LABORATORY FOR PRODUCTION MEASUREMENT

Faculty of Mechanical Engineering
Smetanova 17, 2000 Maribor, Slovenia

QUALITY MANUAL

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Approved by	Bojan Ačko, Ph.D.

Evidence of changes (regarding the previous issue)

Amendment No.	Changed Chapter	Removed Chapter	Added Chapter
1	8.3.2		
2			15.2
3			
4			
5			

Contents

1 INTRODUCTION OF THE LABORATORY

1.1 General information about the laboratory

Statutory name:	Laboratorij za tehnološke meritve (Laboratory for production measurement)
Abbreviation:	LTM
Legal status:	The laboratory is no legal body (a legal body is University of Maribor). It is a part of the Institute of Production Engineering (the Institute is a body inside the Faculty of Mechanical Engineering with unlimited authority regarding all work except education).
Register No.:	University of Maribor (parent organization): 5229901000 Faculty of Mechanical Engineering: 5085462 005 Laboratory of production measurement: 0795-002
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1.1.1 The limits in which the laboratory is working:

- the best measuring capability expressed as uncertainty: 0,05 μm +0,5·10^{-6}·l;
- the greatest measuring range: (800 x 1000 x 500) mm (3D)
  30 m (1D - laser interferometer).

1.2 Functions and technical scope

1.2.1 Fields of work

Work in the laboratory is divided in the following fields:

- calibration of measuring devices for lengths and angles,
- realization, storing and maintenance of the national standard for length,
- work of the inspection body (inspection and verification of legal measures),
- inspection and measurement for industry (especially coordinate measuring technique),
- education (undergraduate and graduate study),
- training of experts,
- research and development of new measuring methods and devices,
- research in the field of dimensional measuring technique and CAQ.

1.2.2 Technological sectors to which our activities apply

Our activities apply to the sectors of quality assurance, production measurement and manufacturing.

1.2.3 Clients

Our clients are industrial and trading companies, companies offering services, institutes, laboratories, universities and ministries.

1.2.4 Geographical areas where the activities take place

The activities take place in the Republic of Slovenia and in smaller amount on European market.

1.2.5 Technical scope of the laboratory

The following methods and procedures are used at our work:

- standard methods of coordinate measuring technique (CMMA, DIN, ISO, ANSI),
- standard and own methods of conventional measuring technique (1D, 2D),
- standard methods of laser interferometry (inspection of machine tools and measuring machines),
- standardized procedures of calibration of measuring devices and standards of measurement (ISO, DIN, ANSI, ...),
- metrological regulations and other legal documents for inspection and verification of legal measures of length (Slovenian legislation, OIML, European directives, …)
- standardized methods for expressing measuring uncertainty (WECC, ISO, DIN, EA, ...),
- finite element method,
- analytical geometry,

- design and technology for production of measuring devices,
- statistical evaluation of measuring results, ...

The limits in which the laboratory is working are stated in chapter 1.1.1.

1.2.6 National standard

The laboratory (res. legal entity is University of Maribor – Faculty of Mechanical Engineering) is keeping and maintaining the national standard of length. The relation to the National Metrology Institute is regulated with the "Provision about the recognition of the standard as national standard", issued by the Slovenian Metrology Institute under number 535-1/98-26, and with the "Decree of national standards". The laboratory is responsible for realization, storing and maintaining the national standard and for assuring its traceability to international level (to BIPM standards) in accordance with its own vision and with the "Decree of national standards". Performance of the work in the field of the national standard is based on identified current and future national needs and on the requirements of the Slovenian Metrology Institute, defined in the two documents stated above, and in the contract between the laboratory and the Slovenian Metrology Institute on performing activities and fulfilling duties of the holder of national standard of length.

Laboratory enables Slovenian industry to perform internationally comparable measurements in the field "length" and herewith better competitive position.

1.3 Relationship to parent organization

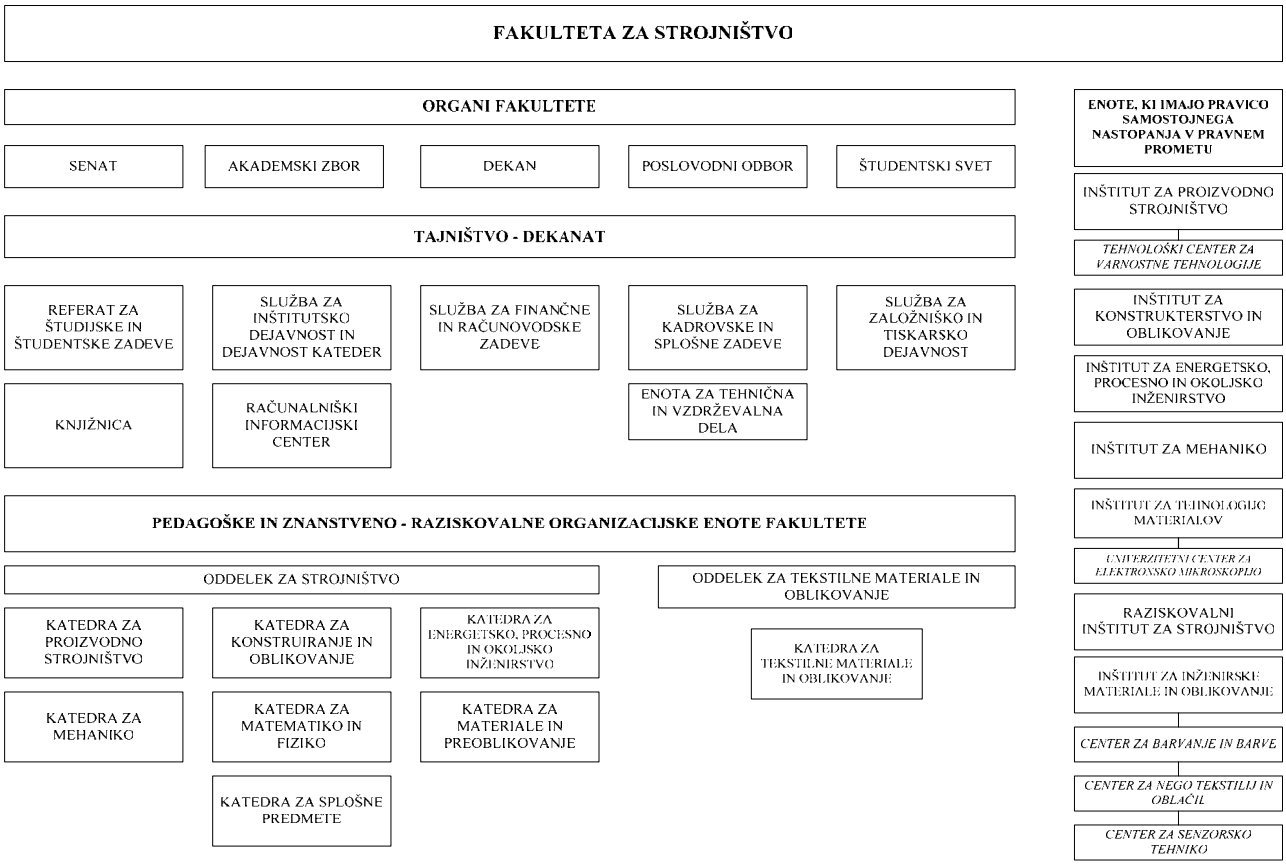
1.3.1 Main activities of the University of Maribor (parent organization)

- education,
- scientific research,
- technological help to industry, tourism and agriculture,
- development of new technologies,
- development of new products,
- metrology.

