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Section 1. Conformity Assessment and Proficiency Testing: Monitoring and Improving Laboratory Performance Under ISO/IEC 17043 and ILAC P9

The information provided herein serves as general commentary and should not be considered definitive results or prescribed methods of implementation. Every laboratory and situation involves unique circumstances and requirements, necessitating tailored solutions and approaches. Final decisions should be based on the requirements of relevant standards and the specifics of implementation processes. Laboratory performance and compliance processes are structured and evaluated according to applicable standards and legal regulations.

1 Introduction and General Concepts

1.1. Conformity Assessment Bodies (CABs)

Conformity assessment encompasses inspection, testing, calibration, and certification activities conducted to determine whether a product, process, system, person, or service meets specified requirements. These processes aim to ensure quality, safety, and compliance with standards by providing reliable results.

Conformity Assessment Bodies (CABs) are independent and competent organizations that perform these activities. CABs provide testing, inspection, calibration, and certification services, verifying that products, systems, and services comply with defined standards. These organizations play a critical role in ensuring compliance with standards and regulations, enhancing industrial safety, consumer confidence, and the reliability of commercial operations.

Accreditation is the process in which an independent authority evaluates a CAB against specific standards to confirm its competence. Accreditation establishes that the results produced by CABs are reliable and widely accepted nationally and internationally. This process is fundamental for market trust and transparency.

1.2. What is ISO/IEC 17043?

ISO/IEC 17043 is an internationally recognized standard defining the requirements for the competence of proficiency testing providers. It includes the design, implementation, and evaluation of proficiency testing (PT) schemes to enhance the accuracy and reliability of results across laboratories.

- **Proficiency Testing (PT):** A method for assessing a laboratory's performance in specific tests or measurements by comparing its results with those of other laboratories.
- **Interlaboratory Comparisons (ILC):** A broader process where multiple laboratories compare their results on the same sample for a given test. While PT evaluates competence against specific standards, ILC often provides a more general performance assessment.

1.3 What is ILAC P9 Policy?

ILAC P9 is an international policy regulating laboratory participation in proficiency testing (PT) and interlaboratory comparisons (ILC). The policy requires laboratories to participate in PT and ILC programs to ensure result accuracy and monitor performance. Laboratories must demonstrate their reliability and competence by engaging in appropriate PT or ILC schemes for the parameters they test. ILAC P9 underscores the critical role of this participation in accreditation processes and encourages regular involvement in PT and ILC activities.

2. Structure and Requirements of ISO/IEC 17043

2.1 General Requirements (Clause 4)

Proficiency testing providers must act according to principles of impartiality, confidentiality, and independence. They are responsible for ensuring the objective execution of tests and protecting participant information.

2.2 Structural Requirements (Clause 5)

Providers must have an appropriate organizational structure. The functioning of management systems is essential to ensure quality and secure testing processes.

2.3 Resource Requirements (Clause 6)

The qualifications of personnel, the use of appropriate equipment and facilities, and the management of outsourced services are addressed. Efficient resource management directly impacts the quality of testing.

2.4 Process Requirements (Clause 7)

Proficiency testing schemes must be meticulously planned and designed. Sample homogeneity and stability must be verified, and preparation and distribution must be carefully managed.

2.5 Data Analysis and Evaluation of Results (Clause 8)

The performance of participating laboratories is assessed using detailed data analysis and statistical techniques. Results are reported, and recommendations for improvement are provided.

3. ILAC P9 Policy and Its Requirements

3.1 Proficiency Testing and Interlaboratory Comparisons (ILC)

Proficiency Testing (PT) and **Interlaboratory Comparisons (ILC)** are critical methods for evaluating laboratory performance and the accuracy of their results. Both methods serve to monitor competence, but they differ in application:

- **Proficiency Testing (PT):** Evaluates a laboratory's performance in specific test or measurement areas independently. Proficiency testing providers send samples to participating laboratories, which analyze these samples and report the results back to the provider. Proficiency testing providers then assess the laboratories' performance and prepare reports. PT is widely used in accreditation processes to demonstrate laboratory competence.
- **Interlaboratory Comparisons (ILC):** A process in which two or more laboratories conduct the same or similar tests and compare their results. ILC can be used when PT is not available. It is generally employed to monitor laboratory performance and evaluate the accuracy of results by benchmarking them against other laboratories.

3.2 Participation Requirement in PT and ILC According to ILAC P9

In line with the **ILAC P9:01/2024** document, accredited laboratories or laboratories applying for accreditation are required to participate in Proficiency Testing (PT) or Interlaboratory Comparisons (ILC) whenever feasible and appropriate for the parameters they test. This requirement aims to ensure the reliability and accuracy of laboratory results.

PT Participation Requirement: If proficiency tests are available for the tests conducted by a laboratory, participation in these tests is mandatory. Participation in PT demonstrates that a laboratory's results are reliable and have been validated by an accredited PT provider.

ILC Participation Requirement: If proficiency tests are not available for a specific test, laboratories are required to participate in interlaboratory comparisons (ILC). ILC enables laboratories to verify the accuracy of their results by comparing them with those of other laboratories. While ILC serves as an alternative to PT, it is generally less formalized than PT. In summary, **ILAC P9** establishes mandatory participation in PT or ILC as a critical measure for ensuring the quality and reliability of laboratory testing processes and results.

3.3 Participation Frequency and Proficiency Testing

The frequency of participation in Proficiency Testing (PT) and Interlaboratory Comparisons (ILC) for laboratories depends on the risk level of the tested parameters, the characteristics of the samples being analyzed, and the scope of the laboratory's activities. According to **ILAC P9**, laboratories are required to participate in PT or ILC at regular intervals to ensure the accuracy of their results. This is a critical step in monitoring laboratory performance and identifying opportunities for improvement.

- **Participation Frequency:** Laboratories must participate in PT or ILC at least once per year for tests with moderate to high risk levels. For tests with higher risks, participation frequency may need to increase. Conversely, for low-risk tests, participation every two years may suffice.
- **Competency Assessment:** Laboratories must analyze their PT or ILC results and report them to accreditation bodies. Accreditation bodies evaluate laboratory competence based on these results. PT or ILC outcomes play a significant role in performance assessments, and proficiency evaluations are structured around these findings.

In summary, **ILAC P9** mandates participation in PT and ILC to monitor laboratory performance, demonstrate competence during accreditation processes, and ensure the reliability of test results. This participation supports laboratories in regularly verifying their results and identifying areas for improvement.

3.4 Development of Participation Plans

Participation in Proficiency Testing (PT) and Interlaboratory Comparisons (ILC) is essential for ensuring the accuracy and reliability of test and measurement results in laboratories. In compliance with **ILAC P9** and **ISO/IEC 17043**, laboratories must organize this participation in a systematic and planned manner. This section provides detailed explanations of the requirements for PT and ILC participation, how participation should be planned, and the methods to follow when proficiency testing is not available.

3.4.1 Proficiency Testing (PT) Participation Requirements

Proficiency Testing (PT) is a crucial process for validating the competence of laboratories and the reliability of their results. PT not only demonstrates a laboratory's proficiency during accreditation processes but also ensures international acceptance of its results.

- **Participation Obligation**: Laboratories are required to participate in PT if proficiency tests are available for the tests they perform. PT programs validate the accuracy of a

laboratory's results through an independent provider. Accredited laboratories or those applying for accreditation must participate in PT whenever possible.

- **Participation Frequency**: The frequency of participation should be determined based on the risk level of the tested parameters. For high-risk tests (e.g., medical analyses, environmental tests, or tests critical to safety), laboratories are recommended to participate at least once a year. For low-risk tests, participation every two years may suffice.

- **Participation Plan**: Laboratories must prepare a comprehensive participation plan for all testing areas. The plan should specify the PT programs for each test parameter, the frequency of participation, and the providers to be engaged. It should also detail the schedule of PT programs and how results will be reported.

- **Analysis and Reporting of Results**: PT results should be analyzed and integrated into the laboratory's management system. If unsatisfactory results are obtained, corrective actions must be planned to improve performance. PT results should also be reported to and monitored by accreditation bodies.

3.4.2 Interlaboratory Comparisons (ILC) Participation Requirements

Interlaboratory Comparisons (ILC) are used as an alternative when proficiency testing is not available. ILC enables laboratories to monitor their performance by comparing their results with those of other laboratories.

- **Participation Obligation**: If PT is unavailable, laboratories are required to participate in ILC. This method ensures the accuracy of a laboratory’s results by comparing them with other laboratories' outcomes.
- **ILC Participation Plan**: Laboratories should prepare a plan specifying the test parameters for which they will participate in ILC. The plan must include details of the laboratories to be compared, the methods for conducting comparisons, and an emphasis on collaborating with internationally recognized laboratories whenever possible.
- **Participation Frequency**: As with PT, the frequency of ILC participation should be based on the risk level of the test parameters. For high-risk tests, participation is recommended at least once a year, while for low-risk tests, every two years may be sufficient.
- **Analysis and Improvement of Results**: ILC results should be analyzed and incorporated into the laboratory's management system. Any deviations identified through comparisons should be corrected, and performance should be enhanced. ILC results should also be utilized during accreditation processes.

3.4.3 Alternative Approaches When Proficiency Testing Is Unavailable

When proficiency testing (PT) is not available for specific test parameters, laboratories must adopt alternative methods to ensure the accuracy of their results.

- **Participation in ILC**:The most suitable alternative to PT is ILC. Laboratories can compare their results with those of other laboratories conducting similar tests to ensure accuracy. While ILC is not as formalized as PT, it is a widely accepted method for monitoring results.
- **Use of Reference Materials**: Certified reference materials can be used to verify results when PT is unavailable. These materials provide a standard for comparison and enhance the reliability of results.

- **In-House Comparisons**: Laboratories can conduct internal comparisons by testing the same samples using different analysis methods. This approach allows for self-assessment and the identification of discrepancies. Tests conducted by different personnel or equipment can also be considered as part of in-house comparisons.
- **Repeat Testing and Correlation Analyses**: Laboratories can verify results by performing repeat tests and correlation analyses. By comparing results obtained through the same or different methods, consistency can be ensured.
- **Risk Assessment and Monitoring**: Laboratories should perform risk assessments to determine which tests require closer monitoring. For high-risk tests, more frequent monitoring and the use of alternative methods are recommended.

Conclusion: Importance of Participation Plans

Developing participation plans for PT and ILC is a critical process for monitoring the accuracy of laboratory results. If proficiency testing is available, laboratories must participate in these tests. When PT is unavailable, laboratories must rely on ILC and other alternative methods to ensure the reliability of their results. Regularly reviewing PT and ILC plans and integrating the outcomes into accreditation processes allow laboratories to continuously demonstrate their competence and maintain high standards of performance.

3.5 Risk Assessment and Alternative Methods

PT and ILC are critical tools for ensuring the accuracy and reliability of laboratory results. However, participation in PT or ILC may not always be feasible or available. In such cases, laboratories must adopt alternative monitoring methods to verify the accuracy and consistency of their results. This section outlines alternative methods, their implementation, and strategies for improving outcomes.

3.5.1 Alternative Monitoring Methods Outside PT and ILC

When PT or ILC participation is not possible, laboratories must implement alternative methods to ensure the reliability of their results. These methods are designed to enhance accuracy and consistency within the laboratory's internal processes and compensate for the absence of PT or ILC.

- **Repeated Testing**

Laboratories can monitor the consistency and accuracy of their results by performing the same test multiple times on the same sample. Comparing results obtained at different times helps identify potential deviations in laboratory processes. **Implementation**: Repeat tests can be conducted by different operators or with different equipment, and the results can be compared.

- **Testing with Different Methods**

Using multiple testing methods on the same sample provides a comparative basis for evaluating accuracy. Employing diverse techniques ensures the reliability of the results. **Implementation**: For example, a chemical composition can be analyzed using both spectroscopy and chromatography methods.

- **Personnel Competency Checks**

The same samples can be tested by different laboratory personnel, and their results can be compared. This method evaluates the competence of personnel and verifies that laboratory processes yield consistent results regardless of the operator. **Implementation**: Independent operators perform the same test, and their results are compared.

3.5.2 Use of Reference Materials and Internal Comparisons

Certified reference materials and internal comparisons are widely used alternatives to PT and ILC. These methods serve as performance monitoring tools within a laboratory's quality control processes.

- **Certified Reference Materials (SRM)**

SRMs are materials with known and validated values for specific test parameters. Testing with SRMs enables laboratories to verify the accuracy and validity of their results. **Implementation**: The laboratory analyzes a reference material with known concentrations of chemical compounds and compares its measurements with the reference values to identify any deviations.

- **Internal Comparisons**

Internal comparisons involve analyzing the same sample using different operators, equipment, or methods within the same laboratory. This ensures consistency in the laboratory's internal processes.
Implementation: The laboratory tests the same sample on multiple devices and compares the results for consistency. Operators can also independently perform the same tests for comparative analysis.

- **Control Charts and Statistical Process Control (SPC)**

Control charts are graphical tools used to monitor variations in results over time, while SPC identifies process variations and prevents abnormal deviations.
Implementation: The laboratory plots its results on a control chart and monitors whether they remain within acceptable limits.

3.5.3 Performance Monitoring and Improvement Processes

Continuous performance monitoring and improvement are essential for laboratories to track the accuracy of their results and take corrective actions when deviations or errors are identified. These processes should be integrated into the laboratory’s quality management system.

- **Analysis of Results**

Laboratories should regularly analyze their results and monitor performance. If significant deviations or inconsistencies are detected, corrective actions must be initiated. **Implementation**: Results are analyzed statistically, and deviations are evaluated against predefined criteria. Corrective actions are applied when necessary.

- **Corrective Actions**

Based on performance monitoring findings, laboratories must plan and implement corrective actions to address errors and prevent their recurrence.
Implementation: If a test result is found to be incorrect, calibration of equipment may be redone, personnel training may be updated, or methods may be adjusted.

- **Continuous Improvement**

Performance monitoring and corrective actions contribute to the ongoing improvement of laboratory processes. Using the **PDCA Cycle** (Plan-Do-Check-Act), laboratories should seek opportunities for improvement in all processes.
Implementation: Laboratories regularly review test results, identify areas for improvement, and implement changes to enhance reliability, which strengthens their accreditation standing.

