1. Introduction

Polytec, Inc Calibration Laboratory was formed in 1990. We have operated as an independent calibration and service supplier for numerous industries, including but not limited to:

- *Aerospace Manufacturing*
- *NDS: Non-destructive Testing*
- *Automotive and Transportation*
- *Steel and Aluminum Casters*
- *Micro and Nano Technology*
- *Life Sciences, Biomedical*
- *Acoustics and Ultrasonics*
- *Data Storage*
- *Military Facilities: US Navy, US Army, and US Air Force*
- *Material Research, Mechanical and Civil Engineering*

Polytec, Inc recognizes its responsibility as a provider of quality services. To this end, Polytec, Inc has developed and documented a management system to better satisfy the needs of its customers and to improve management of the company. The management system complies with the international standard ISO/IEC 17025:2017.

This manual has been prepared to define the calibration management system, establish responsibilities of the personnel affected by the system, and to provide general procedures for all activities comprising the management system. In addition, this manual is utilized for the purpose of informing our customers of the management system and what specific controls are implemented to assure calibration service quality.

Alternative approaches or, when relevant, exclusion of requirements are bolded at their appropriate sections.

2. Controlled Distribution of the Quality Manual

2.1. The Technical Calibration Manager is responsible for maintaining and updating the controlled master copy of the Polytec, Inc. Quality Manual.

2.2. Printed copies of this document are uncontrolled. Users must verify the revision is current before use.

2.3. Current documents and revision index are available on the Polytec, Inc. electronic network. All documents will have electronic approval.

2.4. An uncontrolled copy of this document is available to customers upon request.

3. Definitions

3.1. For the purposes of this document, the relevant terms and definitions given the following documents apply:

3.1.1. ISO/IEC-17025, *General requirements for the competence of testing and calibration laboratories.*

3.1.2. BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, and OIML. *International vocabulary of metrology — Basic and general concepts and associated terms (VIM). Joint Committee for Guides in Metrology, JCGM 200:2012. (3rd edition)*

4. General Requirements

4.1. Impartiality

4.1.1. Laboratory activities are undertaken impartially and structured and managed to safeguard impartiality.

4.1.2. The laboratory management is committed to impartiality.

4.1.3. The laboratory is responsible for the impartiality of its laboratory activities and does not allow commercial, financial, or other pressures to compromise impartiality.

4.1.4. The laboratory identifies risks to its impartiality on an on-going basis by requesting via email any changes that may affect their standing in impartiality or conflict of interest. This includes those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

4.1.5. If a risk to impartiality is identified, the laboratory can demonstrate how it eliminates or minimizes such risk.

Related Documents
Policy Impartiality and Conflict of Interest

4.2. Confidentiality

4.2.1. The laboratory is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory informs the customer in advance of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g., for the purpose of responding to complaints), all other information is considered proprietary information and is regarded as confidential.

4.2.2. When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned is, unless prohibited by law, notified of the information provided.

4.2.3. Information about the customer obtained from sources other than the customer (e.g., complainant, regulators) is confidential between the customer and the laboratory. The provider (source) of this information is confidential to the laboratory and is not shared with the customer, unless agreed by the source.

4.2.4. Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

Related Documents
Confidentiality Policy

5. Structural Requirements

5.1. The laboratory is a defined part of Polytec, Inc that is legally responsible for its laboratory activities. It is located at 1 Cabot Road, Ste 102, Hudson, MA 01749.

5.2. The laboratory has identified management that shall have overall responsibility for the laboratory.

5.3. The laboratory has defined and documented the range of laboratory activities for which it conforms with this document. All equipment listed on the proposed scope will meet the requirements. Polytec, Inc. performs the following calibration activities in accordance with these documents:

5.3.1. Procedure for Electrical Calibration of Polytec Decoders

5.3.2. Procedure for Mechanical Calibration of Polytec Decoders

5.3.3. In the event non-accredited calibrations are performed for the defined scope, these calibrations aren't or may not be required to fully comply with sections 6.5, 7.6 and reporting requirements of 7.8.

