TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	8/29/2012
Department:	Core Techs	**Due Date:**	9/30/2012

DESCRIPTION OF PROCEDURE

Name of procedure:
Process for Notification of Reportable Quality Issues GEC/SGAH/WAH QDMED708 v5.0C
Description of change(s):
No change to SOP, this is merely a review You may review the printed SOP that is in the QA Manual

MEDICAL QUALITY STANDARD POLICY

Non-technical SOP

Title	**Process for Notification of Reportable Quality Issues v5.0**	
Prepared by	National Quality Assurance – Clinical Pathology National Quality Assurance – Anatomic Pathology Medical Quality Assurance – AmeriPath Corporate Medical Quality National Referral Testing	Date: 3/31/2011

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

12-Month Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	
Medical Advisor	Stephen Suffin, MD, Chief Laboratory Officer
Signature	*[Electronic approval on file]*
Corporate Issue Date	April 4, 2011

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PROCESS FOR NOTIFICATION OF REPORTABLE QUALITY ISSUES

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1. POLICY

This document sets forth the mandatory process for ensuring timely notification of National Quality Assurance (NQA), Medical Quality Assurance (MQA), Corporate Medical Quality (CMQ) or National Referral Testing (NRT) staff in the event that a Reportable Quality Issue (RQI) is identified.

2. SCOPE

This process applies to all technical departments [both Anatomic Pathology (AP) and Clinical Pathology (CP)] as well as some non-technical departments (e.g., Logistics, Specimen Processing, Purchasing, Information Technology, Test Send-Outs).

3. RESPONSIBILITY

- **All employees** are responsible for notifying the local site Quality Assurance (QA) Manager or designee of any RQI identified in the laboratory.
- The **Local QA Manager or designee** is responsible for RQI notification to:
  - The CLIA Laboratory Director
  - Other local staff, as locally required AND, as applicable:
    - The Director, Corporate Quality Management – Clinical Pathology or designee OR
    - The Director of National Quality Assurance – Anatomic Pathology or designee OR
    - The Director of Medical Quality Assurance OR
    - The Director of Corporate Medical Quality OR
    - The Director of National Referral Testing
- The **Technical Supervisor** (as designated by the CLIA Laboratory Director) is responsible for implementing this process in the technical department for which he/she is responsible and ensuring the appropriate training of personnel.

- The **Department Manager** is responsible for implementing this process in the applicable non-technical department(s) for which he/she is/are responsible and ensuring the appropriate training of personnel.

- The **Laboratory Operations Director** (or designee) of the **Performing Business Unit** is responsible for the notification, coordination and management of RQIs when the RQI affects or causes reissued reports at a sister laboratory (ies).
- The CLIA **Laboratory Director** is responsible for the initial approval of this SOP and any subsequent revisions. The director is also responsible for reporting any Laboratory Director-approved exceptions to testing procedures using the RQI process. (See Laboratory Director Exception below.)
- The CLIA **Laboratory Director or designee** is responsible for the annual review of this SOP.

4. DEFINITIONS

Term	Definition
Reportable Quality Issue (RQI)	A quality issue with known or potential effect on current patient care that is of sufficient priority to require the notification of National Quality Assurance (NQA), Medical Quality Assurance (MQA), Corporate Medical Quality (CMQ) or National Referral Testing (NRT)
Irreplaceable Specimen *The definition of Irreplaceable Specimens in this document is for defining RQI criteria and may differ from the definition used in policies related to logistics or specimen tracking.*	Within this document, an Irreplaceable Specimen is one for which recollection is difficult or impossible and includes: • Body cavity fluids: amniotic, pleural, peritoneal, pericardial • Cerebrospinal fluid (CSF) • Stone analysis • Product of Conception (POC) for chromosome analysis • All biopsies, or surgical resection specimens • All bone marrow specimens (*biopsy, flow, cytogenetics, molecular, etc*.) • All fine needle biopsies or aspirations, including synovial • Lavages, washings and brushings (*bronchial, esophageal, bladder, etc*.) • Direct smears for Cytology, e.g. slide submitted for Tzanck test (*note: Pap smears or liquid-based Pap tests are not considered Irreplaceable*) NOTE: Excludes routine venipuncture (any age)
Laboratory RQI *(the primary error lies with the laboratory)*	• **Ten or more reports reissued to clients when the cause was attributable to a single event due to laboratory or client error. This includes but is not limited to correcting results, messages, reference ranges, unit of measure or any other report element.** • **Any revised report where a test result was changed** To **a Priority Value (P1, P2, P3) OR** from **a Priority Value** • **Any revised report for the following testing:** ▪ **HIV testing (specifically related to the diagnosis of**