Conclusion: Importance of Risk Assessment and Alternative Methods

Laboratories unable to participate in PT or ILC must adopt alternative methods to ensure the accuracy and reliability of their results. Tools such as reference materials, internal comparisons, repeated testing, and statistical control help laboratories monitor their results, identify errors, and detect deviations. These processes should be based on risk assessments and implemented consistently. If deviations are identified, corrective actions should be initiated, and processes should be improved.

4. Guide for Proficiency Testing (PT) Providers

4.1. Design of Proficiency Testing Programs

Proficiency testing (PT) programs are planned to evaluate the performance of participating laboratories. A risk assessment is conducted to ensure that the tests are prepared appropriately for their purpose. Considering the requirements of participants, all steps related to sample distribution, testing, and result reporting are clearly defined.

4.2. Homogeneity and Stability Testing

Homogeneity and stability tests are critical to ensuring that PT samples are provided to all participants under the same conditions. These tests are applied to determine whether the characteristics of the samples are consistent and reliable before distribution. Homogeneity tests ensure that all samples show the same performance for all participants, while stability tests guarantee that the samples remain consistent over time without degradation.

4.3. Statistical Evaluation of Results

PT results are evaluated using statistical tools such as z-scores and robust methods. These methods allow objective comparisons of the performance of participating laboratories. Z-scores normalize the performance of a laboratory against reference values, while optimization methods offer more flexible and robust evaluations, enabling better performance assessments.

4.4. Performance Evaluation and Reporting

PT providers evaluate the performance of participating laboratories based on the test results. Statistical tools like z-scores and optimization methods are used to detect deviations. Detailed and clear reporting of results is essential. During reporting, transparency, impartiality, and accuracy principles must be strictly followed so that laboratories can objectively understand their performance.

4.5. Corrective Actions and Improvement

Participating laboratories with deficiencies identified in PT results are expected to undertake corrective actions. These actions should address performance deficiencies and aim to improve laboratory processes. Within the framework of the continuous improvement cycle, laboratories should regularly analyze PT results and optimize their processes.

5. Proficiency Testing (PT) and ILC Processes for Participating Laboratories

Proficiency testing (PT) and interlaboratory comparisons (ILC) are two critical processes for evaluating laboratory performance and ensuring the accuracy of results. Participation in these processes plays a vital role in both accreditation and quality assurance systems. This section

details how laboratories can participate in PT and ILC, the steps involved in the processes, and how results are reported and analyzed.

5.1. Participation in Proficiency Testing (PT)
Proficiency testing (PT) is a comparison test organized by a third party (a PT provider) to evaluate the performance of laboratories in a specific test or measurement area. The PT process involves the following steps:

a) Steps of the PT Participation Process

- **Selection of PT Program**: Laboratories must select PT programs appropriate to their areas of activity. This selection depends on the types of tests performed and the availability of relevant PT programs. According to ISO/IEC 17025 requirements, participation in PT is mandatory if a PT program exists for the parameters being tested.
- **Preparation and Receipt of Test Samples**: Samples prepared by the PT provider are delivered to laboratories. Laboratories must inspect the samples for acceptance conditions and integrity before starting the test. It is essential to ensure that the samples are undamaged and meet test conditions.
- **Conducting the Test**: Laboratories analyze the samples using routine test methods. The devices, methods, and operators used during the test must be the same as those in daily operations. Laboratories should document any deviations or special circumstances encountered during testing.
- **Recording Results**: Test results must be recorded and prepared for submission to the PT provider. Laboratories must ensure the results are accurate and complete.

b) Reporting Results to the PT Provider

- **Submission of Results**: Laboratories submit test results to the PT provider in the prescribed format. Results are typically submitted digitally, though written reports may also be used in some cases. The provider will evaluate these results.
- **Evaluation of Results**: The PT provider compares the laboratory's results against reference values or those of other participating laboratories. Statistical analyses, such as z-scores, are used to assess performance and identify deviations.
- **Receiving the Report**: The PT provider reports the results to the laboratory, including performance evaluation, potential deviations, and the need for corrective actions.
- **Corrective Actions**: If deviations or errors are detected in the laboratory's results, corrective actions must be planned. These actions may involve recalibration of equipment, retraining of operators, or a review of test methods.

5.2. Participation in Interlaboratory Comparisons (ILC)
Interlaboratory comparisons (ILC) are used when PT is not available. ILC allows laboratories to monitor their performance by comparing results with those of other laboratories. ILC is more flexible than PT and is often directly organized among laboratories.

a) Steps in the ILC Process and Differences from PT

- **Selection of ILC Program**: Laboratories should plan to participate in ILC if PT is unavailable. ILC programs are typically organized among laboratories and may not adhere to specific standards. Laboratories arrange participation by coordinating with other laboratories conducting similar tests.

- **Sample Sharing**: Laboratories share samples designated for ILC among themselves. Unlike PT, sample preparation is usually managed collaboratively by participating laboratories rather than a third-party provider.
- **Conducting the Test**: Each laboratory analyzes the samples using its routine test methods and records the results for comparison with others.
- **Comparison of Results**: Laboratories share their results with each other and compare them. Unlike PT, ILC results are evaluated more flexibly and often directly among the participating laboratories.

b) The Role of ILC in Ensuring Laboratory Result Accuracy

- **Monitoring Accuracy**: ILC enables laboratories to monitor the accuracy of their results by comparing them with other laboratories. Although less stringent than PT, ILC provides critical feedback on result acceptability.
- **Self-Performance Comparison**: Laboratories can identify deviations in their performance by comparing their ILC results with those of others. These comparisons provide valuable insights into whether test methods need improvement or equipment requires recalibration.

c) Analysis of ILC Results and Internal Comparisons

- **Result Analysis**: Laboratories must carefully analyze ILC results to determine whether they fall within expected limits and are consistent with other laboratories. Performance deviations may indicate problems in laboratory processes.
- **Internal Comparisons**: ILC results can also be used internally. The same sample can be tested with different equipment or personnel to monitor result consistency, thereby enhancing the reliability of internal test processes.
- **Corrective Actions**: If ILC results indicate unacceptable deviations, laboratories should plan corrective actions, such as equipment recalibration, method revision, or operator training.

Conclusion: Importance of PT and ILC Processes

Proficiency testing (PT) and interlaboratory comparisons (ILC) are critical for monitoring laboratory performance and ensuring the accuracy of test results. PT, as a formal process organized by accredited providers, validates laboratory competence. ILC, as an alternative when PT is unavailable, allows laboratories to verify their results through comparison with others. Both processes play an essential role in laboratory accreditation and help laboratories achieve accurate, reliable, and high-quality results.

5.3. Evaluation of Results and Improvement Activities

The proper analysis of proficiency testing (PT) and interlaboratory comparisons (ILC) results is crucial for improving laboratory performance and meeting accreditation requirements. This section addresses how laboratories should evaluate these results, identify performance deviations, and plan and implement corrective actions.

5.3.1 Analysis of PT and ILC Results

Result analysis objectively evaluates laboratory performance. PT and ILC results show how accurate and reliable a laboratory's results are by comparing them to those of other laboratories. The analysis process includes the following steps:

- **Comparison of Results**: Laboratories compare PT or ILC results with reference values or results from other laboratories. Deviations should be assessed for their magnitude and impact on laboratory results.
- **Statistical Analyses**: PT and ILC results are usually evaluated using statistical methods such as z-scores or robust techniques to assess statistical norms. Deviations detected through these analyses indicate potential performance issues.
- **Accuracy and Consistency of Results**: The results for tested parameters are evaluated for alignment with reference standards. If results remain within expected limits, their accuracy is assured. Consistency across tests is also critical; results should be similar in repeated tests.

5.3.2 Detection of Performance Deviations and Improvement Processes

Detecting performance deviations indicates issues in laboratory results. These deviations can arise from test methods, equipment, personnel competence, or environmental factors. After identifying deviations, the following steps should be taken:

- **Identification of Deviations**: Laboratories identify the source of deviations using statistical analyses or by comparing results with reference values. For instance, a z-score outside ±2 indicates a deviation.
- **Determination of Root Cause**: Once a deviation is detected, laboratories must identify its root cause, such as calibration errors, incorrect test methods, or operator mistakes.
- **Improvement Processes**: After identifying the cause, laboratories initiate improvement processes, such as recalibrating equipment, updating personnel training, or revising test procedures. These processes aim to prevent recurrence of the same errors.

5.3.3 Planning and Monitoring Corrective Actions

Corrective actions address errors and provide improvements in areas where deviations are detected. These actions must be planned and monitored systematically.

- **Planning Corrective Actions**: Laboratories plan corrective actions based on the cause of deviations. For example, recalibration may be required for equipment-related deviations, while updated training may be necessary for personnel-related issues.
- **Implementation and Follow-Up**: Planned corrective actions must be implemented, and their effectiveness monitored. Laboratories must track the results of corrective actions to ensure the deviation has been resolved.
- **Continuous Improvement Cycle**: Laboratories should engage in continuous improvement based on PT and ILC results. The **PDCA Cycle** (Plan-Do-Check-Act) can be applied, where potential deviations are monitored after each test, and necessary improvements are implemented.

5.4 Risk Assessment and Alternative Monitoring Methods

Risk assessment involves identifying which tests carry higher risks and selecting appropriate methods to monitor the results of these tests. When proficiency testing (PT) and interlaboratory comparisons (ILC) are not available, laboratories must adopt alternative monitoring methods.

5.4.1 Alternative Methods When PT and ILC Are Unavailable

When PT and ILC programs are not available, laboratories should use alternative monitoring methods to ensure the accuracy of their results:

- **Repeated Testing**: Performing repeated tests on the same sample can help ensure the consistency and reliability of results. Tests conducted at different times are compared to check for any deviations.
- **Testing with Different Methods**: Analyzing the same sample using different methods helps verify the accuracy of results. For instance, a chemical compound can be analyzed using both spectrometry and titration methods.
- **Internal Comparisons**: Testing the same samples within the laboratory using different equipment or personnel helps ensure consistency in internal processes.
- **Use of Reference Materials**: Certified reference materials (CRMs) are samples with known and validated values for specific tests. Laboratories can use these materials to verify their results.

5.4.2 Importance of Internal Comparisons, Reference Materials, and Repeated Testing

Internal comparisons are one of the most commonly used methods for ensuring result accuracy when PT and ILC are unavailable. This process involves testing the same sample using different devices or personnel and comparing the results.

- **Reference Materials**: CRMs play a critical role in verifying result accuracy. Laboratories test these materials with known values and compare their results to monitor accuracy.
- **Repeated Testing**: Tests conducted at different times help monitor the consistency of results and detect potential errors or changes in laboratory processes.

5.4.3 Risk Assessment Process and Prioritizing High-Risk Tests

The risk assessment process helps laboratories identify tests that carry higher risks. High-risk tests are those where results are directly tied to safety, health, or environmental impact. These tests require more frequent and meticulous monitoring to ensure result accuracy.

- **Conducting Risk Assessments**: Laboratories must assess the risk associated with each test. Factors such as the impact of results, potential consequences of errors, and test complexity should be considered in the assessment.
- **Prioritizing High-Risk Tests**: High-risk tests should be monitored more frequently through PT, ILC, or alternative methods. For example, tests in medical analyses or environmental monitoring carry significant risks and demand critical accuracy.

Conclusion: Performance Evaluation and Risk Management
Accurate analysis of PT and ILC results is vital to ensuring the reliability of laboratory results. When performance deviations are identified, corrective actions must be initiated, and laboratory processes improved. When PT and ILC are unavailable, alternative monitoring

methods such as repeated testing, internal comparisons, and reference materials should be utilized, with priority given to high-risk tests. These practices enable laboratories to continuously monitor and improve their results, enhancing their reliability and credibility.

6. Continuous Improvement and Performance Monitoring

Continuous monitoring and improvement of laboratory performance are essential to producing reliable and consistent results. Continuous improvement is a cornerstone of enhancing the effectiveness of laboratory management systems and preventing errors. Tools such as the Plan-Do-Check-Act (PDCA) cycle and data from proficiency testing (PT) are critical for this process. By effectively utilizing PT and interlaboratory comparison (ILC) results, laboratories can monitor and improve their performance.

6.1. Continuous Improvement Cycle (PDCA)

The Plan-Do-Check-Act (PDCA) cycle is an effective tool for laboratories to optimize their quality management processes. This cycle enables laboratories to systematically plan improvement processes, implement them, monitor the results, and continuously improve processes by taking necessary actions.

a) Plan

This stage involves developing a strategy to enhance laboratory performance. Areas for improvement are identified based on PT and ILC results.

- **Setting Objectives**: Laboratories set specific quality objectives, such as reducing result deviations by 2% or aligning results more closely with reference values.
- **Data Analysis and Risk Assessment**: PT and ILC results are analyzed to identify processes requiring improvement. Laboratories evaluate performance deviations and prioritize high-risk tests.
- **Improvement Strategy**: Methods such as personnel training, equipment calibration, and procedure revisions are planned, and a timeline for improvement activities is established.

b) Do

In this stage, planned improvement activities are implemented. Laboratories execute the improvement strategies outlined in the PDCA cycle.

- **Implementation of Improvement Activities**: Activities such as training personnel, calibrating equipment, and revising test methods are carried out according to the established timeline.
- **Pilot Implementation**: If the improvement activities involve significant changes, a small-scale pilot implementation may be conducted first to test the process's effectiveness.

c) Check

In this stage, the effectiveness of improvement activities is monitored and evaluated. Laboratories analyze PT and ILC results to measure the impact of improvements on performance.

- **Result Analysis**: Test results after improvements are compared to reference values and previous performance. Are deviations reduced? Are results more consistent?
- **Statistical Monitoring**: PT and ILC results are evaluated using statistical methods (e.g., z-scores, robust techniques) to determine whether improvements have achieved the desired effect.

d) Act

This is the final step in the continuous improvement process. If the improvement activities are successful, they are integrated into the laboratory's routine operations. If the improvement objectives are not met, the cycle is restarted with a new plan.

- **Integration of Successful Improvements**: Successful improvement activities are incorporated into the laboratory's daily operations and made permanent.
- **Replanning**: If the targeted improvement is not achieved, the PDCA cycle is restarted, and a new strategy is developed.

6.2. Utilization of Data from Proficiency Testing

Proficiency testing (PT) and interlaboratory comparisons (ILC) provide critical data for monitoring and improving laboratory performance. This data can be integrated into the laboratory's quality management systems to enable continuous improvement.