5.4. Laboratory activities are carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities, and organizations providing recognition. This includes laboratory activities performed in its permanent facilities and when working at customer sites.

5.5. The laboratory has:

5.5.1. Defined the organization and management structure of the laboratory, its place in the parent organization, and the relationships between management, technical operations, and support services;

5.5.2. Specified the responsibility, authority, and interrelationship of all personnel who manage, perform, or verify work affecting the results of laboratory activities;

5.5.3. Documented its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.6. The laboratory has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

5.6.1. Implementation, maintenance, and improvement of the management system;

5.6.2. Identification of deviations from the management system or from the procedures for performing laboratory activities;

5.6.3. Initiation of actions to prevent or minimize such deviations;

5.6.4. Reporting to laboratory management on the performance of the management system and any need for improvement;

5.6.5. Ensuring the effectiveness of laboratory activities.

5.7. Laboratory management ensures that:

5.7.1. Communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;

5.7.2. The integrity of the management system is maintained when changes to the management system are planned and implemented.

Related Documents
Organizational Chart
Position Descriptions

6. Resource Requirements

6.1. General

6.1.1. The laboratory has available the personnel, facilities, equipment, systems, and support services necessary to manage and perform its laboratory activities.

6.2. Personnel

6.2.1. All personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, are competent, and work in accordance with the laboratory's management system.

6.2.2. The laboratory documents the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills, and experience.

6.2.3. The laboratory ensures that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4. The management of the laboratory communicates to personnel their duties, responsibilities, and authorities.

6.2.5. The laboratory has procedure(s) and retains records for:

6.2.5.1. Determining the competence requirements;

6.2.5.2. Selection of personnel;

6.2.5.3. Training of personnel;

6.2.5.4. Supervision of personnel;

6.2.5.5. Authorization of personnel;

6.2.5.6. Monitoring competence of personnel.

6.2.6. The laboratory authorizes personnel to perform specific laboratory activities, including but not limited to, the following:

6.2.6.1. Development, modification, verification, and validation of methods;

6.2.6.2. Analysis of results, including statements of conformity or interpretations;

6.2.6.3. Report, review, and authorization of results.

Related Documents
Personnel Training and Competence
Determining Competence
Selection of Personnel
Training of Personnel
Supervision of Personnel
Authorization of Personnel
Monitoring Competence

6.3. Facilities and environmental conditions

6.3.1. The facilities and environmental conditions are suitable for the laboratory activities and do not adversely affect the validity of results.

6.3.2. When applicable, the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities are documented.

6.3.3. The laboratory monitors, controls, and records environmental conditions in accordance with relevant specifications, methods, or procedures or where they influence the validity of the results.

6.3.4. Measures to control facilities are implemented, monitored, and periodically reviewed and include, but are not limited to:

6.3.4.1. Access to and use of areas affecting laboratory activities;

6.3.4.2. Prevention of contamination, interference, or adverse influences on any laboratory activities;

6.3.4.3. Effective separation between areas with incompatible laboratory activities.

6.3.5. When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it ensures that the requirements related to facilities and environmental conditions of this document are met.

Related Documents
Facility and Environmental Requirements

6.4. Equipment

6.4.1. The laboratory has access to equipment that is required for the correct performance of laboratory activities and that can influence the results.

6.4.2. When the laboratory uses equipment outside its permanent control, it ensures that the requirements for equipment of this document are met.

6.4.3. The laboratory has a procedure for handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration.

6.4.4. The laboratory verifies that equipment conforms to specified requirements before being placed or returned into service.

6.4.5. The equipment used for measurement can achieve the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6. Measuring equipment is calibrated when:

6.4.6.1. The measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or

6.4.6.2. Calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7. The laboratory establishes a calibration program, which is reviewed and adjusted as necessary to maintain confidence in the status of calibration.

6.4.8. All equipment requiring calibration, or which has a defined period of validity is labelled, coded, or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity. All calibration standards have a calibration cycle of a maximum of one year, to be removed from service by the end of the month due for recalibration.