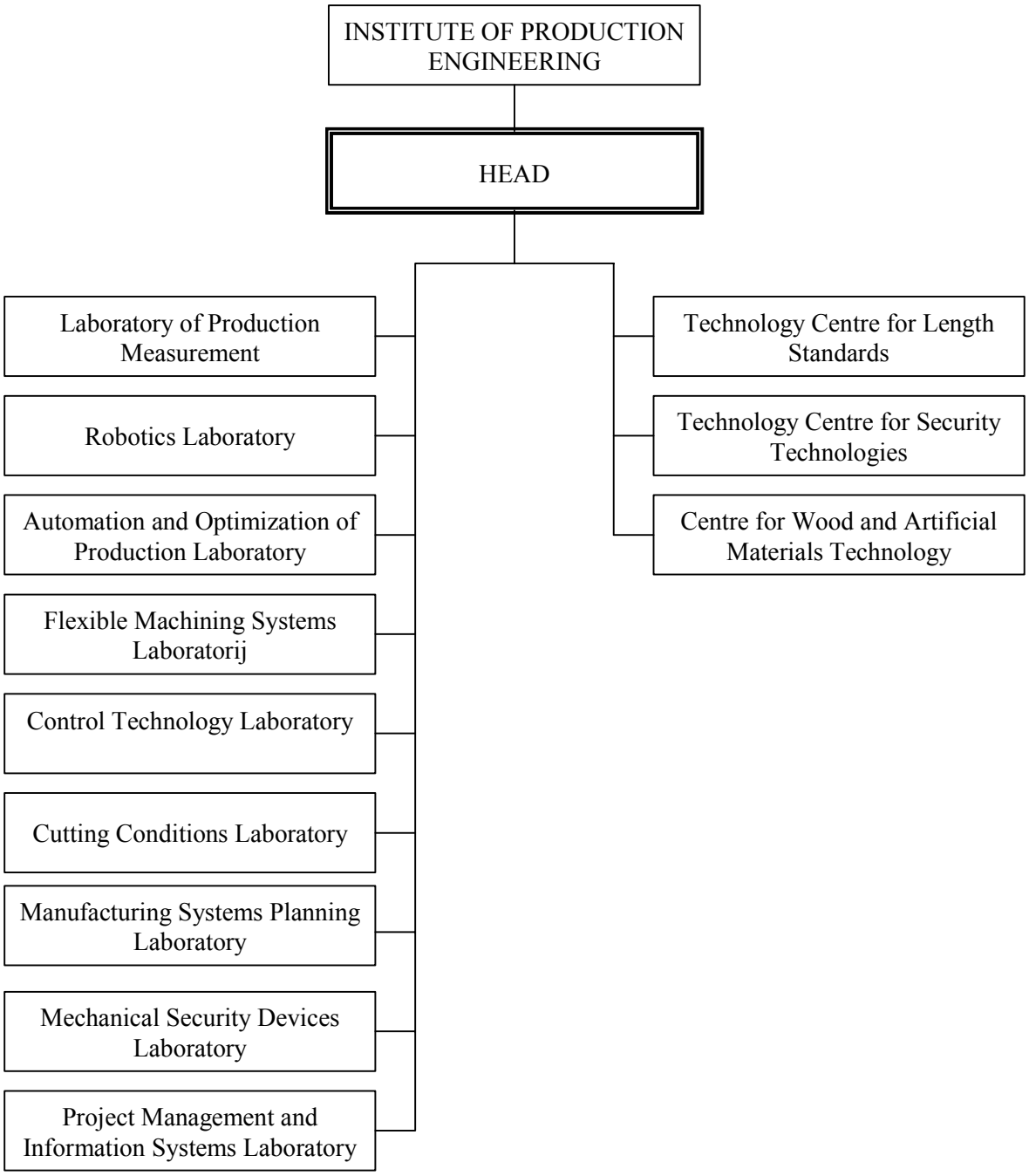
1.3.2 Organizational Chart of the University of Maribor

Organizational Chart of the University of Maribor is available at http://lpt.uni-mb.si/bbr/bbr/sistemizacija/docs/indeks.php.

1.3.3 Organizational Chart of the Faculty of Mechanical Engineering



1.3.4 Organizational Chart of the Institute of Production Engineering



1.3.5 Influence of the University and the Faculty of mechanical engineering on the functioning of the laboratory

The university has no influence on the quality system, finances and the personnel policy of the laboratory. All authorities regarding the functioning of the laboratory has the Faculty of mechanical engineering. The faculty controls the following activities of the laboratory:

- program of education,
- financial state,
- salaries (basic regulations),
- employment (basic conditions and regulation for employment).

All other functioning aspects are under the authority of the laboratory. The financial decisions (purchase of equipment, service charges, stimulation of the staff) are also taken on the laboratory level. The faculty can limit financial actions only in the case of negative financial state of the laboratory.

2 QUALITY POLICY

2.1 Quality policy, the objectives, the management's involvement with quality

Our quality policy is based on the following objectives:

- satisfaction of client's requirements,
- proper uncertainty of measurement and calibration,
- performance of inspection and verification in conformity with legal backgrounds (metrology guidelines, decrees, contracts, provisions, …)
- performance of measurements, calibrations, inspections and verifications on time,
- confidentiality of data and impartiality, independence and integrity in all fields of work,
- competitive prices,
- safety during performance of the work (staff, equipment, objects of calibration and measurement, documentation).

Beside these objectives, the quality system should also assure:

- well feeling of the staff,
- staff affiliation to the laboratory,
- longer life of the equipment,
- maintenance of the laboratory quality level.

In order to fulfil the quality objectives, we have introduced a quality assurance system, which is precisely defined by the quality manual and the supporting documentation. The quality system is designed in such way, that all requirements of the standards ISO/IEC 17025 and ISO/IEC 17020 are met. It is based on the properly qualified and informed staff, precisely defined extent of work, proper equipment (right selection, maintenance, and traceability) and facilities (according to the requirements of ISO standard), and precisely defined work procedures and instructions. The quality policy require continuous learning of the staff, continuous control (audits, checks, ...) and reviews of the quality system, total control of documentation and records, continuous detection and correction of deficiencies, selection of the most suitable and economic work methods, and regular maintenance of the equipment and the facilities. The laboratory management is fully responsible for the quality of work in the laboratory on all levels and for the conformance of the quality system with the standards ISO/IEC 17025 and ISO/IEC 17020. The laboratory manager is personally responsible for fulfilling the requirements of the quality policy. The quality manager is personally responsible for the control (audits, checks, ...) and the review of the quality system. The laboratory staff performing calibration, inspection and verification shall always be familiar with the valid versions of the quality system documentation and shall act in conformance with defined policy and procedures. The laboratory and its staff shall consider principles of independence, impartiality and integrity regarding the policy in chapter 2.2 and for the work of inspection body also in chapter 2.2.1.

Quality policy was defined by the laboratory manager and approved by the dean of the Faculty of Mechanical Engineering. Signed original is in Z 09.

2.2 Assurance of independence, impartiality and integrity

All laboratory employees are shell, while performing their work, respect the principles of independence, impartiality and integrity. They are obliged to act so by a signed statement. The statements are kept in P 01 – Personnel files. If it is found out that a person does not respect the above principles, a disciplinary procedure, respecting legal acts of the Faculty, is initiated.

2.2.1 Additional requirements regarding independence, impartiality and integrity for the field of inspection

The laboratory and its staff are stating that they will not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the items, which they inspect (for the entire scope of accreditation listed in chapter 8), nor they will be an authorized representative of any of these parties. The Laboratory will continuously monitor whether itself or any of the other laboratories of the Faculty of Mechanical Engineering is involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items. In such cases, the laboratory will refuse the inspection of the items, inform the client about the reason for refusal and advice him to apply the service of another inspection body.

2.3 Policy regarding protection of staff against improper influencing

Improper res. negative influences on the staff should be prevented by proper stimulation, good working conditions and democracy regarding determination of the quality policy.

In the case of an attempt of improper influencing a staff member should resolutely refuse any cooperation res. explains the conditions under which the laboratory is ready to cooperate. The laboratory manager should be immediately informed about every attempt of improper influencing.

2.4 Assurance of security of information

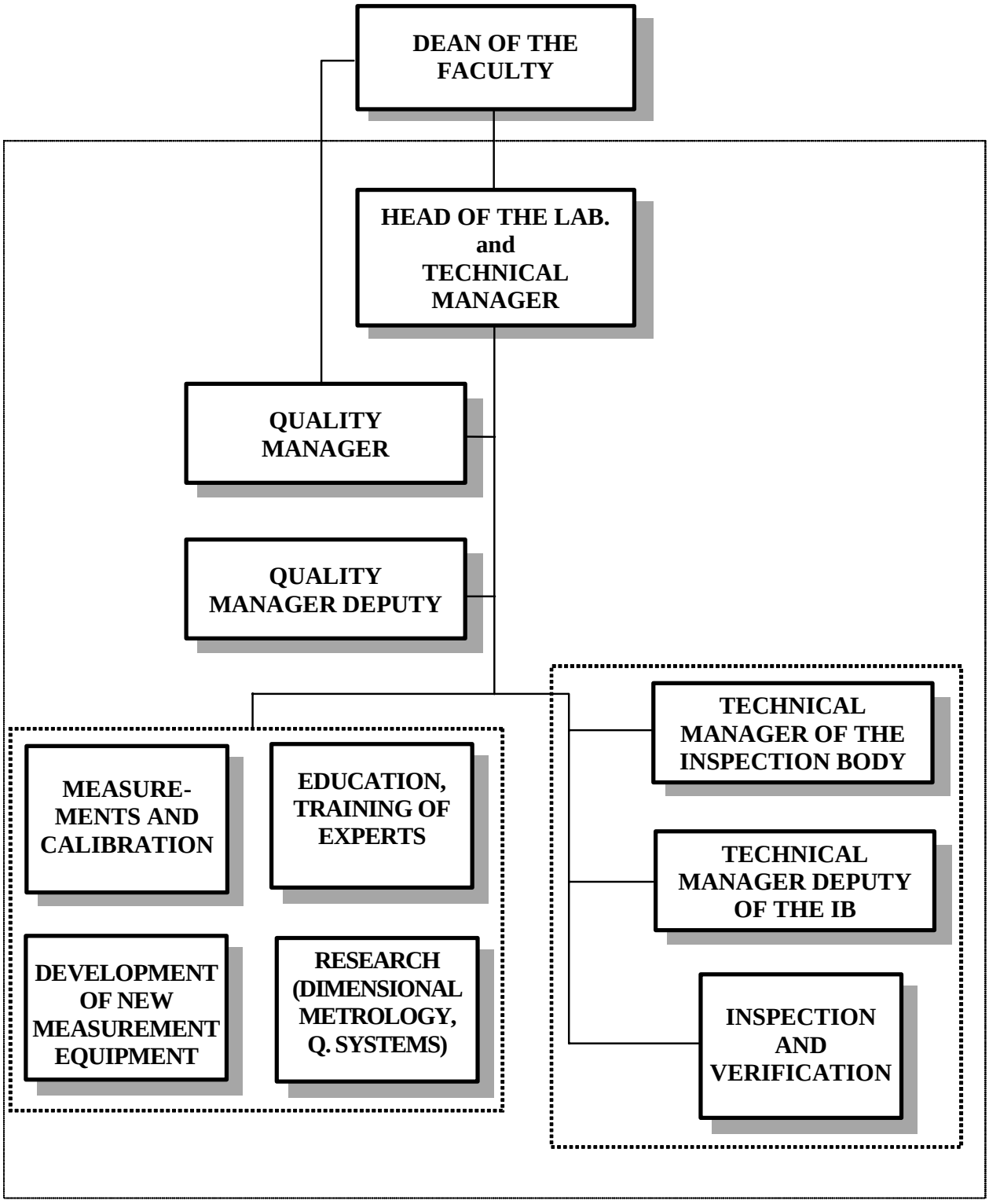
All information got from and given to a client shall be strictly confidential. Therefore, all instructions regarding filing and distribution of documentation should be precisely followed (see chapter 6).

