A Supplemental & Guidance Document to NAPT's ILC/PT Reports

Possible Actions & Risk Evaluation to be Taken by Participants

This guide has been meticulously crafted to assist participants, accreditation bodies, and assessors in effectively interpreting and analyzing the reports issued by the National Association for Proficiency Testing (NAPT). At NAPT, our primary goal is to maximize the value of our Interlaboratory Comparison (ILC) and Proficiency Testing (PT) programs by promoting a deeper understanding of the results, their implications, and the necessary actions that participants must take during and after their involvement in these programs.

Beyond the core guidance provided in this document, NAPT offers a broad range of supplementary services tailored to meet the needs of the Metrology & Test Community. For more information about these services or to discuss specific requirements, please do not hesitate to contact NAPT's Managing Director or any NAPT staff for assistance.

The document is systematically organized into multiple sections, each offering detailed guidelines and customized advice pertinent to its specific area of focus. This structured approach is designed to empower you to navigate the complexities associated with participating in ILC/PT programs, understanding the reports issued by providers, and executing any required actions as part of your enrollment with clarity and precision.

NAPT QUALITY SYSTEM

NAPT's Quality System is explicitly designed to not only meet but exceed international standards for proficiency testing providers, offering an unparalleled level of analysis that goes far beyond the minimum requirements. As an accredited proficiency test provider, NAPT collaborates closely with accreditation bodies to ensure that participation in any NAPT-sponsored Interlaboratory Comparison (ILC) or Proficiency Testing (PT) program is recognized as valid proof of technical competency in the relevant discipline in which an organization participates.

A cornerstone of the NAPT process is the assurance of complete independence, total integrity, and the elimination of any potential bias throughout the entire process. NAPT achieves this by ensuring its proper focus is providing administration of interlaboratory comparisons to the metrology and test community while upholding strict confidentiality agreements among its staff and technical advisors, ensuring that no bias is introduced—whether directly or indirectly—at any stage of the process. This commitment to integrity is a guarantee that only a nonprofit organization like NAPT can confidently provide.

The services provided by NAPT are dedicated to one purpose and only one purpose and that is to help organizations make better measurements. Only through strict adherence to the requirements of ISO 17043 can we ensure integrity, confidence, and independence in every report we issue to our participants.

If we were not to adhere strictly to the requirements set forth in ISO 17043, we would be automatically introducing the potential for bias and introducing the possibility of corruption in the process. This is exactly what is starting to happen with calibration laboratories who assume they are performing a sufficient risk analysis of their technician competency without understanding how they may be introducing bias. ISO 17043 was written to ensure critical components aren't missed in determining competency. If those steps are being missed, bias creeps into the process.

All NAPT ILC/PT kits are developed to meet these rigorous standards. Our full-time staff is highly knowledgeable about laboratory accreditation requirements, ensuring that participants' needs are met with precision and efficiency.

Every ILC/PT scheme is developed in accordance with NAPT's Quality Procedure 404-1, which governs the creation of each scheme. This procedure mandates the use of high-quality artifacts, specifies expected measurement uncertainty ranges, identifies the types of participants who will benefit, selects the pivot laboratory for artifact characterization, and establishes reference values.

Each ILC/PT kit is assigned a technical advisor who provides expert guidance in selecting the appropriate artifacts and determining the measurement set points. The advisor also identifies any specific characterization or performance issues that must be addressed before the kit is issued to the public. This proactive approach ensures that the kits are tailored to meet the specific needs of participants, thereby enhancing the overall value and effectiveness of NAPT's proficiency testing programs.

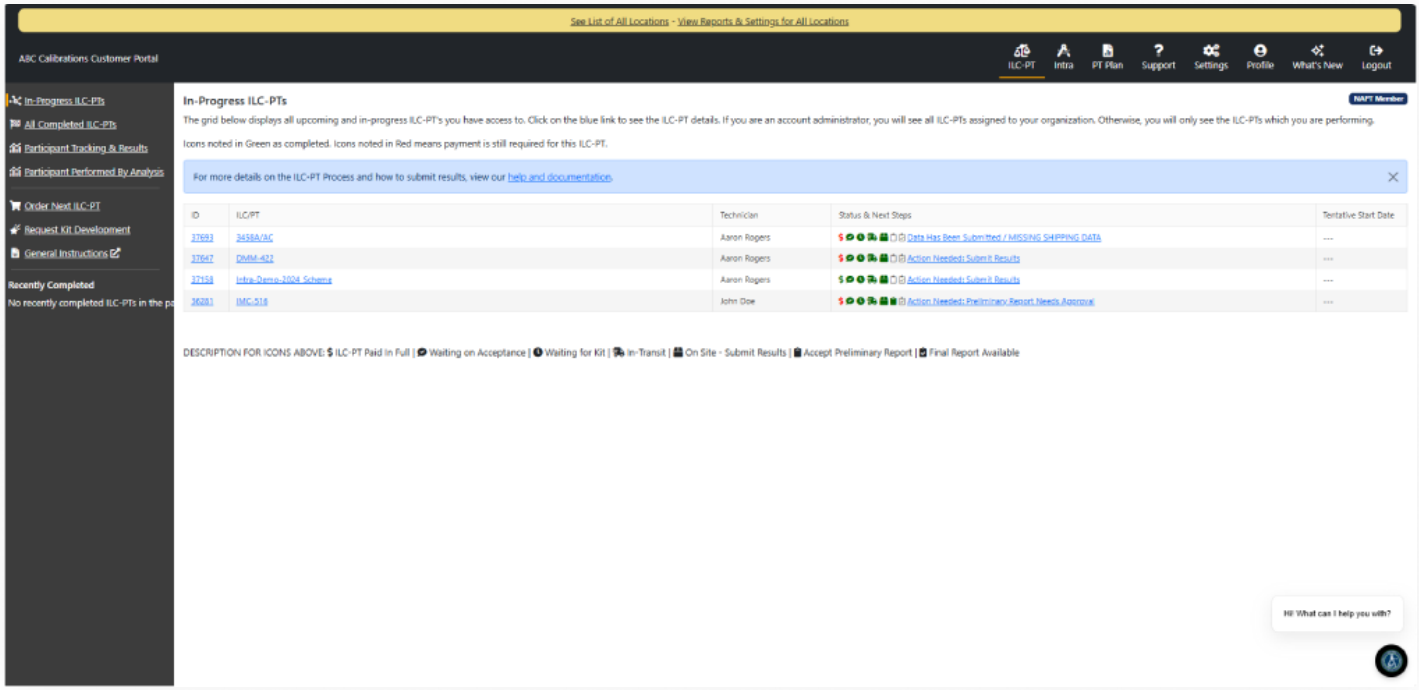
Below is a snippet of the NAPT customer portal, a comprehensive tool designed for current participants, potential participants, and non-participants to fully manage their proficiency testing programs. The portal offers a wide range of features that are automatically updated throughout your enrollment, ensuring that all relevant information is readily accessible to participants and users of the portal.

