AV CONSULTING B.V.
Calibration Laboratory

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AV-Consulting Calibration Laboratory

ISO 17025 Quality Manual

Version QM-001.V3

(dated at last page of this document)

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1. Introduction

AV-Consulting Calibration Laboratory was established in 2001 as an calibration laboratory for sound- en vibration equipment. The company recognizes its responsibility as a provider of quality testing & calibration services. To this end, AV-Consulting Calibration Laboratory has developed and documented a quality management system to ensure customer satisfaction by complying with regulatory requirements and improving management of the company. The quality management system has been designed to comply with international standards ISO/IEC 17025:2005.

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

2. Scope

AV-Consulting Quality System applies to the testing and calibration of (describe type of products, equipment, or industry here) using the appropriate regulatory test methods and specific customer testing requirements.

This document applies to services performed by AV-Consulting Calibration Laboratory when contracts or agreements require “accredited” testing and calibrations or compliance to ISO 17025:2005. These requirements are met whether carrying out work at the permanent laboratory at the laboratory location: Benedenberg 100A, 2861 LH Bergambacht, The Netherlands.

A scope of methods has been established as meeting these requirements and is available for review.

3. References

This manual has been established to meet the requirements of ISO 17025:2005. Subsequently, the principles of the requirements of ANSI/NCSL Z540-1-1994, and ISO 9001:2000 have been met as applicable.

This manual makes reference to AV-Consulting Calibration Laboratory as the “laboratory”.

4. Management Requirements

4.1. Organization

4.1.1. AV-Consulting Calibration Laboratory is incorporated as an private company Ing. buro AV-Consulting B.V. and performs calibrations and tests under the trade name AV-Consulting Calibration Laboratory in Zuid-Holland and is headquartered in Bergambacht, Benedenberg 100A, 2861LH The Netherlands. Our business plan details the specifics of our corporation. Dutch law is required for all disputes concerning the activities and calibrations of AV-Consulting Calibration Laboratory, the parties that do business with AV-Consulting shall agree about Bergambacht The Netherlands as exclusive places of venue.

4.1.2. AV-Consulting Calibration Laboratory is committed to conducting testing and calibration services that satisfy our customer requirements, the requirements of ISO 17025 and requirements of our accrediting body. This is guaranteed in the Quality Commitment and Quality Statement QP-023

4.1.3. The management system as outlined within this quality manual applies and will be followed regardless of where services are rendered (on or offsite).

4.1.4. AV-Consulting Calibration Laboratory provides testing and calibration services and is committed to providing reliable, unbiased test results and interpretations. We are an independent laboratory with strict procedures on Managing Conflicts of Interest (QP-022), Code Ethics and Business Conduct (QP-020), Whistleblower and Protection (QP-021) and Quality Commitment and Quality Statement QP-023.

4.1.5. AV-Consulting Calibration Laboratories personnel

a) The managerial and technical personnel have the authority and resources to carry out their duties; including implementing, maintaining, and improving this management system (site org. charts, budgets, workload metrics and capital plans). The managerial and technical personnel are committed to identifying departures from this management system, our accrediting body's requirements, testing/calibration procedures and customer requirements.

b) Policy: Although AV-Consulting Calibration Laboratory is committed to making reasonable attempts to prevent and minimize such departures, we recognize that departures will occasionally occur. Therefore, it is our policy that any departures shall be explicitly documented and promptly reported to the appropriate parties. AV-Consulting Calibration Laboratory recognizes the risk that personnel may be subjected to commercial, financial, scheduling, and other pressures that may influence their quality of work. Therefore, employees are not permitted to accept gifts or gratuities from clients with a determinable 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). Furthermore, AV-Consulting Calibration Laboratory employees are not permitted to work for another calibration lab, they are bound to the Quality Procedure for Managing Conflicts Of Interest (QP-022). AV-Consulting Calibration Laboratory is committed to conducting business in an ethical manner and will not tolerate any form of bribery or coercion that would compromise the integrity of our calibration and/or test results. Any undue pressures shall be promptly reported to top management ore trustee as described in the procedures Code Ethics and Business Conduct (QP-020), Whistleblower and Protection (QP-021), Quality Commitment and Quality Statement QP-023 and Managing Conflicts of Interest (QP-022). Since there is no practical means of completely insulating our employees from these pressures, the following policies shall be applied in situations where undue pressure affects the quality of work.

   i. If undue pressure exists, employees are encouraged to submit a written complaint to the quality manager or contact the trustee in applicable. As described in Code Ethics and Business Conduct (QP-020) and QP-006 outlines the general formal procedure to be followed when handling complaints and/or concerns.

   ii. In the unlikely circumstance that laboratory personnel deliberately compromise the quality and integrity of their work, the individual will be held accountable for such conduct as deemed appropriate by lab management.

c) AV-Consulting Calibration Laboratory understands the confidential and proprietary nature of our customer's materials, processes and information. It is our policy to protect each customer's information by honoring confidentiality agreements. QP-007: Ensuring Confidentiality during Visits outlines the procedure for ensuring and maintaining customer confidentiality.

d) AV-Consulting Calibration Laboratory is committed to the highest ethical and quality standards. Not only is the management system outlined within this quality manual evidence of our commitment, but also our actions demonstrate these values. QP-020 Procedure Code Ethics and Business Conduct outlines the procedure for ensuring this. AV-Consulting Calibration Laboratory has an procedure to prevent any kind of undo as described in QP-021-Procedure for Whistleblower and Protection Policy. Commitment is made by management and CEO as stated in QP-023 Quality Commitment and Quality Statement. Communication of New documents by are don by the Management System Change Notification (QP-008) using the change notification form FO-006.

e) Refer to section 4.1.1 of this quality manual for a definition of the organization. The structure is outlined in the following organizational chart.

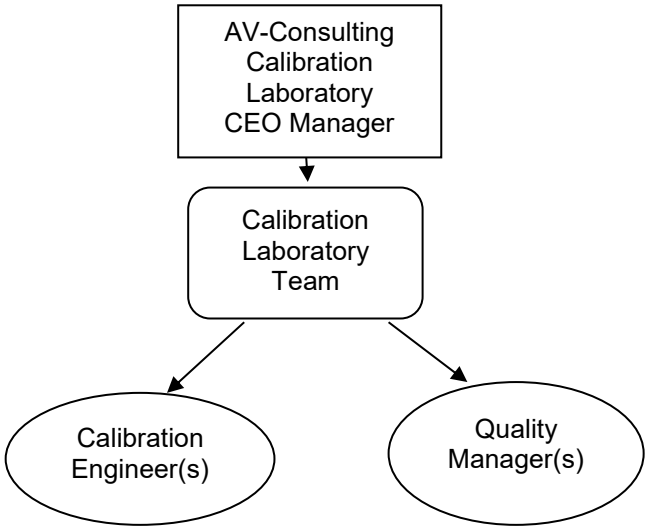

Figure 1: Organizational Chart

f) ISO designated roles are defined in the organizational chart. Each role has the authority to oversee testing and calibration activities and is required to verify results and ensure the overall quality of work.

g) AV-Consulting Calibration Laboratory management team has over 50 years of combined experience in testing. All personnel, including trainees, are under the direct supervision of, and supported by, the management team and/or their designated consultants.

h) The designated technical manager (is this case the CEO) is responsible for technical operations and plans the appropriate resources in the business plan or other appropriate budgets.

i) The quality manager, calibration engineers (and technical manager and deputy, when appropriate, are identified in the organizational chart.

j) The CEO shall act as the deputy of the quality manager when applicable. Two interchangeable calibration engineers ensure continuity of the laboratories work.

k) Additions and changes to the management system are disseminated to laboratory personnel through the QP-008: Management System Change Notification Process. The effectiveness of the management system is evaluated through the management review process outlined in (section 4.15), the complaint handling process (section 4.8) and through the corrective action process (section 4.11).

4.1.6. The CEO and Quality Manager ensures appropriate communication within the laboratory by means of formal and informal work meetings. Work instructions are issued for example WI-003 Electronic Data Interchange, WI-004 Non-Disclosure and WI-012 Work instruction for Managing Conflicts Of Interest. Procedures are outline on QP-020 Procedure Code Ethics and Business Conduct, QP-021-Procedure for Whistleblower and Protection Policy QP-022 Managing Conflicts of Interest. Communication on new documents is done using FO-006: Change Notification and Review Record.

