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Date Created: 26 Jun 2025

Total Weighted Score: 5.15

Summary

The risk assessment conducted for our ISO 17025 accredited metrology company reveals a spectrum of risk levels across various operational domains. Starting with the organizational context, the laboratory is at minimal risk due to its strategic alignment with business goals, quality standards, and market expectations. The laboratory's Proficiency Testing (PT) plan is well-integrated into its operations, which is reflected in its robust performance and proactive capability expansions. The recent Accreditation Body (AB) audit, which included the addition of new capabilities, and the scheduled proficiency tests prior to ISO-17025 audits exemplify the laboratory's systematic and forward-thinking approach.

In terms of the Scope of Accreditation, the risk is assessed as low to moderate. The laboratory has a comprehensive PT plan that covers all parameters listed in the Scope of Accreditation (SoA), with most technicians showing competence through passing PT results. However, there is an opportunity for improvement by increasing technician participation in PTs through the benefits offered by the National Association for Proficiency Testing (NAPT) membership. This could enhance staff qualifications and readiness, mitigating any potential gaps in capability.

The assessment identifies a moderate to high risk in staff capabilities, highlighting a critical area for attention. The recent turnover and retirement of seasoned technicians have created a gap in expertise, particularly noticeable in areas requiring specialized knowledge such as the operation of the Wind Tunnel. The laboratory has initiated training programs for new technicians, but the current situation underscores the need for a more consistent and comprehensive training strategy to ensure all personnel are adequately prepared and qualified, thereby reducing the risk of non-compliance and performance inconsistencies.

Laboratory resources are at low risk due to effective risk management and control measures in place, including the Calibration Management System (CMS) which provides an additional layer of quality checks. The structure of internal audits conducted by independent corporate personnel further strengthens the oversight and reduces quality and metrology risks. However, the Proficiency Tests: Past Failures and Audits: Technical Findings sections reveal moderate to high risks, signaling areas where corrective actions have been only partially effective. Persistent issues in PT performance and recurring audit findings necessitate improvements in root cause analysis and more frequent reviews of the effectiveness of implemented actions.

Lastly, significant risks identified in the Technician Training and Certificate or Report Errors categories underscore urgent areas for intervention. Inconsistencies in training records and qualifications, combined with data review errors leading to customer complaints, call for substantial enhancements in training programs and quality control processes. Addressing these gaps is crucial to maintaining the integrity and reliability of laboratory operations.

Overall, while the laboratory operates effectively in many areas, the highlighted risks in staff capabilities, proficiency test outcomes, and quality control processes require immediate and strategic attention to mitigate potential impacts on service quality and compliance.

Details

Risk Factor	Results	Score	Weighted Score
Workload	Very Low Risk – Scope of Accreditation (SoA) contains all parameters performed by the laboratory; ILC/PTs cover majority of parameters on SoA.	8	0.8
Notes for Workload: The lab Scope of Accreditation covers the high-volume parameter, electrical, dimensional, torque and temperature. The lab participates in dimensional PT's almost every year since this is the highest volume of client work. Due to the high volume of torque and the inconsistency of PT test results, more frequent Torque PT's are recommended. Due to the lab's documented weekly TPW checks on their SPRT's, the current frequency of temperature PT is adequate. Due to the redundance of the electrical calibrators and multiple 8.5-digit DMM's and the lab policy of verifying OOT conditions using alternate equipment, the current interval on electrical PT is adequate.			
Organizational Context	Minimal Risk – The PT plan is fully integrated into the laboratory's operational framework, fostering a seamless connection with business goals, quality standards, and market expectations. Performance is consistently strong.	9	0.45
Notes for Organizational Context: The organization has a clear target market and has aligned the laboratory standards and equipment to support the target market. The company standard practice is to provide ISO-17025 Accredited calibration as a default service level. The Scope of Accreditation (SoA) is in alignment with the services needed by the target client market. As part of a larger laboratory network, customer items received that the SoA does not cover, are transferred to other sites with the necessary capability. A review of the Quality Management Meeting minutes addresses proactive laboratory capability expansions. A review of the most recent AB audit included addition of 2 new capabilities. The lab had scheduled and performed proficiency tests for both additions before their ISO-17025 Audit indicating a systemic approach and proactive plan implementation.			
Scope of Accreditation	Low-Moderate Risk – Successful ILC/PT for every parameter on the Scope; Most technicians qualified for each parameter have passing PTs	6	0.3
Notes for Scope of Accreditation: The laboratory's Proficiency Testing Plan addressed all areas listed on the Scope of Accreditation. This location only tests a single technician for each PT test, with occasionally one or two additional technicians. As a member of NAPT, the location may test up to 3 technicians for each test ordered without additional cost. OFI - lab management should consider taking advantage of this membership benefit. The NAPT technician participation certificate, available in the customer portal, can be printed and used objective evidence of training or qualification.			
Staff Capabilities	Moderate-High Risk – Staff expertise is partially aligned with PT requirements, but deficiencies exist in specific areas. Training programs are available but not consistently applied or comprehensive. There is a moderate risk of noncompliance or performance inconsistencies	4	0.4
Notes for Staff Capabilities: The technical depth of the laboratory has decreased in the last six months due to retirements and technician turn over. There are 2 new technician trainee that require significant training, require additional supervision due to their lack of calibration experience and require additional Quality Verification checks on completed work. The laboratory has enrolled the trainee in the on-line Sine Calibration School program for basic calibration skill development. Neither trainee nor any of the 3 Technician II have participated in any Proficiency Testing. PT history indicates only Sr. Technician have participated. The 2025 Internal Technical Audit ID# 2025.02.13			

