

# AALTO UNIVERSITY

# **Metrology Research Institute**

**Quality System** 

Version: 4.2

Date of Issue: March 19, 2021

**Approved:** 

Erkki Ikonen



# Contents

1.	ORGANISATION AND MANAGEMENT	4
1.1	NAME AND ADDRESS OF THE LABORATORY	4
1.2		
1.3		
1.4		
2.	DESCRIPTION OF QUALITY SYSTEM	7
	Purpose	
2.1		
2.2	(	
2.3		
2.4 2.5		
2.5		
	2.6.1 Definition	
	2.6.2 Equipment	
	2.6.2.1. Description(s) of setup(s)	
	2.6.2.1. Description(s) of secup(s)	0
	2.6.3 Measurement traceability	
	2.6.4 Calibration and measurement procedures including validation methods	1
	2.6.5 Handling of calibration items	1
	2.6.6 Uncertainty budgets	
	2.6.7 Accommodation and environmental conditions	
	2.6.8 Field calibrations	2
	2.6.9 Control data	
	2.6.10 Certificates	2
	2.6.11 Intercomparisons 1	
	2.6.12 References	3
3.	SERVICE TO CLIENT1	3
3.1	General terms1	3
3.2		
	3.2.1 Minor complaints	
	3.2.2 Major complaints	
	3.2.3 Communication with client	
3.3		
4.	CONTROL OF NONCONFORMING CALIBRATION WORK1	
5.	CALIBRATIONS OUTSIDE OFFICIAL SCOPE 1	5
6.	SUBCONTRACTING OF CALIBRATIONS1	6
7.	QUALITY ASSURANCE OF CALIBRATION RESULTS 1	6
7.1	Corrective actions1	6
7.2	PREVENTIVE ACTIONS1	6
8.	SOFTWARE1	7
8.1	STORING AND BACKUPS1	7
8.2		
8.3		
9.	CONTROL OF DATA AND INFORMATION MANAGEMENT1	7



10. AU	DITS AND REVIEWS	EW
10.1	MANAGEMENT REVIEW	
10.2		
10.3		
10.4	RISKS AND OPPORTUNITIES	20
11. PEI	RSONNEL	21
11.1	TERMS OF CONTRACT	21
11.2	QUALIFICATION REQUIREMENTS	
11.3	TRAINING	22
12. CA	LIBRATION AND MEASUREMENT CERTIFICATES	
13. RE	FERENCES	22

# Annexes

AA: List of Authorisations

B: Quality Policy of the University

C: Instructions on Writing Calibration Certificates

D: Quality Policy of the Laboratory

E: Laboratory Premises

F: Digital Signing of Certificates



# 1. Organisation and management

# 1.1 Name and address of the laboratory

Aalto-yliopisto Sähkötekniikan korkeakoulu Signaalinkäsittelyn ja akustiikan laitos MIKES-Aalto Mittaustekniikka PL 15500 00076 Aalto

(Käyntiosoite: Maarintie 8, ESPOO)

Puhelin: 09 - 470 01

For international affairs:

Aalto University School of Electrical Engineering Department of Signal Processing and Acoustics Metrology Research Institute P.O.Box 15500 FI-00076 Aalto FINLAND

(Visiting address: Maarintie 8, ESPOO, Finland)

Telephone: +358 - 9 - 470 01

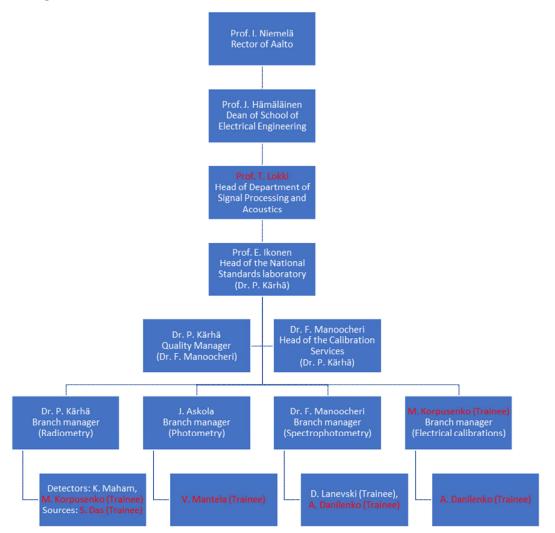
# 1.2 Legal status

The Metrology Research Institute is a joint laboratory of the Aalto University and VTT Mikes. Aalto University is an entity that is legally responsible.

