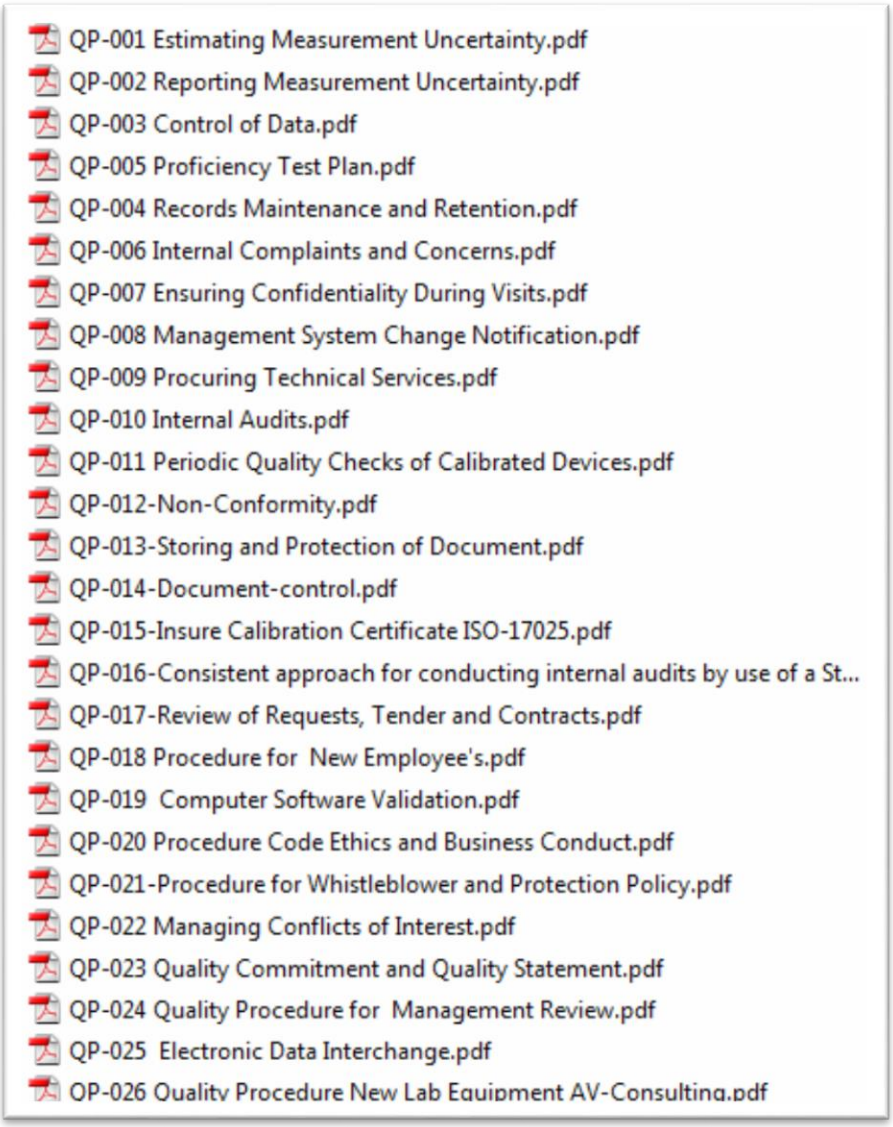
AV CONSULTING B.V.
Calibration Laboratory

# BIJLAGE 3B : KWALITEITSPROCEDURES

AV CONSULTING B.V.
Calibration Laboratory

# Quality Procedure QP-001 to QP-026



## 1. General

**Purpose**

The purpose of this document is to provide a uniform approach for estimating measurement uncertainty.

This document satisfies the requirements of ISO 17025: Section 5.4.6. 5.4.6.1 "A testing laboratory performing its own calibrations shall have and shall apply a procedure to estimate the uncertainty of a measurement for all calibrations and types of calibrations". 5.4.6.2 "Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement".

**Scope**

This procedure applies to all quantitative tests and calibrations performed under the scope of accreditation. Typically only methods and standards classified as category IV methods as defined by this procedure are required to provide uncertainty estimates.

**Definitions**

| | |
|---|---|
| Uncertainty | The unknown difference between a measured result and the actual value. |
| Calibration Uncertainty | The uncertainty associated with the calibration standard or master used while performing a calibration. Generally, this is the expanded uncertainty estimate at 95% confidence. Confidence may also be stated in terms of the coverage factor, k=2. |
| Resolution | The finest increment of change that may be observed on an instruments scale. |
| Repeatability | A statistical value (typically 1 standard deviation) calculated based on the results of repeated measurement. |
| Combined Uncertainty | A calculated statistical value using the root sum squared technique, RSS, (the square root of the sum of the squares) that includes all identified sources of uncertainty |
| Expanded Uncertainty | Calculated uncertainty at the prescribed confidence interval. This lab assumes ~95% confidence and identifies the expanded uncertainty as $U_{95\%}$. |

**Responsibility**

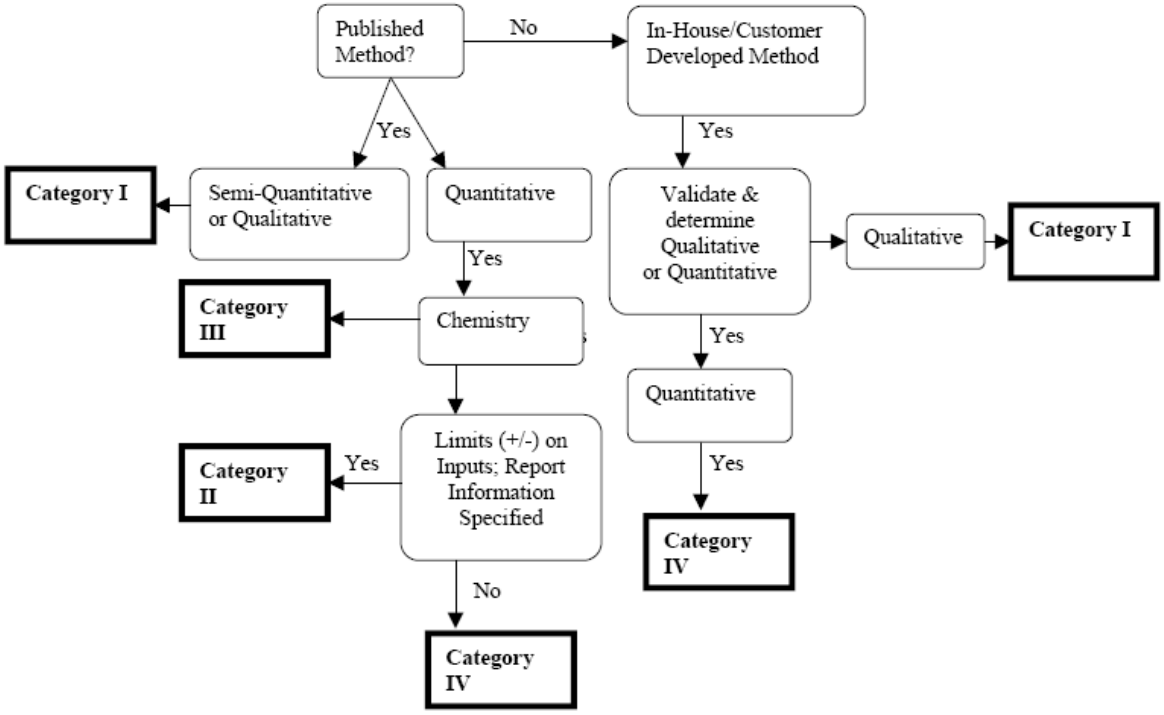
| | |
|---|---|
| Quality Manager | Ensures that uncertainty is applied to tests and measurements as outlined in this procedure. |
| Calibration Personnel | Estimate and certify the uncertainty of calibrated devices covered under the scope of this procedure. |
| | Maintain a log of uncertainty study certificates. |
| Test Personnel | Estimate and certify the uncertainty of tests covered under the scope of this procedure. |
| | Maintain a log of uncertainty study certificates (this may be combined with the calibration log). |

## 2. Procedure

2.1. Determine appropriate category for standard used for test or calibration. The following categories have been adopted from A2LA's P103 - POLICY ON ESTIMATING MEASUREMENT UNCERTAINTY FOR TESTING LABORATORIES.

| Category | Description | Methods |
|---|---|---|
| I. | Qualitative or semi-quantitative tests for which measurement uncertainty budgets will not be required. | ln house methods |
| II. | Well-recognized test methods that specify limits to the values of the major sources of uncertainty of measurement and specify the form of presentation of calculated results. In such cases, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions. | IEC-60651 (SLM's old standard)<br>IEC-61672 (SLM's new standard)<br>IEC-60942 (Calibrators)<br>IEC-61260 (1/1-1/3 Oct. Filters new standard)<br>IEC-225 (1/1-1/3 Oct. Filters new standard)<br>ISO-16063 (vibration transducers) |
| III. | Chemical, environmental, or biological test methods based on published regulatory or consensus methods (examples: FDA, EPA, AOAC, ASTM, APHA/AWWA) for which the measurement uncertainty is not defined in the method. | Not applicable |
| IV. | Test methods that need identification of the major components of uncertainty and a reasonable estimate of measurement uncertainty. | Not applicable |

2.2. Determine if uncertainty is required using the following flow chart adopted from A2LA's P103A:ANNEX TO THE POLICY ON ESTIMATING MEASUREMENT UNCERTAINTY FOR AUTOMOTIVE AND MATERIALS TESTING LABORATORIES dated June 14,2007.




2.3. Identify the significant sources of uncertainty based on the following table and any additional sources.

| Source | Cases for use | Assumed Distribution |
|---|---|---|
| Calibration uncertainty | Calibration uncertainty at ~95% confidence is required for all estimates of uncertainty. | Normal |
| Resolution | Required for all instruments with a scale or digital readout. Includes: protractors, digital scales, rulers, dial indicators, stop watches, etc. Not required on shot bags and other dead weights. | Rectangular |
| Repeatability | Required for all estimates of uncertainty. | Normal |
| Thermal Effects | Required for all estimates of uncertainty on electrical instruments and dimensional instruments subject to thermal expansion and contraction. | Rectangular |

2.4. Repeatability Sampling

2.4.1. Each method shall be performed a minimum of six times. The sample size, (p),=6.

2.4.2. This may be repeated at predetermined increments (typically 4-8) throughout the operating range of the instrument.

2.4.3. The mean and standard deviation shall be calculated for each set of incremental measurements.

2.4.4. When calculating the standard deviation for the mean of multiple incremental sets, the maximum (most generous allowance) shall be substituted as the uncertainty due to repeatability.

2.5. Record all values and assumptions using FO-003: Uncertainty Estimate. Compute uncertainty, report the units of measurement, report to the appropriate number of significant figures.

2.6. Certificates of uncertainty estimates shall be issued for each uncertainty estimate completed.

2.7. Refer to QP-002 when reporting measurement uncertainty.

**3. Change Control Section**

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

Purpose The purpose of this document is to provide a standard approach for reporting measurement uncertainty estimates and conformance with specifications. It is especially important to report measurement uncertainty when a measured value, bound by its uncertainty, encompasses a specified limit. The described approach is in line with publication EA-4/02M: 2013 “Evaluation of the Uncertainty of Measurement in Calibration” and EA-4/16 “EA-guidelines on the expression of uncertainty in quantitative testing”.

Scope This procedure defines the standard approach to be used when reporting uncertainty and conformance with specifications. This procedure applies to category IV test methods within the scope of accreditation as defined by QP-001: Estimating Measurement Uncertainty.

Current affected methods under the scope of accreditation:

IEC-61672 (SLM’s new standard)

IEC-60942 (Calibrators)

ISO-16063 (vibration transducers)

SBR-A&B (low frequency vibration meters)

IEC-61094-5 (microphones)

Current affected methods NOT under the scope of accreditation:

IEC-60651 (SLM’s old standard)

IEC-61260 (1/1-1/3 Oct. Filters new standard)

IEC-225 (1/1-1/3 Oct. Filters new standard)

| | | |
|---|---|---|
| Definitions | Uncertainty | The unknown difference between a measured result and the actual value. |
| | Calibration Uncertainty | The uncertainty associated with the calibration standard or master used while performing a calibration. Generally, this is the expanded uncertainty estimate at 95% confidence. Confidence may also be stated in terms of the coverage factor, k=2. |
| | Resolution | The finest increment of change that may be observed on an instruments scale. |
| | Repeatability | A statistical value (typically 1 standard deviation) calculated based on the results of repeated measurement. |
| | Combined Uncertainty | A calculated statistical value using the root sum squared method, RSS, that includes all identified sources of uncertainty |
| | Expanded Uncertainty | Calculated uncertainty at the prescribed confidence interval. This procedure assumes ~95% confidence and identifies the expanded uncertainty as $U_{95\%}$. |
| Responsibility | Quality Manager | Maintain this procedure and uncertainty estimates of affected test methods. |
| | Test Personnel | Report results in accord with this procedure. |

## 2. Procedure

2.1. Determine test method uncertainty base on QP-001: Estimating Measurement Uncertainty using the following assumptions:

2.1.1. Calibration uncertainty is the most conservative estimate of all devices that could be used to perform the test. The most conservative estimate is based on the device with the highest expanded uncertainty.

2.1.2. Resolution and thermal effects are neglected in determining test method uncertainty since they are already factored into the calibration uncertainty.

2.2. Compare the test or calibration result to the appropriate acceptance criteria.

2.3. Conformance may be determined when a measured value, bound by its uncertainty, does not encompass a specified limit. In this case, test results may be reported without uncertainty bounds.

2.4. Example of meeting requirements. In the examples the measured value [lbf] is used, however this value is not in de scope of the lab. The approach however is the same for the lab's measurement capability.

2.4.1. Uncertainty of the extendible element pull force test is ± 1.6-lbf.

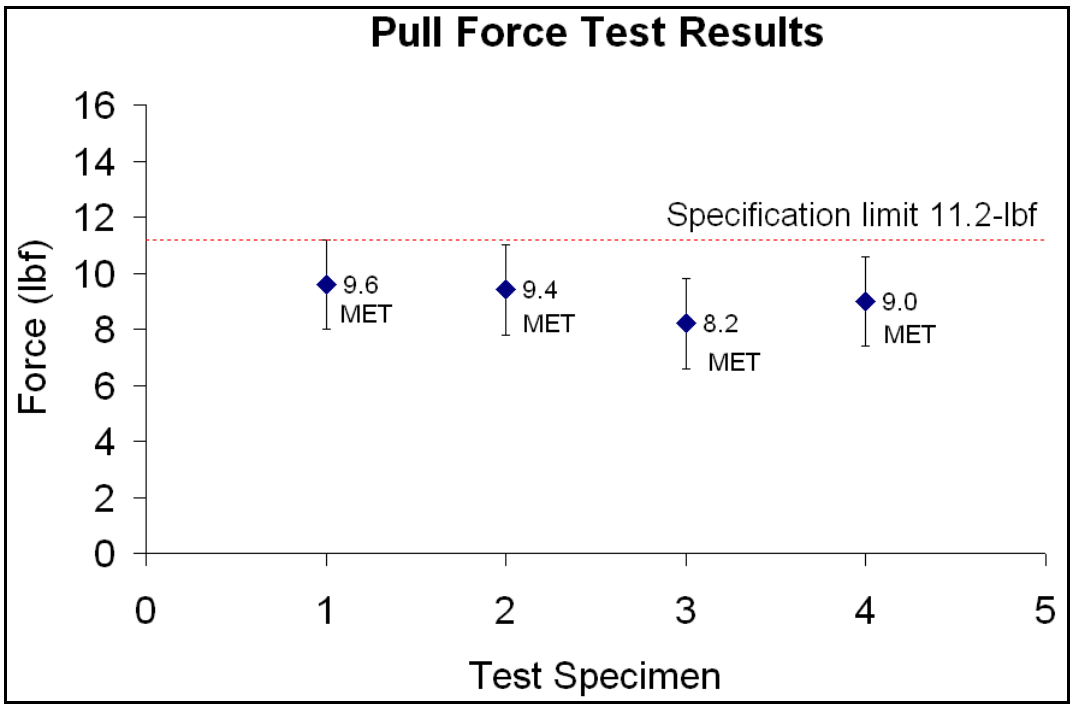
Pull force test data:

| Specimen | Result | Lower | Upper |
|---|---|---|---|
| 1. | 9.6 | 8 | 11.2 |
| 2. | 9.4 | 7.8 | 11 |
| 3. | 8.2 | 6.6 | 9.8 |
| 4. | 9.0 | 7.4 | 10.6 |

Acceptance Criteria:

*The extendible element pull force shall not exceed 11.2-lbf.*

Graphical representation:




2.4.2. In this example, all specimens clearly met the performance requirement.

2.5. Example of not meeting requirements:

Uncertainty of the extendible element pull force test is ± 1.6-lbf.

