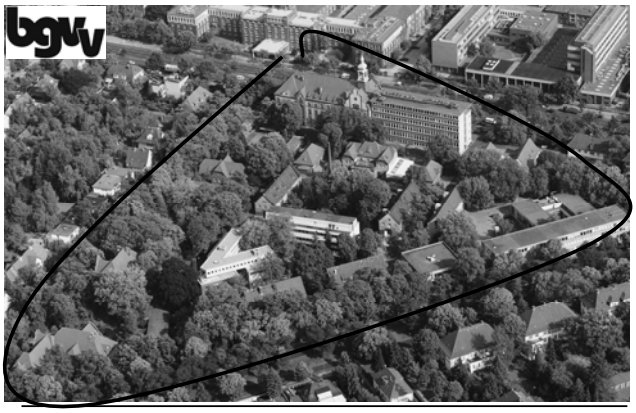
Workshop on Issues relevant for the Accreditation of the Current Quality Control Laboratories (QCL)

I Presentation and Discussion of General Issues

Dieter Arnold

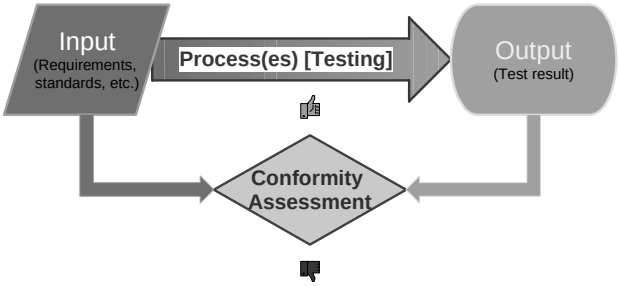
My roots: headquarters of the BgVV in Berlin in 2002

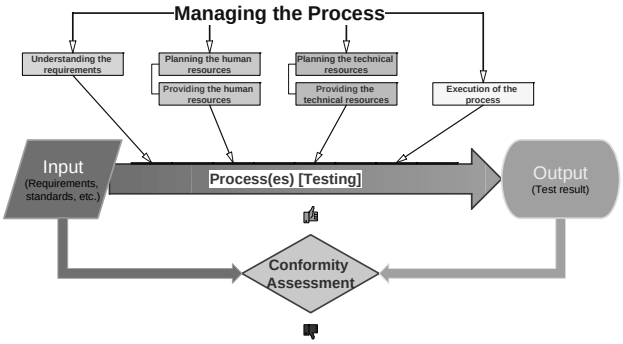


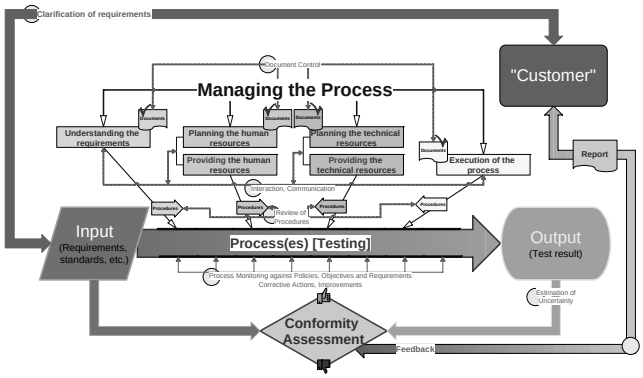
Main laboratories in Berlin 2002

Let‘s start unearthing the secrets of accreditation

It’s not difficult, only complicated and time-consuming







Elements of Quality Management

QMS

Quality Management System (QMS) can be defined as **set of policies, processes and procedures** required by an organisation for planning and execution in their core area of activities. It integrates the various internal processes within the organization and provides a "process approach" for project execution. QMS also enables the organization to control and improve the various core activities which will ultimately lead to **improved performance**.

ISO 9001

ISO 9001 focuses on the effectiveness of a **quality management system** in meeting customer requirements. It specifies requirements for a quality management system that can be used for internal application by organizations, or for **certification**, or for contractual purposes.

It does not cover aspects of technical competence!

Accreditation

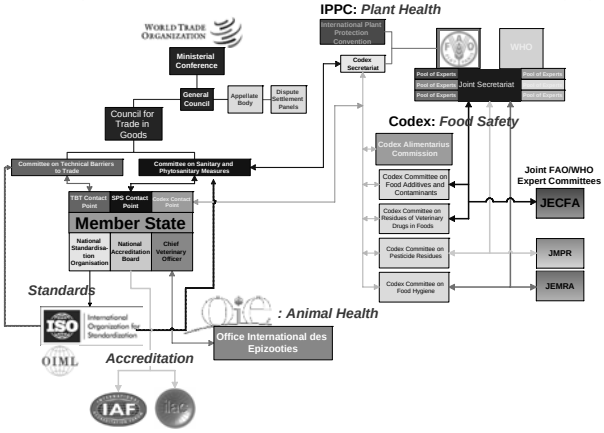
A Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

Important Agreements of the Members of the World Trade Organisation - SPS

The Agreement on Sanitary and Phytosanitary Measures (SPS) allows countries to set their own standards. But it also says that standards to protect human, animal or plant health must be based on risk assessment and encourages governments to adopt internationally harmonized standards.