6.2.1 Statistical Analysis of PT and ILC Results and Performance Monitoring

PT and ILC results are used to objectively evaluate laboratory performance. Statistical analyses play a key role in comparing a laboratory's performance with others and identifying deviations.

- **Z-Scores and Robust Methods**: PT results are evaluated using statistical methods such as z-scores. Z-scores indicate the consistency of laboratory results and their alignment with reference values. Robust methods analyze performance more flexibly by excluding outliers.
- **Comparison of Results**: Laboratories compare PT and ILC results with those from previous periods to monitor changes in performance. They examine whether results are continuously improving and whether performance remains consistent over time.

6.2.2 Using Performance Data to Improve Laboratory Processes

Performance data obtained from PT and ILC results play a crucial role in improving laboratory processes. Laboratories analyze these results to identify areas that need improvement.

- **Identifying Performance Deviations**: PT and ILC results help identify errors in laboratory processes. Deviations such as equipment malfunctions, operator errors, or methodological issues are identified, and corrective actions are initiated.
- **Process Optimization**: The data obtained aids in optimizing processes. For example, if a testing method shows consistent deviations, it may need to be revised. If frequent equipment recalibration is required, these calibrations can be optimized.

6.2.3. Reporting Results and Management Reviews Based on Quality Objectives

PT and ILC results provide valuable feedback for laboratories striving to meet their quality objectives. Laboratories analyze these results regularly and create reports to evaluate their alignment with quality goals.

- **Reporting Results**: PT and ILC results should be regularly reported within the laboratory's quality management system. These reports are evaluated during management meetings, and necessary improvement activities are planned.
- **Management Reviews**: Laboratory management reviews processes based on PT and ILC results. Management evaluates whether quality objectives have been met and

makes strategic decisions. If objectives have not been met, new plans are developed, and the improvement cycle is initiated.

Conclusion: Importance of Continuous Improvement and Performance Monitoring
Continuous improvement and performance monitoring are crucial for ensuring the accuracy and reliability of laboratory results. Using the PDCA cycle, processes are continuously optimized, and data obtained from proficiency testing (PT) and interlaboratory comparisons (ILC) supports this process. Statistical analyses identify performance deviations, which are then corrected to improve laboratory processes. This approach helps laboratories achieve their quality objectives and meet accreditation requirements.

7. Accreditation and Proficiency Testing (Connection to ISO/IEC 17043 and ILAC P9)

Accreditation processes evaluate whether laboratories meet specific requirements to ensure their competence and accuracy. In these processes, proficiency testing (PT) and interlaboratory comparisons (ILC) play a critical role in verifying laboratory performance and the reliability of test results. The ISO/IEC 17043 and ILAC P9 documents clearly define the role of PT and ILC in laboratory accreditation processes and how they should be utilized.
This section explains the role of PT and ILC in accreditation processes, how these results are evaluated, their use in assessments, and the importance of corrective actions after assessments.

7.1. The Role of PT and ILC in the Accreditation Process

Proficiency testing (PT) and interlaboratory comparisons (ILC) are used to ensure laboratory compliance with international standards (e.g., ISO/IEC 17025) and to verify the reliability of results. Accreditation bodies evaluate laboratory participation in PT and ILC as a key indicator of competence.

7.1.1 How Accreditation Bodies Evaluate PT and ILC Participation

Accreditation bodies consider participation in PT and ILC a mandatory requirement. According to ISO/IEC 17025:2017, laboratories must participate in PT for parameters they test if PT is available. If PT is not available, laboratories are required to participate in interlaboratory comparisons (ILC).

- **Importance of PT Participation**: PT participation demonstrates a laboratory's competence and the accuracy of its results as verified by an independent provider. Accreditation bodies review PT results to assess laboratory performance and identify deviations.
- **Requirement for ILC Participation**: If PT is not available, laboratories must participate in ILC. ILC allows laboratories to compare their results with others to monitor accuracy. Accreditation bodies evaluate whether laboratories participate in ILC and how they perform based on ILC results.

7.1.2 Importance of Proficiency Testing in Compliance with ISO/IEC 17025 and ISO/IEC 17043

The ISO/IEC 17025 standard mandates laboratory participation in PT to monitor the accuracy of test results. PT proves laboratory compliance with ISO/IEC 17025 requirements. A laboratory that does not participate in PT may be considered deficient during accreditation.

ISO/IEC 17043 is the standard applicable to PT providers. It governs how PT providers operate and ensures impartiality and quality assurance. Laboratories participating in PT organized by ISO/IEC 17043-compliant providers can trust the reliability of their results, offering a strong reference in accreditation assessments.

7.1.3 ILAC P9 Requirements for PT and ILC Participation

The ILAC P9 document regulates laboratory participation in PT and specifies the required frequency of participation. ILAC P9 mandates that PT or ILC participation must be planned and continuous for parameters tested by the laboratory. The frequency of participation is determined based on the risk level of the tests. For high-risk tests, laboratories may be required to participate annually in PT or ILC.

Example: A laboratory analyzing hazardous chemicals (e.g., environmental pollution tests) must participate in PT more frequently. Accreditation bodies monitor whether laboratories participate in PT regularly in accordance with ILAC P9 requirements.

7.2. Use of PT and ILC Results in Accreditation Assessments

In accreditation assessments, PT and ILC participation results play a significant role. Assessors evaluate laboratory results to monitor performance, accuracy, and improvement processes. This process is a critical step in determining whether the laboratory's accreditation will continue.

7.2.1 How PT and ILC Results Are Used in Accreditation Assessments

Assessors evaluate PT and ILC results in detail during assessments to assess laboratory performance. These results provide objective evidence of a laboratory's competence.

- **Reviewing Results During Assessments**: Assessors compare a laboratory's PT and ILC results to analyze their alignment with internationally accepted reference values. Deviations are flagged, and corrective actions are required.
- **Evaluation of Critical Parameters**: Assessors pay particular attention to laboratory performance in critical test parameters. For instance, results from a food analysis laboratory critical to food safety are scrutinized in greater detail.

7.2.2 Evaluation of Proficiency Testing Results by Assessors

Assessors consider several critical factors when evaluating PT and ILC results:

- **Z-Scores and Statistical Methods**: PT results are often evaluated using z-scores, which indicate how closely laboratory results align with reference values. A z-score outside the ±2 range is considered a deviation.

Example: If a chemical analysis laboratory participates in PT and obtains a z-score of +3, this result is outside acceptable limits and considered an issue.

- **Performance Evaluation Reports**: PT providers prepare performance evaluation reports for participating laboratories. Assessors review these reports to analyze laboratory deviations and accuracy levels.
- **Continuous Participation and Improvement**: Assessors check whether laboratories participate in PT and ILC regularly and take necessary steps to improve performance.

7.2.3 Monitoring Corrective Actions Based on Results

If deviations are identified in PT or ILC results during assessments, laboratories must initiate corrective actions based on these findings. Assessors evaluate the planning, implementation, and monitoring of these corrective actions.

- **Planning Corrective Actions**: Laboratories plan corrective actions to address identified deviations. These actions may include revising methods, recalibrating equipment, or retraining personnel.

Example: If PT results show consistent deviations in a laboratory, the laboratory may recalibrate its equipment or review its testing methods.

- **Implementation of Actions**: Planned corrective actions are implemented, and laboratories must clearly outline the steps taken to resolve deviations.
- **Monitoring and Reporting**: Assessors monitor the effectiveness of corrective actions and evaluate how they impact results. If corrective actions are insufficient, the laboratory may receive a negative evaluation in the accreditation process.

Conclusion: Importance of PT and ILC in Accreditation Processes

Proficiency testing (PT) and interlaboratory comparisons (ILC) are critical tools for laboratories to demonstrate reliability and competence in accreditation processes. Accreditation bodies regularly monitor laboratory participation in PT and ILC and use this participation to evaluate compliance with ISO/IEC 17025 and ISO/IEC 17043 requirements.

Assessors analyze PT and ILC results to identify performance deviations and recommend corrective actions. PT and ILC results are key indicators of the effectiveness of laboratory quality management systems. Regular participation and analysis of these results enable laboratories to continuously improve and ensure success in accreditation processes.

Section 2: ISO/IEC 17025 Standard Clause 7.7: Continuous Monitoring and Improvement of Laboratory Result Validity

Clause 7.7 of the ISO/IEC 17025 standard defines the necessary methods and practices for laboratories to continuously monitor, ensure, and improve the validity of their test and calibration results. This clause aims not just to produce correct results once but to ensure that results remain consistently reliable, traceable, and compliant with standards over time. Through a cycle of monitoring, analyzing, and improving processes as needed, laboratories maintain their technical competence and quality management systems at a level that meets internationally accepted standards. This ensures sustained reliability and enhances the confidence of customers and stakeholders in the laboratory's outputs.

Section 2: ISO/IEC 17025 Clause 7.7: Continuous Monitoring and Improvement of Laboratory Result Validity

Clause 7.7 of the ISO/IEC 17025 standard provides a framework for laboratories to ensure, monitor, and continuously improve the validity of their test and calibration results. This clause emphasizes not just producing accurate results once but implementing systems and measures to ensure the sustained reliability, traceability, and compliance of results with standards over time. Below is a detailed explanation of Clause 7.7 based on its subtopics.

1. Overview (7.7 Ensuring the Validity of Results)

This clause aims to ensure that the data produced by the laboratory are always valid, reliable, and traceable. To achieve this, the laboratory must have a predefined procedure for monitoring result validity, plan and regularly review these processes, and implement improvements as needed.

Detailed Analysis

Clause 7.7 of the ISO/IEC 17025 standard requires laboratories to ensure the continuity and traceability of accurate results rather than focusing solely on one-time accuracy. The concept of "valid results" here encompasses both quantitative (e.g., measurement values) and qualitative (e.g., traceability, accurate determination of uncertainty, method validation) aspects. Laboratories must ensure that their processes are stable, compliant with standards, and open to continuous improvement.

The Need for a Systematic Approach

Predefined Procedure

Laboratories must have a procedure detailing the statistical methods to be used, how reference standards will be evaluated, how process deviations will be monitored using control charts, and what corrective measures will be taken when necessary. This procedure should account for the specific needs of both testing and calibration laboratories.

- *For instance, a calibration laboratory calibrating high-precision mass or volume standards should periodically use the same reference standard to compare the accuracy of its instruments, thereby documenting the consistency of results.*

Planning and Review

Regularly planned monitoring activities ensure periodic control points are established.

- *Example: A calibration laboratory reviews measurement trends of a reference weight standard used in calibration devices monthly. If a significant deviation is detected, preventive measures are taken before the deviation affects customer calibration certificates. This systematic review ensures the continuity of result reliability.*

Continuous Improvement and Dynamic Adaptation

Processes are not static; materials, equipment, software, methods, and even environmental conditions can change over time. Laboratories must analyze the monitoring data to determine where improvements are needed.

- *Example: A calibration laboratory may notice that a hygrometer used in a temperature-controlled room shows unexpected deviations over time. In response, the laboratory may recalibrate or maintain the hygrometer or replace it with a more stable device. This ensures that the fundamental environmental factors affecting all calibration results remain stable.*

Examples

1. ***Testing Laboratory Example (Chemical Analysis):***
   A water analysis laboratory analyzes a reference material weekly and records the results on a control chart. If an unexpected trend in iron concentration occurs (e.g., a gradual increase each week), the laboratory investigates the issue by checking the calibration of its equipment, the purity of the reagents, or the operator's pipetting technique. The problem is then resolved before it affects actual sample results.
2. ***Testing Laboratory Example (Mechanical Testing):***
   A laboratory measuring the tensile strength of steel rods tests a standard control rod monthly. If the results for this control rod consistently remain within a similar range, the process is stable. However, if the average results suddenly increase, the laboratory examines whether there is an error in the calibration of the testing device or the implementation of the test method.
3. ***Calibration Laboratory Example (Mass Calibration):***
   A calibration laboratory calibrating weight sets uses a nationally or internationally traceable standard weight as a reference. Each month, the laboratory compares its reference weight with the output of its measurement device. If, over time, the 1 kg reference weight set shows a small but significant deviation (e.g., measured as 1.0002 kg instead of 1.0000 kg), the laboratory initiates an immediate investigation: Are the device sensors affected, have environmental conditions changed, or has there been a variation in the operator's preparation process before measurement? Even this small deviation can have serious implications for highly precise calibration processes, necessitating a prompt and effective resolution.
4. ***Calibration Laboratory Example (Electrical Calibration):***
   An electrical calibration laboratory performing voltmeter calibrations periodically measures a highly stable reference voltage source. These comparisons reveal whether the voltmeter operates without drift. If systematic drift is detected, the laboratory recalibrates or services the device. This ensures that the calibration certificates issued to customers maintain their accuracy and reliability.

Significance and Benefits

- ***Reputation and Trust****:*
  Continuous monitoring of result validity enhances customer trust, strengthens the laboratory's market position, and creates new business opportunities.

- ***Legal and Regulatory Compliance****:*
  Calibration laboratories, in particular, must ensure the traceability of measurements to international standards (e.g., SI units). Continuous monitoring and improvement demonstrate uninterrupted compliance with these standards.
- ***Economic Efficiency****:*
  Faulty measurements or results lead to corrective actions, additional costs, delays, and customer dissatisfaction. Periodic monitoring allows issues to be identified before they reach the reporting stage, improving overall operational efficiency.

Summary
Clause 7.7 of ISO/IEC 17025 guarantees the accuracy, traceability, and reliability of laboratory results not only at the outset but throughout the process. This approach fosters a culture of quality within the laboratory, enhances staff awareness, and maintains the laboratory's technical competence at an internationally recognized level. By implementing systematic monitoring, regular reviews, and continuous improvement cycles, both testing and calibration laboratories can ensure long-term customer satisfaction and institutional reputation.

2. Procedure for Monitoring the Validity of Results (7.7.1)

Laboratories must establish a monitoring method to ensure that the results they report are accurate and consistent. This monitoring process includes the following key points:

a) Data Recording and Trend Analysis

The data obtained should be recorded in a way that allows the identification of trends over time. For instance, examining deviations in similar types of measurements over time can help detect systematic errors early. Additionally, statistical techniques (e.g., control charts) can assess the validity of results, identifying any abnormalities or instability.