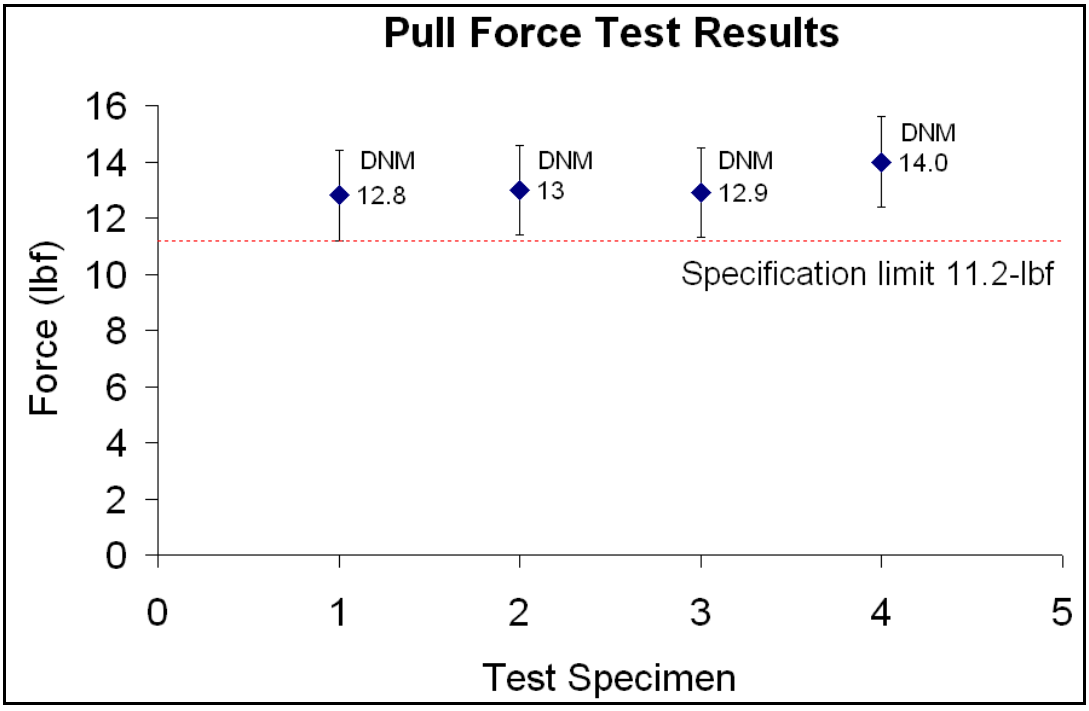
Pull force test data:

| Specimen | Result | Lower | Upper |
|---|---|---|---|
| 1. | 9.6 | 8 | 11.2 |
| 2. | 9.4 | 7.8 | 11 |
| 3. | 8.2 | 6.6 | 9.8 |
| 4. | 9.0 | 7.4 | 10.6 |

Acceptance Criteria:

*The extendible element pull force shall not exceed 11.2-lbf.*

Graphical representation:




2.5.1. In this example, all specimens clearly did not meet the performance requirement.

2.6. Conformance shall be determined according to the following decision rule when a measured value, bound by its uncertainty, encompasses a specified limit.

The measured value shall be compared to the acceptance criteria and reported as either MET[1] or DNM[1]. The following note must accompany the summary:

Note:

1. The uncertainty of the measured result encompasses the specification limit. See test results for more information.

2.6.1. Example where conformance cannot be determined:

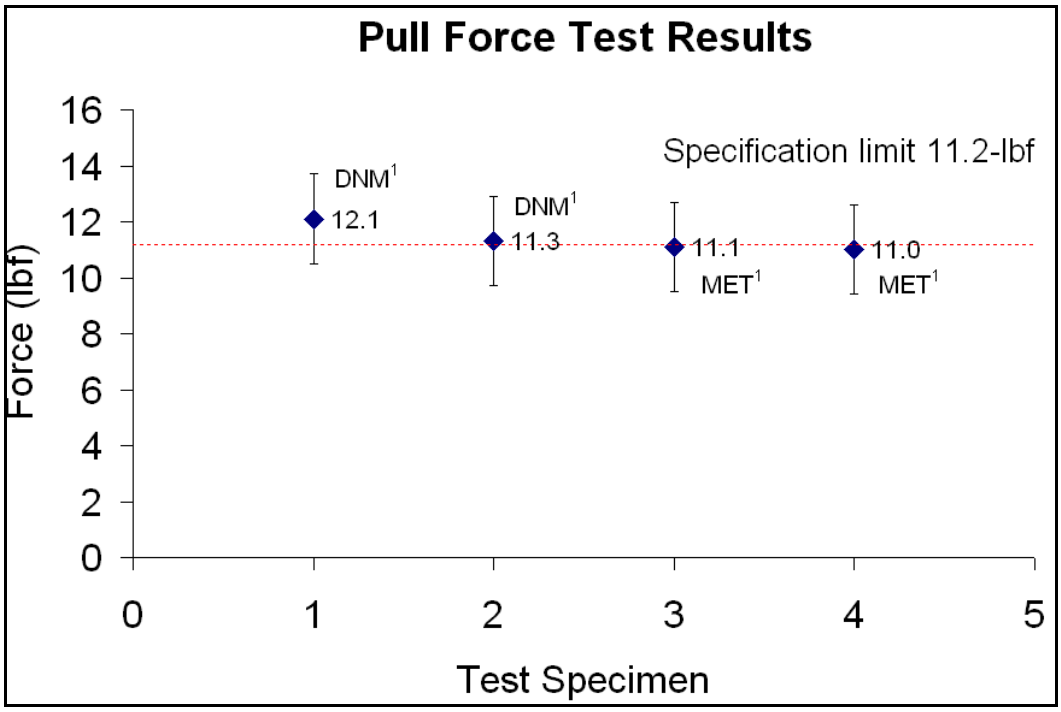
Uncertainty of the extendible element pull force test is ± 1.6-lbf.

Pull force test data:

| Specimen | Result | Lower | Upper |
|---|---|---|---|
| 1. | 12.1 | 10.5 | 13.7 |
| 2. | 11.3 | 9.7 | 12.9 |
| 3. | 11.1 | 9.5 | 12.7 |
| 4. | 11.0 | 12.6 | 9.4 |

Acceptance Criteria:

*The extendible element pull force shall not exceed 11.2-lbf.*




2.6.2. In this case, specimens 1 and 2 did not meet the requirement and specimens 2 and 3 met the requirement. However, all results, when bound by uncertainty, encompass the specified limit of 11.2-lbf. Therefore, there is uncertainty as to whether the specimens did or did not meet the requirements.

2.6.3. The test results shall be reported as follows:

| Specimen | Result | Uncertainty at 95% Confidence |
|---|---|---|
| 1. | 12.1 | ± 1.6-lbf |
| 2. | 11.3 | ± 1.6-lbf |
| 3. | 11.1 | ± 1.6-lbf |
| 4. | 11.0 | ± 1.6-lbf |

2.6.1. Alternatively, if there is only one specimen, the result shall be reported as follows:

"The extendible element pull force was 12.1± 1.6 lbf at 95% confidence

2.6.2. It is generally safe to assume a normal distribution from the viewpoint of providing a coverage interval at the 95% level of confidence when the model is linear in the input quantities and one of the following three possibilities applies:
1. There is a single, dominant contribution to the uncertainty, which arises from a normal distribution, and the corresponding degrees of freedom exceed 30.
2. The three largest uncertainty contributions are of comparable size.
3. The three largest contributions are of comparable size, and the effective degrees of freedom3 exceed 30.
Under these circumstances the following statement shall be made:

*The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k = 2, which for a normal distribution provides a level of confidence of approximately 95%.*

The t-distribution may be assumed if the conditions for normality (above) apply but the degrees of freedom is less than 30. Under these circumstances the following statement (in which the appropriate numerical values are substituted for XX and YY) can be made:

*The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k = XX, which for a t-distribution with veff = YY effective degrees of freedom provides a level of confidence of approximately 95%.*

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

**Purpose**

The purpose of this document is to provide a uniform approach for validating electronic calculations and to define responsibility.

**Scope**

This procedure defines the general operational procedures to be used when validating internally developed or modified software calculations. Commercial, off-the-shelf, software that includes calculations designed within the software range is considered to satisfy this procedure.

**Definitions**

| | |
|---|---|
| Commercial Software | Software that is purchased off-the-shelf. Preprogrammed functions are internal to the programming code and cannot be modified by the end user. Preprogrammed functions may include mean, median and standard deviation. Examples of canned software include: Microsoft Excel. |
| Custom Software | Software that is created in order to perform user defined functions, other than preprogrammed functions, that are reported as test results. The user defined functions may be modified either by the programmer or end user. Examples of custom software include: calculations in an Excel spreadsheet or calculations specific to Think and Do applications. |

**Responsibility**

| | |
|---|---|
| Quality Manager | Maintain a log of validated calculations. |
| Quality Manager | Validate calculations and document results. |
| Test Personnel | Promptly notify the quality manager of any results that do not make sense. |

## 2. Procedure

2.1. All electronic, user-defined functions shall be validated against hand calculations prior to releasing the software. If a discrepancy exists between the output of a programmed function and a hand calculation, the function shall be revised and revalidated until the output agrees with the hand calculation.

2.2. The programmer and/or technical manager is responsible for validating the custom software output against hand calculations.

2.3. The following is an example of an acceptable validation record.

| Date | Software | Function | Variable Description (Units) | Actual Data | Software Output | Hand Calculation |
|---|---|---|---|---|---|---|
| 7/11/01 | Modulus of Rupture of Particular Board - TM-2207.msm | $R = \frac{3PL}{2bd^2}$ | R = Modulus of Rupture<br>P = Max. Load (lbf)<br>L = Span (in)<br>b = Spec. Width (in)<br>d = Spec. Thick. (in) | P = 250 lbf<br>L = 27 in<br>b = 3.00 in<br>d = 1.13 in | R = 2643 psi | $R = \frac{3(250\,lbf)(27\,in)}{2(3.00\,in)(1.13\,in)^2}$<br>$R = 2643\ \frac{lb}{in^2}$ |

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this section is to define the records retention and handling procedures for various Test Lab documents. Some Test Lab records are considered "permanent" documents and must be handled accordingly. This procedure describes which records fall into this category, how they will be used, filed, and safeguarded. | |
| Scope | This procedure applies to all records identified in EIR-008 Control of Records Repository. | |
| Responsibility | Quality Manager | Maintain records and ensure that this procedure is followed. |
| | Test Personnel | Follow this procedure |

## 2. Procedure

2.1. Determine the appropriate storage location for the record based on EIR-013: Records and Documents List and Locations.

2.2. Use the appropriate procedures to identify records.

2.3. Records shall be retained and maintained for the period of time specified in EIR-013: Records and Documents List and Locations.

2.4. Periodically review records to determine if they may be purged. Only records that are expired (based on the appropriate retention time) may be purged.

2.5. Purged records shall be deleted, shredded or otherwise destroyed in order to ensure customer confidentiality.

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
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## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to define the proficiency test plan and procedures to find, initiate and participate in proficiency test programs. In general the lab shall follow the guidance from the European Accreditation as describe in the document EA-4/18 INF :2010 " Guidance on the level and frequency of proficiency testing participation". | |
| Scope | This procedure and plan only applies to quantitative tests included in the scope of accreditation. | |
| Definitions | Quantitative Test | A test that has a traceable, measureable result as defined by ISO 17025. |
| Responsibility | Quality Manager | Follow this procedure to ensure the ongoing requirements for proficiency testing are met. |
| | | Review this procedure and maintain it as new tests are added to the scope of accreditation. |
| | Test Personnel | Promptly notify the quality manager of any results that do not make sense. |

## 2. Procedure

2.1. Identify tests within the scope of accreditation that are quantitative tests.

2.2. Search for commercially available proficiency test programs for the tests that were identified. Record the search using FO-009: Proficiency Test Search Record.

2.3. Participate in and/or subscribe to the available services.

2.4. If no proficiency test programs are identified, the quality manager shall initiate an intra laboratory comparison to meet the proficiency test plan outlined in this procedure.

2.5. Promptly send the proficiency test results and any resulting corrective actions to the appropriate parties (typically includes accrediting bodies).

## 3. Proficiency Test Plan

3.1. The level of risk presented by the laboratory can considered as low in the sector in which the lab operates. This is determined by; ♣ Number of tests/calibrations/measurements undertaken (mediate number of calibrations( ♣ Turnover of technical staff (low) ♣ Experience and knowledge of technical staff (high) ♣ Source of Traceability (well defined and strict) ♣ Known stability/instability of the measurement technique (high stability) ♣ Significance and final use of testing/calibration data (fairly low sins equipment always has to be field calibrated/checked before use)

3.2. Different types of proficiency test's (PT) can be used by the lab: ♣ PT organized by other independent organizations such as accreditation bodies or organizations such as ILAC, EA, APLAC and IRMM ♣ ILC organized by a sufficient number of laboratories as a one off or continual exercise ♣ Submission of an internal sample or object to another or more external laboratories for the purposes of data comparison

3.3. The following is a plan lab to ensure proficiency test requirements are met for all of the appropriate methods under the scope of accreditation.

3.4. The following table outlines the plan that will be followed.

| Frequency | Test Method(s) | Description(s) | Proficiency Test Type |
|---|---|---|---|
| 1x year | Method 1 | Internal quality measure | Comparison techniques |
| 1x year | Method 2 | Internal quality measure | Comparison reference sensors |
| 1x year | Method 3 | Internal quality measure | Analyzing of blind sample in lab |
| 1x two year | Method 4 | External comparison | Submission to internal calibrated sensor/instrument to external lab |

3.5. The lab shall participate in PT's organized by other laboratory's when applicable.

## 4. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to define the process for communicating and handling complaints and concerns that originate within the laboratory. | |
| Scope | This procedure applies to all internal complaints of technical nature and/or related to the management system. | |
| Responsibility | Quality Manager | Follow and maintain this procedure and document internal complaints in accord with this procedure and ISO 17025. |
| | Test Personnel | Follow this procedure |

## 2. Procedure

2.1. Laboratory personnel report all complaints and/concerns to the Quality Manager.

2.2. The quality manager shall review the merits of the complaints and determine the appropriate course of action. Typically, the appropriate course of action will result in either a preventative action or a corrective action.