Important Agreements of the Members of the World Trade Organisation - TBT

The **Agreement on Technical Barriers to Trade (TBT)** tries to ensure that regulations, standards, **testing and certification procedures** do not create unnecessary obstacles to free trade.



International Laboratory Accreditation Co-operation

International Accreditation Forum

Main Tasks of ILAC and IAF

1. Harmonization of accreditation practices between members (establishing guidances)
2. Establishing multilateral recognition agreements/arrangements (peer evaluations)
3. Promoting accreditation as a tool for facilitating trade
4. Helping developping countries

For information: SASO is ILAC member

The Benefits of Accreditation

Lack of formal acceptance of laboratory test results across national borders is a significant barrier to trade, justifies duplication of testing in the importing country and challenge of results of border inspections by an exporting country.
Replicate testing causes additional costs and time delays.
Internationally recognized accreditation reduces the possibility that access of goods to an importing country is denied on grounds of inadequate conformity assessment. To the contrary, under the TBT such a system is evidence of competence to verify compliance of goods with international standards.

The Benefits of Accreditation

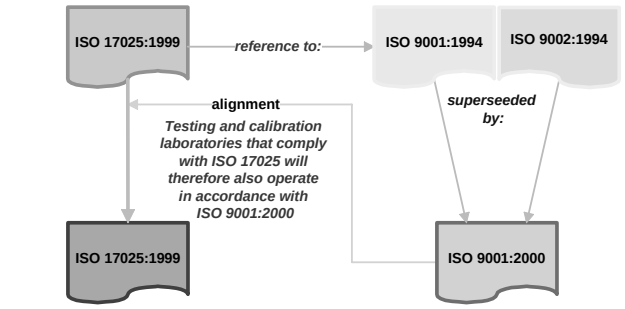
A national accreditation (or regional) system forming part of legally binding Mutual Recognition Agreements (MRAs) between governments and covering the full range of accredited conformity assessment activities, such as testing/calibration, product certification, system certification etc., is of great benefit in developing international competitiveness of national producers and products.

However, engaging an accreditation body from a foreign country to provide those services on mutually agreeable terms may be the only cost-effective solution as long as only few laboratories are candidates for accreditation

Workshop on Issues relevant for the Accreditation of the Current Quality Control Laboratories (QCL)

II The International Norm ISO/IEC 17025:2005

General Applicability and Overview



ISO/IEC 17025:2005 cancels and replaces (ISO/IEC 17025:1999) which has been technically revised.

Conformity of the QMS of a laboratory to the requirements of ISO 9001 does not itself demonstrate the technical competence of the laboratory

Other Norms Required

The norm applicable to the **accreditation of inspection bodies** is ISO 17020:2004 „General criteria for the operation of various types of bodies performing inspection"

Workshop on Issues relevant for the Accreditation of the Current Quality Control Laboratories (QCL)

III

Requirements of the Norm

Management System Requirements

Structure of the Chapter „Management Requirements“

4.1	Organisation
4.2	Management System
4.3	Document Control
4.4	Review of Requests, Tenders and Contracts
4.5	Subcontracting of Tests and Calibrations
4.6	Purchasing Services and Supplies
4.7	Service to Customers
4.8	Complaints
4.9	Control of Nonconforming Test-/Calibration Work
4.10	Improvement
4.11	Corrective Action
4.12	Preventive Action
4.13	Control of Records
4.14	Internal Audits
4.15	Management Review

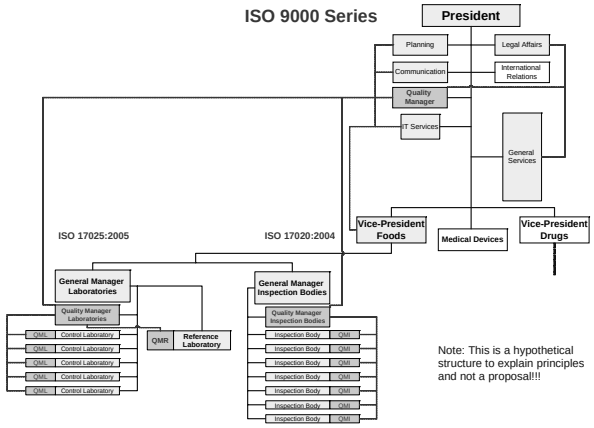
4.3.1	General
4.3.2	Document Approval and Issue
4.3.3	Document Changes

4.11.1	General
4.11.2	Cause Analysis
4.11.3	Selection and Implementation of Corrective Actions
4.11.4	Monitoring of Corrective Actions
4.11.5	Additional Audits

4.13.1	General
4.13.2	Technical Records

4.1 Organisation

Requirements	Details
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.	
Demonstrate impartiality, independence of judgement and **integrity** in relation to its testing	
Demonstrate that managerial and technical personnel have the authority and **resources needed** to carry out their duties in relation to the quality management system.	
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;
	to **avoid involvement in** any **activities** that would **diminish confidence** in competence, impartiality, judgement or operational integrity.
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.	
Specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations.	
Appoint a **quality manager** with defined responsibility for the quality management system and direct access to the highest level of management.	
Appoint deputies for key managerial personnel.	
Provide adequate supervision of testing and calibration staff.	
Ensure	that appropriate **communication** processes are established;
	that **personnel are aware** of the relevance and importance of their activities.



