TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	3/30/2015
Department:	All Staff	**Due Date:**	4/30/2015
		Implementation:	**4/1/2015**

DESCRIPTION OF PROCEDURE

Name of procedure:

Quality Variance Forms GEC /SGAH/ WAH.QA22 v3

Quality Variance Form, Laboratory AG.F14.2
Laboratory Quality Variance Tool AG.F322.0

Description of change(s):

Lab QV form:

Update RQI criteria on page 2 to match new RQI SOP
Move Supervisor action documentation to page 2
Update severity levels
Add CPOE issue (under Ordering) and Quality Concern section
Forms will be color coded by site: SG/GEC = pink; WAH = purple

SOP:

Section 4: remove reference to Nursing Manual
Section 5: update severity classifications,
insert specific job function for recording on QV form,
add requirement to collect tech initials and date upon receipt of QV notification or document phone discussion
Section 6: add tool, update RQI SOP title

QV Tool:

This is a new 'form' to show the usual flow of QV forms

Note: The BB QV form is also revised but a separate update has already been issued to BB staff. Those will also be color coded: SG BB = blue; WAH BB = yellow

The SOP and Forms will be implemented on April 1, 2015

Document your compliance with this training update by taking the quiz in the MTS system.

Quality Variance Form

☐ GEC
☐ SGAH
☐ WAH

Occurrence Date: __ __/ __ __ /__ __ __ __

Patient name (affix label if available): _____ _____MR#_____
(L Name) *(F Name)*

Accession #: _____ Test Code: _____ Patient location: _____

A. Description of Variance: (*Check the appropriate box below and attach* available *ANIQ* documentation)

Ordering
- ☐ CPOE issue
- ☐ Incorrect test ordered by lab
- ☐ Incorrect test ordered by nursing
- ☐ Ordered on wrong visit/FIN by nursing
- ☐ Ordered on wrong visit/FIN by lab
- ☐ Other (explain on reverse)
- ☐ Test ordered on wrong patient by lab
- ☐ Test ordered on wrong patient by nursing
- ☐ Test ordered with wrong priority code
- ☐ Test was on requisition but not ordered by lab

Maintenance/Temperature/QC
- ☐ Lot to Lot crosscheck not performed
- ☐ QC failure, no look back
- ☐ QC not documented
- ☐ Temp/Humidity out of range, action not documented
- ☐ Temp/ Humidity not recorded
- ☐ Centrifuge maintenance not performed
- ☐ Maintenance not reviewed or documented
- ☐ Control lot # not in system

Comments: (use space back on back of form)

Before Testing and Specimen
- ☐ Clotted
- ☐ Delivery problem with pneum tube
- ☐ FES not performed
- ☐ Handled Improperly
- ☐ Hemolyzed
- ☐ Inappropriate container/specimen
- ☐ Incomplete info on requisition
- ☐ Incorrect patient drawn by Lab = RQI
- ☐ Incorrect patient drawn by Nursing
- ☐ Incorrect specimen for requested test
- ☐ Leaked or spilled specimen
- ☐ Lost specimen = RQI if Irreplaceable
- ☐ Mislabeled (Lab) = RQI
- ☐ Mislabeled (Nursing)
- ☐ No order received
- ☐ Information on requisition and specimen don't match
- ☐ QNS
- ☐ Specimen not received in LIS
- ☐ TAT delay in receipt or collection
- ☐ Unlabeled = RQI if collected by Lab
- ☐ Urine C&S not plated; not performed 1st
- ☐ Urine >2 hours; Run at physician request

During Testing
- ☐ Delta failure not investigated
- ☐ Dilution error
- ☐ Failure to follow SOP
- ☐ Instrument error: _____
- ☐ Interpretation error
- ☐ Other (explain on reverse)
- ☐ Results suggest contamination
- ☐ Wrong patient tested
- ☐ Wrong sample tested

Resulting/Reporting
- ☐ Clerical error
- ☐ Critical value not called
- ☐ Key stroke error
- ☐ Other (explain on reverse)
- ☐ Results entered on wrong patient - lab
- ☐ Results entered on wrong patient - nursing
- ☐ TAT complaint (after receipt)
- ☐ TAT Reference Lab Results to LIS

Quality Concerns
- ☐ Tech Quality Concern
- ☐ Manufacture Recall
- ☐ Customer Complaint

Assessment and Actions taken: check the appropriate box below and/or describe actions taken

If this is an RQI *(See reverse)*, reported to: _____Date: _____ RQI # _____

☐ Corrected report issued **(Attach a hard copy of the corrected report)**

☐ Specimen rejected, test canceled and called Redrawn? ☐ Y ☐ N ☐ Unknown

☐ Test credited ☐ Other *(explain on reverse)*

Reported by (**Your Tech Code**) _____ Notified: (Group Lead/TIC) **tech code/initials** _____ (date/time) _____