Commitment of the Helsinki University of Technology / Aalto University to the operation of the MRI as a National Standards Laboratory has been described in <u>Annex</u> <u>B</u>.



# 1.3 Organisational structure



The quantities maintained by the laboratory have been divided into three branches, each of which has been nominated a branch manager. In addition, electrical calibrations needed to maintain traceability, have been nominated a responsible person. The quantities with their ranges and uncertainties are defined in the lists in the BIPM CMC database. Calibration services and maintenance tasks under each branch, with persons authorised to perform them, are listed in <u>Annex AA</u>.

# 1.4 Responsibilities, authorities, and required qualifications of the key personnel

A suitable university degree at master level is required for Branch Managers, Quality Manager, and Head of the Calibration Services. A suitable degree at doctoral level is required for Head of the National Standards Laboratory. Knowledge of SFS-EN ISO/IEC 17025 is required for the Quality Manager.



All key personnel have been nominated a deputy. In the case of long absence of the key person, the deputy shall have the same authorities and responsibilities as the corresponding key person.

### **Rector of the University**

1. No direct impact on the calibration services

### Dean of the School

1. No direct impact on the calibration services

### Head of the Department

1. No direct impact on the calibration services

### Head of the National Standards Laboratory

- 1. Responsible for allocating laboratory space needed for the calibration work
- 2. Overall responsibility for allocating resources (time, funds) to the calibration work
- 3. Approves the top level quality system and changes to it, prepared by the quality manager by signing the front page of the paper copy
- 4. Initiates review of the quality system
- 5. Handles major complaints by customers
- 6. Overall responsibility of the maintenance and development projects of MIKES
- 7. Can also sign calibration certificates when needed.

#### Head of the Calibration Services

- 1. Overall responsibility of the calibration service
- 2. Handles customer service (orders, information, quotations, pricing)
- 3. Delegates calibrations to the corresponding Branch Managers
- 4. Handles minor complaints by customers (related to service)
- 5. Signs calibration certificates in cases where the person doing the calibrations is the branch manager (radiometry preferred).

#### **Quality Manager**

1. Overall responsibility of the quality system



- 2. Prepares and maintains the quality system at the top level (this file)
- 3. Audits the lower level quality documents maintained by Branch Managers
- 4. Prepares, manages and reports the maintenance project of MIKES
- 5. Has direct authority on all personnel for ensuring that the quality system is implemented and followed at all times
- 6. Has direct access to the highest level of management at which decisions are taken on laboratory policy or resources
- 7. Signs calibration certificates in cases where the person doing the calibrations is the branch manager (photometry and spectrophotometry preferred).

### **Branch Manager**

- 1. Overall responsibility of the calibrations within the branch
- 2. Performs calibrations delegated by the Head of the Calibration Services
- 3. Ensures correctness of calibration results in case measurements are done by someone else (for example the Deputy)
- 4. Signs the calibration certificates within the branch. The other signature is made by the person who has done the measurements.
- 5. Prepares and maintains the quality documents required for the quantities within the branch (Documents listed in BIPM CMC database and tasks listed in <u>Annex</u> <u>AA</u>)
- 6. Approves the quality documents by signing the front pages of the paper copies
- 7. Handles minor complaints by customers (related to contents of calibration certificates)

# 2. Description of quality system

The laboratory operates under a quality system based on ISO/IEC 17025.

# 2.1 Purpose

The main purpose of the quality system is to ensure that the calibration results issued as calibration certificates on the quantities listed in the BIPM CMC database are traceable to SI-units and that the given results are within the quoted uncertainties and ranges.



The secondary purpose of the system is to maintain such level of documentation on routine calibration services that change of personnel causes minor difficulties only.

A third purpose of the system is to give third party assessors necessary information to assess the activities.

# 2.2 Quality policy

The quality policy of HUT, a predecessor of the Aalto University, signed by the Rector of the University (Paavo Uronen) and Head of the Department (Pekka Wallin) on May 17, 1995, is included in <u>Annex B</u>. The quality policy of the laboratory, signed by the Head of the National Standards Laboratory (Erkki Ikonen) on Feb 12, 2002, is included in <u>Annex D</u>.