4.1 Organisation - continued

Describe legal identity and background of parent organisation

Describe mission of the parent organisation

Provide an organisational chart of that organisation which indicates the lines of command, the unit having influence on the quality of laboratory work and your QM-network!

Provide detailed chart of the laboratory concerned!

Describe the functions of the key people of the system of the parent organisation!

Provide a business plan of the parent organisation!

Provide the Manual of procedures of the parent organisation!

Have job descriptions of all staff!

4.2 Management System

Requirements	Details
Top management	**provide evidence of commitment** to the development and implementation of the management system and to continually improving its effectiveness;
	communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.
Establish the overall objectives and **review** it during management review	
Issue a concise quality policy statement under the authority of top management. It shall at least contain:	the laboratory management's commitment to **good professional practice** and to the **quality** of its testing and calibration;
	the management's statement of the laboratory's **standard of service;**
	the **purpose of the management system** related to quality;
	a **requirement that all personnel familiarize** themselves with the quality documentation **and implement** the policies and procedures in their work;
	the laboratory management's **commitment to comply with ISO 17025:2500** and to **continually improve** the effectiveness of the management system;
	the requirement that tests and/or calibrations **shall always be carried out in accordance with stated methods and customers' requirements;**
Implement and maintain a **management system** appropriate to the scope of activities	
ensure the integrity of the management system when changes are planned and implemented	
Document to the extent necessary to assure the quality of the test and/or calibration results:	**policies**
	systems
	programmes
	procedures
	instructions
The system's documentation shall be	**communicated to**
	understood by
	available to
....the appropriate personnel	**implemented by**
Define the laboratory's management system policies related to quality in a quality manual	include or make reference to the **supporting procedures including technical procedures.**
	outline the structure of the documentation used in the management system
	define roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard

4.3 Document Control

Requirements	Details
Establish and maintain procedures to control all documents that form part of its management system (These may be on various media, whether hard copy or electronic, and they may be digital, analogue, photographic or written)	regulations;
	standards;
	other normative documents;
	test and/or calibration methods;
	drawings;
	software;
	specifications;
	instructions;
	manuals;
	review and approve by authorized personnel and prior to issue all documents issued to personnel;
	use same procedure for **changes;**
	set rules for **hand made** changes and for changes on **computerised documents**;
	uniquely identify documents (date of issue and/or revision, page number and total number of pages, issuing authority(ies);
	establish and **make readily available** a **master list** identifying revision status and distribution;
	make authorized editions of appropriate **documents available** at all relevant locations;
	review documents **periodically** and **revise,** where necessary;
	remove invalid or obsolete documents promptly;
	mark obsolete documents retained suitably

4.4 Review of Requests, Tenders and Contracts

Requirements	Details
Establish and maintain policies and procedures for the **review of requests, tenders and contracts** ensuring that	**requirements are adequately defined,** documented and understood;
	laboratory has the capability and physical, personnel and information resources **to meet** the requirements;
	method selected is capable of meeting the customers' requirements;
	differences between request or tender and contract are resolved before any work commences;
	records of reviews and pertinent discussions with customer **are maintained**;
	reviews cover subcontracts;
	same contract review process is used for amendments;
	customer is informed of any deviation from the contract

4.5 Sub-contacting of Tests and Calibrations

Requirements	Details
Place subcontracted work with a **competent subcontractor complying with ISO 17025:2005**	
Maintain a register	of all subcontractors;
	of the **evidence of compliance.**
Advise the customer and gain hid approval of the arrangement in writing	

4.6 Purchasing Services and Supplies

Requirements	Details
Have a policy and procedure(s)	for the **selection and purchasing** of services and supplies;
	for **purchase, reception and storage** of reagents and laboratory consumable materials;
	ensuring that purchased supplies, reagents and consumables are not used until they have been **verified as complying** with specifications or requirements;
	that **records of actions taken** to check compliance are maintained;
	that **documents** describing the ordered services and supplies are **reviewed and approved** for technical content prior to release;
	that **suppliers** of critical consumables, supplies and services are **evaluated** and **records of these evaluations and lists those approved** are maintained;

4.7 Services to the Customer

Requirements	Details
Cooperate with customers and in relation to the work performed, provided that the laboratory	in clarifying the customer's request;
Ensure confidentiality to other customers	in monitoring the laboratory's performance;
Seek feedback from customers	
Analyse feedback to **improve**	the **management system**;
	testing and calibration activities;
	customer service;