4.2. Management System

4.2.1. AV-Consulting Calibration Laboratory recognizes that our customers' success depends on timely, accurate and impartial information. Therefore, it is our policy to maintain and continuously improve our management system according to the latest version of the ISO 17025 standard and our accrediting body's requirements. Policies and procedures supporting the management system are outlined by this quality manual and in referenced documents.

The Quality Manager and leadership team are responsible for disseminating, communicating, implementing and ensuring compliance with the management system. QP-009: Management System Change Notification outlines the official notification procedure.

4.2.2. Management System Quality Policy

a) AV-Consulting Calibration Laboratory is committed to providing our customers with professional high quality service. This commitment is insured and endorsed in documents QP-023 Quality Commitment and Quality Statement and QP-020 Procedure Code Ethics and Business Conduct.

b) All testing and/or calibration activities shall be carried out in accordance with stated methods and our customers' requirements. Our standard for service will exceed our customer expectations for accurate, repeatable and impartial test results. To assure the quality of test equipment the there is a procedure "QP-011 Periodic Quality Checks of Calibrated Devices" , "QP-015-Insure Calibration Certificate ISO-17025" and "QP-019 Computer Software Validation".

c) The purpose of this management system is to define a standard approach for providing the highest quality service. Moreover, the management system ensures continuity despite changes in personnel or management. The quality manual serves also as a communication tool as well as a training tool for new employees, next to QP-018 Procedure of new Employee's.

d) All personnel conducting and reporting testing activities shall be familiar with this quality manual as well as other procedures and work instructions that affect the quality of their work.

e) Our leadership team is committed to complying with ISO 17025 and our accrediting body's requirements. We will continually assess and improve the effectiveness of this management system as appropriate. All comments on our work will be carefully evaluated. Our credo; Any comment or complaint is a chance to get even better!

4.2.3. Management is committed (QP-023 Quality Commitment and Quality Statement) to implementing and continually improving this management system as noted in section 4.2.2.e. Our commitment and endorsement is demonstrated through ongoing participation in activities that assess and ensure the integrity of this system and through providing the appropriate resources. Evidence of meeting this commitment includes management review records, preventative actions, corrective actions, and customer surveys.

4.2.4. It is critical that all personnel comply with our customer requirements as well as the relevant statutory and regulatory requirements. To support this, all employees will receive basic training about the quality system and customer expectations as outlined in QP-018: Procedure for New Employee's. Formal checks are made in checklists FO-017 New Employee Checklist (Dutch).

4.3. Outline of Management System Documents

4.3.1.1. The following five categories of documentation exist in AV-Consulting Calibration Laboratory management system:

Level 1	The international standard for this management system (ISO 17025).
Level 2	Include the quality manual and supporting procedures. These documents outline the standard approach and requirements for ensuring the integrity of our management system. Level 2 documents apply to all testing and calibration activities performed by AV-Consulting Calibration Laboratory
Level 3	Include job descriptions, general guidelines, work instructions, internal test and calibration methods. These documents provide detailed directions, specifications and criteria and instruct personnel how to complete tasks in a satisfactory manner.
Level 4	Include forms, labels, tags, etc.
Normative	Include the ISO 17025 standard, national and international standards and policy included within the scope of accreditation such as RvA, ISO, UL, ILAC, IEC, EU- standards etc. and our accrediting body's (RvA) requirements. The latest version and dissemination of such documents is controlled by the associated organization.

4.3.1.2. Supporting documents and sections of this quality manual are referenced throughout this quality manual as appropriate.

4.3.1.3. AV-Consulting Calibration Laboratory document types and identification:

Prefix	Document Type
QM-	Quality Manual
TD-	Test Lab Fixtures, Technical Documents, Tools
TM-	Test Machines
CM-	Internal Calibration Method
QP-	Quality Procedures
WI-	Work Instructions
FO-	Forms
EIR-	Electronic Information Repository (such as document management systems, network directories, databases, spreadsheets, lists, etc.)
CAR-	Corrective Action Report
PAR-	Preventative Action Report
UC-	Uncertainty Estimate Certificate
AVC-	Calibration Certificate
AV-	Lab Equipment Data and Instruments
EA-	European Accreditation
ILAC-	International Laboratory Accreditation Cooperation
RvA-	Raad voor Accreditatie

4.3.1.4. A complete listing of documents is outlined in EIR-013: Records and Document List.

4.3.1.5. Roles and Responsibilities of Technical and Quality Management

Role	Job Description	Responsibilities
Technical Manager	Calibration Engineer	Ensuring that the technical requirements of the ISO 17025 standard and of this management system are met.
Quality Manager	Quality Manager	Ensuring compliance to ISO 17025 and accrediting body's requirements. Controlling content and administration of the Quality Manual. Designated authority for approving the quality manual, policies and procedure. Authorized to take action as seen fit in case wrong do, conflict of interest and conflicts with code of ethics etc.

4.3.1.6. During changes and improvements to the management system, the leadership team will monitor the system and results as appropriate to ensure that the overall integrity is maintained.

4.3.2. Document Control Procedure

4.3.2.1. General

Purpose	The purpose of the document control procedure is to define the system of control for approving, issuing, changing and distributing documents that form the management system.	
Scope	The scope of documents covered by this section includes those that pertain to the management system. See section 4.3.1.1. for an outline of the documents. Note: control of data related to testing and calibration is covered in section 5.4.7 control of records is covered in section 4.13. This procedure applies to all testing and calibration activities performed by AV-Consulting Consulting Calibration Laboratory.	
Responsibility	Document Control	The quality manager is responsible for document control and has the responsibility to review, control and maintain the management system documents.
	Originator	Creates and modifies documents as needed.
	Reviewer	Reviews and offers input in a timely manner.
	Approver	Review and approves documents in a timely manner.
	User	Ensures that the latest approved version of the document is being used, responds to the need for new documents and proposes changes to approved documents as appropriate.

4.3.2.1.1. Document control procedure for level 1-4 documents (content is internally controlled and disseminated)
Level 1-4 documents are created, maintained, changed, approved, issued and disseminated in an electronic format. The electronic copy is the only controlled copy of the document. A complete listing of documents and their latest versions may be found in section 4.3.2.2.1. All printed copies are not controlled.

4.3.2.1.2. Document control procedure for normative documents (content is externally controlled and disseminated). Refer to section 4.2.5.1 for a description of normative documents.
Normative documents are maintained and disseminated by the associated organization. The controlled copies of these documents are maintained in a combination of hard copy and electronic format. The latest versions of these documents may be confirmed by accessing the associated organizations website. A complete listing of documents and their latest versions may be found in section 4.3.2.2.1.

4.3.2.2. Document Approval and Issue

4.3.2.2.1. All documents in the management system shall be reviewed and approved by the quality manager and/or the designed deputy prior to issue. The master list of documents is contained within EIR-013 Records and Documents List used within the quality system.

4.3.2.3. Ensuring Document Integrity

4.3.2.3.1. Authorized versions of the documents are identified in the master document list noted in section 4.3.2.2.1. This list and documents are available to all authorized personnel as needed.

4.3.2.3.2. The documents are reviewed annually and revised as needed to ensure continuing suitability with applicable requirements.

4.3.2.3.3. Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use. The procedure for obsolescing documents is described in QP-014 Document Control

4.3.2.3.4. Obsolete documents (electronic and hard copies) retained for legal or knowledge preservation purposes are suitably marked as “OBSOLETE” ad stored the quarantined directory EIR-020 Obsolete Documents.

4.3.2.4. Document Identification

4.3.2.4.1. Management system document types are determined based on section 4.3.1.3.

4.3.2.4.2. Documents are uniquely identified with the appropriate prefix and a three digit suffix. For example: QP-001 (the QP designates a quality procedure and the 001 designates the specific procedure number)

4.3.2.4.3. Each document shall contain a change control section that includes the document version, revision date, change control comments and document approver. Issuing authority is the CEO.

4.3.2.4.4. Each document page shall be numbered with the current page number as well as the total number of pages within the document.

4.3.2.4.5. Each page of the document shall contain the document version number.

4.3.3. Document Changes

4.3.3.1. Changes to documents shall be reviewed and approved by the quality manager. The originator of the new document or change shall provide an appropriate amount of background information in the change control comments of the document to provide appropriate context.