Instructions regarding data transmission:

- information about calibrations and inspection is given only to the client ordering the calibrations,
- information about verification is given only to the client and the state metrology institute
- all clients' requests on information (exclusively in a written form) should be documented,
- information about calibrations can not be given by telephone.

3 ORGANIZATION AND MANAGEMENT

3.1 Organizational structure of the Laboratory for production measurement



There is no hierarchical structure inside departments. Every staff member performs his work in accordance with job descriptions (P 01), defined procedures and with work instructions (Ch. 12). Certain staff members perform work in two or more departments.

Names of the leading personnel are written in chapter 3.3.

3.2 Description of activities in the departments

3.2.1 Department "Measurements and calibration"

- measurements,
- calibration,
- storing and maintaining national standard of length,
- collection and update of standards,
- communication with clients,
- receipt and issue of calibration and measuring objects,
- calibration of our own measuring and inspecting devices,
- assurance of traceability of our measuring and inspecting equipment,
- maintenance of measuring and inspecting equipment,
- control of the documentation about measuring and inspecting equipment,
- creation and control of the measurements and calibration documentation,
- cooperation with the national standardization institute,
- interlaboratory comparison with domestic and foreign laboratories.

3.2.2 Department "Development of new measuring devices"

- concept of measuring and inspecting devices,
- numeric analysis of measuring and inspecting devices,
- design of measuring and inspecting devices,
- manufacturing technology,
- elaboration of technical documentation,
- creation of software,
- development of system software,
- development and planning of hardware,
- development of user software,
- consulting,
- control of the documentation about the work of the department.

3.2.3 Department "Education, training of experts"

- planning the education programs,
- organization of undergraduate study,
- organization of graduate study,
- performance of education (lectures, theoretical and laboratory exercises, examinations, diplomas, ...),
- work reports (to the management of the faculty),
- organization of training of experts for industry,
- creation of training programs,
- performance of theoretical and practical training,
- issuing the certificates of a successfully finished training.

3.2.4 Department "Research (dimensional metrology, quality assurance)"

- research of quality assurance systems,
- research of software for CAQ,
- consulting regarding introduction of quality assurance systems according to ISO 9000,
- membership in technical committees of SMIS.
- controlling the measuring uncertainty of coordinate measuring machines (CMM),
- research in the field of measuring strategy in coordinate measuring technique,
- research of measuring software,
- research of data exchange between CAD in CMM,
- measurement and digitalization of sculptured surfaces,
- research of measuring uncertainty of the laser interferometer (LI),
- research of measuring strategy in laser interferometry,
- research of measuring software for LI,
- measurement of test measurands,
- consulting,
- control of the documentation about the work of the department.

3.2.5 Inspection body

- inspection and verification of length measures used in legal metrology,
- creation and control of the inspection and verification documentation,
- cooperation with the national standardization institute.

3.3 Managers and their deputies

Rector of the University of Maribor

Prof. Dr. Ivan Rozman

Dean of the Faculty of Mechanical Engineering:

Prof. Dr. Milan Marčič

Principal of the Institute for Production Engineering:

Prof. Dr. Franci Čuš

Leading personnel in LTM and their deputies:

Laboratory manager (technical manager of the LTM and technical manager of the Inspection body):	Dr. Bojan Ačko
Laboratory manager deputy for the field inspection and verification:	Andrej Godina, M.Sc.
Quality manager:	Andrej Godina, M.Sc.
Quality manager deputy:	Jakob Žiljcov

3.4 Management in the absence of manager(s)

If the laboratory manager is absent, his duties are taken over by his deputy. However, the deputy should not exceed his authorities defined in P 01. Al the activities that exceed the authorities of the deputy (e.g. signs of contracts) should be stopped until the laboratory manager comes back to work. If an urgent activity, which is important for the functioning of the laboratory and exceeds the authorities of the deputy, arises during longer absence of the laboratory manager, the deputy should carry it out, but he has to get an agreement from the laboratory manager (at least by phone). After the laboratory manager has returned, the deputy should report him about all performed activities for which the laboratory manager is competent.

If the quality manager is absent, his activities are taken over by his deputy. The deputy should, however, not exceed his authorities. If it is necessary to carry out an activity exceeding the authorities of the quality manager deputy, the activity is carried out by the laboratory manager.

If the laboratory manager and the quality manager are absent, the staff should perform their work in accordance with the instructions and authorities. All activities, for which only the laboratory manager or/and the quality manager are competent, should wait until one of them comes back.

3.5 Supervision of personnel

3.5.1 Procedure for supervising the permanent personnel

The laboratory manager and the quality manager are responsible and authorized for the supervision

of permanent personnel. The following procedure should be followed:

- daily supervision of fulfilling the work plan,
- daily supervision of the condition of the laboratory, equipment, and calibration (inspection) items,
- random supervision of the performance of calibrations (inspection) – whether the work instructions are followed,
- periodic laboratory meetings about current work and problems,
- check of all calibration (inspection) reports and certificates issued.

3.5.2 Procedure for supervising the personnel which is not yet (fully) qualified

New personnel, personnel on education, and hired personnel must be supervised in the laboratory all the time. The quality manager and the staff performing calibrations (inspection) are responsible for the supervision. The following procedure should be followed:

- At least one member of the supervising staff should be always present in the laboratory.
- New personnel and personnel on education are not allowed to use the equipment used for calibrations.
- Hired personnel (which performs calibrations) is allowed to use all the equipment they need, but the first calibrations (inspection) must be supervised by the supervising person and all the mistakes must be discussed and eliminated. When the supervisor decides the work is performed in accordance with the regulations and the work instructions, the supervision is not necessary any more.
- Before the new staff starts to use the work equipment, the quality manager should find out (by means of test calibrations or inspection) if the level of qualification is appropriate and if the work instructions are followed precisely.

3.6 Job description

Job descriptions are written in accordance with the following procedure and kept in P01 - Personnel files.

3.6.1 Procedure for preparing job descriptions

The laboratory management should analyze and define all the jobs res. activities necessary for the laboratory to perform in accordance with the quality policy before preparing the job descriptions.

The organizational structure res. hierarchy in the laboratory should be considered when the job descriptions are prepared.

The laboratory manager and the quality manager define all the responsibilities and authorities necessary for correct operation of the quality system.

The laboratory manager defines the authorities and the responsibilities for each member of the staff considering education, professional qualifications, experiences and the roles of individuals in the organization.

The laboratory manager defines required jobs in accordance with the organizational structure of the laboratory.

The laboratory manager assigns the jobs to the staff. The staff also cooperates with the assigning jobs. The employing conditions prescribed by the Faculty of mechanical engineering should be considered.

The laboratory manager assigns defined activities to the defined jobs. The staff also cooperates actively in this activity.

The quality manager writes the job descriptions, which include the following data:

- full name and academic title of the staff member,
- job title,
- object of the job,
- position of the job in the organization,
- content of the job (activities, duties),
- necessary training, knowledge, skills, and experience,
- responsibilities,
- authority,
- reporting obligations,
- contacts (internal and external).

The job descriptions are checked and signed by the laboratory manager after he makes sure that all the staff members agree with their jobs, responsibilities and authority.

Authorized document (job descriptions) is put into the Personnel files (P 01) by the quality manager.

3.6.2 Procedures for amending job descriptions

The job descriptions are amended in the following cases:

- extended activities of the laboratory,
- some defects of the existing job descriptions were detected during an internal audit,
- increased extent of work.

In the case of extended activities the following procedure should be followed:

- The laboratory manager and the quality manager define supplement activities, authorities, and responsibilities for the extended activities.
- The laboratory management organizes a laboratory meeting to analyze if a new employee is needed.
- The laboratory manager assigns new activities to the existing staff and to new employees.
- The quality manager changes the existing job descriptions.
- The amended job descriptions are checked and authorized by the laboratory manager after he makes sure that all the staff members agree with them.
- The quality manager puts the new job descriptions into the Personnel files (P 01).

In the case of detected defects the following procedure should be followed:

- The laboratory manager and the quality manager define supplement activities, authorities, and responsibilities and/or delete the existing ones.
- The laboratory management organizes a laboratory meeting to analyze if a new employee is needed.
- The laboratory manager assigns new activities to the existing staff and to new employees.
- The quality manager changes the existing job descriptions.
- The amended job descriptions are checked and authorized by the laboratory manager after he makes sure that all the staff members agree with them.
- The quality manager puts the new job descriptions into the Personnel files (P 01).