# 2.3 Quality objectives

The quality objectives of the laboratory are:

- 4 out of the 6 audit areas are audited annually
- In each area audited, at least 3 non-conformities are reported and solved
- Annual management review takes place by March 31
- 6 feedback forms are received from customers annually
- No customer complaints are given on technical issues
- Outside summer months, there should be no complaints on time schedules
- No customer feedback should have average grade less than 3 (on scale 1-5).

# 2.4 Structure of the quality system

The quality system consists of this general part with its annexes, and Quality/Instruction Manuals containing detailed information on calibration services. The Quality and Instruction Manuals belonging to each calibration service are listed in the index page of this quality system (index.html). The minimum requirements on the contents of these Manuals are defined in Chapter 2.6.

Quality Manuals describe a large amount of actions needed in the realisation of certain quantities. For example, Quality Manual of Reference Spectrometer Laboratory describes all actions needed to maintain and use the reference spectrometer in measurements of spectral transmittance.

Instruction Manuals may be considered as subdocuments of the Quality Manuals. They typically define some specific instructions or procedures for applying the



apparatus described in a Quality Manual to some specific measurements. For example, Instruction Manual of Specular Reflectance Measurements describes the use of the reference spectrometer in reflectance measurements. Parts that are common with spectral transmittance measurements are not repeated in the Instruction Manual, so the Instruction Manuals should be used with the corresponding Quality Manuals.

# 2.5 Document control

The Quality System is maintained primarily in the web pages of the laboratory. Editable versions of all quality documents are stored at

```
\work.org.aalto.fi\T405\MIKES-Aalto\Quality\
```

The contents of this directory are shown in the Figure below. Each branch has its own subdirectory for storing the latest version of the relevant quality documents. These subdirectories also contain backups of programs, calibration data of equipment such as stability monitoring, and other relevant material as described in the Quality Manuals. The general Quality System (this file) can be found under \QMS\. Directory \Audit and review\ contains minutes of all quality audits divided under years. Published PDF-versions of documents are stored under \WEB\.

anize  Burn New folder						· =	<b>1</b>
Favorites	Name	Date modified	Туре	Size			
	Audit and review	22/10/2013 12:00	File folder				
Libraries	🎍 Chemical safety	22/10/2013 12:00	File folder				
	JE Electrical	22/10/2013 12:00	File folder				
Computer	Ji fibop	22/10/2013 12:02	File folder				
Windows (C:)	Ja Old files	22/10/2013 12:00	File folder				
MIKES-Aalto (\\work.org.aalto.fi\T405) (Z:)	🍶 photom	22/10/2013 12:01	File folder				
Lalibrations	🔒 QMS	02/12/2013 17:21	File folder				
Je Documents	🔒 radiom	06/11/2013 14:45	File folder				
3 Maintenance	🁪 spphotm	22/10/2013 12:02	File folder				
3 Orders	🎍 Templates	02/12/2013 09:50	File folder				
Pictures	🎍 Trash	22/10/2013 11:59	File folder				
🕌 Projects	🎉 WEB	02/12/2013 16:35	File folder				
3 Quality	.DS_Store	18/05/2010 10:58	DS_STORE File	13 KB			
Audit and review	Calsched.xlsx	18/09/2013 15:43	Microsoft Office E	35 KB			
📕 Chemical safety	ack2.jpg	19/12/2007 13:32	JPG File	282 KB			
lectrical	i robots.txt	10/01/2013 14:34	Text Document	1 KB			
🍌 fibop							
Old files							
🎉 photom							
🎉 QMS							
👪 radiom							
🎉 spphotm							
👪 Templates							
🕌 Trash							
J WEB							
3 Resources							
🔒 Users							
🔒 work							
Network							
16 items Offline status: Online							

The quality system is visible in internet in the address

http://metrology.tkk.fi/quality/index.html

The directory contains an index page, with which all documents belonging to the quality system can be seen and called at the same time.



Quality Manager maintains one paper copy of the general Quality System containing signatures of approval. The web version is updated during management review.

Branch managers maintain one paper copy of each Quality and Instruction Manual within their branch containing signatures of approval. Up-to-date copies are delivered to Quality Manager before auditing the quantities. After auditing, the web versions are updated.

