

## INTRODUCTION

**The Challenge** — The complexity of today’s healthcare environment reinforces the need for an infrastructure that provides the highest levels of quality and patient safety. Quality cannot be taken for granted, especially in the laboratory; yet many of the world’s healthcare organizations are operating without well-defined or even documented policies, processes, and procedures.

**Our Solution** — *The Key to Quality*

CLSI has identified 12 Quality System Essentials (QSEs), which are the fundamental components used to establish any quality management system. Using this workbook, *The Key to Quality*, any healthcare service provider can develop a well-defined path of workflow, from preimplementation through postimplementation and all of the operations between. Figure 1 provides a listing of the 12 QSEs, which are *The Key to Quality*, and illustrates how they are applied across the entire path of workflow.

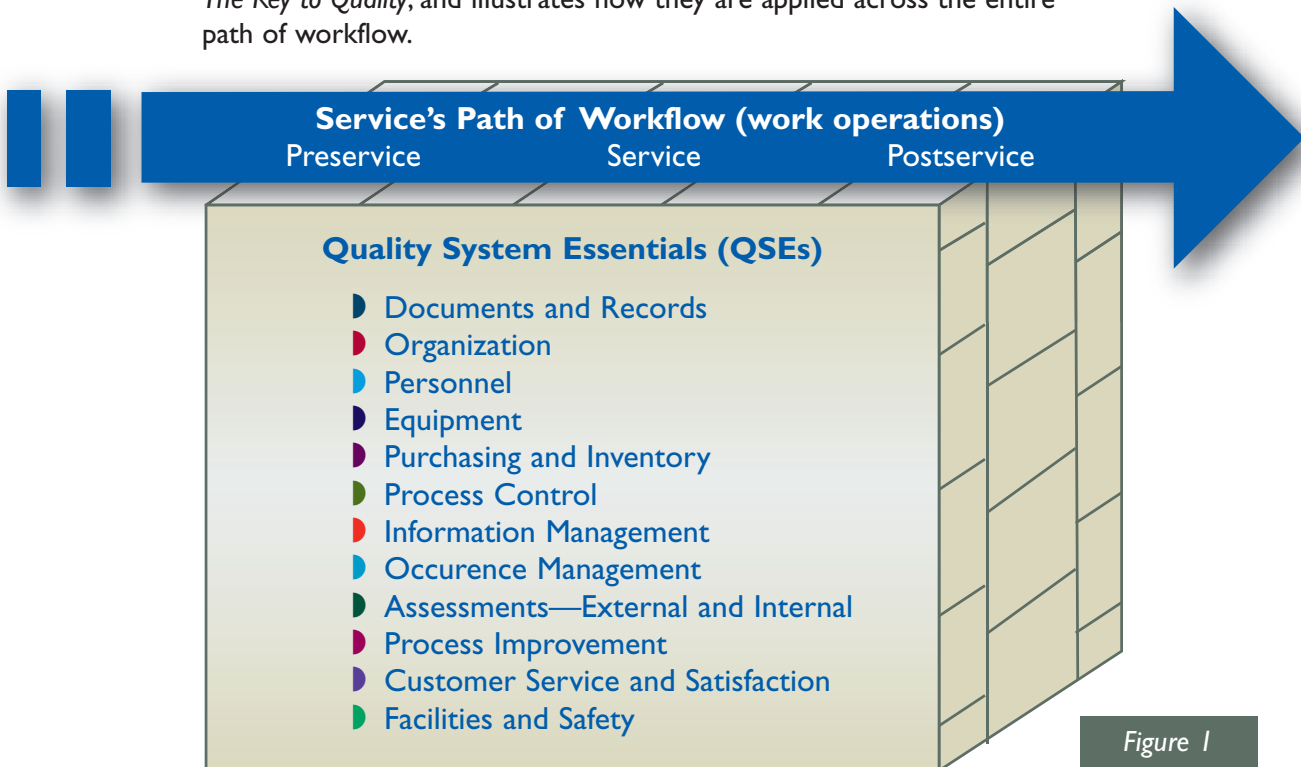


Figure 1

The QSEs are universal and can be applied to any operations, whether simple or complex. They can be used regardless of where you reside on the quality spectrum — establishing, enhancing, or maintaining your policies, processes, and procedures. The 12 QSEs do not have to be implemented sequentially or in any particular order. In fact, you may even decide to implement some actions immediately and others at a later date.

