TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/1/2016
Department:	All staff	**Due Date:**	7/25/2016
		Implementation:	**7/25/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Hospital Notification Process for Reportable Quality Issues GEC / SGAH / WAH. QDHOS708v2.1

Description of change(s):

These changes only affect management team but it is essential that all staff periodically review the RQI process

Section	Description
1	Added "Quest Diagnostics Medical Quality Department" Clarified RQI identification and submission with regard to employee performance.
3	Added "optional" to documentation of monitoring in the Local QA Manager's responsibilities.
6A	Revised wording to indicate reporting to the Quest Diagnostics Medical Quality Department instead of CQA.
6C	Revised required RQI reporting Phases. Added mandatory fields for Phase 1 (Describe/Investigate) reporting when all details are not known. Changed Phase 2(Corrective Action/Improvement) reporting timeline to 21 days. Changed Phase 3 (Monitoring) and 4 (Follow Up) to optional reporting.
6B	Add local numbering

This revised SOP will be implemented on July 25, 2016

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

The quiz covers how to identify and report RQIs so read those sections of SOP carefully.

Non-Technical SOP **Approved draft for training**

Title	**Hospital Notification Process for Reportable Quality Issues**
Prepared by	CQA Hospital Team **Date:** 2/4/2015

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

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	**Corporate Issue Date:**	
Print Name and Title	**Signature**	**Date**
Dianne Zorka, O**wner** **Director, Corp Quality Assessment**	***Signature on file***	**3/1/2016**
Ronald Kennedy, M.D, **Sr. Medical Director, Medical Quality**	***Signature on file***	**3/1/2016**

Retirement Date:	*Refer to the SmartSolve EDCS.*
Reason for retirement/replacement:	

TABLE OF CONTENTS

1. PURPOSE

This document sets forth the mandatory process for the notification to the Quest Diagnostics Medical Quality Department (Corporate Quality Assessment [CQA] and National Quality Assurance [NQA]), in the event that a Hospital Reportable Quality Issue (RQI) is identified.

The purpose of RQI identification and reporting is to improve quality and prevent risk for subsequent events. All individuals should be encouraged to report findings. An individual should not be disciplined for human error; however, intentional rules violations and reckless conduct should be addressed in consultation with Human Resources.

Further, it is the policy of the organization not to include RQI numbers in performance appraisals to avoid potential under-reporting.

2. SCOPE

This process applies to any Reportable Quality Issue identified at any Quest Diagnostics hospital laboratory, owned or managed.

3. RESPONSIBILITY

Note: This procedure addresses reporting of Hospital Reportable Quality Issues to Quest Diagnostics. Hospital laboratories and their staff are expected to follow all reporting requirements of their local medical staff and hospital risk management departments.

- **Laboratory Director** is responsible for:
  - The approval of the initial document and any subsequent revisions.
  - Approving Laboratory Director Exceptions to testing procedures. (See Addendum A: *Guidelines for Tracking Laboratory Director Exceptions*)

- **Laboratory Director or Designee** is responsible for the recurring review of this document.

- **Laboratory Operations Director** (or designee) is responsible for ensuring the notification, coordination and management of RQIs when the RQI affects or causes reissued reports at Quest Diagnostics Hospital laboratory(s) or affiliated Quest Diagnostics laboratory(s).

- **Technical Supervisor** is responsible for:
  - Implementing this process in the department for which he/she is responsible.
  - Ensuring the appropriate training of personnel.

- **Department Manager or Supervisor** is responsible for:
  - Implementing this process in the applicable non-technical department(s) for which he/she is responsible.
  - Ensuring the appropriate training of personnel.

- **Local Quality Assurance (QA) Manager or designee** is responsible for:
  - RQI notification, documentation and submission as defined in this document.
  - Maintenance and security access of the local RQI database, forms and files.
  - Performance and optional documentation of follow up review (Monitoring).

- **All employees** are responsible for notifying their manager or supervisor and local QA Manager or designee of any RQIs identified in the laboratory.

4. DEFINITIONS

Hospital Reportable Quality Issue: A quality issue with known or potential effect on current or future patient care that requires notification.

RQI Form: The spreadsheet used to submit information for Laboratory RQIs.
- The associated files (RQIForm.xlsm, RQIFormDataUser.xlsm, and RQIFormDataSupporting.xlsm) must be placed on a local drive that is accessible only to local laboratory quality assurance, supervisory, and management personnel.
- The location of the RQI form is: G:\AHC_Lab\Quality Assurance\Performance Improvement\ RQI data\NEW RQI FOLDER 4.1.15

Irreparable Loss: A condition in which a specimen is damaged, mishandled or lost while in the laboratory's possession or during transport and therefore cannot be tested.