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Term	Definition
	HIV infection) ▪ **Immunohematology/Blood Bank testing (ABO group, Rh type, atypical antibody screen/identification, RBC antigen typing, FDA-reportable event)** ▪ **Prenatal genetics testing (serum screening, amniotic fluid testing, cytogenetics, molecular genetics). NOTE: A change to the result interpretation caused by any internal data entry error (i.e. Ask at Order Entry (AOE) demographics) is considered an RQI.** • **Irreparable* loss of specimens from 10 or more patients attributable to a single event** **** This category includes specimens that are damaged or ruined while in the laboratory's possession and therefore cannot be tested.*** • **Irreparable✦loss of a single (or more) irreplaceable specimen (or loss of requisitions rendering specimens useless)** ***✦ This category includes specimens that are damaged or ruined while in the laboratory's possession and therefore cannot be tested. Irreparable loss also includes samples that cannot be located within one week (spent in exhaustive search) of having been logged in or having been otherwise documented as received. Refer to* Missing Anatomic Pathology Specimen Alert SOP*, as applicable, for use during the week of exhaustive search*** • **Identification of a patient's tissue specimen/requisition switched with and/or reported as another patient's (includes histopathology, genetic or clinical testing performed on tissue slides, blocks or tissue samples).** • **Information Technology issue where the error lies with the local database, programming, interface, printers or a client's unique electronic medical record system and there is a known or potential effect on test results/interpretations affecting current patient care or non-compliance with a regulatory requirement.** • **Any systemic issue or event judged by a Pathologist or the CLIA Laboratory Director to have known or potential impact on current patient care**
<u>Laboratory Director Exception</u> *(the Laboratory Director approves testing a specimen that would normally not be tested after direct consultation with the ordering physician)*	• **Laboratory Director Exceptions will be tracked using the RQI process.** • **Data is tracked to ensure that the rationale for testing the sample is completely documented. The data will also be used for educational purposes. Laboratory Director Exceptions will not be included in RQI totals.** • **Examples of Laboratory Director Exceptions include: testing a specimen received in expired transport medium**

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Term	Definition
	or testing an irreplaceable sample that is beyond the claimed stability. • **The laboratory must suppress billing for these tests.**
Corporate Information Technology RQI *(the primary error lies with a standard IT system)*	**Information Technology issue where:** • **The error lies with the standard database, standard LIS, standard interface, a type of printer in standard use or an electronic medical records system used by clients in multiple laboratories and;** • **There is a known or potential impact on test results/interpretations affecting current patient care**
Supplier RQI	• **Product (CP and AP): recall or other product correction with known or potential effect on test results or otherwise affecting patients** • **CP Referral: ten or more revised reports and/or letter of correction affecting test results/interpretations issued by a CP national external referral laboratory (local CP external referral laboratory corrections are reported as Laboratory RQIs, e.g., referral to a local hospital).** o **Note: RQIs involving a referral to a Quest Diagnostics Esoteric Testing site is also reported as a Laboratory RQI** • **AP Referral: Laboratory RQI (see definition above) where the primary error lies with an AP external referral laboratory**