Detailed Analysis
This section of the ISO/IEC 17025 standard requires laboratories not only to produce accurate results once but to demonstrate that this accuracy and consistency are maintained throughout the process. The "Data Recording and Trend Analysis" section mandates that every result produced by the laboratory becomes part of a systematic quality assurance process rather than a simple report.
The goal is to go beyond trusting individual measurement results and conduct stability analysis based on time-series data.

Why Trend Analysis?
Single measurements can sometimes be misleading. For example, a slight calibration drift in an instrument might initially appear as a random error. However, if similar measurements over weeks, months, or quarters show deviations trending in the same direction, this indicates a fundamental issue in the laboratory's methods, equipment, or environmental controls. By identifying the source of the issue early, problems can be resolved before they lead to increased measurement uncertainty or incorrect results reaching the customer.

The Role of Statistical Techniques
Statistical process control tools (e.g., Shewhart control charts, moving average charts, or CUSUM charts) guide laboratory managers in "hearing" the story behind the data. These charts clearly show whether results fall within acceptable variation limits or exhibit systematic

drift or excessive variability. If data points fall outside control limits or show statistically significant shifts, laboratories obtain objective evidence that corrective/preventive action is required.

Examples

1. General Testing Laboratory Scenario

Consider a chemistry laboratory measuring the concentration of a specific element in water samples. Each month, the laboratory analyzes a reference material (a control sample with a known concentration) and records the results. Over time, these reference measurements are plotted on a control chart. If the last three measurements consistently trend above statistical acceptance limits (i.e., consistently higher than expected), the laboratory investigates issues such as pipetting errors, equipment calibration drift, reagent purity issues, or operator-related technical errors. By doing so, the source of the problem is identified and addressed before actual samples are reported inaccurately.

2. Calibration Laboratory Scenario (Mass Calibration)

A calibration laboratory providing weight calibration services uses a high-precision weight standard. The laboratory measures the relationship between its reference weight (e.g., a 1 kg standard) and its primary calibration device monthly. All results are recorded as a time series and plotted on a control chart. If initially stable results within the expected range begin to drift upward in the sixth month and continue, this trend may indicate drift in the device's sensors, environmental factors (temperature, humidity, vibrations), or surface corrosion on the standard itself. The laboratory takes action, such as recalibrating the device, tightening environmental controls, or inspecting the standard, to eliminate the deviation. This ensures that the calibration certificates issued to customers remain accurate.

3. Calibration Laboratory Scenario (Electrical Quantities)

Consider a laboratory calibrating voltmeters. It uses a stabilized reference voltage source and records test results weekly. While results are initially consistent around the reference value, a series of measurements exceeding statistical control limits may appear over time. Statistical analysis reveals that this is not random variation but a systematic drift. The laboratory investigates whether the voltmeter's internal components are aging, the lab's temperature stability has been compromised, or human factors (e.g., procedural neglect, varying operator approaches) are influencing results. Once the issue is identified, corrective action ensures the continuity of accuracy and traceability.

Significance and Benefits

- *This approach proves that the laboratory can not only produce accurate measurements but maintain the capacity to produce accurate measurements consistently.*
- *Monitoring data through trend analysis becomes an integral part of the laboratory's internal quality assurance system. It supports risk-based thinking by acting as an early warning mechanism for potential errors before they escalate.*
- *Long-term statistical trend analysis nurtures a culture of continuous improvement. Insights derived from data lead to the development of better measurement methods, optimized training for technical staff, and more effective operation of the quality management system.*

Summary

According to ISO/IEC 17025 Clause 7.7.1, monitoring the validity of results is central to the laboratory's quality assurance process. Regular data recording, trend analysis, and the use of control charts enable laboratories to maintain accuracy, consistency, traceability, and reliability in their results. This approach prevents errors from escalating and causing chain reactions, safeguarding both customer trust and the laboratory's reputation in both testing and calibration environments.

b) Planning and Reviewing the Procedure

Monitoring activities should be planned in advance and reviewed periodically. This review is essential for evaluating the effectiveness of the procedure, the reliability of the tools used (e.g., control charts) or reference materials, and the necessity of corrective measures.
(This section of ISO/IEC 17025 emphasizes not only the monitoring of results but also the examination of the structure, effectiveness, and continuity of the monitoring process itself. A critical aspect is treating the written procedure for ensuring result validity as a "living document." This means the procedure is not static or immutable over the years; instead, the data obtained, encountered problems, changes in industry standards, the introduction of new international reference materials, or technological advancements necessitate dynamic updates to the procedure.)

Detailed Analysis
Planning Phase
Planning monitoring activities involves predefining which parameters will be evaluated, at what frequency, and using which control tools. For instance, a laboratory should specify which reference materials to analyze at specific intervals, which control charts (Shewhart, EWMA, CUSUM, etc.) to use for specific measurement results, and which statistical techniques to employ for tracking trends. The plan should align with the laboratory's operational scale, the frequency of tests or calibrations, the complexity of the methods used, and the targeted uncertainty levels.

Review Phase
At regular intervals (e.g., semi-annually, annually, or per the quality cycle), laboratory managers, quality managers, and technical experts should convene to assess the effectiveness of monitoring procedures. Key questions to address include:

- ***Effectiveness****:*
  Is the implemented procedure consistently ensuring the validity of results? Are control charts identifying trends and deviations in a timely manner? Are reference materials appropriate, fresh, stable, and well-characterized?
- ***Applicability and Flexibility****:*
  Has the laboratory's workload or the methods used changed? Have new test parameters been added? Are new-generation devices being employed? If so, is the current procedure being updated to accommodate these changes?
- ***Corrective Action Needs****:*
  When data exceeding control limits were identified in past monitoring results, were the underlying causes effectively resolved? The recurrence of similar problems may indicate inadequacies in corrective actions or deficiencies in the procedure itself, necessitating a review and improvement of the procedure.

Examples

1. Testing Laboratory Example (Chemical Analysis)

A chemistry laboratory measures the concentration of a heavy metal in drinking water. Its monitoring procedure involves weekly reference material analyses using control charts. Six months later, during a review meeting, the laboratory team notes that a deviation was identified on the control chart, but it was resolved by recalibrating the equipment. However, during the review, they realize that there is no "early warning" mechanism to alert operators. As a result, the procedure is updated to include an automatic internal notification if two consecutive measurements exceed a predefined deviation threshold. This makes the procedure more proactive.

2. Calibration Laboratory Example (Mass Calibration)

A laboratory specializing in high-precision mass calibration reviews its monitoring procedure every three months. The review shows that recent results demonstrate excellent stability. However, the laboratory's client base has expanded, and there are now requests for calibrations across a wider mass range. This requires updating the monitoring procedure: additional reference materials for different mass ranges must be included, the number of control points increased, and the procedure broadened. Additionally, if the laboratory recently adopted a new humidity monitoring system, parameters for monitoring environmental conditions should also be incorporated into the procedure to ensure the consistency of mass calibrations.

3. General Practical Approach

If a laboratory relies solely on control charts in its monitoring procedure, a review meeting might identify the need to expand statistical analysis methods. For instance, CUSUM charts can be added for trend detection, or other statistical methods can be included to understand structural changes in data distribution. Additionally, the laboratory could systematically review certification dates, stability information, and storage conditions of reference materials as part of the procedure to prevent unexpected deviations.

Significance and Benefits

- ***Culture of Continuous Improvement****:*
  The planning and review phases transform the standard from a mere requirement into an internalized quality culture that shapes the laboratory's operational approach.
- ***Risk-Based Approach****:*
  Reviewing the procedure facilitates the early detection of potential risks, timely implementation of preventive actions, and effective management of the laboratory's overall risk profile.
- ***Customer Confidence and Competitive Advantage****:*
  Each review and improvement step reinforces customer confidence in the accuracy of laboratory results. Maintaining an up-to-date procedure demonstrates that the laboratory is closely following scientific and technical developments, adopting a proactive and flexible quality management approach.

Summary

This aspect of ISO/IEC 17025 Clause 7.7.1 aims to transform monitoring procedures from static documents into dynamic and adaptable systems. Planning clarifies when, how, and which quality tools the laboratory will use, while periodic reviews continuously improve the performance, suitability, and effectiveness of this process. Particularly in high-precision

environments like calibration laboratories, this approach is critical for ensuring result validity. By fostering scientific reliability, operational efficiency, and customer satisfaction, laboratories can achieve a competitive edge in the international arena.

2.1 Scope of Monitoring – Sample Applications

- **Reference Materials or Quality Control Materials (a):**
  Using reference or control materials as a comparison point allows you to determine the accuracy of your measurements. This helps verify whether your equipment calibrations are still valid and whether your measurement method has deviated.
- **Use of Alternative Equipment (b):**
  If you have a different but calibrated (traceable) device, you can compare the results obtained with your primary equipment to identify potential errors.
- **Functional Checks of Equipment (c) and Interim Checks (e):**
  Regular functional checks of measurement and testing equipment reveal whether sensors, detectors, and measuring instruments are operating correctly. These checks should not be limited to periodic calibrations but should also be supported by interim checks (e.g., daily or weekly verifications).
- **Working Standards with Control Charts (d):**
  Control charts (e.g., Shewhart control charts) help determine whether the measurement process is stable and whether there is a time-dependent deviation. By monitoring working standards with these charts, changes in the process can be quickly detected and addressed.
- **Repeated Tests or Calibrations (f):**
  Re-testing the same sample using the same or different methods allows you to evaluate the consistency of results. This approach helps identify systematic issues rather than one-off errors.
- **Re-testing of Preserved Items (g):**
  Retaining some samples for potential re-testing allows you to confirm the accuracy of past results or reassess them in case of doubts.
- **Correlation Between Different Characteristics (h):**
  Examining whether results for different properties of the same sample are consistent with each other provides insight into the overall measurement method. For example, assessing whether a material's hardness and density exhibit the expected relationship can reveal abnormalities.
- **Review of Reported Results (i):**
  Regularly reviewing result reports prevents errors or inconsistencies in the reporting process.
- **Intra-Laboratory Comparisons (j):**
  Comparing results obtained by different analyzers, analysts, or methods within the same laboratory strengthens internal consistency.
- **Blind Sample Tests (k):**
  Blind samples, where the analyst or tester is unaware of the sample content, measure the objectivity of the test. This can reveal hidden bias or errors in the method or operator.

Detailed Analysis

This section of ISO/IEC 17025 emphasizes that ensuring the validity of results cannot rely solely on a single verified method or calibration. Laboratories must establish a quality assurance system that spans time. By using various techniques, tools, and strategies, any errors, deviations, or uncertainties in the measurement process can be detected at an early stage.
This approach transforms laboratory activities into a multidimensional quality management process. Each item represents a crucial component of the quality assurance ecosystem. Rather than relying solely on reference materials, laboratories can ensure the accuracy of their results comprehensively by employing a wide range of methods, including alternative equipment, control charts, blind sample tests, and internal comparisons.

Examples

1. Reference Materials or Quality Control Materials (a):

- ***Testing Laboratory Example (Chemical Analysis):***
  A chemistry laboratory uses certified reference materials to measure heavy metal concentrations in water samples. By analyzing this reference material weekly, the laboratory observes whether there is any measurement deviation. If the reference analysis consistently records higher-than-expected values, the laboratory immediately investigates potential equipment calibration issues or systematic errors in the method.
- ***Calibration Laboratory Example (Mass Calibration):***
  A calibration laboratory measures a 1 kg reference weight monthly to monitor the performance of its primary calibration device. If multiple consecutive measurements stabilize at 1.0003 kg instead of 1.0000 kg, this trend indicates a deviation in the calibration process, necessitating reevaluation of the device or environmental conditions.

2. Use of Alternative Equipment (b):

- ***Testing Laboratory Example:***
  By analyzing the same chemical composition with two different spectrometers and comparing the results, discrepancies can be identified. If one device consistently reports higher readings, it may indicate a source of error.
- ***Calibration Laboratory Example (Electrical Quantities):***
  In an electrical calibration laboratory, the primary voltmeter's measurements are compared to those of a second traceable voltmeter from a different manufacturer. If a stable deviation is detected between the two, it may indicate a decline in the performance of the primary device.

3. Functional Checks of Equipment (c) and Interim Checks (e):

- ***Testing Laboratory Example:***
  Daily checks of a pH meter with a buffer solution confirm the instrument's accuracy. This interim check ensures reliability for daily measurements beyond the annual calibration.
- ***Calibration Laboratory Example:***
  A mass calibration laboratory checks its scales daily with small known weights. This ensures consistent measurements between periodic official calibrations.

4. Working Standards with Control Charts (d):

- ***Testing Laboratory Example (Mechanical Testing):***
  The stability of tensile strength test results is monitored over time using control charts. If results suddenly show an upward or downward trend, it may indicate an issue with the hydraulic system of the testing device.
- ***Calibration Laboratory Example:***

Weekly values of a working standard in voltmeter calibration are plotted on a chart. If the values remain within expected statistical limits, the process is under control. Deviations beyond these limits indicate the need for recalibration.

5. Repeated Tests or Calibrations (f):

- ***Testing Laboratory Example:***
  Re-testing the same sample on different days or with different analyzers distinguishes one-off errors from systematic issues.
- ***Calibration Laboratory Example:***
  Repeatedly measuring the same weight standard across different calibration devices helps determine whether results align, identifying any potential method- or device-specific issues early.

6. Re-testing of Preserved Items (g):

- ***Testing Laboratory Example:***
  Critical samples (e.g., environmental water samples) are preserved by freezing or under stable conditions. If a method is changed or a result is questioned, the stored sample can be re-analyzed to compare with previous results.
- ***Calibration Laboratory Example:***
  Some calibrated weights are archived. If a device inconsistency is later detected, the same weight can be re-measured and compared with earlier results.

7. Correlation Between Different Characteristics (h):

- ***Testing Laboratory Example:***
  Comparing hardness and density measurements of the same material reveals whether results are consistent with expected physical relationships. Deviations may indicate issues with the method or equipment.
- ***Calibration Laboratory Example:***
  Environmental parameters like temperature, humidity, and pressure can affect mass calibration deviations. Analyzing the correlation between these parameters helps explain, for instance, why increased humidity led to an out-of-spec measurement result.

8. Review of Reported Results (i):

- ***Testing Laboratory Example:***
  Result reports are periodically reviewed by an independent expert to identify errors or inconsistencies in the reporting format or data transfer.
- ***Calibration Laboratory Example:***
  A technical committee reviews randomly selected calibration certificates each month. Data, uncertainty calculations, and traceability information are evaluated for accuracy before approval.

