

Guidance for Quality Indicators, Monitoring, Auditing, and Identification of Non-conformities

Definitions

- **Quality Indicators** are data driven and are observations or examinations that are identified/chosen by the laboratory or institution as part of the monitoring process to measure conformance with laboratory requirements including but not limited to the Quality Management System, Standard Operating Procedures, etc. Quality Indicator data is collected to identify and correct any nonconformities with laboratory requirements, continuously monitor problems and improve laboratory operations and the accuracy and reliability of patient testing.
- **Monitoring** is defined by the Centers for Medicare and Medicaid Services (CMS) as “an ongoing daily event which includes conducting analyses and tracking trends to correct issues in real time.”

Monitoring is a planned and systematic process that is performed at established intervals (e.g. daily, weekly, monthly, etc.) to observe, verify, and document a process is occurring as expected. Monitoring is used to observe compliance with minimum requirements and performance expectations on a regular basis over time (e.g. daily, weekly, monthly, semi-monthly, bi-monthly, etc.).

The monitoring process includes defining the quality indicators, collecting data on the quality indicator chosen and monitoring those quality indicators.

- **Auditing** is defined by CMS as “a formal retrospective review with a methodical approach and sampling of cases.”

Auditing is also planned and systematic examination or review of some or all the laboratory's Quality Management System (QMS) to determine conformance, or identify nonconformance, with the requirements established in the QMS, based regulatory and accrediting agencies' requirements. The identification of nonconformances is an important tool in identifying areas where improvements can be made.

Please note that a survey/inspection by the New York State Department of Health, College of American Pathologists, Joint Commission, etc. may not be used as the only means to meet the requirement that audits must be performed annually.

There are generally two types of audits:

System Audit

- ❖ A system audit is an audit of the entire laboratory or a part of the laboratory. System audits reveal either conformity or nonconformity with requirements (regulations, standards, laboratory policies and procedures, etc.).

An example of a system audit would be to recreate the testing process by following a series of specimens from collection to the reporting of the result in an area of the laboratory (Blood Bank, Microbiology, Core laboratory, etc.). This would include review of all standard operating procedures, policies and documentation related to this process and the personnel performing the testing. Areas to review include, but not limited to:

- specimen collection,
- personnel training and competency,
- preventive maintenance,
- calibration,
- quality control,
- temperature and humidity records,
- proficiency testing,
- turnaround time,
- reference ranges,
- test reports,
- nonconformances.

Process Audit

- ❖ A process audit is more focused and is often performed in response to identification of nonconformities or suspicions that non-conformities have occurred or are occurring. A process audit is an audit of an individual process against established policies and procedures. Process audits detect inefficiencies, problematic steps in the process, and areas where improvement is needed.

For example, a quality indicator would be used in the monitoring process to identify that the rate of blood culture contamination is unacceptable or is increasing. However, an audit of the process would be helpful to identify the root cause of the blood culture contamination.

- **A Non-conformity** is any occurrence that is not in accordance with policies, procedures or expectations. A non-conformance means that something has gone wrong and must be corrected. Non-conformances are addressed by identifying the root cause of the problem and developing a plan of correction to remediate.

Why is monitoring important?

- To identify nonconformances and implement improvements.
- To collect data and make informed decisions about areas to improve.
- Critical for performance management.
- Supports and influences the Quality Management System and business objectives using quality indicators.

Why is auditing important?

- Learn more about your own organization.
- Ensure compliance with regulatory requirements.
- Identify gaps in compliance and define where improvements are needed.
- Identify non-conformances to be able to make improvements including, but not limited to, developing, revising and implementing new standard operating procedures, training personnel, etc.
- Ensure your Quality Management System is effectively implemented and compliance is maintained.
- Provides a pathway for continuous improvement to ensure quality laboratory services.
 1. Identifies opportunities for improvement and preventive action.
 2. May reveal practice improvements that can be applied to other areas of the laboratory.
 3. Adjustments (revisions, updates, modifications, etc.) to quality indicators in the monitoring process is used to ensure ongoing compliance with the laboratory's QMS and the regulatory and accrediting agencies' requirements.
 4. Focuses on improving the quality of the test result and customer satisfaction.

Examples of Quality Indicators:

- Turnaround time for specimen receipt and test reporting for a stat test.
- Number of Cytopathology gynecological samples received from clients without last menstrual cycle information and the origination of the specimens.
- Number of specimens received missing labels or had incomplete information.
- Time required to be able to contact appropriate individual to report a critical or stat result.
- Disparities in frozen section results as compared to the final diagnosis.
- Disparities between preliminary and final reports.
- Differences between reference range stated in the SOP and the patient report.

Examples of Monitoring:

- Proficiency testing and accuracy testing performance is reviewed throughout the year and corrective action is taken when failures or shifts and trends occur.
- Quality control and calibration records are routinely reviewed and investigation and follow-up action is taken if quality control or calibration results are outside of the acceptable range.
- Reagent inventory is routinely reviewed to ensure that sufficient reagents are on-site to perform the testing required.
- Calculated results are intermittently reviewed for accuracy.
- Blood culture contamination rate to determine if there are any trends related to the contamination (i.e. same person collecting, a certain unit or floor, etc.).

Examples of Audits:

- Review of the Microbiology laboratory to ensure safety procedures and policies are followed.
- Review the instructions to clients, standard operating procedure, and patient report to ensure reference ranges and interpretative data is present, accurate, and identical in all areas;
- Review the process of quality control review to verify that all supervisors are performing the review following the same procedures, documenting the review similarly, documenting investigation of non-conforming quality control in the same manner, and implementing updates in the same manner.
- Mock audit of the laboratory to determine compliance with all requirements prior to an inspection by accrediting or regulatory agencies.

Record Retention:

Documentation must be maintained of all monitoring and auditing performed. The documentation must include the frequency of monitoring and auditing performed; what quality indicators will be used to perform the monitoring of laboratory processes; the date when monitoring or auditing was performed; a report of findings; and the follow-up that was performed in response to the findings.

Graphs and charts are useful to identify patterns and review issues over time.