Training and Competence Assessment — The Building Blocks

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Faculty Disclosure

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“Nothing to disclose”
Objectives

At the conclusion of this program, participants will be able to:

• List the difference between education and training.
• Describe when employees are to be trained and when their competence is to be assessed.
• Name the four stages of the training process as described in CLSI document GP21, and explain the key activities related to each stage.
• Describe the types of training records that are required and what needs to be considered to manage the records.
What Are the Building Blocks?

• A laboratory quality management system (QMS)
  – Defined and documented processes and procedures for training and competence assessment
  – Defined and documented process for managing records
• Documented laboratory workflow processes and procedures
• A basic understanding of training and competence assessment methodology
• An understanding of the requirements
CLSI Quality Management System

**DISCIPLINES**
- Chemistry
- Hematology
- Microbiology
- Transfusion Medicine
- Anatomic Pathology
- Cytology
- Immunology
- Genetics, etc.

**LABORATORY PATH OF WORKFLOW**

- **PREEXAMINATION**
  - Order
  - Sample Collection
  - Sample Transport
  - Receive and Process

- **EXAMINATION**
  - Examination
  - Review and Interpretation

- **POST EXAMINATION**
  - Report Release
  - Sample Management

**QUALITY SYSTEM ESSENTIALS**

- Assessments
- Quality Improvement
- Continual Improvement

- Documents and Records
- Information Management
- Nonconforming Event Management

- Personnel
- Purchasing and Inventory
- Equipment
- Process Management

- Organization
- Customer Focus
- Facilities and Safety

**International • National • Regional • Local • Organizational Requirements**
CLSI Quality Management System (cont’d)

Laboratory Path of Workflow

Preexamination (Preanalytical)  Examination (Analytical)  Postexamination (Postanalytical)
CLSI Quality Management System (cont’d)

Laboratory Path of Workflow

Preexamination (Preanalytical)  Examination (Analytical)  Postexamination (Postanalytical)

Quality System Essentials (QSEs): The Building Blocks

The Laboratory

Organization  Customer Focus  Facilities and Safety  Personnel  Purchasing and Inventory  Equipment
Clinical Laboratory Standards Institute (CLSI) Quality Management System (cont’d)

Laboratory Path of Workflow

Preexamination (Preanalytical) → Examination (Analytical) → Postexamination (Postanalytical)

Quality System Essentials (QSEs): The Building Blocks

The Laboratory
- Organization
- Customer Focus
- Facilities and Safety
- Personnel
- Purchasing and Inventory
- Equipment

The Work
- Process Management
- Documents and Records
- Information Management
CLSI Quality Management System (cont’d)

Laboratory Path of Workflow

Preexamination (Preanalytical)  Examination (Analytical)  Postexamination (Postanalytical)

Quality System Essentials (QSEs): The Building Blocks

The Laboratory
Organization  Customer Focus  Facilities and Safety  Personnel  Purchasing and Inventory  Equipment

The Work
Process Management  Documents and Records  Information Management

The Performance
Nonconforming Event Management  Assessments  Continual Improvement
Quality System Essential Personnel

- Job qualifications
- Orientation of new personnel to organization
- Training and assessment of competence
- Continuing education and professional development
- Performance evaluation
- Personnel files
Training and Assessment of Competence

“We do not rise to the height of our expectations. We fall to the level of our training.”

– Archilochus, Greek soldier and poet, c. 650 BC
### Education and Training — Differences

<table>
<thead>
<tr>
<th>Education in an Academic Setting</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus is on the learner’s future job</td>
<td>Focus is on the learner’s present job</td>
</tr>
<tr>
<td>Awareness of a skill</td>
<td>Demonstration of a skill</td>
</tr>
<tr>
<td>Assessment through tests of knowledge</td>
<td>Assessment through evaluation of performance or outcomes</td>
</tr>
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</table>
## Training — Different Types

<table>
<thead>
<tr>
<th>Professional Training</th>
<th>Employment Training</th>
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<tbody>
<tr>
<td>Conducted as part of study combined with academic material in a setting similar to the work environment</td>
<td>Conducted in the work environment as part of responsibilities and requirements for the job position</td>
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</tbody>
</table>
Procedural-based Training

Sequence of Events

- Process Flowcharts
- Procedures
- Training
- Competence Assessment
Employment Training — More Than Job Tasks

Complete Laboratory Training Curriculum Example

- Work processes and procedures, 60%
- Quality, 20%
- Culture, 5%
- Safety, 5%
- Computer, 10%
# When Is Training Required?

<table>
<thead>
<tr>
<th>Category</th>
<th>Training Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>New employee</td>
<td>Initial employment training</td>
</tr>
<tr>
<td>Existing employee; new task</td>
<td>Comparable to new employee training</td>
</tr>
<tr>
<td>Something new to laboratory</td>
<td>Change in organization, technology, methodology, supplies, customer requirements, etc.</td>
</tr>
<tr>
<td>A newly identified need</td>
<td>Repeated performance problems, problem-prone procedure, customer feedback, etc.</td>
</tr>
</tbody>
</table>
# When Is Competency Assessment Required?

| New Employee                  | • During and/or at end of initial employment training  
<table>
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<tr>
<th></th>
<th>• At six months following initial training</th>
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</table>
| Existing Employee            | • When there are new or changed processes/procedures  
|                              | • Periodically (CLIA requires every 12 months)       |

Abbreviation: CLIA, Clinical Laboratory Improvement Amendments.
**Four-Stage Training Process**