Please note that this comprehensive set of tools contained in the customer portal is available to anyone and you can use this independently or with NAPT or with other PT Providers. It's a free tool that is offered to the metrology and test community throughout the world to use. NAPT provides this service, so everyone involved in proficiency testing has access to an easy-to-use set of tools to manage their enrollments, their plans, and their risk.

It has been specifically designed with ease of use in mind, allowing participants to seamlessly enroll in, manage, and analyze all aspects of their proficiency testing programs.

All participants enrolled in any Interlaboratory Comparison/Proficiency Testing (ILC/PT) program will use this portal as their primary platform for communication and notification regarding their enrollments.

This centralized hub streamlines the process, making it the go-to resource for all related activities and updates.



OVERVIEW OF NAPT REPORTS

Participation in any NAPT-sponsored Interlaboratory Comparison (ILC) or Proficiency Testing (PT) kit results in the issuance of at least two reports to each participant: a preliminary report and a final report. Additionally, more in-depth technical reports are available exclusively to members through the NAPT customer portal. These reports are accessible only to members of the association.

The preliminary and final reports serve distinct yet complementary purposes, which are outlined below.

NAPT's ILC/PT kits are carefully designed to provide participants with meaningful opportunities to demonstrate and assess their technical competence in the specific discipline in which they participated. The development of each kit is guided by NAPT's accredited quality system, ensuring full compliance with all relevant international standards and the stringent requirements set forth by accreditation bodies.

Once participants enroll in a proficiency testing program, kits are distributed, closely monitored, and subsequently evaluated. After all participants have submitted their data, NAPT generates reports based on a thorough analysis of the collected data. This analysis is conducted using a detailed statistical procedure to establish reference values and their associated uncertainties, in strict adherence to ISO 13528. This standard, developed by technical experts, outlines the recommended practices for proficiency testing providers, with the expectation that all providers will follow these guidelines when delivering their services.

If your laboratory is conducting internally developed ILC/PTs or performing a risk analysis to determine the frequency of ILC/PTs, it is crucial to ask yourself: Are you following these expert guidelines to ensure that your results are free from bias? Adhering to these standards is essential for maintaining the integrity and reliability of your proficiency testing outcomes.

By adhering to these rigorous standards, NAPT ensures that the reports issued to participants are both reliable and valuable, enabling them to gain critical insights into their technical performance and make informed decisions about any necessary corrective actions.

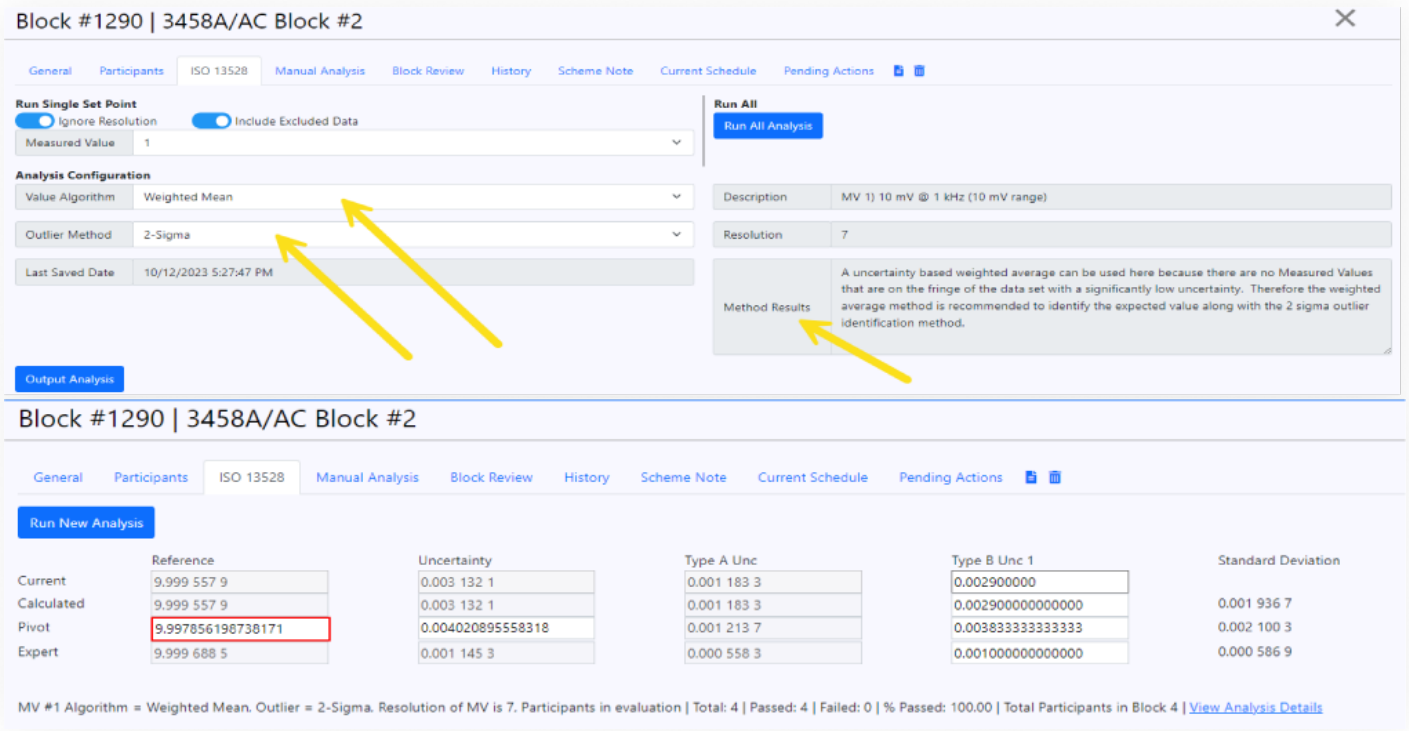
TECHNICAL ANALYSIS

Comprehensive technical reviews are meticulously conducted throughout each ILC/PT distribution to ensure artifact integrity, validate established reference data, and identify any trends or anomalies that may arise. These reviews carried out in strict accordance with ISO 13528, enable NAPT to assist laboratories in taking prompt corrective action, when necessary, thereby helping them identify opportunities for improvement and avoid unnecessary troubleshooting.

