Corrective Action Policy

Purpose: This policy has been developed to meet the Clinical Laboratory Improvement Amendments (CLIA) Standard 493.1239 (Standard Requirements for General Laboratory Systems Quality Assessment).

Principle: A corrective action system enables the laboratory to correct problems and make process improvements. Problems may be identified though a number of different mechanisms; only significant problems trigger the initiation of a corrective action. A root cause analysis must be performed to identify the source of the problem and means to correct the problem. Ultimately, the goal of a corrective action is to prevent the problem's future occurrence. Before a problem may be considered resolved, it may need to be monitored to ensure its effectiveness. In summary, CLIA Standard 493.1239 states that investigations and corrective actions/improvements will be taken any time an error is discovered or a potential problem is identified that may affect testing of patient specimens.

1. Identification of Problem

1.1. Problems arising in any of the following systems trigger the corrective action process.
- 1.1.1. General Laboratory Systems (includes patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency and proficiency testing performance);
- 1.1.2. Preanalytic Systems;
- 1.1.3. Analytic Systems; and
- 1.1.4. Postanalytic Systems.
- 1.1.5. Note: A manufacturer recall notice may require the corrective action process.

1.2. Once a problem or potential problem is identified, the significance and type of problem is evaluated by the Laboratory Director and the section Supervisor to determine if the corrective action process is required.
- 1.2.1. If the problem is an isolated event that is corrected, did not affect the technical accuracy of any customer deliverable, and will not likely recur, the documented corrective action may not be required.

1.3. Once the corrective action process is required, the "Request for Remedial Action (RFRA) Form" must be initiated.

1.4. The "Proficiency Test Corrective Action Form" is completed for proficiency testing investigations. See *Proficiency Testing Policy* for more information.

2. Request for Remedial Action (RFRA) Form

2.1. The RFRA form is composed of four sections.
- 2.1.1. Section 1: States the deficiency or potential problem
- 2.1.2. Section 2: Provides information on the root cause analysis and the corrective or preventive action(s)
- 2.1.3. Section 3: Documents completion of the RFRA and subsequent management review, as applicable.
- 2.1.4. Section 4: Documents staff reviews of the completed RFRA, as applicable.

2.2. Upon identification of the problem, Section 1 of the RFRA Form will be completed by the Initiator of the RFRA and the form will be submitted to the Laboratory Director or designee for review and signature.
- 2.2.1. An investigation date will be provided by the Initiator.
- 2.2.2. The Laboratory Director or designee will assign a unique RFRA number to the RFRA.

2.3. Section 2 of the RFRA Form will be completed by the Investigator and Section Supervisor to describe the root cause of the problem and identify corrective action(s).
- 2.3.1. The investigation should include a determination of whether or not the problem has occurred in the past, and if so, at what frequency.
- 2.3.2. Examples of corrective action include staff training, adding physical controls to an existing process, or the development of a new process.
- 2.3.3. A monitoring process (including a timeframe) to ensure that the proposed corrective/preventive action will be defined, as applicable, in the corrective/preventive action portion of the RFRA.
- 2.3.4. Section 2 will be completed within the investigation timeframe provided in Section 1.

2.4. Upon receipt of the completed Section 2 of the RFRA Form, the Laboratory Director or designee will review and complete Section 3 of the RFRA Form.
- 2.4.1. As applicable, a timeframe to monitor the corrective action will be provided.
- 2.4.2. As applicable, a management review date of the corrective action will be provided.
  - 2.4.2.1. Management review will verify that the corrective action was effective. Should the review indicate that the implemented corrective action(s) was not effective; the process of considering root causes and corrective actions will be re-initiated.

2.5. As applicable, Section 4 of the RFRA Form will be used to document staff review of the corrective action(s).

3. Record Retention

3.1. The completed RFRA form and supporting documents will be maintained by the Laboratory Director or designee for a period of no less than 2 years.

Signature Approvals

Steven York / 6/2/2014
QA Officer — Date

Tammy Barnum / 5/28/2014
Laboratory Director — Date