Department of Pathology	Document No. CLIN 3008 P
Clinical Laboratory Manual	Page 1 of 7
Training and Competency Plan	Origination: 10/2010 Version: 3

Policy Statement	The Clinical Laboratory of St. Agnes Hospital, in accordance with accrediting and regulatory agencies, requires that competency of all laboratory associates be assessed for their respective duties.
Purpose	The Clinical Laboratory must ensure that the competency of all personnel is assessed for knowledge and skills necessary to perform assigned job functions outlined in job descriptions.
Scope	This policy applies all to sections within the Clinical Laboratory. This includes Core Lab, Microbiology, Point of Care Testing and Transfusion Services. Point of Care Testing applies to laboratory associates only.
Responsibility	It is the responsibility of the lead technologist within each section to ensure that this policy is followed as written without exception.

FOUR STAGES OF TRAINING	2
1. TRAINING NEEDS IDENTIFIED	2
2. TRAINING GUIDES DEVELOPED	2
Training Instructions	
Training Guide Packet	
3. TRAINING IMPLEMENTED	3
Trainer Qualifications	3
Training Environment	
Training Schedule	4
Training Checklist	
4. TRAINING OUTCOME EVALUATED	
Learner Assessment	4
Training Program Assessment	4
WHEN PERFORMANCE IS UNACCEPTABLE	5
WHEN PERFORMANCE IS UNACCEPTABLE Process Problems Reassessment	5
Process Problems	5 5
PROCESS PROBLEMS REASSESSMENT DOCUMENTATION OF TRAINING AND COMPETENCE ASSESSMENT	5 5 5
PROCESS PROBLEMS REASSESSMENT DOCUMENTATION OF TRAINING AND COMPETENCE ASSESSMENT TRAINING RECORDS	5 5 5 5
PROCESS PROBLEMS	5 5 5 5 5
PROCESS PROBLEMS REASSESSMENT DOCUMENTATION OF TRAINING AND COMPETENCE ASSESSMENT TRAINING RECORDS	5 5 5 5 5 5 5
PROCESS PROBLEMS	5 5 5 5 5 5 5 6

St. Agnes Hospital, 900 S. Caton Avenue, Baltimore, MD 21229

Department of Pathology	Document No. CLIN 3008 P
Clinical Laboratory Manual	Page 2 of 7
Training and Competency Plan	Origination: 10/2010 Version: 3

Four Stages of Training

1. Training Needs Identified

Regulatory and accreditation requirements specify that training is required at the following times:

- for new associates, to learn their respective work processes and procedures
- for all associates, when organizational or technological changes affect work processes
- when training needs are identified (e.g., repeated performance problems, unsuccessful performance on a competence assessment exercise, or problem-prone process)

Each section of the clinical laboratory needs to identify work process and procedures for which training is needed.

2. Training Guides Developed

Once the need for training has been established, a training guide must be created. Each training guide should include the objectives, methods and materials needed to successfully learn the specified topic.

- Objectives Learning objectives are expectations for training outcomes that can be observed or assessed; therefore, action verbs are used to describe measurable behaviors and goals. Learning objectives for training are of three types:
 - To assess knowledge
 - To assess action taken
 - To assess technique
- Methods Training methods include, but are not limited to, any of the following as applicable to the work process for which training is being conducted:
 - \circ lecture
 - o computer-based exercises
 - o self study
 - o observance of demonstrations
 - o practice under supervision
 - self-assessment of practice outcomes
 - testing or identification of specially provided samples
- Materials Training materials include all items used during delivery of the training event.
 - references text, articles
 - o operator's manuals
 - o manufacturer's instructions
 - o documented work process in the procedure manual

St. Agnes Hospital, 900 S. Caton Avenue, Baltimore, MD 21229

P:\labadmin\Quality Management\CLIN\CLIN QSE 3-Personnel\CLIN 3008 P Clinical Laboratory Training and Competency Plan v3.doc

Department of Pathology	Document No. CLIN 3008 P
Clinical Laboratory Manual	Page 3 of 7
Training and Competency Plan	Origination: 10/2010 Version: 3

- o documented procedures in the procedure manual
- o lecture handouts
- o computer-based programs
- self study programs
- o videos
- o practice materials

Training Instructions

To prepare for the training event, both the trainer and the learner should be provided with instructions.

- Trainer instructions must outline the training event. In order to have a successful and complete training event, all instructions must be followed as written to ensure uniformity.
- Learner instructions must outline skills and objectives that need to be met to complete the training event and be considered competent.

It is the responsibility of both the trainer and learner to notify the lead technologist of the section if the instructions of the training event are not followed as written.

Training Guide Packet

All training events should have an associated training guide packet. The documents in the packet must be in the format of the templates associated with this policy. The packets must include the following documents:

- Training Guide Form
- Instructions for the Trainer
- Instructions for the Learner
- Training Schedule
- Training Checklist
- Direct Observation Checklist(s)
- Technologist Blind Testing
- Technologist Result Entry
- Written Quiz
- Learner Evaluation Form

3. Training Implemented

Trainer Qualifications

All trainers must be approved by the lead technologist of the section prior to the training event. Trainers must meet the following qualifications:

- Accurate knowledge of the process and procedures involved in the training event
- Regular work experience with the specified training event

St. Agnes Hospital, 900 S. Caton Avenue, Baltimore, MD 21229

P:\labadmin\Quality Management\CLIN\CLIN QSE 3-Personnel\CLIN 3008 P Clinical Laboratory Training and Competency Plan v3.doc

Department of Pathology	Document No. CLIN 3008 P
Clinical Laboratory Manual	Page 4 of 7
Training and Competency Plan	Origination: 10/2010 Version: 3

- Good verbal skills
- Good listening skills
- Good observational skills

Training Environment

Training should take place in the area where the work is performed so the learner can observe the work process and procedure in its entirety. The environment should be conducive to non-punitive learning and positive outcomes.