In the case of increased extent of work the following procedure should be followed:

- The laboratory management organizes a laboratory meeting to analyze if a new employee is needed.
- The laboratory manager assigns a part of the job of the person(s) with increased activities to the other staff. If the new staff is employed, new activities are prescribed for this staff.
- The quality manager changes the existing job descriptions.
- The amended job descriptions are checked and authorized by the laboratory manager after he makes sure that all the staff members agree with them.
- The quality manager puts the new job descriptions into the Personnel files (P 01).

4 QUALITY SYSTEM

4.1 Responsibilities

4.1.1 Responsibility of the laboratory for quality of the work performed

The head of the laboratory takes over, in the name of the laboratory, the whole responsibility for the quality of the performed work. All possible complaints are treated in conformance with the policy and procedures describe in chapter 15.

4.1.2 Insurance of the laboratory responsibility

Responsibility for the quality of the performed work is insured in the frame of the general insurance of the Faculty of Mechanical Engineering with a special insurance policy. The insurance premium is paid in the case when a material damage was caused to the client by the work of bad quality. In such cases the laboratory shall only analyze the justification of the complaint. The damage value is defined by the insurance company.

The height of the insurance premium is defined each year when the insurance contract is prolonged.

4.1.3 Personal responsibilities

Personal responsibilities are described in the job descriptions, which are stored in Personal files - P 01. Additional responsibility descriptions can be found in the Quality manual and supporting documents for single quality system elements.

4.2 Quality manager

The quality manager of the laboratory is designated by the laboratory manager. His/her name is stated in Ch. 3.3. The quality manager is responsible and authorized for quality assurance in the laboratory. The responsibilities and authorities are listed in P01 - Personnel files. The quality manager has direct access to the Dean of the Faculty of Mechanical Engineering (Ch. 3.1)

4.3 Preventive actions

The laboratory manager is responsible for initiating and performing preventive actions in cases, when danger of negative influences on the quality system or on technical performance of calibrations, inspection, measurements and other laboratory activities is detected. The laboratory manager is also responsible for monitoring and analyzing the performance of corrective actions.

The aim of preventive actions is diminishing possibility of occurrence of anomalies in the quality system and in the results of the services performed for clients.

4.4 Arrangements for permitting departures from documented policies and procedures or from standard specifications

- Departures from documented policies and procedures or from standard specifications are permitted only in unpredictable circumstances, when departures are necessary for the quality performance of the work.

- Permission for departures from documented policies and procedures or from standard specifications can be given exclusively by the laboratory manager (or by his deputy in the case of absence).
- All activities that were not performed in accordance with documented policies and procedures should be documented in the following form:
  - the name of the activity,
  - the name of the person performing the activity,
  - the date and the place of the activity,
  - the name of the equipment (if any was used),
  - arguments for the departures from documented policies and procedures or from standard specifications,
  - a list of non documented procedures used,
  - a founded state about the correctness of the results of the work.

5 DOCUMENTATION

Documentation of the LTM quality system is divided into the following groups:

- quality manual,
- forms for records and reports about quality system functioning,
- lists of the documents,
- standard operating procedures (SOP).

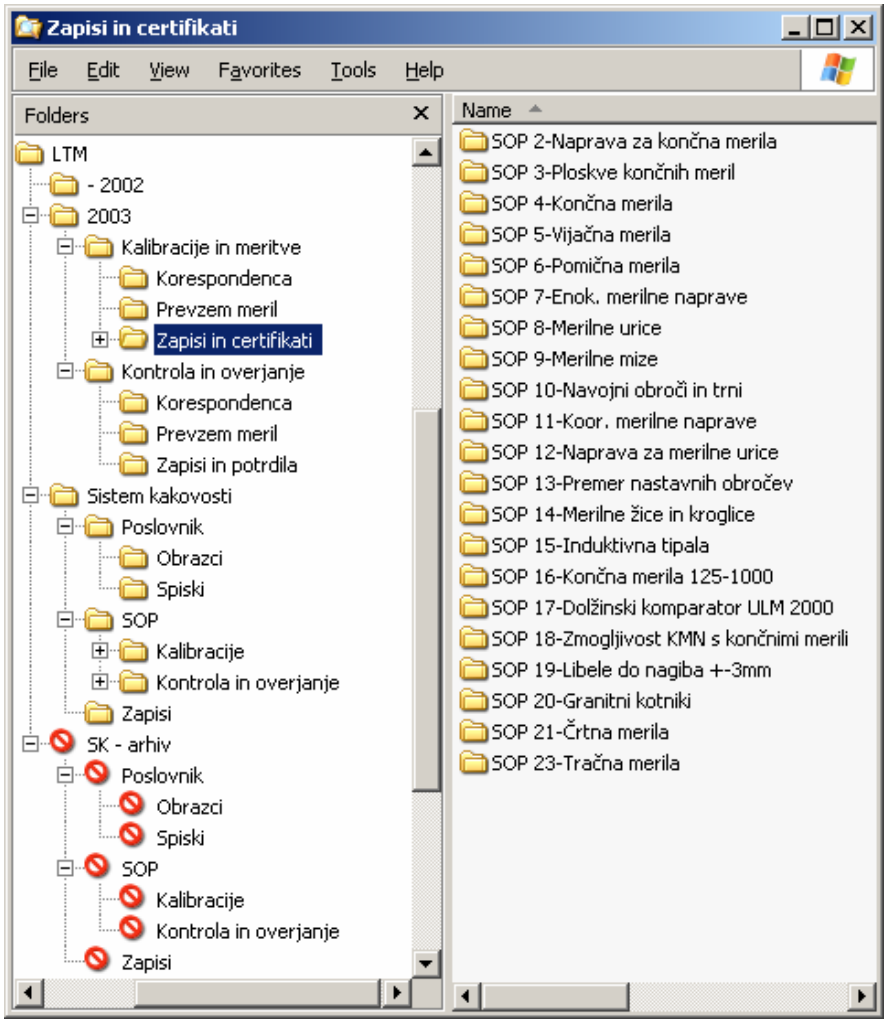
Documentation of the LTM quality system is in electronic media.

5.1 Location and names of the files

Valid versions of the quality manual and calibration/inspection procedures are stored on the FS network server- on the location serving for LTM web page. Access for entering files on this network location (\\fs-server\www$\si\inst\ips\ltm) has only the laboratory manager. The rest of the documentation (forms, records, …) is on FS.LTM5, folder D:\LTM.

Folders structure is shown on the next picture.

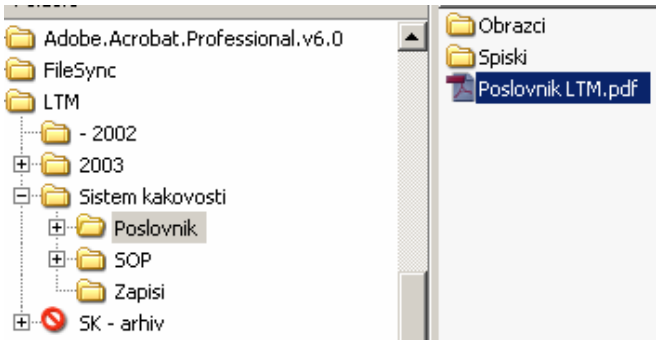
Folders include both databases Baza-kal.mdb and Baza-overjanje.mdb (see Ch. 12.2) as well electronic records and reports (see Ch. 6).



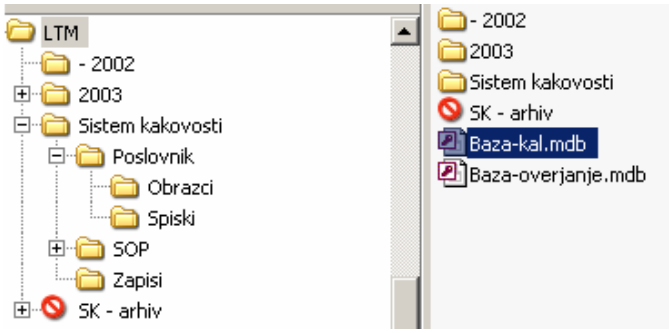
Locations of the electronic documents and rules for naming

English versions of documents are designated with added "-en" ad the end of the filename, e.g. *Poslovnik LTM-en.pdf* for the English version of the quality manual.