6.4.9. Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, is taken out of service. It is isolated to prevent its use, or it is clearly labelled or marked as being out of service until it has been repaired and verified to perform correctly. The laboratory examines the effect of the defect or deviation from specified requirements, and it initiates the management of nonconforming work procedure.

6.4.10. ***In lieu of intermediate checks, the laboratory does the following:***

6.4.10.1. Troubleshooting of the calibration standard and the calibration process will be performed as necessary.

6.4.10.2. Polytec's calibration standards are used frequently. A calibration standard that gives questionable results is normally substituted with a spare standard to ensure the standard is not the cause.

6.4.11. When calibration and reference material data include any reference values or correction factors, the laboratory ensures reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12. The laboratory takes practicable measures to prevent unintended adjustments of equipment from invalidating results.

6.4.13. Records are retained for equipment which can influence laboratory activities. The records include the following, where applicable:

6.4.13.1. The identity of equipment;

6.4.13.2. The manufacturer's name, model information, and serial number or other unique identification;

6.4.13.3. Evidence of verification that equipment conforms with specified requirements;

6.4.13.4. The current location;

6.4.13.5. Calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

6.4.13.6. Documentation of results, acceptance criteria, and the due date of the next calibration or the calibration interval;

6.4.13.7. The maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;

6.4.13.8. Details of any damage, malfunction, modification to, or repair of the equipment.

Related Documents

List of Equipment and Due Dates
Standards Calibration Procedure

6.5. Metrological traceability

6.5.1. The laboratory establishes and maintains metrological traceability of its measurement results by means of a documented, unbroken chain of traceable calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

6.5.2. The laboratory ensures that measurement results are traceable to the International System of Units (SI) through:

6.5.2.1. Calibration provided by a competent laboratory; or

6.5.2.2. **Polytec, Inc. does not use reference material in its laboratory activities. Therefore, this requirement is not applicable.**

6.5.2.3. Direct realization of the SI units is ensured by comparison, directly or indirectly, with national or international standards.

6.5.3. ***Polytec, Inc. uses SI traceable calibration standards in its calibrations. Therefore, this standard requirement is not applicable.***

Related Documents
Metrological Traceability

6.6. Externally provided products and services

6.6.1. The laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used when such products and services:

6.6.1.1. Are intended for incorporation into the laboratory's own activities;

6.6.1.2. Are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

6.6.1.3. Are used to support the operation of the laboratory.

6.6.2. The laboratory has a procedure and retains records for:

6.6.2.1. Defining, reviewing, and approving the laboratory's requirements for externally provided products and services;

6.6.2.2. Defining the criteria for evaluation, selection, monitoring of performance, and reevaluation of the external providers;

6.6.2.3. Ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;

6.6.2.4. Taking any actions arising from evaluations, monitoring of performance and reevaluations of the external providers.

6.6.3. The laboratory communicates its requirements to external providers for:

6.6.3.1. The products and services to be provided;

6.6.3.2. The acceptance criteria;

6.6.3.3. Competence, including any required qualification of personnel;

6.6.3.4. Activities that the laboratory, or its customer, intends to perform at the external provider's premises.

6.6.3.5. **Polytec, Inc. does not subcontract calibrations in its defined scope of laboratory activities, therefore this requirement is not applicable.**

Related Documents
Purchasing Externally Provided Products and Services
Communicating Requirements to External Providers

7. PROCESS REQUIREMENTS

7.1. Review of requests, tenders, and contracts

7.1.1. The laboratory has a procedure for the review of requests, tenders, and contracts. The procedure ensures that:

7.1.1.1. The requirements are adequately defined, documented, and understood;

7.1.1.2. The laboratory has the capability and resources to meet the requirements;

7.1.1.3. Where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

7.1.1.4. The appropriate procedures are selected to meet the customers' requirements.

7.1.2. ***The customer does not specify procedures. The calibration method is determined by the equipment and decoders being calibrated by Polytec, Inc's internal requirements.***

7.1.3. Polytec, Inc issues a statement of conformity to a specification or standard for calibration (e.g., Pass / Fail). The specification, standard, and decision rule are clearly defined. The decision rule selected is communicated to, and agreed with, the customer through the contract agreement or other method, when specified.