4.8 Complaints

Requirements	Details
Have a policy and procedure	for the **resolution of complaints** received from customers or other parties;
	for maintaining **records** of all complaints and of the investigations and corrective actions taken;

4.9 Control of Nonconforming Testing and/or Calibration Work

Requirements	Details
Have a policy and procedures that shall be implemented **when any aspect or the results** of its testing and/or calibration work **do not conform** to its own procedures or agreed requirements of the customer. The policy and procedures shall ensure that:	**responsibilities and authorities for the management of nonconforming work** are designated (including halting of work, withholding of test reports, as necessary, and resumption of work);
	actions are defined and taken;
	an **evaluation of the significance** of the nonconforming work is made and the corrective action procedures given in 4.11 are promptly followed if necessary;
	the **customer is notified** and work is recalled where necessary.

4.10 Improvement

Requirements	Details
Improve the effectiveness of the management system through the use of	quality **policy**;
	quality **objectives**;
	audit results;
	analysis of data;
	corrective actions;
	preventive actions;
	management review.

4.11 Corrective Action

No.	Requirements	Details
4.11	**Establish a policy and a procedure** and **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. Use the following sequence in the procedure.	
4.11.1		
4.11.2	Start with an investigation to **determine the root cause(s)** of the problem.	
4.11.3	**Identify potential corrective** which	**most likely eliminate the problem** and **prevent recurrence**;
		are **appropriate to the magnitude and the risk** of the problem.
	Document and implement any required changes resulting from corrective action investigations.	
4.11.4	**Monitor the results** to ensure that the corrective actions taken have been effective.	
4.11.5	**Audit the appropriate areas** of activity in accordance with 4.14 as soon as possible where a serious issue or risk to the business has been identified due to nonconformities	with its own policies and procedures;
		with compliance with this ISO 17025:2005.

4.12 Preventive Action

Requirements	Details
Identify needed improvements	**Technical;**
	concerning the **management system.**
Develop, implement and monitor **action plans.**	
Identify potential sources of nonconformities	**Technical;**
	concerning the **management system;**
Develop, implement and monitor **action plans**	
Draft Procedures for preventive actions including **initiation** and the **application of controls** to ensure that they are effective.	Base it on review of the operational procedures, **analysis of data, trend and risk analyses and proficiency-testing results.**

4.13 Control of Records I

No	Requirements	Details
4.13 4.13	**Establish and maintain procedures**	identification; collection; indexing; access; filing; storage; maintenance; disposal.
	.....for quality records .....for technical records	
4.13.1	**Include in the list of quality records**	**reports** from internal audits; **management reviews**; records of **corrective actions**; records of **preventive** actions;
	Ensure that all records (in any media, such as hard copy or electronic media)	are legible; are stored and retained in facilities that provide a suitable environment to prevent loss, damage or deterioration; are held secure and in confidence; are readily retrievable; have established retention times.
	Have procedures to	protect and back-up records stored electronically; prevent unauthorized access to or amendment of these records.

4.13 Control of Records II

No	Requirements	Details
4.13.2	**Retain for a defined period technical records** (data and information resulting from carrying out tests and/or calibrations and indicating whether specified quality or process parameters are achieved), such as...	**Forms;** **Contracts;** **work sheets;** **check sheets;** **work notes;** **control graphs;** work books; records of **original observations;** **derived data;** sufficient information to establish an audit trail; copy of each (internal and external) **test report;** **calibration records;** copy of each **calibration certificate** issued; staff **records;** **customers' notes**, papers and feedback;
	Provide sufficient information in test and calibration records to enable	if possible, identification of factors affecting the **uncertainty;** **repetition** of tests or calibrations;
	Include the identity of personnel responsible for	the **sampling;** **performance of each test;** **performance of each calibration;** **checking of results;**
	Correct mistakes in records by	crossing out (not erasing, making illegible or deleting) and entering the correct value alongside.
	Ensure alterations to records are signed or initialled by the person making the correction and equivalent measures are taken for electronically stored records.	

4.14 Internal Audits

Requirements	Details
Periodically (cycle of one year) **conduct internal audits** of activities (to verify that operations continue to comply with the requirements of the management system and ISO 17025:2005	in accordance with a **predetermined schedule** and procedure; **addressing all elements of the management system**, including the testing and/or calibration activities; under the **responsibility of the quality manager;** **by trained and qualified personnel** who are wherever independent of the activity to be audited;
Take the following actions when audit findings cast doubt on the effectiveness of operations, correctness or validity of test or calibration results	**take timely corrective action;** notify customers in writing if laboratory results may have been affected; **record the area of activity audited**, the audit findings and corrective actions that arise from them; **verify and record the implementation** and effectiveness of the **corrective action** taken through follow-up audits.