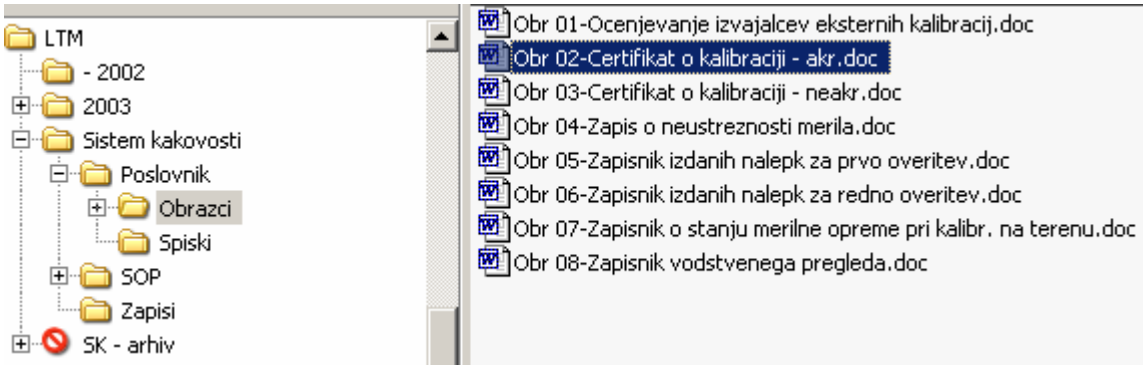
- quality manual: *Poslovnik LTM.pdf* – shortcut to the FS network,



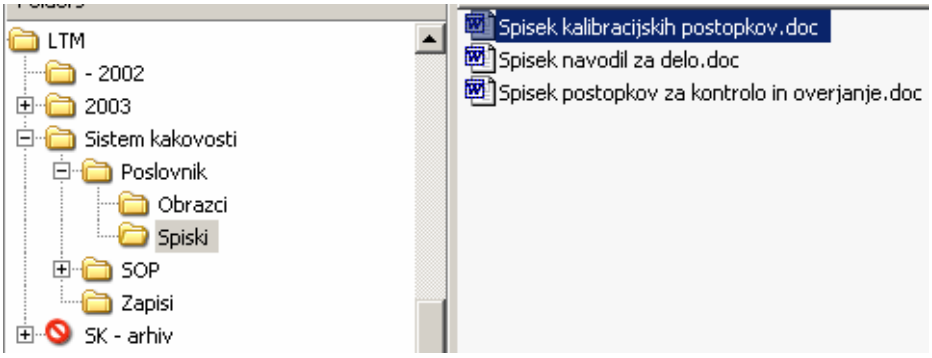
- databases: *Baza-name_of_the_database.mdb*,



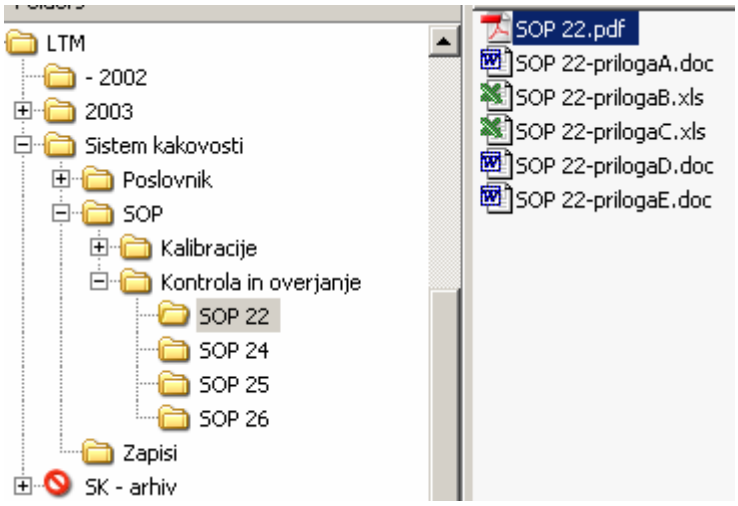
- forms: "Obr *mm-title*.*, mm stays for number of the form,



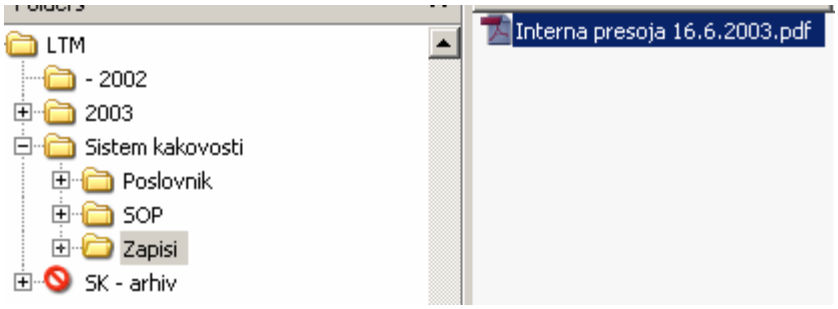
- lists: *Title of the list*.*,



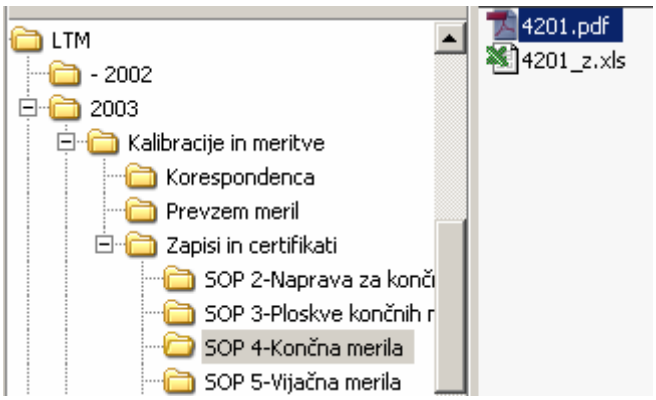
- SOP's and their appendixes: *SOP mm.pdf* (shortcut to the FS network) and *SOP mm-priloga X.**, mm stays for the number of the SOP, X for the name of the appendix,



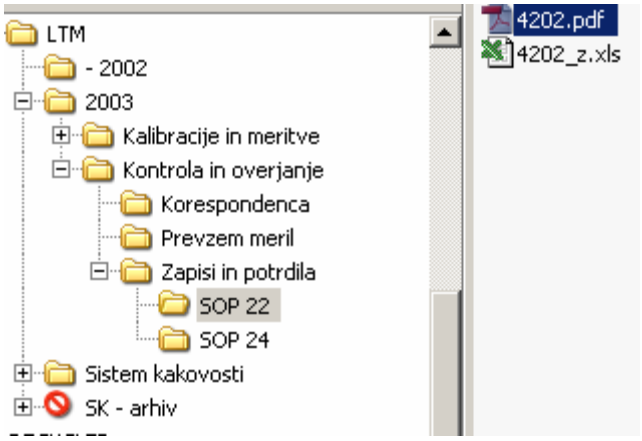
- records and reports about quality system: filename expresses the contents of the file with the date and/or running number, when appropriate,



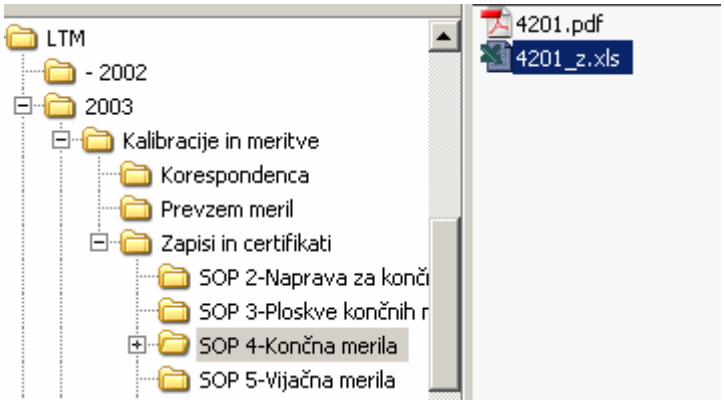
- calibration certificates: *nnnn-p.pdf*, nnnn stays for the calibration number, -p for optional text,



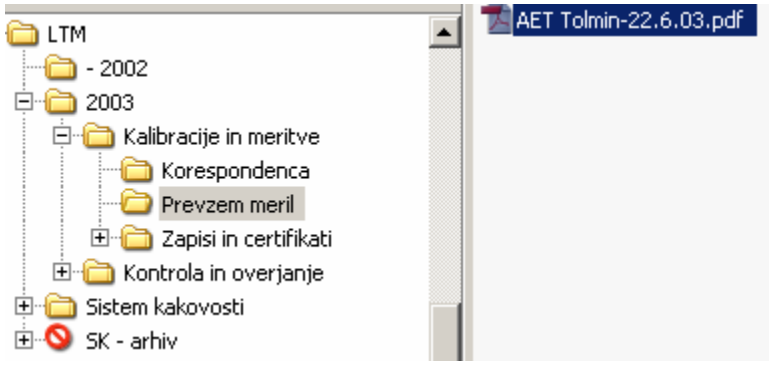
- verification certificates and inspection reports: *nnnn-p.pdf*, nnnn stays for number of the verification/inspection, -p for optional text,



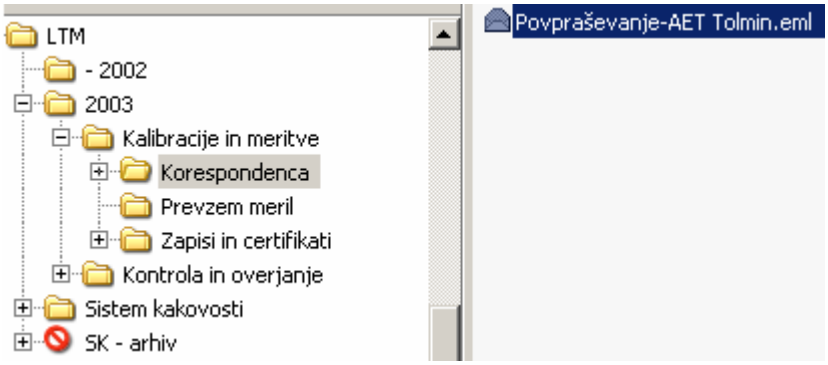
- records (about work): *nnnn_z-p.**, (signs meaning refer above); records are kept in the same folder as the related certificates,



- receipt of equipment: *client_name-date.pdf*.



- e-mails: *subject.eml*, when mail subject is not distinctive enough additional information must be added (e.g. sender name).



5.2 Access to the files

Access to the files in the folders, shown in the previous chapter, is limited with the system of authorized users and passwords. Head of the LTM is responsible for assigning the authorizations and passwords.