4.3.3.2. The altered document text or section shall be explicitly noted in the change control comments.

4.3.3.3. Amendments to document by hand, prior to reissue is acceptable providing that the amendment is clearly marked, dated and initialed by the quality manager. The quality manager is responsible for promptly reissuing the document.

4.3.3.4. Electronically controlled documents shall be protected against inadvertent/unauthorized changes by password protecting the documents against change. The quality manager and/or designee shall maintain a confidential password for altering document content. The process is described in QP-013-Storing and Protection of Document.

4.3.4. Notification of New or Modified Documents

4.3.4.1. A change notification, using FO-006: Change Notification and Review Record, is sent to all affected personnel once a new document version is authorized.

4.3.4.2. Review records of change notifications are maintained by the quality manager.

4.4. Review of Requests, Tenders and Contracts Policy and Procedure

Purpose	The purpose of the review policy and procedure is to ensure that the methods and customer requirements are adequately defined and understood, to ensure that the laboratory has the appropriate resources and capability to conduct the test and the method(s) selected is appropriate and meets the customer's requirements.	
Scope	This procedure applies to all personnel responsible for accepting test requests, tenders and/or contracts.	
Responsibility	Customer	Appropriately describing their need and purpose of test and specifying the methods to be used.
	Reviewer	Reviews request for the appropriate information and offers input in a timely manner.
		Accepts requests and contracts upon satisfactory review.
		Notifies affected personnel of changes to the original request or contract.
	All Personnel	Promptly notify the customer of any deviations from the request or contract.

4.4.1. The procedure on Review of Requests, Tender and Contracts is described in the procedure QP-017. All requests, tenders and contracts shall be reviewed prior to acceptance. Checklist FO-013 Contract and Tender Checklist is to be used: At a minimum, the review should consist of the following

a) Review the purpose (customer need), the methods to be used

b) Confirm that the laboratory has the appropriate capability (laboratory acceptance of the request is sufficient evidence of confirmation)

c) Confirm that the selected methods are appropriate for meeting the customer requirements. (laboratory acceptance of the request is sufficient evidence of confirmation)

d) If appropriate, confirm consistency between the request or tenders and contract(s).

e) Initial of accepting personnel and date of acceptance. The act of initialing and dating signifies that the review has been completed.

4.4.2. Records of reviews, including significant changes, pertinent discussions relating to the customer's requirements during execution of the contract, shall be maintained as described by QP-004: Records Maintenance and Retention Procedure.

4.4.3. Subcontracted work - when applicable - shall be subject to the same review procedure as outlined in sections 4.4.1 and 4.4.2.

4.4.4. The customer shall be promptly notified of any deviation from the request or contract.

4.4.5. The process shall be repeated for any changes that occur when the request or contract has been accepted. The reviewer of the change shall communicate the change to the affected parties.

4.5. Subcontracting of Tests and Calibrations Policy and Procedure

Purpose	The purpose of subcontracting policy and procedure is to ensure that subcontractors are competent to perform tests and/or calibrations and meet ISO 17025 requirements for such work. It is intended to define the procedures that will be followed when subcontracting work.	
Scope	This procedure applies to all personnel responsible for subcontracting tests and/or calibrations covered by the scope of accreditation.	
Responsibility	Quality Manager	Maintaining the list of registered contractors
		Ensure that subcontractor meet the ISO 17025 requirements.
	Originator	Initiate and follow this procedure when subcontracting.
		Notify appropriate parties of intent to subcontract.

4.5.1. From time to time AV-Consulting Calibration Laboratory may subcontract work based on workload, expertise or temporary incapacity or to ensue new business relationships. As required, AV-Consulting Calibration Laboratory will make the appropriate arrangements to ensure that the customer's and ISO 17025 requirements are met.

4.5.2. The originator of subcontracting shall provide the customer with a letter of intent to subcontract using form FO-008. Although other means of granting approval are acceptable (i.e. emails, voicemails, verbal), the customer should preferably sign, date and return the form granting approval.

4.5.3. Except in cases where the customer or regulatory authority dictates a subcontractor to be used, AV-Consulting Calibration Laboratory is responsible for the subcontracted work and ensuring that methods are followed, deviations are noted, and the customer is satisfied with the outcome.

4.5.4. Register of Subcontractors

4.5.4.1. The register of subcontractors is maintained in EIR-016: Register of Subcontractors.

4.5.4.2. The register of subcontractors includes a listing, by name, of testing subcontractors used for testing and/or calibration, their contact information, field of accreditation and a link to their accreditation certificates.

4.5.4.3. The list is periodically reviewed and updated by the Quality Manager.

4.6. **Purchasing Services and Supplies Procedure**

Purpose	The purpose of purchasing services and supplies procedure is to ensure that services and materials meet basic quality standards required by regulatory standards, the customer and AV-Consulting Calibration Laboratory It is intended to define the procedures that will be followed when procuring services and supplies.	
Scope	This procedure applies to all purchasing agents procuring supplies or services related to testing or calibration activities.	
Definitions	Purchasing Agent	Anyone who purchases materials or services for AV-Consulting Calibration Laboratory
	Consumer	End user of the consumable material or service.
Responsibility	Quality Manager	Maintaining the list of consumable materials.
		Maintain consumable supply quality certificates.
	Purchasing employee	Initiate and follow this procedure when purchasing supplies or services related to testing or calibration activities.
	Consumer	Ensures that the consumable supplies are identified with an expiration date and suitable for use.

4.6.1. Materials and services shall be selected based on the appropriate requirements. These include test or calibration standard requirements, customer requirements and AV-Consulting Calibration Laboratory quality control requirements. A comprehensive list of consumable materials is maintained in EIR-015: Consumable Supplies List.

4.6.1.1. Supplies and services may be obtained by initiating a purchase order through our PO system, by using cash, or a credit card.

4.6.1.2. Incoming consumable materials shall be stored in an area to prevent use prior to inspections.

4.6.2. Upon receipt, the purchasing agent shall verify that the consumable materials comply with the appropriate specifications or otherwise coordinate inspection of incoming supplies prior to use.

4.6.2.1. Quality certificates, certificate of conformance and inspection records shall be maintained by the quality manager.

4.6.2.2. When a purchase order is used, the purchase order shall contain the requirements/specifications for the respective supplies. These documents shall be reviewed and approved by the quality manager or designee prior to release.

4.6.2.3. The quality manager shall or designee shall initial and date purchase orders that affect the quality of tests or calibrations.

4.6.3. Approved suppliers are evaluated based on ability to consistently deliver consumable materials that meet the appropriate specifications. A record of review and list of approved suppliers is maintained in EIR-016: Register of Subcontractors.

4.6.4. A list of supplier evaluations is maintained in EIR-016: Register of Subcontractors in the tab titled “Record of Evaluation”.

4.7. **Customer Service Policy and Procedure**

Purpose	One of AV-Consulting Calibration Laboratory primary business objectives is to generate repeat business. This is vital to the ongoing success of our organization. The purpose of the customer service policy and procedure is to ensure a consistent approach to providing excellent customer service. This is stated and indorsed in QP-023 Quality Commitment and Quality Statement.	
Scope	This procedure applies to all personnel interacting with the customer.	
Definitions	Customer	The recipient of the product or service supplied by AV-Consulting
	Laboratory Rep.	Individual interacting with the customer on behalf of AV-Consulting
Responsibility	Quality Manager	Maintain a record of solicitations for customer feedback and responses.
	Laboratory Rep.	Initiate and follow this procedure when interacting with the customer.

4.7.1. All personnel shall cooperate with the customer and/or representatives in clarifying requests, monitoring the laboratories performance and maintaining the highest level of confidentiality.

4.7.1.1. Customers shall be provided with reasonable access to the appropriate areas of the lab for the purpose of witnessing testing and calibration activities. Procedure QP-007 shall be followed to ensure confidentiality during visits.

4.7.1.2. Customers shall have access to test materials and/or calibration items for the purpose of verification. Procedure QP-007 shall be followed to ensure confidentiality.

4.7.1.3. Our customers value responsive service and ongoing communication regarding the status of their work. Any threats to the timing or delivery of services shall be promptly reported to the AV-Consulting Calibration Laboratory leadership team and customer.