9. Intra-Laboratory Comparisons (j):

- ***Testing Laboratory Example:***
  Two analysts within the same laboratory apply the same method. Comparing their results helps identify operator-dependent errors or method-related uncertainties.
- ***Calibration Laboratory Example:***
  Two different technicians calibrate the same weight. If results show no significant difference, the method and equipment are stable; otherwise, corrective action is required.

10. Blind Sample Tests (k):

- ***Testing Laboratory Example:***

A blind sample is provided to the analyst without knowledge of its contents. If results consistently deviate from expected values, it points to human factors or hidden biases rather than methodological issues.

- ***Calibration Laboratory Example:***
  Personnel are provided with a weight whose "true" value is unknown to them. The measured value is compared to the expected reference range. This test helps ensure that the calibration process is free of human errors.

Significance and Benefits

These practices demonstrate that ensuring the validity of laboratory measurements requires a multidimensional approach. Instead of relying on a single control method or tool, a range of complementary techniques supports the laboratory's quality assurance efforts. As a result:

- *The laboratory not only produces "accurate" results but also proves the sustainability of this accuracy.*
- *Errors are identified at an earlier stage, minimizing costs and reputational risks.*
- *Customer satisfaction increases, as the laboratory's results are continuously monitored using internationally accepted methods.*

Summary

Within the framework of ISO/IEC 17025 Clause 7.7, integrating all these tools and methods is essential for ensuring the validity and reliability of laboratory results. While each method is a powerful tool on its own, their combined use creates a comprehensive quality assurance system. This system enables both testing and calibration laboratories to provide reliable, sustainable measurement services and compete confidently in the international arena.

3. Comparison with Other Laboratories (7.7.2)

You should compare your results with those of other laboratories. This enables you to assess your performance through external benchmarking. For this purpose:

a) Proficiency Testing

Participating in internationally or nationally organized proficiency testing programs allows your laboratory to compare its performance with similar laboratories and see where your results stand relative to the general market performance.

Detailed Analysis

This section of the ISO/IEC 17025 standard emphasizes that laboratories should not rely solely on their internal control mechanisms but also validate their performance by comparing their measurement results with those of similar laboratories in the external world. The approach of "comparison with other laboratories" helps place a laboratory's measurement capabilities within a broader context, enabling it to determine its relative position. Even if internal quality control processes appear to function smoothly, industry trends, how methods yield results across different laboratories, and expectations set by globally recognized standards necessitate evaluating your laboratory's competence from an external perspective.

The Role of Proficiency Testing

Proficiency tests are programs conducted by accredited providers in which multiple laboratories independently test the same or similar samples and report their results within a predefined framework. These programs objectively evaluate laboratories' measurement

capabilities, uncertainty management, method reliability, and result accuracy. Proficiency test results produce statistical reports comparing the performance of participating laboratories.

External Evaluation of Performance
This outward-looking comparison reminds laboratories that internal validation activities alone are insufficient. Even when internal controls indicate everything is in order, proficiency testing may reveal unexpected deviations. Such deviations indicate discrepancies between the laboratory's methods and international reference methods or market averages, necessitating a re-evaluation of processes. This ensures that the laboratory is judged not only by "its own standards" but also within a broad and impartial evaluation framework.

Examples
1. Testing Laboratory Example (Chemical Analysis):
A water analysis laboratory participates in an international proficiency testing program. The same water sample is sent to 50 laboratories worldwide, each measuring heavy metal concentrations and reporting their results. The statistical report at the end of the program shows how close or far your laboratory's results are from the average value. If your laboratory's results significantly deviate from the market average, it must re-evaluate equipment calibrations, methods used, or operator training.

2. Calibration Laboratory Example (Mass Calibration):
A calibration laboratory participates in an international proficiency test for high-precision mass calibration. A reference weight with a specific nominal value is sent to multiple laboratories. Each laboratory calibrates the weight according to its system and reports the result. The final report shows how consistent your laboratory's determined value is with those of other prestigious calibration laboratories. If your results consistently deviate above or below the average, you may need to reassess your uncertainty budget, environmental controls, equipment traceability, or calculation methods.

3. Gaining a Broader Perspective:
Proficiency testing allows you to see where you stand globally in a specific test or calibration method, not just among a few national institutions or laboratories. This global perspective enhances your laboratory's competitiveness. For instance, if your mass calibration measurements are statistically aligned with the average results of leading laboratories worldwide, this serves as a prestigious and trust-building factor for your clients.

Significance and Benefits
- ***Input for Continuous Improvement:***
  Proficiency testing is not just a tool for demonstrating competence but also a feedback mechanism for continuous improvement. Unexpected results should be viewed not as "failures" but as opportunities to identify areas for process improvement.
- ***Strengthening Risk-Based Approaches:***
  External comparisons and proficiency testing contribute directly to your laboratory's risk management. If your test results are stable and close to the average, you can be more confident in your risk management. If deviations are present, they highlight potential risk areas and sources, accelerating corrective and preventive actions.
- ***Supporting International Recognition and Accreditation Processes:***
  Strong performance in proficiency tests is a critical reference for international accreditation bodies (e.g., ILAC or regional accreditation authorities). Accreditation

processes consider proficiency test results to evaluate your laboratory's competence. Good performance facilitates maintaining accreditation or adding new accreditation scopes.

Summary:
ISO/IEC 17025 Clause 7.7.2 encourages laboratories to evaluate their performance within a broader, objective framework by supplementing internal quality assurance with external data. Proficiency tests elevate your laboratory's internal control mechanisms to an internationally recognized benchmark, ensuring your results align not just with your methods but with the performance standards of globally respected laboratories. This enables your laboratory to produce reliable, traceable, and world-class results, enhancing competitiveness in a global market.

b) Interlaboratory Comparisons
Other than proficiency tests, you can conduct regular sample exchanges or data comparisons with other laboratories to continuously assess performance.

Detailed Analysis
The ISO/IEC 17025 standard recommends that laboratories assess and improve their performance not only through proficiency testing but also through collaborations with other laboratories. "Interlaboratory comparisons" refer to flexible, participant-driven applications that can be tailored for continuity. Unlike proficiency tests, interlaboratory comparisons do not have to be as formal or systematic, but when planned and executed properly at regular intervals, they provide valuable feedback for laboratory quality assurance systems.
This approach enables laboratories to compare their measurement results not only within their internal practices but also with results from other laboratories operating under similar or different conditions. Regular or periodic interlaboratory comparisons help laboratories track performance trends, update methodologies, and identify personnel training needs.

Examples
1. Testing Laboratory Example (Chemical Analysis):
A water analysis laboratory partners with a nearby laboratory for a monthly sample exchange program. Both laboratories analyze the same water sample and compare results. If one laboratory consistently finds a contaminant concentration higher or lower than the other, the cause is investigated. Differences in equipment brand/model, chemical purity, operator technique, or laboratory environmental conditions can be reviewed and aligned. This process creates a continuous feedback loop beyond one-time proficiency testing, enabling regular improvement.

2. Calibration Laboratory Example (Electrical Quantities):
Two high-precision calibration laboratories periodically measure each other's voltage references. For instance, one laboratory sends a 10 V reference source to the other for comparison. Each laboratory evaluates the source using its primary standards and methods. If Laboratory A measures 10.0002 V instead of 10.0000 V while Laboratory B measures 9.9999 V instead of 10.0000 V, it indicates methodological or equipment-related differences. Repeated comparisons reveal the consistency or scale of these differences, allowing laboratories to enhance environmental controls, re-evaluate measurement uncertainty, or adjust calibration intervals.

3. Comparison Between Different Methods:
Interlaboratory comparisons can occur not only between laboratories using the same method but also between those using different methods or equipment. For example, one laboratory determines a chemical composition using Method A, while another uses Method B. Comparing results evaluates whether the two methods are statistically equivalent. This enables laboratories to explore alternative methods and enhance measurement capability and flexibility.

Significance and Benefits

- ***Continuous Improvement and Adaptation:***
  While proficiency tests are typically conducted periodically with predefined protocols, interlaboratory comparisons can be more frequent and need-driven. This allows laboratories to adapt quickly to changing technology, customer expectations, or regulatory requirements.
- ***Opportunities for Mutual Learning:***
  Interlaboratory comparisons are not merely one-way evaluations. Each participating laboratory can benefit from the best practices, reference materials, software tools, uncertainty calculation techniques, or data analysis approaches used by the others. These comparisons can transform into a learning platform.
- ***Expanded Reliability and Competitive Advantage:***
  A laboratory that continuously improves through such comparisons not only demonstrates compliance with standards but also alignment with industry best practices. This enhances customer appeal and strengthens the laboratory's market position. Laboratories engaging in international collaborations gain opportunities to meet global quality standards.

Summary:
Clause 7.7.2(b) of ISO/IEC 17025 emphasizes that performance evaluation is not limited to proficiency testing but also includes regular data and sample comparisons with other laboratories as a critical tool for continuous improvement. This approach ensures that the laboratory's internal quality assurance system interacts dynamically with the external world, fostering a culture of quality improvement and learning. Particularly for calibration laboratories, interlaboratory comparisons serve as an unrivaled feedback mechanism for validating high-precision measurements and driving continuous improvement.

4. Data Analysis and Improvement (7.7.3)

You must regularly analyze all monitoring data you collect and use the findings to control and, if necessary, improve laboratory processes. For example:

- If your data falls outside your established acceptance criteria (e.g., an unexpected drift in a control chart or a significantly outlying result in a proficiency test), you must immediately take corrective action, identify the source of the error, and rectify it.
- These measures may include revising the method, recalibrating the device, providing additional training for personnel, or reassessing sources of uncertainty.

Detailed Analysis
This clause of the ISO/IEC 17025 standard transforms the collection of monitoring data from a passive storage activity into an active quality management tool. The key idea here is that a laboratory's role should not be limited to continuously collecting data, but also to deriving

meaningful insights from this data and using those insights to improve processes. In other words, a laboratory does not merely produce valid results but develops a data-driven decision-making mechanism to sustain this validity over time.

Data analysis encompasses a wide range of activities, including statistical evaluation of measurement results, trend monitoring with control charts, examining positions in proficiency tests, and recalculating uncertainty components. These analyses aim to better understand the sources of uncertainty, detect systematic errors early, and establish a solid foundation for process improvement.

Examples

1. Testing Laboratory Example (Chemical Analysis):

A chemical laboratory records results from weekly reference material analyses on a control chart. Over the past two weeks, results have begun exceeding statistically acceptable control limits. This may indicate a calibration drift in the device, degradation of reagent purity, or a procedural change by the operator. The laboratory identifies the root cause (e.g., the expiration of the device's light source) and promptly implements corrective actions. These may include replacing the light source, re-certifying the reference material, or retraining personnel.

2. Calibration Laboratory Example (Mass Calibration):

A calibration laboratory records measurements of a 1 kg reference weight every three months. Recent analyses show repeated measurements shifting towards 1.0002 kg. This statistically significant deviation exceeds acceptance criteria. The laboratory investigates potential error sources: Is the balance optic dirty, have environmental conditions (temperature, humidity) changed, or was a calibration procedure step missed? An investigation reveals that slight mechanical wear in the balance's internal components has affected its accuracy. The laboratory recalibrates the balance, performs maintenance if necessary, or replaces components, bringing measurement results back within acceptance criteria.

3. Method Revision and Personnel Training:

Data analysis can reveal that errors are not solely equipment-related. For example, if a laboratory consistently reports higher results than the average in a proficiency test, it may indicate a systematic procedural error in its method. In such cases, the method may need to be revised, step-by-step instructions rewritten, or personnel subjected to additional training for that method. This prevents similar deviations in the future.

4. Reassessment of Uncertainty Sources:

Data analysis may reveal unexpected variations among uncertainty components. In such cases, the laboratory reviews its uncertainty budget, refines critical steps in the measurement procedure with more precise methods, or adopts new, more stable reference standards.

- *For instance, if a calibration laboratory observes a consistently increasing uncertainty trend across various mass values, it may tighten environmental controls (more stable temperature and humidity), acquire higher-grade standards, or improve data analysis techniques to reduce uncertainty.*

Significance and Benefits

- ***Proactive Approach:***

Insights from data analysis enable laboratories to intervene proactively. Errors or deviations can be identified before they reach the reporting stage or even before a client notices a problem. This strengthens the laboratory's reputation and reliability.

- ***Culture of Continuous Improvement:***
  Regular data analysis and the application of findings to process improvement transform the laboratory into a dynamic learning organization. This helps reduce measurement uncertainty, optimize equipment lifecycle use, and enhance the technical competence of personnel over time.
- ***Risk-Based Thinking and Resource Management:***
  Analysis results highlight which parameters or process steps require the most attention. This enables the laboratory to focus resources (time, cost, personnel) on critical areas, minimizing risks and making measurement processes more efficient.

Summary:
ISO/IEC 17025 Clause 7.7.3 represents the "action and improvement" component of the laboratory's quality cycle, complementing the "measurement and evaluation" phase. This clause ensures that laboratories do not merely collect data but transform it into actionable insights, continually improving methods, equipment, personnel, and uncertainty management. These processes are particularly critical in high-precision environments like calibration laboratories, where even a small deviation or increase in uncertainty could undermine the laboratory's entire foundation of reliability. Regular data analysis and translating findings into improvement initiatives cement a laboratory's compliance with internationally recognized quality standards.

General Summary
Clause 7.7 of ISO/IEC 17025 provides a comprehensive approach to ensuring the continuous validity of laboratory results. The aim is not only momentary accuracy but also long-term stability, reliability, and traceability. This clause is a critical element supporting the continuity and improvement of the laboratory’s quality management system.

Section 3: Proficiency Testing and Interlaboratory Comparisons, Managing Accreditation Processes and Continuous Improvement Under the ILAC-P9 Policy

This guideline provides an in-depth analysis of the Proficiency Testing (PT) and/or Interlaboratory Comparisons (ILC) policy, which is of central importance for accredited conformity assessment bodies (CABs) to demonstrate technical competence. It is grounded in international standards such as ISO/IEC 17025, ISO 15189, ISO/IEC 17011, ISO/IEC 17043, ISO 17034, and ISO 20387 and explores their interactions. The guide aims to explain how accreditation bodies (ABs) and CABs can efficiently, sustainably, and consistently manage PT/ILC processes.