Read-only access has all personnel of the LTM and temporary staff (while working at LTM), who signed statement of confidentiality. Write access to the following folders have:

- Sistem kakovosti (quality system): head of the LTM,
- SK – arhiv (QS-archives): head of the LTM,
- Kalibracije in meritve (calibrations and measurements): personnel (and temporary staff) working in the department Measurements and calibration,
- Kontrola in overjanje (inspection and validation): personnel working in the department Inspection body.

Documentation of the quality system is available for the users outside the LTM at the address www.fs.uni-mb.si/si/inst/ips/ltm/. Access to the quality manual is not limited, the password necessary for accessing the other documents is given to:

- Slovenian Accreditation,
- eventual other accreditation body.

5.3 Drafting, changing, approving, validity and archiving of documents

Initiative for preparing a document gives the personnel of the LTM. All documents and changes are drafted by the quality manager. Prepared documents are checked by the laboratory manager, who moves the old version to the folder *SK – arhiv* (to the filename he/she adds the issue number) and the new one to the emptied place. The document is thereby approved in valid at the same time. The laboratory manager immediately informs the personnel of the LTM about the change by e-mail (or oral, if necessary) and the accreditation body by e-mail. The mail with the information shall be stored in the folder »Sistem kakovosti/Zapisi/Interna elektronska korespondenca«.

Documents are archieved for 5 years.

5.4 Protection from the use of obsolete/superseded documentation

Protection from the use of obsolete/superseded documentation (from the archive) is assured by graphical sign of archive folders and by changed filenames.

5.5 Rule for identification of issues

Issue number consists of the letter "E" and successive number (e.g. E-1, E-2, …). All documents, issued before the firs electronic issue of the quality manual (E-1), retain their present number until the first electronic issue.

5.6 Changes in the documents and new issues

At every change in the document the new document with new issue number is issued. The issue number is stated on every document page. Chapters, which were changed, added or removed, are listed in the table Evidence of changes. Changed or added text is written in the document with red color.

5.7 Procedures for protecting data from loss

Data in the folder FS.LTM5\D:\LTM are protected from loss by:

- daily backuping of the data in the above stated folder to the folder C:\LTMBACKUP by the Backup programm, which is the part of Windows and is configured to automatically backup all changes in the folder at the end of the working hours;
- once in a year backuping of the data in the above stated folder to the DVD. Responsible for backuping is the quality manager. Recorded DVD is labeled "ARHIV LTM", year and running number of the DVD in the current year. DVD is archived, as stated in Ch. 6.2.2.

5.8 External documents

External documentation (official documents, standards, messages, offers etc.) is stored in the documentation file (room D 005). External documentation of LTM is divided into three groups:

- technical documentation for performance of measurements, calibrations and inspection (standards, guides, EA documents, Euromet documents, etc.),
- quality management documentation (standards like ISO/IEC 17025, guides, EA documents, SA documents, etc.),
- legal documents for the fields metrology and accreditation (law on metrology, rules, decrees, etc.)
- Quality manager deputy is responsible for collecting (supplementing the documentation) and up-dating the first group o f documents, quality manager is responsible for the second group, while the technical manager deputy for the field inspection and verification is responsible for the third group. The responsible persons shall review data on the web sites, standard catalogues and official gazettes (Official Gazette of Republic of Slovenia, etc.).

The quality manager deputy is responsible for collecting, up-dating, distributing and returning the documentation. He is also responsible for the evidence of distributed documentation (the date of

distribution and the name of the person who borrows a document). Every staff member is authorized to copy the documentation for his own needs.

The valid (updated) version of a standard is always kept in the documentation file. Staff members must check the validity of their copies periodically by comparing them with the version in the documentation file.

Special documentation category is represented by contracts with SA, RvA and MIRS. These contracts define certain operating conditions of LTM. The laboratory manager is responsible for these documents. He keeps the documents in his office. One copy shall be available to the dean of the Faculty of Mechanical Engineering.

6 REPORTS AND RECORDS

6.1 Reports

Performer of the calibration (inspection) writes a report, he prints it and submits it to the authorized person for signing. Signed version is scanned and saved in the pdf format (see Ch. 5). Original report is sent to the client, electronic (scanned) one is archived in the LTM.

6.1.1 Calibration reports

Calibration reports for accredited procedures are based on the form "Obr 02-Certifikat o kalibraciji - akr.pdf", for non- accredited procedures on "Obr 03-Certifikat o kalibraciji - neakr.pdf". Both forms are stored in the folder Obrazci (see Ch. 5.1).

6.1.2 Inspection reports and verification certificates

Inspection reports and verification certificates are defined in corresponding SOP.

6.1.3 Instructions for amending/supplementing reports

- If it is necessary to change a report/certificate after it has been issued, a completely new document, which recalls the original report, should be written.
- All holders of the original report/certificate should get the corrected (new) report/certificate.
- The corrected (new) report/certificate should be filed together with the original report/certificate.

6.1.4 Instructions for distributing copies of the records

When the client demands a copy of the record (e.g. after losing it), the copy is printed from the res. *.pdf file. In the place for signature the word "KOPIJA" (copy) and the current day is to be written by hand. The copy is to be signed by the authorized person.

6.2 Records

Records origin on the paper or in electronic means. Rules for handling with records in electronic means are stated in Ch. 5.

6.2.1 List of records

The following records should be filed in the laboratory:

- Records of orders and performance of calibrations, which should contain sufficient data for repeating the calibration any time. These records are stored in electronic means. Records, written on the paper, are to be scanned to pdf file and related as electronic records (see Ch. 5.1).
- Records of supplies and services (Z 02), which should contain:
  - report about the assessment of suppliers,
  - purchasing documentation,

- report about the inspection (tests) of the incoming goods,
- suppliers' information about the quality of the products,

- Records about the quality system (internal audits, external assessments, management reviews, non-conformities, corrective actions etc.) (Z 04),
- Records about subcontracting (Z 06),
- Records about complaints and related actions (Z 07),
- Records about the environmental conditions in the laboratory (Z 08),
- Statements And Authorizations (Z 09),
- Records about calibration (inspection) software validation (Z10).
- Personal file (P 01),
- Equipment file (E 01).

6.2.2 Indexing, storage and archiving records on paper

- Each record should carry the serial number and the date.
- The records are arranged by serial numbers (and also by dates).
- The records for different months and years are separated with colored cardboard (each cardboard carries the month and the year of following records).
- All valid records for current year are stored in the documentation file in the room D 005.
- All records, stated in previous chapter, are to be archived for 5 years in the room D 004. After elapsing that time records are to be destroyed – cut in pieces and disposed.
- The quality manager is responsible for indexing, storage and archiving of records on paper.

6.2.3 Procedure for lending out the filed records

- The quality manager deputy is responsible for lending out and for returning the documents.
- The original records on paper can be lent to all staff performing calibrations, but they should not be delivered out of the laboratory. The records can be copied only by request of the client, the subcontractor, and the accreditation body.
- Electronic records are not to be printed, with exceptions of the cases in the paragraph above.
- The copies of the records can not be distributed, except to the accreditation body (which can get all records), to the client (who can get only the records related to the calibration of their items), and to the subcontractor (who can get the records of calibrations performed by them).
- and authorized to decide who can get the copies of the records.
- Clients and subcontractors can get copies of records only by sending us a written (official) request. Copies are sent as a registered mail in order to get a clients' confirmation of receipt.
- When a document is returned, the authorized person should check if the document is complete (the number of pages compared with the number on the lending out note).

6.2.4 Guidelines for changing records

- A record can be changed (corrected) only during the creation, if a writing error has been detected. When a record is filed res. put in a folder, it is not allowed to be changed any more. This rule concerns paper and computer records.
- If certain part of a record has to be changed, incorrect text shall be crossed out (not erased or darkened) and the correction shall be signed by the person, who has written (and also corrected) the record.

7 QUALITY SYSTEM CONTROL

7.1 Internal quality audits

7.1.1 Guidelines for performing internal quality audits

- Internal quality audits are planned, organized and documented by quality manager.
- Internal quality audits are performed by a group, composed of the head of the LTM, quality manager and a person from the MIRS, when possible. External auditors shall be properly qualified for performing internal audits. The quality manager shall prove their qualification by reviewing available education and training certificates. Each verified auditor shall be entered into the Register of verified auditors, which is stored in the folder Z 04 »Zapisi o sistemu kakovosti«.

7.1.2 Planning of the internal quality audits

Periodical (regular) internal quality audits are performed once in a year, in May or June, when possible. Quality manager informs in time the LTM personnel and audit performers by e-mail. Audit of performance of calibration (inspection) on site is defined in Ch.13.6.1.

7.1.3 Instructions/checklists for performing audits

The person who audits components of the quality system should use the form "Obr 11-Spisek preverjanj int.presoje v lab.doc", stored in the folder Obrazci (see Ch. 5.1).

7.1.4 Audit report

Audit report is to be written on the form "Obr 09-Poročilo o interni presoji.doc", stored in the folder Obrazci (see Ch. 5.1). Reports are filed in the folder Z 04. A report number consists of running number (X) and year (LL): X-LL.

7.1.5 Nonconformance and corrective actions

Ascertained nonconformance are written in reports of nonconformance (form "Obr 10-Poročilo o neskladnosti.doc"), stored in the folder Obrazci (see Ch. 5.1), and filed together with audit report. Report of nonconformance includes proposals for correcting actions and checking of correcting actions. A report number consists of an abbreviation NS, running number (X) and year (LL): NS X/LL.