4.15 Management Reviews

Requirements	Details
Periodically (every 12 months) **conduct** (by top management) **a review of the laboratory's management system and testing and/or calibration activities** in accordance with a predetermined schedule and **procedure** taking account of:	the **suitability of policies and procedures**
	reports from managerial and supervisory personnel;
	the outcome of recent internal audits;
	corrective and preventive actions;
	assessments by external bodies;
	the results of **inter-laboratory comparisons or proficiency tests**;
	changes in the volume and type of the work;
	customer feedback;
	complaints;
	recommendations for improvement;
	other relevant factors, such as **quality control activities**, resources and staff training.
Ensure that	**findings f**rom management reviews **are recorded**;
	arising **actions are recorded** and **carried out within an appropriate and agreed timescale**;
	results (goals, objectives and action plans) are **fed into the laboratory planning system** for the coming year;
	management review related subjects are **considered at regular management meetings.**

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IV

Requirements of the Norm

Technical Requirements

Structure of the Chapter „Technical Requirements“

5.1	General
5.2	Personnel
5.3	Accommodation and environmental conditions
5.4	Test and calibration methods and method validation
5.4.1	General
5.4.2	Selection of methods
5.4.3	Laboratory-developed methods
5.4.4	Non-standard methods
5.4.5	Validation of methods
5.4.6	Estimation of uncertainty of measurement
5.4.7	Control of data
5.5	Equipment
5.6	Measurement traceability
5.6.1	General
5.6.2	Specific requirements
5.6.3	Reference standards and reference materials
5.7	Sampling
5.8	Handling of test and calibration items
5.9	Assuring the quality of test and calibration results
5.10	Reporting the results
5.10.1	General
5.10.2	Test reports and calibration certificates
5.10.3	Test reports
5.10.4	Calibration certificates
5.10.5	Opinions and interpretations
5.10.6	Testing and calibration results obtained from subcontractors
5.10.7	Electronic transmission of results
5.10.8	Format of reports and certificates
5.10.9	Amendments to test reports and calibration certificates

5.1 General

Requirements	Details
Consider and take account of all factors influencing correctness and reliability of the tests and/or calibrations contributing to different extent to the total uncertainty of measurement when developing test and calibration methods and procedures, training and qualifying personnel, and selecting and calibrating equipment.	human factors (see 5.2);
	accommodation and environmental conditions (see 5.3):
	test and calibration methods and method validation (see 5.4);
	equipment (see 5.5);
	measurement traceability (see 5.6);
	sampling (see 5.7);
	handling of test and calibration items (see 5.8).

5.2 Personnel I

Requirements	Details
Ensure the competence of all who	operate specific equipment;
	perform tests and/or calibrations;
	evaluate results;
	sign test reports and calibration certificates;
Qualify personnel performing specific tasks on the basis of	appropriate education;
	training;
	experience;
	demonstrated skills.
Supervise appropriately staff undergoing training.	
Ensure that personnel responsible for the opinions and interpretation included in test reports have in addition	**relevant knowledge** of the manufacturing technology, the intended uses, the defects or degradations likely occurring during service for the items, materials, products, etc. tested;
	knowledge of the general requirements expressed in the legislation and standards;
	an **understanding of the significance of deviations** found with regard to the normal use of the items, materials, products, etc. concerned.
Management formulate the goals with respect to the personnel's	Education;
	Training;
	Skills;
Have a policy and procedures for	identifying training needs relevant to the present and anticipated tasks of the laboratory
	providing such training to personnel
	evaluating the effectiveness of the training
Use personnel who are employed by, **or under contract** to the laboratory.	

5.2 Personnel II

Requirements	Details	
Maintain current job descriptions for	**managerial** personnel;	
	technical personnel;	
	key **support** personnel involved in tests and/or calibrations;	
Define the following as part of job descriptions	**responsibilities** for:	
	Planning;	tests and/or calibrations
	Performing;	
	Evaluating;	
	Reporting;	
	Interpreting;	
	method modification;	
	method development;	
	method validation.	
Authorize specific personnel to	perform particular types of sampling, test and/or calibration; issue test reports and calibration certificates give opinions and interpretations; operate particular types of equipment.	
Maintain readily available **records** of …	the relevant authorization(s) and dates of its confirmation;	
	competence and date of its confirmation;	
	educational and professional qualifications;	
	Training;	
	skills and experience….	
…for all technical personnel.	do not adversely affect the required quality…	

5.3 Accomodations and Environmental Conditions

Requirements	Details
Document the technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations	
and ensure that the environmental conditions … …of any measurement correct performance of the tests and/or calibrations	facilitate and do not invalidate the results; do not adversely affect the required quality…
Monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results (and stop tests and calibrations when the environmental conditions jeopardize the results of the tests and/or calibration), for example…	biological sterility; Dust; Temperature; etc.
Separate neighbouring areas in which there are incompatible activities to prevent cross-contamination.	