4.7.2. In order to evaluate our performance and improve our service, periodic feedback shall be solicited from the customers during and upon completion of requests or contracts. The feedback shall be disseminated to the appropriate audience, summarized and reviewed during management review sessions. Form FO-010: Customer Survey Form shall be used to get feedback from customers. Also on the website there is a customer feedback option: https://calibration-lab.com/contact-kalibratie-lab/klanttevredenheid-feedback-kalibratie/.

4.8. Complaint Handling Policy and Procedure

Purpose	The purpose of the complaint handling policy and procedure is to define a standard approach for recording, investigating and responding to customer complaints.	
Scope	This procedure applies to customer complaints and internal complaints regarding the quality and technical aspects of testing and calibration. Examples include accuracy, uncertainty, report content and implementation of the quality system. This procedure is not intended to cover non-technical aspects such as lead time, hours of operation, and interpersonal conflict.	
Responsibility	Quality Manager	Investigate the complaint and need for action.
		If appropriate, promptly issue a corrective action for the complaint.
		Validate corrective action is implemented and effective.
	Calibration Engineer	Investigate the technical aspects of the complaint and initiate changes to permanently correct the situation. Document change in corrective action document.

4.8.1. Complaints (either internal or external) shall be handled in a timely manner. The internal complaint procedure is outlined in QP-006: Internal Complaints and Concerns. If applicable and necessary procedure QP-021-Procedure for Whistleblower and Protection Policy or QP-022 Managing Conflicts of Interest shall be followed

4.8.2. Complaints shall be directed to the Quality Manager and logged into EIR-018: Complaints Log. The Quality Manager or designee will investigate the complaint and determine the appropriate course of action.

4.8.3. If the investigation shows that the complaint is invalid, the originator of the complaint shall be notified of the findings and that this issue is closed. If a complaint is appealed, a new investigation will commence.

4.8.4. If the investigation reveals a problem, the quality manager shall be immediately notified, a corrective action shall be initiated per section 4.11 and the control of non-conforming work procedure shall be followed per section 4.9.

4.8.5. A written response detailing the findings of the investigation and ensuing actions shall be sent to the originator of the complaint and appropriate audience.

4.8.6. Complaints shall be summarized and reviewed during management review sessions.

4.9. Nonconforming Testing and/or Calibration Work Policy and Procedure

Purpose	The purpose of the control of nonconforming testing and/or calibration work procedure is to ensure reliable test and calibration results and to provide a standard procedure for containing and correcting results that do not conform to the agreed requirements of the customer.	
Scope	This procedure applies to all testing and/or calibration activities.	
Definitions	Nonconforming Work	Includes any work that does not conform to the agreed requirements of the appropriate methods (internal or external), standards and customer.
Responsibility	Quality Manager	Investigate the situation and need for action.
		If appropriate, promptly issue a corrective action for the complaint.
		Validate corrective action is implemented and effective.
		Authorize resumption of work
	Technical Manager	Investigate the technical aspects of the situation and initiate changes to permanently correct the situation. Document change in corrective action document.
	All personnel	Responsible for halting nonconforming work and following this procedure.

4.9.1. Any testing or calibration activities that do not or are suspected of not conforming to the appropriate requirements shall be reported to and promptly investigated by the quality manager or designee.

a) All laboratory personnel involved in testing and/or calibration activities have the authority and are responsible for halting work and withholding test reports and calibration certificates when nonconforming work is identified.

b) The individual halting the work shall promptly report the situation to the Quality Manager. Together, the individual halting the work and Quality Manager shall evaluate the significance and/or acceptability of nonconformance and the extent of nonconformance on previous testing or calibration.

c) A corrective action shall be immediately initiated per section 4.11.

d) The Quality Manager or designee shall notify the affected parties, as appropriate, and recall nonconforming work.

e) Once the corrective action is implemented and verified effective, the Quality Manager or designee shall authorize resumption of work.

f) To establish a procedure for the control and disposition of nonconforming equipment, sensors, products and materials, to prevent unintentional use or shipment procedure QP-012 “Non Conformity” shall be followed.

4.9.2. The correction action procedure per section 4.11 shall be followed in the event that nonconforming work may recur or that internal policies and procedures are suspect.

4.10. **Continuous Improvement Policy**

4.10.1. AV-Consulting Calibration Laboratory shall regularly monitor and continuously improve the effectiveness of the management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review.

4.10.2. The effectiveness of the management system is continuously evaluated informally and is formally evaluated at least once per year during the management review process as outlined in section 4.15. Corrective actions, internal complaints or concerns, proficiency testing, and customer feedback are other means through which the effectiveness of the management system is evaluated.

4.10.3. The preventive action procedure shall be followed when opportunities are identified for improvement.

4.10.4. Additions and changes to the management system are disseminated to laboratory personnel as outlined in QP-008: Management Change Notification.

4.11. **Corrective Action Policy and Procedure**

Purpose	The purpose of the corrective action policy and procedure is to define a standard approach for solving problems.	
Scope	This applies to all problems identified while completing day to day tasks or performing testing and calibration activities. Typical problems involve deficiencies with the management system, audit findings, customer complaints and nonconforming work.	
Definitions	Countermeasure	One possible solution in a set of possible solutions to a problem.
	Problem	Nonconformance with the management system, ISO requirements, test or calibration specification, accrediting body requirements or customer requirements.
Responsibility	Quality Manager	Evaluate need for corrective action.
		Maintain a record of and log of corrective actions.
		Verify and monitor the effectiveness of corrective actions.
	Originator	Initiate and follow this procedure when solving problems within the scope of this policy.

4.11.1. All personnel have the authority and responsibility for initiating a corrective action when nonconforming work (section 4.9) or departures from the policies and procedures in the management system or technical operations have been identified.

4.11.1.1. The originator of the corrective action shall notify the Quality Manager. The Quality Manager shall evaluate the situation and the need for corrective action.

4.11.1.2. Each corrective action shall be documented using FO-004: Corrective Action Report. Each CAR shall be uniquely identified as a CAR-XXX and maintained in EIR-005: Corrective Action Repository.

ISO 17025 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, and feedback from customers and staff observations.

4.11.4. A scientific approach to problem solving shall be used for the corrective action process. AV-Consulting Calibration Laboratory uses an approach modeled after the Plan, Do, Check, Act approach developed by Toyota in 1930's and is still one of the most effective methods.

4.11.4.1. PLAN: The originator of the CAR shall complete a thorough root cause analysis of the problem. There are various approaches to root cause analysis that depend on the situation. The preferred approach is the "5 why" approach that addresses why the problem was caused and why the problem was allowed to persist. Effective use of this approach isolates one problem with one cause that can be turned on and off.

4.11.4.2 DO: Possible countermeasures shall be identified (hypotheses) and experimentally evaluated.

4.11.4.3. CHECK: Experimental results are evaluated against hypothesis. The quality manager or designees shall monitor the experiment for an appropriate period of time to determine if the countermeasure is effective.

4.11.4.4. ACT: Upon satisfactory completion of this process the appropriate steps are taken to adopt the countermeasure as new standard practice and the appropriate personnel are notified.

4.11.5. Internal audits according to 4.14 shall promptly occur to ensure compliance with the management system, ISO 17025 and our accrediting body's requirements.

ISO 17025 Note: Such additional audits often follow the implementation of the corrective actions (during the ACT process) to confirm their effectiveness. An additional audit should be necessary only when a serious risk to the business is identified.

4.12. Preventive Action Policy and Procedure

Purpose	The purpose of the preventive action policy and procedure is to define a standard approach for identifying and solving potential nonconformance.	
Scope	This applies to potential or anticipated problems identified while completing day to day tasks or performing testing and calibration activities. Typical problems involve deficiencies with the management system, audit findings, customer complaints and nonconforming work.	
Definitions	Countermeasure	One possible solution in a set of possible solutions to a problem.
	Problem	Nonconformance with the management system, ISO requirements, test or calibration specification, accrediting body requirements or customer requirements.
Responsibility	Quality Manager	Evaluate need for preventive action.
		Maintain a record of and log of preventative actions.
		Verify and monitor the effectiveness of preventive actions.
	Originator	Initiate and follow this procedure when solving problems within the scope of this policy.

4.12.1. All personnel have the authority and responsibility for initiating preventative actions when the potential for nonconformance exists and is identified.

4.12.1.1. The originator of the preventive action shall notify the Quality Manager. The Quality Manager shall evaluate the situation and the need for preventive action.