(Notified must record their Tech Code to this form AND initials)

B. Supervisor Action and Recommendation: (*document all follow-up actions taken on reverse*) (*Tracking*) Tech code:_____
No lab involvement (√)_____

C. Level of severity
☐ No patient impact ☐ Minor impact ☐ Major impact

D. Follow-Up: Hospital Incident Report # _____ Date: _____

E. Signatures (Sign/Initial and date)

Supervisor: _____ Medical Director: _____

QA Specialist: _____ Operations Director: _____

CONFIDENTIAL **Case #** _____

Quest Diagnostics	Quality Variance Form	☐ GEC ☐ SGAH ☐ WAH

Laboratory RQI (Reportable Quality Issues)
Any FDA reportable event
Five or more revised reports attributable to a single event, includes product/reagent recalls, local LIS issues and referral laboratory issues.
Any revised report where a test result was changed To a Critical Value OR from a Critical Value
Any revised report that causes a change in patient treatment:
Any revised result for Blood Bank testing including but not limited to ABO group, Rh type, atypical antibody screen/identification, DAT, RBC antigen typing
Any Significant Procedural Delay resulting in known or potential impact to patient care (treatment or discharge) including: ▪ Specimen collection delay (by laboratory staff) ▪ Result reporting delay (excessive TAT) ▪ Critical value notification delay ▪ Inability to provide timely blood products during an emergent event
Any Significant Specimen Collection issue (by laboratory staff) causing physical or psychological harm to the patient
Irreparable loss* of • specimens from 5 or more patients attributable to a single event • a single (or more) irreplaceable** specimen (or loss of requisitions rendering specimens useless) • any single mislabeled specimen or aliquot submitted for testing that was collected or labeled by laboratory staff • any single unlabeled specimen or aliquot submitted for testing that was collected by laboratory staff
Any issue or event judged by a Pathologist or the CLIA Laboratory Director to have known or potential impact on current patient care
A variation or deviation from the local Hospital Policy and Procedure that has known or potential impact on current patient care.

*specimen is damaged, mishandled or lost while in the laboratory's possession or during transport and therefore cannot be tested.
** body fluids, CSF, Stone analysis, Product of Conception (POC) for chromosome analysis, All bone marrow specimens, Lavages, washings and brushings, Cord blood, Meconium for drug testing

For RQI - Notify a Supervisor immediately and document on the front of the form

Use these lines for additional information or to document Tech Quality Concerns:

_____

_____

_____

_____

_____

_____

_____

_____

Supervisor Action and Recommendation:

_____

_____

_____

_____

_____

CONFIDENTIAL **Case #** _____

Approved draft for training (version 3)

Non-Technical SOP

Title	**Quality Variance Forms**	
Prepared by	Leslie Barrett	Date: 7/21/2009
Owner	Cynthia Bowman-Gholston	Date: 7/21/2009

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

To provide procedural guidelines for documentation of laboratory issues/incidents that may affect the quality of patient care. The Quality Variance (QV) form provides a framework for staff reporting, supervisory evaluation and corrective action, and QA tracking and trending of laboratory issues.

2. SCOPE

This procedure applies to all laboratory personnel

3. RESPONSIBILITY

All laboratory staff participates in reporting, recording, and investigating incidents or events as appropriate.
The Senior QA Specialist or designee is responsible for content and review of this procedure.

4. DEFINITIONS

These variances/occurrences must be reported as Quality Variances:

1. Any incident that generates inaccurate or delayed beyond accepted standards test results.

2. Any incident in which the collection of specimens or recollection of unreceived or received specimens is outside accepted standards as defined in the Laboratory policy and section-specific procedure manuals.

3. Any patient identification errors, including specimen labeling and Blood Bank or Hospital armband errors.

4. Any delayed or non-notified critical values.

5. Any incident, which requires reporting to hospital Quality Assurance/Risk Management, defined as: "Any occurrence, accident or event that is not consistent with normal patient care or the routine safe operation of the hospital".

6. Any service complaint registered by any staff member from a customer (patient, physician, pathologist, nurse, technician, etc.).

7. Any staff/employee concerns or complaints that reflect concern about quality of patient testing and safety.

8. Any Blood Bank variance that qualifies as an FDA reportable event. Refer to specific procedures in the Blood Bank Quality Plan.

9. Any other incidents designated by the Laboratory Performance Improvement Committee (LPIC).

5. PROCEDURE

1. The person responsible for the error or any person aware of the incident will generate a Quality Variance Form.

2. There are two versions of Quality Variance form. (See Related Documents)
   - One is used to document issues relating to all areas of the Laboratory.
   - The other is specific to Blood Bank events and occurrences.