Irreplaceable Specimen: A specimen for which an invasive collection procedure is performed on the patient or for which it is not possible to recollect a specimen.
- Includes:
  - Body cavity and cyst fluids e.g., amniotic, pleural, peritoneal, pericardial fluids, ovarian cyst
  - Cerebrospinal fluid (CSF)
  - Urinary tract or other stones submitted for analysis
  - Products of Conception (POC)
  - Tissue for histology (including biopsies, surgical resections, paraffin blocks and/or slides)
  - All bone marrow specimens (biopsy, flow, cytogenetics, molecular, etc.)
  - All fine needle biopsies or aspirations, including synovial collections
  - Lavages, washings and brushings (bronchial, esophageal, bladder, etc.)
  - Cord blood
  - Meconium for drug screening

- Also includes the following samples specific to this policy:
  - All neonatal/newborn specimens
  - Specimens collected during hospital procedures (adrenal vein sampling, etc.)
  - Specimens collected prior to specific treatment (drug/antibiotic administration)
  - Any parasite

Laboratory Director Exception: Testing approved by the Laboratory Director on a specimen that would normally not be acceptable (e.g., due to sample type or sample stability). The exception to perform the test requires direct consultation between the ordering physician and the Laboratory Director.

- Laboratory Director Exceptions must be documented and monitored following a local process (Addendum A).

Mislabeled:
Any specimen or aliquot submitted for testing, labeled with one or more incorrect patient identifiers including:

- Wrong first and/or last name
- Wrong last name suffix (e.g. Jr. instead of Sr.)
- Wrong neonatal first name (e.g., Baby A instead of Baby B)
- Numeral discrepancies (exact match required)

Revised Report: Revised reports include changes to a patient's medical report that involve different test result(s), message(s), reference interval(s), unit(s) of measure or other report elements that could potentially have an impact on patient care.

Unlabeled:
Any specimen or aliquot submitted for testing that is missing one or more patient identifiers.

5. RQI TYPES

- **Any FDA Reportable Event:** See FDA Reportable Event Notification Process (QDHOS707) or Process for Complying with FDA Regulations Requiring Device User Facilities to Report MDR Reportable Events (QDCMQ700)

- **Revised Reports**
  - **Five (5) or more revised reports when the cause is attributable to a single event due to a laboratory issue**. This includes product/reagent recalls, local LIS issues and referral laboratory issues.

  - **Any single revised report for the following testing:**
    - **Critical Value:** Test result revised to **OR** from a critical value.

    - **The revised result causes a change in patient treatment:** Examples include, but are not limited to, revised Gram stain results that require a change in antibiotic therapy; revised cardiac marker results that require a change in treatment (e.g. Cath Lab procedures); etc.

- **Immunohematology Testing:** Any revised test result, including but not limited to: ABO group, Rh type, atypical antibody screen/identification, DAT, and RBC antigen typing.

Note: If the issue is also FDA Reportable, use RQI type FDA Reportable Event.

- **Any Significant Procedural Delay resulting in known or potential impact to patient care (treatment or discharge) including:**
  - **S**pecimen 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 (See definition):**
  - Five (5) or more patient specimens attributable to a single event
  - One, or more, **Irreplaceable specimen(s) (see definition**), or loss of requisition(s) rendering the specimen(s) useless
  - Any single mislabeled specimen or aliquot submitted for testing that was collected or labeled by laboratory staff (S**ee Mislabeled definition)**
  - Any single unlabeled specimen or aliquot submitted for testing that was collected by laboratory staff (**See Unlabeled definition)**

- **Pathologist or the CLIA Laboratory Director determined patient care issue:** An issue or event judged by a Pathologist or the CLIA Laboratory Director to have known or potential impact on current patient care.

- **Hospital Policy and Procedure Variance:**
  A variation or deviation from the local Hospital Policy and Procedure that has known or potential impact on current patient care.

6. PROCESS FOR REPORTING HOSPITAL QUALITY ISSUES

A. Identification of an RQI

- **Any employee** recognizing a potential Hospital RQI (see Section 5: RQI Types) shall notify the manager or supervisor immediately.
- If the issue is determined to be a Hospital RQI, the **Local QA Manager** or designee shall notify the Quest Diagnostics Medical Quality Departments by submitting a Hospital RQI form.
- Local **QA Manager or designee** shall also notify
  - The Regional Business Unit Quality Assurance Department
  - Hospital personnel as required by hospital policy
  - Local staff, as required, AND as applicable

B. Documentation

Initial Set-Up for RQI Form:

- The Laboratory must transfer the master files to a secure local network drive that is accessible only to QA, supervisory and management personnel. **All three of the following files must be located in the same folder**:
  2014 RQIForm.xlsm
  2014 RQIFormDataUser.xlsm
  2014 RQIFormDataSupporting.xlsm
- This form is required for AP and CP Hospital Laboratory RQIs.
- If a new copy of the forms is needed, please contact the CQA Hospital Team.