7.1.4. Any differences between the request or tender and the contract are resolved before laboratory activities commence. Each contract is acceptable both to the laboratory and the customer. Deviations requested by the customer do not impact the integrity of the laboratory or the validity of the results.

7.1.5. The customer is informed of any deviation from the contract.

7.1.6. If a contract is amended after work has commenced, the contract review is repeated, and any amendments are communicated to all affected personnel.

7.1.7. The laboratory cooperates with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

7.1.8. Records of reviews, including any significant changes, are retained. Records are also retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

Related Documents
Contract Review

7.2. Selection, verification, and validation of methods

7.2.1. Selection and verification of methods

7.2.1.1. Polytec, Inc uses calibration methods provided by Polytec, GmbH to calibrate the equipment manufactured by Polytec, GmbH.

7.2.1.2. All methods, procedures, and supporting documentation, such as instructions, standards, manuals, and reference data relevant to the laboratory activities, are kept up to date and are made readily available to personnel (see 8.3).

7.2.1.3. The laboratory ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.

7.2.1.4. The laboratory verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary.

7.2.1.5. Polytec, Inc does not develop its own methods. Therefore, this requirement is not applicable. The calibration methods are proprietary and controlled by Polytec, GmbH. Polytec, Inc only follows the procedures laid out by Polytec, GmbH.

7.2.1.6. Deviations from methods for all laboratory activities or procedures occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

7.2.2. Validation of methods

7.2.2.1. This facility verifies it can perform the calibration methods as determined by Polytec, GmbH. Therefore, validation is irrelevant.

7.2.2.2. There has not been and will not be a published method for the calibration processes completed by Polytec, Inc

7.2.2.2.1. *Calibration of Polytec equipment is a fully proprietary process and will not be shared with other calibration bodies*

7.2.2.3. Polytec, GmbH holds the requirement to prove its processes are valid, and their processes are proprietary. Polytec, GmbH does not approve of its subsidiaries, like Polytec, Inc, to provide outside persons with the full mathematical proof of their processes and procedures

7.2.2.3.1. *The only externally available document to customers and outside persons is available upon request – Vib_Calibration_1217_02*

7.2.2.4. All Polytec, Inc employees are trained to the standards required at Polytec, GmbH to complete the calibration processes, by training at Polytec, GmbH or training at Polytec, Inc. Training completed at Polytec, Inc will be conducted by either the Calibration Technical Manager or the Quality Manager, who are approved by Polytec, GmbH to complete the necessary trainings

Related Documents
Selection of Methods

7.3. Sampling

7.3.1. ***Polytec, Inc. does not sample as part of its laboratory activities. Therefore, this requirement is not applicable.***

7.4. Handling of calibration items

7.4.1. The laboratory has a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of calibration items, including all provisions necessary to protect the integrity of the calibration item, and to protect the interests of the laboratory and the customer. Precautions are taken to avoid deterioration, contamination, loss, or damage to the item during handling, transporting, storing/waiting, and preparation for calibration. Handling instructions provided with the item are followed.

7.4.2. The laboratory has a system for the unambiguous identification of calibration items. The identification is retained while the item is under the responsibility of the laboratory. The system ensures that items will not be confused physically or when referred to in records or other documents. The system, if appropriate, accommodates a sub-division of an item or group of items and the transfer of items.

7.4.3. Upon receipt of the calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for calibration, when antitamper seals are present but broken, or when an item does not conform to the description provided, the laboratory consults the customer for further instructions before proceeding and records the results of this consultation. When the customer requires the item to be calibrated acknowledging a deviation from specified conditions, the laboratory includes a disclaimer in the report indicating which results may be affected by the deviation.

7.4.4. ***Polytec, Inc does not store customer equipment outside of the standard working environment. Therefore, the laboratory does not monitor environmental conditions of customer equipment storage space.***

Related Documents
Handling of Calibration Items

7.5. Technical records

7.5.1. The laboratory ensures that technical records for each laboratory activity contain the results, report, and sufficient information to facilitate, if possible, identification of factors affecting the measurement result, and its associated measurement uncertainty, and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data, and calculations are recorded at the time they are made and are identifiable with the specific task.

