QUALITY INCIDENT REVIEW		
DATE EFFECTIVE 06-20-2016	APPROVED BY QUALITY ASSURANCE MANAGER	PAGE 1 OF 4

Quality Incident Review

GUIDING PRINCIPLES AND SCOPE

Action must be taken when major departures from the policies and procedures in the Management System have been identified. These quality incidents shall be identified and reported so that appropriate follow-up action can be implemented. The identification of problem areas and subsequent preventive actions will improve the quality of our Department.

This document describes the Department's process for dealing with quality incidents when major departures from the policies and procedures in the Management System have been identified. Problems or difficulties can arise in all phases of laboratory operations, and these must be evaluated and dealt with appropriately. Listing each potential problem is impractical, and this topic is considered in general terms.

Technical errors or problems related to casework testing are dealt with as per the CONTROL OF NON-CONFORMING TESTING procedure. The procedure provides direction with respect to when such problems must be dealt with via a Root-Cause Analysis.

This procedure ensures that, when required, our accrediting bodies and/or appropriate entities are notified in a timely manner.

PROCEDURE

A problem with the Management System of the laboratory may be identified through a variety of activities such as internal or external audits, management reviews, feedback from customers, and from staff observations.

Not every quality incident or departure from Management System policies and procedures is serious enough to require a Quality Incident Review.

It is impossible to anticipate all situations in which a Quality Incident Review must be conducted; therefore, sound judgment is required in determining the extent and level of reporting and documentation required.

Issues which require a Quality Incident Review include, but are not limited to:

- Systemic non-conformance with the policies and procedures in the Management System (e.g., failure to properly document staff qualifications and training)

The Quality Assurance Manager should be consulted if there is any question as to whether a Quality Incident Review is required.

A. Quality Incident Reporting

1. All staff members are responsible for reporting apparent quality incidents that come to their attention.
   i. All quality incidents are reported to the staff member's immediate supervisor.
   ii. Supervisors or managers who become aware of any non-technical quality incidents, either directly or through notification from other staff members, must proceed to Step 2.
   iii. Any member of staff who believes that the potential quality incident is of major concern, but is concerned about confidentiality, may inform the Quality Assurance Manager immediately and directly

2. The supervisor or manager investigates the issue to determine the details of the potential problem.

3. If the initial investigation indicates that a quality incident occurred, but that a formal Quality Incident Review is not needed, the investigating supervisor/manager shall inform the Quality Assurance Manager of the incident via email.

4. If the initial investigation indicates that a formal Quality Incident Review is needed, the investigating supervisor/manager consults with the Quality Assurance Manager.

5. The Quality Assurance Manager determines whether to proceed with a formal Quality Incident Review.

6. The Quality Assurance Manager informs the investigating supervisor/manager of the decision.

7. The decision not to proceed with a formal Quality Incident Review does not prevent a supervisor or manager from conducting other follow-up action, e.g., counseling of an individual.

B. Quality Incident Review

1. The Quality Assurance Manager assigns a supervisor or manager to conduct the Quality Incident Review.

2. The Quality Incident Review (QIR) form guides the steps of the process.

3. The incident is described in detail on the QIR, including the effect(s) of the discrepancy.

4. The assigned supervisor/manager conducts an investigation to determine the **root cause** of the incident. The root cause(s) may not be obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include, but are not limited to, problems with:

   - customer requirements
   - the samples
   - sample specifications
   - methods and procedures
   - staff skills and training
   - consumables, or
   - equipment and its calibration.

   The assigned supervisor/manager conducting the QIR shall use the OCME Root Cause Analysis Procedure as a guide to determine the root cause of the incident.

5. Follow-up actions are proposed to correct the immediate problem and minimize the potential for recurrence of the problem. Corrective actions may include, for example, personnel counseling, modifying procedures or forms, etc. The follow-up action plans should also include:

   - The parties responsible for implementing the corrective actions
   - The monitoring that will be conducted to ensure that the proposed actions have been effective. Very serious and/or systemic issues may require follow-up audits of the affected areas of activity.

6. The QIR is forwarded to the Quality Assurance Manager for review and approval of the proposed corrective actions.

C. Close-out of Quality Incident Reviews

1. The completion of corrective actions is documented on the QIR.

2. If the monitoring activities indicate that the initial follow-up actions were insufficient to address the quality incident, the Quality Assurance Manager may initiate additional follow-up actions.

3. The Quality Assurance Manager determines which incidents must be disclosed to accrediting bodies and/or appropriate entities.

4. The QIR is "closed" when monitoring activities are completed and all individuals agree that corrective action(s) have been satisfactorily implemented and effectively addressed the quality issue.

5. The QIR and any supporting records are filed with the Quality Assurance Unit.