TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	11/6/2014
Department:	QA & Mgmt	**Due Date:**	11/30/2014
		Implementation:	**12/1/2014**

DESCRIPTION OF PROCEDURE

Name of procedure:
Inspection Responses GEC.QA228, SGAH.QA891, WAH.QA890 v0
Description of change(s):
New SOP that describes the process for preparing responses to inspection deficiencies This SOP will be implemented on December 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	**Inspection Responses**	
Prepared by	Leslie Barrett	Date: 10/23/2014
Owner	Cynthia Bowman-Gholston	Date: 10/23/2014

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

This procedure describes the process to prepare and submit responses after an inspection by an outside regulatory facility.

2. SCOPE

This procedure applies to inspection responses for an outside regulatory facility. It does not apply to inspections performed by NQA/CQA.

3. RESPONSIBILITY

All laboratory management and quality assurance (QA) personnel must have knowledge of and comply with this procedure.

4. DEFINITIONS

QD – Quest Diagnostics
ADV – Adventist Healthcare
CAP – College of American Pathologists

5. PROCEDURE

A. Preparation of Draft Responses

1. The inspectors' observations are documented as deficiencies, non-conformances and / or recommendations. These findings are provided at the summation meeting.

2. All findings are transcribed onto a summary spreadsheet which is saved on the shared drive in a folder labeled for the agency and year. For example: G:\AHC_Lab\Quality Assurance\Regulatory Compliance\Inspections\CAP 2014
    a. The spreadsheet contains the following elements

- Checklist item and phase
- Checklist question / statement
- Inspector Comment/Observation
- Corrective action
- Attachments
- Due date
- Responsible person(s)

b. Separate tabs are created for deficiencies for each laboratory site and each parent facility (QD or ADV, as appropriate)
c. A separate tab is maintained for recommendations for ALL sites

3. A timeline for corrective actions is established based upon the regulatory agency's due date.

4. Corrective action for each deficiency is determined by the section manager or supervisor. Actions may include creating or revising a procedure, staff training administering a competency, etc. Other laboratory leaders and/or the QA team may serve as resources for determining appropriate corrective action.

5. The manager or supervisor documents the planned action on the regulatory agency's response form.
   a. Any supportive documentation is listed as attachment(s). Refer to the regulatory agency's instructions to determine when documentation is required.
   b. Draft response forms are submitted to the designated QA specialist by the assigned due date.

6. The designated QA specialist
   a. Reviews draft responses and recommends edits as needed
   b. Saves draft responses in separate facility / site folders on the shared drive
   c. Transcribes corrective action onto the summary spreadsheet
   d. Tracks all responses to ensure deadlines are met
   e. Emails draft response forms and the summary to the Medical Director by the due date.

7. The Medical Director will approve or reject responses. If rejected, the manager or supervisor must make the necessary corrections and re-submit the response form. This process is coordinated by the designated QA specialist.

8. The manager or supervisor is responsible for submitting all required supporting documentation prior to the due date.

9. If a decision is made to challenge a deficiency, clearly state that on the response sheet, and explain the reason for the challenge. Attach required documentation supporting the claim that your laboratory was in compliance prior to the inspection, including records of ongoing implementation dated prior to the inspection. Supporting documentation is required for both phase I and II deficiencies.

B. Final Response Preparation

1. Add checklist item number, facility and attachment number to the first page of each attachment
2. If the same supporting documentation will be used for multiple responses, a copy must be attached to each deficiency.
3. For QD procedures add “Proprietary” to the top of the cover page

C. Submission Process

1. Prepare a deficiency response signature page for each facility / site and obtain medical director’s signature, if applicable.
2. Create a PDF file of each document
3. Compile a single PDF file of all documents for each facility / site. File size must be compressed.
4. Submit by email

D. Request for Additional Information

1. If regulatory agency asks for clarification or rejects, take the issue back to the Medical Director for discussion/action.
2. Respond to the regulatory agency as appropriate.

E. Completion Process
1. When corrective action is finished, the spreadsheet is updated with completion dates.

6. RELATED DOCUMENTS
None

7. REFERENCES
N/A

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES
None