Procedure for updating a manual in the quality system:

- 1. Branch manager prepares a new version of a quality document.
- 2. Branch manager prints the document into PDF, places it into the subdirectory \\work.org.aalto.fi\T405\MIKES-Aalto\Quality\WEB\ and notifies the quality manager.
- 3. Quality manager checks and approves the document, stores the old version of the document to be replaced into subdirectory \Old files\ and places the new version into the internet.
- 4. Paper copy of the new manual is signed by the Branch Manager and stored.

# 2.6 Contents of Quality Manuals

This section defines minimum requirements for the Quality Manuals. Some of the contents may also be in Instruction Manuals.

# 2.6.1 Definition

Each Manual should begin with description on the contents of the Manual, which facilities, services, operations are included.

# 2.6.2 Equipment

Equipment needed for calibrations is listed.

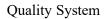
# 2.6.2.1. Description(s) of setup(s)

Setups used for calibrations are described preferably using figures.

# 2.6.2.2. Calibration requirements

Devices that need to be calibrated in order to assure that measurements are traceable within their uncertainties need to be identified. Calibration intervals are specified.

Devices may be calibrated by-demand, that is, status of calibration is checked before customer calibrations, and devices are calibrated if found necessary.





Alternately, branch managers may define calibration schedules for their equipment.

Devices needing regular maintenance are collected into the database Calsched.xls. This database has separate sheets for Electrical, Photometric, Spectrophotometric, and Radiometric calibrations. Calibration intervals are defined, and dates of latest calibrations are recorded.

### 2.6.3 Measurement traceability

Traceability of the measurements to the SI-units is described preferably in form of a traceability chart.

### 2.6.4 Calibration and measurement procedures including validation methods

Measurement procedures must be described with such level of details that a thirdparty assessor with experience in optical metrology can judge adequacy of the procedures. A person with basic knowledge and background in optical metrology should be able to perform calibrations using the material after a brief introduction to the measurement setups.

Validation methods of the calibration setups, including maintenance and calibration work necessary to ensure traceability, have to be described accordingly.

# 2.6.5 Handling of calibration items

All items are handled with care and stored in locked rooms/laboratories.

Upon arrival, items are checked visually to note possible damage in the transport. Before calibration, operation of the items is tested.

If a defect in an item is noted, the item is not repaired without notifying the customer. This applies to cleaning or service of items as well.

Some calibration items, e.g. delicate optics such as diffuse reflectance standards, may require special handling procedures. If such requirements exist, they should be defined in the Quality or Instruction manuals.

# 2.6.6 Uncertainty budgets

All uncertainties are calculated according to ISO Guide to the Expression of Uncertainty in Measurement.

Guidelines on the uncertainty estimations are given. These include lists of sources of uncertainty to be taken into account.



Measurement ranges and uncertainties are accepted by MIKES. In practice this takes place when quantities are accepted to the CMC database. Uncertainty calculations justifying the accepted figures should be given.

# 2.6.7 Accommodation and environmental conditions

Laboratory allocated for the calibrations is specified. Laboratory rooms available are specified in Annex E. If calibrations require environmental conditions different from ordinary room conditions, these are given. Specific conditions may include e.g.

- 1. Clean room facilities,
- 2. Controlled humidity and temperature.

# 2.6.8 Field calibrations

Some calibrations can be done in the laboratories of customers. This concerns e.g. spectral irradiance measurements. Transferring standard lamps is risky and may increase the calibration uncertainty. Transferring the filter radiometer serving as national standard is therefore often preferred.

If field calibrations apply to quantities of the Manual, these should be described. Equipment transferred to customer laboratory is listed. Requirements for the customer devices and procedures used may be defined.

# 2.6.9 Control data

The raw data of the measurements must be archived. Quality/Instruction Manuals describe which data is archived and where.

With many quantities, stability of the scale is monitored using reference samples, e.g. consistency of the optical power scale is monitored using trap detectors. Recording procedures for such data should be described.

# 2.6.10 Certificates

General instructions for preparing calibration certificates are given in <u>Annex C</u>. Quality manuals should describe the specific contents of the certificates, e.g. parameters that are measured or calculated and should be given to customers.