5.4 Test and calibration methods and method validation I

General	
Requirements	**Details**
Use appropriate methods and procedures for all tests and/or calibrations including	Sampling; Handling; Transport; Storage; preparation of items to be tested and/or calibrated; statistical techniques for analysis of test and/or calibration data; estimation of the measurement uncertainty.
Have up to date and readily available instructions (deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer).	on the use and operation of all relevant equipment; on the handling and preparation of items for testing and/or calibration.
Do not supplement or rewrite international, regional or national standards or other recognized specifications that they can be used as published and contain sufficient and concise information on how to perform the tests and/or calibrations It may be necessary to provide additional documentation for optional steps in the method or additional details.	
Selection of methods	
Use only 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.	
Use preferably methods published 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.	use the latest valid edition of a standard unless it is not appropriate or possible to do so; only when necessary, supplement the standard with additional details ensuring consistent application.
Use laboratory-developed methods or methods adopted by the laboratory **only** if they are appropriate for the intended use and if they are validated.	
Use any method only following confirmation that the laboratory can properly operate it and repeat this conformation if the standard/method changes.	
Inform the customer as to the method chosen.	

5.4 Test and calibration methods and method validation II

Laboratory-developed methods		
Requirements	**Details**	
Plan the introduction of test and calibration methods developed by the laboratory for its own use and **assign** this activity **to qualified personnel** equipped with adequate resources. **Update plans** as development proceeds and **ensure effective communication** amongst all personnel involved.		
Non-standard methods		
Develop procedures for the introduction of validated methods not covered by standards and ensure that the method description contains at least the following information	appropriate identification;	
	Scope;	
	description of the type of item to be tested or calibrated;	
	parameters or quantities and ranges to be determined;	
	apparatus and equipment, including technical performance requirements;	
	reference standards and reference materials required;	
	environmental conditions required and any stabilization period needed;	
	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;
	criteria and/or requirements for approval/rejection;	
	data to be recorded and method of analysis and presentation;	
	the uncertainty or the procedure for estimating uncertainty.	

5.4 Test and calibration methods and method validation III

Validation of methods	
Requirements	**Details**
Confirm by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled by non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods:	validate **as extensively** as is necessary to meet the needs of the given application or field of application and include sampling, handling and transportation – if relevant;
	record the procedure used for the validation, the results obtained, and a statement as to whether the method is fit for the intended use.
Use one or a combination of the following techniques for the determination of the performance of a method	calibration using reference standards or reference materials;
	comparison of results achieved with other methods;
	Inter-laboratory comparisons
	systematic assessment of the factors influencing the result;
	assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.
Investigate the influence on method performance of changes later introduced into the validated method or carry out a new validation, if appropriate **Verify that the range and accuracy of the values obtainable from validated methods**, e.g.,	
	uncertainty of the results;
	limit of detection;
	limit of quantification;
	selectivity of the method;
	Linearity;
	limit of repeatability and/or reproducibility;
	robustness against external influences;
	cross-sensitivity against interference from the matrix…
…are relevant to the customers' needs.	

5.4 Test and calibration methods and method validation IV

Estimation of uncertainty of measurement		
Requirements	**Details**	
to estimate the uncertainty of measurement for all calibrations and types of calibrations.		
Establish and apply procedures for estimating uncertainty of measurement for test methods (unless a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and the form of presentation of calculated results). **Take account of sources** contributing to the uncertainty, such as 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:	where **possible rigorou**s, metrologically and statistically valid, calculation of uncertainty of measurement (degree of rigor mainly depending on limits on which decisions on conformity to a specification are based;	
	in all other cases attempt to identify all components of uncertainty and make a reasonable estimation, to avoid that the form of reporting of the result gives a wrong impression of the uncertainty;	
	base estimation on	knowledge of the performance of the method;
		measurement scope;
		use of, for example, previous experience;
		validation data.

5.4 Test and calibration methods and method validation V

Control of data	
Requirements	**Details**
Check calculations and data transfers **systematically** and in an appropriate manner.	
Ensure in all situations where computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data that:	**computer software** developed by the user **is documented** in sufficient detail **and** is suitably **validated** as being adequate for use;
	procedures are established and implemented for **protecting the integrity and confidentiality** of data (e.g., during entry or collection, storage, transmission and processing);
	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;
	laboratory specific configurations / modifications of commercial off-the-shelf software (e.g. word-processing, database and statistical programmes) **are validated**.