7.5.2. The laboratory ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

Related Documents
Control of Records

7.6. Evaluation of measurement uncertainty

7.6.1. The laboratory identifies the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, are considered using appropriate methods of analysis.

7.6.2. A laboratory performing calibrations, including of its own equipment, evaluates and documents the measurement uncertainty for all calibrations.

7.6.3. ***Polytec, Inc does not perform testing for its customers. Therefore, this requirement is not applicable.***

Related Documents
Identification of Contributions to Measurement Uncertainty
Electrical Uncertainty Calculator
Mechanical Uncertainty Calculator

7.7. Ensuring the validity of results

7.7.1. The laboratory has a procedure for monitoring the validity of results. The resulting data are recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but not be limited to:

7.7.1.1. Recalibration of retained items;

7.7.1.2. Review of reported results.

7.7.2. The laboratory monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed in the following manner:

7.7.2.1. The Polytec, Inc calibration lab will recalibrate a new system from Polytec, GmbH annually. All current engineers and technicians will complete the recalibration individually. These results will be compared to the calibration certificate prepared by Polytec, GmbH. This process will cover the annual proficiency testing.

7.7.3. Data from monitoring activities are analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action will be taken to prevent incorrect results from being reported.

Related Documents
Ensuring Validity of Calibrations

7.8. Reporting of results

7.8.1. General

7.8.1.1. The results are reviewed and authorized prior to release.

7.8.1.2. The results are provided accurately, clearly, unambiguously, and objectively, usually in a report (e.g. calibration certificate), and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports are retained as technical records.

7.8.1.3. When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer are readily available.

7.8.2. Common requirements for reports

7.8.2.1. Each report includes at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

7.8.2.1.1. A title (e.g. “Calibration Certificate”);

7.8.2.1.2. The name and address of the laboratory;

7.8.2.1.3. The location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;

7.8.2.1.4. Unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

7.8.2.1.5. The name and contact information of the customer;

7.8.2.1.6. Identification of the method used;

7.8.2.1.7. A description, unambiguous identification, and, when necessary, the condition of the item;

7.8.2.1.8. The date of receipt of the calibration item(s), where this is critical to the validity and application of the results;

7.8.2.1.9. The date(s) of performance of the laboratory activity;

7.8.2.1.10. The date of issue of the report;

7.8.2.1.11. A statement to the effect that the results relate only to the items tested, calibrated, or sampled;

7.8.2.1.12. The results with, where appropriate, the units of measurement;

7.8.2.1.13. Additions to, deviations, or exclusions from the method;

7.8.2.1.14. Identification of the person(s) authorizing the report;

7.8.2.1.15. Clear identification when results are from external providers;

7.8.2.1.16. A statement, that the calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

7.8.2.2. The laboratory is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer are clearly identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it states in the report that the results apply to the sample as received.

7.8.3. ***Polytec, Inc. measurement facilities perform calibrations and issues calibration certificates. Thus, section 7.8.3 of ISO/IEC 17025 dealing with Test Reports is not applicable.***

7.8.4. Specific requirements for calibration certificates

7.8.4.1. In addition to the requirements listed in 7.8.2, the calibration certificates include the following:

7.8.4.1.1. The uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

7.8.4.1.2. The conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

7.8.4.1.3. A statement identifying metrologically traceability of the measrurements;

7.8.4.1.4. The results before and after any adjustment or repair, if available. Certificates or reports designate any special limitations of use;

7.8.4.1.5. Where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

7.8.4.1.6. Where appropriate, opinions and interpretations (see 7.8.7);

7.8.4.1.7. The following or a similar statement on its issued certificates: "Reported uncertainties (where applicable) represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of 2 (k=2)";

7.8.4.1.8. The measurement uncertainty, unless it has been established and documented during contract review that only a statement of compliance to a specification is required by the customer;

