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

Title:	**TQ-Unusual Occurrence Management**	**WI Number** SFOWI-0155 **Revision:** 13
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 capture, investigate and monitor unusual occurrences which include deviations, nonconformances and adverse events. This procedure applies to all events in which collection of information and analysis can result in process improvement, better patient care and increased safety, purity, potency, or efficacy of blood products.

EQUIPMENT

A. Variance Log
B. Responsible Reporting Form (RRF)
C. Biological Product Deviation Report Form
D. Internal Assessment Review Summary
E. External Assessment Review Summary
F. Quality Management Quarterly Report

CONTROLS

A. The Transfusion Service Supervisor will submit a quarterly QA report to the hospital Quality department.
B. The Asst. Lab Director will submit a quarterly Variance Log report to hospital Quality department.

PROCEDURE

A. **Type and Definitions of Occurrences**
   1. Minor errors are caught in-house and cause no risk to patient care.
   2. Incident is occurrence that could lead to serious consequences, which pose a real threat to patient care.
   3. Accident is unexpected or unplanned event not attributable to a human error.
   4. A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury.
   5. Deviation is a departure from the standard process, policy or procedures.

6. Variance is the difference/discrepancy between what is expected and what actually occurs.
7. A nonconformance is a failure to conform to standards, compliance and regulatory requirements.
8. An adverse event are defined by federal and state statutes and regulations, that which require external reporting to the CA Department of Public Health (CDPH) and FDA CBER.

B. **The Staff will:**

1. Detect and identify errors, nonconformances or unplanned deviation from cGMP and standard policy or procedure, usually attributable to human, reagents, equipment or system problems:
    a. quality control failure
    b. equipment failure e.g. storage temperature alarms, broken instruments
    c. contaminated reagents
    d. nonconforming blood and blood products e.g. bacterial contaminated, clotted, leaking, defaced, missing tags/labels/segments, not irradiated as required, etc.
    e. technical/clerical errors
    f. erroneous patient results
2. Report and document all unusual occurrences including nonconforming product/service on Variance Log in a timely manner
3. Self report errors using Variance Log
4. Participate in investigation of nonconforming occurrences and efforts aimed at prevention
5. Take immediate corrective action when necessary:
    a. repeat quality control and patient testing
    b. retrieve/quarantine/discard nonconforming blood products, supply, reagents and equipment
    c. error correction of test results
    d. call hotline for technical support or repair
    e. notify patient's physician and Medical Director
    f. notify blood supplier or manufacturer.

C. **The Transfusion Service Supervisor or designee will:**

1. Encourages staff to identify and report unusual occurrences
2. Review the unusual occurrence or variance
3. Investigate the occurrence and determine the root cause
4. Take immediate remedial action when necessary
5. Evaluate the risk level, either low, moderate or high
6. Determine the mechanism for reporting
7. Determine if tracking of occurrence is necessary
8. Implement long-term corrective or preventive action
9. Monitor and follow up corrective action
10. Periodically monitor for continued effectiveness by analysis and trending when needed
11. Present the unusual occurrence in the next staff meeting
12. Trains employees in cGMP and occurrence reporting.

D. **Assistant Lab Director will:**

1. Filed completed Variance Logs and and printed copy of eBPDR

2. Track and trend occurrences quarterly using Variance Logs and submit report to hospital Quality department
3.. Be responsible for corrective and any follow-up action in the absence of the Transfusion Service Supervisor.

E. **Transfusion Service Medical Director will:**

1. Review and approve corrective/preventive action plan
2. Evaluate clinical/safety impact of inaccurate test results and nonconforming blood product on patient
3. Provide consultation to physicians when needed.

F. **Management of Nonconformances discovered on site**

1. Nonconforming blood, blood products, critical materials, will be quarantine immediately upon discovery and evaluated.
2. Dispensed unused nonconforming blood products will be retrieved and quarantined upon discovery.
3. Nonconforming test results will be evaluated upon discovery and corrected immediately when indicated.
4. Patient impact assessment will be performed when indicated i.e. repeat testing, physician notification.
5. If the nonconformance is found to be acceptable after investigation, donor units will be released to inventory.
6. Unacceptable unused nonconforming donor units and critical materials:
   a. will be returned e.g. recall, blood related DD units not irradiated, missing tags/labels/segments or damaged face label

      OR

   b. will be destroyed e.g. leaking, broken, hemolyzed or contaminated.

G. **Reporting and Documentation**

NOTE: All unusual occurrences will be documented on Variance Log including the investigation findings, corrective action and follow up.