5. RQI: LABORATORY

Initial Notification

- Any employee **recognizing a Laboratory RQI (see Section 4. Definitions) shall notify either verbally or via email the Local QA Manager or designee as soon as the issue/event is identified.**
- **The** Local QA Manager **or designee shall notify either verbally or via email**
  - The CLIA Laboratory Director
  - Local staff, as required AND, as applicable:
    - The Director of Corporate Quality Management or designee – Clinical Pathology OR
    - The Director of National Quality Assurance or designee – Anatomic Pathology OR
    - **The Director of Medical Quality Assurance (AmeriPath/ Dermpath Diagnostics)**
- **The RQI form and associated spreadsheets (see Section 5.3 below) are located on a local drive that is accessible only to Laboratory supervisory and management personnel. The location of the RQI form is:**

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G:\AHC_Lab\Quality Assurance\Performance Improvement\ RQI data\NEW RQI FOLDER 4.7.11

- **The** Local QA Manager **or designee shall start a new RQI form, assign a Local Event Number, and upon completion of each major section of the "RQI Notification Form" (see Step 5.2 below for timeframes) shall email the form to:**
  - **DGX RQI for Quest Diagnostics Clinical Pathology RQIs; also copy the NQA "Partners in Quality" (PIQ) mentor**
    OR
  - **DGX RQI AP for Quest Diagnostics Anatomic Pathology RQIs**
    OR
  - **AMP RQI for all AmeriPath/Dermpath Diagnostics RQIs**
- For **Email** Notifications:
  - Use "RQI_*Name of laboratory*_Local Event *#"* in the Subject Line of notification and all subsequent emails related to the specific RQI.
  - When sending e-mail notification directly from the RQI form, the subject line automatically includes:
    - RQI
    - Main Laboratory Name
    - Local RQI #
- 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 Appendix A, Guidelines for Use of RQI Form.

Process

Phase I- Initial Reporting, Investigation and Corrective Action

Phase I requires reporting of the following within 3 calendar days **of RQI discovery/identification, declaring an irreplaceable specimen lost, or declaring 10 or more specimens lost from a single event:**

- **Descriptive Information**
- **Problem Suspected**
- **Initial Investigation, including root cause**
- **Expanded Investigation**
- **Immediate Corrective Actions**

Phase II – **Process Improvement and Replication**

Phase II requires reporting the following within 7 calendar days **of the discovery/identification of the RQI:**

- Any additional or revised information not included in the initial reporting (Phase I)
- **Process Improvement**
- **Replication of the process improvement**

Phase III – **Monitoring**

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Phase III requires reporting the following within 30 calendar days **of the discovery/identification of the RQI:**

- **Plan for monitoring process improvement and replication**

Phase IV – **Follow-Up**

"Reportable Quality Issue Follow-Up" is also part of the Monitoring section and requires follow- up audits be performed by the QA Manager or designee.

- **The QA department will determine the date of the follow-up audit. This date must be after the process improvement has been completed and is in place.**
- **The QA Department will conduct the follow-up audit to confirm that process improvement steps are complete and effective.**
- **The QA Department will document findings from the audit in the Monitoring section Laboratory RQI Notification Form.**
- **The QA Department will submit the completed form to the appropriate RQI distribution list**

Using the RQI Form

- Use of this form is required for AP and CP Laboratory RQIs, and Laboratory Information Technology RQIs. (See Section 6 for Laboratory Director Exceptions.)
- Do not edit the basic format or content of the form in any manner. Enter requested information only.
- The master templates for the form are available on the NQA intranet site.
- The Laboratory must transfer the following master files to a secure local network drive that is accessible only to supervisory and management personnel. **All three files must be located in the same folder**.
  - RQIForm.xls
  - RQIFormDataUser.xls
  - RQIFormDataSupporting.xls
- All RQI data is entered using the RQI Form.xls located on the secure local drive.
  - Open RQI Form.xls
  - Enable Macros
  - 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.
- Select the **Descriptive Information** tab and enter the requested information.
  - Enter all fields
  - Use drop-down lists when available
  - Use the Help Text at the bottom of the form for guidance
  - Forms (complete or incomplete) may be saved at any time using the Save option
- Select the **Immediate Corrective Action** tab. All four sub-sections must be completed (**Problem Suspected, Initial Investigation, Expanded Investigation,** and **Immediate Corrective Action**). For each sub-section:
  - Enter all fields