7.8.4.1.9. When a customer requests only a statement of compliance without data and measurement uncertainty (as evidenced in contract review records), contract review records indicate the customer was notified that the calibration is not intended to be used in support of further dissemination of metrological traceability (i.e., to calibrate another device);

7.8.4.1.10. At specific customer request (as documented in contract review records), the laboratory may issue a statement of compliance without taking the measurement uncertainty into consideration. In this case, the results and measurement uncertainty are included in the calibration certificate and the following statement is included in the certificate: "The statement of compliance in this certificate was issued without taking the uncertainty of measurement into consideration. The customer shall assess the results and uncertainty when determining if the results meet their needs." This is considered "shared responsibility";

7.8.4.1.11. The laboratory maintains records of measurement uncertainty for all accredited calibrations;

7.8.4.1.12. The uncertainties reported to, at most, two significant digits, where feasible;

7.8.4.1.13. The laboratory ensures it does not report a smaller uncertainty of measurement on its issued accredited certificates than the CMC on the scope of accreditation.

7.8.4.2. Where the laboratory is responsible for the sampling activity, calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

7.8.4.3. A calibration certificate or calibration label does not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

7.8.5. Reporting sampling – specific requirements

7.8.5.1. **Polytec, Inc. measurement facilities perform calibrations and does not sample. Therefore, section 7.8.5 of ISO/IEC 17025 dealing with Test Reports is not applicable.**

7.8.6. Reporting statements of conformity

7.8.6.1. When a statement of conformity to a specification or standard is provided, the laboratory documents the decision rule employed, considering the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

NOTE: Where the decision rule is prescribed by the customer, regulations, or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2. The laboratory reports on the statement of conformity, such that the statement clearly identifies:

7.8.6.2.1. To which results the statement of conformity applies;

7.8.6.2.2. Which specifications, standards, or parts thereof are or are not met;

7.8.6.2.3. The decision rule applied (unless it is inherent in the requested specification or standard).

7.8.7. Reporting opinions and interpretations

7.8.7.1. When opinions and interpretations are expressed, the laboratory ensures that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory documents the basis upon which the opinions and interpretations have been made.

7.8.7.2. The opinions and interpretations expressed in reports are based on the results obtained from the calibrated item and are clearly identified as such.

7.8.7.3. When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue is retained.

7.8.8. Amendments to reports

7.8.8.1. When an issued report needs to be changed, amended, or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change is included in the report.

7.8.8.2. Amendments to a report after issue are only made in the form of a further document or data transfer, which includes the statement “Supplement to Calibration Certificate, serial number [or as otherwise identified]”, or an equivalent wording. Such amendments shall meet all the requirements of this document.

7.8.8.3. When it is necessary to issue a completely new report, this is uniquely identified and contains a reference to the original that it replaces.

Related Documents
Reporting of Results

7.9. Complaints

7.9.1. The laboratory has a documented process to receive, evaluate, and make decisions on complaints. Where applicable, complaints are promptly resolved.

7.9.2. A description of the handling process for complaints is available to any interested party on request. Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, deal with it. The laboratory is responsible for all decisions at all levels of the handling process for complaints.

7.9.3. The process for handling complaints includes at least the following elements and methods:

7.9.3.1. Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

7.9.3.2. Tracking and recording complaints, including such actions that are undertaken to resolve them;

7.9.3.3. Ensuring that any appropriate action is taken.

7.9.4. The laboratory receiving the complaint is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5. Whenever possible, the laboratory acknowledges receipt of the complaint, and provides the complainant with progress reports and the outcome.

7.9.6. The outcome(s) to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7. Whenever possible, the laboratory gives formal notice of the end of the complaint handling to the complainant.

Related Documents
Complaint Handling Process
Corrective Action Process (Section 8.7)

7.10. Nonconforming work

7.10.1. The laboratory has a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). Out of tolerance calibration standards are nonconforming calibration work. The procedure ensures that:

7.10.1.1. The responsibilities and authorities for the management of nonconforming work are defined;

7.10.1.2. Actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

7.10.1.3. An evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

7.10.1.4. A decision is made on the acceptability of the nonconforming work;

7.10.1.5. Where necessary, the customer is notified, and work is recalled;

7.10.1.6. The responsibility for authorizing the resumption of work is defined.

7.10.2. The laboratory retains records of nonconforming work and actions as specified in 7.10.1.1 – 7.10.1.6.

7.10.3. Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory implements corrective action.