1. Minor errors will be written and tracked on the internal Variance Log.
2. Incident will be filed using Responsible Reporting Form (RRF) in addition to the Variance Log.
   a. Also verbally report serious incident or adverse/sentinel event immediately to the Supervisor, Assistant Laboratory Director, the Transfusion Service Medical Director and the CLIA Director.
   b. Hemolytic Transfusion Reaction and any adverse reaction that are confirmed to be fatal will also be reported using hospital policy, 'Sentinel, Significant, and Other Event Management' procedure (SF RISK-19-05), to the FDA CBER (see Procedure Notes A.) and to the Ca State Department of Public Health (CDPH). Also see SFOWI-0120, 'Transfusion Reaction Workup' and SFOWI-0121, 'Delayed Transfusion Reaction'.
   c. Blood Supplier will be notified immediately and in writing subsequently in cases of transfusion reaction caused by bacterial contamination, TRALI, infectious diseases or an attribute of the donor. Also refer to SFOWI-0050, 'Transfusion-Transmitted Diseases', SFOWI-0051, 'Lookback Notification' SOPs and SFOWI-0120, 'Transfusion Reaction Workup'.
   d. Biological Product Deviation will also be reported to the FDA CBER. **NOTE:** If the error/accident or equipment failure affects the identity,

safety, purity or potency and any blood products a Biological Product Deviation Report must be completed and sent to the FDA within 45 calendar days. See SFOWI-0156, 'Biological Product Deviation Reporting' SOP.

e. Incidents determined to be caused by nonconforming materials, reagents and equipment will also be reported to the respective manufacturers for further investigation.

3. Accident will be reported using the Variance Log and/or Responsible Reporting Form depending on the severity. Follow the same instructions above for incident reporting when applicable.

4. **Fatality Reporting**

a. Section 606.170(b) of Title 21, Code of Federal Regulations (21 CFR 606.170(b)), requires that facilities **notify** the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ), **as soon as possible after confirming a complication of transfusion to be fatal**.

b. Refer to SFOWI-0120 Transfusion Reaction Workup for FDA CBER contact information.

H. **Upon receipt of notification from supplier**, **customers, or other outside agency regarding nonconforming products or services:**

1. Supervisor or designee will immediately quarantine, evaluate and determine disposition of nonconforming blood, components, reagents, test results and critical materials.
2. The same reporting process as outlined in section above will be followed.
3. When determine to be appropriate, the supervisor releases nonconforming blood, components, reagents, test results and critical materials with the Medical Director's approval.
4. Document the discard or acceptance for use of nonconforming products or services on the Variance Log or Notification Letter from blood supplier or manufacturer.
5. For bacterial contamination of blood products or infectious disease lookback, refer to SFOWI-0050, 'Transfusion-Transmitted Diseases' and SFOWI-0051, 'Lookback Notification' SOP.
6. For blood products, document in Excel Worksheet titled 'Current Positive Donor Testing' and filed the notification letter in the Lookback binder.
7. When a nonconforming blood or component is issued for transfusion where quality may have been affected, inform the patient's attending physician as well as the Medical Director.

I. **Investigation, Follow-up and Patient Impact Assessment**

1. **Perform when any of the following occurs:**

a. Unacceptable QC performance is identified after patient results were released.

b. Unacceptable instrument function check(s) affecting test performance is identified after patient results were released.

c. Equipment malfunctions or reagent problems that are determined to effect the accuracy of test results or the safety of blood products.

d. Components that are determined after release not to conform to specified requirements.

e. Unacceptable Proficiency Testing performance (80% or lower) due to

analytical error.

f. Unacceptable instrument correlation with significant discrepancy observed between two instruments.
g. Pre and post analytical errors that affect test accuracy.
h. Manufacturers' errors, such as product recalls and product correction.
i. Erroneous patient results verified due to technical or clerical error.
j. Erroneous patient results verified due to patient mis-identification.

2. **Investigation and corrective action**
   a. Identify root cause of the unacceptable variance.
   b. Take appropriate corrective action(s) to ensure deficient practice does not recur.
   c. Assess and determine the tests and/or products that may be affected since the equipment was last known to be functioning per manufacturer's written instructions, or facility-defined specifications.
   d. Retrieve/quarantine/discard nonconforming blood products, supply and reagents.
   e. Suspend the use of faulty equipment.
   f. Repeat patient testing if samples are still available and are within the stability period.
   g. Correct patient results immediately when indicated e.g. mis-identification, technical/clerical error, and document provider notification.
   h Inform the patient's attending physician and the Medical Director of transfused nonconforming blood product.
   i. Report equipment malfunctions and reagent problems to manufacturer when indicated.
   j. Requalify equipment after repair and before use.
3. **Patient impact assessment**
   a. Perform and document patient impact assessment as soon as problems/errors are identified.
   b. When samples are no longer available for repeat testing, a determination is made by the Transfusion Service Medical Director on the clinical impact of the inaccurate results reported during the affected period.
      i) Patient history check:
         Obtain patient results stored in the instrument, if still available.
         Check LIS for previous results and other related test results.
      ii) For qualitative test, request reports showing % positive finding during the affected period vs. % positive finding of an unaffected period.
   c. Medical Director will evaluate the effect of the nonconforming blood product on patient safety.
   d. Medical Director will review patient's chart if necessary.
4. **Follow up actions**
   a. If negative patient impact is identified, consult with the Medical Director on the appropriate course of action:
      i) Error correction of test results
      ii) Provider notification
      iii) Patient recall etc.
   b. If the patient impact is of moderate to high magnitude, hospital Risk management will be informed.