4.12.1.2. Each preventive action shall be documented using FO-005: Preventative Action Report. Each PAR shall be uniquely identified as a PAR-XXX and maintained in EIR-006: Preventive Action Repository.

ISO 17025 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, and feedback from customers and staff observations.

4.12.2. A scientific approach to problem solving shall be used for the preventive action process. AV-Consulting Calibration Laboratory uses the Plan, Do, Check, Act approach developed by Toyota. This approach is outlined in section 4.11.

4.13. **Control of Records Policy and Procedure**

Purpose	The purpose of the control of records policy and procedure is to define a standard approach for controlling records.	
Scope	This applies to all records related to the management system and test or calibration activities.	
Definitions	Authorized Personnel	Any individual or contractor working directly or indirectly for AV-Consulting Calibration Laboratory bound by a signed confidentiality agreement.
	Technical Records	Accumulations of data (see section 5.4.7) and information which result from carrying out test 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, calibration certificates, customers' notes, papers and feedback.
Responsibility	Quality Manager	Identify records and ensure the control of records policy is implemented and followed.
	Authorized Personnel	Follow this procedure when creating, retrieving, storing or distributing records.

4.13.1. Records shall be uniquely identified, collected, indexed, disposed and stored with appropriate security to protect against breaches in confidentiality and damage.

4.13.1.1. Refer to QP-004: Records Maintenance and Retention Procedure for a complete listing of record types, associated forms, retention times, transmission, and handling procedures.

4.13.1.2. Records shall be legible and are stored per section 4.13.1.1. This procedure was developed to prevent damage, deterioration, and loss. Retention times are assigned per section 4.13.1.1.

4.13.1.3. All records are stored in a secure location as specified in section 4.13.1.1. and are accessible to authorized personnel only.

4.13.1.4. Electronic records are maintained on a secure location as defined by 4.13.1.1 and are backed up real time through the use of a redundant RAID enabled network drive and are protected against unauthorized access and amendment through the use of a secure network and document passwords (as appropriate). Procedure QP-013-Storing and Protection of Document is part of this. Electronic Backup is automatic monitored on the server, CEO end/or quality manager shall receive an automated e-mail on the status of the back-up, an example is given in document FO-018.

4.13.2. Technical Records

4.13.2.1. The procedure for storing Technical records such as original observations, derived data, calibration records, staff records, test reports and calibration certificates are maintained based on QP-004: Records Maintenance and Retention Procedure.

4.13.2.1.1. The required information by record type is outlined in the associated form. This required information shall be sufficient enough to identify sources of uncertainty and enable the test or calibration to be repeated under conditions similar to the original.

4.13.2.2. All observations are record recorded at the time they occur. Observations are date and time stamped.

4.13.2.3. When mistakes occur, each mistake shall be crossed out, (but not erased, deleted or made illegible), and corrected alongside the original entry. Alterations to records shall be initialed by the individual making the correction.

4.13.2.3.1. Electronic alterations shall be made to ensure loss or alteration of original data. The preferred process should involve preserving and original copy of the original data prior to making changes.

4.14. **Internal Audit Policy and Procedure**

Purpose	The purpose of the internal audit policy and procedure is to define a standard approach and frequency for auditing the management system and testing and calibration activities.	
Scope	Internal audits encompass all testing and calibration activities included in the scope of accreditation.	
Definitions	Auditor	Individual conducting the audit.
Responsibility	Quality Manager	Ensure that internal audits are completed on a timely basis, at the frequency specified by the management system, by qualified personnel.
	Auditor	Perform an audit of the management. Document concerns and nonconformance and supply an audit report.

4.14.1. Internal and external audits shall be performed using ISO/IEC 17025 as the basis of the audit. Whenever possible, internal audits shall be conducted by an independent and impartial third party. The lab shall provide appropriate accommodations for auditing activities. Internal quality system audits shall be conducted annually between the months of October and December. Internal audits shall adhere to the following rotation schedule to assure that all tests, within the scope of accreditation, are audited within two internal audit cycles.

Audit Cycle	Scope of Audit
Odd Year Audits	ISO 17025 Section 5.1 - 5.10.9 (assessment of random sections)
Even Year Audits	ISO 17025 Section 4.1 – 4.15 / 5.1 - 5.10.9 (assessment of random sections)

QP-010: Quality Procedure for Internal Audits and Reviews AV-Consulting and QP-016-Consistent approach for conducting internal audits by use of a Standard Audit Checklist is used to provide a consistent approach for conducting internal audits and reviews.

4.14.2. The Quality Manager is responsible for initiating and completing corrective and/or preventive actions per sections 4.11 and 4.12.

4.14.3. If nonconforming work is discovered, Section 4.9.1: Control of Nonconforming Testing and/or Calibration work shall be employed.

4.14.4. The results of any audit performed shall be submitted in writing to the Quality Manager.

4.14.5. A follow up audit at the appropriate time in the corrective action process will be conducted to validate effectiveness of the corrective action(s).

4.15. **Management Review Policy and Procedure**

Purpose	The purpose of the management review policy and procedure is to define a standard approach and frequency conducting management reviews.	
Scope	Management reviews encompass all testing and calibration activities included in the scope of accreditation.	
Responsibility	Quality Manager	Ensure that management reviews are completed on a timely basis, at the frequency specified by the management system, with the appropriate personnel.

4.15.1. Management reviews shall be conducted on an annual basis between around October - December as outlined in QP-024 “Quality Procedure for Management Review”.

4.15.1.1. FO-007: Management Review Form shall be used to document the management review agenda and meeting minutes. The management review shall consider, but not be limited to, the following:

- Actions taken since the previous management review
- Suitability of policies and procedures.
- Reports from managerial and supervisory personnel.
- Outcome of recent audits.
- Effectiveness of previous actions.
- Corrective and preventive actions.
- Assessments by external bodies.
- Technical Leader annual report.
- Results of inter-laboratory comparisons or proficiency tests.
- Changes in the volume and type of the work.
- Client feedback.
- Complaints.
- Recommendations for improvement.
- Non-conformity Records
- Work Authorizations
- Other factors, such as quality control activities, resources, and staff training.
- Resulting assignments
- Quality control activities
- Recommendations for improvement
- Changes in the volume and type of work

4.15.2. Findings and resulting assignments shall be recorded and completed within an appropriate timeframe. Assignment time frames shall be established during the management review.

5. Technical Requirements

5.1. General Procedures

5.1.1. Many factors determine the correctness and reliability of the tests and/or calibrations performed by the laboratory. At a minimum, the following factors are considered with varying degrees of significance:

- Human (section 5.2)
- Accommodation and environmental conditions (section 5.3)
- Test and calibration methods and method validation (section 5.4)
- Equipment (section 5.5)
- Measurement traceability (section 5.6)
- Sampling procedures (section 5.7)
- Handling of test and calibration items (section 5.8)

5.1.2. AV-Consulting Calibration Laboratory evaluates and considers the significance of each factor both quantitatively and qualitatively as appropriate for the particular test or calibration activity. Evaluation and understanding of the factors leads to improved controls for monitoring, stabilizing and lowering overall uncertainty. Specific procedures for each factor are outlined in 5.2-5.8. sections

5.2. **Procedure for Ensuring Competent Personnel**

Purpose	The purpose of the competent personnel procedure is to ensure, maintain and develop competency in all areas of test and calibration. In addition the procedure should enable smooth transfers of responsibility and mitigates the risk of losing key personnel.	
Scope	Includes all activities related to testing and calibration, the application of the management system and management.	
Definitions	Trainee	Individual undergoing training to develop competency in a specific area.
Responsibility	Quality Manager	Institute a training program and ensure the requirements of this procedure are met.
	All personnel	Seek the appropriate support when uncertain of skills and competence.
	Trainee	Document training activities and plans in the appropriate locations.

5.2.1. AV-Consulting Calibration Laboratory ensures the competence of all personnel performing testing and/or calibration activities. Activities include performing tests and calibrations, evaluating results, signing test reports and calibration certificates.

5.2.1.1. Form FO-017 New Employee Checklist (Dutch) is to be used to when new personal is hired.

5.2.1.2. Quality Procedure for New Employee's AV-Consulting (QP-018) assures that 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.

5.2.1.3. Personnel are issued the following document (in Dutch) to insure they are completely informed about the laboratory regulations, rules, rights and obligations: "WI-005 Personeelshandboek, WI-006 Bewerkingsovereenkomst, WI-011 Risico Inventarisatie en Evaluatie".