2.3. The whistleblower policy and protection procedures shall be followed when applicable.

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to protect customers' confidential and proprietary information during onsite visits by other customers. | |
| Scope | This procedure applies to all onsite visits. | |
| Responsibility | Quality Manager | Follow and maintain this procedure. |
| | Test Personnel | Follow this procedure. |

## 2. Procedure

2.1. All access points to the lab are appropriately secured to prevent unauthorized access.

2.2. Customer information and test materials shall be concealed, as appropriate, to prevent unauthorized viewing.

2.3. All visitors must enter through the designated access point front door of the office at address Benedenberg 100A, 2861LH Bergambacht and shall be accompanied by authorized laboratory personnel during the entire visit.

2.4. Taking photos in the laboratory is prohibited.

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to define the process for notifying personnel of changes to the management system. | |
| Scope | This procedure applies to all changes that occur to the management system. | |
| Responsibility | Quality Manager | Follow and maintain this procedure. |
| | Test Personnel | Follow this procedure. |

## 2. Procedure

2.1. The quality manager completes the change notification form FO-006 and distributes it to the laboratory personnel.

2.2. The laboratory personnel review the changes and initial FO-006 to signify that they are aware of the change.

2.3. The quality manager collects the completed copy of FO-006 and maintains it in the appropriate location (refer to EIR-013 Records and Documents List and Locations)

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to ensure technical service providers meet quality standards of this lab and the requirements of ISO 17025 and the appropriate accrediting body. | |
| Scope | This procedure applies to all technical services procured under the scope of the laboratory's accreditation. | |
| Definitions | Technical Service | Any service that may affect the quality of test results. Typical examples would include calibration services and consumable material quality certification. |
| Responsibility | Quality Manager | Maintain and follow this procedure to ensure the ongoing requirements are met. |
| | Test Personnel | Follow this procedure. |

## 2. Procedure

2.1. All technical service providers are listed in EIR-001: Register of Subcontractors.

2.2. The appropriate service provider shall be selected from EIR-001.

2.3. Review and approve purchasing documents prior to ordering service. Purchasing documents should include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required, and the management system under which they were made.

2.4. The required tolerances of the service shall be specified in writing. The appropriate tolerances shall be determined on an individual basis.

2.5. The appropriate forms shall be completed and maintained as records by the quality manager.

2.6. Once the service has been rendered, the appropriate certificates shall be reviewed and accepted by initialing and dating. If a device has been removed from the laboratory, the device shall be inspected.

2.7. At a minimum, the review shall consist of the following:

- Were all the required documents provided?
- Was an accrediting body's logo displayed on the certificate (if, applicable)?
- Was the uncertainty calculation provided (if, applicable)?
- Were the required tolerances met?
- Is there any visual damage or defects?

2.8. Upon acceptance, initial and date the appropriate certificates and/or documents.

2.9. Retain all records as appropriate.

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to provide a consistent approach for conducting internal audits and reviews. | |
| Scope | This procedure applies to all internal audits and reviews of the ISO 17025 management system as well as testing and/or calibration activities conducted within the scope of the laboratory's accreditation. | |
| Definitions | Audit | Impartial review and examination of the management system, quality records, and testing activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures. |
| Responsibility | Quality Manager | Maintain and follow this procedure to ensure the ongoing requirements are met. Schedule and facilitate the internal audit. |
| | Test Personnel | Follow this procedure and participate in the audits. |
| | Auditor | Complete an internal audit of the lab's ISO 17025 management system, testing activities, and calibration activities. Document and communicate all deficiencies and areas for improvement. |

## 2. Procedure

2.1. Prior to the audit, the Quality Manager shall:

2.1.1. Print the latest versions the Quality Manual, Quality Procedures, and work instructions and assembles them into a binder labeled "Management System Documents – UNCONTROLLED COPIES".

2.1.2. Print EIR-TBD: Quality System Documents + Records List

2.1.3. Print, review, and complete, the appropriate ISO 17025 management system checklist (Attachment 1 of QP-016) indicating the appropriate cross reference between the ISO 17025 requirement and management system document.

2.1.4. Print, review, and complete the internal audit checklists for testing and calibration activities (Attachment 1 of QP-016 ).

2.1.5. Provide the auditor with the uncontrolled copy of the management system documents and checklists.

2.2. Prior to the audit, the Auditor shall:

2.2.1. Determine the scope of the audit based on Quality Manual, Section 4.14.1 by use of QP-016.

2.2.2. Conduct a preliminary review of all documents and checklists

2.2.3. Prepare an audit plan/agenda

2.2.4. Send the plan/agenda to the Quality Manager

2.3. During the audit the auditor shall interview personnel to the extent that the auditing requirements are met.

2.4. Upon completion, the auditor and quality manager shall jointly review all findings, deficiencies, and areas for suggested improvement.

2.5. The auditor shall provide the Quality Manager with a signed and dated copy of the audit report with compliance score and priority score as describe in QP-016.

2.6. The auditor shall attach objective evidence of compliance to the audit report.

2.7. The Quality Manager shall promptly initiate the appropriate action based on the audit. Such actions include communicating results, containing nonconformance's, initiating preventative actions, and initiating corrective actions.

2.8. The audit report shall be maintained according to the records retention procedure.

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to provide a consistent approach for conducting periodic quality checks of calibrated devices. It also helps to ensure that a device is performing satisfactorily between scheduled calibrations. | |
| Scope | This procedure applies to all calibrated devices used within the laboratory. | |
| Definitions | Quality Check | Verification activity that ensures a calibrated device is within its acceptable limits of use. |
| Responsibility | Quality Manager | Maintain and follow this procedure to ensure the ongoing requirements are met. Periodically review quality check records. |
| | Test Personnel | Follow this procedure and perform quality checks as required. |

## 2. Procedure

2.1. Intervals and frequencies of quality checks are contained in EIR-014: Equipment and Tools List.

2.2. Develop and document an appropriate method for performing a quality check.

2.3. Develop a form to collect recorded data. At a minimum, the form should include:

- Identification of the quality check method
- Unambiguous description of the device (number + name)
- Date of the check
- Environmental conditions
- Units of measure
- Observer's initials
- The device's limits of acceptable use
- Some area to confirm that the device is still performing within the acceptable limits.

2.4. Conduct an appropriate analysis of the results to ensure all specifications are met and that the sampling interval and frequency is adequate.

2.5. Retain records of the checks, analysis, and results as required by QM-001, Section 4.13: Control of Records Policy and Procedure.

2.6. Any nonconforming results shall be promptly reported to the Quality Manager.

2.7. The Quality Manager shall take the appropriate action as outlined in QM-001, Section 4.9: Nonconforming Testing and/or Calibration Work Policy and Procedure

## 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | To establish a procedure for the control and disposition of nonconforming equipment, sensors, products and materials, to prevent unintentional use or shipment | |
| Scope | This procedure applies to all nonconforming equipment, transducers, sensors, products and materials detected within the lab, whether obtained from vendors, produced in-house, or in company stock. | |
| Definitions | Nonconforming | Does not to comply with the prevailing standards, attitudes, good practices |
| Responsibility | Quality Manager (QM) | Maintain this procedure and ensures that it is appropriately followed. |
| | Test Personnel | Follow this procedure. Request assistance if needed. |

## 2. Procedure

2.1. Nonconforming product detected at the lab

2.1.1. Nonconforming product can be detected in many ways, by any person, at any time.

2.1.2. When nonconforming material, equipment, sensor, transducer is detected, it is immediately removed from the normal process flow and one of the following people is notified: Quality Manager.

2.1.3. The product or material is removed from the normal process flow by being placed outside the lab's environment.

2.1.4. Nonconforming material, products etc. is identified with a HOLD tag, which is filled out and attached to the affected item(s). The HOLD tag contains part number, quantity, description, reason for being on hold, name of the person who detected the problem, and the date.

2.1.5. Disposition of nonconforming materials, products etc. can be determined by the Quality Manager. The Quality Manager will periodically (normally weekly) go thru all the items on with the hold-tag to take the appropriate action depending on the item; like dispose of the products, send back to venders, contact clients about the found nonconformity, send for repair or re-calibration.

2.2. Nonconforming detected after delivery or use.

2.2.1. Depending on the nature of the nonconformance, it may be necessary to generate a Corrective Action.

2.2.2. Corrective action is taken appropriate to the nonconformance. Appropriate action may be in the form of parts and/or information sent to customers, a recall of the product, or other action deemed necessary by management or QP to correct the nonconformance and prevent its recurrence.

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is the control of documents | |
| Scope | This procedure applies to all documents relating to the calibration process | |
| Definitions | Documents | All relevant documents relating to the calibration process en QMS |
| Responsibility | Quality Manager (QM) | Maintain this procedure and ensures that it is appropriately followed. |
| | Test Personnel | Follow this procedure. Request assistance if needed. |

## 2. Procedure

2.1. Relevant documents.

2.1.1. Document and data relating to the calibration process are stored on the lab's server stored electronically within the management system. This provides a set of category and sub-category headings that enable users to drill down into the different levels of the documentation category tree. QMS documents are created and maintained within a top level category folder entitled ISO-17025.

2.1.2. Only the digital document under folder are leading for the QMS and calibration process. The map on the server is only accessible for the lab's personal. It is not accessible for NON laboratory personal.

2.2. Protect the integrity of the electronically stored documents and data by performance of system backups.

2.2.1. The relevant documents under the folder entitled ISO-17025 are backuped every day for 7 days a week. On the eight day the backup disk (with encrypted data) is replaced by a second backup disk and taken outside the lab's building to the house of the quality manager.

2.3. Lab Computers.

2.3.1. The computer used in the laboratory is visually marked as "Laboratory computer. This computer shall not be taken outside the lab environment.

2.3.2. When repairs or updates on the laboratory computer is necessary calibration-data is deleted form the computer. Than the computer is taken out the laboratory by the QM for repair/maintenance outside the lab's environment.

2.4. Server

2.4.1. When repairs or updates on the laboratory server is necessary it is done by the company I-Tonline that's works for more than 20 years for AV-Consulting B.V. The responsible IT-engineer has to sign a nondisclosure form before working on the server.

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is the control of revisions documents required by the Quality Management System (QMS) | |
| Scope | The requirements of this procedure apply to all drawings, procedures, work instructions, forms, etc. used within the QMS that affect the quality of products or services. | |
| Definitions | Documents | All relevant documents relating to the QMS |
| Responsibility | Quality Manager (QM) | Maintain this procedure and ensures that it is appropriately followed. |
| | Test Personnel | Follow this procedure. Request assistance if needed. |

## 2. Procedure

2.1. Relevant documents

2.1.1. QMS documents are stored electronically on the lab's server under the management system, the following requirements will be met for QMS document control:

- all documents shall be approved for adequacy prior to use;
- review and update as necessary and re-approve documents;
- ensure that changes and current revision status of documents are identified;
- ensure that relevant versions of applicable quality documents are available at points of use;
- for the correct subsequent document numbering and prefix document EIR-013 Records and Documents List should be used;
- prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

2.1.2. The standard format for QMS procedures shall include, as appropriate:

- Header on each page containing: document name, document number, revision level,
- latest revision date, latest printed date, page number
- scope and objectives
- applicability
- related documents
- procedure
- responsibilities
- document revision history
- approval and date

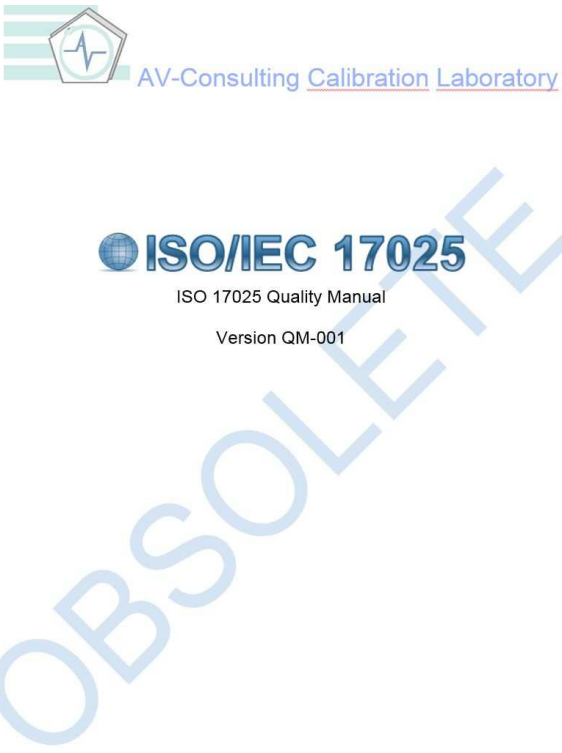
2.2. Control of External Documents

2.2.1. Documents of external origin such as quality standards, industry standards, customer specifications, customer marks, etc. may be used as part of the product realization process.

External documents are stored electronically on the server within the management system in a clearly designated folder; verified as current and when necessary have their distribution controlled. It is the responsibility of the QM to review, implement, and maintain these documents and verify that they remain current at appropriate frequencies.

2.3. Obsolete Documents

2.3.1. Document can be marked as obsolete. An obsolete document is subsequently displayed with a watermark across all pages of the applicable document. This display gives a visual indication to all users that the document is obsolete and should not be used. The watermark shall look like the picture below




2.3.2. Obsolete Documents are stored electronically electronically on the server within the management system in folder EIR-020 Obsolete Documents; verified as obsolete documents. The file name shall contain the original file name preceded with OBSOLETE and the data of obsoleting. For example, document “QM-001 ISO 17025 Quality Manual.doc” shall be saved as “OBSOLUTE Month-day-year QM-001 ISO 17025 Quality Manual.doc”.

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this work instruction is to insure calibration certificate is in accordance with ISO/IEC 17025: 2005 | |
| Scope | This work instruction applies to process of issuing test reports | |
| Definitions | Calibration Certificate | Certificate that is issued by an accredited calibration laboratory that contains results from activities that have been carried out within the laboratory's official Scope of Accreditation |
| | Traceability | Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. |
| Responsibility | Quality Manager | Maintain this work instruction and ensures that it is appropriately followed. |
| | Test Personnel | Follow this work instruction. Request assistance if needed. |

2. ISO/IEC 17025 section 5.10.4.1.b allows for three options when reporting results:
   2.1. Reporting the measurement uncertainty;
   2.2. Reporting a statement of compliance with an identified metrological specification; or,
   2.3. Reporting both measurement uncertainty and a statement of compliance.
3. If the measurement uncertainty of the calibration is not included in the report the certificate would not be suitable in ensuring that metrological traceability is established and would not meet the international "Policy on Traceability".
4. In accordance with ISO/IEC 17025:2005, section 5.10, in general, the accredited calibration certificate should include the following:
   - A title (e.g. "Calibration Certificate");
   - The name and address of the laboratory and the location where the calibrations were carried out, if different from
   - the address of the laboratory;
   - Unique identification of the calibration certificate (such as the serial number);
   - Inclusion on each page an identification in order to ensure that the page is recognized as a part of the calibration
   - certificate (i.e. page 1 of 3), and a clear identification of the end of the calibration certificate;
   - The name and address of the customer;
   - Identification of the method used;
   - A description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;
   - The date of receipt of the calibration item (where this is critical to the validity and application of the results) and
   - the date of performance of the calibration;
   - Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to
   - the validity or application of the results;
   - The calibration results with, where appropriate, the units of measurement;

- The name, function and signature or equivalent identification of those authorizing the calibration certificate;
- A statement to the effect that the results relate only to the items calibrated;
- The conditions (e.g. environmental) under which the calibrations were made that have an influence on the
- measurement results;
- Evidence that the measurements are traceable;
- In cases of adjustment or repair of an instrument, the before and after results adjustment, if available, are to be reported;
- The uncertainty of measurement (and/or statement of compliance with a specification)

## 5. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 17.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to provide a consistent approach for conducting internal audits and reviews by use of a Standard Audit Checklist. | |
| Scope | This procedure applies to all internal audits and reviews of the ISO 17025 management system as well as testing and/or calibration activities conducted within the scope of the laboratory's accreditation. | |
| Definitions | Audit | Impartial review and examination of the management system, quality records, and testing activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures. |
| Responsibility | Quality Manager | Maintain and follow this procedure to ensure the ongoing requirements are met. Schedule and facilitate the internal audit. |
| | Test Personnel | Follow this procedure and participate in the audits. |
| | Auditor | Complete an internal audit of the lab's ISO 17025 management system, testing activities, and calibration activities. Document and communicate all deficiencies and areas for improvement. |

## 2. Procedure

2.1. Prior to the audit, the Quality Manager shall:

2.1.1. Print, review, and complete, this system checklist (attachment 1).

2.1.2. Provide the auditor with the uncontrolled copy of the management system documents and this checklists.

2.1.3. Determine the scope of the audit based on the Quality Manual, Section 4.14.1 using this checklist.

2.1.4. Mark criteria for the Assessment; **ORANGE** highlighted fields represent criteria used during the **Assessment.**

2.1.5. During the assessment auditor shall fill in the column under compliance using the following keys: **OK** = Meets criteria**, C** = Comment**, X** = Nonconformity with priority score: **High** = 1, **Intermediate** = 2, **Low** = 3.

