

AALTO UNIVERSITY
Metrology Research Institute

Quality System

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Annexes

AA: List of Authorisations

B: Quality Policy of the University

C: Instructions on Writing Calibration Certificates

D: Quality Policy of the Laboratory

1. Organisation and management

1.1 Name and address of the laboratory

Aalto-yliopiston teknillinen korkeakoulu
Elektroniikan, tietoliikenteen ja automaation tiedekunta
Signaalinkäsittelyn ja akustiikan laitos
MIKES-Aalto Mittaustekniikka
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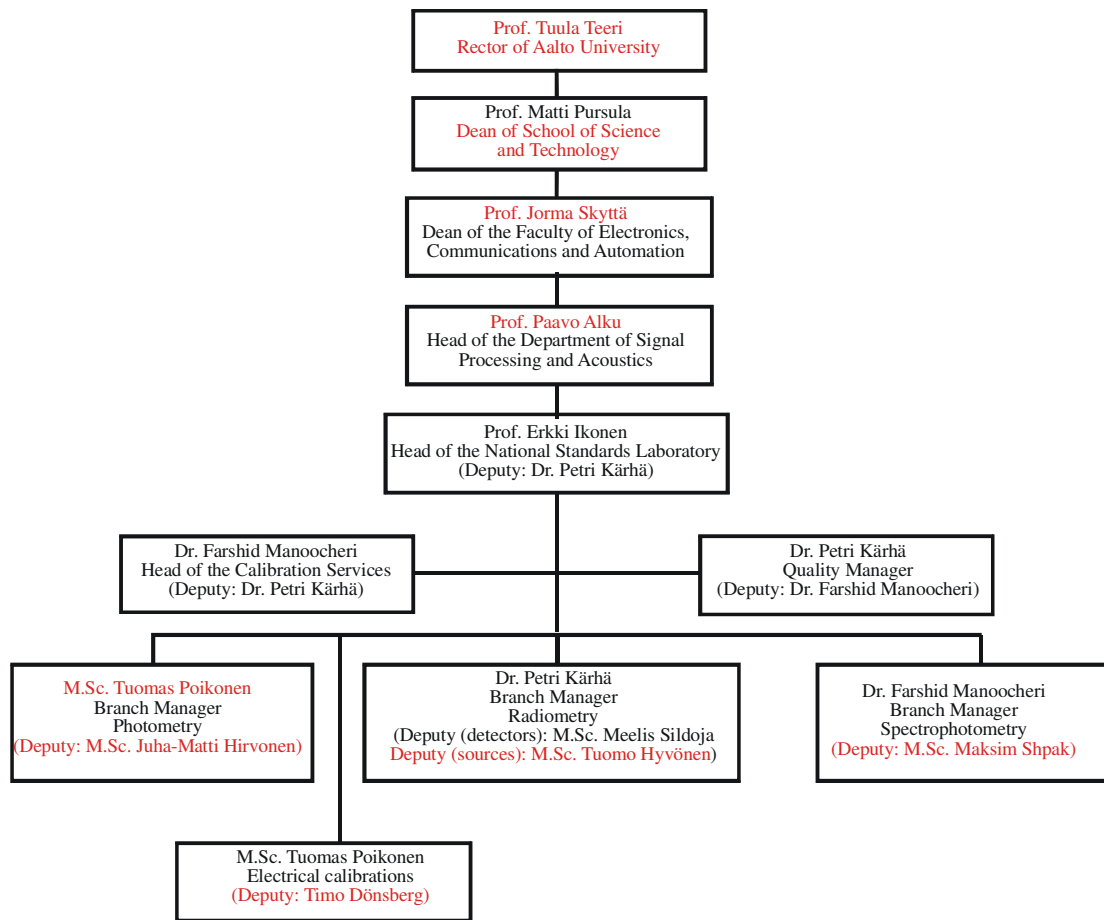
Telephone: +358 - 9 - 470 01 Fax: +358 - 9 - 470 22222

1.2 Legal status

The Metrology Research Institute is a joint laboratory of the **Aalto University** and the Centre for Metrology and Accreditation (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 Annex B.

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 Annex AA.

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

Dean of the Faculty

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 (fibre optics 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
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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 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 Annex AA)
6. Approves the quality documents by signing the front pages of the paper copies
7. Prepares, manages and reports the development projects of MIKES within the branch
8. 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, signed by the Rector of the University (Paavo Uronen) and Head of the Department (Pekka Wallin) on May 17, 1995, is included in Annex B. The quality policy of the laboratory, signed by the Head of the National Standards Laboratory (Erkki Ikonen) on Feb 12, 2002, is included in Annex D.

