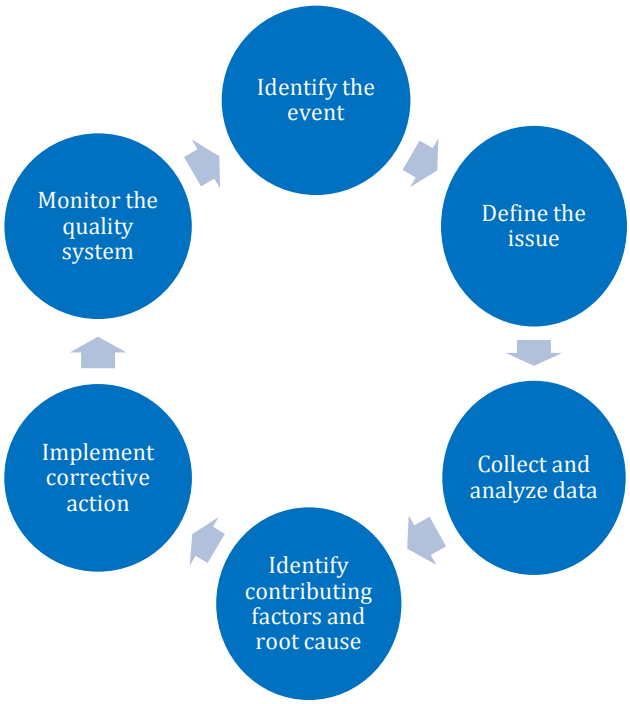
OFFICE OF CHIEF MEDICAL EXAMINER ROOT CAUSE ANALYSIS GUIDELINES

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 learn what happened, to identify the contributing factors that lead to the issue and to identify ways in which the system may be improved upon to prevent recurrence. 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 event. Potential issues may come from many sources, including complaints, incident reports, nonconformities, audits, quality control data, etc.

Step 2: Define the issue. Once an event is identified, preliminary information should be gathered to focus the issue and narrow the scope of the RCA.

Step 3: Collect and analyze the data. Review and assess the issue by collecting detailed information and data specific to the issue. The goal is to fully understand what happened.

Step 4: Identify the contributing factors and the root cause.

Step 5: Implement corrective actions. Corrective actions are actions implemented to eliminate the cause of a nonconformity or other undesirable condition. Corrective 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 to measure the effectiveness of the corrective actions.

THE ROOT CAUSE ANALYSIS PROCESS

The identification and determination of whether an event has occurred within the OCME will be determined by each Department based on its practices and procedures. An event 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 event is discovered, remedial 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 Officer 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.

- 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 RCA 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 RCA Officer determines the discovered or reported issue constitutes a 'significant event', the following next steps will occur:

Within 5 business days of determining a 'significant event' has occurred, the RCA Officer will convene a Root Cause Analysis Committee (RCAC) for the purpose of conducting a RCA and producing a RCAC report.

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 departments 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.

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

Depending on the nature 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 the causal factors of the 'significant event' and recommends operational and/or systemic corrective 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

- Tools that may be helpful in defining and understanding the problem are the process map and event chronology. A process map may be used to illustrate the steps and major decision points of a workflow. An event chronology is a timeline that details the specific sequence of events for a given issue.

- Cause and effect analysis should be used to identify contributing factors and root causes. Visual tools, such as cause maps and fishbone diagrams, may be used to organize and sort possible causes and to structure the analysis.

  Causal factors include, but are not limited to:
  - Environment (facilities, temperature, organizational culture)
  - Information (suitable dissemination of necessary instructions)
  - Machines (instrumentation and equipment)
  - Materials (proper reagents to perform testing, supplies)
  - Measurement (instrumentation is properly maintained and/or calibrated)
  - Method (procedures, directives, practices)
  - People (training, fatigue, scheduling)

- 5 Whys analysis is a recommended tool used to conduct a deeper analysis of identified causes. This is an effective tool to 'drill down' into the contributing causes and further explore cause-and-effect relationships.

CORRECTIVE ACTIONS

After the root cause(s) of the issue is determined, recommendations should be drafted with the aim of eliminating or minimizing the likelihood of recurrence in the future.

A corrective action plan should do the following:

- Provide a defined course of action/plan to eliminate or minimize causal factor(s).
- Identify who will be responsible for implementing recommended corrective actions.
- Define the implementation timeframe.
- Identify resources required to effectively implement the agreed upon course of action.

MONITORING FOR EFFECTIVENESS

After the root cause(s) have been determined and corrective 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.

Root Cause Analysis Process