2.2. Upon completion, the auditor and quality manager shall jointly review all findings, deficiencies, and areas for suggested improvement.

2.2.1. Fill in the appropriate list plans for: **Corrective Actions (CA)**:**Preventive Actions (PA)** and **Improvement Actions (IA)**.

2.2.2. Attach objective evidence of compliance to the filled in checklist.

**3. Change Control Section**

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

# Attachments

1. **Internal Audit Checklist**
2. **Objective Evidence Attachment**

1

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| **4** | **MANAGEMENT REQUIREMENTS FOR ACCREDITATION** | | | | | |
| **4.1** | **Organization** | | | | | |
| 4.1.1 | The laboratory or the organization of which it is part shall be an entity that can be held legally responsible. | | | | | |
| 4.1.2 | It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition. | | | | | |
| 4.1.3 | The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities. | | | | | |
| 4.1.4 | If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest. | | | | | |
| NOTE 1 | Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| NOTE 2 | If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities. | | | | | |
| 4.1.5 | The laboratory shall: | | | | | |
| a) | have managerial and technical personnel who, irrespective of other responsibilities have the authority and resources needed to carry out their duties including the implementation, maintenance and improvement of the management system and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2); | | | | | |
| b) | have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work; | | | | | |
| c) | have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results; | | | | | |
| d) | have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity; | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| e) | define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services; | | | | | |
| f) | specify the responsibility, authority and interrelationships of all personnel who manage, perform and verify work affecting the quality of the tests and/or calibrations; | | | | | |
| g) | provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results; | | | | | |
| h) | have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations; | | | | | |
| i) | appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources; | | | | | |
| j) | appoint deputies for key managerial personnel. (see Note). | | | | | |
| k) | ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| NOTE | Individuals may have more than one function and it may be impractical to appoint deputies for every function. | | | | | |
| 4.1.6 | Top management shall ensure that the appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system. | | | | | |
| **4.2** | **Management system** | | | | | |
| 4.2.1 | The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel. | | | | | |
| 4.2.2 | The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following: | | | | | |
| a) | the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers; | | | | | |
| b) | the management's statement of the laboratory's standard of service; | | | | | |
| c) | the purpose of the management system related to quality; | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| d) | a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and | | | | | |
| e) | the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system. | | | | | |
| NOTE | The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents. | | | | | |
| 4.2.3 | Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness. | | | | | |
| 4.2.4 | Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements. | | | | | |
| 4.2.5 | | | | | | |
| a) | The quality manual shall include or make reference to the supporting procedures including technical procedures. | | | | | |
| b) | It shall outline the structure of the documentation used in the management system. | | | | | |
| 4.2.6 | The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| 4.2.7 | Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented. | | | | | |
| **4.3** | **Document Control** | | | | | |
| 4.3.1 | General | | | | | |
| | The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. | | | | | |
| NOTE 1 | In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written. | | | | | |
| NOTE 2 | The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13. | | | | | |
| 4.3.2 | Document Approval and Issue | | | | | |
| 4.3.2.1 | | | | | | |
| a) | All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| b) | A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents. | | | | | |
| 4.3.2.2 | The procedure(s) adopted shall ensure that: | | | | | |
| a) | authorized editions of the appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed; | | | | | |
| b) | documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements; | | | | | |
| c) | invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; | | | | | |
| d) | obsolete documents retained for either legal or knowledge preservation purposes are suitably marked. | | | | | |
| 4.3.2.3 | Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include. | | | | | |
| a) | the date of issue and/or revision identification, | | | | | |
| b) | page numbering, | | | | | |
| c) | the total number of pages or a mark to signify the end of the document, | | | | | |
| d) | and the issuing authority(ies). | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| 4.3.3 | Document changes | | | | | |
| 4.3.3.1 | Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval. | | | | | |
| 4.3.3.2 | Where practicable, the altered or new text shall be identified in the document or the appropriate attachments. | | | | | |
| 4.3.3.3 | | | | | | |
| a) | If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. | | | | | |
| b) | Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable. | | | | | |
| 4.3.3.4 | Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled. | | | | | |
| **4.4** | **Review of requests, tenders, and contracts** | | | | | |
| 4.4.1 | The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that: | | | | | |
| a) | the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2); | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| b) | the laboratory has the capability and resources to meet the requirements; | | | | | |
| c) | the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements; (see 5.4.2). | | | | | |
| d) | Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer. | | | | | |
| NOTE 1 | The request, tender and contract review shall be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way. | | | | | |
| NOTE 2 | The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using certified reference materials in order to determine uncertainties of measurement, limits of detection, confidence limits, etc. | | | | | |
| NOTE 3 | A contract may be any written or oral agreement to provide a customer with testing and/or calibration services. | | | | | |
| 4.4.2 | Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| NOTE | For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained. | | | | | |
| 4.4.3 | The review shall also cover any work that is subcontracted by the laboratory. | | | | | |
| 4.4.4 | The customer shall be informed of any deviation from the contract. | | | | | |
| 4.4.5 | If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel. | | | | | |
| **4.5** | **Subcontracting of tests and calibrations** | | | | | |
| 4.5.1 | When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question. | | | | | |
| 4.5.2 | The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| 4.5.3 | The laboratory is responsible to the client for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used. | | | | | |
| 4.5.4 | The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question. | | | | | |
| **4.6** | **Purchasing services and supplies** | | | | | |
| 4.6.1 | The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations. | | | | | |
| 4.6.2 | The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained. | | | | | |
| 4.6.3 | Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release. | | | | | |
| NOTE | The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| 4.6.4 | The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved. | | | | | |
| **4.7** | **Service to the customer** | | | | | |
| 4.7.1 | The laboratory shall be willing to cooperate with customers or their representatives cooperation to clarify the customer's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to their customers. | | | | | |
| NOTE 1 | Such cooperation may include: | | | | | |
| a) | providing the customers of the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer; | | | | | |
| b) | preparation, packaging, and dispatch of test and/or calibration items needed by the customers for verification purposes. | | | | | |
| NOTE 2 | Customer's value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations. | | | | | |
| 4.7.2 | The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| NOTE | Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers. | | | | | |
| **4.8** | **Complaints** | | | | | |
| | The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11). | | | | | |
| **4.9** | **Control of nonconforming testing and/or calibration work** | | | | | |
| 4.9.1 | The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that: | | | | | |
| a) | the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified; | | | | | |
| b) | an evaluation of the significance of the nonconforming work is made; | | | | | |
| c) | correction is taken immediately, together with any decision about the acceptability of the nonconforming work; | | | | | |
| d) | where necessary, the customer is notified and work is recalled; | | | | | |
| e) | the responsibility for authorizing the resumption of work is defined. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| NOTE | Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits. | | | | | |
| 4.9.2 | Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed. | | | | | |
| **4.10** | **Improvement** | | | | | |
| | The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. | | | | | |
| **4.11** | **Corrective action** | | | | | |
| 4.11.1 | General | | | | | |
| | The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| NOTE | A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations. | | | | | |
| 4.11.2 | Cause analysis | | | | | |
| | The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem. | | | | | |
| NOTE | Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration. | | | | | |
| 4.11.3 | Selection and implementation of corrective actions | | | | | |
| a) | Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. | | | | | |
| b) | Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. | | | | | |
| c) | The laboratory shall document and implement any required changes resulting from corrective action investigations. | | | | | |
| 4.11.4 | Monitoring of corrective actions | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| | The laboratory shall monitor the results to ensure that the corrective actions taken have been effective. | | | | | |
| 4.11.5 | Additional audits | | | | | |
| | Where the identification of nonconformance's or departures casts doubts on the laboratory's compliance with its own policies and the procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible. | | | | | |
| NOTE | Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified. | | | | | |
| **4.12** | **Preventive action** | | | | | |
| 4.12.1 | | | | | | |
| a) | Needed improvements and potential sources of nonconformities, either technical or concerning the management system shall be identified. | | | | | |
| b) | When improvement opportunities are identified or if preventive action is required, action plans shall be developed implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement. | | | | | |
| 4.12.2 | Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective. | | | | | |
| NOTE 1 | Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| NOTE 2 | Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency testing results. | | | | | |
| **4.13** | **Control of records** | | | | | |
| 4.13.1 | General | | | | | |
| 4.13.1.1 | The Laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions. | | | | | |
| 4.13.1.2 | | | | | | |
| a) | All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. | | | | | |
| b) | Retention times of records shall be established. | | | | | |
| NOTE | Records may be in any media, such as hard copy or electronic media. | | | | | |
| 4.13.1.3 | All records shall be held secure and in confidence. | | | | | |
| 4.13.1.4 | The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| 4.13.2 | Technical Records | | | | | |
| 4.13.2.1 | | | | | | |
| a) | The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. | | | | | |
| b) | The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. | | | | | |
| c) | The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results. | | | | | |
| NOTE 1 | In certain fields it may be impossible or impracticable to retain records of all original observations. | | | | | |
| NOTE 2 | Technical records are accumulations of data (see 5.4.7) and information, which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback. | | | | | |
| 4.13.2.2 | Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task. | | | | | |
| 4.13.2.3 | | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| a) | When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. | | | | | |
| b) | In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data. | | | | | |
| **4.14** | **Internal audits** | | | | | |
| 4.14.1 | | | | | | |
| a) | The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. | | | | | |
| b) | Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. | | | | | |
| NOTE | The cycle for internal auditing shall normally be completed in one year. | | | | | |
| 4.14.2 | When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| 4.14.3 | The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. | | | | | |
| 4.14.4 | Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken. | | | | | |
| **4.15** | **Management reviews** | | | | | |
| 4.15.1 | In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of: | | | | | |
| a) | the suitability of policies and procedures; | | | | | |
| b) | reports from managerial and supervisory personnel; | | | | | |
| c) | the outcome of recent internal audits; | | | | | |
| d) | corrective and preventive actions; | | | | | |
| e) | assessments by external bodies; | | | | | |
| f) | the results of interlaboratory comparisons or proficiency tests; | | | | | |
| g) | changes in the volume and type of the work; | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| h) | customer feedback; | | | | | |
| i) | complaints; | | | | | |
| j) | recommendations for improvement; | | | | | |
| k) | other relevant factors, such as quality control activities, resources and staff training. | | | | | |
| NOTE 1 | A typical period for conducting a management review is once every 12 months. | | | | | |
| NOTE 2 | Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year. | | | | | |
| NOTE 3 | A management review includes consideration of related subjects at regular management meetings. | | | | | |
| 4.15.2 | | | | | | |
| a) | Findings from management reviews and the actions that arise from them shall be recorded. | | | | | |
| b) | The management shall ensure that those actions are carried out within an appropriate and agreed timescale. | | | | | |
| **5** | **TECHNICAL REQUIREMENTS FOR ACCREDITATION** | | | | | |
| **5.1** | **General** | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| 5.1.1 | Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from: | | | | | |
| i) | human factors (5.2) | | | | | |
| ii) | accommodation and environmental conditions (5.3) | | | | | |
| iii) | test and calibration methods and method validation (5.4) | | | | | |
| iv) | equipment (5.5) | | | | | |
| v) | measurement traceability (5.6 and Annex B) | | | | | |
| vi) | sampling (5.7) | | | | | |
| vii) | the handling of test and calibration items (5.8). | | | | | |
| 5.1.2 | The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses. | | | | | |
| **5.2** | **Personnel** | | | | | |
| 5.2.1 | | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| a) | The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. | | | | | |
| b) | When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. | | | | | |
| NOTE 1 | In some technical areas (e.g., non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might by regulatory, included in the standards for specific technical field, or required by the customer. | | | | | |
| NOTE 2 | The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: | | | | | |
| i) | relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service; | | | | | |
| ii) | knowledge of the general requirements expressed in the legislation and standards; and | | | | | |
| iii) | an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned. | | | | | |
| 5.2.2 | | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| a) | The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. | | | | | |
| b) | The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. | | | | | |
| c) | The training program shall be relevant to the present and anticipated tasks of the laboratory. | | | | | |
| d) | The effectiveness of the training actions taken shall be evaluated. | | | | | |
| 5.2.3 | | | | | | |
| a) | The laboratory shall use personnel who are employed by, or under contract to, the laboratory. | | | | | |
| b) | Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system. | | | | | |
| 5.2.4 | The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations. | | | | | |
| NOTE | Job descriptions can be defined in may ways. As a minimum, the following should be defined: | | | | | |
| i) | the responsibilities with respect to performing tests and/or calibrations; | | | | | |
| ii) | the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results; | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| iii) | the responsibilities for reporting opinions and interpretations; | | | | | |
| iv) | the responsibilities with respect to method modification and development and validation of new methods; | | | | | |
| v) | expertise and experience required; | | | | | |
| vi) | qualifications and training programs; | | | | | |
| vii) | managerial duties. | | | | | |
| 5.2.5 | The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed. | | | | | |
| **5.3** | **Accommodation and environmental conditions** | | | | | |
| 5.3.1 | | | | | | |
| a) | Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| | The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and test and/or calibrations are undertaken at sites other than a permanent laboratory facility. | | | | | |
| b) | The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented. | | | | | |
| 5.3.2 | | | | | | |
| a) | The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where thy influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. | | | | | |
| b) | Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations. | | | | | |
| 5.3.3 | There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination. | | | | | |
| 5.3.4 | Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances. | | | | | |
| 5.3.5 | Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary. | | | | | |
| **5.4** | **Test and calibration methods and method validation** | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| 5.4.1 | General | | | | | |
| a) | The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data. | | | | | |
| b) | The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. | | | | | |
| c) | All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). | | | | | |
| d) | Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. | | | | | |
| NOTE | International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details. | | | | | |
| 5.4.2 | Selection of methods | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| a) | The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional, or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. | | | | | |
| b) | When necessary, the standard shall be supplemented with additional details to ensure consistent application. | | | | | |
| c) | When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. | | | | | |
| d) | The customer shall be informed as to the method chosen. | | | | | |
| e) | The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated. | | | | | |
| f) | The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date. | | | | | |
| 5.4.3 | Laboratory developed methods | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| a) | The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. | | | | | |
| b) | Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured. | | | | | |
| 5.4.4 | Non-standard methods | | | | | |
| a) | When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. | | | | | |
| b) | The method developed shall have been validated appropriately before use. | | | | | |
| NOTE | For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information: | | | | | |
| a) | appropriate identification; | | | | | |
| b) | scope; | | | | | |
| c) | description of the type of item to be tested or calibrated; | | | | | |
| d) | parameters or quantities and ranges to be determined; | | | | | |
| e) | apparatus and equipment, including technical performance requirements; | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| f) | reference standards and reference materials required; | | | | | |
| g) | environmental conditions required and any stabilization period needed; | | | | | |
| h) | description of the procedure, including: | | | | | |
| • | affixing of identification marks, handling, transporting, storing and preparation of items, | | | | | |
| • | checks to be made before the work is started, | | | | | |
| • | checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use, | | | | | |
| • | the method of recording the observations and results, | | | | | |
| • | any safety measures to be observed; | | | | | |
| i) | criteria and/or requirements for approval/rejection; | | | | | |
| j) | data to be recorded and method of analysis and presentation; | | | | | |
| k) | the uncertainty or the procedure for estimating uncertainty. | | | | | |
| 5.4.5 | Validation of methods | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
|---|---|---|---|---|---|---|
| | | OK/ C/X | Action | Priority | | |
| 5.4.5.1 | Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. | | | | | |
| 5.4.5.2 | | | | | | |
| a) | The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. | | | | | |
| b) | The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. | | | | | |
| NOTE 1 | Validation may include procedures for sampling, handling and transportation. | | | | | |
| NOTE 2 | The techniques used for the determination of the performance of a method should be one of, or a combination of the following: | | | | | |
| i) | calibration using reference standards or reference materials; | | | | | |
| ii) | comparison of results achieved with other methods; | | | | | |
| iii) | interlaboratory comparisons; | | | | | |
| iv) | systematic assessment of the factors influencing the results; | | | | | |
| v) | assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| NOTE 3 | When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out. | | | | | |
| 5.4.5.3 | The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs. | | | | | |
| NOTE 1 | Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity. | | | | | |
| NOTE 2 | As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized. | | | | | |
| NOTE 3 | Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information. | | | | | |
| 5.4.6 | Estimation of uncertainty of measurement | | | | | |
| 5.4.6.1 | A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| 5.4.6.2 | Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data. | | | | | |
| NOTE 1 | The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: | | | | | |
| • | the requirements of the test method; | | | | | |
| • | the requirements of the customer; | | | | | |
| • | the existence of narrow limits on which decisions on conformance to a specification are based. | | | | | |
| NOTE 2 | In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10). | | | | | |
| 5.4.6.3 | When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| NOTE 1 | Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator. | | | | | |
| NOTE 2 | The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty. | | | | | |
| NOTE 3 | For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement. | | | | | |
| 5.4.7 | Control of Data | | | | | |
| 5.4.7.1 | Calculations and data transfers shall be subject to appropriate checks in a systematic manner. | | | | | |
| 5.4.7.2 | When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that: | | | | | |
| a) | computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use; | | | | | |
| b) | procedures are established and implemented for protecting data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing; | | | | | |
| c) | computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| NOTE | Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2.a. | | | | | |
| **5.5** | **Equipment** | | | | | |
| 5.5.1 | | | | | | |
| a) | The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). | | | | | |
| b) | In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met. | | | | | |
| 5.5.2 | | | | | | |
| a) | Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. | | | | | |
| b) | Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| c) | Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6). | | | | | |
| 5.5.3 | Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel. | | | | | |
| 5.5.4 | Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified. | | | | | |
| 5.5.5 | Records shall be maintained for each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following: | | | | | |
| a) | the identity of the item of equipment and its software; | | | | | |
| b) | the manufacturer’s name, type identification, and serial number or other unique identification; | | | | | |
| c) | check that equipment complies with the specification (see 5.5.2); | | | | | |
| d) | the current location, where appropriate; | | | | | |
| e) | the manufacturer's instructions, if available, or reference to their location; | | | | | |
| f) | dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| g) | the maintenance plan, where appropriate, and maintenance carried out to date; | | | | | |
| h) | any damage, malfunction, modification or repair to the equipment. | | | | | |
| 5.5.6 | The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. | | | | | |
| NOTE | Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling. | | | | | |
| 5.5.7 | | | | | | |
| a) | Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. | | | | | |
| b) | The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9). | | | | | |
| 5.5.8 | Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date of expiration criteria when recalibration is due. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| 5.5.9 | When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service. | | | | | |
| 5.5.10 | When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure. | | | | | |
| 5.5.11 | Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated. | | | | | |
| 5.5.12 | Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results. | | | | | |
| **5.6** | **Measurement traceability** | | | | | |
| 5.6.1 | General | | | | | |
| a) | All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. | | | | | |
| b) | The laboratory shall have an established program and procedure for the calibration of its equipment. | | | | | |
| NOTE | Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| 5.6.2 | Specific Requirements | | | | | |
| 5.6.2.1 | Calibration | | | | | |
| 5.6.2.1.1 | | | | | | |
| a) | For calibration laboratories, the program for calibration of equipment shall be designated and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI). | | | | | |
| | A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. | | | | | |
| b) | When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. | | | | | |
| c) | The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2). | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| | | OK/ C/X | Action | Priority | | |
| NOTE 1 | Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability to the calibration data reported. | | | | | |
| NOTE 2 | Traceability of SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weight and Measures (CGPM) and the International Committee for Weights and Measures (CIPM). | | | | | |
| NOTE 3 | Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute. | | | | | |
| NOTE 4 | The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification. | | | | | |
| NOTE 5 | When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units. | | | | | |
| NOTE 6 | Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located. | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| NOTE 7 | If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participated in the activities of BIPM either directly or through regional groups. | | | | | |
| NOTE 8 | The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability. | | | | | |
| 5.6.2.1.2 | There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as: | | | | | |
| a) | the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; | | | | | |
| b) | the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. | | | | | |
| c) | Participation in a suitable program of interlaboratory comparisons is required where possible. | | | | | |
| 5.6.2.2 | Testing | | | | | |
| 5.6.2.2.1 | For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed. | | | | | |