7.2 Management review

Management reviews are to be performed using the next procedure:

- Review is carried out once a year after the internal audit,
- Review is conducted by the laboratory manager,
- Review is attended by:
  - the laboratory manager,

- the quality manager deputy.
- the technical manager deputy of the inspection body,
- the quality manager deputy.

➢ Review should include at least the following items:

- matters arising from the previous review,
- reports on surveillance and re-assessment visits carried out by any accreditation body,
- results of internal audits carried out since the last review,
- results of the laboratory's participation in any proficiency testing or interlaboratory comparison schemes and the need for such participation in other areas of calibration,
- results of any in-house quality control checks,
- details of any complaints received from customers,
- need for amendment of the quality system, including the quality manual,
- plan for the implementation of decided changes to the quality system, including a timetable,
- adequacy of current human and equipment resources,
- future plans and estimates for new work, additional staff, new equipment etc.,
- training of new staff and updating of existing staff,

➢ A record should be written after each review using the form "Obr 08-Zapisnik vodstvenega pregleda.doc)", stored in the folder Obrazci (see Ch. 5.1).

➢ The quality manager is responsible for the control of the performance of activities defined at the review.

7.3 Quality system control during the work

7.3.1 Procedures for reporting and registering nonconformities

After finding a nonconformity or equipment defect in a part of the quality system, a person, responsible for this part of the system, immediately write a nonconformity report in the form "Obr 10-Poročilo o neskladnosti.doc", stored in the folder Obrazci (see Ch. 5.1) and hand it over to the quality manager. A report number consists of an abbreviation NS, running number (X) and year (LL): NS X/LL.

The nonconformity report has to include following information:

➢ name of the person, who registered the nonconformity,

➢ date and location of the nonconformity registration,

➢ type of the nonconformity,

➢ name and identification of defected equipment (if any),

➢ the circumstances at the registration of the nonconformity,

➢ the expected influence on the calibration (inspection) results.

7.3.2 Procedures for execution of corrective actions

Instructions for correcting the nonconformities are given from the quality manager after examining the nonconformities report and analysis for appearance of nonconformities (procedure for analyzing in Ch.7.3.3). The nonconformity is to be corrected by a person, responsible for a part of the quality system where nonconformity has appeared. Instructions given from the quality manager are to be precisely followed.

Report of the correction of the nonconformity is to be written in an appropriate place in the nonconformity report.

Corrective action is checked by the head of the LTM.

7.3.3 Procedure for analyzing deficiencies, complaints etc. and for investigating their causes

The analysis of deficiencies, complaints etc. and the investigation of their causes is performed by the quality manager.

The quality manager deputy and the staff performing calibrations (inspections) are also involved in the analysis and investigation.

The analysis is performed in the following steps:

- historical examination of the quality system element containing deficiency resp. defective equipment (have some deficiencies or defects occurred before?),
- which personnel is involved,
- consideration whether the deficiency res. the defect occurred because the quality policy had not been respected,
- searching for causes (objective, personal),
- analysis of the deficiency influence on the operation of the quality system,
- analysis of the deficiency influence on the calibration (inspection) results,

The quality manager makes conclusions of the analysis and investigation and proposes corrective actions in order to eliminate deficiency and the causes for deficiencies.

The quality manager writes an investigation report, which includes conclusions and proposed corrective actions. The report is given to the laboratory manager, who approves (or rejects) the proposed corrective actions. The report is stored into Quality system records (Z 04).

7.3.4 Procedure for checking whether work is required to be either wholly or partially redone

The quality manager deputy checks calibration (inspection) records in order to find out which (if any) were performed in the time when the deficiency or equipment defect was present. After that possible influence of the deficiency on the calibration (inspection) results are defined using the investigation report (Ch. 7.3.3). Data about the calibrations (inspections) that are suspected to be irregular are given to the quality manager.

The quality manager informs the clients about the possibility of irregular calibration (inspection) results by phone. Written explanation including the causes for irregular results is sent to the clients as well.

The laboratory manager decides whether work is required to be either wholly or partially redone. This decision is based on the deficiency analysis and investigation report. The quality manager and the calibration (inspection) staff are also involved in this decision. If certain calibration (inspection) is required to be redone, the calibration (inspection) staff and the client are informed by the laboratory manager.

The repeated calibration (inspection) should be included into the work plan. However, the schedule for other calibrations (inspections) must not be changed and client's requirements must be considered. The calibration (inspection) must be repeated after the regular working time if necessary.

The results of the repeated calibration (inspection) must be reported to the quality manager and the laboratory manager.

The quality manager checks the results of the original and the repeated calibrations (inspections) and writes conclusions about the validity of the original calibrations (inspections). These conclusions should be filed into the register of corrective actions. All records of invalid calibrations (inspections) should be marked with "INVALID" and filed into a separate folder.

After the quality manager has written the conclusions about the validity of the original (first) calibration (inspection), he should send a report to the client. The results of the repeated calibration (inspection) should be included in this report.

8 PERSONNEL

8.1 Policy regarding the personnel performing calibrations, inspection and verifications

- Personnel performing calibrations, inspection and verification shall be properly qualified. Requirements regarding formal education, technical knowledge and experiences are defined in chapter 8.2.1 and in job descriptions (P 01), whether the requirements regarding periodical education are in chapters 8.3.1 and 8.3.2;
- proper supervision for not yet fully qualified personnel and for personnel in education process shall be assured in accordance with the procedure 3.5.2;
- in the case of hiring personnel we shall properly define requirements, supervision and qualification of such personnel. The procedure 8.2.2 shall be followed;
- unique job descriptions shall be available for all employees according to the procedures 3.6.1 and 3.6.2;
- persons performing calibrations, inspection and verifications shall be authorized by the laboratory manager. Permanently authorized persons are listed in chapter 10.4 and in job descriptions (P 01). Hired personnel shall get a written authorization from the laboratory manager before performing any kind of work in calibration or inspection field.

8.2 Selection and recruitment

8.2.1 Procedure for recruiting and selecting personnel

- The laboratory manager is authorized and responsible for recruiting and selecting personnel.
- The laboratory manager decides to employ new personnel when the work extent increases, a worker leaves certain working position or a worker is moved to another working position.
- The decision about employing new personnel is reported to the authorized body of the Faculty of mechanical engineering, which brings an official decision about employing new personnel and advertises a vacancy.
- New personnel must meet all the requirements (education, knowledge, skills, and experiences) defined in job descriptions (Personnel files P 01).
- When selecting a new worker among all the candidates who meet the requirements, the level of education, skills, and experiences should be considered in the following order:
  - level of education,
  - working experiences in the field of dimensional metrology,
  - physical skills (for the personnel performing calibrations),
  - knowledge and experiences in the field of quality systems,
  - results res. quality of the past work.
- A new worker is employed for a test period of six months. During the time he (she) works in the laboratory under supervision of authorized permanent staff.

- A supervising person sends a report to the laboratory manager in the end of the test period. This report serves as a basis for the decision about permanent employment of a new worker.

8.2.2 Procedure for hiring temporary personnel

- The laboratory manager is authorized and responsible for hiring temporary personnel.
- A temporary personnel is hired exclusively for calibration.
- The laboratory manager decides to hire temporary personnel when the work extent increases or when a permanent staff member is absent for a period longer than six months because of illness, education, training, etc.
- The laboratory manager writes the contract (by the help of the lawyer at the Faculty of mechanical engineering), which should be signed by a hired person and the laboratory manager. The agreement of the Faculty of mechanical engineering is not required.
- The hired person must meet all the requirements (education, knowledge, skills, and experiences) defined in job descriptions (Personnel files P 01).
- When selecting a worker among all the candidates who meet the requirements, the level of education, skills, and experiences should be considered in the following order:
  - working experiences in the field of dimensional metrology,
  - results res. quality of the past work (known from the cooperation in the past),
  - physical skills (sight, concentration, ...),
  - level of education,
  - knowledge and experiences in the field of quality systems,
- Hired person should perform test calibrations (typical examples) under supervision of the permanent staff (an authorized staff member). The supervising person evaluates the work and decides whether the hired person is able to work correctly or not.

8.3 Education

8.3.1 Procedure regarding the period of qualification of staff

- The laboratory manager is responsible for the periodic check of staff qualification.
- The periodic check of qualification of the management staff is ensured by increasing education level to doctor's degree (internal check) and after that by working on professional projects and by publishing in professional magazines, proceedings etc. (external check).
- The qualification of the staff performing calibrations is checked by the management staff once a year. The following items are checked:
  - completed professional training in the check period,
  - working methods (comparison with the methods used in other accredited laboratories),
  - optimal use of computers for calculation and transfer of measuring data.

The periodic qualification check is a part of the quality system audit.