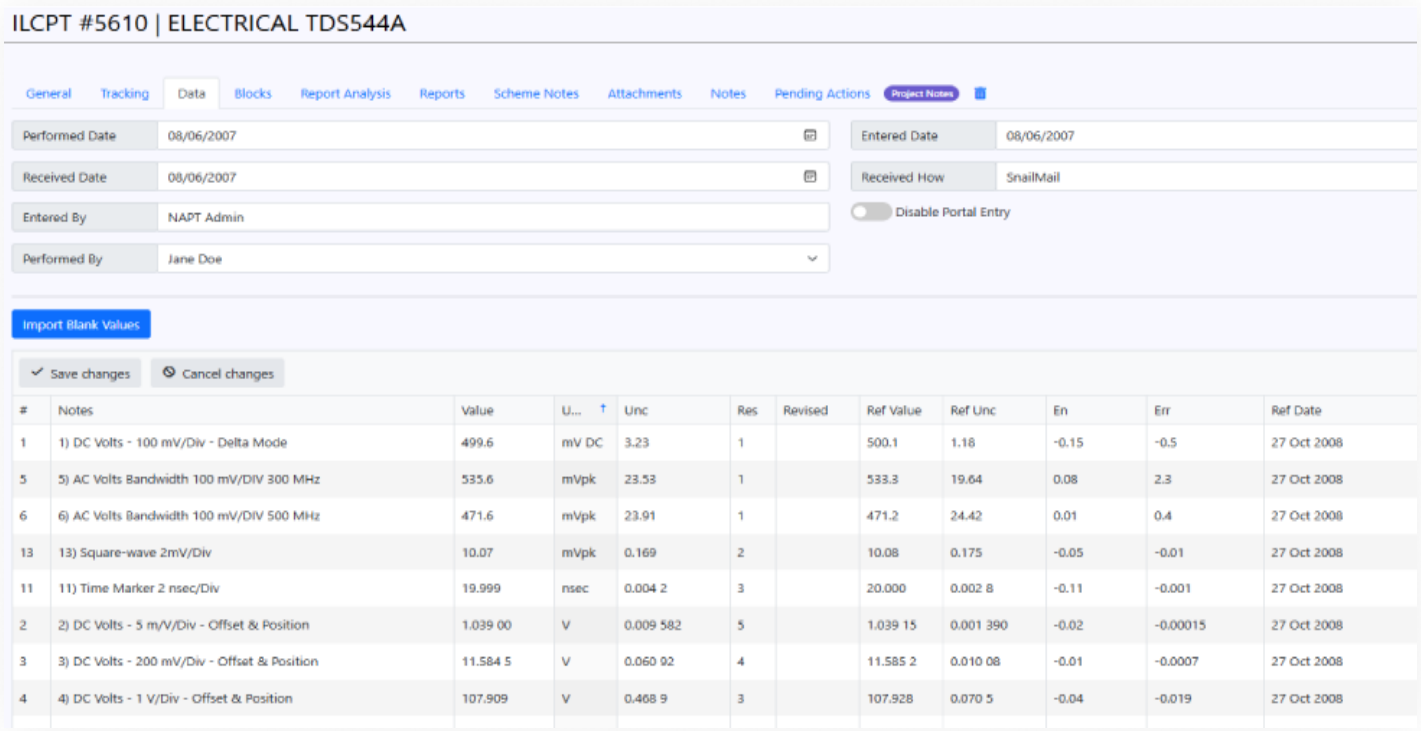
NAPT's statistical review process, as detailed in Quality Procedure 304-1, outlines the methods used for data and statistical analysis. The process for establishing reference values is developed with input from statisticians in the metrology community and includes oversight from experts at the National Institute of Standards and Technology (NIST). By adhering to ISO 13528, NAPT ensures that reference values remain stable and reliable for comparison. A variety of statistical methods are employed, including Robust, Weighted Mean, and Robust Weighted methods, as well as implementing outlier detection techniques, including the Two Sigma, Three Sigma, Chauvenet Criterion, Sample Median, Trimmed Mean, Interquartile Range, Q-Test, and Thompson Technique. Only after thorough analysis is a reference value assigned, ensuring confidence in the published results. In this document, you will see snippets of examples of technical analysis that are embedded for reference purposes only.

Below is an example of a technical review being performed on a single measurement within a larger set of measurements. The form illustrates the numerous calculations that are readily available for the technical advisor's use in determining the appropriateness of the measurements and data submissions. All NAPT participants can be confident that each evaluation of a data submission is conducted in strict accordance with approved methods. Additionally, advanced statistical analyses are available when needed to support and defend the assignment of reference values and associated uncertainties.

The example also demonstrates that all required documentation for compliance with ISO 17043 is meticulously adhered to and managed within a singular, integrated database. This database is not only highly complex but also exceptionally user-friendly, offering a wealth of data and results that surpass standard requirements. However, should the need arise, we are fully capable of presenting and sharing advanced statistical analyses with participants to ensure the highest level of accuracy and transparency.



Below is a snippet of an individual record of participation by a client, showcasing the advanced tools that NAPT has developed to automate and ensure the integrity of statistical analysis. These tools are second to none in the industry and are designed to uphold the highest standards of accuracy and reliability.



Participants can have complete confidence in the independence and impartiality that is guaranteed with every analysis. Additionally, they can trust that each report undergoes a thorough and comprehensive analysis before it is submitted, ensuring the highest level of quality and precision.

Artifact stability is particularly crucial for items prone to drift, such as resistance standards. To manage this, NAPT conducts periodic evaluations of the artifact in the kit, then performs a technical review of all data submittals and closely monitors participant data on all kits that have the potential to drift, allowing for necessary compensation.

Pivot laboratories play a key role in maintaining artifact stability and integrity during the distribution of kits. Initially, an artifact is characterized by a pivot lab, which establishes the initial reference values. These values are continuously monitored, and additional data is collected during distribution to ensure appropriate characterization. Following predefined quality requirements, participant results are then incorporated into the calculation of the reference values at the appropriate time. As more data is accumulated, more robust statistical methods are applied to finalize the reference values and associated uncertainties, as recommended by ISO 13528.