  - Use drop-down lists when available.
  - Use the Help Text at the bottom of the form for guidance
  - Forms may be saved at any time using the Save option
  - Phase I is complete when the Descriptive Information and Immediate Corrective Action section (all sub-sections) are complete
  - Select Submit to NQA to save Phase I information and notify the appropriate RQI distribution list members
  - Phase I notification must be completed within **3 calendar days** of the date the RQI is confirmed.
- Select the **Process Improvement** tab and enter the requested information. Both sub-sections must be completed (**Process Improvement** and **Replication**).
  - Enter all fields
  - Use the Help Text at the bottom of the form for guidance
  - Forms may be saved at any time using the Save option
  - Phase II is complete when the Process Improvement and Replication sub-sections are complete
  - Select Submit to NQA to save Phase II information and notify the appropriate RQI distribution list members
  - Phase II notification must be completed within **7 calendar days** of the date the RQI is confirmed.
- Select the **Monitoring** tab and enter the requested information.
  - Enter all fields
  - Use the Help Text at the bottom of the form for guidance
  - Forms may be saved at any time using the Save option
  - Phase III is complete when the Monitoring section is complete
  - Select Submit to NQA to save Phase III information and notify the appropriate RQI list members
  - Phase III notification is complete after a target date for QA follow-up review has been set
  - Phase III notification must be completed within **30 calendar days**.
  - After the target date for follow-up review, the Laboratory QA department audits the process improvement to determine if it is complete and effective (Phase IV). The following information is documented:
    - Date of Laboratory QA review
    - Person performing the review
    - Follow-up audit findings
  - The results of the Phase IV review are submitted to the appropriate distribution list
- Review the **Warnings and Errors** tab.
  - 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.
  - NOTE: Only key date and time fields and drop down lists are checked for warnings and flags.

5.4. RQIs due to Transport Issues Involving Two or More Business Units

- When two or more Business Units are involved in a Reportable Quality Issue, all BUs must investigate and submit an RQI form.
- Each BU 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:
    - If a Referral (receiving) Laboratory believes the error occurred at the Referring (shipping) Laboratory, use "Client Error." (The shipping laboratory is your client.)
    - If a Referring (shipping) Laboratory believes the error occurred at the Referral (receiving) Laboratory, use "Supplier/Vendor." (The referral laboratory provides a service. This includes internal Quest Diagnostics referral sites.)
    - If either the Referral Laboratory or Referring Laboratory suspects that the error was primarily their fault, use an appropriate Error Code other than the two listed above.
    - If the RQI is caused solely by an intermediary (airline or shipper) or the primary responsibility for the RQI cannot be definitively determined, the Referring (shipping) Laboratory assumes primary responsibility for the RQI.
- BUs complete the RQI form from each Business Unit's perspective.
- Before submitting the RQI to the distribution list, add a message alerting the recipients that another lab(s) is involved and briefly describe the situation from the Business Unit's perspective, then submit the RQI.
- Upon receipt, the responsible NQA Manager(s) will:
    - Work with the NQA Manager responsible for the other site(s) to ensure RQI forms are completed at each BU.
    - Ensure that each BU has the other Business Unit's NQA RQI number so that the RQIs can be cross-referenced.
    - **Ensure that each BU adds the NQA RQI number to the "Other Laboratory Location Involved" field** for cross-reference and to ensure the incident is not counted as separate RQIs.
    - Reconcile differences in number of clients and number of accessions affected, if necessary.
    - Assist in determining primary responsibility for the RQI.
    - At the completion of the investigation, notify the site(s) that is not responsible to change the number of clients and accessions affected to zero and resubmit the RQI
- Information from each Business Unit RQI submissions will be retained.
- Each Business Units must look for opportunities to ensure that interlaboratory processes are robust and user-friendly, regardless of which BU is primarily responsible for the RQI.

