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Kaiser Permanente Medical Center, San Francisco
Northern California Region
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Work Instruction

Title: TQ-Equipment Repair		**WI Number** SFOWI-0141 **Revision:** 10
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Policy		**Review Period -** 340 **Days**

PURPOSE

To provide a process to report equipment malfunction, follow-up repair and validation before putting back into service.

EQUIPMENT

A. BF0022 Instrument not in Service form
B. Variance Log

CONTROLS:

A. Supervisory review of equipment repair report before putting back into service.

PROCEDURE:

A. Staff, who discovers an equipment malfunction, will fill out and put BF0022 Instrument not in Service form on the equipment to remove the equipment from service and place a service request with Manufacturer or BioMed.
   1. Complete a Variance Log if necessary (e.g. when patient test results may have been impacted)
      a. Enter the date problem was discovered.
      b. Enter reported by the initial investigator.
      c. Enter equipment name, serial number and equipment identification number and the description of the problem.
      d. Forward report to the Blood Bank supervisor or the technologist in charge.
   2. The Blood Bank supervisor or designee will assess the problem of the equipment.
      a. The supervisor will document on the Variance Log if used, the date and the assessment of the impact on patient safety.
      b. The supervisor will contact biomedical engineers or equipment manufacturer.
      c. The supervisor will document on BF0022 Instrument not in Service form, the date notified and person contacted.
      d. The supervisor will assess what tests or products are affected since the

equipment was last known to be functioning per manufacturer's written instructions, or facility-defined specifications.

e. The supervisor will determine corrective action which includes review of test results and repeat testing if necessary. Affected products will be assessed for safety, purity and potency by the Transfusion Service Medical Director. If transfused, patient impact assessment will also be performed by the Transfusion Service Medical Director.

3. The engineer will perform the equipment repair.
   a. The engineer will document repair on a detailed report and forward to the supervisor.
   b. The supervisor will attach the report to BF0022 Instrument not in Service form and the Variance Log if used.
   c. The supervisor will review the report and document on BF0022 Instrument not in Service form or the Variance Log
      i. The date when the repair is completed.
      ii. The supervisor will briefly describe what has been done or enter 'see separate report' in the corrective action space.
4. The Blood Bank supervisor will assess the equipment after repair if revalidation or recalibration is necessary.
   a. Revalidation or recalibration needed:
      i. The scope of the revalidation/recalibration will be based on the extend of the repair i.e. major vs minor or at the Medical Director's discretion.
      ii. The Blood Bank supervisor will review validation/calibration results and determine acceptability.
      iii. The Medical Director or designee will approve the validation/calibration results.
      iv. The Blood Bank supervisor will document release to service date.
      v. The Blood Bank supervisor will remove BF0022 Instrument not in Service form on the equipment.
   b. Revalidation or recalibration not needed:
      i. The Blood Bank supervisor will document release to service date.
      ii. The Blood Bank supervisor will remove BF0022 Instrument not in Service form on the equipment.

PROCEDURE NOTE(S)

A. The repair report will be filed in the Equipment Repair book.

REFERENCE:

A. AABB Standards for Blood Banks and Transfusion Services, current edition, Bethesda, MD.

Associated Documents:

External Documents

Associated Documents:

SFOFCD-0279 -- BF0022 Instrument Problem Log
SFOWI-0139 -- TQ-Equipment Calibration and Maintenance
SFOWI-0149 -- TQ-Process or Equipment Validation Protocol
SFOWI-0147 -- TQ-Process Control
SFOWI-0155 -- TQ-Unusual Occurrence Management

Click to Open an Associated Document

Documents Generated:

``Check As Applicable (X or NA)	Format History	New Format Requirements
	A document created before September 1, 2005 was written before the new document format template and electronic approving process were implemented. Documents were copied from another document database and pasted on the QSI Quality Management System in order to be included in the Kaiser Permanente San Francisco Laboratory electronic document control database.	This document will be re-written to conform to the new Kaiser Permanente San Francisco Laboratory document format template whenever this document is revised.
Comments:	Documents created after QSI implementation have been directly entered in the QSI environment.	

Document Revision History:

Revision: 10	**Date Created:** 10/02/2005 **Date of Last Revision:** 06/29/2018	**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	1/15/07
3	Approver	New Lab Director	7/31/07
4	Procedure	BB Supervisor should document if validation or QC is necessary or not and release to service date.	11/22/08
5	Approver	New Lab Director.	06/01/11
6	Approver	New Lab Director.	4/18/13
7	Approver	New BB Medical Director.	10/4/13
8	Whole procedure Procedure Notes Procedure A.4. Associated Documents	Replaced red Out of Order tag with BF0022 Instrument not in Service form. Deleted separate filing of Variance Log. Revised and reformatted. Added scope of validation and instructions for validation not needed. Added SFOWI-0147 and SFOWI-0149.	2/10/15
9	Approver	New CLIA Director.	12/29/16
10	Procedure A. Procedure A.2.e.	Added current practice of CLS placing service call to manufacturer or BioMed. Added revised language from 31st edition AABB Std 3.5.2 1) 'since the equipment was last known to be functioning .....'.	6/26/18

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM
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Second Approver's Signature

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Document History Section