Ensuring the accuracy and reliability of established reference values and their associated uncertainties is a top priority for NAPT and should be for any proficiency testing (PT) provider. Given the complexity involved in this process, NAPT is committed to maintaining transparency and offering clear guidance and support to all participants.

If a participant has any questions or concerns, we encourage them to reach out to the technical manager, who will provide assistance and explain the processes that guarantee the assigned values are defensible.

This approach ensures that participants can have full confidence in the reference values and associated uncertainties.

At NAPT, the assignment of reference values to a data set is one of our highest priorities. Participants depend on the thorough and rigorous analysis conducted throughout the distribution of each kit, as these assigned values must be capable of withstanding scrutiny when necessary.

By upholding these standards, NAPT ensures the reliability of our results, fostering trust and confidence in our proficiency testing process.

PRELIMINARY REPORTS

The primary objective of the preliminary report issued to participants is to ensure that the data submitted to NAPT has been accurately validated and correctly processed into the NAPT database. This report offers participants a crucial opportunity to verify the precision of their data submission. Participants are provided with a five-day window to report any discrepancies. During this period, NAPT may request additional documentation to validate and, if necessary, correct any data submissions.

Preliminary reports serve as an initial review of the data, providing participants with an early opportunity to identify and address potential errors or anomalies. A key requirement outlined in ISO/IEC 17043 is that proficiency testing providers must offer a mechanism to identify possible gross errors and correct them when appropriate. The issuance of a preliminary report is a vital component in fulfilling this requirement, as it allows participants to pinpoint and rectify any significant inaccuracies before the final report is generated.

Participants are often surprised to discover how often errors occur in the submission of data! Please pay attention to detail as you enter your measurement data.

It is important to emphasize that preliminary reports are not intended to provide a definitive assessment of performance. As the Interlaboratory Comparison / Proficiency Testing (ILC/PT) cycle advances and additional data is collected, the final report may differ from the preliminary report. This is due to the comprehensive and rigorous analysis that follows the initial data review. A thorough technical analysis of all data is essential to accurately evaluate the artifact being measured by multiple organizations. To overlook this step would constitute a significant error on the part of the proficiency testing provider.

Accreditation bodies and ISO/IEC 17025 assessors recognize that preliminary reports are not conclusive and, therefore, do not require immediate corrective action. However, participants may find preliminary reports valuable for identifying potential issues early on, such as inconsistencies in test results between different technicians or instruments.

It is critical to understand that preliminary reports should not be used as definitive evidence of satisfactory or unsatisfactory performance. This determination is reserved exclusively for the final report issued by NAPT to the participant.

Nevertheless, preliminary reports can serve as documentation of participation and compliance with a laboratory's proficiency testing (PT) plan, offering an initial indication that the laboratory is actively engaged in the testing process. This early engagement can be instrumental in ensuring that any necessary adjustments or corrections are made promptly, thereby contributing to the overall accuracy and reliability of the results.

FINAL REPORTS

The final report provides a comprehensive summary of the measurement results submitted to NAPT by a participant, along with their associated uncertainties. Depending on the selected report type, several key comparisons are made to assess the performance of participants

En (Normalized Error)

Defined by ISO/IEC 17043, En is the ratio of the deviation between the reported value and the reference value to the root sum square of their associated uncertainties. An En value of ≤1 (less than or equal to one) indicates satisfactory performance, while values >1 (greater than one) are considered unsatisfactory. The En is visually represented in a chart, showing its dispersion around the acceptable range, providing a clear and immediate understanding of performance.

Satisfactory/Unsatisfactory Indicator (S/U)

Based on the En analysis, this indicator offers a quick assessment of a participant's performance. Most accreditation bodies require satisfactory performance (En ≤1) for participation in ILC/PTs to be deemed successful. This indicator helps participants quickly identify whether their performance meets the necessary standards.

Z Score

In certain cases, a Z score is included in the final report, particularly when outliers are identified in the data. The Z score, a statistical measure described in ISO/IEC 17043, is used to evaluate a participant's performance relative to the entire group. A Z score of ≤2 is considered satisfactory, while a Z score of ≥3 indicates unsatisfactory performance. Scores between 2 and 3 are categorized as questionable. Z scores are especially useful in testing laboratories' ILC/PT results, offering more detailed insights into performance variations.

I-W-O (In-Within-Out)

Originally implemented by NAPT in 1997, the I-W-O concept aids in understanding the reporting of measurements in interlaboratory comparisons. This graph is included in selective reports and is defined as follows:

- **In**

  The participant's reported value falls within the uncertainty limits of the established reference value, indicating precise alignment with the expected results.

- **Within**

  The reported value falls outside the uncertainty limits of the reference value but overlaps with the uncertainty of the reference value, suggesting that while the result is not ideal, it is still within an acceptable range.

- **Out**

  Both the reported value and its associated uncertainty fall outside the uncertainty limits of the reference value, indicating a significant deviation from expected results.

The final report serves as a critical tool for evaluating the performance and capabilities of multiple laboratories conducting similar measurements on a single type of artifact. By participating in a NAPT ILC/PT, participants gain valuable insights into how their measurement uncertainties compare to those of other organizations performing similar measurements. This comparative analysis not only highlights areas of excellence but also identifies potential areas for improvement in calibration practices.

Per ISO/IEC 17025 accreditation requirements, the participant is responsible for reviewing the final report, identifying any possible improvements or shortcomings, and taking appropriate actions based on the findings. This process is essential for maintaining high standards of measurement accuracy and reliability across participating laboratories.

REVIEW OF REPORTS ISSUED

Each organization should thoroughly review the reports issued to them and critically evaluate their content by asking the following key questions:

- **Does the report demonstrate technical competence?**

  Assess whether the report reflects the organization's ability to perform accurate and reliable measurements. This includes evaluating the quality of data analysis, the appropriateness of methodologies applied, and the overall precision of the results.

- **Are there any areas in the report that identify potential opportunities for improvement?**

  Consider whether the report highlights specific areas where the organization can enhance its processes, techniques, or methodologies. Early identification of these opportunities can be instrumental in driving continuous improvement within the organization.

- **Does the report establish a baseline for routine measurements, enabling the organization to focus on continuous improvement?**

  Evaluate whether the report provides a reliable reference point for the organization's routine measurements. This baseline can serve as a foundation for tracking progress and implementing targeted improvements over time.

