


Staff Competence: A Matter of Assessment

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Updated CLSI Guideline



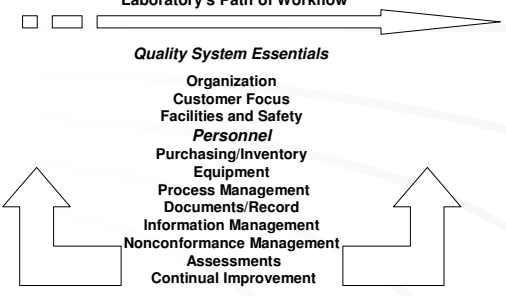
GP21-A3: Training and Competence Assessment

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Quality System Model

Laboratory's Path of Workflow

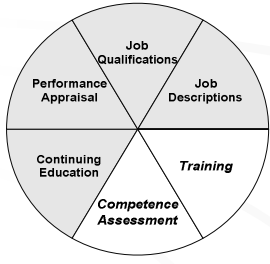


Quality System Essentials
Organization
Customer Focus
Facilities and Safety
Personnel
Purchasing/Inventory
Equipment
Process Management
Documents/Record
Information Management
Nonconformance Management
Assessments
Continual Improvement

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QSE: Personnel



Job Qualifications
Job Descriptions
Training
Competence Assessment
Continuing Education
Performance Appraisal

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Who Says So??



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Who Says So? 1.

- Regulatory agencies - the power of law
 - U.S. Centers for Medicare Services (CLIA '88)
 - State Departments of Health



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Who Says So? 2.

- Accreditation organizations
 - JCAHO
 - AABB
 - CAP
 - COLA
 - OLA
- Certification Organizations
 - ISO (International Organization for Standardization)



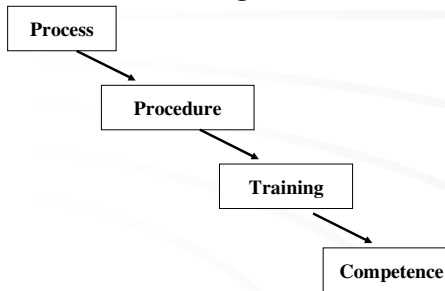
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Knowledge vs Competence

Sequence	Manifested by	Evaluated by
Education	Knowing it	Written/oral assessments
Training	Knowing how it's done	Competence assessment
Practice	Showing how it's done	Performance
Experience	Doing it	Actions
Competence	Correctness and completeness of actions	Written/oral assessments and observations

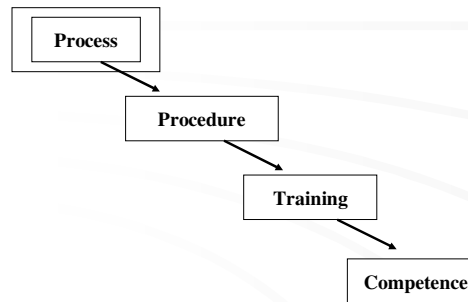
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Ideal Progression



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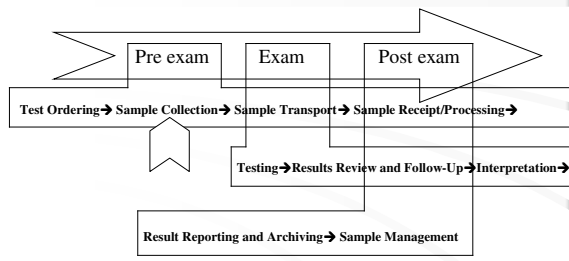
Ideal Progression



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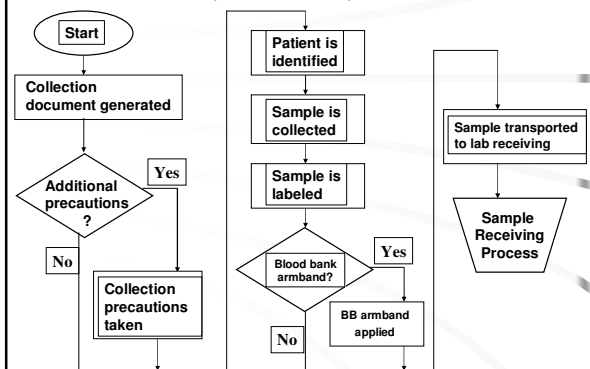
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Laboratory Path of Workflow