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| | | OK/ C/X | Action | Priority | | |
| NOTE | The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed. | | | | | |
| 5.6.2.2.2 | Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards are required as for calibration laboratories (see 5.6.2.1.2) | | | | | |
| 5.6.3 | Reference standards and reference materials. | | | | | |
| 5.6.3.1 | Reference standards | | | | | |
| a) | The laboratory shall have a program and procedure for the calibration of its reference standards. | | | | | |
| b) | Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. | | | | | |
| c) | Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment. | | | | | |
| 5.6.3.2 | Reference materials | | | | | |
| | Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable. | | | | | |

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| 5.6.3.3 | Intermediate checks | | | | | |
| | Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules. | | | | | |
| 5.6.3.4 | Transport and storage | | | | | |
| | The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity. | | | | | |
| NOTE | Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling. | | | | | |
| **5.7** | **Sampling** | | | | | |
| 5.7.1 | | | | | | |
| a) | The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. | | | | | |
| b) | The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results. | | | | | |

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| NOTE 1 | Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability. | | | | | |
| NOTE 2 | Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information. | | | | | |
| 5.7.2 | Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel. | | | | | |
| 5.7.3 | The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon. | | | | | |
| **5.8** | **Handling of test and calibration items** | | | | | |
| 5.8.1 | The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. | | | | | |

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| 5.8.2 | The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory. | | | | | |
| 5.8.3 | Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion. | | | | | |
| 5.8.4 | The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned. | | | | | |

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| NOTE 1 | Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting process. | | | | | |
| NOTE 2 | A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples. | | | | | |
| NOTE 3 | Reasons for keeping a test or calibration item secure can be the reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later. | | | | | |
| **5.9** | **Assuring the quality of test and calibration results** | | | | | |
| 5.9.1 | The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to the following: | | | | | |
| a) | regular use of certified reference materials and/or internal quality control using secondary reference materials; | | | | | |
| b) | participation in interlaboratory comparison or proficiency-testing programs; | | | | | |
| c) | replicate tests or calibrations using the same or different methods; | | | | | |
| d) | retesting or recalibration of retained items; | | | | | |
| e) | correlation of results for different characteristics of an item. | | | | | |

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| NOTE | The selected methods should be appropriate for the type and volume of work undertaken. | | | | | |
| 5.9.2 | Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. | | | | | |
| **5.10** | **Reporting the results** | | | | | |
| 5.10.1 | General | | | | | |
| 5.10.1.1 | The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods. | | | | | |
| 5.10.1.2 | The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4. | | | | | |
| 5.10.1.3 | In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations. | | | | | |
| NOTE 1 | Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively. | | | | | |

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| NOTE 2 | The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met. | | | | | |
| 5.10.2 | Test reports and calibration certificates | | | | | |
| | Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so: | | | | | |
| a) | A title (e.g., "Test Report" or “Calibration Certificate"); | | | | | |
| b) | the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory; | | | | | |
| c) | unique identification of the test report or calibration certificate (such as the serial number), and on each page the identification in order to ensure that the page is recognized as part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate; | | | | | |
| d) | the name and address of the customer; | | | | | |
| e) | identification of the method used; | | | | | |
| f) | a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated; | | | | | |
| g) | the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration; | | | | | |
| h) | reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results; | | | | | |

| No. | Requirement | Compliance | | | Reference | Objective Evidence |
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| i) | the test or calibration results with, where appropriate, the units of measurement; | | | | | |
| j) | the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate; | | | | | |
| k) | where relevant, a statement to the effect that the results relate only to the items tested or calibrated. | | | | | |
| NOTE 1 | Hard copies of test reports and calibration certificates should also include the page number and total number of pages. | | | | | |
| NOTE 2 | It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory. | | | | | |
| 5.10.3 | Test reports | | | | | |
| 5.10.3.1 | In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following: | | | | | |
| a) | deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions; | | | | | |
| b) | where relevant, a statement of compliance/non-compliance with requirements and/or specifications; | | | | | |
| c) | where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instructions so requires, or when the uncertainty affects compliance to a specification limit; | | | | | |
| d) | where appropriate and needed, opinions and interpretations (see 5.10.5); | | | | | |

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| e) | additional information which may be required by specific methods, customers or groups of customers. | | | | | |
| 5.10.3.2 | In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results: | | | | | |
| a) | the date of sampling; | | | | | |
| b) | unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); | | | | | |
| c) | the location of sampling, including any diagrams, sketches or photographs; | | | | | |
| d) | a reference to the sampling plan and procedures used; | | | | | |
| e) | details of any environmental conditions during sampling that may affect the interpretation of the test results; | | | | | |
| f) | any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned. | | | | | |
| 5.10.4 | Calibration certificates | | | | | |
| | In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results: | | | | | |
| a) | the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results; | | | | | |
| b) | the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof; | | | | | |

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| c) | evidence that the measurements are traceable (see note 2 in 5.6.2.1.1). | | | | | |
| 5.10.4.2 | The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met. | | | | | |
| | When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference. | | | | | |
| | When statements of compliance are made, the uncertainty of measurement shall be taken into account. | | | | | |
| 5.10.4.3 | When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported. | | | | | |
| 5.10.4.4 | A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations. | | | | | |
| 5.10.5 | Opinions and interpretations | | | | | |
| | When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report. | | | | | |
| NOTE 1 | Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65. | | | | | |
| NOTE 2 | Opinions and interpretations included in a test report may comprise, but not be limited to the following: | | | | | |

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| a) | an opinion on the statement of compliance/noncompliance of the results with requirements; | | | | | |
| b) | fulfillment of contractual requirements; | | | | | |
| c) | recommendations on how to use the results; | | | | | |
| d) | guidance to be used for improvements. | | | | | |
| NOTE 3 | In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down. | | | | | |
| 5.10.6 | Testing and calibration results obtained from subcontractors | | | | | |
| | When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically. | | | | | |
| | When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory. | | | | | |
| 5.10.7 | Electronic transmission of results | | | | | |
| | In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7). | | | | | |
| 5.10.8 | Format of reports and certificates | | | | | |

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| | The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse. | | | | | |
| NOTE 1 | Attention should be given to the layout of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader. | | | | | |
| NOTE 2 | The headings should be standardized as far as possible. | | | | | |
| 5.10.9 | Amendments to test reports and calibration certificates | | | | | |
| | Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: “Supplement to Test Report (or Calibration Certificate), serial number…(or otherwise identified)”, or an equivalent form of wording. | | | | | |
| | Such amendments shall meet all the requirements of this International Standard. | | | | | |
| | When it is necessary to issue a complete new report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces. | | | | | |

# Objective Evidence
## (Attachments)

## 1. General

| | | |
|---|---|---|
| Purpose | To establish a procedures for review of requests, tenders and contracts | |
| Scope | This procedure applies to requests, tenders and contracts | |
| Definitions | Contract strategy | The contract strategy determines the level of integration of work scope and ongoing maintenance for a given project |
| Responsibility | Quality Manager (QM) | Maintain this procedure and ensures that it is appropriately followed. |
| | Test Personnel | Follow this procedure. Request assistance if needed. |

2. Procedure contract strategy

2.1.1. This procedure describes the practicalities of the procurement process. It explains the steps to take in determining the procurement route and outlines the main points to consider before procuring the test/calibration project.

3. The factors that influence the procurement strategy should be considered as listed below.

3.1.1. EU Procurement Rules
3.1.2. The project objectives
3.1.3. Constraints – such as budget and funding; the timeframe of the work
3.1.4. Exit strategy
3.1.5. Cultural factors – such as considerations about the best support
3.1.6. The way people work
3.1.7. Risks – such as late completion of the facility; innovative use of materials
3.1.8. Capabilities to manage a project of this type
3.1.9. The length of operational service required
3.1.10. Appropriate methods to use
3.1.11. Capabilities and resources
3.1.12. Deviations from contact
3.1.13. Amendment after works has commenced

4. Contract Strategy

4.1.1. The contract strategy determines the level of integration of work for a given project, and should support the project objectives in terms of risk allocation, delivery, incentivisation and so on.

5. Decide on the form of contract

5.1.1. The contract requirement sets out what the integrated project team is required to do under the contract. The specification forms a key part of the requirement (together with the project brief). The requirement should include milestones and targets that are SMART – specific, measurable, agreed, realistic and time-based. Amendments should be made when possible and applicable.

6. Procurement Process

6.1.1. Procurement Stage and Review process

| Procurement Stage | Gateway review | Key procurement tasks up to each Gate |
|---|---|---|
| Establish need | Gate 0: Strategic assessment | Identify high-level options for meeting the needs |
| Develop business case | Gate 1: Business justification | Produce high-level business case (Strategic Outline Case) and detailed options appraisal |
| Develop procurement strategy | Gate 2: Procurement strategy | Produce Outline Business Case; determine procurement and contract strategy; require specification and criteria for selection |
| Competitive procurement | Gate 3: Decisions | Competitive tendering (where there is no existing arrangement with a client) leading to contract award; Full business Case |
| Receive and implement contract | Decision point 1: Outline plan | Following approval of outline plan, proceed to detailed setup |
| Detailed plan and setup | Decision point 2: Detailed plan | Following approval of detailed calibration plan, proceed to calibration/work plan |
| Delivery of calibration work; settle final accounts/payments | Gate 4: Readiness | Handover the calibration work to contract management where applicable |
| Manage contract for services where applicable | Gate 5: Benefits evaluation | Post implementation review, to confirm achievement of business benefits |

7. Resolving differences and conflicts

7.1.1. Conflict resolution of differences or conflicts process.

7.1.2. Identify the source of the conflict/differences. The more information about the cause of the conflict/ differences, the more easily it is to resolve it. To get the information use a series of questions to identify the cause.

7.1.3. Look beyond the incident. Often, it is not the situation but the perspective on the situation that causes to fester conflict.

7.1.4. Request solutions. After getting the viewpoint on the conflict/differences, the next step is to identify how the situation could be changed. Ask to solicit ideas.