3. Documentation should be legible (preferably printed), contain only factual information and objective comments, and be complete. Do not include opinions or personal judgments in the report. Written entries may be continued on the back of the form.

4. The following information is required:
   a. Site
   b. Occurrence information:
      - occurrence date
      - patient name and medical record number, when the incident involves a patient
      - location
      - accession number
      - test, QC or maintenance documentation
      - select the appropriate variance description from the list, providing additional information in comment space or on reverse side as needed
      - assess the incident to determine if it qualifies as an Reportable Quality Issue (RQI), refer to reverse side of form – **if yes, complete the notification section**
      - indicate corrective action taken, i.e. corrected report, notified caregiver, etc.
      - tech code of person reporting and notification information

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- Physician name is required, only if the issue involves a physician complaint or dispute.

5. Supervisory Documentation:

   a. Quality variance forms must include Supervisor Action and Recommendation as appropriate. The Supervisor or designee, QA Specialist, Administrative Laboratory Director or Medical Director may complete this section.

   b. Any corrective action(s) to be taken must be followed-up and documented by QA Specialist as follows:
      - Log the events into the event database
      - Attach a copy of the follow-up action to the original Quality Variance form if action was documented. Documentation examples are memos, meeting minutes, etc.
      - If future follow-up will occur, enter the internal follow-up date and free text comment into the database.
      - Attach written documentation (if applicable) of the action taken and completion date to the Quality Variance form.
      - When available, attach a copy of the LIS documentation report from LIS function ANIQ by accession number.

6. The Supervisor, Group Lead, or tech-in-charge will notify the pathologist or on-call pathologist for the following events (24 hours/day, 7 days/week):
   - any event as specified in the hospital policy Significant Event Reporting and Analyzing
   - any other event causing severe harm or death to a patient
   - any immediate hemolytic transfusion reaction, or mistake resulting in a near-miss incident in the Blood Bank
   - any event with significant impact on patient care such that pathologist intervention or follow up with physician is required immediately
   - any severe dispute with a physician

7. Perform an overall assessment to summarize and review errors/incident reports (performed and reported at the quarterly LPIC meetings). This review is utilized to identify trends and initiate corrective and/or preventive actions.

8. The section Supervisor, Administrative Director, Medical Director or designee may review Quality Variance forms.

9. All variances will be categorized to indicate severity as follows:

   No patient impact
   Minor impact = Redraw / recollection of specimen, treatment delay, rework, patient inconvenience
   Major impact = Therapy required, increased LOS, change in participation in study, potential for serious injury, or more significant outcome

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10. Blood Bank Quality Variances that reflect patient-significant variances are sent directly to the Medical Director or designee by the section supervisor. This fast track mechanism ensures timely intervention in areas in which either specimens are irreplaceable, or the incident occurs in an especially high risk section, or both. The pathologist will document any intervention taken. The form is then forwarded to the appropriate reviewers.

11. If follow-up outside the laboratory is required, the event is reported electronically on the Adventist Hospital Intranet.

    a. Document occurrence date, time and location.
    b. Document event type.
    c. Document patient and/or employee involved or affected.
    d. Provide a brief, concise summary of the problem.
    e. Once submitted, the event is reviewed by Risk Management and referred to the appropriate manager/supervisor for follow-up.
    f. Document the follow-up information, including the tracking number, on the Quality Variance form.

12. When appropriate, Quality Variance forms are discussed with the employee involved to prevent recurrence of the incident/accident. If a laboratory employee error is involved, the section supervisor will document notification of the employee involved on the Quality Variance form, and the employee will date and initial the form to acknowledge receipt of the notification. If employee notification occurs via telephone, the supervisor will document the date and time of the discussion.

13. Completed, signed Quality Variance forms, with corrective measures, notifications and follow-ups attached, are kept in a site-specific area for a period of two (2) years. Blood Bank Quality Variance forms are retained for five (5) years. These files will be under the guidance of QA/Risk Management.