**International Application** — The guidelines in this workbook are closely aligned with International Organization for Standardization (ISO) quality management standards. ISO 9001 defines a process model for quality that any business should use to manage its operations, while ISO 15189 defines standards for quality management in the medical laboratory. The ISO standards are written in very broad terms; *The Key to Quality* provides details and “how to” guidelines for implementation. While the examples included in the portfolio are not all-inclusive, they do provide a representative cross-section. Additional examples are available on the CD-ROM that is included with the workbook. The checklists at the end of each section of *The Key to Quality* represent an “ideal quality” state. All of the requirements of ISO 15189 are included in the checklists.

**The Benefits** — Using the guidelines and tools in this workbook, you can establish the infrastructure for a quality management system or a methodology for continuous quality improvement with the following outcomes:

- streamline laboratory processes;
- enhance employee potential;
- meet accreditation requirements;
- reduce risk of medical errors;
- improve patient care;
- increase productivity and efficiency; and
- reduce costs.

Before you begin, we suggest that you take a few minutes to review our Getting Started Guide, which follows.

As you use this binder, please refer to the source documents cited throughout for more detailed information.

**The Key to Quality CD-ROM:** Included on the CD-ROM is a site map for easy navigation. Basically, the CD includes a PowerPoint introduction to quality management; all of the policy, process, and procedure examples from the workbook; and additional examples not included via paper.

- PowerPoint introduction to Quality Management — The presentation is written so that managers can use it with employees to introduce the CLSI concept of quality management and how *The Key to Quality* can assist them with implementing or enhancing their programs. It includes speaker notes with additional background information to assist the presenter. It's important that you use this presentation with personnel before embarking on making changes. In general, people become comfortable with a certain routine and are often intimidated by change.
- Examples from *The Key to Quality* workbook for each of the 12 QSEs
- Additional examples, checklists, templates, and tools not included in the printed materials in *The Key to Quality*

### Moving Forward

After you have had an opportunity to review the contents in this workbook, the following might represent a logical path of next steps:

1. Using *The Key to Quality* checklists, perform a gap analysis.
  - a. What do you have?
  - b. What do you need?
  - c. What is missing?
2. Fill in the gaps — Develop/improve policies, processes, and procedures.
3. Evaluate your system routinely — Identify opportunities for continuous quality improvement.

# INTRODUCTION

## QSE: Equipment

This QSE refers to general and service-specific equipment, instruments, and analytical systems, and includes computer system hardware and software. The organization or service needs to be provided with all items of equipment required for the provision of its services. Any additional regulations and accreditation requirements for specific healthcare services are to be followed.

The major requirements for QSE: Equipment are summarized below.

### Policy

*State intent and direction for:*

- selection;
- acquisition;
- installation qualification;
- identification;
- validation or verification;
- calibration program;
- maintenance program;
- service and repair; and
- equipment files and records.

### Processes

*Describe activities that transform the intent into action.*

- Establish an organizational mechanism to determine criteria and methods for:
  - ◆ acquisition or replacement;
  - ◆ installation;
  - ◆ identification;
  - ◆ calibration;
  - ◆ maintenance;
  - ◆ operation;
  - ◆ inspection; and
  - ◆ troubleshooting, service, and repair of all equipment, including computer hardware and software.
- Develop a means to uniquely identify equipment, its status of calibration, and due date.
- Develop a mechanism for validating before use that new equipment performs in the facility as intended (see examples, pages 3 to 9, 10 to 14, and 15 to 20).
- Develop a means to remove defective (or suspected) equipment from service and determine the effect of defect on previous service.
- Develop a means to reverify proper equipment performance before returning it to service.
- Develop criteria and a mechanism for retiring outmoded or obsolete equipment.
- Maintain records of above items for each piece of equipment that contributes to quality.