7.1.5. Identify solutions both disputants can support. Listening for the most acceptable course of action. Point out the merits of various ideas, not only from each other's perspective, but in terms of the benefits to the organizations.

7.1.6. Agreement. Shake hands and agree to one of the alternatives identified in 8.1.6. Sometimes we need to go as far as to write up a contract in which actions and time frames are specified.

7.1.7. Make action plans to prevent conflicts/differences from arising in the future.

8. Decide on the form of contract

8.1.1. The contract requirement sets out what the integrated project team is required to do under the contract. The specification forms a key part of the requirement (together with the project brief). The requirement should include milestones and targets that are SMART – specific, measurable, agreed, realistic and time-based. Amendments should be made when possible and applicable.

9. Assessing the contract

9.1.1. Have improvement targets and measurement arrangements been agreed with the project team and quantified? have incentives been included in the contract to encourage the integrated project team to perform well and achieve the objectives? Have the requirements been quantified?

9.1.2. Requirements for final payment

10. Deviations and amendments from contract

10.1.1. Identify deviations / amendments from contract.

10.1.2. Action should be taken in addressing the deviations / amendments and they should be discussed with the client.

10.1.3. When applicable on official report of the deviations should be made or contact should be revised.

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 07.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | *After one year employee is fully engaged in new role – applies skills and knowledge, makes sound decisions, contributes to team goals, understands how his/her assignments affect others in the organization, and develops effective working relationships. He/she has a strong understanding of lab's mission and culture. Employee continues to be engaged in his/her role and has gained greater confidence in position; begins to take on additional assignments and works with some level of autonomy.* | |
| Scope | HRM | |
| Definitions | Buddy | Experienced employer hoe helps new Employee's on the way in the company |
| | Term 2 | Definition 2 |
| Responsibility | CEO-Manager | Maintain this procedure and ensures that it is appropriately followed. |
| | Quality Manager | Follow this procedure. Request assistance if needed. |

## 2. Process

**BEFORE THE EMPLOYEE'S START DATE**

Outcomes: *This is a welcoming work environment with informed colleagues and a fully-equipped work space; new employees feel "settled in" on their first day.*

**3. Schedule and Job Duties before start date employee**

3.1. Submit the Hire transaction
3.2. Call employee:
3.3. Confirm start date, time, place, dress code, etc.
3.4. Identify computer needs and requirements.
3.5. Provide name of their onboarding buddy.
3.6. Remind employee to provide documents (copy ID, address and bank information, copy of diploma's etc., see sheck-list)
3.7. Add regularly scheduled meetings to employee's calendar.
3.8. Prepare employee's calendar for the first two weeks.
3.9. Plan the employee's first assignment.

**4. Socialization**

4.1. Inform /email team/functional area of the new hire. Include start date, employee's role.
4.2. Set up meetings with critical people for the employee's first few weeks.
4.3. Meet with the buddy, and provide suggestions and tips.
4.4. Arrange for a tour in the company.

**5. Work Environment**

5.1. Put together welcome packet and include: job description, employers handbook en RI&E.
5.2. Setup the work area, with office space with supplies.
5.3. Order office area keys.
5.4. Order business cards, if needed.
5.5. Arrange for parking, if needed.

**6. Technology Access and Related**

6.1. Order technology equipment (computer, printer, iPad) and software.
6.2. Contact IT to have the system set up in advance.
6.3. Arrange for access the servers, and coordinate authorizations.
6.4. Arrange for phone installation.

**7. Training/Development**

7.1. Arrange pertinent trainings required for the job.

**FIRST DAY**

Outcomes: *The employee feels welcomed and prepared to start working; begins to understand the position and performance expectations.*

**8. Schedule, Job Duties, and Expectations**

8.1. Clarify the first week's schedule, and confirm required and recommended training.
8.2. Provide an overview of the functional area – its purpose, organizational structure, and goals.
8.3. Review job description, outline of duties, and expectations.
8.4. Describe how employee's job fits in the department, and how the job and department contribute to the laboratory.
8.5. Review hours of work. Explain policies and procedures for overtime, use of vacation and sick time, holidays, etc. Explain any flexible work policies or procedures.

**9. Socialization**

9.1. Be available to greet the employee on the first day.
9.2. Introduce employee to others in the workplace.
9.3. Introduce employee to his/her buddy.

**10. Work Environment**

10.1. Give employee key(s) and (code's) for building access and lab access if applicable
10.2. Escort employee to the lab is applicable.
10.3. Discuss transportation and parking.
10.4. Provide safety information (RI&E)
10.5. Take employee on a tour through the office.
10.6. Explain how to get additional supplies.

**11. Technology Access and Related**

11.1. Provide information on setting up computer and telephone..

**FIRST WEEK**

Outcomes: *New employee builds knowledge of internal processes and performance expectations; feels settled into the new work environment.*

**12. Schedule, Job Duties, and Expectations**

12.1. Give employee his/her initial assignment. (Make it something small and doable.)
12.2. Debrief with employee after he/she attends initial meetings, attends training, and begins work on initial assignment. Also touch base quickly each day.
12.3. Provide additional contextual information about the organization to increase understanding of the purpose, value's, goals, and initiatives.
12.4. Explain review's and goals
12.5. Review the process related to the probationary period.

**13. Socialization**

13.1. Arrange for a personal welcome

**14. Technology Access and Related**

14.1. Ensure employee has fully functioning computer and systems access and understands how to use them.

**FIRST MONTH**

Outcomes: *Employee is cognizant of his/her performance relative to the position and expectations; continues to develop, learn about the organization, and build relationships.*

**15. Schedule, Job Duties, and Expectations**

15.1. Schedule and conduct regularly occurring one-on-one meetings.
15.2. Continue to provide timely, on-going, meaningful "everyday feedback."
15.3. Elicit feedback from the employee and be available to answer questions.
15.4. Explain the performance management process.
15.5. Discuss performance and professional development goals. Give employee an additional assignment.

**16. Socialization**

16.1. Continue introducing employee to key people and bring him/her to relevant events.
16.2. Meet with employee and buddy to review first weeks and answer questions.

**17. Training and Development**

17.1. Ensure employee is signed up for necessary training.

**FIRST THREE MONTHS**

Outcomes: *Employee is becoming fully aware of his/her role and responsibilities, beginning to work independently and produce meaningful work. He/she continues to feel acclimated to the environment, both functionally and socially.*

**18. Schedule, Job Duties, and Expectations**

18.1. Continue having regularly occurring one-on-one meetings.
18.2. Meet for informal three-month performance check-in.
18.3. Continue giving employee assignments that are challenging yet doable.
18.4. Create written performance goals and professional development goals.
18.5. Discuss appropriate flexible work options.

**19. Socialization**

19.1. Have employee "shadow" you at meetings to get exposure to others and learn more about the organization.
19.2. Take employee out to lunch, and have informal conversation about how things are going.

**20. Training and Development**

20.1. Ask if needed training is completed.
20.2. Provide information about continued learning opportunities.

**FIRST SIX MONTHS**

Outcomes: *Employee has gained momentum in producing deliverables, has begun to take the lead on some initiatives, and has built some relationships with peers as go-to partners. Employee feels confident and is engaged in new role while continuing to learn.*

**21. Schedule, Job Duties, and Expectations**

21.1. Conduct six-month performance review.
21.2. Review progress on performance goals and professional development goals.

**22. Socialization**

22.1. Create an opportunity for employee to attend or be involved in an activity outside of his/her work area.
22.2. Invite employee to business events, and introduce him/her to others.
22.3. Arrange for employee to meet with appropriate new contacts/employees.

22.4. Meet with employee and buddy at the end of their structured buddy-relationship. Discuss how things went and what else would be helpful for the employee.

**FIRST YEAR**

Outcomes: *Employee is fully engaged in new role – applies skills and knowledge, makes sound decisions, contributes to team goals, understands how his/her assignments affect others in the organization, and develops effective working relationships. He/she has a strong understanding of lab's mission and culture. Employee continues to be engaged in his/her role and has gained greater confidence in position; begins to take on additional assignments and works with some level of autonomy.*

**23. Schedule, Job Duties, and Expectations**

23.1. Celebrate successes and recognition of employee's contributions.
23.2. Continue providing regular informal feedback; provide formal feedback during the annual review process.
23.3. Have a conversation with employee about his/her experience at the lab to date:
23.4. Extent to which employee's expectations of role and lab align with reality.
23.5. Extent employee's skills and knowledge are being utilized and ways to better utilize them; what's working, what they need more of, etc.
23.6. Begin discussing the year ahead.

**24. Socialization**

24.1. Support and encourage employee participating on committee's or cross-functional team (when applicable).
24.2. Solicit employee's feedback and suggestions on ways to improve the onboarding experience. Do this one-on-one or with a small group of new employees.

**25. Training and Development**

25.1.1. Discuss employee's professional development goals and identify relevant learning opportunities.

**26. Change Control Section**

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 17.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is the Computer Software Validation Procedures | |
| Scope | This procedure applies to software used in the lab | |
| Definitions | NA | NA |
| | NA | NA |
| Responsibility | Quality Manager | Maintain this procedure and ensures that it is appropriately followed. |
| | Test Personnel | Follow this procedure. Request assistance if needed. |

## 2. Procedure

2.1. Software validation

2.1.1. Software validation/version (5.4.7, 5.5.2) – When computers or automated equipment is used for acquisition, processing, recording, storage or retrieval of calibration data:

2.1.1.a. Any custom computer software developed by the user, or by others on behalf of the user, must be validated to assure proper function and adequacy of use before the software is placed into use. The software version, name, model or other unique identification for the software is to be recorded to aid in identifying the software for updates or recalls.

2.1.1.b. Procedures must be in use to protect recorded data. Some examples are: protecting data integrity and confidentiality via passwords in the

2.1.1.c. Software, secure data storage and / or access to data system areas via physical security measures. c) Commercially available software (purchased “off-the-shelf” requiring no alterations) or software provided with, or embedded into, commercially available calibration equipment is considered to be sufficiently validated. However, software that has been configured or modified by the user must be validated. For example, Microsoft Excel spreadsheet software would not require validation, but equations entered by the user would require checks to confirm the formula was entered correctly and provides the correct results. The way this is done is explained in the QP-003 about this topic.

2.1.2. Where custom-written computer software is utilized in data recording, retrieval, processing, calculation, analysis, or reporting, the laboratory is to provide proof that the computer software is documented and verified for use with respect to proper function and data manipulation. This proof may be in the form of an analysis of the software output using known input values, comparisons to manual calculations, statistical analysis, etc.

2.2. The lab’s software

2.2.1. At this time the lab uses of the shell software for example from Microsoft or Adobe. Other commercial used software used from Keysight, Bruel and Kjaer, is from liable sources an can be considered to be sufficiently validated.

2.2.2. Equations entered by the user would require checks to confirm the formula was entered correctly and provides the correct results. The way this is done is explained in the QP-003 about this topic.

2.2.3. Checks are also made in change of measurement equipment for instance calculated values versus direct readout values (digital versus digital validation).

### 3. Change Control Section

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 17.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure communicate the companies code of ethics and business contact | |
| Scope | The requirements of this procedure applies to all the companies/lab's actions | |
| Definitions | Documents | All relevant documents |
| Responsibility | Quality Manager (QM) | Maintain this procedure and ensures that it is appropriately followed. |
| | Test Personnel | Follow this procedure. Request assistance if needed. |

## 2. Procedure

2.1. Code of Conduct or Code of:

2.1.1. When considering any action, it is wise to ask: will this build trust and credibility for [Company Name]? Will it help create a working environment in which [Company Name] can succeed over the long term? Is the commitment I am making one I can follow through with? The only way we will maximize trust and credibility is by answering "yes" to those questions and by working every day to build our trust and credibility.

2.2. Respect for the Individual

2.2.1. We all deserve to work in an environment where we are treated with dignity and respect. AV-Conulting is committed to creating such an environment because it brings out the full potential in each of us, which, in turn, contributes directly to our business success. We cannot afford to let anyone's talents go to waste.

2.3. Create a Culture of Open and Honest Communication

2.3.1.At AV-Consulting everyone should feel comfortable to speak his or her mind, particularly with respect to ethics concerns. Managers have a responsibility to create an open and supportive environment where employees feel comfortable raising such questions. We all benefit tremendously when employees exercise their power to prevent mistakes or wrongdoing by asking the right questions at the right times.

2.4. AV-Consulting's whistleblower policy is as follows:

2.4.1. AV-Consulting will investigate all reported instances of questionable or unethical behavior. In every instance where improper behavior is found to have occurred, the company will take appropriate action. We will not tolerate retaliation against employees who raise genuine ethics concerns in good faith.

2.5. AV-Consulting's whistleblower policy is as follows:

2.5.1. Employees are encouraged, in the first instance, to address such issues with their managers or the CEO, as most problems can be resolved swiftly. If for any reason that is not possible or if an employee is not comfortable raising the issue with his or her manager or Ceo. Bureau Freyee (accountant), mr. Cees Freyee does operate with an open-door policy. Management shall implement the advices he gives. Mr. Freyee is hereby mandated to take action, also in regard of contacting the accredited body to take corrective actions if applicable.

2.6. Set Tone at the Top

2.6.1. Management has the added responsibility for demonstrating, through their actions, the importance of this Code. In any business, ethical behavior does not simply happen; it is the product of clear and direct communication of behavioral expectations, modeled from the top and demonstrated by example. Again, ultimately, our actions are what matters.

2.7. Uphold the Law

2.7.1. AV-Consulting's commitment to integrity begins with complying with laws, rules and regulations where we do business. Further, each of us must have an understanding of the company policies, laws, rules and regulations that apply to our specific roles. If we are unsure of whether a contemplated action is permitted by law or AV-Consulting policy, we should seek the advice from the resource expert. We are responsible for preventing violations of law and for speaking up if we see possible violations.

2.7.2. Competition

2.7.2.a. We are dedicated to ethical, fair and vigorous competition. We will sell AV-Consulting services based on their merit, superior quality, functionality and competitive pricing. We will make independent pricing and marketing decisions and will not improperly cooperate or coordinate our activities with our competitors. We will not offer or solicit improper payments or gratuities in connection with the services for AV-Consulting or the sales of its products or services, nor will we engage or assist in unlawful boycotts of particular customers.

2.7.3. Proprietary Information

2.7.3.a. It is important that we respect the property rights of others. We will not acquire or seek to acquire improper means of a competitor's trade secrets or other proprietary or confidential information. We will not engage in unauthorized use, copying, distribution or alteration of software or other intellectual property.

2.7.4. Selective Disclosure

2.7.4.a. We will not selectively disclose (whether in one-on-one or small discussions, meetings, presentations, proposals or otherwise) any material nonpublic information with respect to AV-Consulting, its securities, business operations, plans, financial condition, results of operations or any development plan. We should be particularly vigilant when making presentations or proposals to customers to ensure that our presentations do not contain material nonpublic information.

2.7.5. Health and Safety

2.7.6. AV-Consulting is dedicated to maintaining a healthy environment. A Risk Assessment has been designed to educate you on safety in the workplace. You can find a copy of this Risk Assessment under the directory EIR-021 Staff Handbook and Safety.

2.8. Avoid Conflicts of Interest

2.8.1. We must avoid any relationship or activity that might impair, or even appear to impair, our ability to make objective and fair decisions when performing our jobs. At times, we may be faced with situations where the business actions we take on behalf of AV-Consulting may conflict with our own personal or family interests. We owe a duty to AV-Consulting to advance its legitimate interests when the opportunity to do so arises. We must never use AV-Consulting property or information for personal gain or personally take for ourselves any opportunity that is discovered through our position with AV-Consulting.

