



**Kaiser Permanente Medical Center, San Francisco
Northern California Region**

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 Work Instruction		
Title: TQ-Training	WI Number SFOWI-0134 Revision: 10	
Department: Immunohematology	Approved & Released Work Instruction	Implementation Date: 01/03/2017
Area: 2425 Geary Blvd SFO Hospital Lab		
Type of Document: Policy		Review Period - 340 Days

PURPOSE

To describe the protocol for training staff in the Transfusion Service. All staff in the Transfusion Service must have documented training of activity prior to performing said activity. Staff must also demonstrate initial competency of test procedures prior to performing patient testing.

EQUIPMENT

Appropriate Training Checklist, Training Materials and Competency forms.

CONTROLS

Completion of Training Checklist and Competency Assessments when appropriate.

PROCEDURE

A. Staff Qualifications

1. Human Resources is responsible to verify a new employee's qualifications, i.e. education, training, experience, certification and license.
2. Human Resources and Laboratory Administration are responsible to maintain personnel records and current job descriptions with specified qualifications for each position.

B. New Employee Training:

1. New Employee Orientation /Training (Clinical Lab)

- a. All staff must satisfactorily complete the initial laboratory training on policies and safety to meet compliance requirements.
- b. Lab Services Coordinator or Assistant Lab Administrative Director monitors the completion of Orientation Checklist for New Employees.
- c. Assistant Lab Administrative Director files the completed checklists and any supplemental documents.

2. Transfusion Service Initial Training

a. Transfusion Service Checklist

- i) List of tests, procedures, and policies (including QA) in the Transfusion Service.
 - ii) Location of the procedures.
 - iii) Date on the 'procedure read column' indicates the date when reading of the procedure is completed by trainee.
 - iv) When the trainee has demonstrated proficiency, the trainer will initial and date the appropriate fields.
 - v) When the checklist is completed, the trainee and trainer will initial and date.
 - vi) The supervisor reviews the checklists for completion.
 - vii) At the completion of each critical test/task training, the trainee will be assessed for its competency before performance of patient testing.
- b. RILIS Millennium Laboratory Information System**
- i) Trainee will be given access to the Training Environment for practice.
 - ii) Trainee will read protocol and complete given practice scenarios.
 - iii) Trainee will be given access to the Live System after successful completion of the training exercise and competency.
3. Supervisor monitors employee's performance and provides input to Assistant Lab Administrative Director or Lab Services Coordinator for probationary evaluations.
4. A new hire's competency will be assessed twice in the first year and annually thereafter.

C. Procedure and Policy Changes

1. New Process and Major Revisions

- a. A new process or a major procedure change requires staff training and competency assessment prior to implementation.
- b. Major revisions include procedural step change that is critical or requires special attention to ensure accurate results.
- c. The supervisor or designee writes/revises the training checklist/materials to include the new procedure/revise procedural steps.
- d. CLS/LA will be trained using the training checklist and materials.
- e. CLS/LA will be required to demonstrate competency (whether wet, written or both) when appropriate.
- f. The trainee and trainer will initial and date to document the training.
- g. CLS are required to complete training and demonstrate competency on all instruments and test methods relevant to their job requirements.

2. Minor Revisions

- a. Minor changes to existing process/procedure do not require staff training or competency.
- b. Minor changes include small modification to workflow/process/procedure that does not impact accuracy of test results.
- c. Staff are alerted to the minor changes via email or Communication Binder or in staff meeting, or via all three mediums.

3. Knowledge of Procedures and Policies

- a. A copy of the new or revised procedure/policy is placed in the current BB New and Revised Procedures binder for CLS/LA to review.
- b. An email is sent out to CLS/LA alerting them to the new/revise

procedure/policy and the due date for review completion.

- c. CLS/LA are required to read the new or revised procedure/policy as soon as possible, not exceeding the specified due date.
- d. If the new or revised procedure involves test related changes, CLS/LA are required to read the new or revised procedure prior to performing the test.
- e. CLS/LA are required to sign and date on the sign-off sheet as attestation that they have read and understood the contents of the procedures/policies including changes which are relevant to the scope of their testing activities.
- f. CLS are required to satisfactorily pass the Transfusion Service annual written competency test which assesses the CLS' blood bank knowledge and understanding of procedures and policies.