- **Does the report increase confidence in our measurement accuracy?**

  Reflect on whether the findings in the report reinforce the organization's confidence in its measurement capabilities. A well-substantiated report should validate the accuracy of the measurements and provide assurance that the processes in place are effective.

- **Can the report be used to verify the effectiveness of the organization's training programs?**

  Analyze whether the report can be leveraged to assess the effectiveness of the training provided to staff. The report should indicate whether the organization's personnel are adequately skilled and whether the training has successfully equipped them to perform precise measurements.

- **Does the report provide insights into our measurement process, suggesting improvements or identifying deficiencies?**

  Consider whether the report offers valuable insights into the organization's measurement process, such as suggestions for refining techniques or identifying any existing deficiencies. This information can be crucial for making informed decisions on process enhancements.

- **Should we benchmark our performance against others making similar measurements?**

  Finally, evaluate the report in the context of benchmarking. Compare the organization's performance with that of other entities conducting similar measurements. This comparison can help identify where the organization stands in relation to its peers and highlight areas where further improvements may be necessary.

By asking these questions, organizations can ensure that the reports issued to them are not only a reflection of their current capabilities but also a roadmap for future growth and excellence in measurement accuracy and reliability.

OBJECTIVE RESULTS

NAPT's primary objective is not to pass or fail participants, but rather to provide objective, technically sound results that accurately reflect a laboratory's performance in an Interlaboratory Comparison / Proficiency Testing (ILC/PT) program.

Proficiency testing is a critical assessment tool used to validate and support the technical competency of a laboratory. The results generated through these programs are derived from a carefully managed process that adheres to international standards and is recognized by accreditation bodies worldwide. By delivering these results, NAPT empowers laboratories with the data necessary to make informed, technically sound decisions about their measurement processes and overall quality assurance.

It is essential to understand that sharing relevant proficiency testing reports with the Accreditation Body (AB) that granted a laboratory's accreditation is an accreditation requirement. However, it is important to clarify that NAPT does not share the results of any reports directly with the accreditation body. The responsibility for determining which reports should be provided to which accreditation bodies—and at what point in time—rests solely with the participant, who is the customer of the PT provider. NAPT's role is to generate and deliver the results; it is up to the laboratory to fulfill its obligation to notify the appropriate accreditation body as required.

Accreditation bodies typically require timely notification of proficiency testing results that indicate outlying or concerning data, along with a corresponding corrective action investigation. Unfortunately, this critical activity is often overlooked, leading to few documented nonconformances, which undermines the purpose of proficiency testing and the benefits of a well-managed PT process to the laboratory. The results of proficiency testing should be thoroughly reviewed during an assessment and may be required to be submitted within a specific timeframe after the report is issued.

In summary, NAPT's role is to provide laboratories with objective data that can be used to assess and improve their technical performance. While the sharing of these results with accreditation bodies is mandatory, the responsibility for doing so lies with the participant, not the PT provider.

This process ensures that laboratories maintain their accreditation status and continue to meet the stringent requirements set forth by accreditation bodies, thereby upholding the integrity and reliability of their measurement processes.

The following aspects are strongly recommended for review during an assessment:

- **Were the results reviewed and approved by appropriate personnel within the organization?**

  Ensure that the results have been thoroughly reviewed and endorsed by qualified personnel, confirming that the data has been properly evaluated.

- **Did the participant correctly interpret the results of the enrollment?**

  Assess whether the participant has accurately interpreted the results, understanding their implications and relevance to the laboratory's performance.

- **Was the measurement uncertainty assigned appropriately for the measurement made?**

  Verify that the measurement uncertainty has been accurately calculated and is appropriate for the type of measurement conducted. This ensures that the reported data reflects true measurement precision.

- **Is the technical expertise within the organization adequate?**

  Evaluate whether the technical expertise within the organization is sufficient to conduct the proficiency test and interpret the results effectively. This includes assessing the skills and knowledge of the personnel involved.

- **Was a variety of technicians used in the enrollments?**

  Consider whether different technicians participated in the enrollments, ensuring that the results are not dependent on a single individual's performance but rather reflect the overall competence of the laboratory.

By addressing these points, laboratories can better demonstrate their technical competence and adherence to accreditation requirements, ultimately contributing to continuous improvement and reliable measurement processes.

THE IMPORTANCE OF A ROBUST PT PLAN

A Proficiency Testing (PT) plan is a critical component for any laboratory seeking to maintain its accreditation and ensure ongoing quality improvement. The assessment of a PT plan by an assessor is of vital importance to a Conformity Assessment Body (CAB). A well-structured PT plan helps guarantee that every aspect of a laboratory's operations is regularly evaluated and improved, thereby upholding the highest standards of quality and compliance.

KEY ELEMENTS OF A COMPREHENSIVE PT PLAN

A thorough PT plan should encompass several essential elements:

Sample Preparation

Include detailed procedures for preparing samples to ensure consistency and accuracy across all tests. This consistency ensures that every test is performed under standardized conditions, leading to reliable and comparable results.

Testing Procedures

Clearly defined testing protocols should align with industry standards and best practices. This alignment ensures that the methods used are recognized and validated, thereby maintaining the credibility and reliability of the test results.

Data Analysis

Outline methods for analyzing test results, incorporating statistical tools and techniques to identify trends, outliers, and potential sources of error. Accurate data analysis is crucial for interpreting the results and making informed decisions based on the findings.

Corrective Actions

Establish a framework for addressing any discrepancies or failures identified during testing. If corrective actions are not directly part of the PT plan, they should be included in an internal review procedure. This framework ensures that any issues are promptly identified and rectified, preventing their recurrence and enhancing the overall reliability of the laboratory's operations.

STRUCTURING THE PT PLAN

Coverage

The PT plan should comprehensively cover all areas within the laboratory's scope of accreditation. It is recommended that at least one area be tested per accreditation cycle (the period between full reassessments) to ensure a thorough evaluation of the laboratory's capabilities.

Defined Areas, Levels, and Frequency of Participation

Clearly identify the specific areas of testing that will be included in the PT plan. This ensures that all critical functions of the laboratory are systematically evaluated, leaving no gaps in the assessment of technical competence.

Level of Participation

Determine the required level of technical competency for each area of testing. This step ensures that personnel are adequately trained and capable of performing the required tests to the standards expected within the scope of accreditation.