RQI Form Completion and Submission

- The Local QA Manager or designee shall start a new RQI form, assign a Local Event Number, and submit the RQI form at the completion of each phase following the deadlines specified below. Local event numbering uses the following format:
  Site-year-month-date of event-two digit YTD count for site
  Example: an event occurring on May 6, 2016 at Washington Adventist which is the third occurrence year to date = "WAH-2016-05-06-03"
- All RQI data are entered using the RQIForm.xlsm using the following steps:
  1. Open RQIForm.xlsm.
  2. Enable Macros
  3. Open the RQI Editor
     - Select **Start New RQI** to document a new RQI
     - Select **Manage RQIs** to edit a previously started RQI. Select the RQI to edit then click on **Edit Selected RQI**.
  4. Complete the RQI form.
     (Specific directions for completion of the RQI form are provided in the Help Text at the bottom of each section of the form and in the *Reference Guide for Use of the Hospital RQI Form.xlsm Fields and Drop-Down Lists* (QDHOS400))
     - Do not edit the basic format or content of the form in any manner.
     - Enter requested information only.
     - Each RQI may be saved at any time during data entry.
  5. Review the **Warnings and Errors** tab. (Only key date and time fields and drop down lists are checked for warnings and flags.)
     - Warnings: flag unexpected data for each tab (e.g. unexpected dates). These fields are highlighted in yellow on each individual tab.
     - Errors: flag incorrect or missing data. These fields are highlighted in red on each individual tab.
     - "OK" indicates that key fields have been filled in as expected.
  6. Submit the **RQI:**
     - Upon completion of each major section of the "RQI Notification Form," select the Submit **to NQA** button. This will generate an email to: DGX Hospital RQI.
     - When sending e-mail notification directly from the RQI form, the subject line automatically includes: Hospital RQI; Laboratory Name; and Local Event #.
     - Use **Hospital RQI; Name of laboratory Local Event #** in the Subject Line of all subsequent emails related to the specific RQI.

- Additional information and addresses may be added to the email before sending.
- Each RQI must be submitted from the database to update information at the corporate level.

C. Process and Timing

- **Phase 1 – Describe/Investigate:** Complete, as much as possible, the following data sections within 3 calendar days of when the RQI was confirmed:

  - Descriptive Information
    - All fields are mandatory fields in this section.

  - Problem Suspected
    - All fields are mandatory fields in this section.
      - # Clients/Physicians affected, (provide estimate initially, if actual number is not available)
      - # Accessions affected, (provide estimate initially, if actual number is not available)

  - Initial Investigation
    - Mandatory fields in this section include:
      - Laboratory Director Assessment of Possible Patient Impact
      - Date patients first affected
      - Date patients no longer affected

  - (If the details are known, complete the **Expanded Investigation** and **Remedial Action** sections on the Phase 2 Tab.)

- **Phase 2 – Corrective Action/Improvement:** Report the following within 21 calendar days of when the RQI was confirmed:
  - Any additional or revised information not included in the initial reporting (Phase I Tab)
  - Expanded Investigation
  - Remedial Action
  - Corrective Action/Process Improvement
  - Replication

  Note: It is always expected that a thorough and credible root cause analysis will be performed before corrective actions and improvements are proposed. Corrective actions should specifically address the identified root cause(s) of the observed events.

Note: Phases 1 and 2 are mandatory reporting phases. While Phases 3 and 4 are important steps in the process, they do not have mandatory reporting requirements and timelines.

- **Phase 3 – Monitoring:**
  - Any additional or revised information,

- Plan for monitoring process improvement and replication, specifically focused on the root causes identified and other risk situations that emerge from the root cause analysis discussion and investigation.

- **Phase 4 – Follow-Up:** Perform and report follow-up reviews described in the Monitoring section.

