requirements (e.g. regulations, accreditation standards).
- A management tool to meet contract requirements.
The 8 Management Principles
The Philosophical Basis of ISO 9001-2000

1. Customer focused organization;
2. Leadership;
3. Involvement of People;
4. Process approach;
5. Systems approach to management;
6. Continual Improvement;
7. Factual approach to decision making;
8. Mutually beneficial supplier relationships.
ISO 9001:2000 Clause 5.2 Ensures that Customer requirements are determined.

ISO 9001:2000 Clause 5.2 Ensures that Customer requirements are met. Customer Satisfaction is enhanced.

NOTE: Interested parties do not apply to ISO 9001
ISO 9001-2000 Clause 5

Management Responsibility

- Management Commitment
- Customer Focus
- Quality Policy
- Planning
  - Quality Objectives
  - Responsibility and Authority
  - QMS Planning
- Responsibility, Authority and Communication
  - Management Representative
  - Internal Communication
- Management Review
  - Review Inputs
  - Review Outputs
ISO 9001-2000 Clause 6

• **Resource Management**
  – Provision of Resources
  – Human Resources
    • General
    • Competency, awareness and training
  – Infrastructure
  – Work environment
ISO 9001-2000 Clause 7
Product Realization

• Planning of Realization
• Customer Related Processes
  – Determination of requirements
  – Review of requirements
  – Customer Communication
ISO 9001-2000 Clause 7
Product Realization

- Design and Development
  - Planning, Inputs, Output, Review, Verification, Validation and Changes
- Purchasing
  - Purchasing process
  - Purchasing information
  - Verification of purchased products
ISO 9001-2000 Clause 7
Product Realization (continued)

• Production and Service Provision
  – Control of production and service provision
  – Validation of processes
  – ID and Tracability
  – Customer Property
  – Preservation of product

• Control of measuring and monitoring devices.
ISO 9001-2000 Clause 8

Measurement, Analysis and Improvement

• General
• Monitoring and Measurement
  – Customer Satisfaction
  – Internal Audit
  – Monitoring and measurement of processes
  – Measurement and monitoring of product
• Control of Nonconforming Product
• Analysis of Data
• Improvement
  – Continual improvement
  – Corrective Action
  – Preventive Action
ISO 9001-2000 Clause 4

Quality Management System

• General requirements
• Documentation requirements
  – General
  – Quality Manual
  – Control of documents
  – Control of records
So.....how do I do it?
IN SEARCH OF THE EMERALD CITY.

Implementing ISO 9001-2000
in a Kansas Hospital
Who Is Newton Medical Center?
NMC

- Community hospital
- Not for profit
- Result of a merger in 1988
- Accredited
- Close proximity to tertiary facilities
- Approx 500 employees
History of Quality at NMC

- 1990’s-CQI efforts began as a result of JCAHO’s “Agenda for Change”; Deming was studied at length
- MD Quality ran parallel to medical center quality efforts
- Jan 2002-attempt to “mesh” MD quality with hospital efforts at request of new CEO
2002-Year of Attempted Change

- Quality Council expanded to include MDs
- Theoretical operating framework redefined with emphasis on the “Circle of Quality”
- Clinical team
- Support team
So What Were the Results?

- MDs asked for process improvement: i.e. delayed OR start times
- Data gathering increased
- All managers were forced to be involved
- Hospital Quality Plan revised
- JCAHO continued to force increased indicators
- Council members assigned additional organizational responsibilities
Results

- Quality indicator reporting increased to BOD
- Medical staff committee quality reporting back to Quality council did not occur; continued to run parallel
- National Voluntary Quality Initiative activity began
- Efforts for improvement based on data were feeble in most cases
- Increased meetings for managers
- Manager “burn out” and apathy
2003-Year of Change Exploration

• Successful JCAHO survey
• Alternatives to JCAHO explored
• Evaluated value of patient survey process
• Evaluated value of core measure vendor
• Began reporting for CMS Initiative
Benefits of JCAHO

• Had traditionally been perceived as the “gold standard”
• Provided a mechanism for organizational on-going assessment
• Historically NMC had done well
“Down Side”

• Surveyor interpretation
• Excessive policies & data gathering activities that did not impact patient care
• Costly
• Dynamic standards/changes
• “Shared Visions-New Pathways” in 2004
So How Much Does JCAHO Cost?

