TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	5/11/2014
Department:	All Staff	**Due Date:**	5/31/2014
		Implementation:	**6/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Management of Vendor Notifications **GEC / SGAH / WAH. QA43 v1**
Description of change(s):
All lab employees must be aware that any letters or faxes about a recall, defect or other product issues are to be given to QA This revised SOP will be implemented on June 1, 2014

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

Approved draft for training all sites (version 1)

Non-Technical SOP

Title	**Management of Vendor Notifications**	
Prepared by	Amanda Engles/Rachel Strother	Date: 9/26/2011
Owner	Cynthia Bowman-Gholston	Date: 4/24/2012

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

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1. PURPOSE

The purpose of this policy is to establish a process to further notify end users and manage notifications (including recalls, defects, or general issues) from vendors for their products (hard or soft) that may affect patient care.

2. SCOPE

This procedure applies to all laboratory personnel.

3. RESPONSIBILITY

1. The Quality Assurance (QA) department is responsible for:
   a. The maintenance and periodic review of this SOP
   b. The maintenance and retention of any notification documentation and any resolutions and/or responses.
   c. Assisting the medical director with preparation of any physician recall letters

2. It is the responsibility of the department directors, managers, supervisors and Group Leads
   a. To forward vendor notifications to the QA department
   b. To act on any vendor required response through the QA department

4. DEFINITIONS

Notifications – Documents that may take the form of product recalls, market withdrawals, or software patches and upgrades. Notifications can come directly from the manufacturer or as a corporate correspondence.

RASMAS – A web-based database community of 17,000 United States and Canadian healthcare professionals to track manufacturer recalls.

5. PROCEDURE

Mail Notifications

1. Should vendor notifications arrive in the affected department, the department will forward them to the Quality Assurance department.

2. If the notifications are initially received by the QA department, they will be photocopied and forwarded to the appropriate testing department. QA will file the copy in the designated location.

3. The QA specialist works with department designee to investigate purchased products within 48 hours.

4. The QA specialist will return the completed documentation response to the manufacturer and file all paperwork.

5. The Quality Assurance staff will collaborate with the department and the medical director, with any patient-centered corrective actions, in response to the notification as necessary. Corrective action may include but is not limited to physician (client) notification, alternate testing sites (test referred out), alternate test methodologies (different kit or instrument), etc.

RASMAS Notifications

1. The subscribing hospitals have designated RASMAS managers who identify the responders within the system. These designees control the alerts for specific departments and are e-mail recipients for the notifications.

2. Each designee will establish their username and password.

3. The primary recipient can designate backup responders, who will also receive the notifications. In our lab, the primary and backup responders are QA specialists.

4. Each notification arrives with a 72 hour response due date. The responder logs into the site: http://info.rasmas.noblis.org/ and clicks the link for ‘My work’, which indicates the number of alerts on the banner with a green (in-date) light or a red (overdue) indicator.

5. All laboratory associated recall notices will appear on the list, designated as either routine or escalated notices (backlit in buff). All escalated notices require the responder to indicate that the notice was read, prior to closing the coordination and they must be closed one at a time.

6. Any alert that does not have a response within the 72 hours will be considered overdue.

7. If all notices are routine, the responder can click a box and simultaneously close all, using one explanation, such as, 'Product not purchased.'

8. If the recall is for a purchased product, the responder will print the recall notice and work with the department designee to verify the product status, i.e. 'lot not received.'

9. Once the recall has been processed, the responder closes the RASMUS alert with the appropriate explanation or action. All supportive documentation will be returned to the QA department for final filing.

6. RELATED DOCUMENTS

- QDMED708 – Process for Notification of Reportable Quality Issues
- QDMED706 – Guidelines for Communication of Medical Quality Events to Corporate Personnel
- QDCMQ700 – Process for Complying with FDA Regulations Requiring Device User Facilities to Report MDR Reportable Events (Medical Device Reporting)

7. REFERENCES

College of American Pathologists (CAP) Checklist

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	4/8/14	Section 3: Inserted assisting with preparation of recall letters, add Group Leads Section 4: added RASMUS Section 5: Removed requirement to notify Chantilly QA of recalls. Update investigation and response process. Removed filing specifications. Inserted medical director collaboration for patient-centered corrective actions. Added steps for processing the RASMAS notifications.	C. Bowman L. Barrett L. Loffredo	C. Bowman

9. ADDENDA AND APPENDICES

N/A