### Procedures and Forms/Records

*Document instructions for:*

- using (operating) the equipment;
- performing routine calibrations and calibration verifications;
- maintaining, inspecting, troubleshooting, servicing, and repairing equipment per manufacturer's instructions (see examples, pages 21 to 23);
- decontaminating equipment before repair or decommission; and
- maintaining computer software.

## REPRESENTATIVE EXAMPLES

These examples, although not all-inclusive, represent policies, processes, and procedures and forms/records that can be used in developing your quality management system. The first group of representative examples is provided within this tabbed section; all examples listed herein can be accessed on the accompanying CD-ROM.



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### Examples on CD-ROM

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Processes: Demonstration of Trueness With Comparison of Patient Samples Sample Data Recording Sheet—Trueness Experiment With Reference Materials Example of a Completed Sample Data Recording Sheet—Trueness Experiment With Reference Materials	
Procedures and Forms/Records: Instrument History Record	
Procedures and Forms/Records: Instrument In-Use Record	
Procedures and Forms/Records: Sample Preventive Maintenance Record Form	



## QSE: Occurrence Management Self-Assessment Checklist

### CHECKLIST

Checklist Element	YES	NO
A policy and procedures for the resolution of customer complaints (including those of clinicians and patients) have been developed, and are implemented appropriately.	<input type="checkbox"/>	<input type="checkbox"/>
Records of complaints, investigations, and corrective actions taken by the laboratory are maintained.	<input type="checkbox"/>	<input type="checkbox"/>
A policy and procedures to be implemented upon detection of nonconformance with established laboratory testing procedures or within the requirements of the quality management system have been developed. The policy and procedures: <ul style="list-style-type: none"> <li>• designate the responsible party;</li> <li>• define actions to be taken in the event of a nonconformance;</li> <li>• consider the medical/clinical significance of the nonconformance and, when applicable, outline provision for informing the requesting clinician;</li> <li>• set guidelines for discontinuation of testing and results reporting as necessary;</li> <li>• ensure corrective action is taken immediately;</li> <li>• set guidelines for recall of already released test results;</li> <li>• assign responsibility for authorizing resumption of testing and results reporting;</li> <li>• ensure documentation and recording of nonconformance; and</li> <li>• outline the cycle of review of documented nonconformances to detect trends and to initiate preventive action.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
Procedures to identify, document, and eliminate the root cause(s) of nonconforming events are properly implemented.	<input type="checkbox"/>	<input type="checkbox"/>
Procedures have been defined and implemented for the review and release of laboratory results in the case of nonconforming events.	<input type="checkbox"/>	<input type="checkbox"/>
All nonconforming events are recorded.	<input type="checkbox"/>	<input type="checkbox"/>
Corrective action procedures outline an investigative process to determine the root cause(s) of problems and, where appropriate, lead to preventive actions.	<input type="checkbox"/>	<input type="checkbox"/>
Corrective actions are appropriate to the magnitude of the problem and commensurate with the risks encountered.	<input type="checkbox"/>	<input type="checkbox"/>
Operational procedure changes resulting from corrective action investigations are documented and implemented.	<input type="checkbox"/>	<input type="checkbox"/>
Results of any corrective action are monitored to ensure that they have been effective in overcoming the identified problems.	<input type="checkbox"/>	<input type="checkbox"/>
When the identification of nonconformance or the corrective action investigation casts doubt on compliance with policies and procedures or the quality management system, laboratory management ensures that appropriate areas of activity are audited.	<input type="checkbox"/>	<input type="checkbox"/>
Corrective action results are reviewed by laboratory management in accord with the established review cycle.	<input type="checkbox"/>	<input type="checkbox"/>