ISO 9001:2000--Setting the Standard for Quality Management

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How will you approach the next quality management initiative? This article offers an introduction to the ISO 9001:2000 quality management system standards that can be applied to the HIM industry and how these standards can improve your department's policies and procedures.

Healthcare organizations have a range of accreditation and certification options to choose from when quality management becomes a priority. The ISO 9001:2000 quality management system offers generic standards that can be applied to any industry's quality efforts, but will bring particular benefits to HIM, a field that relies on explicit procedures and audit functions. Further, ISO 9001:2000 standards can lay the foundation for other accreditation activities. This article provides an overview of the system.

Defining and Documenting the Process

The essence of an ISO 9001 quality management system can be summarized in four quick steps:

- **say what you do** (by documenting your quality critical procedures)
- **do what you say** (by training and requiring staff to follow those procedures)
- **prove it** (prove that you follow your own procedures via internal auditing and management reviews)
- **improve it** (with corrective and preventive actions on those issues where deficiencies or non-conformances are discovered between the documented procedures and the actual work performance)

Defining and documenting all quality-critical processes is the core of the ISO 9001 quality management system. The advantage of creating a documented system is twofold. First, accurate and adequate documentation of key processes, such as building or filing a medical record, discarding/archiving confidential medical information, or other HIM procedures, ensures that all employees have access to the same policies and procedures. As a result, all employees on all shifts are performing work in the same manner. Further, as new employees are hired, training becomes smoother and more accurate because trainers and trainees rely on the same documented procedures as all other staff in the department.

A Distinct Approach to Certification

Approximately 40 healthcare organizations in North America have certified their quality management systems to the ISO 9000 series of standards.1 These organizations range from hospitals and private practices to blood banks and home health agencies. The certification process is accomplished by hiring a third-party independent auditing firm, called a registrar, to visit your organization and perform a quality audit against the requirements of the ISO 9001 standard. There are approximately 100 registrars operating in the US, but they are not all accredited, nor do they all work within the healthcare sector. The Registrar Accreditation Board, in Milwaukee, WI, provides a list of all accredited registrars and their respective scopes of service.

The audit and certification process varies significantly from the healthcare accreditation bodies with which organizations are probably already familiar. Agencies such as the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care (AAAHC), and the National Committee for Quality Assurance (NCQA) tend to use trained surveyors or auditors with strong clinical backgrounds. The registrars who perform ISO 9000 audits may use healthcare experts with both clinical and non-clinical backgrounds; they may have experts from other industries on the audit team as long as at least one member of the team is an expert in healthcare. If your organization chooses to pursue

ISO 9001 certification, ask for references of the registrars you are considering, and then contact some of their customers (preferably within the healthcare industry) to see if this registrar might be a good match for your team. Also, you have the right to review the resumes of any potential auditors the registrar is planning to send to your facility. Consider also contacting the registrar's planned lead auditor for your organization to confirm that you have philosophical agreement on matters of interpretation of the standard. Choosing an ISO 9001 registrar early in the implementation process and building a rapport with that registrar's staff can assist in a smooth audit and successful certification process.

The ISO 9001:2000 quality management system standards provide a sound, stable framework on which other accreditation requirements can then be layered. More importantly, an ISO 9001 quality management system requires that all employees at every level of an organization take part in planning for and ensuring quality. Creating and maintaining such a system cannot be accomplished in a few weeks to impress the third-party auditors or surveyors. It is a system that should be thought of as dynamic, living, breathing, and evolving—just as an organization lives, breathes, and evolves.

The Standard's Healthcare Application

Although some organizations do not have the motivation or resources to pursue certification at this time, the ISO 9001 standard can serve as a "toolbox" of techniques and concepts that will improve the internal operations of any organization. Following is a closer look at several selected specific requirements of ISO 9001:2000 plus discussion to help HIM professionals to better understand how this standard can improve quality in the healthcare organization and HIM department.

The standard is divided into eight sections. A brief description of each section follows:

• **Section 1** refers to the scope of the standard itself, defining it as the requirements for building a quality management system

• **Section 2** refers to the normative reference documents that provide guidance to the ISO 9001 standard

• **Section 3** provides basic terms and definitions

• **Sections 4 through 8** define the quality management system requirements

The following paragraphs will use the same numbering references as those found in the ISO 9001:2000 document paragraphs 4 through 8.

The standard begins with general requirements for building a quality management system (paragraph 4.1). This means that you must design, develop, and document a **quality management system** in which you define quality critical processes and describe how these processes are interrelated. Implementation of the quality system includes maintaining and improving it by developing methods to effectively implement the quality system and monitor the performance of key quality processes.

Documentation requirements, as stipulated in the standard, include writing a quality manual that addresses all of the ISO 9001 requirements, maintaining document control such that only the current version of documents critical to quality operations are in use, and creating quality records verifying that the required work was completed according to customer and procedural specifications (4.2). The control of **quality records** is of particular interest in the HIM field because the product is a quality record (4.2.4). The standard requires that quality records, for example, medical records, remain legible, readily identifiable, and retrievable. Controls must exist to ensure identification, storage, protection, retrieval, retention periods, and disposition procedures for quality records are in place.