5.5 Equipment I

Requirements	Details
Ensure that …	the **laboratory is 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);
	the requirements of ISO 17025:2005 are met in those cases where the laboratory needs to use equipment outside its permanent control;
	calibration programmes are established for key quantities or values of the instruments where these properties have a significant effect on the results;
	equipment (including that used for sampling) **is calibrated or checked** to establish that it meets the laboratory's specification requirements **before it is placed into service and before it is used;**
Ensure that …	only **authorized personnel** operates the equipment;
	Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available;
	Each item of equipment and its software is **uniquely identified** - where practicable.
Maintain records of each item of equipment and its software significant to the tests and/or calibrations performed which contain at least:	the **identity** of the item of equipment and its software;
	the **manufacturer's name, type identification, and serial number** or other unique identification;
	checks that equipment complies with the specification;
	the **current location**, where appropriate
	the **manufacturer's instructions**, if available, or reference to their location;
	dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
	the **maintenance plan**, where appropriate, and maintenance carried out to date;
	any **damage, malfunction, modification or repair** to the equipment;

5.5 Equipment II

Requirements	Details
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.	
Take out of service, isolate or clearly label as being out of service (until it has been repaired and evidently performs correctly) all equipment that has been subjected to overloading or mishandling, or has been shown to be defective or outside specified limits, or gives suspect results.	**examine the effect** of the defect or departure from specified limits on previous tests and/or calibrations; institute the "**Control of nonconforming work**" **procedure.**
Label all equipment under the control of the laboratory and **requiring calibration** to indicate, including the and the	the **status of calibration;** date when **last calibrated;** date or expiration criteria **when recalibration is due.**
Verify satisfactory function and calibration status when, for whatever reason, equipment goes temporarily outside the direct control of the laboratory, the laboratory.	
Carry out all necessary **intermediate checks** of the calibration status of the equipment **according to a defined procedure**	
Have procedures to ensure that copies (e.g. in computer software) are correctly updated where calibrations give rise to a set of correction factors.	
Safeguard all test and calibration equipment including its software **from adjustments** which would **invalidate** the test and/or calibration results.	

5.6 Measurement Traceability I

General	
Requirements	**Details**
Calibrate all equipment having a significant effect on the accuracy or validity of the result of the test, calibration or sampling used for tests and/or calibrations **before putting it into service** and **have an established programme and procedure** for the calibration of this equipment.	**Have 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.
Specific requirements	
Design and operate calibration laboratories and **have a programme for calibration** of equipment **so as to ensure** that calibrations and measurements made by the laboratory are traceable to the International System of Units (Système international d'unités, SI).	**establish traceability** of 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 (may be achieved in several steps carried out by different laboratories that can demonstrate traceability);
	achieve the link to SI units by reference to national measurement standards (primary or secondary) **or**
	use **calibration services** from laboratories issuing calibration certificates that can demonstrate competence, measurement capability and traceability. In this case **ensure that certificates** 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).
Establishing traceability of calibration laboratories to appropriate measurement standards in case of calibrations that currently cannot be strictly made in SI units by . In these cases calibration shall provide confidence in measurements by such as:	**use of certified reference materials** provided by a competent supplier to give a reliable physical or chemical characterization of a material;
	use of specified methods and/or **consensus standards** that are clearly described and agreed by all parties concerned;
	participation in a suitable programme of interlaboratory comparisons;
Apply the above requirements to measuring and test equipment with measuring functions of **testing laboratories** depending on the contribution to the total uncertainty of the test result of the calibration.	ensure that the equipment used can provide the uncertainty of measurement needed;
	if calibration is the dominant factor, the requirements of traceability should be strictly followed;
	use certified reference materials, agreed methods and/or consensus standards as required for calibration laboratories - where traceability of measurements to SI units is not possible or not relevant.

5.6 Measurement Traceability II

Reference standards and reference materials	
Requirements	**Details**
Have a programme and procedure for the calibration of **reference standards** by a body that can provide traceability. Reference standards shall be calibrated before and after any adjustment.	Use reference standards of measurement for calibration only.
Use **reference materials traceable to SI units** of measurement, where possible **or to certified reference materials** and check internal reference materials as far as is technically and economically practicable.	
Have defined procedures and schedules for intermediate checks needed to maintain confidence in the calibration status of:	reference standards; primary standards; transfer standards; working standards; reference materials;
For reference standards and reference materials **have procedures** for	safe handling; transport; storage; use.

5.7 Sampling

Requirements	Details
Have a sampling plan and procedures for sampling of substances, materials or products for subsequent testing or calibration.	**Make** the sampling plan as well as the sampling procedure **available at the location** where sampling is undertaken.
	Base sampling plansl, whenever reasonable, **on appropriate statistical methods**.
	The **sampling process** shall address the factors to be controlled to ensure the validity of the test and calibration results.
Record in detail with the appropriate sampling data and include in all documents containing test and/or calibration results if the customer requires deviations, additions or exclusions from the documented sampling procedure. Communicated these to the appropriate personnel.	
Have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. Include in the records:	the sampling procedure used; the identification of the sampler; environmental conditions (if relevant); diagrams or other equivalent means to identify the sampling location as necessary; the statistics the sampling procedures are based upon;

