



(9133-QE) Development and Implementation  
of an Organizational Training and  
Competency Plan

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October 12, 2013 ✧ 4:00 PM - 5:30 PM

## Event Faculty List

**Event Title:** 9133-QE: Development and Implementation of an Organizational Training and Competency Plan

**Event Date:** Saturday, October 12, 2013

**Event Time:** 4:00 PM to 5:30 PM

### **Director/Moderator**

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Disclosures: No

### **Speaker**

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Disclosures: **Did not disclose**

### **Speaker**

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Disclosures: No

### **Speaker**

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Administrative Director, Transfusion  
Medicine  
Long Island Jewish Medical Center  
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Disclosures: No

Training and Competency Program: An Evolution  
Kelly Danyow

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**Background**

**In 2012, BBD began an initiative to investigate.....**

**Why is a training and competency program important?**

- Regulatory compliance
- Error reduction
- Audit findings

**Where are we?**

- What is our current program?
- Where do we want to be?

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**Charge**

- Cross functional team was developed made up of representatives from major operational areas
  - Quality served as facilitator from a regulatory perspective

**WHO** conducts training?

**WHEN** is training conducted?

**WHEN** is competency assessed?

**WHAT** types of training?

**WHAT** tools are used?

**HOW** is training conducted?

**HOW** is competency measured?

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## Assessment

- Documented independent training programs
- Missing key definitions

Who can train? What is a preceptor?

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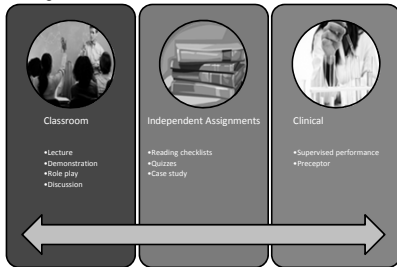
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## Assessment

Types of training



- All areas use multiple methods for training and assessment
- How is this documented?

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## Assessment

- Different formats for documenting training and competency
- Checklists!

Lots of boxes - increased potential for completion errors

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## Assessment

- Different timelines for required assessment
- Missing information

3. Competency Checklist

a) The Department Supervisor/designee should initiate and complete Training/Competency Checklist at the following intervals:

- (1) Upon initial training.
- (2) Annually thereafter, unless otherwise indicated.

**NOTE:** In accordance with the Clinical Laboratory Improvement Act of 1988 (CLIA 88) competency will also be assessed at six months

**When is retraining performed?**

**CLIA?**

**Training / Annual Competency**

File Date: \_\_\_\_\_

Competency Assessment     Initial Training     Retraining

6 month     1 year

**C. Competency Checklist - Donor Screening (Example included)**

The supervisor/designee will complete this checklist:

1. Approximately every week during medical interview training until individual is released to perform task independently.
2. At the 2, 4, 6, and 12 month employee evaluation.
3. Annually thereafter unless:

**Competency Assessment**

Initial Training     Retraining

3 Month     6 Month     Annual

CLIA 88 COMPLIANCE

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## Assessment

Additional discussions/investigations included...

- Needed a way to capture what training/competency is needed for each employee for ongoing monitoring
- Clear way to capture training plan, especially for less frequent trainings
- How to document remove from task/release to task

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## Assessment

- Team completed assessment and developed new tools to use based on needs identified
  - Worked together to "drill down" to 9 generic templates
  - Goal to structure program in a GMP-like fashion so that all departments could effectively use the same tools
- Focus on filling in gaps identified:
  - Define trainer, preceptor
  - Define retraining, remove/release to task
  - Fulfill CLIA requirements for assessment of moderate and high complexity tasks

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### Outcome

**Program Structure**

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### Outcome

**Clear definitions/requirements incorporated**

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### Outcome

11.1.2 Trainer

11.1.2.1 CHARACTERISTICS AND REQUIREMENTS

- 11.1.1.1 Ability to facilitate and drive the transfer of knowledge.
- 11.1.1.2 Ability to process failure, to identify solutions, and to design improvements for success.
- 11.1.1.3 Organized, prepared and deemed competent.
- 11.1.1.4 Project a positive image of BBD and possesses appropriate people skills.
- 11.1.1.5 Ability to articulate and ensure understanding and comprehension of information to a targeted audience.