Related Documents
Nonconforming Calibrations

7.11. Control of data and information management

7.11.1. The laboratory has access to the data and information needed to perform laboratory activities.

7.11.2. The laboratory information management system used for the collection, processing, recording, reporting, storage, or retrieval of data are validated for functionality, including the proper functioning of interfaces within the laboratory information management system by the laboratory before introduction. Whenever there are any changes to the Excel worksheets, they are authorized, documented, and validated before implementation.

7.11.3. The laboratory information management system:

7.11.3.1. Is protected from unauthorized access;

7.11.3.2. Is safeguarded against tampering and loss;

7.11.3.3. Is operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

7.11.3.4. Is maintained in a manner that ensures the integrity of the data and information.

7.11.4. The laboratory ensures that instructions, manuals, and reference data relevant to the laboratory's information management system are made readily available to all personnel.

7.11.5. Calculations are checked in an appropriate and systematic manner.

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1. Options

8.1.1. The laboratory establishes, documents, implements, and maintains a management system that can support and demonstrate the consistent achievement of the requirements of this document and assure the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory implements a management system in accordance with Option A.

8.1.2. Option A: The management system of the laboratory addresses the following:

8.1.2.1. Management system documentation (see 8.2);

8.1.2.2. Control of management system documents (see 8.3);

8.1.2.3. Control of records (see 8.4);

8.1.2.4. Actions to address risks and opportunities (see 8.5);

8.1.2.5. Improvement (see 8.6):

8.1.2.6. Corrective actions (see 8.7);

8.1.2.7. Internal audits (see 8.8)

8.1.2.8. Management reviews (see 8.9).

8.1.3. Option B

8.1.3.1. Polytec, Inc. has chosen Option A. Thus, section 8.1.3 of ISO/IEC-17025 is not applicable.

8.2. Management system documentation (Option A)

8.2.1. Laboratory management, under the direction of top management, establish, document, and maintain policies and objectives for the fulfilment of the purposes

of this document and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

8.2.2. The policies and objectives address the competence, impartiality, and consistent operation of the laboratory.

8.2.3. Laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. The laboratory management, under the direction of top management, ensures the integrity of the management system when changes are planned or implemented to the laboratory management system.

8.2.4. All documentation, processes, systems, and records related to the fulfilment of the requirements of this document are included in, referenced from, or linked to the management system.

8.2.5. All personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3. Control of management system documents (Option A)

8.3.1. The laboratory controls the documents (internal and external) that relate to the fulfilment of this document.

8.3.2. The laboratory ensures that:

8.3.2.1. Documents are approved for adequacy prior to issue by authorized personnel;

8.3.2.2. Documents are periodically reviewed, and updated as necessary;

8.3.2.3. Changes and the current revision status of documents are identified;

8.3.2.4. Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

8.3.2.5. Documents are uniquely identified;

8.3.2.6. The unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

Related Documents
Control of Documents

8.4. Control of records (Option A)

8.4.1. The laboratory establishes and retains legible records to demonstrate fulfilment of the requirements in this document.

8.4.2. The laboratory implements the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory retains records for a period consistent with its contractual obligations. Access to these records is consistent with the confidentiality commitments, and records are readily available.

Related Documents
Control of Records (Section 7.5)

8.5. Actions to address risks and opportunities (Option A)

8.5.1. The laboratory considers the risks and opportunities associated with the laboratory activities to:

8.5.1.1. Give assurance that the management system achieves its intended results;

8.5.1.2. Enhance opportunities to achieve the purpose and objectives of the laboratory;

8.5.1.3. Prevent and/or reduce undesired impacts and/or potential failures in any of the laboratory activities;

8.5.1.4. Achieve improvement.

8.5.2. The laboratory plans:

8.5.2.1. Actions to address these risks and opportunities;

8.5.2.2. How to integrate and implement these actions into its management system;

8.5.2.3. How to evaluate the effectiveness of these actions.

8.5.3. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

Related Documents
Risks and Opportunities

8.6. Improvement (Option A)

8.6.1. The laboratory identifies and selects opportunities for improvement and implements any necessary actions.

8.6.2. The laboratory seeks feedback, both positive and negative, from its customers. The feedback is analyzed and used to improve the management system, laboratory activities, and customer service.