D. RQIs Involving Two or More Laboratories

- When two or more laboratories are involved in an RQI, the initial hospital laboratory must submit an RQI form and the other involved laboratory must submit their own separate form. Each laboratory completes the form from their laboratory's perspective. The involved laboratories must work together to address root causes and implement corrective action.
- Each laboratory must list the other site(s) involved in the "Other Laboratory Location Involved" field in the Descriptive Information tab.
- In the Initial Investigation tab, use the following Error Codes:
  - Client Error: If a Referral (receiving) Laboratory believes the error occurred at the Referring (shipping) Laboratory. (The shipping laboratory is considered the client.)
  - Supplier/Vendor: If a Referring (shipping) Laboratory believes the error occurred at the Referral (receiving) Laboratory. (This includes internal Quest Diagnostics referral sites.)
  - If either the Referral Laboratory or Referring Laboratory suspects that the error was resulted from a variance at their site, use an appropriate Error Code other than the two listed above.
- If the RQI is caused solely by an intermediary (e.g., airline or shipper) or the primary responsibility for the RQI cannot be definitively determined, the Referring (shipping) laboratory assumes primary responsibility for the RQI reporting.
- Before submitting the RQI to the distribution list, add a message at the beginning of the email alerting the recipients that another laboratory(ies) is involved, briefly describe the situation from the laboratory's perspective and submit the RQI.
- Information from each laboratory's RQI submission will be retained.
- The discovering laboratory must contact (preferably by phone) the QA department of the other laboratory involved to help ensure that each laboratory has the necessary information to investigate the problem and file a meaningful RQI with root cause analysis.
- Each laboratory must look for opportunities to ensure that inter-laboratory processes are robust and user-friendly, regardless of in which laboratory the primary variance that resulted in the RQI occurred. The laboratories must collaborate on necessary improvements.

7. RECORDS MAINTENANCE

Records are maintained according to the requirements indicated by the hospital or the Quest Diagnostics Records Management Program, whichever is longer.

8. RELATED DOCUMENTS

- Reference Guide for use of the Hospital RQIForm.xlsm Fields and Drop-down Lists (QDHOS400)
- RQI Tracking Log (QDHOS300) , optional
- RQI Report of Observations Form (QDHOS309) , optional
- RQI Local Investigation Report Form (QDHOS303) , optional
- RQI Document Guidance (QDHOS406)
- FDA Reportable Event Notification Process (QDHOS707)
- Process for Complying with FDA Regulations Requiring Device User Facilities to Report MDR Reportable Events (QDCMQ700)

9. REFERENCES

- Reportable Quality Issue Notification Process (QDNQA709)

10. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	2/4/15	All	New SOP		Lee Hilborne,MD
2	2/10/16	1	Added "Quest Diagnostics Medical Quality Department" Clarified RQI identification and submission with regard to employee performance.	M. Kircher	Ronald Kennedy, MD
2	2/29/16	3	Added "optional" to documentation of monitoring in the Local QA Manager's responsibilities	M. Kircher	Ronald Kennedy, MD
2	2/10/16	4	Clarified definitions of Mislabeled and Unlabeled.	M. Kircher	Ronald Kennedy, MD
2	2/10/16	6A	Revised wording to indicate reporting to the Quest Diagnostics Medical Quality Department instead of CQA.	M. Kircher	Ronald Kennedy, MD
2	2/10/16	6C	Revised required RQI reporting Phases. Added mandatory fields for Phase 1 (Describe/Investigate) reporting when all details are not known. Changed Phase 2 (Corrective Action/Improvement) reporting timeline. Changed Phase 3 (Monitoring) and 4 (Follow Up) to optional reporting.	M. Kircher	Ronald Kennedy, MD

2		 Cover pg 4 6 8 11 Add A	Adopting corporate issued version 2. Add Local Effective Date message Add Hospital RQI form location Add local numbering Specify optional forms Add Addendum B Add local process to document	L Barrett	C Bowman-Gholston

11. ADDENDA

Addendum	Title
A	Tracking Laboratory Director Exceptions
B	Hospital RQI Notification Reference Guide (See Attachments pane in EDCS)

ADDENDUM A: TRACKING LABORATORY DIRECTOR EXCEPTIONS

Testing for specimens that are not normally acceptable must be resolved following established laboratory processes. When a Laboratory Director Exception is granted, the following guidelines must be followed:

1) Exceptions may only be granted after direct consultation between the Laboratory Director and the physician to determine reason need for granting an exception.

2) The Laboratory Director must approve and document all exceptions.

3) The laboratory must have a system to track each exception. The system must track the following data elements:
    a. Date exception was granted
    b. Accession number(s) of affected specimen(s)
    c. Test(s) involved
    d. Unresolved sample problem (stability, sample type, etc)
    e. Reason for exception
    f. Name of physician
    g. Hospital department or name of outside client

4) The laboratory must monitor the exceptions as part of the laboratory's Quality Management System. Routine review of these exceptions must document:
    a. Number of exceptions
    b. Types of exceptions
    c. Frequency by hospital department or outside client
    d. Actions taken to eliminate or reduce the need for similar Laboratory Director Exceptions. (These actions often include education or replacing outdated supplies.)

5) Exceptions are documented on a Quality Variance (QV) form and tracked via PI (Performance Improvement) Database.