- Trainer/ Preceptor Elements:
  - BBD felt it was of critical importance to address
    - New procedure defines qualities/attributes
    - Roles and differences

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# Outcome

New, general templates for initial training

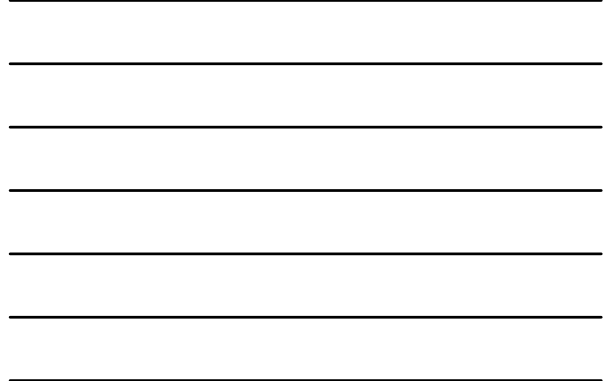
The image shows three overlapping form templates for initial training. The top-left form is a general form with fields for Employee Name, Department, and Supervisor. The middle form is titled 'TRAINING PLAN' and includes fields for Department, Date Developed, and a list of tasks. The bottom-right form is titled 'INITIAL TRAINING PROFILE' and includes fields for Employee Name, Dept/Position, and Start Date, followed by a table for tracking tasks.



# Outcome

New general templates for assessing and monitoring competency

The image shows three overlapping form templates for assessing and monitoring competency. The top-left form is titled 'COMPETENCY ASSESSMENT FORM' and includes fields for Employee Name, Department, and Supervisor. The middle form is titled 'ON-GOING COMPETENCY ASSESSMENT PROFILE' and includes fields for Employee Name, Dept, and Position, followed by a table for tracking tasks. The bottom-right form is titled 'COMPETENCY ASSESSMENT RESULTS OR MODERATE TO HIGH COMPETENCY PROFILE' and includes fields for Employee Name, Dept, and Position, followed by a table for tracking tasks.



# Outcome

New form for assessment of other duties

(expand program to other areas in organization)

New form for remove/release to task

The image shows two overlapping form templates. The top form is titled 'REMOVE FROM TASK/DUTY TO TASK REASSIGNMENT' and includes fields for Employee Name, Department, and Supervisor. The bottom form is titled 'COMPETENCY ASSESSMENT FOR TASKS OUTSIDE JOB PROFILE' and includes fields for Employee Name, Dept, and Position, followed by a table for tracking tasks.



## Evolution...

**COMPONENT PREPARATION**  
Training Checklist

Employee Name: \_\_\_\_\_ Section: \_\_\_\_\_ Initial Training:  Re-training:  Other: \_\_\_\_\_

Associated SOPs of applicable:  CIP/CR/188,  Shoplifting and Fire of the Registered Retailer (C)  C-16,  Shoplifting and Fire of the Registered Retailer (C)  C-16,  Shoplifting of Other Goods (C),  Shoplifting (C),  Shoplifting (C)

Skill Task	Initial	Re-train	Other	Pass
<b>Initial and Re-training:</b>				
<ul style="list-style-type: none"> <li>Check and verify all items being</li> <li>Check inventory on a weekly basis</li> <li>Carry out all the responsibilities for shoplifting and fire</li> </ul>				
<b>Competency of the Employee:</b>				
<ul style="list-style-type: none"> <li>Report any issues promptly, such as regular</li> <li>Check that all items are properly</li> <li>Check that all items are properly</li> <li>Check that all items are properly</li> <li>Check that all items are properly</li> <li>Check that all items are properly</li> </ul>				
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**COMPONENT PREPARATION**  
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## Evolution...

**COMPONENT PREPARATION**  
Training

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Initial training

Re-training

Other

Simplified training timelines

Fewer boxes- reduced potential for documentation errors

Employee and trainer statements incorporated for accountability

Employee Statement:  
I have read and I understand all associated SOPs. I have had the opportunity to have all my questions answered. I am confident that I will be able to perform the functions correctly. I understand that I must seek my supervisor/manager if I encounter any questions or problems.

Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Trainer/Designee Statement:  
This employee has been instructed and is competent to perform the assigned skills/tasks listed above.

Trainer/Designee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Department Director/Designee Signature: \_\_\_\_\_ Date: \_\_\_\_\_



## Moving Beyond Checklists...

**COMPETENCY ASSESSMENT FORM**

DEPARTMENT: Comp Lab Employee Name: 2103

CALENDAR YEAR: 2016

PROCESS: Shoplifting Type of Competency (check one):  Initial  Re-train  Other

Associated Document(s) (if applicable): see attached

Skill/Task/Process	Verification Method	Assessor Initials	Date	Competency Results
<u>Component Task/initial assessment</u>	<u>D</u>	<u>SM B122</u>	<u>11/12/16</u>	<u>C</u>

**Verification Method Key:** D = Direct Observation, T = Test/Quiz, F = Final Process, E = Oral Evaluation of Knowledge

**Competency Results Key:** C = Competent, NC = Not Competent, N/A = Not Applicable/Employee does not task

New form provides a way to assess competency through alternate methods while still using a uniform template throughout the organization. Any documentation may be attached to form.





## Next Steps

- Team met in spring 2013 to discuss status of program
  - Tools are working!
  - Gaps identified:
    - employee leave of absence
    - Qualifications of individuals performing assessments
    - Incorporation into audit schedule to ensure compliance
      - To be added to program at next revision
- Moving towards electronic system for training and competency assessment monitoring
- Roll-out to non-regulated departments

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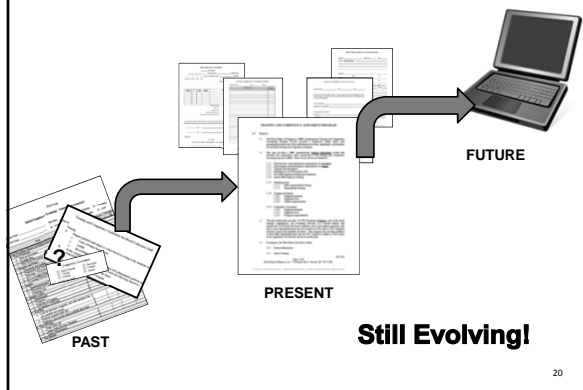
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## Conclusion



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Questions?

Thank you!

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Blood Bank of Delmarva  
100 Hygeia Drive  
Newark, DE 19713

Telephone: (302) 737-8405  
Toll free: (800) 548-4009  
Fax: (302) 737-8233

[www.delmarvablood.org](http://www.delmarvablood.org)

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North Shore-Long Island Jewish Health System

## Transfusion Medicine 2013 Training and Competency Program

Jennifer Dikeman



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- Define Competency
- Explain difference between training and competency
- List the 6 elements required for competency assessments
- Discuss who can perform competency assessments
- Understand new requirements from CMS/CLIA



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## Quality Management System QSE: Personnel

- “Obtaining and training an adequate number of qualified, well trained, and competent laboratory staff to perform and manage the activities of the laboratory.”

GP26-A4





Figure 2. Key Elements of QSE: Personnel




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## What Is Competency and Competency Assessment?

- Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.
- Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation.

Centers for Medicare and Medicaid Services

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## Training vs. Competency

- The difference between training and competency –  
Training occurs **before** someone begins testing AND  
Competency assessment confirms that they are doing the test correctly.

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## Who Requires Competency?

- CAP
- CMS
- State DOH
- AABB
- FDA
- FACT
- Joint Commission

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## AABB

### STD 2.1.2 Training

- The blood bank or transfusion service shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.

**Not Just Testing  
Personnel!**

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## CLIA

- Considered a minimum set of guidelines for quality
- All clinical labs in the USA must meet these guidelines in order to receive Medicare and Medicaid reimbursement
- Assessed through various means
- CMS currently grants deemed status to:
  - CAP, AABB, Joint Commission

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## Minimum Requirements

The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing:

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
2. Monitoring the recording and reporting of test results;
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
4. Direct observations of performance of instrument maintenance and function checks;
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Assessment of problem solving skills.

Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.