8.7. Corrective actions (Option A)

8.7.1. When a nonconformity occurs, the laboratory:

8.7.1.1. Reacts to the nonconformity and, as applicable:

8.7.1.1.1. Takes action to control and correct it;

8.7.1.1.2. Addresses the consequences;

8.7.1.2. Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

8.7.1.2.1. Reviewing and analyzing the nonconformity;

8.7.1.2.2. Determining the cause(s) of the nonconformity;

8.7.1.2.3. Determining if similar nonconformities exist, or could potentially occur;

8.7.1.3. Implements any action needed;

8.7.1.4. Reviews the effectiveness of any corrective action taken;

8.7.1.5. Updates risks and opportunities determined during planning, if necessary;

8.7.1.6. Makes changes to the management system, if necessary.

8.7.2. Corrective actions are appropriate for effects of nonconformities encountered.

8.7.3. The laboratory retains records as evidence of:

8.7.3.1. The nature of the nonconformities, cause or causes, and any subsequent actions taken;

8.7.3.2. The results of any corrective action.

Related Documents
Corrective Action Process

8.8. Internal audits (Option A)

8.8.1. The laboratory conducts internal audits at planned intervals to provide information on whether the management system:

8.8.1.1. Conforms to the laboratory's own requirements for its management system, including the laboratory activities;

8.8.1.2. Conforms to the requirements of ISO/IEC-17025:2017;

8.8.1.3. When applicable, conforms to related regulatory requirements;

8.8.1.4. Is effectively implemented and maintained.

8.8.2. The laboratory:

8.8.2.1. Plans, establishes, implements, and maintains an audit program, including the frequency, methods, responsibilities, planning requirements, and reporting, which takes into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

8.8.2.2. Defines the audit criteria and scope for each audit;

8.8.2.3. Ensures that the results of the audits are reported to relevant management;

8.8.2.4. Implements appropriate correction and corrective actions without undue delay;

8.8.2.5. Retains records as evidence of the implementation of the audit program and the audit results.

Related Documents
Internal Audit Process

8.9. Management reviews (Option A)

8.9.1. The laboratory management reviews its management system at planned intervals, in order to ensure its continuing suitability, adequacy, and effectiveness, including the stated policies and objectives related to the fulfilment of this document. The management review is conducted annually, at a minimum.

8.9.2. The inputs to management review are recorded and include information related to the following:

8.9.2.1. Changes in internal and external issues that are relevant to the laboratory;

8.9.2.2. Fulfilment of objectives;

8.9.2.3. Suitability of policies and procedures;

8.9.2.4. Status of actions from previous management reviews;

8.9.2.5. Outcome of recent internal audits;

8.9.2.6. Corrective actions;

8.9.2.7. Assessments by external bodies;

8.9.2.8. Changes in the volume or type of work or in the range of laboratory activities;

8.9.2.9. Customer and personnel feedback;

8.9.2.10. Complaints;

8.9.2.11. Effectiveness of any implemented improvements;

8.9.2.12. Adequacy of resources;

8.9.2.13. Results of risk identification;

8.9.2.14. Outcomes of the assurance of the validity of results; and

8.9.2.15. Other relevant factors, such as monitoring activities and training.

8.9.3. The outputs from the management review are recorded for all decisions and actions related to at least:

8.9.3.1. The effectiveness of the management system and its processes;

8.9.3.2. Improvement of the laboratory activities related to the fulfilment of the requirements of this document;

8.9.3.3. Provision of required resources;

8.9.3.4. Any need for change(s).

Related Documents
Management Review Process