Frequency of Participation

Determine the frequency at which each area will be tested by carefully considering risk assessments and the laboratory's organizational context. This method ensures that the testing frequency is appropriately aligned with the potential risks associated with each specific test area and reflects the overall significance of these areas to the laboratory's operations. However, it is crucial to exercise caution to ensure that your risk assessment does not inadvertently introduce bias or lead to an incorrect level of confidence in your testing strategy.

Documentation and Justification

The laboratory should thoroughly document and justify the structure of its PT plan. This includes providing detailed records of the risk assessments conducted and the technical arguments that support the decisions made in the plan. Such documentation offers a clear rationale for the laboratory's approach and demonstrates compliance with accreditation requirements. It also provides a solid basis for review and audit by accreditation bodies.

STRUCTURING THE PT PLAN

Agility and Review:

Include a review process within the PT plan to ensure it remains flexible and can adapt to changing needs, such as updates in standards, equipment, methods, or staffing. This agility allows the laboratory to stay current with industry developments and maintain its accreditation status. Regular reviews of the PT plan also help in identifying any emerging risks or areas that may require increased attention, ensuring that the laboratory continues to meet accreditation standards and industry best practices.

By structuring the PT plan with these elements in mind, laboratories can ensure a robust and comprehensive approach to proficiency testing, ultimately supporting continuous improvement and sustaining accreditation.

CONSIDERATIONS FOR DEVELOPING A PT PLAN

When developing a Proficiency Testing (PT) plan, laboratories should consider a variety of factors to ensure that the plan is both effective and compliant with accreditation standards:

Organizational Context

Consider the unique environment in which the laboratory operates, including its goals, culture, and market demands. This consideration ensures that the PT plan aligns with the laboratory's overall mission and business objectives, fostering a cohesive approach to quality and performance.

Scope of Accreditation

Consider the specific areas and activities covered under the laboratory's accreditation. The PT plan should be designed to encompass all areas within this scope, ensuring comprehensive coverage and addressing all critical aspects of the laboratory's operations.

Workload

Evaluate the volume and variety of tests the laboratory conducts, as this can significantly influence the frequency and focus of PT participation. A higher workload may necessitate more frequent testing to maintain quality and prevent lapses in performance.

Staff Capabilities

Assess the expertise and experience of the laboratory staff, ensuring they are equipped to meet the demands of the PT plan. Adequate training programs and competency assessments should be in place to support staff in their roles, enabling them to perform at the highest standards.

Risks

Identify potential risks associated with the laboratory's operations, including the likelihood of errors or failures and their potential impact. The PT plan should incorporate measures to mitigate these risks, thereby ensuring reliable and accurate test results.

Changes in Standards, Equipment, and Methods

Consider any recent or upcoming changes that could affect the laboratory's processes and the relevance of its PT plan. The plan should be regularly updated to reflect these changes, ensuring that the laboratory remains compliant with current standards and continues to operate effectively.

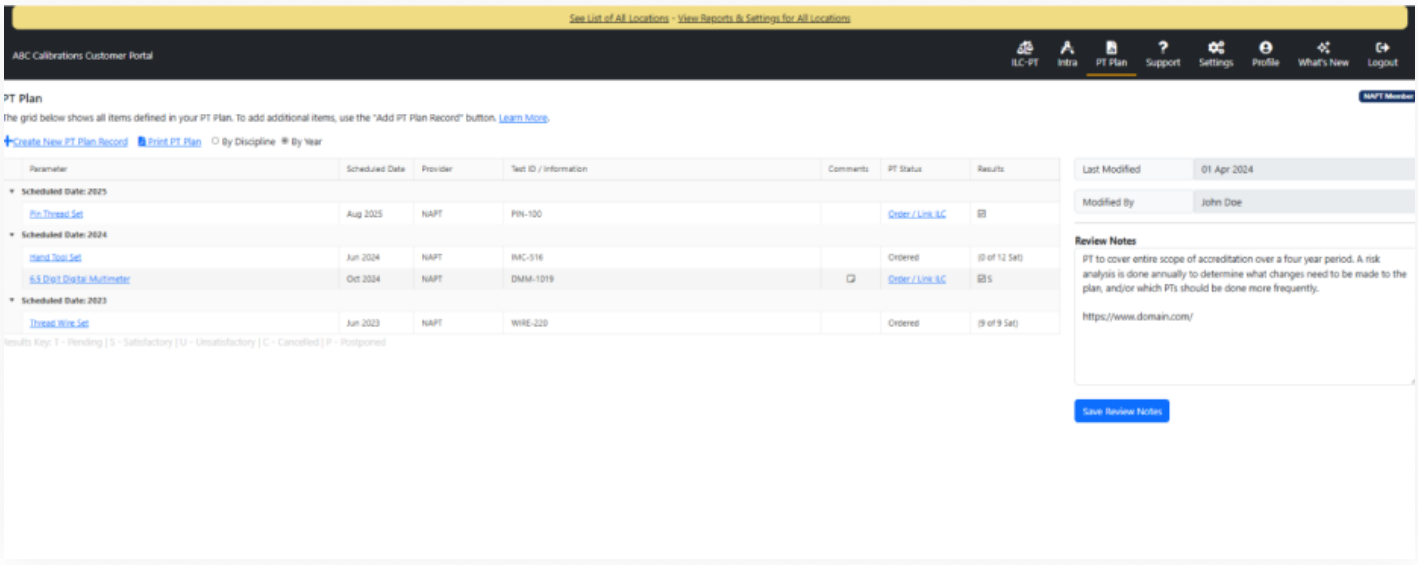
Past Failures

Review historical performance in PTs to identify areas where improvement is needed. This analysis can help prevent recurring issues, enhance the laboratory's overall quality, and improve future performance in proficiency testing.

By taking these considerations into account, laboratories can develop a PT plan that is not only robust and comprehensive but also tailored to their specific operational context, ensuring sustained excellence and compliance with accreditation requirements.

Below is a snippet of the NAPT PT Planning Tool, available within the customer portal. This free comprehensive tool is designed for anyone looking to create a proficiency testing (PT) plan that meets both current and future needs. The PT Planning Tool allows users to fully set up a PT plan, outlining planned enrollments, tracking the status of those enrollments, and displaying the results. Additionally, it provides the capability to document risk analysis, enabling users to have objective evidence of their risk assessments all in one convenient location.