5.2.1.4. AV-Consulting Calibration Laboratory assesses competence through a variety of means as appropriate. Such means include:

- Education
- Training
- Experience
- Demonstration of skills

5.2.1.5. In areas that require technical certification, AV-Consulting Calibration Laboratory will fulfill the requirements as required.

5.2.2. AV-Consulting Calibration Laboratory shall assess the knowledge, skills and attitudes of personnel performing test and calibration activities. Such assessments evaluate the effectiveness of training and shall result in a training plan that satisfies the identified need. General educational and training goals include:

- More than 1 individual trained and competent to perform tests under the scope of accreditation.
- Evaluate competence through internal audits
- Actively seek and participate in proficiency testing offered within our field.
- Personnel attend in two training seminars per year (as appropriate)

5.2.3. Only personnel who are employed by or contracted to AV-Consulting Calibration Laboratory shall perform test and calibration activities. All work shall be supervised and completed in accord with this management system. Any contracted personnel shall supply a resume detailing education, training and previous experience. In addition, contracted personnel should supply personnel references prior work.

5.2.4. Job descriptions for employees are maintained in the EIR-019: Job Descriptions Repository.

5.2.4.1. At a minimum, these job descriptions include:

- Responsibilities while performing tests and/or calibrations;
- Responsibilities while planning tests and/or calibrations and evaluating results;
- Responsibilities for reporting opinions and interpretations;
- Responsibilities for developing, modifying and validating new methods;
- Required expertise and experience
- Qualifications and training programs
- Managerial Duties (if any)

5.2.5. Personnel are authorized to perform work upon satisfactory demonstration of competence. Records of authorizations are maintained in individual training records.

5.3. Accommodating and Environmental Conditions Policy and Procedure

Purpose	The purpose of environmental conditions policy and procedure is to create and maintain an environment that is suitable for testing and calibration and ensure that it meets the requirements of the governing standards.	
Scope	Includes all areas where testing and calibration activities are performed.	
Responsibility	Quality Manager	Ensure the requirements of this procedure are met.
	All personnel	Monitoring and recording pertinent environmental conditions as outlined in this procedure.

5.3.1. The AV-Consulting Calibration Laboratory facility provides an environment that facilitates the correct performance of tests and calibrations. Our facility is supplied with reliable electrical service, overhead fluorescent lighting, and an HVAC system capable of sustaining the environmental conditions specified by governing standards. Unless otherwise specified, these conditions include:

5.3.1.1. The relevant environmental conditions shall be monitored and recorded at the time observations are made.

5.3.2. AV-Consulting Calibration Laboratory controls, monitors and records the relevant environmental conditions as required by governing standards. All testing shall be paused when environmental conditions are present that threaten accurate test and/or calibration results. Threatening environmental conditions may include:

- Biological sterility
- Dust
- Electromagnetic disturbances
- Radiation
- Temperature and Humidity
- Electrical supply
- Noise and vibration

5.3.3. AV-Consulting Calibration Laboratory facility is isolated from neighboring areas with incompatible activities and the appropriate countermeasures have been implemented to prevent cross contamination. The laboratory is actually situated near an area that is planned as quiet (“Stiltegebied” in Dutch).

5.3.4. Access to the testing facility is controlled to maintain confidentiality and prevent unauthorized modification of tests. The lab is code locked and not directly accessible from the outside.

5.3.5. Good housekeeping is maintained to ensure a safe, clean, efficient and productive work environment.

5.4. **Test and Calibration Methods and Method Validation Policy and Procedure**

5.4.1. General Method Policies and Procedure

5.4.1.1. AV-Consulting Calibration Laboratory uses methods and procedures that are appropriate for all the tests and calibrations for testing and calibration activities.

5.4.1.2. When the absence of a work instruction jeopardizes the results of a test or calibration, work instructions that detail procedures for operating equipment, and handling and preparation of items are provided.

5.4.1.3. Work instructions, standards, manuals and reference data are maintained in a current state and subject to the document control procedure in section 4.3. Section 4.4 details handling and reporting deviations from procedures.

5.4.2. Method Selection Policy

5.4.2.1. AV-Consulting Calibration Laboratory only uses methods which meet the needs of the customer and are appropriate for the tests and/or calibration services provided.

5.4.2.2. Unless otherwise specified, AV-Consulting Calibration Laboratory only uses internationally, nationally or regionally accepted standards. Any methods selected by the laboratory shall be approved for use by the customer prior to test or calibration. As noted under section 4.4, AV-Consulting Calibration Laboratory will perform the appropriate review of its capability prior to recommending standards.

5.4.2.3. Unless otherwise specified, only the latest version of the standard will be used. As appropriate, methods will be supplemented with additional details to ensure consistent application and interpretation.

5.4.2.4. AV-Consulting Calibration Laboratory will notify its customers if a selected method is considered inappropriate or becomes out of date.

5.4.2.5. AV-Consulting Calibration Laboratory does not develop methods for its own use under the scope of accreditation.

5.4.3. In House Method Development Policy

5.4.3.1. AV-Consulting Calibration Laboratory does not develop test or calibration methods for its own use under the scope of accreditation.

5.4.4. Non Standard Methods Policy

5.4.4.1. AV-Consulting Calibration Laboratory does not offer nonstandard tests under the scope of accreditation.

5.4.4.2. Any nonstandard test or calibration services provided shall be documented with enough detail to sufficiently reproduce the test.

5.4.5. Validation of Non Standard Methods Policy and Procedure

5.4.5.1. AV-Consulting Calibration Laboratory does not offer Non Standard Methods for test or calibration services under the scope of accreditation.

5.4.6. Estimation of Measurement Uncertainty Policy and Procedure

5.4.6.1. QP-001: Estimating Measurement Uncertainty outlines the procedure used for estimating measurement uncertainty. QP-002 Reporting Measurement Uncertainty, outlines the 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”.

5.4.7. Control of Data Policy and Procedure

5.4.7.1. QP-003: Control of Data outlines the procedure used for controlling calculated data and WI-003 outlines the procedure for transmitting electronic data. QP-019 Computer Software Validation outlines software validation.

5.4.7.2. AV-Consulting Calibration Laboratory Commercial only uses off-the-shelf software (e.g. word processing (Microsoft Word) database (Microsoft) and statistical programs (Microsoft Excel) and analyzing software like Lab-shop (Bruel & Kjaer Puls) or VA-Lab etc.). In general the use within their designed application range may be considered to be sufficiently validated.

5.5. Test Equipment Policy and Procedure

5.5.1. Equipment used for testing is selected based on its capability to meet the test and/or calibration standard's and customers' requirements.

5.5.1.1. Only equipment that is under permanent control of AV-Consulting Calibration Laboratory and contained in EIR-014: Tools and Equipment List is used for testing and calibration activities under the scope of accreditation when this is indicated in this list as "Used for Accredited Testing : Y". Refer to EIR-014: Tools and Equipment List for a complete listing of equipment and specifications used for testing and calibration purposes.

5.5.1.2. AV-Consulting Calibration Laboratory will ensure that the ISO 17025 requirements are met under any circumstance that the lab uses equipment that is not permanently controlled.

5.5.2. Equipment shall be calibrated prior to use to ensure it meets the requirements of test and calibration standard's, the laboratory, and the customer.

5.5.2.1. AV-Consulting calibration laboratory program monitors and calibrates all significant aspects of equipment at a frequency appropriate to ensure that the relevant standards are met. QP-011 Periodic Quality Checks of Calibrated Devices is used for this purpose. To provide a consistent approach to ensure that a new lab device has been labeled, check en data and manuals are stored in the QMS quality procedure QP-026: Quality Procedure New Lab Equipment AV-Consulting shall be followed.

5.5.2.2. Specifications, inspection and/or calibration frequencies are contained in EIR-014: Tools and Equipment List. EIR-014B contains the data of the lab equipment. EIR-014C contains the calibration certificates of lab equipment. EIR-014C contains data of repair and modifications to lab equipment.

5.5.2.3. Unless otherwise specified, calibrations due dates have a 30 day total grace period for calibrations. In other words, the date the actual calibration should occur lies within a window that is 15 days before or after the due date.

5.5.2.4. Historical calibration results should demonstrate that the calibration grace period is appropriate and ensures the device complies with the appropriate standards.