5.8 Handling of Test and Calibration Items

Requirements	Details
Have procedures for samples of test and/or calibration items covering:	transportation; receipt; handling; Protection; Storage; retention and/or disposal;
Lay down provisions necessary to protect	the integrity of the test or calibration item; the interests of the laboratory; the interests of the customer.
Have a system for identifying test and/or calibration items throughout the life of the item in the laboratory or upon transfer from the laboratory which excludes confusion of items either physically or when referred to in records or other documents.	
Record any abnormalities of items or departures from normal or specified conditions, as described in the test or calibration method upon receipt of the test or calibration item.	
Consult the customer for further instructions before proceeding and record the discussion 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.	
Have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation.	follow handling instructions provided with the item; maintained, monitor and record specified storage and environmental conditions; **have arrangements for storage and security** for test or calibration item or a portion of an item that is to be held secure; provide a copy of the sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, to those responsible for taking and transporting the samples;

5.9 Assuring the Quality of Test and Calibration Results

Requirements	Details
Have quality control procedures for a planned monitoring of the validity of tests and calibrations undertaken	**use regularly** certified reference materials and/or internal quality control using secondary reference materials;
	participate in inter-laboratory comparison or proficiency-testing programmes;
	perform replicate tests or calibrations using the same or different methods;
	retest or recalibrate retained items;
	correlate results for different characteristics of an item;
	record the resulting data in such a way that **trends** are detectable;
	apply statistical techniques to the reviewing of the results where practicable;
	take planned corrective action where quality control data fall outside pre-defined criteria;

5.10 Test Reports and Calibration Certificates I

General	
Requirements	**Details**
Report accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration method the results of each test, calibration, or series of tests or calibrations carried out by the laboratory.	**Report results** in a test report or a calibration certificate issued as hard copy or by electronic data transfer and including 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.
	Include normally for this purpose the information required by 5.10.2, and 5.10.3 or 5.10.4 of ISO 17025:2005 (internal reports may be simplified).
	Have readily available all information listed in 5.10.2 to 5.10.4 including parts not reported to the customer in the laboratory which carried out the tests and/or calibrations.
Test reports and calibration certificates	
Have a format for test reports or calibration certificates that contains at least the following information	**title** (e.g. "Test Report" or "Calibration Certificate");
	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;
	• **unique identification** of the test report or calibration certificate (such as the serial number); • an **identification on each page** in order to ensure that the page is recognized as a part of the test report or calibration certificate; • a **clear identification of the end** of the test report or calibration certificate;
	name and address of the customer;
	identification of the **method** used;
	unambiguous **identification, description, and the condition of the item**(s) tested or calibrated;
	date of receipt of the test or calibration item(s);
	reference to the **sampling plan and procedures** used by the laboratory or other bodies;
	results with, where appropriate, the **units of measurement** of the test or calibration;
	name(s), function(s) and signature(s) of person(s) authorizing the test report or calibration certificate;
	where relevant, a **statement** to the effect that the results relate only to the items tested or calibrated.

5.10 Test Reports and Calibration Certificates II

Test reports	
Requirements	**Details**
Include the following additional information on test methods in the format for **test reports**	**deviations from, additions to, or exclusions** from the test method, and information on specific test conditions;
	a statement of **compliance/non-compliance** with requirements and/or specifications;
	where applicable, a statement on the estimated **uncertainty of measurement**;
	where appropriate and needed, **opinions and interpretations** (see 5.10.5);
	additional information which may be required by specific methods, customers or groups of customers;
Include the following additional information on sampling – where applicable - **in** the format for **test reports**	date of sampling;
	unambiguous **identification of the substance**, material or product sampled;
	the **location of sampling**, including any diagrams, sketches or photographs;
	a **reference to the sampling plan and procedures** used;
	details of any **environmental conditions** during sampling that may affect the interpretation of the test results;
	any **standard or other specification for the sampling method or procedure**, and deviations, additions to or exclusions from the specification concerned.
Calibration certificates	
Include the following additional information in the format for **calibration certificates**	the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
	the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;
	evidence that the measurements are traceable.
Opinions and interpretations	
Mark clearly opinions and interpretations as such in a test report and **document** the basis upon which they have been made. Provide the following information	an **opinion on the statement of compliance/noncompliance** of the results with requirements;
	fulfilment of contractual requirements;
	recommendations on how to use the results;
	guidance for improvements;
Testing and calibration results obtained from subcontractors	
Identify clearly any results of tests performed by subcontractors and use the calibration certificate of the laboratory performing the work.	

5.10 Test Reports and Calibration Certificates III

Electronic transmission of results	
Requirements	**Details**
Ensure compliance with ISO 17025:2005 in case of electronic transmission of test or calibration results	
Format of reports and certificates	
Design the format to **accommodate each type of test** or calibration carried out but harmonise the layout and minimize the possibility of misunderstanding or misuse.	
Amendments to test reports and calibration certificates	
Make material amendments to a test report or calibration certificate after issue **only in the form of a further document, or data transfer**.	Fulfil all requirements of ISO 17025:2005.
	Refer to the original document and uniquely identify the new one if a complete new report or certificate is to issued.
	Include the statement: "Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]".

Workshop on Issues relevant for the Accreditation of the Current Quality Control Laboratories (QCL)