- Cost of survey
- Data collection
- Data collection vendor
- Subscriptions
- Employee education
- Staff time
JCAHO Cost NMC

$60,662.00 + annually
ISO 9000

- Another option for quality
- Nationally/Internationally recognized
- Generic standards for QA & QM
- Becoming more common in healthcare
Maryland Study

- NMC has used since 1990
- Provides external benchmarking
- Acute Care Indicator set
- Submits core measure data to JCAHO
- Submits data to CMS as required
- Costs $15,250.00/annually
So......

- IF JCAHO is no longer the accrediting entity, core measures are not required.
- The CMS Initiative data is required but can be transmitted to both CMS & HFAP via CART through KFMC at no cost.
- We need to ask ourselves, “What data is important to us? Does the Maryland Study continue to meet our needs?”
Will the quality of care provided at NMC decrease without JCAHO accreditation?
Recommendations

• Discontinue JCAHO accreditation

• State of Kansas certification or
  **HFAP accreditation as directed by the BOD

• Explore ISO certification as an additional option to improve on quality management esp. if state certified

** Suggested as a higher standard
2004-Hang on; Here we go....

• Dropped core measure vendor
• Dropped pt satisfaction vendor
• Some internal job responsibilities changed
• Disbanded Quality Council; moved responsibility to BOD
• CMS quality data released for the public
• Successful HFAP survey
• ISO education started/ organizational assessment
• Dropped JCAHO accreditation
ISO in Healthcare

• “Can be the answer to business critics who do not believe that healthcare professionals can bring industry costs under control & provide Americans with the type of service they expect.”
  
  Jean Smith, VPO of an ISO Certified hospital

• The vehicle that balances cost & quality in a positive way
**ISO in Healthcare**

- A common structure to grow accountability
- Based on customer satisfaction of all stakeholders

The Journey Begins........
Courage Helps......

- Leadership commitment
- Perseverance
- Resource allocation
- “Thinking outside of the box”
Getting Started Took Some “Brains”

- Finding a consultant
- Going it alone
- Realizing we needed help
- Finding the “right” consultant
Obstacles Were Encountered...

“I’m going to get you, my pretty….

…and your little dog too.”

Intranet problems
Human factors
KS RM law
But perseverance is the key to success
The MR has to Have “Heart”...

- The “nay-sayers”
- The “procrastinators”
- The “ignorant”
- Being supportive, but not doing the work for everyone else
- “Have a hard hat & a good friend to listen”
But We Finally Got There...

- Successful registration audit
- First ISO hospital in Kansas
- Successful QM *system*, not a program
- Front line staff serving as auditors
What we have seen ..... 

• Process improvement that is meaningful 
• Tearing down of “silos” 
• Improved control of documents 
• Decreased process variation 
• Continual prep for accreditation survey 
• LESS STRESS!!
But let me tell you about document control.....
Clause 4.2.3 says.....

• “Documents shall be controlled”
• Approved prior to issue
• Review & updated as necessary
• Current revision & changes are identified
• Legible & identifiable
• Obsolete documents are not used

But most importantly.......
that the current version is available at the point of use.
Documents are “Tiered”

Tier 1 - Quality Systems Manual
  quality policy and objectives

Tier 2 – Organization Wide Documents

Tier 3 Department Specific Documents

Tier 4 Instructions
327 obsolete forms in use...

- Manager Education
- Forms Party
- Obsolete documents were removed
Do YOU have the courage?