# 2.6.11 Intercomparisons

All quantities take part in international intercomparisons regularly. The minimum interval is set such that the entries stay in the CMC database. Lists and results of past intercomparisons are included in the Quality Manuals.



# 2.6.12 References

References relevant to performing calibrations are filed with the paper copy of the Quality/Instruction Manual. This includes e.g. publications and intercomparison results.

# 3. Service to client

### 3.1 General terms

Customers may contact the head of the calibration services or the corresponding branch manager if they already know who does the calibrations.

Price and delivery time for the calibration must be accepted mutually before calibration takes place. The customer will be notified whether the price includes the value added tax (VAT) or not.

If required by customer, a written quotation will be given.

The person carrying out the negotiations shall store the records of the correspondence, typically E-mails, for possible later use. The price agreed is recorded in the list of calibration Certificates.

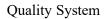
Before starting calibrations, it has to be made sure that the customer understands what he/she wants.

If calibration item needs service or cleaning before calibration, this has to be agreed with the customer. If found necessary, calibration results should be given for the item before and after the service.

A calibration report on the measurements will be written according to <u>Annex C:</u> <u>Instructions on Writing Calibration Certificates</u>. If the customer does not need the certificate, but only wants the results e.g. in the form of a computer file, it is allowed to act accordingly. In such case branch manager will archive such amount of information that the calibration report could be written later.

If the customer wishes, he may come to the laboratories to follow the calibration work. In such a case, calibration items of other customers should be hidden to assure confidentiality.

Invoicing of the calibrations is handled at the Aalto Department of Signal Processing and Acoustics. Invoicing information is sent by e-mail to the financial secretary. There is an e-mail template "invoicing.txt" for submitting the information required in directory \\work.org.aalto.fi\T405\MIKES-Aalto\Calibrations\Templates\.





# 3.2 Complaints

Complaints from customers will be written down, unless the customer already gives the complaint in written form. Template form "poikkeama\_lomake" in folder \\work.org.aalto.fi\T405\MIKES-Aalto\Quality\Audit and review\ is used.

# 3.2.1 Minor complaints

Minor complaints, such as spelling mistakes in calibration certificates that do not need additional measurements, are corrected by the corresponding branch manager. A new corrected calibration report with the same ID number, as the original one is prepared. The new certificate is marked with text "This certificate replaces the earlier calibration certificate bearing the same number issued on <date>." The changes made shall be clearly identified e.g. with colour. Changes made and, where appropriate, the reason for the change shall be written to the "Remarks" section of the certificate. The new certificate is archived with the old one. In the electrical archive, the new version will be identified by adding letter "b" in the file name. Customer is asked to archive/handle the old version of the certificate according to their quality system. Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Certificate / Report Number...", or an equivalent form of wording.

Minor complaints, not related with the measurement results, will be handled by the Head of the Calibration Services. This category includes e.g. customers that are not satisfied with service or pricing.

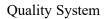
# 3.2.2 Major complaints

Major complaints, such as suspects of incorrect measurement results, should be reported to the Head of the National Standards Laboratory, who decides on actions necessary. These may include repeating the calibrations or studying/repairing the calibration equipment. If the cause of incorrect measurement results is violation of the quality system, the Quality Manager should be informed.

In case of major complaints, cause of the error will be studied. Preventive actions are planned such that the error can not take place again.

# **3.2.3** Communication with client

The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question. In the case of major complaints, this will be the Head of the National Standards Laboratory. In the minor complaints, this will be the Quality Manager or the Head of Calibration Services, which ever has not been involved in the laboratory activity involved.





# 3.3 Customer feedback

With each calibration, customer feedback is collected. If calibration certificate is sent electrically, also the feedback will be electrical. The following sentence is added to the e-mail:

"We would appreciate your feedback on our calibration services. Please take a minute to complete a survey in <u>https://webropol.com/s/mrifeedback</u>."

"Vastaanotamme mielellämme palautetta kalibrointipalveluistamme. Palautetta voi antaa täyttämällä kyselyn osoitteessa <u>https://webropol.com/s/mrifeedback</u>."

If results are communicated on paper, a customer feedback form is sent to the customer with the calibration certificate. Return address of the form is the quality manager of MIKES. Customers may include their names in the form or they can reply anonymously. Customer feedback is analysed in the annual management review.