6. RQI: LABORATORY DIRECTOR EXCEPTION

- The **Laboratory Director** (or designee) shall start a new RQI form whenever a testing exception is allowed.
- The following applicable sections must be addressed. (Some sections may not be applicable for Laboratory Director Exceptions.)
    - **Descriptive Information** tab: Fill in all applicable information.

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- **Immediate Corrective Action/Problem Suspected** tab: Fill in all requested information.
- **Immediate Corrective Action/Initial Investigation** tab:
  - **Date Investigation Started:** (The date approval for the exception is given.)
  - **Time Investigation Started:** (The time approval for the exception is given.)
  - **Describe the investigative process:** (Describe the rationale for giving the exception.)
  - **Error Code:** Select an error code from the drop-down list.
  - **Root Cause:** Select a root cause from the drop-down list.
- **Process Improvement tab:**
  - **Describe the process improvement that you will implement:** Describe what actions will be taken to eliminate or reduce the need for similar Laboratory Director Exceptions. (These actions often include client education or replacing outdated supplies.)
  - **What is the target date for implementation of the process improvement?** (Document the expected date of the process improvement.)
- All other fields and tabs are not required, but may be used if applicable to the event at the laboratory's discretion.

- See Section 5.3 and Appendix A for additional instructions in using the form.

7. RQI: CORPORATE IT

- Any employee **recognizing a Corporate IT RQI that has known or potential impact on test results/interpretations affecting current patient care shall notify either verbally or via email the Local QA Manager or designee as soon as the issue is identified.**
- **The** Local QA Manager **or designee shall notify either verbally or via email:**
  - The CLIA Laboratory Director
  - Local staff, as locally required
- **For a** Quest Pathology System (QPS) **RQI, the** Local QA Manager **or designee shall notify either verbally or via email the Director of NQA-Anatomic Pathology or designee (DGX RQI AP).**
- **For an** Ameripath/Dermpath Diagnostics **Corporate IT RQI, the** Local QA Manager **or designee shall notify either verbally or via email the Director of Medical Quality Assurance (AMP RQI).**
- **For all other Corporate IT RQIs, the** Local QA Manager **or designee shall notify either verbally or via email the Director of Corporate Medical Quality (DGX RQI CMQ).**
- **For** Email **notifications, label with the Record Classification LEG210, if this classification is available.**

8. RQI: SUPPLIER

Product recalls/corrections

- Any employee **recognizing a Supplier RQI involving a recall or other product correction with known or potential effect on test results or otherwise affecting patients shall notify either verbally or via email the Local QA Manager or designee as soon as the issue is identified.**
- **The** Local QA Manager **or designee shall notify either verbally or via email:**

- The CLIA Laboratory Director
- Other local staff, as locally required
- **The Director of Corporate Medical Quality (DGX RQI CMQ), AND**
- **Corporate Purchasing's "Supplier Quality" email address.**

- **Any letter or other notification received from the Supplier must be emailed to the Director of CMQ and Corporate Purchasing's "Supplier Quality" email address by the employee who received it or the Local QA Manager or designee (scan and email a hard copy letter rather than faxing).**

National CP External Referral Laboratory corrections

- Test Send-Outs (TSO) personnel **receiving ten or more revised reports and/or letter of correction affecting test results/interpretations from a CP national external referral laboratory shall notify either verbally or via email the Local QA Manager or designee as soon as the letter/report is received.**
- **The** Local QA Manager **or designee shall notify either verbally or via email the Director of National Referral Testing.**
- **The letter and/or sample revised report (devoid of patient specific information) must be emailed to the Director of National Referral Testing by the employee who received it or the** Local QA Manager **or designee (scan and email hard copy documents rather than faxing).**

Note: Local CP external referral laboratory corrections are reported as Laboratory RQIs.

AP External Referral Laboratory corrections

The directions are the same as for an AP Laboratory RQI (see above).