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## CLIA Competency Assessment

- 6 assessment elements
  - Must be performed for each routine test
  - Must be performed for each tech who performs the test
  - Must be performed twice during first year of performing the test
  - Must be performed at least annually thereafter

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## CLIA Competency Assessment Key Requirement

493.1413(b)(8)(9) & 1451(b)(8)(9)

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

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## Who Cannot

- Peer testing personnel who do not meet the regulatory qualifications of a TC, TS, or a GS cannot be designated to perform competency assessments.
- Ultimately, it is the Lab Director's responsibility to ensure all testing personnel are competent and maintain competency.

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## Competency Frequency

- *How often should competency assessment be performed?*  
Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual tests patient specimens. Thereafter, competency assessments must be performed at least annually.  
*Competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.*

\*\*if test methodology or instrumentation changes, an individual's competency must be re-evaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.



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## Training & Competency Documentation

- The requirements are clear on what needs to be documented for training & competency.
- The requirements do not guide you on how to easily document this process.
- The NSLIJ model is simple, streamlined, effective and green friendly.



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## Training & Competency Model

- The NSLIJ training & competency model is based on 3 main elements.
  1. Consolidated training modules
  2. A single multi-purpose competency document
  3. Crosswalk documents which link all associated documents together for organization & auditing purposes.



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## Training Documentation

- Individual training checklists are utilized for each test/task performed in the laboratory
- Training checklists emulate the key steps in the laboratory SOP's
- The training checklists have areas for training attestation, training verification & corrective action / follow-up for training re-mediation.



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## Training Modules

- The training checklists have been combined into modules for the purposes of streamlining documentation.
- ( 7 ) training module documents were created to emulate the training flow of a new employee in the Blood Bank; 1. Safety, 2. Patient Samples, 3. Quality Control, 4. Patient Testing, 5. Compatibility Testing, 6. Blood Issuing & 7. Antibody / Problem Desk.
- Each training module document has multiple combined training checklists with all the associated SOP related tasks for training documentation & verification.



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## Training Module Checklist

Long Island Jewish Medical Center  
270-05 70<sup>th</sup> Avenue  
New Hyde Park, NY 11040

**TRAINING & RE-EVALUATION**  
Evaluation of Blood and Blood Components

Employee Name: \_\_\_\_\_  
Trainer Name: \_\_\_\_\_

**17114 - Clinical Laboratory Techniques - Blood Bank - Item of Training**

Item Number	Revised/Retired	Comments
1. Complete the instruction card on digital display and correctly collect specimen into the 50cc control vial.		
2. Place a 50cc vial of control specimen into the rack. The first two labels must be added to the rack in the correct order. Question regarding the first label, without adding anything to the rack. If you do not know the correct order, please refer to the instruction process, please refer to the rack.		
3. Minimum one (1) vial for individual use in this procedure.		
4. When dependent on the procedure, the control vial should be added after the first vial of the specimen.		
5. Place 1st in control vial in rack.		
6. Place control vial in rack.		
7. Return control vial to rack and add 1st vial to rack. The rack should be in the rack and the control vial for the rack.		

\*The Employee for the training is currently Blood Banker of the Hospital

Training SOP 17114-01 Evaluation of Blood and Blood Components

Final procedure is training complete. \_\_\_\_\_ Initials

All training objectives / effectiveness met

Long Island Jewish Medical Center  
270-05 70<sup>th</sup> Avenue  
New Hyde Park, NY 11040

All training objectives / effectiveness NOT met

Remedial Training required

Date of Completion: \_\_\_\_/\_\_\_\_/\_\_\_\_

Corrective Action Follow Up

Criteria to assess effectiveness of training:

Provide verbal questions to test the trainee.

Provide written quiz to test trainee.

Provide opportunities for questions.

Acceptable self assessment

Hands on work.

Over Training Rate

CC Category	Count	Overall Competency Rate
1	0%	100%
2	0%	100%
3	0%	100%
4	0%	100%

EMPLOYEE'S COMMENT: \_\_\_\_\_

Employee Training Competency Statement:

I have had the opportunity to have all my questions answered concerning this procedure. I feel adequately trained and feel confident that I will be able to perform the steps correctly. I understand that I must ask my supervisor if I encounter any questions or problems with this procedure.

