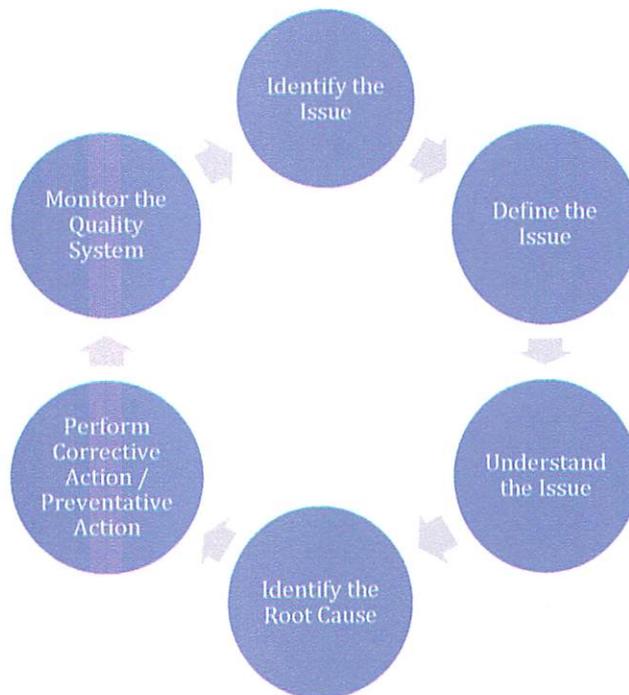


GUIDING PRINCIPLES AND SCOPE

Root Cause Analysis (RCA) is a tool used to determine the cause of deviations from procedure, practice and/or expected results. The goal of carrying out an RCA is to identify the contributory factors that lead to the issue and to identify ways and means in which the system may be improved upon such that the issue does not recur in the future. RCA utilizes the experience and expertise of those performing the analysis, and uses common sense techniques which produce a documented, quantified, and systematic approach to identifying, understanding and resolving underlying causes. RCA Guidelines provide a step-wise structure in the event a deviation from procedure, practice and/or expected results is identified.

Root Cause Analysis involves the following steps:



Step 1: Identify the Issue. Potential issues may come from many sources, including direct observation from an employee, inferred observation from data analysis, ordinary quality monitoring, etc.

Step 2: Define the Issue. When defining the issue, it is best to use SMART principles (Specific, Measureable, Actionable, Realistic and Time-constrained). Until an issue is properly defined, it cannot be resolved.

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Step 3: Understand the Issue. Review and assess the issue by gathering all information and data specific to the issue.

Step 4: Identify the Root Cause.

Step 5: Perform Corrective Actions / Preventative Actions (CAPA). CAPA are improvements to processes which eliminate root causes of non-conformities. Corrective actions / Preventative actions may require minimal changes if those improvements are able to immediately correct an issue, or may require long term corrective actions and implementation plans if the issue is identified as serious or pervasive.

Step 6: Monitor the Quality System. The Quality System must be continuously monitored by gathering and graphing key performance indicators specific for each Department.

IDENTIFICATION AND REVIEW OF THE ISSUE

The identification and determination of whether an issue has occurred within the OCME will be determined by each Department based on its practices and procedures. An issue being one which involves the substantial likelihood that an act, error or omission has affected the accuracy, reliability and integrity of reported results of evidence examination or reported results of analysis. Once an issue is discovered, temporary corrective actions should be immediately implemented as necessary. This is to ensure that additional issues, errors or defects do not occur.

Once the occurrence of an issue has been confirmed, the designated OCME RCA Officer will determine if the issue constitutes a “significant event.”

Within 10 days of the discovery of an issue, the RCA Office shall make a formal determination whether a ‘significant event’ has occurred.

A “significant event” is defined as:

- Intentional fabrication of work product, evidence examination, analysis or test results.
- Significant error(s) by an employee, or deficiency in a system or procedure that may have affected the accuracy of reported results of evidence examination or the accuracy of the reported results of analysis in one or more cases.
- Failure of an employee to follow protocol such that it may have affected the accuracy of reported results of evidence examination or the accuracy of the reported results of the analysis in one or more cases.

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- Statements made in the course of testimony by which an employee significantly misrepresents or misstate her/his education, experience, training or qualification or the reported results of any evidence examination or analysis.