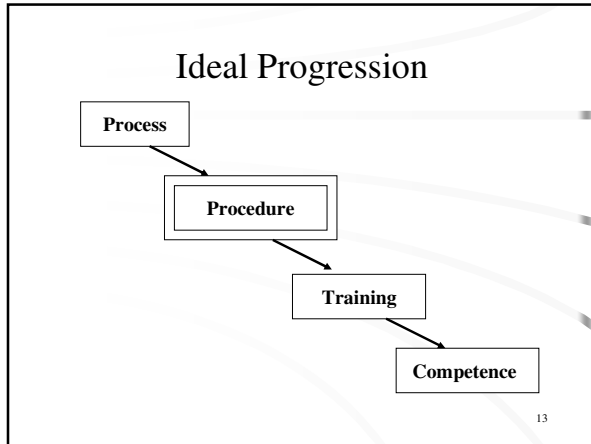


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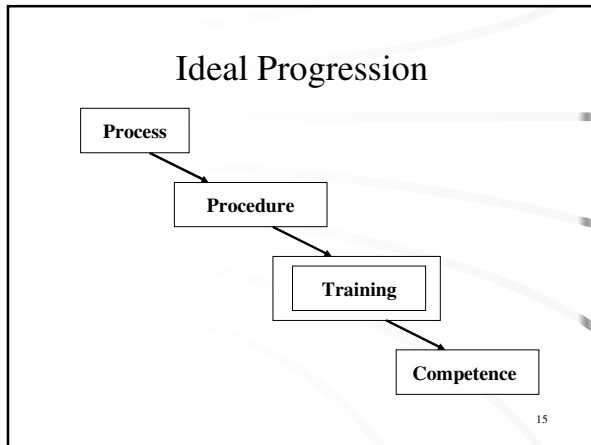
Example: Blood Sample Collection Process



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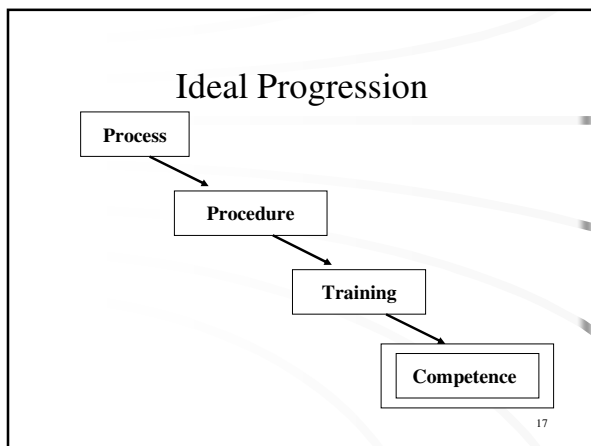
- ### Procedures for Blood Sample Collection Process
- Generating Sample Collection Documents From the LIS
 - Blood Sample Collection Procedure
 - Venipuncture
 - Capillary Puncture
 - Sample Collection Precautions Procedure
 - Sample Labeling Procedure
 - Blood Bank Armband Procedure
 - Patient Identification Procedure
 - Sample Transport Procedure
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Train to the process and the procedures!

CLSI guideline GP21-A3


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- ### D. Outcomes Evaluation*
- 1) Did the learner like the training experience?
 - 2) Did the learner learn the material?
 - 3) Were the skills learned transferred to the workplace?
 - 4) How was transfer of skills to the workplace measured?
- *Kirkpatrick's levels of evaluation
-
- 18

D. Outcomes Evaluation*

- 1) Did the learner like the training experience?
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*Kirkpatrick's levels of evaluation

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D.2

Did the learner learn the material?

This is:

Initial assessment of competence after training!

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Initial Competence Assessment – What

- Before working independently did the employee *demonstrate* the:
 - necessary knowledge of the process?
 - skills required for the tasks?
- Assessment of all work processes and procedures that affect quality of products and services

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Initial Competence Assessment - When

- New employees in all the processes and procedures in their jobs
- All employees after changes to processes and procedures



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Initial Competence Assessment – How

- Challenge what the new employee
 - knows (cognitive), and
 - *can do* (psychomotor)
- Verify that the learning objectives have been met
- Use predetermined criteria
 - passing score for quiz
 - level of performance on direct observation

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Question Types for Assessment of Knowledge (Tests)

- Theory
- Technique
- Interpretation
- Problem solving

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Theory Question Examples

- Important background information
- Principle of the technique or method
- Key reactions in the method

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Technique Question Examples

- Critical issues for success
 - Pipetting
 - Needle angle
 - Key measurements
 - Computer entries
 - Temperatures, times, incubations
- Rationale for technique specifics