Training performed by: Trainer \_\_\_\_\_ Date: \_\_\_\_\_

Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Lab / QM Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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# Competency Documentation

- A single competency checklist is utilized for each test/task performed in the laboratory
- The competency checklist is a consolidated mirror image of the training modules.
- The competency checklist is setup to perform an assessment on all 6 required procedures for CMS compliance for all test procedures performed in the department.
- Task are also incorporated into the document which do not require the 6 areas of assessment.
- The consolidated competency document is multi-purpose in that it can be utilized to perform an initial, 6 month & annual assessment all one form.




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# Competency Checklist

BLOOD BANK COMPETENCY EVALUATION CHECKLIST

BS 950 Employee: \_\_\_\_\_ Department: Blood Bank Rev: 05/28/13

Fundamental Area/Competency/Criteria	SOP(s) A Training	Evaluation of Professional Performance						
		Initial Competency		6 Months		1 Year Assesed		Supporting Document
Includes Code	Initial Code	Initial Competency Assessment	Includes Code	Final Code	Includes Code	Final Code		
14. Crisis manik OBS: Demonstrate the ability to perform and interpret emergency tests. Complete paperwork with all documentation. (OBS) - All 6 areas of assessment required	<input type="checkbox"/> SOP(s) Code _____ <input type="checkbox"/> Training Code _____ <input type="checkbox"/> Compliance Code _____ Supervisor Initials _____	D M Mean R JM Mean A P Final I S Final O Q Final	1 The employee has been trained in all SOP's related to the task. Employee Sign _____ 2 The employee has completed to perform this task. Employee Sign _____ Supervisor Sign _____ Date _____ QA Sign _____ Date _____	D M Mean R JM Mean A P Final I S Final O Q Final	Below Standards Below Standards Meet Standards Meet Standards Above Standards	D M Mean R JM Mean A P Final I S Final O Q Final	Below Standards Below Standards Meet Standards Meet Standards Above Standards	Use Checklist Document
15. Identifying & Testing Blood in Blood Containers OBS: Complete the testing of products within the allocated time, set up any required consumables and complete all work in a timely manner. (OBS)	<input type="checkbox"/> SOP(s) Code _____ <input type="checkbox"/> Training Code _____ <input type="checkbox"/> Compliance Code _____ Supervisor Initials _____	D M Mean R JM Mean A P Final I S Final O Q Final	1 The employee has been trained in all SOP's related to the task. Employee Sign _____ 2 The employee has completed to perform this task. Employee Sign _____ Supervisor Sign _____ Date _____ QA Sign _____ Date _____	D M Mean R JM Mean A P Final I S Final O Q Final	Below Standards Below Standards Meet Standards Meet Standards Above Standards	D M Mean R JM Mean A P Final I S Final O Q Final	Below Standards Below Standards Meet Standards Meet Standards Above Standards	Use Checklist Document

Problem Codes: D - Deficient observations of performance; M - Marginal performance; R - Remedial action required; A - Adequate observations of performance; P - Proficient observations of performance; I - Inadequate observations of performance; S - Satisfactory observations of performance; O - Outstanding observations of performance; Q - Outstanding observations of performance.  
 Final Codes: B - Below Standards; MS - Meet Standards; A - Above Standards.  
 Training: T - Training; C - Compliance; O - Observation; S - Signatures of the assessor and the employee.

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# Competency Remediation

- Competency remediation can be easily documented on the bottom of each competency assessment area.
- Corrective actions for ongoing assessments can be easily documented on the last page of the document.
- Training remediation is also easily documented on the initial assessment area.




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### Competency Remediation

**BLOOD BANK COMPETENCY EVALUATION CHECKLIST**

BB 950 Employee: "Employee" Department: Blood Bank Rev: 03/28/13  
 \*Complete below for competencies assessed as "Below Standards"

	Reason(s)	Corrective Action(s)	Target Date For Completion
6 Month			
1 Year / Annual			