It is important to note that the NAPT planning module is continuously updated based on feedback from participants. Our ongoing commitment is to consistently enhance not just the customer portal, but all the tools within it, ensuring that participation in proficiency testing is an enjoyable experience rather than a burden.



CONDUCTING ROOT CAUSE ANALYSIS FOR PROFICIENCY TESTING

Conducting root cause analysis (RCA) in proficiency testing is essential for maintaining high standards of measurement accuracy and reliability. By systematically identifying and addressing the root causes of performance issues, laboratories can ensure continuous improvement and sustained compliance with accreditation requirements.

DRIVING FREQUENCY OF PROFICIENCY TESTING

The results of proficiency testing should be the primary factor in determining the frequency of Proficiency Test enrollments.

Frequent Testing for Poor Performance

If failures are observed, the frequency of PTs should be increased. This proactive approach ensures that any underlying issues are identified and corrected promptly.

Establishing a Baseline

Initially, PTs should be conducted annually to verify that the accreditation process was thorough and that the results are within an acceptable risk level. This approach is like setting calibration intervals.

Monitoring Reliability

Until a process or system is proven reliable, it should be monitored more frequently or have robust controls in place.

Impact of Changes

When there is a change in personnel or other major aspects of the quality system, PTs should be included as part of the verification and validation process for the changes.

Justifying Reduced PT Frequency

If a laboratory seeks to reduce the frequency of PTs, it must demonstrate that other quality control measures are in place and effective. Examples include control charts, check standards, and random retesting by different personnel.

RISK CONSIDERATIONS

When determining the need for PTs, several risk factors should be considered:

Volume of Activities

The number of tests, calibrations, sampling, or measurements undertaken can impact the risk of errors.

Staff Turnover

High turnover of technical staff can lead to inconsistencies in performance.

Experience and Expertise

The knowledge and experience level of technical staff play a crucial role in maintaining quality.

Traceability

The source of traceability, such as the availability of reference materials or national measurement standards, must be reliable.

Measurement Technique Stability

The known stability or instability of the measurement technique should guide the frequency of the Proficiency Test.

Significance of Data

The final use of testing, calibration, or sampling data, particularly in areas like forensic science, food safety, and medical laboratories, requires a high level of assurance.

ASSEMBLING A CROSS-FUNCTIONAL TEAM

A successful RCA requires a diverse team with clear roles:

Diverse Expertise

personnel from various functions, such as quality assurance, technical staff, and management. This diversity ensures that different perspectives are considered during the analysis.

Clear Roles

Define roles for team members, such as facilitator, recorder, and subject matter experts, to ensure an organized and efficient analysis process.

DEFINING THE PROBLEM

The problem must be clearly identified and understood before root cause analysis can begin:

Identify the Issue

Start by describing the specific issue identified in the PT, such as an En value greater than 1, a Z score indicating questionable or unsatisfactory performance, or any other discrepancies noted in the final report.

Collect Supporting Data

Gather all relevant data, including PT results, calibration certificates, measurement procedures, environmental conditions, and any other information that might have influenced the results.

IDENTIFYING POSSIBLE CAUSES

Once the problem is defined, potential causes should be identified:

Brainstorming Session

Use brainstorming techniques to list all potential causes of the issue. Encourage open discussion and consider all possibilities, including equipment failure, operator error, environmental factors, and procedural issues.

Use RCA Tools

Apply tools like the 5 Whys (asking "why" repeatedly until the root cause is identified), Fishbone (Ishikawa) Diagrams (categorizing causes into groups such as Methods, Materials, Equipment, Environment, and Personnel), or Failure Mode and Effects Analysis (FMEA) to systematically explore potential causes.

ANALYZING THE CAUSES

The next step is to analyze the identified causes:

Data Analysis

Review the collected data and compare it with the possible causes identified. Look for correlations and patterns that point to the most likely root causes.

Cause Verification

Test or simulate potential causes (if feasible) to verify their impact on the PT results. This may involve repeating measurements, conducting equipment checks, or reviewing calibration records.

IDENTIFYING THE ROOT CAUSE

Narrow down the potential causes to identify the root cause:

Narrow Down Causes

Based on the analysis, identify the most probable root cause(s) that led to the PT issue. Ensure that the identified cause is specific, actionable, and supported by evidence.

Document Findings

Clearly document the root cause, including how it was determined and the supporting data.

DEVELOPING CORRECTIVE ACTIONS

With the root cause identified, corrective actions should be developed:

Action Plan

Develop a detailed corrective action plan that addresses the root cause. This may involve revising procedures, retraining personnel, recalibrating equipment, or implementing process changes.

Preventive Measures

Consider implementing preventive measures to avoid similar issues in future proficiency tests. This could include additional training, regular equipment maintenance, or enhanced quality control procedures.

IMPLEMENTING AND MONITORING CORRECTIVE ACTIONS

Corrective actions must be implemented, and their effectiveness monitored:

Execution

Assign responsibilities and timelines for implementing the corrective actions. Ensure that all team members are informed of their roles in the process.

Effectiveness Review

Monitor the effectiveness of the corrective actions by conducting follow-up measurements or audits. Ensure that the issue is resolved and that the corrective actions have led to the desired improvement.

REPORTING AND DOCUMENTING THE PROCESS

Finally, the entire RCA process should be thoroughly documented:

Comprehensive Report

Prepare a report detailing the RCA process, findings, corrective actions, and results. Include all relevant data, analysis, and documentation to provide a clear record of the investigation.

Continuous Improvement

Use the insights gained from the RCA to drive continuous improvement in the laboratory's measurement processes. Share lessons learned with the broader team to prevent similar issues in the future.

REVIEW WITH THE ACCREDITATION BODY

If required, submit the RCA findings and corrective actions to the accreditation body:

Submit Findings

Ensure that all documentation complies with the accreditation body's requirements.

Feedback Incorporation

Incorporate any feedback from the accreditation body into your processes to further enhance quality and compliance.

By following these steps, laboratories can effectively conduct root cause analysis for proficiency testing, ensuring that performance issues are addressed and that the highest standards of quality are maintained.

CORRECTIVE ACTION

Participants should not limit their focus solely to the satisfactory or unsatisfactory rating as determined by the En analysis. A comprehensive review of the final report is crucial. Even if a laboratory's performance is rated as satisfactory across all measurements, there may still be areas that require attention. For example, if the En value is close to 1, or if the laboratory's reported uncertainty values differ significantly from those of other participants, these discrepancies should be investigated further. This review aims to ensure that the laboratory's performance aligns with its own standards and to identify opportunities for continuous improvement. Ultimately, it is the responsibility of the laboratory and its accreditation body to determine the appropriate corrective actions based on the ILC/PT results.