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Interpretation Question Examples

- A given set of results
- Color reactions
- Instrument alerts
- Patient conditions

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Problem Solving Examples

- Problems the staff are likely to encounter when performing the process
- Troubleshooting instruments/equipment
- Actions in critical situations
- Case studies

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Assessment of Skills (Demonstrations)

- Self-assessment after practice
- Observe employee
 - Work through a given process
 - Perform a procedure
- Verification that all required activities/steps were performed according to the approved documents
- Use of a Direct Observation Checklist

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Direct Observation Checklist

- Can be prepared for
 - The activities in the process
 - The steps of a procedure
 - Include applicable safety requirements
- Observers need to be qualified
- Results documented on a DOCL



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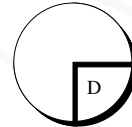
Documenting Initial Competence Assessment

- Records of training
- Records of knowledge assessment (quiz)
- Records of performance assessment
- Records of action taken, when needed

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D. Outcomes Evaluation*

- 1) Did the learner like the training experience?
- 2) Did the learner learn the material?
- 3) Were the skills learned transferred to the workplace?
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*Kirkpatrick's levels of evaluation

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D.3
Were the skills learned transferred to the workplace?

This is:

Ongoing assessment of competence throughout employment!

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Ongoing Competence Assessment 1.

- Were the skills transferred to the workplace?
- Ongoing demonstration of knowledge *and* skills



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Ongoing Competence Assessment 2.

- All employees who perform processes and procedures that affect quality of products and services
- On a periodic, scheduled basis (annually, per CLIA)

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Means to determine* 1.

- Direct observation of routine work processes and procedures
 - Use of process or procedure DOCL
 - Be sure to observe for any necessary safety requirements

* per U.S. CLIA '88

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Means to determine* 2.

- Monitoring recording and reporting of test results
 - Routine supervisory review of results and reports
 - Includes computer entry
 - Use “monitor by exception”

* per U.S. CLIA '88

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Means to determine* 3.

- Review of
 - intermediate test results or worksheets
 - quality control records
 - proficiency testing results
 - preventive maintenance records
- Same means as for review of results
 - routine supervisory review of results and records
 - includes computer entry
 - use “monitor by exception”

* per U.S. CLIA '88

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Means to determine* 4.

- Direct observation of equipment maintenance and function checks
 - Use of a DOCL
 - Be sure to observe for any necessary safety requirements

* per U.S. CLIA '88

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Means to determine* 5.

- Use of specially-provided materials
 - Previously tested patient samples (unknowns)
 - Previously tested proficiency assessment samples (after results returned)
 - “Blind” samples

* per U.S. CLIA '88

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Means to determine* 6.

- Assessment of problem-solving skills
 - Technical problem solving
 - Blood bank antibody identifications
 - Microbiology organism identifications
 - Remedial action on nonconformances
 - Handling of complaints
 - “MBWA”

* per U.S. CLIA '88

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Don't Make Yourself Crazy!

- Make ongoing assessment part of the supervisory routine
- State this approach in your competence assessment program description
- Minimize use of “specially prepared materials” for routine situations



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Competence Assessment Plan by Job Title
Example: Technologist / Scientist

Area	Skill, Task, Knowledge	How Assessed
Hematology	-Operating hematology analyzer in open and closed mode	-1
	-Proper use of cancellation codes	-2
	-Performing / documenting analyzer QC	-2
	-Basic analyzer preventive maintenance	-3, 4
	-Basic analyzer troubleshooting	-3
	-Performing CBCs on the analyzer	-5
	-Hematology problem solving (records and case studies)	-6

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Documenting Ongoing Competence Assessment

- Records of knowledge assessment
 - Quizzes or case studies
- Records of performance assessment
 - DOCL, specially provided materials
- Records of action taken, when needed

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Before “retraining” ...ask these first!

- Work processes documented?
- Written procedures?
- Clear and understandable?
- Documented training program?
- Training conducted and documented?
- How was training effectiveness determined?
- Is employee only person with this problem?

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Remedial Action Plan

- Specific skill or knowledge to be demonstrated
- Action to be taken
- Competence / Learning to be reassessed by (how and when)
- Outcome of reassessment

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Benefits of Competence Assessment

- Contribution to patient safety
- Assurance of customers of laboratory quality
- Assurance of fellow employees of quality of one’s work
- Improvement of staff morale and productivity
- Meeting regulatory / accreditation requirements

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Training

+ Competence

= Effective Performance!!

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