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Identified only 1 Qualified technician to operate the Wind Tunnel, this situation creates a single-point failure risk should this technician leave the organization, further since this technician also performs Field Service work there is a significant risk to missing customer delivery commitments.			
Laboratory Resources	Low Risk – Risks are well-identified and managed, with effective controls in place. The likelihood of significant errors is minimal, and the PT plan successfully integrates risk mitigation strategies. Only minor enhancements are needed	7	0.7
Notes for Laboratory Resources: As part of a large laboratory network this location's Internal Audits are conducted by Corporate Quality and Corporate Metrology personnel who operate independent from local laboratory management. This structure is able to provide a greater unbiased oversite reducing overall quality and metrology risks. The Calibration Management System (CMS) has built-in random quality check on completed work in addition to the Data Review process, this addition layer of checks further mitigate overall technical risks. The organization CMS also has the ability to quickly and easily perform Reverse-Traceability Investigations and generate reports down to the individual reading, thereby reducing the potential impact to completed work. Through the CMS, corporate Quality, Metrology, and Regional Managers have the ability to access multiple quality reports remotely at any time which are also monitored on q Quarterly basis and annually during the Quality Management Review. All these layers of quality check allow for the potential reduction in the frequency of Proficiency Testing intervals within the plans.			
Changes in Standards, Equipment, and Methods	Very Low Risk – The laboratory consistently integrates process and regulatory changes into its PT plan in a timely manner. There is minimal risk of noncompliance or inefficiency, and staff are well-prepared for transitions.	8	0.8
Notes for Changes in Standards, Equipment, and Methods: The lab has a plan to expand the torque capability to 2000 lbf-ft. They have submitted the capital request to acquire the necessary standards. The have a written plan to perform gage repeatability and reproducibility studies to support target measurement uncertainty required and has submitted the necessary forms required by their AB to approve an Intra-Laboratory Test since no commercial PT test is available for 2000 lbf-ft. the Intra-Laboratory test is listed on the current PT Plan.			
Proficiency Tests: Past Failures	Moderate-High Risk – Some recurring issues have been identified in PT performance, but the review and corrective action process is only partially effective. Improvements have been made in some areas, but other weaknesses persist, posing a moderate risk to quality.	4	0.6
Notes for Proficiency Tests: Past Failures: Lab PT results since 2020 (4-years of history) were reviewed. Lab has done very well (no unsatisfactory test points) with Gage Blocks, Digital Thermometers, Infrared Thermometers, Humidity, Dimensional Plug & Ring Gages, Dimensional Hand tools, Protractors, Tachometers & Stopwatches, Mass Calibration Proficiency Tests. The following areas have had an occasional unsatisfactory test point, but is not considered a systemic concern: Pin gages, Thermocouple Calibrators, DC/LF Power Meter; Oscilloscopes; The following 2 areas have exhibited multiple unsatisfactory test points over multiple years and are a concern: Digital Force Gages and Torque Wrenches.			
Audits: Technical Findings	Moderate Risk – The laboratory generally responds to audit findings in a timely manner, but corrective actions may not always be fully effective. Some technical findings persist across multiple audits, indicating a need for more robust improvement measures.	5	0.5
Notes for Audits: Technical Findings: The following audits were reviewed: 2025 Internal Quality Audit, 2025 Internal			

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Technical Audit, 2024 Accreditation Audit. All audit findings, observation and Opportunities for Improvement related to technical execution were logged in the Corrective Action System, Action plans were developed and appear to be implemented. Corrective actions are opened within the organizational requirements. There are repeat findings related to training records, unsatisfactory torque wrench proficiency testing which indicate the need to improve root cause techniques and indicate a need for more frequent effectiveness reviews. The Accreditation Audit issues failure to participate in an Anemometry PT in the past 4-years, and lacks adequate internal controls such as cross-checks, process control charts or Intra-laboratory testing to assure the validity of test results.			
Technician Training	Severe Risk – Training records exist but contain major gaps or inconsistencies. Many technicians perform tasks they are not officially qualified for, and laboratory capabilities are not adequately supported by training documentation. Redundancy among qualified technicians is minimal, increasing vulnerability to staffing shortages	2	0.3
Notes for Technician Training: The most recent internal QA Audit issued a repeat Lab Finding for incomplete Technician Training Records. The 2025 Internal QA Audit ID # 2025.01.25 stated Technician Training Records were not complete; 5 technicians were behind on completing the signoff for new or revised documents, 2 technician trainees did not have a signed Ethics Form, 6 technicians had not signed off on the most recent HR Employee Handbook release. A review of 20 completed units identified 3 instances where Technicians had completing customer work and did not have signed-off Qualifications in the Calibration Management System (CMS). A review of the CMS Technical Qualification lacked the objective evidence supporting the qualification required by corporate policy.			
Certificate or Report Errors	Significant Risk – Errors in the data review process occur regularly, and while corrections are made, some inaccuracies still reach customers. Customer complaints are rising, indicating gaps in quality control. Processes need significant improvement to enhance reliability and accuracy.	3	0.3
Notes for Certificate or Report Errors: The last quarterly review of the Certificate Error Report metric had a 76 % First Time Passing rate, and a 98% Correction Passing rate for the Data Review process for this location. The top 2 categories identified for error were incorrect uncertainties and missing customer special requirements identified on the customer PO. This was identified as an Opportunity for Improvement (OFI) during the last Internal Quality Audit (ID # 2025.01.25). A review of the Open OFI plan was deemed acceptable by QA, and included additional Training for Data Reviewers, and Uncertainty Training for Technicians. The plan has been implemented. The metric Calibration Certificate corrections attributed to the lab after return to customers was running in the 3% to 5% rate. The QA audit report identified 8 customer complaints since the previous annual internal audit.			