Beyond the conceptual framework of PT/ILC programs, the guide examines their contributions to technical competence, result validity, and the strengthening of Mutual Recognition Agreements (MRAs). PT and ILC thereby become not only performance benchmarks but also integral parts of laboratories' continuous improvement-focused quality management strategies.

Additionally, the guide outlines ways to integrate the risk-based thinking central to ISO/IEC 17025 and ISO 15189 into PT/ILC planning, implementation, and result evaluation. This enables CABs to effectively manage potential technical uncertainties and opportunities in their testing/calibration activities and strengthen strategic decisions using these data.

The criteria used by accreditation bodies to evaluate PT/ILC participation plans, address deficiencies, and provide guidance are explored in detail with practical examples. Similarly, the guide focuses on methodological, statistical, and operational aspects for CABs, as well as monitoring performance indicators and implementing improvement mechanisms.

By integrating PT and ILC practices with accreditation processes, laboratories' quality assurance systems are positioned at the core of their operations. Testing and calibration laboratories, medical laboratories, inspection bodies, biobanks, reference material producers, and PT providers strengthen their technical capacities while developing internationally recognized quality management approaches.

Ultimately, this guide aims to present the infrastructure of PT/ILC policies, implementation requirements, risk management, continuous improvement, and the roles and responsibilities of stakeholders from a holistic perspective. It strives to enhance global technical competence, service quality, mutual recognition, and international trust.

1. Context and Purpose

ILAC P9 addresses how performance evidence obtained through Proficiency Testing (PT) or Interlaboratory Comparisons (ILC) should be evaluated during the accreditation process of conformity assessment bodies (CABs), including testing, calibration, and medical laboratories, as well as inspection bodies, biobanks, PT providers, and reference material producers. This policy emphasizes the structured use of PT/ILC to demonstrate the validity of results. It aims to ensure global confidence among accredited organizations, enhance the acceptability of results under Mutual Recognition Agreements (MRA), and encourage continuous improvement in laboratory performance.

2. Alignment with Standards and Expanded Scope

ILAC P9 has been revised to align with the latest versions of relevant standards, including:

- **ISO/IEC 17025:2017**: Requires testing and calibration laboratories to monitor the validity of their results and, where available and appropriate, participate in PT or other ILCs.
- **ISO 15189:2022**: Replaces the term PT with External Quality Assessment (EQA) for medical laboratories. When an EQA program is unavailable, laboratories are encouraged to use ILCs to monitor performance.
- **ISO/IEC 17011:2017**: Specifies that accreditation bodies can use CABs' PT/ILC performance as a tool during accreditation assessments.

ILAC P9 offers a broadened approach encompassing all CABs involved in testing and calibration activities. This includes not only traditional testing and calibration laboratories but also sample collection organizations, inspection bodies, biobanks, PT providers, and reference material producers.

3. Definitions and Roles of PT and ILC

Testing and calibration laboratories operating under ISO/IEC 17025 must consistently demonstrate the reliability of their measurements and analyses. The most commonly used method for this purpose is proficiency testing (PT). However, PT programs may not always be available or suitable for a laboratory's specific needs.
Since the standard mandates continuous monitoring of result validity and performance, interlaboratory comparisons (ILCs) serve as an alternative when PT is unavailable or unsuitable. ILCs form a vital part of a quality assurance strategy under ISO/IEC 17025, supporting measurement reliability, method validity, and result accuracy.

a) Key Differences Between PT and ILC

- **Proficiency Testing (PT):**

As defined by ISO/IEC 17043, PT refers to comparison exercises where two or more laboratories test or measure results against predefined acceptance criteria. The primary purpose is to statistically evaluate each participant's technical performance and compare results with internationally accepted quality and accuracy standards.

Example:

Consider a food laboratory participating regularly in a program provided by a PT provider accredited to ISO/IEC 17043. The program involves analyzing the toxin concentration in

milk samples. The laboratory performs the analysis on the same sample as many other laboratories and submits its results to the PT provider. The provider performs a statistical evaluation (e.g., z-scores, En scores) to compare the laboratory's performance. This process allows the laboratory to objectively determine how well its measurements align with those of other laboratories. If performance issues are identified, the laboratory can plan corrective actions accordingly.

- **ILCs Other than PT:**

Not every interlaboratory comparison qualifies as a PT. PT is generally aimed at performance evaluation, with results statistically assessed and the laboratory's technical competence "graded" against specific acceptance criteria. Conversely, the term "ILC other than PT" encompasses a broader range of interlaboratory comparisons. These comparisons do not always seek to rank participants' performance or assign a proficiency score. Instead, ILCs can be organized as part of a method validation process, characterization of a new reference material, or general evaluation of measurement capacity across an industry.

Example:

In the same milk sample scenario, a group of laboratories may exchange samples to develop a new reference material or test a measurement method during its validation process. The purpose here is not to identify the "best" or "worst" laboratory but to test the homogeneity, stability, and usability of the newly developed reference material. Alternatively, a medical laboratory may routinely exchange serum samples with another laboratory to compare their internal quality control (IQC) results. This ILC does not require proficiency scoring or z-scores but functions as mutual "calibration" or "benchmarking." The goal in such cases is not direct performance measurement but improving methods or reference materials and enhancing measurement reliability between laboratories.

b) The Role and Benefits of PT

- **Performance Evaluation**

Proficiency testing (PT) serves as an objective external mirror for evaluating the accuracy and repeatability of a laboratory's test or measurement results. PT results can quickly reveal trends of inaccurate measurements, deviations caused by equipment or methods, personnel training needs, or inadequacies in uncertainty analysis.

Example:

A chemical analysis laboratory consistently shows a significant positive bias in measuring the concentration of a toxic element during PT. This deviation may indicate issues such as insufficient reference materials, errors in standardization, or systematic issues in uncertainty evaluation. This information helps the laboratory pinpoint areas for quality improvement efforts.

- **Fostering Trust and International Acceptance:**

PT is a fundamental mechanism for enhancing the global acceptability of laboratory results. In accreditation processes, PT performance demonstrates that a laboratory conducts tests according to internationally recognized standards. This facilitates the removal of technical barriers to trade and ensures that results are reliably accepted across countries.

Example:

A pharmaceutical company aiming to market its products across different continents can leverage PT performance records from its quality control laboratories to provide regulatory

authorities with assurances about product quality. This becomes a key factor in gaining international acceptance for the product.

c) The Role and Functions of ILCs Other Than PT

ISO/IEC 17025 requires laboratories to continuously monitor the validity of their results, performance, and the reliability of their methods. In cases where PT is unavailable or unsuitable, interlaboratory comparisons (ILCs) other than PT serve as valuable tools to support measurement reliability, method validity, and result accuracy. ILCs can be integrated into a quality assurance strategy aligned with ISO/IEC 17025 requirements in the following ways:

- **A Practical Option for New or Rarely Used Methods**

Some testing and calibration laboratories utilize methods that are still under development, in the R&D phase, or applied under highly specific conditions. Structured PT programs may not yet exist for these methods. In such cases, ILCs provide a practical means for comparing results with other expert laboratories, enabling the evaluation of method validity, measurement uncertainty, and repeatability.

Example:

A chemical analysis laboratory begins measuring extremely low concentrations of pollutants using a novel spectrometric technique but cannot find a PT program tailored to this method. The laboratory organizes an ILC with several laboratories possessing similar technical expertise to compare results. This process allows the laboratory to optimize method parameters, validate equipment accuracy, and strengthen method validity.

Example:

A chemical laboratory accredited under ISO/IEC 17025 seeks to add a new analytical method (e.g., measuring trace contaminants with advanced spectrometry) to its test portfolio. The laboratory organizes an ILC with other accredited laboratories specializing in similar methods. The aim is to test the interlaboratory consistency of results, compare measurement uncertainties, and assess the robustness of the methodological approach. By obtaining ILC data before implementing the new method, the laboratory establishes reliable evidence of validity and risk assessment as required by ISO/IEC 17025.

- **Regional Constraints for Routinely Conducted Measurements**

In some cases, PT programs for routine testing and calibration activities conducted by laboratories may not be available in the region or sector where the laboratory operates. This can occur even for widely used methods. Even globally renowned test parameters may not always have easily accessible PT programs in every region. ILCs other than PT provide a suitable alternative for measuring and validating a laboratory's performance under these geographical or sectoral constraints.

Example:

Consider a water quality testing laboratory routinely performing heavy metal analyses in drinking water. In the laboratory's region, a suitable PT program for these specific analyses may not be available. In this case, the laboratory can organize an ILC with other accredited laboratories in the region or nearby areas working in similar scopes. By analyzing the samples reciprocally and comparing the results, the laboratory gains indirect assurance about the

accuracy and consistency of its measurements. Additionally, this allows the laboratory to continue meeting ISO/IEC 17025 requirements for performance monitoring.

- **Alternative Evidence When No Suitable Indicator for the Method Exists**

In some test areas (e.g., measuring a very rarely requested parameter or evaluating a highly specific industrial process), no PT program may currently exist. In such situations, ILCs allow laboratories to perform at least a relative comparison of their measurement results with those of other reliable laboratories, providing indirect assurance of the validity of the reported results.

Example:

A materials testing laboratory seeks to include the microstructural analysis of a highly specific alloy within its accreditation scope, but no PT program is available for this analysis. The laboratory organizes an ILC with several other accredited laboratories performing similar analyses to evaluate the consistency of microstructural analysis results (e.g., grain size, phase distribution, hardness values). This ILC provides the laboratory with objective feedback under ISO/IEC 17025, demonstrating that the measurement method is valid and reliable in its application.

- **Comparison of Reference Equipment, Software, or Standardization Tools**

ISO/IEC 17025 laboratories are often required to demonstrate measurement traceability and the reliability of the calibration chain. ILCs other than PT help ensure consistency in the measurement traceability chain by comparing results obtained by different laboratories using similar reference materials, measuring devices, or software. The validity of new reference standards or verification equipment can also be tested through ILCs.

Example:

An electrical calibration laboratory collaborates with another laboratory with a similar accreditation scope to conduct reciprocal measurements for better understanding the uncertainty of a reference standard used to validate a new digital multimeter. This ILC demonstrates how both laboratories use the reference standard, evaluate uncertainty components, and whether the results are statistically comparable. Thus, the laboratory strengthens the quality assurance of the reference standard used in compliance with ISO/IEC 17025 requirements.

- **Sectoral Benchmarking in Relevant Industries or Application Areas**

In some cases, ILCs other than PT are organized to evaluate the general level of methods widely used in a sector or to determine the laboratory’s position relative to industry standards. ISO/IEC 17025 encourages participation in external comparisons whenever possible. These ILCs help laboratories align their technical competence with industry practices.

Example:

An environmental testing laboratory compares its method for measuring ultra-low levels of a contaminant in drinking water with those used by other accredited environmental laboratories. Although this ILC is not part of a PT program, the results indicate how the laboratory's performance compares to the industry average. This benchmarking allows the laboratory to align its methods more closely with industry norms and apply improvements to reduce measurement uncertainty or increase precision.

- **Deepening Technical Knowledge and Optimizing Method Parameters**

ISO/IEC 17025 laboratories must continually work to reduce measurement uncertainty, improve repeatability, or optimize conditions for measuring specific analytes or metrics. ILCs other than PT allow laboratories to enhance technical expertise, identify critical control points in methods, and compare and improve measurement procedure parameters.

Example:

A calibration laboratory working in a specialized calibration area (e.g., low vacuum range calibration) collaborates with other similarly accredited laboratories to better understand method uncertainty. Data obtained from this ILC may reveal which types of reference standards produce more stable results, which environmental conditions have less impact on measurements, or which statistical data processing methods are more reliable. This allows the laboratory to implement ISO/IEC 17025's continuous improvement cycle more effectively.

- **Deepening Sectoral Knowledge and Continuous Improvement**

ILCs other than PT offer opportunities for improving existing and routinely used methods. Laboratories can share data to identify best practices, method variations, and critical factors affecting measurement uncertainty for specific analytes or calibration parameters.

Example:

A calibration laboratory aims to validate its standards for a specific thermal calibration range (-20 °C to -10 °C), commonly used regionally but lacking a PT program. The laboratory conducts an ILC with two similar laboratories, calibrating the same type of reference thermometer and comparing results. This allows the laboratory to test the stability of its reference standard, the reliability of its procedure, and the accuracy of its uncertainty analysis from different perspectives.

- **Risk-Based Approach and Identifying Suitable Alternatives**

ISO/IEC 17025 requires laboratories to adopt a holistic approach to risk-based thinking in managing their processes. This does not mean PT or ILC participation is conducted uniformly or at the same frequency under all circumstances. Instead, laboratories must analyze their activity areas, methods used, measurement devices, personnel skill levels, and the intended use of their results to develop a PT/ILC strategy that minimizes risks. This approach ensures optimal resource use while maintaining high levels of quality and reliability.

- **Technical Complexity of Tests and Calibrations**
  - **Testing Example (Complex Chemical Analyses):**

    A chemical testing laboratory may use a complex, multi-step analysis method to detect toxic substances at very low concentrations. Such methods are characterized by high uncertainty, lengthy analysis times, and multi-step preparation processes. Under a risk-based approach, an error in such a complex method could pose significant issues for the client (e.g., a food manufacturer facing food safety risks due to incorrect analysis). Therefore, the laboratory should increase the frequency of PT participation for such complex and high-risk methods or rely more frequently on ILCs other than PT when PT is unavailable. This allows the laboratory to detect potential measurement deviations or unidentified weaknesses in the method early on.

  - **Calibration Example (Advanced Measurement Standards):**

    A calibration laboratory performing high-frequency RF (radio frequency) calibrations, which are carried out by only a few laboratories in the industry, may face challenges due to the extreme precision required, high equipment costs, and limited expertise available in the market. Under a risk-based approach, ensuring measurement accuracy in such a specialized area can be difficult. Therefore, the laboratory should not miss

opportunities to participate in PT or ILCs with other similarly skilled laboratories. When PT programs are unavailable, ILCs other than PT become highly valuable. Regular comparisons help the laboratory demonstrate calibration competence and mitigate risks inherent to the complex technological process.