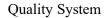
# 4. Control of nonconforming calibration work

If a nonconformity is noted that affects calibration results, the following procedures apply:

- Authorities are as with complaints. Minor nonconformities are corrected by the corresponding branch manager. Major nonconformities are reported to the Head of the National Standards Laboratory, who decides on actions necessary. Template form "poikkeama\_lomake" in folder \\work.org.aalto.fi\T405\MIKES-Aalto\Quality\Audit and review\ can be used to record the nonconformity.
- If nonconformity is such that it may affect further calibrations, such as a faulty or uncalibrated device, calibrations utilizing the device are halted before the nonconformity is cleared. If it is clear that the device works, and it can be calibrated later, it can be used, but the results are not to be communicated before calibration.
- Effects of the nonconformity on the calibration where it was noted, and other calibrations that it may have affected, are evaluated. Head of the national standards laboratory decides on actions to be taken.
- If necessary, customers are notified on the noted nonconformity. Devices are called back for calibration if necessary, or new certificates accounting for the nonconformity may be issued.

# 5. Calibrations outside official scope

Calibration certificates may only be issued for the quantities, ranges and uncertainties that have been included in the BIPM CMC database.





If other measurements are carried out, the certificates may not contain CIPM logo and reference to MIKES, and the certificates may not be called "Certificate of Calibration." Suitable terms to be used are "Mittauspöytäkirja" or "Measurement report." Customer must be clearly informed that the report is not an official calibration certificate, and the reason for the procedure must be explained.

Measurements reported on a Measurement Report must be done as carefully and using the same principles as with the calibration certificates.

# 6. Subcontracting of Calibrations

Laboratory does not subcontract calibrations. If certain calibration service is not available at Aalto, the customers are informed about laboratories where calibration can be carried out, and asked to contact them directly.

# 7. Quality assurance of calibration results

# 7.1 Corrective actions

Corrective actions in the case of customer complaints are described in chapter 3.2.

If somebody (anybody) notes an error in measurement procedures or maintenance that may affect calibration results, he must immediately notify the branch managers, whose calibrations may be erroneous. Customers will be informed immediately about erroneous calibration data. Actions are taken according to chapter 3.2, including filling in the non-conformity form.

# 7.2 Preventive actions

Nonconformances in calibrations are prevented in the following ways:

- 1. Calibrations are performed according to the written Quality and Instruction Manuals. If there are noticed things that may cause erroneous measurement results if not taken into account, these will be written as notes in the instructions.
- 2. All quantities take part in intercomparisons regularly if possible.
- 3. When realising quantities, reference samples are stored if possible. This concerns e.g. optical power (trap detectors used as reference) and luminous intensity (commercial photometers and a group of lamps used as reference). This prevents errors in the next realisation, because the new results may be compared with the old realisation.



# 8. Software

Most measurements are automated and controlled using PCs. The computer program most often used is National Instruments LabVIEW. The measurement programs read digital multimeters, control shutters and linear translators, etc. Sometimes results are analysed using programs. This may take place e.g. using Excel or Matlab.

Quality and Instruction Manuals list the measurement computers. In addition they list the software needed, and the latest version numbers if applicable.

# 8.1 Storing and backups

Up-to-date copies of all measurement programs are stored in the Metrology server in the subfolders of \\work.org.aalto.fi\T405\MIKES-Aalto\Quality\. Also old versions are stored in separate subfolders. This directory is routinely backed-up by the IT maintenance of Aalto. The branch manager of each branch is responsible for maintaining and making backups of the contents of the measurement computers. Each branch has its own subfolder for the programs. Subfolders are not accessible outside MRI.

The backup files on the server should not be used directly. Instead, copies of the latest versions in the measurement computers are used. The default settings of the measurement programs should not be overwritten. For minor changes, a new copy of the program is made and stored with measurement results.

# 8.2 Verification

When new measurement programs are written, their operation is verified before taking into use. In case of a new program, this can be done for example by comparing the results with manual calculations. In case of taking new program versions into use, the functionality of the program can be compared with the earlier version of the program.

# 8.3 Version handling

When practical, computer programs are numbered to indicate the version. Changes between the versions are documented. It is often necessary to do minor changes in the program code, e.g. to hot-wire parameter-values to LabVIEW codes, that cannot be considered as a version. In such cases, the measurement program used is stored with the measurement data. This also applies to Matlab and Excel models used to analyse data.