9. RECORDS MAINTENANCE

- Laboratory QA Manager or designee shall retain completed records of each RQI. Electronic copies (spreadsheets) generated by the RQI form are acceptable.
- Records shall be maintained with reference to the Local Event Number.
- Records are subject to review during NQA on-site inspections.
- Records are maintained according to the Quest Diagnostics *Records Management Program.*

10. RELATED DOCUMENTS

- *Locating Misplaced Anatomic Pathology Specimen(s),* SOP# AP796
- *Biological Product Deviation Reporting – FDA Reportable Event,* SOP# QDHBB601
- *Priority Result Reporting Policy,* SOP# QDMED704
- *Reference Guide for use of RQIForm.XLS (3/31/11)*

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11. REVISION HISTORY (immediate retired and prior three years)

Version	Date	Reason for Revision and Reviser	Approval

Version	Date	Reason for Revision and Reviser	Approval
3.0	10.06.08	NQA	
3.0	1/26/2009	Section 10: Added site specific Prior Version History to corporate SOP Supersedes NQA version 2.0 dated 01.08.04 (SGAH-WAH QA205)	
4.0	12.01.09	NQA: revised RQI form, modified RQI reporting timeframes, required reporting of Phase IV (follow-up) audit findings, and added notification of "Supplier Quality" email address for supplier RQIs.	
4.0	12.23.09	Adopting newly issued corporate version 4.0. Page 1: added non-technical SOP designation. L. Barrett, Chantilly BU, Adventist Hospitals	C. Bowman
4.1	03.31.10	NQA: Revised electronic RQI form issued. Laboratory Director Exception added as an RQI type. Instructions modified to match the requirements of the new RQI form.	Corporate
A	05.10.10	Adopting corporate issued version 4.1. 5.1: added Hospital RQI form location. L. Barrett 11: Updated table column header and added approval column. L. Barrett	C. Bowman
5.0	04.04.2011	1) Revised electronic forms to add new error codes for tissue specimens (RQI Form.xls and RQIFormDataSupporting, version 3.0) 2) Added Responsibilities: Lab Ops Director of performing BU manages/coordinates RQIs that affect or cause reissued reports at sister lab(s) 3) Expanded/clarified Laboratory RQI definitions (includes examples of reissued reports, limits HIV to diagnostic testing only, prenatal genetics includes internal data entry errors, tissue ID switched includes all types of testing on tissue) 4) Dermpath added to AmeriPath references 5) New section on use of Warnings and Errors tab. 6) New section (5.4) for handling RQIs that occur between two or more Business Units. 7) Defined process for Laboratory Director Exceptions. 8) Added examples of AP RQIs to Appendix A under Functional Groups 9) Clarified use of "Message to Client" 10) Reference Guide available for using other drop-down lists.(separate document for reference only)	Corporate
B	4/25/2011	Adopting corporate issued version 5.0. Update Local Effective Date message on cover page 5.1 update Hospital RQI form location. L. Barrett 12 add Appendix B L. Barrett	C. Bowman

12. APPENDICES

Appendix	File Name	Title
A	N/A- at end of this file	Guidelines for Use of RQI Form
B	RQI Notification Reference Guide	See Attachment Tab of Infocard

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APPENDIX A – GUIDELINES FOR USE OF RQI FORM

Descriptive Information

- **Functional Group:**
  - Select AP for all Anatomic Pathology RQIs (including AP IT RQIs, kidney stones and bone marrow testing)
  - Select CP for all Clinical Pathology RQIs (including Laboratory-specific IT RQIs)
  - Note: CP Corporate IT RQIs, Corporate Supplier/Vendor RQIs, and CP External Referral Lab RQIs will be managed by a related process described in sections 7 and 8 above.
- **NQA RQI #:** This number is automatically assigned when a new RQI is started.
- **Local RQI #:** Enter a Laboratory-assigned RQI tracking number
- **Region:** Select the laboratory region (or other description) from the drop-down list.
- **Business Unit:** Select the Business Unit (or other description) from the drop-down list
- **Main Laboratory:** Select the Main Laboratory from the drop-down list
- **Site Location:** Select the best available description of the site where the RQI occurred. If possible, avoid using "Other."
- **Other:** May be used if the drop-down list for Site Location is not adequate.
- **Type of Facility:** Select the type of facility where the RQI occurred.
- **Department:** Select the best available description of the department where the RQI occurred.
- **Other Site Involved:** If other sites were involved in the RQI, list them.
- **Type of RQI:** Select the type of RQI.
- **Name of Tests Affected:** Enter the names of the tests affected. If more than 5 tests or panels are involved, describe as "Multiple."
- **Brief Description of Event:** Give a concise description of what happened. For example: "Shipment lost between PSC and Main Lab" or "Two electrophoresis plates accidentally switched."
- **Form Started By:** Enter the name of the person starting the form.
- **Title:** Enter the title of the person starting the form.
- **Telephone:** Enter the telephone number of the person starting the form.
- **Date Started:** Enter the date the form is started.