2.3 *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 2.5.

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.

2.4 *Document control*

The Quality System is maintained primarily in the web pages of the laboratory. The most recent up-to-date version of this general part of the Quality System (this document) can be found in location:

\\Metrology\webpages\quality\

Latest versions of other documents belonging to the quality system are maintained in the same directory. Old versions of the documents belonging to the quality system are archived in the sub-directory \Old files\

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

\\Metrology\webpages\quality\index.html

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 field containing signatures of approval. Up-to-date copies are delivered to quality manager before auditing the quantities. After auditing, the web versions are updated.

The files in Megamuisti are editable through the intranet of the laboratory. The pages can be viewed anywhere in the internet using address

<http://metrology.tkk.fi/quality/>

2.5 Contents of Quality Manuals

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

2.5.1 Definition

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

2.5.2 Equipment

Equipment needed for calibrations is listed.

2.5.2.1. Description(s) of setup(s)

Setups used for calibrations are described preferably using figures.

2.5.2.2. 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.

Some devices of the laboratory that are needed in various calibrations (DVM's, current-to-voltage converters, environmental meters) are calibrated collectively. A calibration schedule has been defined for these instruments.

2.5.3 Measurement traceability

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

2.5.4 Calibration and measurement procedures including validation methods

Measurement procedures must be described with such level of details that a third-party 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.

2.5.5 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.

2.5.6 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.

2.5.7 Accommodation and environmental conditions

Laboratory allocated for the calibrations is specified. 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.

2.5.8 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.

2.5.9 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.

2.5.10 Certificates

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

2.5.11 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.

2.5.12 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.

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 Annex C: Instructions on Writing Calibration Certificates. 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.

Invoicing of the calibrations is handled by the secretary of the laboratory.

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.

3.2 Complaints

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 new certificate is archived with the old one. Customer is asked to archive/handle the old version of the certificate according to their quality system.

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.

3.3 Customer feedback

With each calibration, 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 non conforming calibration work

Calibration certificates may only be issued for the quantities, ranges and uncertainties on which HUT has a contract with MIKES (BIPM CMC database).

If other measurements are carried out, the certificates may not be printed on the official paper, 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.

5. Subcontracting of Calibrations

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

6. Quality assurance of calibration results

6.1 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.

6.2 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.

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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.

7. 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.

7.1 Storing and backups

Up-to-date copies of all measurement programs are stored in the Metrology server in the subfolders of \\METROLOGY\webpages-quality\. Also old versions are stored in separate subfolders. This directory is routinely backed-up by the IT maintenance of the department. 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.

7.2 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.

7.3 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.

8. Control of records

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.

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

\\Metrology\webpages\quality\

In addition, the people in charge of the documents store the documents in their own computer for backup-purposes.

Archiving of calibration certificates is described in Instructions on Writing Calibration Certificates.

9. Audits and reviews

9.1 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:

1. Corrective actions taken after the previous review,
2. Suitability of the Quality System and measurement procedures, possible development needs in either technology or quality system,

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3. Outcome of internal audits (report of Quality Manager),
 4. Calibrations since last review, changes in the volume and type of work (report of the Head of the Calibration Services),
 5. Corrective and preventive actions,
 6. Possible assessments by MIKES or other external bodies,
 7. Results of intercomparisons,
 8. Customer complaints and feedback,
 9. Resources (personnel, laboratories, equipment, funding),
 10. Training requirements.

Minutes of the review meeting are written.

9.2 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 Annex A.
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.
4. Updating CV's of the corresponding personnel.

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.

9.3 External audits

Laboratory is regularly audited by MIKES. Schedule should be arranged such that recent management review and internal audit reports are available.

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

10. Personnel

10.1 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.

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.

10.2 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.

Persons authorized to do different calibrations have been defined in AnnexAA of the quality system. New authorizations shall be granted and recorded by the branch managers 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.

10.3 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.

11. Calibration and measurement certificates

Calibration certificates are written according to Annex C: Instructions on Writing Calibration Certificates.

12. References

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

CMC, *Calibration Measurement Capabilities* (<http://kcdb.bipm.fr/BIPM-KCDB/AppendixC>)

ISO Guide to the Expression of Uncertainty in Measurement.

ISO/IEC/FDIS 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories.*