<table>
<thead>
<tr>
<th></th>
<th>Training needs are identified.</th>
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<tbody>
<tr>
<td>2</td>
<td>Training guides are developed and packets prepared.</td>
</tr>
<tr>
<td>3</td>
<td>Training is conducted.</td>
</tr>
<tr>
<td>4</td>
<td>Training outcomes are evaluated.</td>
</tr>
</tbody>
</table>
Four-Stage Training Process – Stage 1

| Training needs are identified. | Identify training needs, including:
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<tbody>
<tr>
<td></td>
<td>• Work processes performed in a given job</td>
</tr>
<tr>
<td></td>
<td>• Procedures performed in each work process</td>
</tr>
<tr>
<td></td>
<td>• Expectations (e.g., rules) that apply to work processes and procedures</td>
</tr>
</tbody>
</table>
| Training guides are developed and packets prepared. | A training guide consists of the following elements:  
• Objectives for training  
• Identification of the methods used in training  
• Identification of the materials used in training  
• Criteria to assess the effectiveness of training |
### Four-Stage Training Process – Stage 2 (cont’d)

#### Contents of a Typical Training Guide Packet

<table>
<thead>
<tr>
<th>Contents</th>
</tr>
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<tbody>
<tr>
<td>Completed training guide</td>
</tr>
<tr>
<td>Instructions for the trainer</td>
</tr>
<tr>
<td>Instructions for the learner</td>
</tr>
<tr>
<td>Training schedule</td>
</tr>
<tr>
<td>Related material</td>
</tr>
<tr>
<td>Training checklist</td>
</tr>
<tr>
<td>Direct observation checklist</td>
</tr>
<tr>
<td>Written quiz or test</td>
</tr>
<tr>
<td>Learner evaluation form</td>
</tr>
</tbody>
</table>
Four-Stage Training Process – Stage 3

Training is conducted.

- Trainers are engaged.
- Training is underway.
Four-Stage Training Process – Stage 4

| Training outcomes are evaluated. | • Training effectiveness is evaluated.  
|                                 |   – Initial competence assessment (Did the employee learn the material and acquire the skill?)  
|                                 |   – Periodic competence assessment (Was the knowledge and skill transferred to the workplace?)  
|                                 | • Learner’s experience is evaluated.  
|                                 |   -What was the impact of the training experience? |
Ongoing/Periodic Competence Assessment

493.1413(b)(8)(9) and 493.1451(b)(8)(9)—(CLIA)

• **Technical Consultant/Supervisor Responsibilities:**
  – *Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently.*
• Requirement: annual (at a minimum) assessment of competence of all employees (College of American Pathologists)

• Include preexamination (preanalytical), examination (analytical), and postexamination (postanalytical) activities in the laboratory’s path of workflow.
  – Including aspects of quality management activities to which employees are assigned is good laboratory practice

• If an employee fails to demonstrate satisfactory performance on the competency assessment, a plan of corrective action is required to reassess the employee’s competency.
Six Elements

• Direct observation of routine work processes and procedures related to testing of patient samples
• Direct observation of equipment maintenance and function checks
• Monitoring the recording and reporting of results
• Reviewing intermediate test results or worksheets, quality control records, proficiency testing (PT) results, and preventive maintenance records
• Assessment of problem-solving skills
• Performance of a given procedure using specially provided materials (e.g., previously analyzed samples)
Benefits of an Annual Competency Assessment Plan

- Can incorporate anticipated changes in technology or work processes
- Enables achievement of customer service or performance improvement goals
- Provides a comprehensive and balanced set of assessments across the Laboratory’s entire path of workflow
- Enables planning by providing notice on the amount of time needed for creating or compiling the competence assessment materials
- Engages employees by seeking their input
- Provides the laboratory medical director a complete view of the coming year’s competence assessment activities
Ongoing/Periodic Competence Assessment (cont’d)

**Tips**

- Training and competence assessment before testing is critical and required.
- Competency assessments must be documented.
- Individual conducting competency assessments must be qualified.
- Competency is not PT. PT can be used to meet some elements of competency, but not all.
- All elements do not have to be completed at once, but can be combined.
- Analytes can often be combined on multichannel analyzers.
- Competency records should match the laboratory’s actual procedures performed by its personnel.
# Training and Competency Assessment Records

<table>
<thead>
<tr>
<th>Training Type</th>
<th>Records</th>
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</table>
| **Individual Training**       | • Training checklist(s) of processes and procedures on which the employee was trained that includes names of all trainers  
• Related training material                                      |
| **Group Training**            | • In-service Acknowledgement Forms, with employee signatures |
| **Competence Assessment**     | • Annual Competence Assessment Plan (if applicable)  
• Written assessments test(s)  
• Performance of a given procedure using specially provided materials  
• Direct observation checklists completed by the observer  
• Plans of corrective action for failures to demonstrate competency and reassessments |
Considerations

- Type of record system (paper or electronic)
- Periodic review of records – process needed
- Record retention
  - Duration
  - Storage medium
  - Access
  - Destruction
Summary

• Unique programs: each laboratory should design its training and competence assessment programs with its own “building blocks” based on:
  – Requirements (organizational, regulatory, accreditation)
  – QMS
  – Path of workflow processes and procedures
  – Composition of staff

• Common program goals:
  – New employees are able to perform their duties correctly before performing them independently.
  – All employees can properly execute new processes and procedures, and continue to perform at an acceptable level.
A laboratory’s best assurance of contributing to patient safety is developing and sustaining a staff with:

- A clear understanding of the sequence of work activities
- The instructions for completing the activities at the right time and in the right way
- The ability to put their understanding and instructions into practice when presented with typical and atypical situations

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Thank You

It's QUESTION TIME!!