# 9. Control of data and information management

Control of records directly related with quantities is described in the Quality and Instruction Manuals. This includes archiving of raw data and characterisation



measurement results. References and publications concerning the quantities are archived with the paper copy of the manuals.

All workers have a personal folder in directory:

 $\label{eq:linear} $$ work.org.aalto.fi\T405\MIKES-Aalto\Users\$ 

These personal folders are accessible by laboratory personnel, and contain folder named "Calibrations", where raw data and analysis of calibrations are stored.

General documents belonging to the quality system are collected in the web-page

\\METROLOGY\webpages-quality\index.html

Electronic documents are included as links. In case of paper documents, the location and the person in charge of maintaining the latest version is mentioned.

Documents are installed in the system mainly in PDF-format that is non-editable. In this case the latest versions are stored in editable format (usually DOC) in the subdirectories of

\\work.org.aalto.fi\T405\MIKES-Aalto\Quality\

\\work.org.aalto.fi\ is backed up by Aalto IT.

Archiving of calibration certificates is described in <u>Instructions on Writing</u> <u>Calibration Certificates</u>.

Equipment records such as operation and maintenance manuals are stored in

\\work.org.aalto.fi\T405\MIKES-Aalto \Resources\Equipment\

Standards relevant to calibrations are stored in

 $\work.org.aalto.fi\T405\MIKES-Aalto\Resources\Standards\$ 

# **10.Audits and reviews**

#### 10.1 Management review

A management review initiated by the Head of the National Standards Laboratory is arranged once a year. Participants of the review include

- 1. Head of the National Standards Laboratory (Chairman),
- 2. Quality Manager (Secretary),
- 3. Head of the Calibration Services,



- 4. Branch Managers,
- 5. Deputies of the above.

At least the following points will be reviewed in the meeting (ISO17025 8.9.2):

- 1. Changes in internal and external issues that are relevant to the laboratory (new and planned projects, changes at Aalto or VTT Mikes, personnel issues) (*a*),
- 2. Corrective actions taken after the previous review, effectiveness of the implemented improvements (d, f),
- 3. Suitability of the Quality System and measurement procedures, possible development needs in either technology or quality system (*c*),
- 4. Outcome of internal audits (report of Quality Manager) (*e*),
- 5. Possible assessments by MIKES or other external bodies (g),
- 6. Calibrations since last review, changes in the volume and type of work (report of the Head of the Calibration Services) (*h*),
- 7. Results of intercomparisons and other assurance of the validity of results (n),
- 8. Customer complaints and feedback, personnel feedback (*i*, *j*),
- 9. Purpose and objectives of the laboratory, with identified risks and opportunities (*b*, *m*),
- 10. Resources (personnel, laboratories, equipment, funding) (*l*),
- 11. Training requirements, plans for conferences and meetings (o).

Minutes of the review meeting are written.

# 10.2 Internal audits

Each branch of quantities (photometry, radiometry, spectrophotometry) is audited nominally once a year. Contents of the audit include:

- 1. Checking that the Quality and Instruction manuals are up-to-date and cover all quantities listed in the CMC.
- 2. Review of a couple of calibration certificates to see that personnel act according to the quality system and their instruction manuals.
- 3. Review of intercomparisons and maintenance since last audit, including procedure for monitoring the validity of results.



4. Qualifications (Annex AA) of the personnel involved.

Audits may also be carried out on archives (checking that electronic and paper archives include all certificates of calibrations carried out since last audit), electrical calibrations, personnel, and the calibration schedule of the equipment.

Not everything can be audited each year. Quality manager selects most important actions to be audited and changes the focus of the audits depending on needs so that everything is regularly audited with approximately 2-3 year intervals.

Audits typically take place in November – December. People concerned are notified in advance so they can prepare for the coming audit. Before the audit, the branch manager delivers paper copies of the latest versions of the Quality and Instruction Manuals to be reviewed. Alternately the web versions of manuals can be used.

# 10.3 External audits

Laboratory is regularly audited by VTT-MIKES, typically in December. The audit is carried out by the VTT-MIKES quality manager and an external expert from a National Standards Laboratory or a Designated Institute. Minutes of the audit are prepared. The results, possible non-conformities, and recommendations are reviewed in the management review.

