ISO 9000:2000 – A Primer

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Introduction

The regularly scheduled update of the ISO 9000 international quality management standard was completed at the end of the year 2000 and approved by the international member countries for publication and distribution. The revisions have made the standard easier to read and understand and compare better to the NCCLS quality system essentials. (see the table).

To lead and operate any organization successfully, it is necessary to direct and control it in a systematic and transparent manner. This quality system model is designed to implement and maintain a management system to continually improve performance and respond to the needs of internal and external customers.

The FDA said in the 1987 Guideline on Process Validation that "Quality, safety, and effectiveness must be designed and built into the product." The same quote is true of the services we provide in laboratory medicine. The quality system model allows us to build quality into every management and operations activity in the laboratory so that our patient, physician and employee customers are assured of the best quality and safest laboratory results possible.

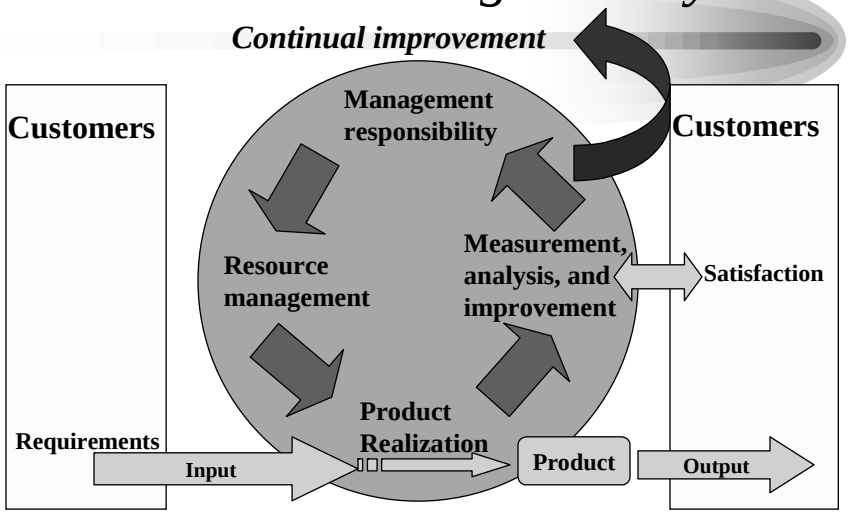
Process-based Quality Management

The ISO-9000:2000 quality management system is now a process-based model. (see figure below). In the ISO model, process flow (at the bottom of the figure) is described as "Input →Product Realization→Product (or Service)." In the laboratory environment, our process flows from an input of the order for a laboratory test or service through the processes of specimen collection, transport, receipt and testing, the final output of reporting results, archiving specimens, and , consultation about any test results. This is equivalent to NCCLS QSE: Process Control.

The circle in the center of the figure represents the role of the quality system in the process model. Quality starts at the top of the circle with management responsibility to authorize, maintain, and support the quality system (equivalent to NCCLS QSE: Organization). Management maintains and supports the quality system through allocation and management of human and material resources so that production processes can take place and goals can be met (equivalent to NCCLS QSEs: Facilities and Safety, Personnel, Equipment, and Purchasing and Inventory).

Through measurement and analysis, management becomes aware of areas in operations and the quality system that need improvement. Savvy management will responsibly allocate the necessary human and material resources to ensure that quality problems are resolved so that quality and customer satisfaction can be improved. This is equivalent to NCCLS QSEs: Occurrence Management, Assessments, and Process Improvement.

Process-based quality management system



ISO 9000:2000 Documents
The ISO 9000:2000 family of documents contains 3 booklets, available from the American Society for Quality, www.asq.org.

ISO 9000:2000 Fundamentals and Vocabulary
The fundamentals booklet is required reading to understand the terminology used in the remainder of the documents. The standard is based on eight (8) quality management principles that set the stage for the process model approach. The important role of top management is reviewed and clarified, as is the role of (policy, process, and procedure) documents in the quality system. Finally the importance of evaluating the quality system is discussed.

ISO 9000:2000 Quality management systems—Requirements
This booklet is the actual standard and the source of the clauses presented in Table 1. The requirements are much easier to read than the previous version and one can see direct correlation to many of the requirements in the NCCLS quality system model.

ISO 9000:2000 Quality management systems—Guidelines for performance improvements
Whereas the above booklet is the actual standard, this document provides further explanation of the standards and guidance for how to effectively implement them. This document could be thought of as similar to the NCCLS guidelines that provide examples of implementation of the QSEs and laboratory path of workflow.

Making the Leap
It is a short leap from a fully developed NCCLS quality system to the new ISO 9000 standard. Facilities should read the ISO standard with the understanding that the laboratory environment is headed in that direction because quality and safety must be built into laboratory practice!

Comparison of NCCLS Quality System Essentials to ISO 9001:2000

NCCLS Quality System Essentials[1]	**ISO 9001:2000**[2]
Organization	4.1 General requirements 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, communication 5.6 Management review 5.7 Provision of resources
Personnel	6.2 Human resources
Equipment	7.6 Control of measuring and monitoring devices
Purchasing and Inventory	7.4 Purchasing
Process Control	7.1 Planning of product realization 7.2 Customer-related processes 7.3 Design and development 7.5 Production and service provision
Documents and Records	4.2 Documentation requirements
Information Management	
Occurrence Management	8.3 Control of nonconforming product
Assessments-Internal and External	8.1 General 8.2 Monitoring and measurement 8.4 Analysis of data
Process Improvement	8.5 Improvement
Customer Service	5.2 Customer focus
Facilities and Safety	6.3 Infrastructure 6.4 Work environment

Source:

1. NCCLS. A quality system model for health care; Approved guideline HS1-A. Wayne, PA: NCCLS, 2002.

2. ISO 9001:2000. Quality management systems—Requirements. Milwaukee, Wi: American Society for Quality Press, 2000.