The ISO 9001:2000 standard recognizes that an effective quality management system must be built on **strong management responsibility and commitment** (5.1). Management is expected to demonstrate strong commitment to meeting customer requirements and regulatory and legal requirements. This is the organization's opportunity to specify other accreditation requirements they may choose or need to meet.

At its core, the premise of the standard is to meet customer needs and requirements. The next facet of the standard, therefore, is **customer focus** (5.2). To this end, it is essential for the HIM department to be very clear in defining the internal and external customers and what those customers require from your organization or department. Further, the standard requires that you determine if you have met customer needs, expectations, and requirements. Therefore, it is not enough to know what your customers demand, you must additionally demonstrate that you can meet their demands.

Establishing a **quality policy** ensures that the department mission and purpose, relative to quality, is clear (5.3). The policy must include language that demonstrates that the standard's requirements will be met and that the effectiveness of the quality system will continually improve. Policy language must also stipulate that quality objectives will be periodically reviewed, that the quality policy itself is communicated and understood throughout the department, and that the policy will be reviewed for continuing suitability. Essentially, this is the department's opportunity to state its mission, objectives, and commitment to quality and to verify that the ongoing mission and policy are appropriate and effective to the nature of business.

The standard requires that planning for quality by **establishing quality objectives** is crucial for successful operations (5.4). Measurable quality objectives must be determined for relevant functions within the department. For example, measurable objectives might include that records will be filed within three hours of receipt, transcription onto electronic media will be completed within five hours of receipt, and 98 percent of medical records are retrievable within 15 minutes of request. Keep in mind that quality objectives should always be consistent with the quality policy.

The need for establishing **responsibility, authority, and communication of quality matters** throughout the organization is another component of the standard (5.5). To this end, management is required to appoint a team member to the role of management representative (5.5.2). The representative is responsible for maintaining the quality management system, reporting on the performance of the quality management system, and promoting awareness of customer requirements throughout the organization.

A **management review** component of the standard stipulates particular information that must be considered during this process, such as audit results, customer feedback, and status of corrective and preventive actions (5.6). The review results must include decisions and action plans for improving the effectiveness of the quality management system, improving the service provided relative to customer requirements, and the identification of resource needs.

The **provision of resources** addresses the requirement that all personnel performing work that may affect quality shall be competent based on education, training, skills, and experience (6.1). The standard further states that personnel must be aware of the importance of their activities and contributions to achievement of the quality objectives. Additionally, the organization is responsible for maintaining an infrastructure, including buildings, workspace, storage units, hardware, and software that allows the staff to meet quality objectives (6.3).

Section 7 of the standard focuses on the heart of the business: **product or service realization**. Planning of product realization means that the organization takes the time to determine appropriate quality objectives and requirements; processes, documents and resources; verification, validation, monitoring; and inspection activities (7.1). These activities might include verifying that a lab slip placed into a medical record has been filed accurately or verifying that the correct medical chart is pulled 99 percent of the time.

Some organizations have a **design and development function**, such as engineering firms that design new materials or structures, or a physician who designs a treatment plan for a particular patient (7.3). The design requirements typically are not required in the HIM arena unless the organization is developing a new method of creating or maintaining medical records. For example, an HIM specialist designing new software for an online medical record would need to meet the ISO 9001:2000 requirements for paragraph 7.3 through 7.3.7.

Where materials or services are purchased or subcontracted, the standard requires that **purchasing process requirements** be addressed (7.4). Subcontractors should be selected based on their ability to supply products or services in accordance with your organization's requirements. From a quality standpoint, this assumes that your suppliers were evaluated and selected based on their ability to deliver the correct product or service, at the right time, for the negotiated price while meeting the negotiated quality criteria as stipulated on contracts and purchase orders. This applies to all purchases of quality-critical supplies or services, such as shelving and storage unit suppliers, courier services, hard copy and computer archival service providers, transcription services, and other services.

The ISO 9001 standard addresses the core purpose and processes for which the organization exists through its attention to **production and service provision** (7.5). Working under controlled conditions to improve operational quality requires that staff have work instructions, suitable equipment, quality monitoring for accuracy of the work performed and a method for release, delivery, and post-delivery activities (7.5.1). HIM is a particularly interesting field because the department provides

both a product (creation of a medical record, be it in hard copy or online) and a service (storage, retrieval, and delivery of records to the requesting practitioner).

Identification and traceability is another quality-critical aspect in HIM (7.5.3). The standard requires that where appropriate, identification and traceability be obvious. In HIM, this standard applies to every item added to a record. Most healthcare facilities accomplish this using a patient name, birthdate, and a unique patient identification number assigned to every individual. This is intended to avoid obvious problems like lab results filed in the wrong patient's chart or tests performed on the wrong specimen.