Training Schedule

A schedule should be prepared for the training event so both the trainer and the learner know how the training activities will unfold. The training event may take more or less time than shown on the schedule, because of the different levels of learners' experience and pace of learning. All training scheduled for new associates must be completed by their six month evaluation.

Training Checklist

Training checklists serve as a means to document the training event. A training checklist must be completed by the end of each training event.

4. Training Outcome Evaluated

Learner Assessment

Following initial employment training, the new associate's competence is assessed to determine the effectiveness of the training, as well as the person's readiness to function in his or her work environment. Competence assessment of new employees should be administered during and at the end of employment training, at six months and annually thereafter. After the initial training event, the learner must be evaluated by direct observation and a written quiz. Training checklists must be reviewed and signed by the lead technologist of the section before the learner is released to be scheduled for patient care testing. The lead will notify the section scheduler when the learner can be assigned to a work station without a trainer present.

Competence assessment should also be performed when all associates are introduced to new or changed work processes or procedures. When new tests are involved, competence needs to be assessed before reporting test results. This is necessary to ensure readiness for effective delivery of those processes and procedures in the work environment.

Training Program Assessment

Associates must be given the opportunity to provide feedback on the training experience to determine where there might be opportunities for improvement.

St. Agnes Hospital, 900 S. Caton Avenue, Baltimore, MD 21229

Department of Pathology	Document No. CLIN 3008 P
Clinical Laboratory Manual	Page 5 of 7
Training and Competency Plan	Origination: 10/2010 Version: 3

When Performance is Unacceptable

Process Problems

Before deeming an associate as requiring retraining, the lead technologist should answer the following questions:

- Have all work processes been clearly documented?
- Are there documented procedures for all activities in the work process?
- Are the documented procedures clear and easy to understand?
- Has the associate been trained in the process or procedure in question and was the training documented?
- How was the effectiveness of the associate's training determined?
- Is the associate the only individual with this performance problem?

If a process problem is discovered, it then becomes incumbent upon the section lead or designee to correct the problem, document and communicate the fix to the entire staff including the trainee. If the associate is the only person with this performance problem, it is then necessary to perform a reassessment.

Reassessment

When there is clear evidence the associate is not competent to perform the assigned task, management must create and document follow-up actions with a formal plan. The criteria for reassessment should be established, documented and communicated to the associate before the periodic retraining events. Criteria should include guidance on how many chances the trainee should get to pass the assessment. During the reassessment process, the scope of the retraining is determined.

Documentation of Training and Competence Assessment

Training Records

Individual Training

At the conclusion of each training event, the following records should be completed and retained in the associate's training file:

- Checklists
- Written tests
- Direct observation checklists

Group Training

There are instances when information is relayed to all associates or a specific group of associates, instead of individually. These instances include, but are not limited to inservices, vendor training (for new analyzers, test kits, computer programs, etc.) or

St. Agnes Hospital, 900 S. Caton Avenue, Baltimore, MD 21229

Department of Pathology	Document No. CLIN 3008 P
Clinical Laboratory Manual	Page 6 of 7
Training and Competency Plan	Origination: 10/2010 Version: 3

online programs. At the conclusion of each group training event, the following records should be completed and retained in the associates training file:

- Group training record or acknowledgement form for each individual participating in the session
- Checklists (if applicable)
- Written tests
- Direct observation checklists

Note: All paper copies must contain the signatures of both the trainer and learner. All training documents must be reviewed by the lead technologist or designee of the section.

Competency Records

At the conclusion of each competency assessment event, the following records should be completed and retained in the associate's competency file:

- Direct observation checklists
- Outcome of the review of the assessments, records, reports or results of blind sample testing.

Note: All paper copies must contain the signatures of both the trainer and associate. All competency assessments must be reviewed by the lead technologist or designee of the section.

Competency Plan

Technical staff competencies are designed to cover the six methods or elements of competency as prescribed by the Clinical Laboratory Improvement Act of 1988. Elements of competency assessment include but are not limited to:

- Direct observation of routine test performance or other required job assignment.
- Monitoring the reporting and recording of test results.
- Review of intermediate results, worksheets, and quality control and maintenance records.
- Direct observation of performance of instrument maintenance and function checks.
- Assessment of test performance through testing previously analyzed samples, internal blind samples or external proficiency samples.
- Assessment of problem-solving skills.

Any or all of the elements may be assessed together in any combination for a single competency event. All six elements must be assessed for each training event annually.

St. Agnes Hospital, 900 S. Caton Avenue, Baltimore, MD 21229

P:\labadmin\Quality Management\CLIN\CLIN QSE 3-Personnel\CLIN 3008 P Clinical Laboratory Training and Competency Plan v3.doc

Department of Pathology	Document No. CLIN 3008 P
Clinical Laboratory Manual	Page 7 of 7
Training and Competency Plan	Origination: 10/2010 Version: 3

A competency event can be conducted by either the lead technologist or a designated trainer. All competency assessments must be reviewed by the lead technologist of the section.

Retention of Records

Training and competency records are kept in the associate's training/competency binder or electronically. Current associate files are stored in a secure location within the laboratory section or on the network drive. Former associate records are kept electronically or stored off-site. Records can be accessed by the associate, laboratory management and regulatory agencies only. Records must be kept for the required period of time (2 year minimum except for Blood Bank records which must be kept for 5 years.)