5.5.3. Only personnel authorized by AV-Consulting Calibration Laboratory shall operate equipment for the purpose of perform testing and/or calibration activities. Refer to section 5.2 and section 5.4.1 for ensuring competent personnel and providing appropriate instructions policies and procedures.

5.5.4. Each item of equipment and software significant to the outcome of test and calibration is uniquely identified with a corresponding TD or AV number. Refer to the EIR-014: Tools and Equipment List, in the directory EIR-014: Equipment + Tools List.

5.5.5. The following records are maintained in EIR-014 Tools and Equipment List

- Unique identification number of the equipment and/or software
- Description of the equipment and/or software
- Manufacture's name, type/model identification and serial number
- Equipment capability and accuracy specifications
- Current location (as appropriate)
- Manufacturer instructions and specifications
- Dates, results and copies of reports and certificates (or location of) of the most recent and previous calibrations, adjustments, acceptance criteria and the next due date of calibration and/or maintenance.
- Maintenance plan, where appropriate
- Any damage, malfunction or repair to the equipment

5.5.5.1. Calibration certificates, maintenance records and inspection records are maintained by the Quality Manager. They are contained in EIR-014B: Lab Equipment Data, EIR-014C: Calibration Certificates of Lab Equipment and EIR-014D: Repair and Modification of Equipment.

5.5.6. In general, all equipment (including reference standards and reference materials) shall be carefully handled and transported in order to prevent contamination, damage and ensure proper functioning. Equipment shall be used only within its specified range of capability. All equipment will be maintained in suitable environments complying with section 5.5. and section 5.3 and/or relevant standards like IEC or ISO etc.

5.5.6.1. Work instructions shall be written for specific equipment requiring special handling, transportation or storage beyond the general accommodations.

5.5.7. Equipment that has been subjected to overloading or mishandling, gives suspect results, is shown to be defective or out of service shall be immediately removed from service. The equipment will be quarantined and labeled with FO-014: Out of Service Tag.

5.5.7.1. The quality manager and/or technical manager shall be promptly notified and initiate the appropriate action as noted under section 4.9 for the control of nonconforming work.

5.5.8. As practical, all equipment under the control of the lab and requiring calibration shall be labeled, coded or otherwise identified in order to indicate the status of calibration, including the last date calibrated and date or expiration criteria for the next calibration.

5.5.8.1. Internal calibrations: FO-012: Calibration Status Tag shall be used to comply with the requirements of 5.5.8.

5.5.8.2. External calibrations: Calibration tags shall comply with section 5.5.8 and our accrediting body's requirements.

5.5.8.3. External calibration tags shall include the accrediting body's scope logo and certificate number or other reference to its scope of accreditation.

5.5.8.4. Refer to section 5.5.2.3 and 5.5.2.4 for additional information.

5.5.9. Equipment that goes outside the laboratories control, the equipment shall be inspected to ensure that it is functionally satisfactory before it is returned to service. FO-011: Incoming Equipment Inspection Checklist shall be used to record incoming equipment inspections.

5.5.10. Intermediate checks shall follow the same procedure a routine calibrations and inspections.

5.5.11. Correction factors resulting from calibrations shall be documented in the appropriate calibration certificates. The corrected output shall be confirmed and recorded during the calibration process.

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. FO-028 Void-Sticker-Calibration shall be used for hardware safeguard, software shall be protected by password.

5.6. Measurement Traceability Policy and Procedure

5.6.1. All equipment (including reference standards and reference materials) shall be calibrated by an accredited calibration lab ilac-MRA or NIST prior to use for testing and calibration activities completed under the scope of accreditation (either directly or indirectly). In addition, all calibrations shall include a statement of uncertainty for the calibration provided as required by ISO 17025. Refer to section 5.10.4.1 for additional details.

5.6.1.1. All equipment (including reference standards and reference materials) shall be routinely calibrated or otherwise verified according to a predetermined interval.

5.6.1.2. Calibration intervals are established for each piece of equipment based on the following factors:

- Manufacturer's recommendations
- Universally accepted practices
- Frequency of use
- Durability and resistance to damage
- Historical performance and device stability

5.6.1.3. All test and calibration measurements and results shall be directly traceable to the international units system (SI *Système international d'unités)* through an unbroken chain of calibrations. The accreditation assures the direct traceability to ilac-MRA, NIST accredited laboratories. The ilac-MRA allows us to make use of a global network of testing and calibration laboratories and inspection bodies that have been accredited to provide accurate and reliable results.

5.6.1.4. All test calibration results and uncertainty estimates shall be linked to SI (*Système international d'unités* units either directly or through universally accepted physical constants and/or transformations.

5.6.1.5. Test equipment, instruments and measuring devices shall comply with sections 5.6.1 and 5.6.2. Refer to section 5.10.3.1 for additional details about reporting measurement uncertainty.

5.6.2. Reference Standards and Reference Materials

5.6.2.1. Reference standards are subject to the calibration program outlined in 5.5.1. Reference standards used for calibration shall be used exclusively for calibration. Refer to EIR-014: Tools and Equipment List for a complete listing of reference standards.

5.6.2.2. AV-Consulting Calibration Laboratory does not use reference materials for test or calibration activities under the scope of accreditation.

5.6.2.3. Intermediate checks of reference standards are subject to the calibration program outlined in 5.5.1. QP-011: Periodic Quality Checks of Calibrated Devices is to be followed for lab equipment.

5.6.2.4. Reference standards and materials are handled according to section 5.5.6.

5.7. Sampling Policy

5.7.1. AV-Consulting Calibration Laboratory does not perform sampling under the scope of accreditation.

5.8. Handling of Test and Calibration Items Procedure

5.8.1. WI-001: Test and Calibration Sample Handling outlines the procedure followed for receiving, transporting, handling, protection, storage and disposal of test and calibration items.

5.8.2. Each item and specimen is uniquely identifiable through the combination of the request or job number, item number and specimen number. Items are labeled upon receipt using an appropriate method to protect against loss of identification. Paint pens, permanent markers and printed labels are generally acceptable methods of identification.

5.8.3. Test and calibration items are visually inspected for defect upon arrival to the lab. Form FO-011: Incoming Equipment Checklist shall be used. Any defects or abnormalities shall be recorded and explicitly noted in the test report and/or calibration certificate. The customer will be consulted under any circumstances that the item is not suitable for test and/or calibration. The customer will be consulted for additional information pertaining to the request if the information provided is inadequate (refer to section 4.7 for more details on this procedure).

5.8.4. In general, all test and calibration items shall be carefully handled and transported in order to prevent contamination, damage and ensure proper functioning. All test and calibration items will be maintained in suitable environments complying with section 5.3 and/or the relevant standards.

5.9. Assuring the Quality of Test and Calibration Results

5.9.1. QP-005: Quality Procedure for the Proficiency Test Plan AV-Consulting outlines the 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". As part of the continuous improvement policy noted in section 4.10, various activities are monitored and analyze to detect trends. Monitoring may include any the following activities:

5.9.1.1. The European Accreditation Guidance EA-4/18 INF:2010 states that different types of PT (proficiency test) that can be used by laboratories and should be accepted by accreditation bodies, include:

- PT (proficiency tests) organized by other independent organizations such as accreditation bodies or organizations such as ILAC, EA, APLAC, ERAMET and IRMM.
- ILC (intra laboratory comparison) organized by a sufficient number of laboratories as a one off or continual exercise. It is noted that these (very limited) ILC for acoustics & vibrations in Europe are usually limited to primary lab's.
- Submission of an internal item or object to another or more external laboratories for the purposes of data comparison. For acoustic en vibration laboratories this is the most used method.

5.9.1.2. Using of certified and/or internally developed reference materials on a regular basis.

5.9.1.3. Participating in inter laboratory comparisons and proficiency test programs, actual plan is outlined in QP-005: Proficiency Test Plan. FO-009 Proficiency Test Search Form shall be used to look voor PT-programs.

5.9.1.4. Replicating tests using the same or different methods.

5.9.1.5. Retesting or recalibrating retained items.

5.9.1.6. Correlating results for different characteristics of an item.

5.9.1.7. The level of risk presented by AV-Consulting Calibration Laboratory can considered as low in the sector in which the lab operates. This is determined by:

a) Number of tests/calibrations/measurements undertaken (mediate number of calibrations).

b) Turnover of technical staff (low).

c) Experience and knowledge of technical staff (high).

d) Source of Traceability (well defined and strict).

e) Known stability/instability of the measurement technique (high stability).

f) Significance and final use of testing/calibration data (fairly low sins equipment always has to be field calibrated/checked before use).