Immediate Corrective Action

Problem Suspected:

- **# Clients Affected:** Enter the number of clients affected by the RQI.
- **# Accessions Affected:** Enter the total number of accession numbers (or number of patients if samples were not accessioned) affected by the RQI. Do not list actual patient accession numbers in this field.
- **Discovery:** Select Internal or External. Note: Any client inquiry regarding a specimen or result that initiates an RQI investigation is considered to be external discovery.
- **Who First Suspected the Problem:** Select the individual who first suspected something was wrong. In many cases, this individual may be external to the laboratory, such as a client or physician.
- **Describe How the Problem Was Suspected:** Give a brief description of the series of events that caused someone to suspect that a problem existed.

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Initial Investigation:

- **Date Investigation Started:** Enter the date that investigation of the problem started.
- **Time Investigation Started:** Enter the approximate time the investigation started.
- **Describe the Investigative Process:** Give a concise narrative of how the investigation occurred. Include only relative events. Explain how you came to your conclusion.
- **Date RQI Confirmed:** Enter the date that your investigation determined the problem was actually an RQI. (This is when the clock starts for the Immediate Corrective Action, Process Improvement, and Monitoring phases.)
- **Time RQI Confirmed:** Enter the approximate time the RQI was confirmed.
- **Date Lab QA Notified:** Enter the date that the Laboratory QA Manager or designee was notified.
- **Time Lab QA Notified:** Enter the approximate time that the Laboratory QA Manager or designee was notified.
- **Date CLIA Laboratory/Medical Director Notified:** Enter the date that the Medical Director was notified.
- **Time Medical Director Notified:** Enter the approximate time that the Medical Director was notified.
- **Medical Director Assessment of Possible Patient Impact:** Select the best description of the Medical Director's assessment of patient impact.
- **Irreplaceable/Difficult to Obtain Samples:** Document any irreplaceable or difficult to obtain samples that were part of the RQI.
- **Non-critical Results Revised to Critical or Vice Versa:** Document any results that were revised to or from a critical value.
- **Error Code:** Select an error code that best describes the cause of the RQI.
- **Describe What Went Wrong:** Give a concise description of what went wrong. Focus on flaws in process, not on human error.
- **Root Cause:** Select the best root cause of the RQI. Important: You must rule out Process Failure and Procedure Failure before selecting Personnel Failure. Human error occurs, so processes must be developed to prevent the adverse effect of human error.
- **Describe Why the Problem Occurred:** Describe the primary reason why the RQI occurred.

Expanded Investigation:

- **Could This RQI Affect Other Patients or Samples:** Determine whether this error could have happened previously and affected other patients, batches, or samples.
- **Additional Investigative Steps:** If the answer to the previous question is "No", explain why you are sure other patient results or samples were not affected. If the answer is "Yes", describe additional investigative steps taken to determine which results or samples were affected.
- **Date Patients First Affected:** If other patients were affected, enter the date they were first affected (i.e. the date the problem started).
- **Date Patients No Longer Affected:** If other patients were affected, enter the date they were no longer affected (i.e. the date the problem was corrected).

Immediate Corrective Action:

- **Steps Taken to Minimize Patient Impact:** Describe what you did to ensure that patients were not adversely affected by this RQI.