If the Root Cause Analysis Officer determines the discovered or reported issue is not a 'significant event,' the RCA Officer shall provide a written explanation to the Chief Medical Examiner documenting why the issue does not constitute a 'significant event.'

If the Root Cause Analysis Officer determines the discovered or reported issue constitutes a 'significant event,' the RCA Officer will promptly inform the Chief Medical Examiner.

Within 5 business days of determining a 'significant event' has occurred, the Root Cause Analysis Officer will convene a Root Cause Analysis Committee (RCAC) - for the purpose of conducting a RCA and producing a RCAC report. It is recommended that the RCA Office prepare a summary of the identified 'significant event' and distribute to the RCA Committee in advance of its first meeting.

The RCAC will consist of the following members:

- At least 1 member who is knowledgeable in the subject area of the significant event and is a lab member or other employee who performs scientific or technical services and works in a non-managerial capacity;
- 1 member who serves in the Executive Management of the OCME;
- 2 members who are from divisions, departments or laboratories of the OCME that is not implicated by the significant event; 1 of the 2 members works in a non-managerial capacity;
- 1 member who is an external expert (i.e., a non-OCME employee) who works in a medical or scientific research field (who shall serve without compensation);
- Ad hoc members, if necessary. These would be individual(s) directly involved in the 'significant event' which is under review by the RCA Committee.

The RCAC members will have equal roles and responsibilities - with the RCA Officer serving as the Chair of the Committee.

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Depending on the nature and spectrum of the 'significant event,' the RCA Officer will determine when and how frequently the RCA Committee shall meet.

Within 30 days of a determination by the RCA Officer that a 'significant event' has occurred, the OCME shall report the occurrence of the 'significant event' to the Mayor and City Council, and to the respective District Attorney's Office (if applicable) and defense counsel of record (if applicable).

No later than 90 days after its assembly by the RCA Officer, the RCAC will prepare a RCA report which identifies and assesses the causal factors of the 'significant event,' and recommends operational and/or systemic corrective action(s) and/or preventative action(s).

Within 7 days after the issuance of a RCA report, the OCME will distribute the RCA report to the Mayor, City Council, New York State Forensic Science Commission (if applicable), ASCLD/LAB or ABFT (if applicable) and to the respective District Attorney's Office (if applicable) and defense counsel of record (if applicable).

Recommended Tools and Techniques for performing Root Cause Analysis

Identify causal factors to correct the issue and to minimize and/or prevent future occurrence.

Causal factors include, but are not limited to:

- i. Materials (proper reagents and supplies to perform testing)
- ii. People (education, experience, training of personnel)
- iii. Machines (instrumentation)
- iv. Method (protocols, practices, guidelines)
- v. Measurement (instrumentation is properly maintained and/or calibrated)
- vi. Environment (appropriate space to perform testing, temperature)
- vii. Information Flow (suitable dissemination of necessary instructions)

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Identifying and assessing the causal factors which caused or contributed to the issue can be mapped out in a variety of ways. A 'Chronological Map' and 'Fishbone Diagram' are two commonly utilized RCA tools. Where the identified issue has many causal factors, it is recommended they be assessed in priority order.

Once the causal factors associated with the issue are identified, the next recommend step is to determine why the issue occurred. There may be 'barriers' purposely in place which are intended to prevent deviations from practice and protocol. It is important to assess why the barriers in place failed to prevent the issue from occurring, and if additional 'barriers' must be created to prevent reoccurrence of the issue. Once it is determined which barrier(s) failed, it is necessary to determine why.

A "5 Why's" approach is a recommended step in all Root Cause Analysis. This is an effective tool to 'drill down' into the contributing causes of the issue.

Recommendations RE: Corrective Action / Preventative Action

After the root cause(s) of the issue is determined, recommendations of corrective actions / preventative actions should be drafted with the aim of eliminating or minimizing the likelihood that the issue recur in the future.

Recommendations may include:

- i. Defined course of action/plan to eliminate or minimize causal factor(s)
- ii. Identify who will be responsible for implementing recommended corrective and preventative actions
- iii. Define implementation timeframe
- iv. Identify resources required to effectively implement agreed upon course of action

Monitor for Effectiveness

After the root cause(s) have been determined and corrective actions / preventative actions have been implemented, it is vital that the implementations be continuously monitored. This is an important phase of the RCA, and must not be overlooked.

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