5.9.1.8. Therefor the PT (proficiency test) "Submission of an internal sample or object to another or more external laboratories for the purposes of data comparison" as stated in The European Accreditation Guidance EA-4/18 INF: 2010 can in general be sufficient also due to the lack of PT projects. The lab shall participate in PT's organized by other laboratory's when applicable.

5.9.2. Any quality control data that is found to be outside acceptable limits shall be subject to section 4.9 for the control of nonconforming work.

5.9.3. Quality control data is subject to the control of records policy and procedure outlined in section 4.13.

5.10.Reporting Results

5.10.1. General Policy and Procedure for Reporting Results

5.10.1.1. Results of each test and/or calibration or series of tests and/or calibrations shall be recorded accurately, objectively and in accordance with the relevant standards and customer requirements. Procedure QP-015 insures that the calibration certificate is in accordance with ISO-17025.

5.10.1.2. Sections 5.10.2 and 5.10.3 detail the required information to be provided in test reports.

5.10.1.3. Any raw data or related information collected during a test and/or calibration that is not reported shall be retained and accessible to the customer for further review.

5.10.1.4. All reports and calibration certificate are subject to the control of records policy and procedure outlined in section 4.13.

5.10.2. General Test Report and Calibration Certificate Policy and Procedure

a) Calibration Certificate Forms to be used are (for example) FO-026 (Sound Level Meter), FO-016/FO-F38b (SBR-vibration meters), FO-015 (accelerometers), FO-027 (calibrators), FO-029 (microphones), FO-032-036 (amplifiers). Calibration Certificate (template) Forms shall be used for reporting results in case of other specific calibrations when applicable. QP-015 insures calibration certificate is accordance is used with ISO should be followed. At a minimum, the following information shall be provided on each report:

b) Title (e.g. “Calibration Certificate”)

c) The name and address of the laboratory, and the location where the tests and/or calibrations were carried out if different from the lab’s address.

d) Unique identification of the test report or calibration certificate (such as a serial number) on each page to ensure the page is recognized as part of the report and/or certificate. Each page of the report contains a page number and total number of pages. The end of the report is signified when the two values are equivalent.

e) The name and address of the customer.

f) Identification of the methods and or standards used.

g) Descriptions, conditions and unambiguous identification of the items tested or calibrated.

h) The date of receipt of the samples and/or calibration items (as needed to ensure validity of the test and or calibration results)

i) Environmental conditions, observations, deviations or relevant information to reproduce the test, test or calibration results, units of measure.

j) The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test and/or calibration certificate. The name of the technician, their title and electronic signature is an acceptable means of authorization. Refer to WI-002: Process for Issuing Calibration Reports for more detailed information.

k) A statement that the results relate only to the items tested under the specified conditions.

l) A statement specifying that the report or calibration certificate shall not be reproduced, except in full, without written permission from the laboratory.

5.10.3. Test Report Policy and Procedure

5.10.3.1. In addition to the requirements outline in 5.10.2, test reports shall include the following as required to interpret results:

a) Any deviation (additions, exclusions or otherwise alterations) from the test method and or environmental conditions.

b) Where required, a statement of compliance/non-compliance with relevant requirements or acceptance criteria.

c) Where applicable (all ways with calibrations under accredited calibrations), a statement of measurement uncertainty (as determined in 5.4.6). Measurement uncertainty shall be reported according to QP-002: Reporting Measurement Uncertainty.

d) Measurement uncertainty calculations are saved under EIR-023 Uncertainty Estimate Certificates.

e) When appropriate, opinions and interpretations of the results.

f) Additional information required by specific methods or customers.

g) Details of the environmental conditions during sampling that may affect the interpretation of results.

h) Any standard or specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification.

5.10.4. Calibration Certificate Policy and Procedure

5.10.4.1. In addition to the requirement listed in 5.10.2, calibration certificates include:

a) The conditions during under which the calibration was performed if conditions have a significant influence on measurement results.

b) The measurement uncertainty and/or statement of compliance with an identified metrological specification or clauses thereof.

c) Evidence that the measurements are traceable (reference section 5.6.2).

d) Evidence that the measurements are traceable (reference section 5.6.2).

5.10.4.2. Calibration certificate shall relate only to quantities and the results of physical/functional tests. Statements of compliance (as appropriate) shall identify the specific clauses which met or did not meet. Statements of compliance shall also account for measurement uncertainty. Refer to QP-002: Reporting Measurement Uncertainty.

5.10.4.3. When an item undergoing calibration has been repaired and/or adjusted, the calibration results before and after the adjustment shall be reported.

5.10.4.4. Calibration certificates shall not contain recommendations or requirements for calibration intervals.

5.10.5. Opinions and Interpretations Policy and Procedure

5.10.5.1. Professional opinions and interpretations shall be explicitly noted as such in test reports.

5.10.5.2. Opinions and interpretations shall include a statement regarding the basis for the opinion or interpretation.

5.10.5.3. Acceptable means for identifying opinions and interpretations include:

a) Adding a separate section in the test report entitled “COMMENTS”

b) In case of opinions and interpretations, adding a statement preceding the opinion and interpretation such as “The following is an opinion/interpretation” or equivalent statement.

5.10.6. Testing and Calibration Results Obtained from Subcontractors Policy and Procedure

5.10.6.1. Test reports and calibration certificate containing results of tests performed by subcontractors shall be identified with the subcontractor’s name and contact information.

5.10.6.2. Results and reports obtained through subcontractors shall conform to the requirements of ISO 17025. QP-015 “Ensure Calibration Certificate ISO-17025” shall be used to check this.

5.10.6.3. Subcontracted calibration certificates shall be issued to the contracting laboratory.

5.10.7. Electronic Transmission of Results Policy and Procedure

5.10.7.1. Data that is transmitted electronically shall be secured to maintain confidentiality and protect against unauthorized alterations.

5.10.7.2. Refer to WI-003: Process for Transmitting Electronic Data.

5.10.8. Format of Reports and Certificates Policy and Procedure

5.10.8.1. The format of reports and certificates are controlled through the use of forms. Forms are designed to ensure that each type of test and calibrations are guarded against misunderstanding and misuse. Refer to EIR-004: Forms Repository for a complete listing of forms.

5.10.9. Amendments to test reports and calibration certificates

Purpose	The purpose of environmental conditions policy and procedure is to provide a uniform approach for amending test reports and calibration certificates.	
Scope	Includes all test reports or calibration certificates.	
Definitions	Reports	Reports of testing or calibration activities. Interchangeable term that includes both test reports and calibration certificates.
Responsibility	Quality Manager	Ensure the requirements of this procedure are met.
	All personnel	Amend reports as outlined in this procedure.

5.10.9.1. Amended test reports shall include the words "supplement to", the report number and version number of the original report in the header section of the document.

5.10.9.2. Amended reports shall include a revisions section that lists the details of all the revisions made to the document.

5.10.9.3. Amended reports shall be reviewed, authorized and reissued following WI-002: Process for Issuing Test Reports.

5.10.9.4. The reissued report shall be redistributed to all individuals and/or libraries that received the original report. It may be appropriate to recommend that all copies of the original (incorrect) report be destroyed upon receipt of the amended report.

5.10.9.5. Report amendments typically occur as the result of incomplete or erroneous information, typographical errors, or editorial changes.

5.10.9.6. In the case of repeating a test due to suspect data, use one of the following:

- If the reason for the suspicion is known (ex: Test Method was not followed, equipment malfunction) then state the reason for the suspicion
- If the reason for the suspicion is unknown, then state "unknown reasons"

5.10.9.7. Amended reports are uniquely identified with a combination of the original number and suffix such as “AV16100–A1”. Amended reports shall contain a direct reference to the original report.

Change Control Section

Version	Rev. Date D / M / Y	Section	Change Control Comments	Approver
1	17.01.2015	NA	Created new document.	A.Vreeswijk
2	20.09.2016	All	Created new document	A.Vreeswijk
3	20.01.2017	§5.5.2.1.	New QP-026 implemented	A.Vreeswijk