Understanding the results is fundamental to the ILC/PT process. Laboratories should thoroughly familiarize themselves with the procedures used in the proficiency test, the sources of data, and the methods for calculating measurement uncertainty. If an En value greater than 1 is observed, it is essential to initiate a formal corrective action to identify the root cause and implement suitable remedies.

ACCREDITATION RELATIONSHIP TO PROFICIENCY TESTING PROVIDERS

Participation in proficiency testing is a fundamental requirement of ISO/IEC 17025 and is rigorously enforced by accreditation bodies (ABs). It is crucial to clearly understand that the proficiency testing provider supports the accreditation process, but the participant—meaning the laboratory—is the client of the proficiency testing provider, not the accreditation body.

While many laboratories participate in proficiency testing as a key element of their overall measurement assurance process, it is also a critical component for maintaining accreditation.

Most accreditation bodies mandate that laboratories establish and adhere to a four-year proficiency testing plan. NAPT strongly recommends that laboratories carefully evaluate the proficiency testing provider they select to ensure there is no inappropriate relationship between the accreditation body and the provider. This scrutiny is vital to guarantee that the results remain unbiased, completely independent, and free from any potential conflicts of interest. The chosen provider must fully comply with the requirements of ISO/IEC 17043 as well as the specific requirements set by your accreditation body.

To ensure both compliance and consistency, laboratories should develop a comprehensive procedure for proficiency testing. This procedure should include the following key elements:

SELECTION OF PROFICIENCY TESTING PROVIDER

Ensure that the chosen provider is accredited and strictly adheres to ISO/IEC 17043 standards, demonstrating both independence and impartiality. NAPT strongly recommends that participants consult a highly respected paper that offers detailed guidance on selecting a proficiency testing provider. If you need a copy of this paper, please feel free to contact us, and we will provide it to you.

DEVELOPMENT OF A PROFICIENCY TESTING PLAN

Establishing a Comprehensive Proficiency Testing Plan:

Develop a robust plan that aligns with the laboratory's scope of accreditation and encompasses all required proficiency tests. This plan should be meticulously detailed, providing a clear and forward-looking outline of the schedule and scope of proficiency tests over a four-year period. It is critical that this plan is tailored to meet the specific accreditation requirements of the laboratory, ensuring full compliance with all relevant standards.

Regular Review and Updates

The proficiency testing plan should not remain static; it must be a dynamic document that is regularly reviewed and updated as necessary. This periodic review ensures that the plan remains aligned with any changes in accreditation requirements, laboratory operations, or industry best practices. By maintaining an up-to-date plan, the laboratory can proactively address any emerging needs or challenges in their proficiency testing regimen, thereby safeguarding the integrity of their measurement processes.

Integration of Proficiency Testing into Quality Management

The plan should also be integrated into the laboratory's overall quality management system, ensuring that proficiency testing is a continuous and integral part of the laboratory's commitment to excellence. This integration facilitates a holistic approach to quality assurance, where proficiency testing results are consistently used to drive improvements in measurement processes and overall laboratory performance.

Review and Interpretation of Results

Implement a systematic process for the regular review and interpretation of proficiency testing results. This process should include the identification of any outliers, discrepancies, or anomalies that may arise during the testing.

Corrective Actions

Develop a robust mechanism for initiating and documenting corrective actions in response to any unsatisfactory results or identified nonconformances. This step is critical to ensuring that any issues are promptly addressed and resolved.

Communication with Accreditation Bodies

Establish a clear procedure for the timely communication of relevant proficiency testing results to the accreditation body, as required by ISO/IEC 17025. This procedure ensures that accreditation bodies are kept informed of the laboratory's performance and any necessary corrective actions.

Performance Review Methodology

Develop a structured methodology for reviewing ILC/PT performance. This should include criteria for assessing results, comparing performance against established benchmarks, and identifying areas for improvement.

Selection of Proficiency Testing Provider

Ensure that the chosen provider is accredited and adheres to ISO/IEC 17043 standards, demonstrating independence and impartiality. There is a highly respected paper that NAPT highly recommends participants read and adhere to when selecting a proficiency testing provider, If you need a copy of that paper feel free to contact us and we will provide you with that with that paper.

OUTCOME-BASED ACTIONS

- Define clearly articulated actions based on the outcomes of the ILC/PT review. These actions might include implementing corrective measures to address deficiencies, adjusting measurement processes, or enhancing quality control procedures to improve overall performance.
- Laboratories should regularly consult with their accreditation bodies to ensure that their procedures and plans meet all specific requirements and standards.
- As an accredited ILC/PT provider, NAPT is committed to ensuring that participation in its programs fully meets the stringent requirements set forth by accreditation bodies. By participating in a NAPT ILC/PT program, laboratories can be confident that their participation will be recognized and accepted by their respective accreditation bodies. NAPT's proficiency testing programs are highly regarded within the metrology community and are known for their rigor and alignment with industry best practices.

CONCLUSION

NAPT's unwavering commitment to thorough analysis and participant support ensures that the Interlaboratory Comparison/Proficiency Testing (ILC/PT) process not only meets accreditation requirements but also significantly enhances the technical competence of its participants.

Our comprehensive approach, which includes both preliminary and final reports, provides a robust framework for evaluating and refining measurement practices.

NAPT's dedication to excellence ensures that every participant receives the essential support and guidance needed to succeed in their proficiency testing endeavors.

However, it is important to exercise caution when selecting a provider. Not all ILC/PT providers offer the same level of support or adhere as strictly to standards like ISO 17043 and ISO 13528.

Some providers present a direct conflict of interest, particularly when the provider's owner also serves as an ISO 17025 assessor and offers proficiency testing services to the same clients. This dichotomy poses significant red flags, as it can introduce bias and lead to less reliable results.

Choosing a provider that maintains impartiality and upholds the highest standards is critical to obtaining trustworthy and valuable proficiency testing outcomes. NAPT remains dedicated to providing an unbiased and rigorous testing process, free from conflicts of interest, ensuring the reliability and integrity of the results our participants rely on.

If you have any questions or require further information, please do not hesitate to contact NAPT's Managing Director for assistance.