

## QSE 11: Assessment

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|---|---|
| Policy                                  | The laboratory will undergo internal and external assessments to determine the effectiveness of the laboratory's quality management system.   |
| Purpose                                 | This policy provides direction for the processes and procedures to effectively manage Quality Assessment of the laboratory.   |
| Responsibility                          | <p>The Laboratory Medical Director is responsible for reviewing the Quality Assessment Report.</p> <p>The Quality Manager is responsible for developing and implementing a Quality Assessment Program.</p> <p>The Laboratory Supervisor and Lead Technologists are responsible for carrying out the activities of the Quality Assessment Program.</p> |
| Internal Quality Indicator Surveillance | The laboratory has procedures to identify the path of workflow and then select and monitor quality indicators that measure the performance of processes.  |
| Internal Audits                         | Internal process audits are performed for both Quality System essentials and operations on a predetermined schedule.  |
| External Quality Assurance              | Assessments provided by external organizations determine the laboratory's performance based on regulatory, accreditation, and predetermined values.   |
| External Benchmark                      | Laboratory performance is compared to self and others for continuing improvement goals.   |
| Quality Assessment Report               | A quality report is prepared and presented to the Quality Assurance Team and Laboratory Management on a regular basis.  |
| Supporting Documents                    | <p>The following processes support this policy:</p> <ul style="list-style-type: none"> <li>• Internal Quality Indicator Surveillance</li> <li>• Internal Audits</li> <li>• External Quality Assurance</li> <li>• External Benchmarking</li> <li>• Quality Assessment Reports</li> </ul>   |

## Process for Internal Quality Indicator Surveillance

| What Happens  | Who's Responsible  | Procedures  |
|---|--|---|
| Path of workflow is identified  | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Lead Technologist</li> <li>• Quality Manager</li> </ul>       | <ul style="list-style-type: none"> <li>• Specimen Tracking and Handling</li> <li>• Section-Specific Testing Procedures</li> <li>• Laboratory Test Menu</li> </ul>                               |
| Quality indicators are selected   | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul> | <ul style="list-style-type: none"> <li>• Specimen Tracking and Handling</li> <li>• Section-Specific Testing Procedures</li> <li>• Laboratory Test Menu</li> <li>• Quality Management</li> </ul> |
| Data from Quality Indicators is collected   | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> </ul>  |
| Data from Quality Indicators is analyzed  | <ul style="list-style-type: none"> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul>   | <ul style="list-style-type: none"> <li>• Quality Management</li> </ul>  |
| Quality indicator data is presented to facility and laboratory management and follow-up actions are initiated | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• Preparing a Quality Assessment Report</li> <li>• Process Improvement</li> </ul>  |

## Process for Internal Audits

| What Happens  | Who's Responsible  | Procedures   |
|---|--|--|
| An internal audit schedule is determined                      | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Quality Assessment Team</li> <li>• Internal Audit Team</li> </ul>                            | <ul style="list-style-type: none"> <li>• Internal Audit Procedures</li> <li>• Quality Management</li> </ul>  |
| An internal audit is conducted                                | <ul style="list-style-type: none"> <li>• Quality Assessment Team</li> <li>• Internal Audit Team</li> </ul>   | <ul style="list-style-type: none"> <li>• Internal Audit Procedures</li> <li>• Quality Management</li> </ul>  |
| A report of internal audit findings is submitted and reviewed | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Quality Assessment Team</li> <li>• Internal Audit Team</li> <li>• Quality Manager</li> </ul> | <ul style="list-style-type: none"> <li>• Internal Audit Procedures</li> <li>• Quality Management</li> <li>• Preparing a Quality Assessment Report</li> </ul> |
| Follow-up actions are initiated                               | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> </ul>                                  | <ul style="list-style-type: none"> <li>• Internal Audit Procedures</li> <li>• Quality Management</li> <li>• Process Improvement</li> </ul>                   |

## Process for External Quality Assurance

| What Happens  | Who's Responsible   | Procedures  |
|---|---|---|
| Laboratory participates in audits/assessments conducted by external agencies (including agencies for accreditation and licensure) | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Lead Technologists</li> <li>• Technicians/Technologists</li> <li>• Quality Assessment Team</li> <li>• Auditing Agency</li> </ul>              | <ul style="list-style-type: none"> <li>• External Audit Procedures</li> <li>• Quality Management</li> </ul>   |
| Laboratory participates in external proficiency testing program for all analytes tested   | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Lead Technologists</li> <li>• Technicians/Technologists</li> <li>• Quality Assessment Team</li> <li>• Proficiency Testing Provider</li> </ul> | <ul style="list-style-type: none"> <li>• External Proficiency Testing Procedures</li> <li>• Quality Management</li> </ul>   |
| Information from external audits and proficiency testing is analyzed  | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul>  | <ul style="list-style-type: none"> <li>• External Audit Procedures</li> <li>• External Proficiency Testing Procedures</li> <li>• Quality Management</li> </ul>  |
| Report of external assessment is submitted and reviewed   | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Quality Assessment Team</li> <li>• Quality Manager</li> </ul>   | <ul style="list-style-type: none"> <li>• External Audit Procedures</li> <li>• External Proficiency Testing Procedures</li> <li>• Quality Management</li> <li>• Preparing a Quality Assessment Report</li> </ul>                           |
| Follow-up actions are initiated   | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul>  | <ul style="list-style-type: none"> <li>• External Audit Procedures</li> <li>• External Proficiency Testing Procedures</li> <li>• Quality Management</li> <li>• Laboratory Section-Specific SOPs</li> <li>• Process Improvement</li> </ul> |

## Process for External Benchmark

| What Happens   | Who's Responsible  | Procedures   |
|--|--|--|
| Quality Indicators are selected  | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• Specimen Tracking and Handling Procedures</li> <li>• Laboratory Section-Specific SOPs</li> </ul>          |
| Data is collected for Quality Indicators                               | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> </ul>   |
| Performance on Quality Indicators is compared to an external benchmark | <ul style="list-style-type: none"> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul>   | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• External Benchmarks</li> </ul>  |
| Results of benchmark performance are analyzed and presented            | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul>                                  | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• External Benchmarks</li> <li>• Preparing a Quality Assessment Report</li> </ul>                           |
| Follow-up actions are initiated  | <ul style="list-style-type: none"> <li>• Laboratory Director</li> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Monitoring Team</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• External Benchmarks</li> <li>• Laboratory Section-Specific SOPs</li> <li>• Process Improvement</li> </ul> |

## Process for Quality Assessment Report

| What Happens   | Who's Responsible   | Procedures  |
|--|---|---|
| Quality Assessment Team collects data generated from quality indicator surveillance, internal audits, external audits and proficiency testing, benchmark performance, occurrences, customer suggestions/complaints and staff suggestions | <ul style="list-style-type: none"> <li>• Laboratory Supervisor</li> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• Preparing a Quality Assessment Report</li> </ul>   |
| Quality Assessment Team writes and submits to management a quality assessment report on at least an annual basis   | <ul style="list-style-type: none"> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> <li>• Laboratory Management</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• Preparing a Quality Assessment Report</li> </ul>   |
| Management reviews data and allocates resources for process improvement  | <ul style="list-style-type: none"> <li>• Quality Manager</li> <li>• Quality Assessment Team</li> <li>• Laboratory Management</li> </ul> | <ul style="list-style-type: none"> <li>• Quality Management</li> <li>• Quality Assessment Report</li> <li>• Process Improvement</li> <li>• Allocation of Resources</li> </ul> |