



I. How can ISO 9001:2000 be applied to Healthcare?

Definition of ISO:

- ISO means “all sides being equal”. To date, more than ½ a million organizations in 149 countries have implemented the ISO Standards.
- ISO 9001:2000 is a fundamental quality management system standard that requires an organization to identify, define, document, implement (follow), monitor/measure, and continually improve the effectiveness of its processes. It is a self-directed system that requires the organization to identify and address all imposed requirements; as well as improve its organizational performance by modifying systemic issues (e.g. those traditionally associated with the “hand-offs”).

Application of ISO in Healthcare:

Using the ISO Family of Standards, the organization can establish a comprehensive Quality / Business Management System which:

- Provides a solid basis for compliance with all imposed requirements (e.g., JCAHO, AABB, Federal & State regulations).
- Makes all other certification & accreditation processes easier and less costly.
- Facilitates improved understanding of roles & responsibilities among employees; and enhanced communication/coordination between departments.
- Requires the establishment of measurable improvement objectives and accountability to those objectives through monitoring/measuring and reporting.
- Results in improved systems, processes, and outcomes.

Structure of the ISO 9001:2000 Standard:

The ISO:9001 2000 Standard is comprised of 8 Clauses. The 1st 3 are introductory in nature. The subsequent 5 clauses include the requirements the organization must address. They are:

- Clause 4 – Quality Management System
 - Process Management, Documentation Requirements, Records Control
- Clause 5 – Management Responsibility
 - Customer/Patient Focus, Policy, Objectives, Planning, Responsibility & Authority
- Clause 6 – Resource Management
 - Human Resources, Infrastructure, Work Environment
- Clause 7 – Product / Service Realization
 - Planning of New Products & Services, Customer Interface/ Communication, Design, Purchasing/Supplier Management, Production/ Service Operations, Calibration
- Clause 8 – Measurement, Analysis, and Improvement
 - Internal Audits, Customer/Patient Satisfaction, Monitoring/Measurement of Products/Services and Processes, Handling Nonconformances, Corrective & Preventive Action, Continual Improvement



II. Process / Methodology

While the standard does not prescribe the approach or methodology to be utilized by an organization, the following is recommended.

- 1) Obtain Management commitment to support, understanding, involvement, provision of resources
- 2) Educate Management & Staff about the ISO 9001:2000 Standard, Scope of Work, Organizational impact
- 3) Define Key Improvement Objectives (*see next page)
- 4) Identify and Map Organizational Processes, key as well as support. Address all imposed requirements. (*see next page Sample Process Interaction Diagram)
- 5) Develop the organization's Quality Policy and Quality Manual (*see next page, Sample Quality Policy)
- 6) Establish approach to document control and access.
- 7) Develop, review/revise, and incorporate all required support documentation (e.g. Department Policies/Procedures, forms).
- 8) Educate Staff on QMS documentation
- 9) Establish and implement monitoring/measurement for each process
- 10) Train internal auditors. Implement an Internal Audit 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
- 14) Submit Document Review to Registrar (Quality Manual, Processes)
- 15) Undergo the Certification Audit

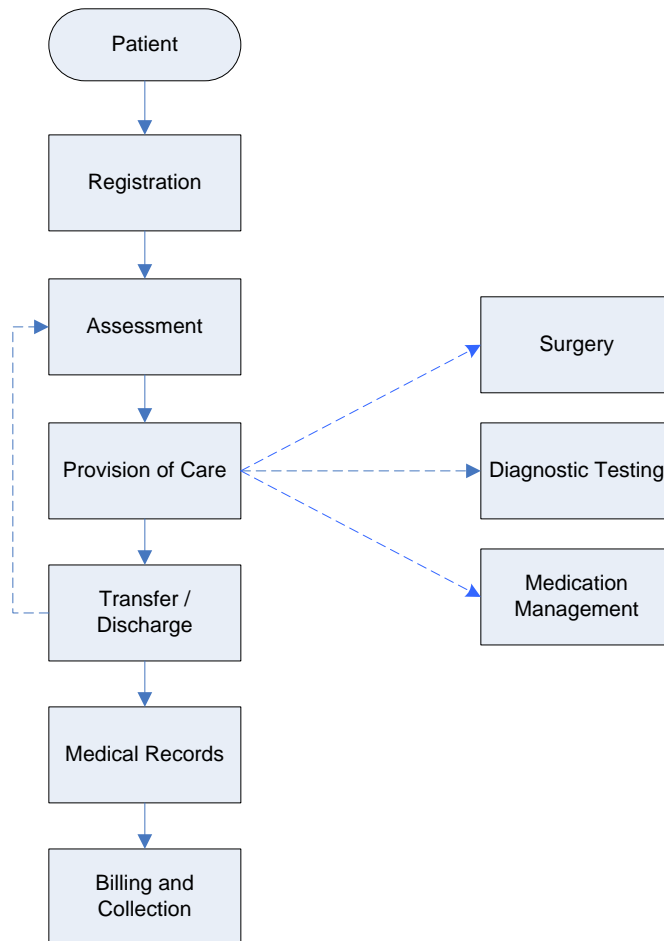


Sample Key Improvement Objectives

- Improve Patient Satisfaction
 - Goal: Improve to 70th Percentile
 - Department Goal: Reduce Wait time for Outpatient Registration to < 4 minutes
- Improve Patient Safety
 - Goal: Reduce Medication Error Rate to < .3%
 - Goal: Reduce fall rate to < 2.6 per 1,000 patient days

Note: Organizational/Hospital-wide objectives are then translated to related departmental, process, individual goals/objectives

Sample Process Interaction Diagram





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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.

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