2.9. Some other ways in which conflicts of interest could arise:

2.9.1. Being employed (you or a close family member) by, or acting as a consultant to, a competitor or potential competitor, supplier or contractor, regardless of the nature of the employment, while you are employed with AV-Consulting.
2.9.2. Hiring or supervising family members or closely related persons.
2.9.3. Serving as a board member for an outside commercial company or organization.
2.9.4. Owning or having a substantial interest in a competitor, supplier or contractor.
2.9.5. Having a personal interest, financial interest or potential gain in any AV-Consulting transaction.
2.9.6. Placing company business with a firm owned or controlled by a AV-Consulting employee or his or her family.
2.9.7. Accepting gifts, discounts, favors or services from a customer/potential customer, competitor or supplier, unless equally available to all AV-Consulting employees.
2.9.8. Determining whether a conflict of interest exists is not always easy to do. Employees with a conflict of interest question should seek advice from management. Before engaging in any activity, transaction or relationship that might give rise to a conflict of interest, employees must seek review from their managers or the CEO.

2.10. Gifts, Gratuities and Business Courtesies

2.10.1. AV-Consulting is committed to competing solely on a merit of our products and services. We should avoid any actions that create a perception that favorable treatment of outside entities by AV-Consulting was sought, received or given in exchange for personal business courtesies. Business courtesies include gifts, gratuities, meals, refreshments, entertainment or other benefits from persons or companies with whom AV-Consulting does or may do business. We will neither give nor accept business courtesies that constitute, or could reasonably be perceived as constituting, unfair business inducements that would violate law, regulation or polices of AV-Consulting or customers, or would cause embarrassment or reflect negatively on AV-Consulting's reputation.

2.10.2. Accepting Business Courtesies

2.10.2.a. Most business courtesies offered to us in the course of our employment are offered because of our positions at [Company Name]. We should not feel any entitlement to accept and keep a business courtesy. Although we may not use our position at AV-Consulting to obtain business courtesies, and we must never ask for them, we may accept unsolicited business courtesies that promote successful working relationships and good will with the firms that AV-Consulting maintains or may establish a business relationship with.

2.10.3. Gifts

2.10.3.a. Employees may accept unsolicited gifts, other than money, that conform to the reasonable ethical practices of the marketplace, including: Flowers, fruit baskets and other modest presents that commemorate a special occasion. Gifts of nominal value, such as calendars, pens, mugs, caps and t-shirts (or other novelty, advertising or promotional items). Generally, employees may not accept compensation, honoraria or money of any amount from entities with whom [Company Name] does or may do business. Tangible gifts (including tickets to a sporting or entertainment event) that have a market value greater than Euro 100 may not be accepted unless approval is obtained from management.

2.10.3.b. Employees with questions about accepting business courtesies should talk to their managers or CEO.

2.10.4. Offering Business Courtesies

2.10.5. Any employee who offers a business courtesy must assure that it cannot reasonably be interpreted as an attempt to gain an unfair business advantage or otherwise reflect negatively upon AV-Consulting. An employee may never use personal funds or resources to do something that cannot be done with AV-Consulting resources. Accounting for business courtesies must be done in accordance with approved company procedures.

- The practice does not violate any law or regulation or the standards of conduct of the recipient's organization.
- The business courtesy is consistent with industry practice, is infrequent in nature and is not lavish.
- The business courtesy is properly reflected on the books and records of AV-Consulting.

3. Set Metrics and Report Results Accurately

3.1. Accurate Public Disclosures

3.1.1. We will make certain that all disclosures made in financial reports and public documents are full, fair, accurate, timely and understandable. This obligation applies to all employees, including all financial executives, with any responsibility for the preparation for such reports, including drafting, reviewing and signing or certifying the information contained therein. No business goal of any kind is ever an excuse for misrepresenting facts or falsifying records.

3.2. Corporate Recordkeeping

3.2.1. We create, retain and dispose of our company records as part of our normal course of business in compliance with all AV-Consulting policies and guidelines, as well as all regulatory and legal requirements.

3.2.2. We must not improperly influence, manipulate or mislead any unauthorized audit, nor interfere with any auditor engaged to perform an internal independent audit of AV-Consulting books, records, processes or internal controls.

4. Promote Substance Over Form

4.1. At times, we are all faced with decisions we would rather not have to make and issues we would prefer to avoid. Sometimes, we hope that if we avoid confronting a problem, it will simply go away.

4.2. At AV-Consulting, we must have the courage to tackle the tough decisions and make difficult choices, secure in the knowledge that [Company Name] is committed to doing the right thing. At times this will mean doing more than simply what the law requires. Merely because we can pursue a course of action does not mean we should do so.

4.3. Although AV-Consulting's guiding principles cannot address every issue or provide answers to every dilemma, they can define the spirit in which we intend to do business and should guide us in our daily conduct.

5. Accountability

5.1. Each of us is responsible for knowing and adhering to the values and standards set forth in this Code and for raising questions if we are uncertain about company policy. If we are concerned whether the standards are being met or are aware of violations of the Code, we must contact the HR department.

5.2. AV-Consulting takes seriously the standards set forth in the Code, and violations are cause for disciplinary action up to and including termination of employment.

6. Be Loyal

6.1.1. Confidential and Proprietary Information

6.1.1.a. Integral to AV-Consulting's business success is our protection of confidential company information, as well as nonpublic information entrusted to us by employees, customers and other business partners. Confidential and proprietary information includes such things as pricing and financial data, customer names/addresses or nonpublic information about other companies, including current or potential supplier and vendors. We will not disclose confidential and nonpublic information without a valid business purpose and proper authorization.

6.1.2. Use of Company Resources

6.1.2.a. Company resources, including time, material, equipment and information, are provided for company business use. Nonetheless, occasional personal use is permissible as long as it does not affect job performance or cause a disruption to the workplace. Employees and those who represent AV-Consulting are trusted to behave responsibly and use good judgment to conserve company resources. Managers are responsible for the resources assigned to their departments and are empowered to resolve issues concerning their proper use. Generally, we will not use company equipment such as computers, copiers and fax machines in the conduct of an outside business or in support of any religious, political or other outside daily activity, except for company-requested support to nonprofit organizations. We will not solicit contributions nor distribute non-work related materials during work hours. In order to protect the interests of the AV-Consulting network and our fellow employees, AV-Consulting reserves the right to monitor or review all data and information contained on an employee's company-issued computer or electronic device, the use of the Internet or AV-Consulting's intranet. We will not tolerate the use of company resources to create, access, store, print, solicit or send any materials that are harassing, threatening, abusive, sexually explicit or otherwise offensive or inappropriate.

6.1.3. Media Inquiries

6.1.3.a. AV-Consulting is a high-profile company in our community, and from time to time, employees may be approached by reporters and other members of the media. In order to ensure that we speak with one voice and provide accurate information about the company, we should direct all media inquiries to the CEO. No one may issue a press release without first consulting with the CEO.

7. Do the Right Thing

7.1. Several key questions can help identify situations that may be unethical, inappropriate or illegal. Ask yourself:

- Does what I am doing comply with the [Company Name] guiding principles, Code of Conduct and company policies?
- Have I been asked to misrepresent information or deviate from normal procedure?
- Would I feel comfortable describing my decision at a staff meeting?
- How would it look if it made the headlines?
- Am I being loyal to my family, my company and myself?
- What would I tell my child to do?
- Is this the right thing to do?

8. Information and Resources

**A.Vreeswijk, CEO**

**H.J.J. Schipperen QM**

**K.Freyee, accountant & trustee (Tel.: +31172614439, e-mail : burofreyee@xs4all.nl**

**J.Rommens, argoadvies (Tel,: 088 – 031 3246, e-mail E.joyce.rommens@argoadvies.nl**

| Version | Rev. Date | Change Control Comments | Approver |
|---|---|---|---|
| 1 | 17.10.2016 | Created new document. | A.Vreeswijk |

## 1. General

**Purpose**

Whistleblower policies en tools for protecting individuals who report activities believed to be illegal or not comply with the rules and policies of the Public body such as the Accredited Body (RvA).

**Scope**

The requirements of this procedure applies for the whole organization.

**Definitions**

| | |
|---|---|
| Documents | All relevant documents relating to the QMS |
| Whistleblower | An employee who reports, to one or more of the parties specified in this policy, an activity that he/she considers to be illegal, dishonest, unethical, or otherwise improper. |
| Employee or public employee | A person who performs a service for wages or other remuneration under a contract of hire, written or oral, express or implied, for the district. |
| Matter of public concern | a. Violation of a state, federal, or municipal law, regulation, policies and rules of Accredited Body (RvA) or ordinance.<br>b. Danger to public health or safety; and/or gross mismanagement, substantial waste of funds, or a clear abuse of authority. |
| Public body | An officer or agency of:<br>a. The federal government.<br>b. The state.<br>c. A political subdivision of the state including a municipality or a school district.<br>d. A public university in the state.<br>c. Accredited Body (RvA) |
| Trustee | A person who is allowed to do certain tasks, give asked and on-ask advice to the management and holds the authority to take actions against the business such as make a formal complaint at the accredited body (RvA). |

**Responsibility**

| | |
|---|---|
| Quality Manager (QM) | Maintain this procedure and ensures that it is appropriately followed. |
| Personnel | Follow this procedure. Request assistance if needed. |
| Management | Follow this procedure. |

## 2. Whistleblower Protection Policy

2.1. The organization will not retaliate against a whistleblower. This includes, but is not limited to, protection from retaliation in the form of an adverse employment action such as termination, compensation decreases, or poor work assignments and threats of physical harm. Any whistleblower who believes he/she is being retaliated against must contact the trustee immediately. The right of a whistleblower for protection against retaliation does not include immunity for any personal wrongdoing that is alleged and investigated.

2.2. Whistleblower protections are provided in two important areas: confidentiality and retaliation. Insofar as possible, the confidentiality of the whistleblower will be maintained. However, identity may have to be disclosed to conduct a thorough investigation, to comply with the law, and to provide accused individuals their legal rights of defense.

2.3. Individuals protected include

2.4. a. the employee, or a person acting on behalf of the employee, who reports to a public body or is about to

- report to a public body or accredited body a matter of public concern; or
- the employee who participates in a court action, an investigation, a hearing, or an inquiry held by a public;
- body on a matter of public concern.

2.5. The organization may not discharge, threaten, or otherwise discriminate against an employee regarding the employee's compensation, terms, conditions, location, or privileges of employment.

2.6. The organization may not disqualify an employee or other person who brings a matter of public concern, or participates in a proceeding connected with a matter of public concern, before a public body or court, because of the report or participation, from eligibility to bid on contracts with the organization; ordinance; or receive another right, privilege, or benefit.

2.7. The provisions of this policy do not

- require the organization to compensate an employee for participation in a court action or in an investigation, hearing, or inquiry by a public body;
- prohibit the organization from compensating an employee for participation in a court action or in an investigation, hearing, or inquiry by a public body;
- authorize the disclosure of information that is legally required to be kept confidential; or diminish or impair the rights of an employee under a collective bargaining agreement.

2.8. Limitation to protections

- A person is not entitled to the protections under this policy unless he or she reasonably believes that the information reported is, or is about to become, a matter of public concern; and reports the information in good faith.
- A person is entitled to the protections under this policy only if the matter of public concern is not the result of conduct by the individual seeking protection, unless it is the result of conduct by the person that was required by his or her employer.
- Before an employee initiates a report to a public body on a matter of public concern under this policy, the employee shall submit a written report concerning the matter to the organization's chief executive officer.
- However, the employee is not required to submit a written report if he or she believes with reasonable certainty hat the activity, policy, or practice is already known to the chief executive officer; or that an emergency is involved.

2.9. Relief and penalties

- A person who alleges a violation of this policy may bring a civil action and the court may grant appropriate relief.
- A person who violates or attempts to violate this policy is also liable for a civil fine of not more than ten thousand euro.

## 3. Procedures

3.1. If an employee has knowledge of or a concern of illegal or dishonest/fraudulent activity, the employee is to contact his/her immediate supervisor or the trustee as he wishes . All reports or concerns of illegal and dishonest activities will be promptly submitted by the receiving supervisor/trustee, who is responsible for investigating and coordinating any necessary corrective action. Any concerns involving the supervisor or trustee should be reported to the CEO or AgroAdvies.

3.2. The whistleblower is not responsible for investigating the alleged illegal or dishonest activity, or for determining fault or corrective measures; appropriate management officials are charged with these responsibilities.

3.3. Examples of illegal or dishonest activities include violations of federal, state, or local laws rules of accredited bodies (RvA); billing for services not performed or for goods not delivered; and other fraudulent financial reporting. The employee must exercise sound judgment to avoid baseless allegations. An employee who intentionally files a false report of wrongdoing will be subject to disciplinary action.

3.4. Supervisor can contact the trustee at al time to seek advice. He is authorized to ask to open an investigation, cost for such an investigation shall be paid by the company AV-Consulting.

3.5. Trustee is authorized to give binding advice ask or unasked to the management, management shall comply accordingly as soon as possible.

3.6. Trustee authorized to open en investigation ask or not asked. He is authorized to report to the Public body as he sees fit.

## 4. Information and Resources

A.Vreeswijk, CEO

H.J.J. Schipperen QM

K.Freyee, accountant & trustee (Tel.: +31172614439, e-mail : burofreyee@xs4all.nl

J.Rommens, argoadvies (Tel,: 088 – 031 3246, e-mail E.joyce.rommens@argoadvies.nl

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## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to provide a consistent approach for conducting internal audits and reviews for conflict of interest. | |
| Scope | This procedure applies to ISO 17025 management requires to have a Conflict of Interest Management Policy in place to ensure that conflicts of interest are managed appropriately in the business. | |
| Dfinitions | Conflict of interest | Any situation, including financial interest, ownership interest, or any relationship with a third party, in which a provider or representative has an actual or potential interest that may:<br>I. influence the objective fulfilment of obligations to a client;<br>II. influence the offering of unbiased and fair advice or service to a client; or<br>III. prevent the provider or representative from acting in the best interests of a client. |
| | Trusty | A person who is allowed to do certain tasks, give asked and on-ask advice to the management and holds the authority to take actions against the business such as make a formal complaint at the accredited body (RvA). |
| Responsibility | Quality Manager | Maintain and follow this procedure to ensure the ongoing requirements are met. Schedule and facilitate the internal audit. |
| | Test Personnel | Follow this procedure |
| | Trustee | Follow this procedure take action if necessary en/or applicable. |

## 1. Policy and Procedure

1.1. The company is committed to avoiding, and where this is not possible, mitigating any conflict of interest that may arise between the Company, as a financial services provider, and its clients when rendering calibration services.

## 2. Who is subject to the policy

2.1. The company, its employees and all individuals authorized by the Company, whether in terms of an employment agreement or a mandate, to render calibrations and/or intermediary services, to clients of the Company, are bound by this policy.

## 3. Mechanisms for identifying Conflicts of Interest

3.1. Avoiding conflicts of interest, or mitigating such conflicts, is primarily based on the principle of trust. In a nutshell this means that clients should trust our judgement without reservation. Whether a client would indeed trust our judgement in particular situation or activity, given the existence of a conflict- or potential conflict of interest, is a question of fact and must be determined on a case by case basis, using objective judgement.

3.2. Similarly, the principle of "treating clients fairly" can also be applied to identify the existence of conflicts of interest. This principle requires one to consider whether the calibrations, guidance or proposal furnished to a client will result in fair treatment of the client. In considering one's obligations to treat clients fairly.

3.3. All employees and representatives must disclose, to the Management ore Trustee, any immaterial- or other financial interest, as defined above, received from a product provider or other third party. This disclosure must be made within one week after the relevant activity has taken place or have come to the attention of the employee or supervisor.

3.4. Irrespective of the above principles, a conflict of interest will be deemed to have arisen if the Company, or any employee or representative, receives a "disallowed interest" as listed in Chapter 5.