The standard's attention to **preservation of product** has interesting applications for HIM (7.5.5). The standard requires that the product (in this case, the medical record itself) and its constituent parts be protected against damage and deterioration. Preservation includes identification, proper handling, packaging, storage, and protection.

Measurement, analysis, and improvement of the quality system are aimed at helping the organization demonstrate conformity to the requirements of its customers' requirements, conformity to the documented quality system, and to continually improve the effectiveness of the quality system (8.1). This is typically accomplished through appropriate statistical studies that demonstrate that measurable objectives are being met and that higher quality standards or more stringent objectives are self-imposed.

The **customer satisfaction** component of the standard is intended to encourage the department to obtain feedback from customers regarding their the organization's success at fulfilling their requirements (8.2.1). Departments are required to devise a method for obtaining customer feedback as well as use the data gleaned as part of the management review process.

According to the standard's **internal audit** requirement, the organization must use trained, independent internal auditors to monitor the success and compliance of the quality management system against the ISO 9001 standard and against the department's own documented procedures (8.2.2). This requirement urges organizations to monitor their own performance, because of their familiarity with operations, and not wait until the third-party auditors or surveyors visit the site. Third-party auditors provide the benefit of "outside" eyes and expertise, and they may see potential practice improvements simply because they are not entrenched in the day-to day-operations. But a strong, rigorous internal audit program is one of the best ways to maintain and improve quality in your operations.

Corrective and preventive action are intended to help the organization take practical, effective steps to improve non-conforming conditions (8.5.2, 8.5.3). Non-conforming conditions may be identified in numerous ways, including internal audits, customer complaints, and self-reporting by staff. Corrective and preventive actions as imposed by ISO 9001 requirements include taking steps to remedy the problem at its root cause, plus re-verifying that the action taken was indeed effective. This is similar to filing an incident report with the added requirement that you actually prove the action taken was successful.

A Standard for Business Success

One of the key components in successfully implementing the ISO 2001:2000 quality management system standard in the healthcare industry is adequate interpretation of the generic requirements. The standard has helped thousands of businesses and organizations improve efficiencies, effectiveness, and helped them better meet customer needs. When the standard is implemented within the spirit of continuous quality improvement and when senior executives promote and encourage the implementation of a quality management system, the ISO 9001:2000 standard amounts to smart business practice in any organization.

Notes

1. ISO registered companies in North America available at www.qualitydigest.com/html/iso9000.html.

2. "ISO 9000's Popularity Soars." *Quality Digest*, February 2001. Available at www.qualitydigest.com.

3. Reid, Dan. "Guidelines for Process Improvement in Health Care Organizations." Presented at "Assurance in the Health Care Sector," Dublin, Ireland, September 2000. Available at www.healthcare.org/ITAEAMeetingReport.htm.

Infinite Applications, Unique Results

ISO 9000 refers to a family of generic standards defining a quality management system applicable in any industry. The standards, authored by volunteer teams of quality experts worldwide, were originally published in 1987, revised in 1994, and revised again in 2000 by the International Organization for Standardization (ISO) in Switzerland. The standards were intended to bring consistency into managerial operations in the manufacturing arena, but the standards were soon applied in service-related industries as well. Today, more than 343,000 certificates have been issued worldwide.2

Documents carrying the ISO 9000 and ISO 9004 designations are advisory in nature and provide helpful guidelines for the selection, development, implementation, and use of the procedural standards (ISO 9001, 9002, or 9003). The ISO 9001:2000 iteration eliminates the ISO 9002 and 9003 certification options because the three documents are now bundled into one standard. More specific detail regarding the requirements of an ISO 9001 quality management system and interpretations for the healthcare and medical information arenas can be found in this article.

The ISO 9001:2000 standard is non-prescriptive and generic in its design. While there are more than 150 requirements that together constitute smart business practice, the standard itself does not specify how each requirement must be met. Recognizing that organizations and businesses are unique, the authors of ISO 9001:2000 indicate quality management issues that must be adopted, but leave it to each individual organization to specify how they will achieve compliance to the requirements.

Although many users consider the generic nature of the standard a strength, that attribute is also a source of criticism because the standard must be interpreted for each industry to which it is applied. Matters of interpretation have led to a worldwide effort to publish a guidance document specifically for the healthcare arena.3 This document is intended to assist healthcare professionals in building sound quality management systems for their organizations, but is not intended to replace existing industry specific accreditation schemes, such as the Joint Commission, AAAHC, NCQA, or those of other agencies. Similar guidance documents were published and subsequently replaced the ISO 9001 standard in other industries. For example, QS 9000 is the automotive equivalent of ISO 9001 with additional requirements specified by the automotive "Big 3": Ford, Chrysler, and GM. Similarly, AS 9000 was developed by General Electric for use in the aerospace industry.

Copies of the ISO 9000 series of standards may be purchased from the American Society for Quality in Milwaukee, WI, by calling (800) 248-1946 or online at www.asq.org. The standard is available in both hard copy and in downloadable format.

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