Program Objectives

- Following the program, you will be able to:
  - Explain the logic behind the reordering of the quality system essentials (QSEs).
  - List the major sources of QSE requirements.
  - Describe the major additions and changes to the QSEs.
  - Start implementing a QSE-based quality management system OR describe a transition plan for your laboratory’s existing QSE-based quality program.

Audience Response

Does your laboratory currently have a Quality Management System (QMS) based on the CLSI Quality System Essentials?

1. YES
2. NO
What’s New About GP26?

- Combination of HS01 and GP26-A3
- Logical reordering of QSEs
- Revision of QSE Model figure
- Sources of QSE requirements
- Additions and changes to QSE requirements
- Transition from existing QSE-based QMS

GP26-A (1999) - A Novel Approach!

- Adapted from AABB.
- Sorting of requirements into QSEs
- Model showing QSEs supporting the laboratory’s path of workflow (PoW).
- Introduction of document hierarchy
  - Policy, process, procedure, form
- Concept of laboratory as a model for other health care services

HS01 and GP26; 2002, 2006

- HS01 has QSEs only, which apply to any health care service.
- GP26 only contains the laboratory path of workflow.
- Additional guidelines exist for service-specific paths of workflow
  - Respiratory care
  - Medication use
  - Diagnostic imaging

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GP26-A4 Same QSEs, Different Perspective

GP26-A4 (2011): Reordered QSEs

- Organization
- Customer Focus
- Facilities and Safety
- Personnel
- Purchasing and Inventory
- Equipment
- Process Management
- Documents and Records
- Information Management
- Nonconforming Event Management
- Assessments
- Continual Improvement

A Quality Management System for the Laboratory

Laboratory Path of Workflow

Preexamination
Examination
Postexamination

The Laboratory
The Work
Measurement

Quality System Essentials: The Building Blocks

Organization
Customer Focus
Facilities and Safety
Personnel
Purchasing and Inventory
Equipment
Process Management
Documents and Records
Information Management
Nonconformance Mgmt
Assessments
Continual Improvement

2011 CLSI QMS Model for Laboratories

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ML20 Change "Nonconformance Mgmt" to "Nonconforming Event Management."
Megan Larrisey, 9/16/2011
Sources of QSE Requirements

- ISO 15189:2007
- ISO 17025:2005
- ISO 9001:2008
- CLIA ’88 with 2003 revisions
- 21 CFR 211, GMP
- 21 CFR 606, BB GMP
- 21 CFR 58, GLP

Additional requirements:
- Biological requirements
  - Safety
  - Hazardous waste
  - Transport
- The Joint Commission Laboratory Standards
- CAP Checklists
- AABB Standards
- COLA Accreditation Manual
- OLA Accreditation Program

What’s New About GP26-A4?

- Combines HS01 and GP26-A3
- Logical reordering of QSEs
- Addition of new QSEs
- Additions and changes to QSE requirements
- Transition from existing QSE-based QMS

Audience Response

According to what you know today about GP26:

1. My existing QMS will need major revisions
2. My existing QMS will need moderate revisions
3. My existing QMS will need minimal revisions
4. My existing QMS is not based on a QSE model
5. I do not have a QMS yet
Additions and Changes to QSEs

GENERAL
• More information on the processes and procedures necessary to achieve an effective QMS
  • Improved and reorganized to clarify policies, processes, and procedures
  • Policies vs action items (processes and procedures)

ORGANIZATION
• Emphasis on criticality of this QSE
• Strengthened
  – Leadership commitment
  – Effective implementation
  – Communication
• More information on quality planning

CUSTOMER FOCUS
• Laboratory’s capability to meet customer expectations

• Terminology
  – “Needs to” vs “should/could” is recommended throughout all CLSI QMS documents
• Updates for any new or changed requirements:
  International, national, accreditation
• Expanded explanations and examples
### Additions and Changes to QSEs

#### FACILITIES AND SAFETY
- Greatly expanded explanations
- Emergency management
  - Preparing for, response to, mitigation of, recovery from

#### PERSONNEL
- Similar to previous edition

#### PURCHASING AND INVENTORY
- Similar to previous edition

#### EQUIPMENT
- Expanded information on equipment qualification
  - Selection qualification, installation qualification, operational qualification, performance qualification

#### PROCESS MANAGEMENT
- Expanded validation and verification
- Introduced measurement uncertainty
- Expanded change management