J. **Variance Log**

1. Variance Log is used to document and track all unusual occurrences including incidence, accident, error, deviation, nonconformance, and complaint that involves product, service, procedure, policy, process, quality control etc.
2. The Assistant Laboratory Director assigns a code to the error or occurrence and enters them on Transfusion Service Variance Log Indicator Form. These will be presented to the Medical Director and the hospital QA department quarterly.
3. The error categories are:
    a. Inadequate/barrier communication (COMM)
    b. S.O.P. not followed (SOP)
    c. Equipment limitations/malfunction/missing calibration or maintenance (EQIP)
    d. Defective/contaminated material and control/reagent (REAG)
    e. Mislabeled recipient sample/requisition (MISR)
    f. Mislabeled blood products (MISB)
    g. Unacceptable storage/transport condition (STOR)
    h. Fail to notify/quarantine nonconforming units (QUAR)
    i. Incorrect/missing testing/reaction strength/reaction result in computer (INCR)
    j. Incorrect selection of blood components (INCB)
    k. Incorrect issue of blood products (INCI)
    l. Special needs not met (SPEC)
    m. Clerical errors (CLER)
        i) Wrong procedure or component code
        ii) Wrong unit status/data entry
        iii) Wrong/no unit details/report
        iv) Wrong/missing patient data/testing results/tech ID
    n. Patient Transfusion HX in CIPS not checked (HIST)
    o. Double Check Policy not followed (DBCK)
    p. TAT not met (TAT)
    q. Misfiled/lost requisition/specimen/product (MISF)

REFERENCE

A. AABB Technical Manual, current edition, Bethesda, MD.
B. AABB Standards for Blood Banks and Transfusion Services, current edition, Bethesda, MD.
C. AABB Association Bulletin, #97-4.
D. CFR-21, Parts 600 - 799.

Associated Documents:

External Documents

Associated Quality System Documents - None

Documents Generated:

Document Revision History:

Revision: 13	**Date Created:** 10/02/2005 **Date of Last Revision:** 05/06/2019	**Last Approval Date:** 10/30/2017

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Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	Approver	New Director	1/15/07
3	Approver	New Lab Director	7/31/07
4	Procedure; Procedure Notes	Add patient impact assessment; Add release of nonconforming blood,	11/22/08
5	Procedure	Changed UOR to RRF	4/29/10
6	Approver	New Lab Director	6/1/2011
7	Procedure	Delete LURS report	11/13/2011
8	Whole document Procedure A. Procedure Note B. Procedure B.4. & 5., D, E, F.2.e., G.5. Associated Documents Procedure Notes	Reformatted and consolidated sections. New section. Changed to Procedure F.2.d. New. Added 8 SOPs. Updated FDA email and address.	10/12/2012
9	Approver Procedure F. Procedure I.1.h & i Procedure I.2.d. Procedure B.1.a - f, 5.a - f Procedure Notes	New BB Medical Director. New section. New. Added erroneous patient results. New. Added when to correct results immediately. New. Listed out examples. Moved Fatality Reporting to Reporting and Documentation section. Updated FDA contact information.	10/2/13
10	Procedure G.4.b.	Revised FDA CBER information as reference to SFOWI-0120.	9/12/14
11	Procedure B.2. Procedure B.5.f. Procedure F.6.a. Procedure F.6.b. Procedure H.4. Procedure J. Approver	Added to document nonconforming product/service on Variance Log. Added to notify manufacturer of nonconforming materials. Added return of recalled product/material. Added discard of hemolyzed product/material. Replaced Supplier Notification binder with Variance Log or Notification Letter from blood supplier or manufacturer. Reformatted. Added use of Variance Log to document and track all occurrences. New CLIA Director.	10/25/16
12	E.2., I.2.e. and I.3.c.	Specified nonconforming blood product.	10/20/17
13	Procedure I.1.c. Procedure I.2.c.i.& j. Procedure I.2.e. Approver	New. Added revised language from 31st edition AABB Std 3.5.2. Added as per current practice. New CLIA Director and new TS Medical Director.	4/24/19

Notification List:

Approvals:

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Document History Section