**Comments:** \_\_\_\_\_

Initial Competency Assessment	6 Month Competency Assessment	1 Year / Annual Competency Assessment
I _____ the employee feel competent to perform all of the above tasks/tests/procedures in the Blood Bank relating to patient care. Signature: _____ Date: _____ Supervisor: _____ Signature: _____ Date: _____ QA / AD: _____ Signature: _____ Date: _____	I _____ the employee feel competent to perform all of the above tasks/tests/procedures in the Blood Bank relating to patient care. Signature: _____ Date: _____ Supervisor: _____ Signature: _____ Date: _____ QA / AD: _____ Signature: _____ Date: _____	I _____ the employee feel competent to perform all of the above tasks/tests/procedures in the Blood Bank relating to patient care. Signature: _____ Date: _____ Supervisor: _____ Signature: _____ Date: _____ QA / AD: _____ Signature: _____ Date: _____

Competency Assessments are to be performed by Managers / Supervisors / senior techs, not on a peer-to-peer or subordinate level.

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### Crosswalk Documents

- A single crosswalk document exists for each training module.
- The crosswalk document is a guide for the competency assessor to keep track of all the necessary documents that are needed to be complete training & competency for each module.
- The crosswalk contains lists of SOP's for reading, training records to be completed, quizzes to be completed by the employee and the specific associated competencies for the designated module.
- Included are minimum testing criteria for experienced vs. non experienced techs.
- The document ultimately serves as a tool to assure that all records are complete in the auditing of personnel files.

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### Crosswalk Document



North Shore University Hospital  
The Sanjour Atlas Bass Campus  
Department of Laboratory - Blood Bank  
Safety Training & Competency Module

SOP's / Reading Material	Training Record	Quiz	Competency
<input type="checkbox"/> cGMP Lecture - Powerpoint	<input type="checkbox"/> cGMP DO-05	<input type="checkbox"/> cGMP Quiz	<input type="checkbox"/> cGMP CM-05
<input type="checkbox"/> Handwashing	<input type="checkbox"/> Handwashing DO-05	<input type="checkbox"/> N/A	<input type="checkbox"/> Handwashing CM-05
<input type="checkbox"/> Radiation Safety Lecture - Powerpoint	<input type="checkbox"/> Radiation Safety DO-05	<input type="checkbox"/> Radiation Safety Quiz	<input type="checkbox"/> Radiation Safety CM-05
<input type="checkbox"/> JCAHO HFSS's Document	<input type="checkbox"/> JCAHO Safety DO-05	<input type="checkbox"/> N/A	<input type="checkbox"/> JCAHO Safety CM-05
<input type="checkbox"/> HPC Liquid Nitrogen Safety SOP	<input type="checkbox"/> Nitrogen Safety DO-05	<input type="checkbox"/> Liquid Nitrogen Safety Quiz	<input type="checkbox"/> Nitrogen Safety CM-05
<input type="checkbox"/> Lab Safety Inservice	<input type="checkbox"/> General Lab Safety DO-05	<input type="checkbox"/> Lab Safety Quiz	<input type="checkbox"/> General Lab Safety CM-05

**Minimum Testing Criteria**

Training Task	Experienced Tech	Non-Experienced	Comments
cGMP	N/A	<input type="checkbox"/> N/A	<input type="checkbox"/>
Handwashing	N/A	<input type="checkbox"/> N/A	<input type="checkbox"/>
Radiation Safety	N/A	<input type="checkbox"/> N/A	<input type="checkbox"/>
JCAHO Safety	N/A	<input type="checkbox"/> N/A	<input type="checkbox"/>
Nitrogen Safety	N/A	<input type="checkbox"/> N/A	<input type="checkbox"/>
General Lab Safety	N/A	<input type="checkbox"/> N/A	<input type="checkbox"/>

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## Supporting Documentation

- All related documents that are evidence of competency are filed with the consolidated competency checklist.
- Related documents consist of machine printouts, equipment maintenance records, proficiency survey results, blind sample test results, equipment PM documents and any other documents in connection with the testing.
- Supporting documents are numbered in correlation with the competency test/task # on the competency checklist to easily identify evidence of procedure completion.

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## Responsibilities

- Techs are responsible for performing test/tasks with oversight & collecting copies of documents in connection with the associated tasks / tests.
- Supervisors / Lead Tech's are responsible for performing / coordinating training & competency assessments.
- QA Officer / Lab Manager is responsible for performing audits assuring training & competency documents are complete, signed off & overall program meets all regulatory standards.

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## Questions?

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