#### DOCUMENTS AND RECORDS
- Similar to previous edition

#### INFORMATION MANAGEMENT
- Enhanced planning for information needs
- Enhanced confidentiality of information

#### NONCONFORMING EVENT MANAGEMENT
- Defined NCE management as a program
- Introduced recall of laboratory’s own products and services
- Enhanced classification, analysis, and trending
Additions and Changes to QSEs

ASSESSMENTS
• Added section on blood utilization
• External quality assessment to proficiency testing
• Benchmarking (performance comparisons) from external to internal assessments

CONTINUAL IMPROVEMENT
• QSE reorganized
• Added section on participation of quality improvement at organization level
• Added use of a defined strategy for CI

Additions and Changes to Appendixes

• Comparison of QSEs to ISO
  – Added ISO 17025, “General requirements for the competence of testing and calibration laboratories.”

• Validation examples
  – Greatly enhanced validation protocol example
  – Added example for process validation
  – Added example for examination validation
  – Added example of software validation worksheet

Additions and Changes to Appendixes

• Expanded record retention schedule form
• Updated nonconforming event report form
• Greatly expanded list of published quality indicators
• Added audit report form

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### Transition From Existing QSE-Based QMS

**PROCESS FOR TRANSITION**
- **Familiarize yourself with GP26.**
- **Identify new concepts/missing components from your QMS.**
- **Determine requirement vs recommendation.**
- **Do you want to make change?**
  - Benefit to patients, staff, and others
  - Easy to add into existing policy, process, or procedure documents or other documents to be developed

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### Transition From Existing QSE-Based QMS

**PROCESS FOR TRANSITION**
- **Prioritize.**
  - Areas in which laboratory has previously struggled
  - Nonconforming events, customer complaints, inspection findings
  - Benefits to patients, staff, and other customers
  - Complexity and resources
- **Develop plans for these improvements.**
  - Identify best fit in your QMS.

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### Transition From Existing QSE-Based QMS

**EXAMPLE: QSE EQUIPMENT**
- **Acquisition and selection**
- **Impact on environment, future disposal**
- **Physical requirements:**
  - Load-bearing, space, electrical, ventilation, air, humidity, temperature, water
- **Hazards**
- **Organizational mechanism to determine criteria**

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Transition From Existing QSE-Based QMS

**EXAMPLE: QSE EQUIPMENT**

- Selection qualification process
  - Functional specifications
  - Facility, environmental, engineering requirements
  - Comparison of laboratory’s needs to supplier’s functional specifications, capabilities, and requirements
  - Assessing and comparing alternatives
  - Documentation of specifications, requirements, comparisons, decisions, justifications, follow-up actions

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Transition From Existing QSE-Based QMS

**EXAMPLE: COMMUNICATION**

- **Organization**
  - Policies, processes, procedures
  - Quality principles
- **Facilities and Safety**
  - Communication system for size and complexity of organization
  - Efficient transfer of messages
- **Information Management**
  - Commitment to confidentiality and privacy
- **Personnel**
  - Staff concerns

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Transition From Existing QSE-Based QMS

**EXAMPLE: COMMUNICATION**

- Organization
  - Quality policy, commitment to quality
  - Quality goals and objectives
  - Strategic plan
  - Compliance with international, national, local, and organizational requirements
  - Outcome of management review, eg, effectiveness checks and process improvements

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Transition From Existing QSE-Based QMS

**DOCUMENT MANAGEMENT**
- No change
- Develop crosswalk
- Renumber

Transition From Existing QSE-Based QMS

1. Documents and Records
2. Organization
3. Personnel
4. Equipment
5. Purchasing and Inventory
6. Process Control
7. Information Management
8. Occurrence Management
9. Assessments-Ext./Int.
10. Process Improvement
11. Customer Service
12. Facilities and Safety
13. Organization
14. Customer Focus
15. Facilities and Safety
16. Personnel
17. Equipment
18. Purchasing and Inventory
19. Process Management
20. Information Management
21. Nonconforming Event Mgmt
22. Assessments
23. Continual Improvement

Audience Response

According to what you know today about GP26:
1. There is no change in my previous answer regarding the amount of revision necessary.
2. My existing QMS needs more revision than I previously thought.
3. My existing QMS needs less revision than I previously thought.
4. My existing QMS is not based on a QSE model.
5. I do not have a QMS yet.
GP26-A4: Same Quality System Essentials, Different Perspective

Questions and Answers