- **Purpose and Criticality of Results**
  - **Testing Example (Forensic Testing):**

Results from forensic laboratories are often used as evidence in courts. A single erroneous analysis could lead to the conviction of an innocent person or the acquittal of a guilty one. This high criticality directly influences the laboratory's PT/ILC participation strategy. Under a risk-based approach, the laboratory should frequently participate in PT programs for forensic analyses. If no PT programs are available, organizing ILCs with other trusted laboratories ensures the reliability of its results. Regular external comparisons minimize the risk of erroneous outcomes.

  - **Calibration Example (Aviation Sector):**

A calibration laboratory may perform sensor calibrations for use in the aviation sector. Errors in these results, which could impact flight safety, are unacceptable. Under a risk-based approach, reference equipment used in aviation applications should be periodically tested in PT programs or ILCs other than PT. If PT programs are limited, the laboratory must frequently organize ILCs with technically equivalent laboratories to identify any measurement discrepancies promptly and take corrective/preventive measures as necessary.

- **Personnel Experience and Competence**
  - **Testing Example (New Personnel):**

If a laboratory hires new staff or has personnel with limited experience in a specific measurement method, it may increase the frequency of participation in PT or ILCs under a risk-based approach. For example, when a new technician joins a food testing laboratory, the laboratory can intensify its involvement in PT programs or ILCs other than PT during this period to monitor the technician’s performance. This allows for early detection of learning errors, methodological misunderstandings, or instrument operation deviations.

  - **Calibration Example (Departure of Expert Personnel):**

If an experienced expert responsible for critical calibration processes retires or leaves, the laboratory may perceive this as an increased risk. The departure of such personnel can create a knowledge and experience gap. During the transition, the laboratory increases the frequency of PT/ILC participation to monitor the performance of the new team through external validation mechanisms. This manages the risk of potential quality issues due to the absence of experienced personnel.

- **Equipment Reliability and Measurement Traceability**
  - **Testing Example (Aging of Sensitive Equipment):**

Certain analytical devices (e.g., high-precision chromatographs or mass spectrometers) may experience performance degradation over time. Under a risk-based approach, as equipment ages, the laboratory increases the frequency of PT or ILC participation to detect potential performance declines early. This allows the laboratory to proactively identify the need for maintenance, repair, or calibration of the equipment.

- **Calibration Example (Traceability-Controlled Devices):**

A pressure calibration laboratory may use a reference device traceable to an international primary standard. Ensuring the reliability of this reference device is critical for error-free measurements throughout the chain. The laboratory regularly verifies the accuracy of this device through PT or ILCs other than PT. If any break or error in the traceability chain is detected, the laboratory addresses the issue before it escalates into a more serious risk.

- **Stability of Tested Matrices and Method Resilience**
  - **Testing Example (Food Matrices):**

Certain food matrices, such as fruit-based beverages, may have highly variable chemical compositions. Analyte concentrations in these matrices can vary due to seasons, production batches, or storage conditions. This variability increases the risk to performance reliability. The laboratory evaluates the unique characteristics of the matrix and increases the frequency of PT or ILC participation based on its risk profile. This allows the laboratory to track how matrix variability affects results through external comparisons.

  - **Calibration Example (Environmentally Sensitive References):**

Some reference equipment or materials are highly sensitive to environmental factors such as temperature, humidity, or vibrations. If a laboratory operates in a measurement area highly affected by these factors, data indicating high risk necessitates increasing the frequency of PT or ILC participation. This helps the laboratory better understand how challenging environmental conditions impact measurement accuracy through interlaboratory comparisons.

A risk-based approach moves a laboratory's PT/ILC strategy beyond a simple formula like "participate in PT a certain number of times per year." Instead, the laboratory dynamically determines its level of PT/ILC participation by considering the nature of the testing or calibration activity, the purpose of the results, the technical specifications of the equipment, personnel competence, and the complexity of the matrix. This approach enables the laboratory not only to meet standard requirements but also to effectively implement principles of continuous improvement, quality assurance, and risk management.

4. Principle of Availability and Suitability

a) First Preference: Participation in PT Programs When Available and Appropriate

- Why is PT Prioritized?

Proficiency Testing (PT) evaluates a laboratory's performance within an independent reference framework using statistically established criteria. Programs offered by PT providers accredited to ISO/IEC 17043 enable laboratories to objectively compare their test or calibration results with those of similar laboratories. Derived metrics such as z-scores, standard deviation-based evaluations, and other statistical performance indicators reveal the laboratory's accuracy, repeatability, and success in managing measurement uncertainty.

- Testing Example (Chemical Analyses):

A food testing laboratory measures the salt content in cheese samples. Various PT programs for this analysis are available in the market, held several times a year, and include laboratories from diverse regions. By regularly participating in this PT program, the laboratory statistically evaluates its scores. This confirms the alignment of its results with those of other laboratories,

identifies potential deviations in its methodology or equipment, and, if necessary, plans corrective actions.

- Calibration Example (Pressure Calibrations):
A calibration laboratory performs pressure calibrations in the range of 1 bar to 10 bar. By participating in an annual pressure calibration PT program provided by an internationally recognized PT provider, the laboratory compares its results against reference values and statistical tolerance ranges. This validates the stability of its reference equipment, the effectiveness of its procedures, and the accuracy of its uncertainty analysis.

2. Second Tier: Evaluation of ILCs Other Than PT When PT is Unavailable or Unsuitable

- Why Consider ILC Other Than PT?
In some cases, no established PT program exists for the laboratory's testing or calibration activities. This may be due to the method being novel, niche, geographically inaccessible, or not widely applied. In such situations, ILCs other than PT offer an effective alternative. These comparisons may not always follow a proficiency testing format. Instead, they may aim to verify the consistency of methods, the stability of reference materials, or traceability. Since ISO/IEC 17025 emphasizes comparing results with other laboratories to monitor validity, ILCs are a valuable alternative when PT is unavailable.

- Testing Example (Rare Matrices):
A geological testing laboratory analyzes heavy metal content in a rare earth sample from a local mining site. It is typical for no PT program to be available for such a unique matrix. The laboratory organizes an ILC with two or three other laboratories with similar expertise and accreditation scopes to analyze the same sample. If the results are consistent, the laboratory demonstrates alignment with other reputable laboratories, providing indirect assurance of its performance in the absence of a PT program.

- Calibration Example (Specific Measurement Fields):
A calibration laboratory performs high-precision RF measurements in a narrow frequency range, an area with no established PT program. The laboratory organizes an ILC with another calibration laboratory of similar competence to calibrate the same reference standard and compare results. If the results align, the laboratory gains external evidence supporting the accuracy and traceability of its measurements, enhancing both client confidence and its quality system.

3. Third Tier: Development of Alternative Approaches When Neither PT Nor ILC is Feasible

- Importance of Alternative Methods:
If neither a PT program nor an ILC can be arranged for the parameter in question, the laboratory must use other tools to support the validity of its results as prescribed by ISO/IEC 17025. These alternative methods include internal quality control mechanisms, method validation/verification studies, the use of reference materials, or intra-laboratory comparisons. The aim is to enable the laboratory to self-monitor, demonstrate the adequacy of its methods, and keep measurement uncertainty under control.
By applying this tiered approach, laboratories can effectively align their PT/ILC strategies with the principles of continuous improvement, quality assurance, and compliance with ISO/IEC 17025.

- Testing Example (Rare Parameters):
A chemical laboratory occasionally performs measurements for a highly critical parameter (e.g., the analysis of a very specific organic contaminant) requested by its clients. For this measurement, neither a PT program nor the opportunity to arrange an ILC exists, as very few laboratories worldwide perform such analyses. In this case, the laboratory deepens its method validation studies, uses certified reference materials when available, regularly measures blind samples to monitor deviations, employs control charts, and conducts internal laboratory comparisons to track consistency over time. Such evidence supports the validity of the laboratory's results even in the absence of PT/ILC participation.
- Calibration Example (Highly Specialized Instruments):
A calibration laboratory calibrates an extremely specialized research instrument. Since this device exists in only a few laboratories worldwide, PT or ILC opportunities are unavailable. The laboratory validates its method in detail, supports its uncertainty analysis with comprehensive datasets, and periodically calibrates its reference equipment at a national metrology institute to maintain high-level traceability. Additionally, internal quality control procedures are used to monitor the instrument’s performance over time. This ensures the laboratory establishes the technical evidence needed to ensure the reliability of its measurements, even without PT/ILC participation.
The principle of availability and suitability requires laboratories to prioritize internationally recognized PT programs when utilizing external verification tools. If this is not possible, laboratories should turn to ILCs other than PT, and if neither option is available, they should rely on internal mechanisms, reference materials, and in-depth validation studies. This hierarchical approach helps laboratories find objective evidence to support their measurement results under any circumstance, thereby ensuring compliance with ISO/IEC 17025’s fundamental principle of result validity.

5. Role in the Accreditation Process

Accreditation is the formal recognition by a third party of a laboratory’s technical competence to perform specific activities. Under ISO/IEC 17025, the accreditation of testing and calibration laboratories requires regular proof of result validity. The ILAC P9 policy emphasizes that PT or ILCs other than PT are critical tools for fulfilling this requirement. Accreditation bodies (ABs), in line with ILAC-P9, rigorously review, approve, improve, or reject CABs’ PT/ILC participation plans. Each step of this process requires careful attention.

a) Development of the PT/ILC Participation Plan

Purpose and Scope of the Plan:
Testing or calibration laboratories must develop a strategy to demonstrate the validity of results for each parameter, test method, or measurement range within their accreditation scope. This strategy should clearly define which parameters will involve PT or ILC participation, the frequency of participation, the preferred providers, and the types of performance indicators (e.g., z-scores, En values) to be monitored.

- **Testing Laboratory Example:**

A food testing laboratory includes chemical analyses of milk, cheese, meat, and water samples in its accreditation scope. The laboratory reviews available PT programs and plans to participate in relevant PT programs for each matrix and parameter at least once a year. For example, mycotoxin analysis in dairy products, nitrite/nitrate determination in meat products, and heavy metal measurements in water analyses are supported by PT programs. For rarely

measured parameters without PT availability, the laboratory organizes ILCs with one or two laboratories working in the same field. This plan is designed to cover all accredited scope areas.

- Calibration Laboratory Example:
A pressure calibration laboratory provides services in the 0–10 bar and 10–100 bar ranges. While regular PT programs are available for the 0–10 bar range, PT programs are harder to find for the 10–100 bar range. The laboratory plans to participate in a PT program annually for the first range and conduct an ILC annually for the second range with similar laboratories. Additionally, it plans to monitor deviations in reference equipment through supplementary internal comparisons or verification activities using reference materials if necessary.

Integration of Risk-Based Approach:
The laboratory applies the principle of risk-based thinking when determining PT/ILC participation. For parameters of critical importance, measurements with high uncertainty, or tests vital for customer reliability, PT participation frequency is increased. In lower-risk areas or for well-established methods with stable internal quality control data, frequency may be reduced.

b) Evaluation of the Plan (Accreditation Body Review)
Examination of Suitability and Representativeness:
The accreditation body (AB) reviews the laboratory's PT/ILC participation plan in detail during the accreditation evaluation process. The purpose is to assess whether the plan fully represents the accreditation scope, considers critical parameters, and reasonably aligns PT/ILC frequency with measurement complexity.

- Testing Laboratory Example:
A food testing laboratory plans to participate in a PT program for salt analysis in cheese only once a year, despite testing thousands of cheese samples annually with high variability in method sensitivity. The AB may deem the plan insufficient and request additional PT participation or ILCs to improve traceability of the method.

- Calibration Laboratory Example:
A pressure calibration laboratory conducts no external comparisons for the 10–100 bar range, relying solely on internal quality control records despite performing hundreds of calibrations annually in this range. The AB may object, stating that the plan does not adequately represent this range and request the laboratory to explore PT or ILC options or validate the reference standard with another laboratory.

Identification of Nonconformities and Deficiencies:
If the AB identifies deficiencies or nonconformities in the plan, these are communicated to the laboratory. Deficiencies may include omitting a specific test parameter, relying on a single PT participation for extensive test areas, insufficient monitoring of high-risk parameters, or creating a theoretical plan that is not practical to implement. Based on this feedback, the laboratory updates its plan by adding PT participation, organizing new ILCs, or developing alternative verification approaches.

c) Process Monitoring, Performance Indicators, and Corrective Actions
Reviewing Performance Evidence:

The laboratory executes its PT/ILC participation plan and records the results. The AB examines these results during accreditation or surveillance audits. Statistical analysis of the results (e.g., z-scores, En values) demonstrates the laboratory's measurement accuracy and repeatability. Based on this data, the AB evaluates how effectively the laboratory implements its plan and whether it improves result quality.

- Testing Laboratory Performance Example:
A laboratory participates in four different PT programs for mycotoxin analysis in milk samples over a year. If the statistical scores for each PT are within acceptable ranges (e.g., z-scores within ±2), the AB may consider the laboratory's methodology consistent. However, if one PT reveals a systematic deviation (e.g., z-score +3), the laboratory must explain the deviation, investigate its causes, and submit corrective action plans to the AB.
Through this structured approach, the laboratory not only demonstrates compliance with ISO/IEC 17025 but also continuously improves its quality systems and measurement accuracy.

Planning and Evaluation of Corrective Actions
If PT or ILC results are unsatisfactory (e.g., consistently falling outside statistical acceptance limits, showing inconsistencies within the method, or having measurement uncertainty significantly exceeding predicted limits), the laboratory must take immediate action. Corrective actions may include method revision, equipment maintenance and calibration, personnel training, changes in the selection of reference materials, or improvements in data processing techniques.
Accreditation bodies (ABs) review the effectiveness of these corrective actions during surveillance or follow-up assessments. If corrective actions yield results and the laboratory's performance improves, the AB records this and contributes positively to the continuity of accreditation. Otherwise, the laboratory may be directed to implement additional corrective actions, or its accreditation status could be at risk.

d) Continuous Monitoring and a Culture of Improvement
Accreditation bodies do not view PT/ILC participation as a static requirement. Instead, it is a dynamic process that is continuously monitored, reviewed, and improved. Over time, laboratories may add new methods, customer expectations may change, equipment may be upgraded, or PT providers may introduce new programs. All these changes necessitate that laboratories update their PT/ILC participation plans, revise risk assessments, and submit updated plans for re-evaluation by the accreditation body.

