TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	6/2/2014
Department:	All staff	**Due Date:**	6/30/2014
		Implementation	**7/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Quality Variance Forms GEC/SGAH/WAH. QA22 v2
Description of change(s):
Minor revisions to make the SOP match our actual practice. **Note in section 5 step 6**, SOP now specifies who is responsible to notify a pathologist. The events that require notification have **NOT** changed. This revised SOP will be implemented July 1, 2014

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

Approved draft for training

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**

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1. PURPOSE

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

The following list of variances/occurrences requires reporting as Quality Variances:

1. Any incident that generates inaccurate or delayed beyond accepted standards (turn-around-times as defined in the Nursing Laboratory Manual) 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-notification of 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 (refer to flowchart, attachment A).

2. There are two versions of Quality Variance form. (Refer to attachments B and C)
   - 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

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- tech code of person reporting and notification information
- Physician name is required, only if the issue involves a physician complaint or dispute.

c. 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.

d. Any further corrective action(s) to be taken must be followed-up and documented by QA Specialist as follows:
   - 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 follow-up will occur at a future date, enter the internal follow-up date and free text comment in the database.
   - Attach written documentation (if applicable) of the action taken and completion date to the Quality Variance form.

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

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

8. All variances will be categorized by a numerical level. Definitions are:

   Level 1: Did not reach patient/involve patient.

   Level 2: Event occurred - no patient harm.

   Level 3: No redraw/recollection of specimen. Specimen recollection decision made by nursing staff or physician, or patient refused recollection.

   Level 4: Redraw/recollection of specimen

Level 5: Therapy required, or increased LOS, or change in participation in study, or potential for serious injury

Level 6: Permanent injury or organ system failure

Level 7: Death.

9. 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.

10. 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.

11. 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.

12. 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. File confidentiality will be maintained at all times. Release or review of information from those 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
Process for Notification of Reportable Quality Issues, QA procedure
Quality Variance Form, Laboratory (AG.F14)
Quality Variance Form, Blood Bank (AG.F15)

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7. REFERENCES

N/A

8. REVISION HISTORY

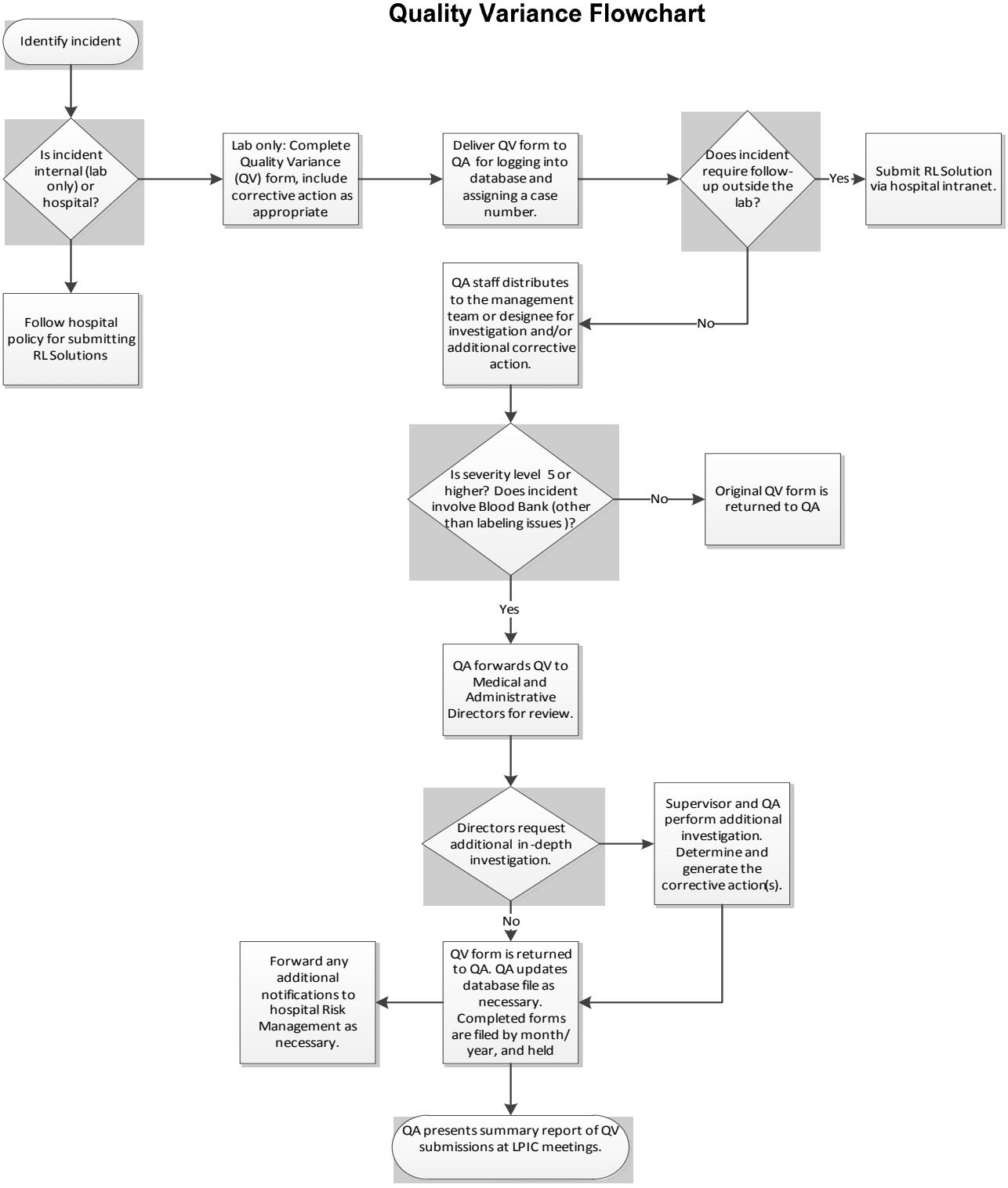
Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA202.01		
000	4/18/2012	Sections 1,4,5,9: Update PI variance to Quality Variance form Section 5: Item 4.b updated to match form Section 6: update titles, add RQI SOP Section 9: revised forms attached	L Barrett C Bowman-Gholston	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

9. ADDENDA AND APPENDICES

A: Quality Variance Flowchart

Addenda A

Quality Variance Flowchart



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