## 4. Consequences of not adhering to this policy

4.1. Violation of this Policy by an employee or representative may result in disciplinary action being taken against the employee / representative.

## 5. Policy and Advice

### 5.1. Interest Allowed under Operation Procedures

| Interest allowed | Disclosure required | Operating procedures |
|---|---|---|
| Commission, in accordance with IEC or technical standards | Disclosed in Initial Disclosure document and quotation. | Financial interest disallowed |
| Fees as provided for lectures or educational purposes, if those fees are reasonably commensurate to the service being offered | Disclosed in Initial Disclosure document and quotation. | Financial interest in the organizations were lectures of education is given are disallowed |
| Ownership interest | Disclosed in conflict of interest register | Financial interest allowed |
| Promotional items | Disclosed in conflict of interest register | Financial interest allowed: Marketing and advertising, provided a fair value for the service, as would have been charged elsewhere, is charged |
| Calibration of instruments from other companies of owner | List the brands in the conflict of interest register | All employees and representatives shall report to Trustee if the find any influence of owner regarding the calibration process, outcome, commercial pressure or what so ever. Trustee shall take appropriate actions as he is authorized |

### 5.2. Interest Disallowed under Operation Procedures

| Interest disallowed | Disclosure required | Operating procedures |
|---|---|---|
| Any interest with adeterminable monetary value exceeding 100 euro This could be made up of 1 gift or of several gifts from one product supplier in one calendar year (as recorded in internal gift register). | Disclosed in Initial Disclosure document. | Financial interest disallowed Gift may not be accepted |
| Receiving money or gifts with the purpose to influence the calibration process or outcome | Disclosed in Initial Disclosure document. | Report to QM, CEO or Trustee. |
| Commercial obligations regarding calibration process or outcome | Disclosed in conflict of interest register | When pressure of manipulation is felt report to QM, CEO or Trustee as see fit by employer. |

## 6. Change Control Section

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## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure to providing a quality service to all our customers. The Laboratory Quality Manual will secure the quality management system, competence of testing and calibration. | |
| Scope | This procedure applies to all technical services procured under the scope of the laboratory's accreditation. This Quality Commitment and Statement applies to our laboratory facility at the following location. Benedenberg 100A, 2861LH Bergambacht. | |
| Definitions | N/A | N/A |
| Responsibility | Quality Manager | Maintain and follow this procedure to ensure the ongoing requirements are met. |
| | Test Personnel | Follow and endorse this procedure. |
| | Management | Follow and endorse this procedure |

## 2. Quality Policy Statement

2.1. The Laboratory's Management System policies related to quality, including a quality policy statement, are defined as follows; This Quality Policy is issued under the authority of AV-Consulting Quality Manager. Our commitment is to provide the highest level of calibration and testing services in compliance with the governing standards of this industry and ISO/IEC 17025 and demonstrate compliance by third party accreditation through, client audits, internal audits, management reviews and an effective corrective action system. It is laboratory management's commitment to maintain good laboratory practices and good professional practice of our testing and calibration services to our clients. It is the policy of this laboratory that test, calibrations and services shall always be carried out in accordance with stated standardized methods and/or our client's requirements. It is a requirement that all staff concerned with test and calibration activities within the laboratory familiarizes themselves with the quality documentation and implement these policies and procedures.

## 3. Quality Commitment Statement

3.1. AV-Consulting Calibration Laboratory is legally responsible for the laboratory.
3.2. It is the policy of AV-Consulting Calibration Laboratory to conform to comply with the Accredited Body Rules and Guidelines en Policy and the requirements of ISO-17025.
3.3. The Laboratory Management System applies to the work carried out in the laboratory's permanent facilities located at Benedenberg 100A, 2861 LH Bergambacht.

## 4. Quality Statement Conflict of Interest

4.1. The laboratory has a well-defined and documented organizational structure in order to identify potential conflicts of interest and prevent an involvement or influence on the testing activities of the laboratory as described in QP-022 an QP-020.
4.2. Through organizational structure and policy, the Laboratory ensures that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

## 5. Quality Statement on Confidentiality, Confidence, Integrity and Protection

5.1. The Laboratory ensures the protection of its customers' confidential information and proprietary, including procedures for protection the electronic storage and transmission results as defined in rights with the use of the WI-012 (Non-Disclosure Agreement Procedure) and QP-007 (Ensuring Confidentiality During Visits), QP-003 (Control of Data Document), QP-013 (Storing and Protection of Document) and QP-023 (Document Control).

5.2. The Laboratory policy is to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.

## 6. Quality Statement on Ethics and Business Conduct

6.1. The laboratory has a procedure of code Ethics and Business Conduct (QP-020 Procedure Code Ethics and Business Conduct.

6.2. The laboratory has a procedure for Whistleblower and Protection Policy (QP-021-Procedure for Whistleblower and Protection Policy).

## 7. Quality Statement on Management System

**7.1.** The laboratory has established, implemented and maintains a Laboratory Management System appropriate to the scope of its activities. The Laboratory Management System documents its policies, systems, programs, procedures and work instructions to the extent necessary to assure the quality of the test results. System documentation is communicated to, understood by, available to, and implemented by the appropriate personnel. The relevant documents are listed in EIR-013 (Records and Documents List**)** on the companies server.

7.2. The CEO, in conjunction with the Quality Manager and supported by the Staff of AV-Consulting defines the management structure of the AV-Consulting Calibration Laboratory and the relationship between quality management, technical operations and support service.

7.3. The Quality Manager specifies the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations.

7.4. The Laboratory Manager, acting as Quality Manager, irrespective of other duties and responsibilities, has the responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times. The Laboratory Manager has direct access to the highest level of management at which decisions are made on laboratory policy or resources.

## 8. Quality Statement on Management Commitment and Endorsement

8.1. Executive Management Team and CEO endorses the Quality Manual en is committed to the development and implementation of the management system and to continually improving its effectiveness through the QP-010, Internal Audits and Management Responsibilities. The CEO, management and Staff commits to the Quality Procedures of Quality Manual.

## 9. Quality Statement on Ensuring Compliance

9.1. The Quality Manager has responsibility and authorization for technical management within the laboratory quality system. The Quality Manager has responsibility and authorization within the laboratory quality system. These responsibilities and authorization are included in the job descriptions and Quality Procedures and include ensuring compliance with this standard, ISO/IEC17025 and other relevant documents from Accredited Bodies and relevant International Standard (IEC/ISO/DIN/NEN).

9.2. The Quality Manager has responsibility to ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented. All changes to the management system are generated in accordance with QP-03 (Control of Data) and QP-014 (Document Control).

## 10. Quality Statement on Prevention of use of invalid documents

10.1. All documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use by authorized personnel prior to issue. A master list identifying the current revision status and distribution of documents in the management system is established and readily available in the the QM directory EIR-013 on the companies server to prevent the use of invalid and/or obsolete documents.

## 11. Change Control Section

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## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to establishes the method by which Management Reviews are performed within the AV-Consulting Calibration Laboratory (Laboratory). | |
| Scope | Management reviews encompass all testing and calibration activities included in the scope of accreditation. This procedure applies to all Laboratory personnel who conduct audits and management reviews. | |
| Definitions | Management Review | An assessment by management of the Quality System to determine effectiveness, suitability, and future direction. |
| | Audit | A planned and documented investigative evaluation to compare various aspects of the Laboratory's performance against established requirements, standards, policies, and procedures. |
| Responsibility | Quality Manager (QM) | Ensure that management reviews are completed on a timely basis, at the frequency specified by the management system, with the appropriate personnel. Maintain this procedure and ensures that it is appropriately followed. |
| | Management | Follow this procedure. |

## 2. Management Review

2.1. Management reviews shall be performed annually in conjunction with the internal audit program. An annual review of each Section quality system shall be performed by the CEO.
2.2. The management review shall be documented via memo to the Assistant Director of Technical Operations, with a copy to the QM.
2.3. The management review shall examine the Quality System of each Section and determine if it meets the standards set by the Laboratory and ISO. The review shall also serve as a guide for future determinations regarding the effectiveness and direction of the Quality System due to changes in the organization, facilities, staffing, equipment, activities, or workload.
2.4. As necessary, the QM shall provide any needed information and/or records for the review and forward them to the CEO.

## 3. The management review shall consider, but not be limited to, the following

3.1. Actions taken since the previous management review
3.2. Suitability of policies and procedures.
3.3. Reports from managerial and supervisory personnel.
3.4. Outcome of recent audits.
3.5. Effectiveness of previous actions.
3.6. Corrective and preventive actions.
3.7. Assessments by external bodies.
3.8. Technical Leader annual report.
3.9. Results of inter-laboratory comparisons or proficiency tests.
3.10. Changes in the volume and type of the work.
3.11. Client feedback.
3.12. Complaints.
3.13. Recommendations for improvement.
3.14. Non-conformity Records

3.15. Work Authorizations
3.16. Other factors, such as quality control activities, resources, and staff training.
3.17. Resulting assignments
3.18. Quality control activities
3.19. Recommendations for improvement
3.20. Changes in the volume and type of work

**4. Corrective or preventive actions**

4.1. Corrective or preventive actions identified during the management review shall be addressed as provided in the Procedure for Corrective Action and Procedure for Preventive Action.

**5. Follow up**

5.1. The QM shall review the Management Reviews and follow up with a summary report to the Laboratory Director. The summary report shall include a review of the overall objectives of the Laboratory, overall effectiveness of the Quality System, proficiency testing program, court testimony monitoring system, corrective and preventive action records, etc.

**6. Report**

6.1. Around October, the summary report of the Management Review outlining findings and observations shall be included in the Laboratory Quality System Review and assessed in a meeting with Laboratory Management. This meeting shall be documented in a memorandum prepared and provided by the QM. The memo shall include recommendations for any corrective or preventive actions that the management deems appropriate.

**7. Documentation**

7.1. The QM shall retain the management reviews and audit reports for five years,

**8. Change Control Section**

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## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to layout the framework conditions for the electronic transfer information between the laboratory and customers or other parties and suppliers. | |
| Scope | This procedure applies to EDI | |
| Definitions | EDI | Electronic Data Interchange |
| | Parties | The Laboratory and its business partners and clients |
| Responsibility | Quality Manager | Maintain this procedure and ensures that it is appropriately followed. |
| | Test Personnel | Follow this procedure. Request assistance if needed. |

## 2. Procedure

2.1. Transmitting electronic information

2.1.1. Responsibility for security, correctness and accuracy

2.1.1.a. Within their own areas, the parties to the contract will provide measures which ensure the correctness of the electronically transmitted information. In particular, the parties to the contract undertake to carry out the necessary security and monitoring actions to protect the EDI transmissions from access by unauthorized third parties, as well as modification, loss or destruction.

2.1.1.b. The party to the contract making a transmission must ensure that the information is accurate. All messages received must be checked to see whether they are from a legal sender and whether they have been directed to the actual recipient. As a minimum, a check must be made on the accuracy of :

1.1.1..1. The identifications and/or sender/receiver identifications in the service segments of the message.
1.1.1..2. The sequential number of the transmission (date and time stamp).
1.1.1..3. Any other, individually agreed security features (passwords).
1.1.1..4. Also with atomized procedures, the information received must be checked for the accuracy of checksums, compliance with syntax and - as far as possible - for plausibility. In case of exceptions, a manual investigation is required.

1.1.2. Each party receiving information is entitled to and obliged to process the information in the form it has arrived in his data-processing system.

2.2. Archiving and protocolling

2.2.1 Each message which has been sent or received must be stored in its exact format as send. In addition, a protocol file must be maintained, in which a data-record of each message is stored, which contains at least the date, time, partner and type of message.

2.3. Protecting information against loss

2.3.1. To protect information against loss, the sender must allocate a clear and sequential number to each document transmitted

2.4. Action in the event of a system failure

2.4.1. If one or more data connections between the parties to the contract should fail, the other party to the contract must be informed without delay. If one party is temporarily unable to use EDI, data exchange shall be carried out as previously, following mutual agreement (e.g., printed paper documents). To avoid multiple bookings of the same documents or other disorders in the process, there has to be agreed by phone about the handling of the last EDI transmission, the paper documents and the following EDI transmissions.

2.5. Action in case of rejections or errors

2.5.1. If a check on an EDI message leads to its rejection or to the detection of an error, the recipient must advise the sender as quickly as possible. Following receipt of such a message, the recipient takes no action until he has received appropriate instructions from the sender

2.6. Liability for unauthorized transmission of messages

2.6.1. Anyone receiving messages where there is a suspicion of misuse at the sender's premises or elsewhere, must immediately inform the sender's contact personnel of his / her suspicions. Each party to the contract is liable for the unauthorized transmission of messages sent from his data processing system.

2.7. Confidentiality; data protection

2.7.1. Each party is individually responsible for compliance with legal data protection regulations. The basic principles relating to data processing and data storage must be complied with. With regard to the confidentiality of electronically transmitted data, the same principles apply as for data transmitted in any other way. Messages and information must be protected in all computers against unauthorized access

2.8. The laboratories data protection

2.8.1. The laboratory will use when sending report an adobe password controlled document password signed digitally by the legal signatory.

2.8.2. Reports will be saved in a the assigned directory on the laboratories server. The directory is only accessible for the legal laboratory personnel.

2.8.3. On e-mail traffic a legal disclaimer is added as follows:

*The information contained within this document is confidential and is intended for the exclusive use of the address; it may also contain copyright or legally privileged information. If this message is received in error please respect the confidentiality of the document and advise the sender immediately or send an email at info@calibration-lab.com Disclosure, reproduction, distribution or other dissemination of this document or its contents is strictly prohibited. AV-Consulting Laboratory BV The Netherlands*

3. Law applied and Place of Venue

3.1. Dutch law is required. For all disputes concerning this EDI agreement, the parties of the contract shall agree about Bergambacht The Netherlands as exclusive places of venue.

**4. Change Control Section**

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## 1. General

| | | |
|---|---|---|
| Purpose | The purpose of this procedure is to provide a consistent approach to ensure that a lab device has been labeled, check en data and manuals are stored in the QMS. | |
| Scope | This procedure applies to all new devices to be used within the laboratory. | |
| Definitions | Quality Check | Verification activity that ensures this procedure is followed. |
| Responsibility | Quality Manager | Maintain and follow this procedure to ensure the ongoing requirements are met. Periodically review records. |
| | Test Personnel | Follow this procedure and perform quality checks as required. |

## 2. Procedure

2.1. Follow QP-009 “Quality Procedure for Procuring Technical Services AV-Consulting”

2.2. Before putting new equipment in to service it must be recorded in EIR-014: Equipment and Tools List.

2.3. At a minimum, the following should be recorded:

- Unambiguous description of the device (number + name)
- Serial number(s)
- Specifications, check if they meet the minimum requirements.
- Units of measure
- Uncertainties of measuring values
- The device’s limits of acceptable use
- Mark if this equipment is to be used for calibration process.
- Mark calibration date, and check calibration if its valid for the lab

2.4. Make sure the manual and data of the new instrument is put in the directory EIR-014B Lab Equipment Data.

2.5. Record the new instrument documents in Excel sheet EIR-013: Records and Documents List.

2.6. Intervals and frequencies of quality checks are contained in EIR-014: Equipment and Tools List.

2.7. After registration.

- Tag the new instrument with the assigned tag number AV-0??
- Apply void stickers


2.8. New equipment should be validated against old equipment when applicable.

2.9. Any nonconforming results shall be promptly reported to the Quality Manager.

2.10. The Quality Manager shall take the appropriate action as outlined in QM-001, Section 4.9: Nonconforming Testing and/or Calibration Work Policy and Procedure

### 3. Change Control Section

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