Summary
1. **Plan Development:**
   Laboratories must clearly specify which PT or ILC programs they will participate in, at what frequency, and based on what risk assessments, for all testing and calibration activities within their accreditation scope.
2. **AB Review:**
   Accreditation bodies carefully analyze these plans, assessing the laboratory's test/calibration coverage, risk profile, and the representativeness of PT/ILC options. Any deficiencies or inadequacies are communicated to the laboratory for correction.
3. **Performance Monitoring:**
   Laboratories collect and analyze PT or ILC results, which are re-examined by ABs during surveillance assessments. Unsatisfactory results necessitate corrective actions.

4. **Continuous Improvement:**
   This entire process represents a dynamic improvement cycle. Over time, the laboratory's PT/ILC strategy evolves to become more appropriate, targeted, and effective. This process continuously validates the laboratory's technical competence, supporting the "continuous improvement" approach central to ISO/IEC 17025.

By implementing ILAC P9 requirements in this manner, accreditation bodies ensure the reliability of results and the internationally recognized performance of laboratories under Mutual Recognition Agreements (MRAs) on a global scale.

6. Risk-Based Approach

ILAC-P9 incorporates the risk-based thinking approach required by standards such as ISO/IEC 17025 and ISO 15189. A laboratory's PT/ILC participation level and frequency should be determined by factors including the technical complexity of tests/calibrations, criticality, the purpose of results, personnel experience, equipment reliability, measurement traceability, and stability of the tested matrices. Each laboratory's PT/ILC strategy must be shaped according to its specific operational risk profile.

7. Alternative Approaches and Validation of Results

Laboratories accredited under or seeking accreditation to ISO/IEC 17025 are required to validate the reliability of their results. ILAC-P9 prescribes that this validation should ideally be achieved through PT or ILCs. However, appropriate or available programs may not always exist, particularly for laboratories conducting highly specialized tests or operating in specific calibration fields. In such cases, laboratories are obligated to take additional measures and adopt alternative mechanisms to provide evidence of result validity.
The following examples illustrate how these alternative approaches can be implemented and how accreditation bodies (ABs) evaluate such efforts:

a) Use of Certified Reference Materials (CRMs)

Fundamental Principle:
Certified Reference Materials (CRMs) are materials with well-defined values and uncertainties for specific parameters. When PT or ILCs are unavailable, CRMs offer a robust tool to demonstrate the accuracy, traceability, and stability of a laboratory's methods.

- Testing Laboratory Example:
A food testing laboratory analyzes a rarely encountered mycotoxin for which no PT or ILC programs exist. The laboratory acquires a CRM with known concentration and uncertainty and measures it during every analytical series. Consistency between CRM measurement results and certified values indirectly demonstrates the suitability of the laboratory's method, equipment, reagents, and personnel performance, supporting the reliability of its results.

- Calibration Laboratory Example:
A mass calibration laboratory regularly measures a CRM produced by a highly specialized mass standard manufacturer for a specific nominal value. When PT programs are unavailable or unsuitable, the laboratory tracks the long-term measurements of this CRM. The results reflect the stability of its calibration procedures and equipment. Systematic deviations in CRM measurements prompt corrective actions, such as equipment maintenance, recalibration, or reassessment of uncertainty components.

b) Comparisons Based on Method Validation/Verification Data
Role of Method Validation and Verification:
In accordance with ISO/IEC 17025, laboratories must ensure their test or calibration methods achieve verified performance characteristics through validation (for new methods) or verification (for established methods under specific laboratory conditions). Validation/verification data must address parameters such as accuracy, precision, repeatability, reproducibility, detection limits, and selectivity.

- Testing Laboratory Example:
An environmental laboratory measures a highly specific organic compound in water samples, for which neither PT nor ILC options exist. During method validation, the laboratory conducts extensive accuracy and repeatability studies at various concentration levels and monitors long-term results using internal control materials. By submitting the validation report, historical data, statistical trend analyses, and uncertainty evaluations to the AB, the laboratory provides indirect but concrete evidence of its method's consistency and reliability. The AB may accept this evidence as sufficient to ensure method performance in the absence of PT/ILC.

- Calibration Laboratory Example:
A temperature calibration laboratory performs calibrations for a narrow range (e.g., -20°C to -10°C) using a specialized reference thermometer. If PT or ILC programs are unavailable, the laboratory uses previously conducted method validation data. This includes measurements of known reference points (e.g., freezing point constants) and comparisons across different equipment. The laboratory demonstrates the stability, traceability, and validation of its method, which can satisfy AB requirements.

c) Organizing Small-Scale ILCs and Adhering to ISO/IEC 17043 Principles
Value of Small-Scale ILCs:
Small-scale interlaboratory comparisons resemble PT programs but typically involve fewer laboratories, sometimes only bilateral comparisons. These ILCs should adhere as closely as possible to ISO/IEC 17043 principles, including sample homogeneity, statistical evaluation methods, confidentiality, impartiality, and effective organization.

- Testing Laboratory Example:
A materials testing laboratory conducts hardness testing of metal samples. With no PT program available, the laboratory collaborates with another accredited laboratory to periodically test the same metal sample. Both laboratories evaluate results using a defined statistical method. While this small ILC may not fully adhere to PT formats, applying key ISO/IEC 17043 principles—such as proper homogeneity testing, clear statistical criteria, and standardized reporting formats—makes the results acceptable for performance benchmarking. The AB can evaluate this mini ILC by considering factors such as statistical methodology, sample preparation protocol, data analysis, and reporting procedures, deeming it sufficient to support result validity.

- Calibration Laboratory Example:
An electronics calibration laboratory performs low-frequency AC voltage calibrations, an area lacking comprehensive PT programs. The laboratory collaborates with two similar calibration laboratories to annually measure the same reference source. All participants adhere to

ISO/IEC 17043 principles, including documentation, homogeneity, statistical analysis, and reporting. While the comparison involves a limited number of participants, it provides meaningful performance evaluation data for the AB.

d) Role and Approval of Accreditation Bodies
Examination of Objective Evidence:
The AB thoroughly reviews all evidence produced through these alternative approaches. This evidence may include CRM usage records, method validation reports, statistical trend analyses, small-scale ILC reports, internal control charts, blind sample results, and justification of uncertainty components.

Assessment Criteria:
The AB assesses whether the evidence answers the following questions satisfactorily:

- Does the laboratory demonstrate measurement traceability through reference standards or CRMs?
- Do method validation/verification data confirm the claimed performance characteristics (e.g., accuracy, repeatability, uncertainty levels, selectivity)?
- Are small-scale ILCs conducted in sufficient alignment with ISO/IEC 17043 principles? Was the participation process, statistical evaluation of results, reporting format, and confidentiality managed professionally?

Approval Process:
If the AB determines that the laboratory's alternative evidence sufficiently supports result validity despite the absence of PT/ILC, this is accepted for granting or maintaining accreditation. Otherwise, the laboratory may need to take additional measures, such as improving measurement methodologies, enhancing traceability, expanding the type or number of CRMs, or organizing additional ILCs with other laboratories.

Alternative approaches enable laboratories to demonstrate technical competence and meet ISO/IEC 17025 requirements when PT or ILC participation is not feasible. These methods provide flexibility in the laboratory's quality assurance strategy while allowing ABs to make fair, impartial, and informed accreditation decisions. Supported by rigorous preparation, robust documentation, statistical analyses, and continuous improvement principles, these alternative mechanisms may not equate to PT/ILC but provide a comparable level of reliability, playing a critical role in the laboratory's accreditation journey.

8. Evaluation of Results and Quality Assurance

ILAC P9 emphasizes that laboratories should place data obtained from PT and/or ILCs other than PT at the center of their quality management systems. This data is not merely an external performance indicator but a critical quality parameter that demonstrates the stability, reliability, and capacity for continuous improvement of the laboratory's measurement processes.

a) Role of Statistical Analysis and Long-Term Trend Monitoring
Selection and Application of Statistical Techniques:
Laboratories should not limit their evaluation of PT/ILC results to single instances but analyze accumulated results over time using statistical methods to identify trends, variabilities, and

potential drifts. These analyses often involve control charts (e.g., Shewhart charts, Cusum, or EWMA charts), z-scores, En values, means, and standard deviations.

- Testing Laboratory Example:
A chemical testing laboratory participates in a PT program for mycotoxin analysis four times a year. Each result is expressed as a z-score. The laboratory records these scores on a control chart. While initial results may show balanced z-scores around 0, systematic scores above +2 in the third and fourth rounds indicate a positive drift. This trend suggests an underlying issue in standardization, equipment calibration, or sample preparation, enabling the laboratory to identify and address the problem early, preventing erroneous reporting.

- Calibration Laboratory Example:
A calibration laboratory participates in PT or ILC for pressure calibration in the 0–10 bar range twice a year. Each PT/ILC provides data on measurement bias and uncertainty. The laboratory subjects this data to trend analysis. An increase in standard deviation over time or a gradual drift in average measurement values may indicate a stability issue with reference equipment or exposure of calibration procedures to non-routine influences.

Long-Term Data Management:
Laboratories that systematically record PT/ILC results and review this data regularly demonstrate long-term methodological stability. This serves as robust evidence for both internal audits and accreditation evaluations, showcasing not just isolated successful performances but a sustained standard of quality.

b) Root Cause Analysis for Underperforming Parameters
Problem Identification and Differential Diagnosis:
When PT/ILC results fall outside statistical limits (e.g., z-scores exceeding ±3), the laboratory must promptly investigate the causes of such deviations. Root cause analysis is critical for accurately identifying the source of the issue and implementing effective corrective actions.

- Testing Laboratory Example:
A water analysis laboratory consistently reports higher-than-expected results for nitrate measurement in a PT program. During root cause analysis, the laboratory examines potential issues such as contamination in the automatic sample preparation system, reagent purity, extraction efficiency of the method, or wavelength calibration errors in the device. If a detailed investigation reveals that impure chemicals in the reagent are causing consistently high results, the laboratory takes corrective measures, such as replacing the reagent, contacting the supplier, or improving control steps.

- Calibration Laboratory Example:
A length calibration laboratory experiences consistent positive bias in ILC results for a specific gauge block. Root cause analysis identifies uncontrolled environmental temperature, insufficient thermal stabilization of the measurement device, or a missed procedural step as potential factors. Solutions include stricter control of environmental conditions, ensuring adequate stabilization time before measurements, or revising procedures.

Planning Corrective and Preventive Actions:
Once the root cause is identified, the laboratory implements corrective actions, which may range from method revision and personnel training to more frequent equipment calibrations

or the use of new quality control materials. After implementing these measures, the laboratory should verify improved performance in subsequent PT/ILC participation and take additional steps if necessary.

c) Establishing an Internal Quality Improvement Cycle
Culture of Continuous Improvement:
Analyzing PT/ILC results and implementing corresponding improvements are integral to the laboratory's overall quality management system. The continuity of this process demonstrates that the laboratory aligns with the principles of ISO/IEC 17025 by continually improving itself, managing risks, and maintaining result accuracy. This builds trust not only for external audits and accreditation but also among customers and stakeholders.

- Testing Laboratory Example:
A food laboratory reviewing five years of PT results for salt analysis may observe a slight positive drift during specific months. Trend analysis enables the laboratory to assess seasonal effects (e.g., temperature changes during storage, personnel turnover, or reagent quality from different suppliers) and take necessary precautions. This cycle helps the laboratory optimize testing capacity, reduce uncertainties, enhance method robustness, and improve customer satisfaction.

- Calibration Laboratory Example:
An electrical calibration laboratory analyzing ILC results over three years identifies that accuracy consistency in a specific measurement range is weaker than in others. This insight prompts the laboratory to review its reference standard, improve calibration procedures, or enhance personnel training. Over time, this cycle refines the calibration process, minimizes error sources, and ensures measurement traceability.

d) Management Reviews and Strategic Decisions
Sharing Data with Top Management:
PT/ILC results, statistical trend analyses, root cause analysis reports, and corrective action outcomes should be discussed in management review meetings. These discussions provide valuable insights for making strategic decisions, optimizing resource allocation, identifying training needs, and guiding technology investments.

Accreditation Body Evaluation:
Accreditation bodies examine how effectively laboratories manage this quality improvement cycle during surveillance audits. Regular records, trend analysis results, corrective action reports, and consistently improving or stable performance enhance the AB's confidence in the laboratory's technical competence and quality management system.

Evaluating results and ensuring quality assurance go far beyond merely collecting and filing PT/ILC data. This data transforms laboratories into continuously learning and improving entities. Statistical analyses provide a long-term perspective, root cause analyses delve deeply into problems, and corrective/preventive actions enable meaningful and sustainable improvements to measurement processes. This approach underpins the operation model of testing and calibration laboratories, emphasizing measurement accuracy, traceability, repeatability, and customer trust.

9. Global Harmonization and Mutual Recognition

ILAC-P9 emphasizes the need for Accreditation Bodies (ABs) to consistently define and implement policies regarding the use of PT/ILCs to achieve global harmonization. This harmonization facilitates the mutual recognition of accreditation results under the ILAC Mutual Recognition Arrangement (MRA). Consequently, the results of a laboratory accredited in one country are accepted with the same level of confidence in other countries, reducing international trade and technical barriers between laboratories.

10. Competence and Evaluation Criteria for PT Providers

ILAC-P9 recommends the use of PT providers accredited to ISO/IEC 17043 whenever possible. Accredited PT providers, evaluated and recognized under the ILAC MRA, ensure that participation in their programs objectively assesses laboratory performance based on internationally accepted criteria. If no accredited PT provider is available, the AB evaluates the competence and reliability of the PT/ILC organization used to verify the CAB's results.

11. Guidance Documents and Addenda

ILAC-P9 references guidance documents such as EA-4/18 G:2021 to provide CABs with additional direction for determining PT participation levels and frequencies. Appendix C summarizes the fundamental principles of EA-4/18, offering systematic and rational strategies for ABs and laboratories to develop effective PT participation plans.

Summary

The **"ILAC Policy on Proficiency Testing and/or Interlaboratory Comparisons Other Than Proficiency Testing" (ILAC P9)** provides a detailed, risk-based framework for laboratories, medical laboratories, inspection bodies, PT providers, and other conformity assessment bodies (CABs) to demonstrate the validity of their results during accreditation processes.

This policy defines how, when, and based on which criteria PT or PT/ILC programs should be utilized. Rooted in internationally accepted requirements, it supports performance evaluation, continuous improvement, transparency, and global acceptance for both accreditation bodies and organizations seeking accreditation or maintaining their accredited status.