

CIPM MRA WORKSHOP

QMS – TECHNICAL REQUIREMENTS

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PERSONNEL

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- policy and procedure for identification of training needs
- To ensure the competence of these persons:
 - ▣ who operate specific equipment,
 - ▣ who perform calibrations (tests),
 - ▣ who evaluate results and
 - ▣ who sign calibration certificates (test reports).
- To ensure supervision for personnel undergoing training.

PERSONNEL

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- Personnel performing specific tasks – in accordance with requirements, on the basis of appropriate education, training, experience and demonstrated skills.
- Formulation the goals with respect to the education, training and skills of the laboratory personnel from the laboratory management,
 - ▣ it is necessary to have a policy and procedure for identifying training needs and providing training of personnel,
 - ▣ the training programme has to be relevant to the present and anticipated tasks of the laboratory,
 - ▣ evaluation of the effectiveness of the training actions.

PERSONNEL

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- Personnel who are employed by, or under contract to, the laboratory.
- additional technical and key support personnel – contract, supervision, to ensure competence, in accordance with management system in laboratory.
- Maintenance of current job descriptions for managerial, technical and key support personnel.
- Authorization of specific personnel to perform calibrations (tests, sampling, to give opinions and interpretations and to operate particular types of equipment),
- maintenance the records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel,
- readily available including the date on which authorization or competence is confirmed.

PERSONNEL - summary

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- ☐ education
- ☐ relevant knowledge of the technical and general requirements
- ☐ qualification
- ☐ training
- ☐ experiences
- ☐ authorization (to calibration, tests etc.)

RECORDS ABOUT PERSONNEL

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- records about plan and training with the help of „Database of organization“
- inserting of records, confirmation of meet with the plan and training record and confirmation from employee's superior,
- training from the quality management system – ideally every year by Quality Manager

Databáze organizace

Program Okna Telefoný Nastavení Uživatel Návod

VOJ

VOJ	VOJ - název	Střed.	Středisko - název	Fun...	Funkce - popis	Zaměst.	Příjmení	Jméno
0100	úsek generálního ředitele	0111	generální ředitel, sekretariát	011111	generální ředitel	2001	Klenovský	Pavel
0100	úsek generálního ředitele	0111	generální ředitel, sekretariát	011112	manažerka jakosti ČMI	1031	Meistrová	Jana
0100	úsek generálního ředitele	0111	generální ředitel, sekretariát	011113	manažerka jakosti ČMI (t.č. RD)	1022	Hoffmanová	Silvie
0100	úsek generálního ředitele	0111	generální ředitel, sekretariát	011121	sekretářka generálního ředitele	2005	Poláček	Miroslav
0100	úsek generálního ředitele	0111	generální ředitel, sekretariát	011122	referent zahraničních pracovních cest	1006	Žáková	Helena

Osobní karty

011112 Ing. Jana Meistrová

Vložil: 1.4.2010 Ing. Jana Meistrová
Schválil: 23.6.2010 RNDr. Pavel Klenovský
Souhlasil: 3.6.2010 Ing. Jana Meistrová

Pracovní náplň: 23.6.2010 Ing. Jana Meistrová
Karta osobního rozvoje: 23.6.2010 RNDr. Pavel Klenovský

OK

Zaměstnanec: Funkce: Funkce je zastupována: Středisko: VOJ: Telefoný

Číslo zaměstnance: 1031
Jméno zaměstnance: Ing. Jana Meistrová
Funkce: manažerka jakosti ČMI
Úvazek [%]: 100
Hlavní funkce: ANO
Hlavní zaměstnanec: ANO

Uživatelské jméno: jmeistrova
Email základní: jmeistrova@cmi.cz
Emaily dle alias: koncepce@cmi.cz ikovrzkova@cmi.cz kvalita@cmi.cz jakost@cmi.cz
Email volný:

Filtr - počet záznamů: 5

VOJ: 0100
Středisko: 0111
Funkce: [všechny]

Číslo zaměstnance: [všechny]
Příjmení: [všechny]
Jméno: [všechny]
Skupiny funkcí: [všechny]

Najít

Přihlášený uživatel: jsabata (Ing. Jindřich Šabata)

Ukončit

ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

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- ❑ Correct performance of calibrations (tests) – it is influenced by laboratory facilities including but not limited to energy sources, lighting and environmental conditions,
- ❑ the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement,
- ❑ particular care – sampling and calibrations (tests) at sites other than a permanent laboratory facility,
- ❑ documentation of the technical requirements for accommodation and environmental conditions (that can affect the results of calibrations (tests)).

ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

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- Monitoring, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results,
- attention to specific influence e.g. to biological sterility, dust, electromagnetic disturbance, radiation, humidity, electrical supply, temperature, and sound and vibration levels as appropriate to the technical activities concerned,
- stop calibrations (tests) when the environmental conditions can negatively influence the results.

ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

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- ❑ Separation between neighbouring areas in which there are incompatible activities to prevent cross-contamination.
- ❑ Description of access to areas affecting the quality of the calibrations (tests), to control the access, determination the extent of control range.
- ❑ Procedure for housekeeping in the laboratory.

ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

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- ❑ superior laboratory facility
- ❑ stability of environmental conditions in laboratory + influence of environmental condition and accommodation the calibrations (tests) outside the permanent areas of laboratory
- ❑ monitoring, controlling and record the environmental conditions
- ❑ controlled access to laboratories, procedure for access
- ❑ procedure for housekeeping in the laboratory

TEST AND CALIBRATION METHODS AND METHOD VALIDATION

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- appropriate methods and procedures
 - ▣ sampling,
 - ▣ handling,
 - ▣ transport,
 - ▣ storage
 - ▣ preparation of items to be calibrated (tested)
 - ▣ an estimation of the measurement uncertainty
 - ▣ statistical techniques for analysis of calibration (test) datas

TEST AND CALIBRATION METHODS AND METHOD VALIDATION

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□ Selection of methods

- meeting the needs of the customer during the using of calibration (testing) methods including sampling methods,
- preferably using of methods published in international, regional or national standards,
- the latest valid edition of a standard + supplementation the standard with additional details,
- customer does not specify the method – the laboratory shall select appropriate methods (published 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),

RECOMMENDED INFORMATION IN PROCEDURE

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- appropriate identification,
- scope,
- description of the type of item for calibration (test),
- parameters or quantities and ranges,
- apparatus and equipment,
- reference standards and reference materials required,
- environmental conditions required and any stabilization period needed,
- criteria and/or requirements for approval/rejection,
- 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,
 - ▣ any stabilization period needed,
 - ▣ results, any safety measures to be observed,
- data to be recorded and method of analysis and presentation,
- the uncertainty or the procedure for estimating uncertainty.

TEST AND CALIBRATION METHODS AND METHOD VALIDATION

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- validation procedures (including software)
- All approved working procedures and software shall be validated. As the basic method for validation, the positive results from ILCs are estimated. Following methods are the comparing of the results, had been taken by the other methods or by means of another standards. Also, the systematical estimation of the factors which influence the results of measurements, or the estimation of the uncertainty of results on the basis of scientific knowledges, knowledges of theoretical principles and practical experiences.
- records of validations

TEST AND CALIBRATION METHODS AND METHOD VALIDATION

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- procedures for protecting data
- electronically saved information are backed-up in every time (on floppy disc, on CD-ROM or on the other storage medium).

EQUIPMENT

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- ❑ calibration programmes
- ❑ records for each item of equipment
- ❑ acceptance criteria
- ❑ identification of equipment
- ❑ procedures for safe handling, transport, etc
- ❑ procedure for intermediate checks

EQUIPMENT

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- ❑ Laboratory has to have all items of sampling, measurement and test equipment required for the correct performance of the calibrations (tests) (including sampling, preparation of calibration (testing) items, processing and analysis of calibration (testing) data),
- ❑ the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of Standard are met.
- ❑ Equipment and its software – shall be capable of achieving the accuracy required and shall comply with specifications relevant to the calibrations (tests),
- ❑ key quantities or values of the instruments – where these properties have a significant effect on the results – establishment of calibration programmes,
- ❑ before being placed into service – equipment shall be calibrated or checked,
- ❑ before use – equipment shall be checked or calibrated (see 5.6).

EQUIPMENT

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- ❑ Operation of equipment by authorized personnel.
- ❑ Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) – to be available for use in laboratory.
- ❑ Unique identification of each item of equipment and its software.
- ❑ Maintenance of records about each item of equipment and its software [see metrological card of instruments](#)
- ❑ Procedures to ensure proper functioning and in order to prevent contamination or deterioration for:
 - ❑ safe handling,
 - ❑ transport,
 - ❑ storage,
 - ❑ use and planned maintenance of measuring equipment.