D. Quality System Training

1. cGMP training
2. Blood Bank Quality Assurance initial training
3. Kaiser Permanente Annual Compliance and Quality Training

E. Safety Training

1. Medical Center new hire orientation
2. Annual Safety Training (includes radiation, biological and chemical safety)
3. Records of safety training are maintained by Lab Administration and Human Resources.
4. The Assistant Lab Administrative Director reviews safety and health training during employee's annual evaluation to ensure requirements are met.

F. Training and Competency Records

Department specific training and competency records are kept either by the supervisor or in the Laboratory Administration office.

G. Retraining

Retraining, if appropriate, will be initiated when problems are identified with an employee's performance either through error discovery or competency assessment.

H. Sources of Continuing Education

1. CLS/LA are given access to API-PT.com (American Proficiency Institute), medtraining.org or bloodsystemseducation.org to obtain CEUs for continuing education and to fulfil licensure requirement.
2. Staff can also attend professional seminars and do home study to obtain CEUs (continuing education units).

PROCEDURE NOTES

A. Trainer

1. The Transfusion Service staff will be trained by the supplier/vendor whenever possible and appropriate.
2. The Transfusion Service supervisor or designee will be trained adequately and serves as the trainer.
3. Only the supplier/vendor or the supervisor who is trained adequately can train the trainer.
4. It will be at the Transfusion Service supervisor's discretion to name a trainer(s) for the task.

5. The trainer must demonstrate knowledge of the subject and prove proficiency by hands-on performance or competency test.

REFERENCE

- A. AABB, Standards for Blood Banks and Transfusion Service, current edition, Bethesda, MD.
- B. CAP Checklist, current version, Northfield, IL.
- C. CLIA and Ca State regulations, current.

Associated Documents:

External Documents

SFOWI-0018 Competency Assessment for Licensed Testing Personnel GEN.55500
Associated Quality System Documents - None

Documents Generated:

Document Revision History:

Revision: 10	Date Created: 10/02/2005 Date of Last Revision: 01/03/2017	Last Approval Date: 01/03/2017
Document Author: Cara H Lim/CA/KAIPERM	Document Manager: Richard Chui/CA/KAIPERM	

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	Approver	New Lab Director	12/10/06
3	Approver	New Lab Director	1/14/07
4	Approver	New Lab Director	7/27/07
5	Procedure A. Procedure Notes A. Approver	Changed Lifeline to RILIS Millennium. Added vendor. Changed Medical Director.	6/2/11
6		No changes.	10/7/11
7	Approver Procedure: A.1.a. A.2.a.i). B.6. and C.2. D.1. H I	New Lab Director. Changed 'have' to 'must'. Added 'QA policies'. Added 'procedures, policies (including QA)'. Deleted 'sign off'. Added 'Annual'. Added 'medtraining.org and bloodsystemseducation.org'. New.	5/17/12
8	Approver Procedure A.2.a.vii) Procedure A.2.a.viii) Associated Documents Procedure F, G, H & I Reference	New BB Medical Director. New. Added initial competency assessment. New. Added competency assessment for the first year of hire. Added SFOWI-0018. Reformatted. Added CAP and regulations.	10/1/13
10	Purpose Equipment Procedure A. Procedure C. Procedure C.3 Procedure I. revision 8 Procedure G.	Added competency required prior to patient testing. Added Training Materials. New. Added staff qualification verification and personnel records maintenance by HR and/or Lab Administration. Reformatted. Clarified major and minor changes and the respective training requirements for each. Revised to current practice. Annual attestation of knowledge has been discontinued and replaced with sign-off sheet for individual SOP as changes occur. Added CLS have to pass the BB annual written competency test. Moved to Procedure C.3. Revised. Changed from 'retraining must occur' to retraining	5/18/15

		will be initiated if appropriate.	
11	Approver	New CLIA Director.	12/29/16

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM
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Jan 3, 2017 09:06:35 AM PST - Approved by: Maria F Serrano/CA/KAIPERM

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Jan 3, 2017 11:04:22 AM PST - Approved by: Eric Suba/CA/KAIPERM

Document History Section