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- **Reports TNPed or Revised/What the Client Saw:** Describe how many results were TNPed and/or revised. Also briefly describe what the clients may have seen. For example: "13 positive results revised to negative" or "6 elevated results revised to normal results."
- **Date Revised Reports Completed:** Enter the date that all revised reports were complete issued to clients.
- **Time Revised Reports Completed:** Enter the approximate time that all revised reports were complete issued to clients.
- **Date Client Calls Completed:** Enter the date that all client calls were complete.
- **Time Client Calls Completed:** Enter the approximate time that all client calls were complete.
- **Will Client Letters Be Sent:** Select Yes or No.
- **Estimated Date of Completion:** Enter the date that sending of client letters will be complete.
- **Message to Client:** Select the <u>first applicable</u> choice for the message the RQI event sent to clients. For example, if a Client Letter was sent and revised reports were also issued, select Client Letter (the first applicable choice).
  - **Client Letter –** Always use this choice if a letter or letters were (or will be) sent directly to the client(s) explaining the incident.
  - **Phone Call Only –** Use this choice if letters are not sent, but affected clients are contacted by telephone to discuss the specific incident. (Do not use for routine phone calls that are part of the laboratory's standard revised report process.)
  - **Revised Report (with comment) –** Use this choice if the majority of affected results are revised and reissued with a special comment created for the specific purpose of explaining the revised report and the choices above do not apply.
  - **Revised Report (standard) –** Use this choice if the majority of affected samples result in revised reports issued by the laboratory's standard revised report process and the choices above do not apply.
  - **Test Not Performed –** Use this choice when the majority of the affected samples are TNPed (i.e., testing cannot be performed).
  - **None –** This choice is rarely applicable. Use only when clients, physicians, nurses, patients or other external parties are totally unaware that a problem occurred.
- **Additional Comments or Clarifications:** This area may be used for additional information that was not adequately addressed as part of the Immediate Corrective Action.
- **Others Notified:** Select Yes or No for the other key individuals within the laboratory (other than the QA Manager and Medical Director) who were notified of this RQI event.

<u>Process Improvement (PI)</u>

Process Improvement:

- **Specific Steps That Broke Down:** Describe the specific steps in the process that failed and caused the RQI to occur.
- **Describe How Process Can Be Changed:** Describe how the process can be changed to prevent recurrence of the problem.
- **Describe the Process Improvement That Will Be Implemented:** Describe what you will do to prevent recurrence of this problem.

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- **Describe How the Process Improvement Will Be Implemented:** Describe the SOP revisions, training, supervision, monitoring, etc. that will be necessary to implement this improvement.
- **Target Date for Implementation of Process Improvement:** Enter the date that this improvement activity will be complete.

Replication:

- **List Similar Tests or Job Assignments:** Describe other tests or job assignments for which this process improvement is applicable.
- **When Will Replication Be Complete:** Set a target date for completion of process improvement replication.
- **Additional Comments:** This area is for additional information that was not adequately addressed elsewhere in the Process Improvement section.

Monitoring

- **Date PI Reviewed by Medical Director/QA:** Enter the date that the Medical Director and/or QA committee reviewed and approved the process improvement for this RQI.
- **Changes to Process Improvement:** Describe any changes to the process improvement that were made as a result of Director/QA review.
- **Training Learning Objectives:** Describe any modifications to the training program that were made in response to this RQI.
- **Competency Assessment Activities:** Describe any competency assessment activities that will be added in response to this RQI (i.e. specific quiz questions, specific direct observation activities, specific record review processes).
- **Date PI, Replication, and Monitoring in Place:** The QA department must establish a target date for the complete implementation of this process improvement. A follow-up audit will be performed after that date.
- **Date BU QA Review Performed:** Enter the date that the Laboratory QA audit of the process improvement was performed.
- **Performed By:** Enter the name of the individual who performed the process improvement audit.
- **Findings:** Describe the results of the audit. Was the process improvement completed? Is it still in place? Was it effective? Are additional improvements necessary?