6. RELATED DOCUMENTS

Quality Management (QM) Plan, QA procedure
PI (Performance Improvement) Database, QA procedure
Hospital Notification Process for Reportable Quality Issues, QA procedure
Quality Variance Form, Laboratory (AG.F14)
Quality Variance Form, Blood Bank (AG.F15)
Laboratory Quality Variance Tool (AG.F322)

7. REFERENCES

N/A

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8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA202.01		
000	4/18/2012	Sections 1,4,5,9: Update PI variance to Quality Variance form Section 5: Item 4.b updated to match form Section 6: update titles, add RQI SOP Section 9: revised forms attached	L Barrett C Bowman-Gholston	C Bowman-Gholston
001	5/28/2014	Section 3: change QA supervisor to Senior QA Specialist or designee Section 5: change LPIC reporting to quarterly; specify who must notify pathologist Section 6: add forms Section 9: revise addenda A to match current practice; move forms to section 6 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	C. Bowman-Gholston	C. Bowman-Gholston
2	3/16/2015	Section 4: remove reference to Nursing Manual Section 5: update severity classifications, insert specific job function for recording on QV form, add requirement to collect tech initials and date upon receipt of QV notification or document phone discussion Section 6: add tool, update RQI SOP title Section 9: remove flowchart	C. Bowman-Gholston	C. Bowman-Gholson

9. ADDENDA AND APPENDICES

None

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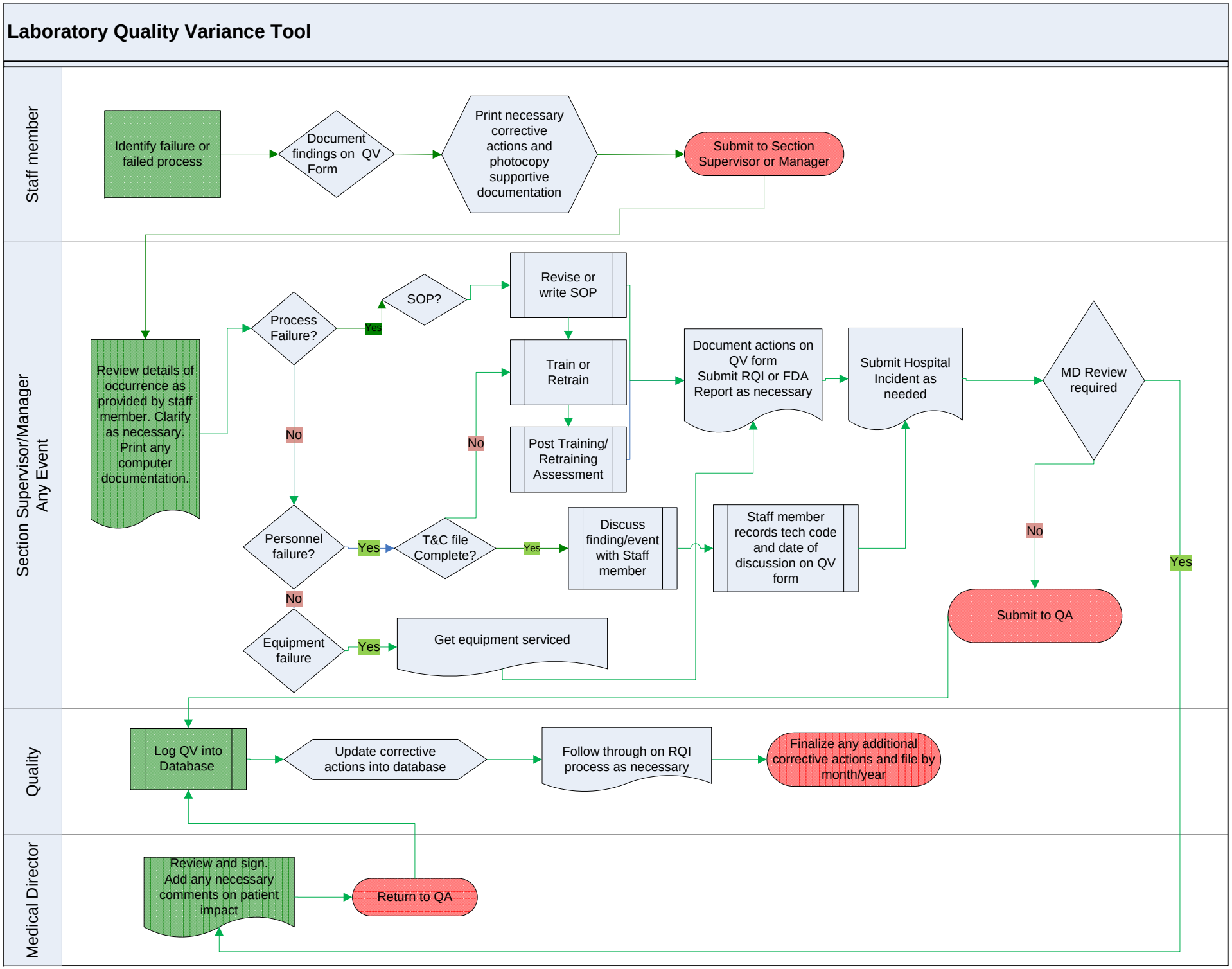
Laboratory Quality Variance Tool



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