Laboratory prepares an annual report for the Euramet Quality Forum and presents its maintenance annually. Once in five years, the whole quality system is presented.

If MRA and its CMC database require an external evaluator from an other NMI, this will be arranged.

# 10.4 Risks and opportunities

Major consideration of risks and opportunities takes place minimum once in five years in the form of an activity in a laboratory development day. Laboratory personnel will review the earlier risk assessment report and consider whether the risks and opportunities are the same, or if they have changed. After the mapping, the risks are discussed in the weekly laboratory meetings to find solutions. The risk evaluation shall include impartiality of the laboratory and its personnel.

Impartiality issues are governed by the Aalto University procedures:

https://www.aalto.fi/en/services/outside-employment-and-other-interests-related-to-business-activities-secondary-occupation

Impartiality problems may arise from secondary occupations, side businesses such as start-up companies, or owing significant amounts of stock bonds. Employees shall report such activities to their supervisors.



Risks and opportunities shall be discussed annually in the management review.

Occupational risks in laboratories are evaluated on a 5-year interval by the Alto University.

# 11.Personnel

# 11.1 Terms of contract

The key personnel and all persons performing calibrations shall have a fixed salary. Income shall not be influenced by results or amount of calibrations. Workers have a working contract with Aalto. The contract defines terms of confidentiality.

Head of the National Standards Laboratory ensures that all personnel involved with calibration and quality work shall have enough resources required for the work.

All personnel shall report to Head of the National Standards Laboratory immediately, if they can not ensure the quality of calibrations due to

1. Lack of authority,

2. Lack of resources (time, funds),

3. Internal or external commercial, financial or other pressure.

All deviations from the quality system shall be reported to the Quality Manager.

All persons involved with the calibrations shall be familiar with the quality system.

# 11.2 Qualification requirements

Qualification requirements for people taking part in the calibration work have been defined in chapter 1.4. New persons starting calibrations shall be trained for the measurements. Branch Managers are responsible for the training of new personnel in their branch. Quality Manager will arrange training for the quality system. New persons typically start working by making special assignments related with their studies. These assignments typically form part of the training.

Training plan is recorded on a template "Training Record Template.xlsx". Training records are stored in

 $\work.org.aalto.fi\t405\MIKES-Aalto\Quality\Training\ records$ 

and reviewed annually in personnel audit.

Persons authorized to do different calibrations are defined in <u>AnnexAA</u> of the quality system. New authorizations shall be granted and recorded by the branch managers or



quality manager after they consider training appropriate. Training shall be provided under supervision of the authorized persons. The minimum requirement is that a person performs one calibration under supervision before getting authorization. Authorisations and progress of training are monitored in Personnel Audit.

Starting Deputies of Branch Managers shall have a suffix trainee. Training will be provided by the branch manager in the form of assisted calibrations, scale realisations, intercomparisons, etc. These activities are recorded in AnnexAA of the quality system and reviewed at least annually. When the trainee has been trained to do most of the activities in the branch, and the branch manager has full confidence to his/her skills, the trainee period ends.

# 11.3 Training

All people taking part in the calibration work will maintain Curriculum Vitae (CV). The CV's should contain at least the following information:

- 1. Education,
- 2. Work history,
- 3. Publications,
- 4. Conferences,
- 5. Training related to calibration work/duties.

If some of the points violate the persons ordinary use of the CV, these items may be on separate paper. Part of training (such as participation in conferences) is also recorded in annual reports of the laboratory.

The personnel carrying out calibrations mainly consist of undergraduate and postgraduate students. Undergraduate students typically maintain their professional skills by taking part in national conferences. Postgraduate students take part in international conferences. Additional training needs will be identified in the management review.

# **12.**Calibration and measurement certificates

Calibration certificates are written according to Annex <u>C: Instructions on Writing</u> <u>Calibration Certificates</u>.

# 13.References

CIPM MRA, Mutual Recognition Arrangement (http://www.bipm.fr/enus/8 Key Comparisons/mra.html).



CMC, Calibration Measurement Capabilities (<u>http://kcdb.bipm.org/appendixc/</u>)

JCGM 100:2008, ISO Guide to the Expression of Uncertainty in Measurement. http://www.bipm.org/en/publications/guides/gum.html

ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.