CIPM MRA workshop Skopje, FYR Macedonia, April 27 – 29, 2011

EQUIPMENT

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- ❑ Taking of service of equipment in these situations:
- ❑ To be subjected to overloading or mishandling
- ❑ Equipment gives suspect results or
- ❑ Equipment has been shown to be defective or
- ❑ outside specified limits.
- ❑ Isolation of equipment (prevention its use) or clearly labelled or marked – until its reparation and its verification (by new calibration or test).
- ❑ Examination the effect or departure from specified limits on previous calibrations (tests) and shall institute the "Control of nonconforming work" procedure (see 4.9).
- ❑ Indicated equipment in laboratory by label, code or otherwise identification – to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

EQUIPMENT

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- ❑ Going outside of equipment the direct control of the laboratory – after returning to service – check of the function and calibration status of equipment.
- ❑ Intermediate checks to maintain confidence in the calibration status of the equipment – periodically performance.
- ❑ To ensure of copies for files with a set of correction factors (e.g. in computer software) according to the procedures.
- ❑ Safeguard of calibration (testing) equipment (hardware and software) from adjustment (it could invalidate calibrations (tests) results).
 - ❑ procedures for manipulation with equipment
 - ❑ measurement traceability (calibration, verification, adjustment)
 - ❑ Clearly identified equipment
 - ❑ Records about equipment
 - ❑ Handling of equipment by authorized persons only
 - ❑ Equipment with necessary calibration – marked with label with necessary information.

MEASUREMENT TRACEABILITY

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- calibration procedure and programme (see 5.5) for equipment/reference standards
- procedures for safe handling, transport, etc
- procedure for intermediate checks

MEASUREMENT TRACEABILITY

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- ❑ Calibration of equipment before being put into service,
- ❑ programme and procedure for the calibration of its equipment.
- ❑ Calibration of equipment – calibration and measurement by laboratory – its traceability to SI.
- ❑ Traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement.
- ❑ The link to SI units may be achieved by reference to national measurement standards.
- ❑ National measurement standard = primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards = are calibrated by another national metrology institute.

MEASUREMENT TRACEABILITY

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- ❑ External calibration services – to ensure the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability, the calibration certificates shall contain the measurement results, including the measurement uncertainty (or a statement of compliance with an identified metrological specification (see also 5.10.4.2)).
- ❑ Calibrations that currently cannot be strictly made in SI units → traceability to appropriate measurement standards e.g.:
 - ❑ the use of certified reference materials provided by a competent supplier;
 - ❑ the use of specified methods or consensus standards that are clearly described and agreed by all parties concerned.
- ❑ Participation in a suitable programme of interlaboratory comparisons.

MEASUREMENT TRACEABILITY

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- ❑ *Intermediate checks*
- ❑ Carried out according to defined procedures and schedules.
- ❑ *Transport and storage*
- ❑ Procedures for safe handling, transport, storage and use of reference standards and reference materials (to prevent contamination or deterioration and in order to protect their integrity).

HANDLING OF TEST AND CALIBRATION ITEMS

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- ❑ Procedure for:
 - ▣ transport, receipt, handling, protection,
 - ▣ storage and retention of calibration (test) items.
- ❑ Protection the integrity of the calibration (test) item and protection the interests of the laboratory and the customer.
- ❑ System for identification
- ❑ Procedures and facilities for avoiding deterioration

ASSURING THE QUALITY OF RESULTS

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- Procedures for monitoring the validity of tests and calibrations undertaken.
- Arrangements for analysing quality control data and for implementing corrective actions when required

ASSURING THE QUALITY OF RESULTS

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- ❑ Procedures for monitoring the validity of calibrations (tests),
- ❑ records of the resulting data in such a way: trends are detectable, statistical techniques,
- ❑ monitoring includes:
 - ▣ regular use of certified reference materials and/or internal quality control using secondary reference materials,
 - ▣ participation in interlaboratory comparison or proficiency-testing programmes,
 - ▣ replicate tests or calibrations using the same or different methods,
 - ▣ retesting or recalibration of retained items,
 - ▣ correlation of results for different characteristics of an item.

ASSURING THE QUALITY OF RESULTS

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- analysis of data from this monitoring,
- corrective action (where they are found to be outside of predefined criteria),
- prevention from incorrect results to be reported.

REPORTING THE RESULTS

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- ❑ calibration certificate includes all information
- ❑ They include this information
 - ▣ requested by the customer,
 - ▣ necessary for the interpretation of the calibration (test) results,
 - ▣ required by the method used.
- ❑ In detail requirements in 5.10.2, and 5.10.3 or 5.10.4.
- ❑ Simplified way of reporting the results – for internal customers, or in the case of a written agreement with the customer → information in 5.10.2 to 5.10.4, which is not reported to the customer shall be readily available in the laboratory.

REPORTING THE RESULTS

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- ❑ Documentation of opinions and interpretations
- ❑ To document the basis upon which they have been made, clear identification in test report.
- ❑ Testing and calibration results obtained from subcontractors:
 - ▣ clear identification in calibration certificate (test report),
 - ▣ report the results from the subcontractor in writing or electronically,
 - ▣ calibration on the basis of contract → issuing of calibration certificate by the contracting laboratory.