8.3.2 Description of the training system

- The training is divided to:
  - regular (periodic) training, which assures that the knowledge level of the personnel follows the development in the field of their work,
  - special training in the cases of buying new equipment, extending the field of work, changing the measuring and calibration methods, etc.
- The staff is required to train periodically in the following ways:
  - following and ordering new editions of important professional literature and informing the colleges,
  - getting information about the newest professional literature available in libraries, by international library cooperation, and by order,
  - visiting important metrological fairs. Every staff member should visit at least one domestic fair per year and one international fair every two years,
  - attending conferences, workshops, etc. The staff with the 7th degree of education are obliged to send their contributions to at least two conferences a year,
- If some special training is necessary, the laboratory manager consults the quality manager and the staff performing calibrations and brings the decision about the organization of the training.
- Special training can be performed in the following ways:
  - training for the use of new equipment (training at the manufacturer, practical training in the laboratory, study of the supporting literature, guides etc.). Training at the manufacturer and/or training in the laboratory must be attended by all the staff members who will work with the new equipment. Other staff members should be informed by the trained staff about the purpose, applicability, and operating principles of the new equipment,
  - attendance at selected conferences and fairs (new measuring methods, new measuring equipment, ...),
  - study of a selected new literature (new standards, work instructions, legal requirements, work methods, ...),
  - studying at other universities and institutes.
- The laboratory manager is responsible and authorized for the preparation of the program for special training and for financial realization.
- After the training the staff member should write a training report (Obr 25), in which he shall give his opinion on training effectiveness. The laboratory manager supplements the report with his evaluation of the usefulness and success of the training. A certificate of a successfully finished training (if it is granted) shall be attached to the training report. Training reports are analysed on management review.
- All certificates of a successfully finished training, training reports, and laboratory manager evaluations should be included in the personal files.

8.4 Documentation

8.4.1 Instructions on keeping the personal files

- Complete personal documentation (with the exception of certificates regarding periodic and special training) is filed at the personnel department of the Faculty of mechanical engineering.
- The copies of the personal documentation are filed in the documentation file in the room D 005.
- The personal file is marked with the code P 01.
- The rules regarding filing, protection, lending and copying are the same as in the Ch.6.2.2.

9 FACILITIES

9.1 Properties of the spaces

9.1.1 List of requirements to be complied with by the spaces

The properties of the spaces should meet the requirements VDI/VDE 2627 Blatt 1 for quality class 1 (precise measuring rooms).

9.1.1.1 Location of the measuring room

- basement room without windows or with windows on the northern wall,
- no significant vibration and noise sources close to the room,
- transportation possibility for big measuring objects (settled transport ways).

9.1.1.2 Building requirements

- 2 measuring rooms (measuring room with three-coordinate measuring device, measuring room with conventional measuring equipment),
- auxiliary room for air conditioner and compressor,
- no basement is allowed under the measuring room,
- walls must be thermal isolated (heat transfer max. 0,5 W/m^2K),
- thermal isolated windows (heat transfer max. 1,7 W/m^2K),
- humidity isolation of the floor and the walls,
- enter through separate room,
- suitable door dimensions for the transport of big measurands (minimum width of 1500 mm),
- pastel wall colors, no sharp borders between different colors (well feeling of staff),
- illumination min. 1000 lx, fluorescent lights with dispersal light,
- suitable installations (see section 2).

9.1.1.3 Dimensions

- height min. 3 m (the highest measuring device 2,9 m),
- area of the room with the three-coordinate measuring device min. 30 m^2 (the device, loading and operating area, desks, book cases),
- area of the room with the conventional measuring equipment min. 60 m^2 (the devices, loading and operating areas, desks, book cases, measuring tables, and transport ways).

9.1.1.4 Protection of the spaces

- doors with automatic locks.

There are no special requirements regarding the office rooms except the requirements regarding protection (as in paragraph 9.1.1.4) and necessary installations (section 9.2.2).

9.2 Environment and installations

9.2.1 Required environment conditions

- mean temperature: 20 °C±1 °C,
- temporal thermal gradients: 0,4 K/h
  0,8K/24 hours,
- volumetric temperature gradient: 0,2 K/m (for all three space coordinates),
- humidity: 30 % - 60 %,

9.2.2 Necessary installations

- electrical supply 220 V 50 Hz (in the room D 005 at least five sockets, in the room D 004 at least twelve sockets, in the office rooms (D 008, D 009) at least ten sockets, in the room with air conditioner and compressor at least two sockets),
- water supply (hot and cold water in one of the measuring rooms, cold water in office rooms),
- compressed air (own compressor with the minimum capacity of 10 l/min. and the minimum pressure of 5 bar),
- laboratory PC network in all rooms,
- WAX network in the office rooms,
- air condition in the measuring rooms (location of central unit and air sensor in the separate room, air channels in both measuring rooms),
- illumination of the spaces (minimum of 1000 lx in each room).

9.3 Using the special installations

9.3.1 Operating instructions for special installations

There are three special installations in the laboratory - air conditioner for measuring rooms, air conditioner for the air-conditioned chamber and the air compressor.

9.3.1.1 Air conditioner

- the air conditioner is adjusted and maintained exclusively by the authorized service,
- if a staff member detects disturbances in the operation of the air conditioner (disallowed temperature deviations), he (she) should inform the quality manager deputy, who is authorized and responsible for contacts with the authorized service.

9.3.1.2 Air conditioner for the air-conditioned chamber

- the authority for adjusting parameters of the air conditioner is assigned to the same personnel as the authority for using calibration equipment (chapter 10.4.1),
- parameters can be changed only in cases of special measurements and disallowed deviations from required climatic conditions in the chamber,
- the original manufacturer's (IZR) user's guide should be used for changing parameters, the guide is available in the chamber,
- all parameter changes should be recorded on a special form, that is hanging in the chamber,
- if a staff member detects disturbances in the operation of the air conditioner (disallowed temperature deviations), he (she) should inform the quality manager deputy, who is authorized and responsible for contacts with the authorized service.

9.3.1.3 Air compressor

- when the compressor is not in use, it is turned on, but the air valve must be closed,
- the compressor is activated by opening the valve on the output pipe,
- the condensed water should be eliminated from the compressor by opening the valve under the output pipe before using the compressed air.

9.4 Access and use of spaces and installations

9.4.1 Access to the spaces and installations

- all permanent staff members have an access to the measuring and the office rooms,
- the staff performing calibrations, the laboratory manager, and the quality manager have access to the room with the air conditioner and the air compressor,
- unlimited access to the climatic chamber is assigned to the same personnel as the authority for using calibration equipment (10.4.1),
- other laboratory members are allowed to enter the climatic chamber under supervision of the authorized personnel,
- persons, who are not employed in the laboratory, are not allowed to enter the climatic chamber (exceptions are special occasions like services, installation of equipment etc. - in these cases entrance should be allowed by the laboratory manager and persons entering the laboratory should be supervised by at least one authorized person),
- other installations are available to all staff members.

9.4.2 Instructions for the use of spaces

- all permanent staff members have keys of all laboratory rooms,
- a staff member can get new res. spare keys only with the agreement of the laboratory manager,
- the keys must not be lent to the people who are not employed in the laboratory,

- people who do not work in the laboratory can enter the rooms only in the presence of a staff member,
- temporary laboratory staff can get the keys, but they must sign a statement in which they confirm an agreement with the laboratory quality policy,
- when a staff member leaves a laboratory room, he (she) must close the door, which is then automatically locked. After the working time the doors must be additionally locked,
- when entering or leaving the measuring room only one door can be opened at the time (the glass door can be opened after the main door has been closed or vice versa),
- staff should wear white coats in the measuring rooms,
- in the separation room the shoes must be cleaned and the upper clothes (coats etc.) must be changed with a white coat,
- smoking is forbidden in all rooms,
- furniture and measuring equipment (except handy measuring devices) can be moved only with the agreement of the laboratory manager. All changes should be updated in the laboratory plan,
- for climatic chamber we should apply the same rules as for other spaces (except the rules regarding access to the spaces and the possession of keys), and the following three additional rules,
- climatic chamber should be locked when the authorized personnel is absent,
- only personnel performing calibrations have keys of the climatic chamber,
- the climatic chamber is cleaned by the personnel performing calibrations (cleaning personnel has no right to enter the chamber).

10 EQUIPMENT

10.1 Policy for achieving traceability of measurements

- All calibrations and inspections shall be traceable to a primary (international) standard of measurement.
- Every new measuring device must be calibrated before the first use.
- All measuring devices and standards used for calibrations and inspections shall be calibrated in the defined calibration intervals (see E 01).
- Measuring devices and work standards are calibrated in the laboratory. Calibrations shall be performed in accordance with the instructions in 10.7 and in SOP.
- Reference standards of measurement are calibrated in selected accredited or national laboratories by primary standards or by standards that were calibrated directly by primary standards.
- Calibrations shall be documented (instructions in 10.7). Calibration documentation should be filed in the record about the equipment.
- The date of following (next) calibration must be clearly marked on the equipment and standards in order to provide the user with information about traceability.
- The quality manager deputy is responsible for regular and correct calibration and for calibration documentation.

10.2 Identification and evidence

10.2.1 Equipment file

10.2.1.1 List of capital goods (equipment of greater value)

- A list of basic means of the Laboratory (expense account No. 2101) is filed and maintained on the level of the Faculty (controlled by bookkeeping department). It is also filed in the Computer center of the University in Maribor.
- The list contains:
  - inventory number,
  - name of equipment,
  - status,
  - real and write off value,
  - begin of the balance,
  - amortization and revalorization group,
  - account,

- location

- A new basic good (equipment) is accepted by a protocol that is signed by:
  - the Dean of the Faculty,
  - the laboratory manager,
  - designated user of the equipment.
- An inventory number is attached to the equipment.
- A copy of the list of basic goods is filed in the folder Equipment files (E 01), filed in the documentation file in the room D1 005.

10.2.1.2 Evidence sheet

- Traceable measuring devices are registered on evidence sheets.
- A field of evidence contains:
  - name of a device,
  - measuring range,
  - resolution,
  - evidence number (inventory number),
  - owner,
  - manufacturer,
  - manufacturers' identification,
  - date (year) of manufacture,
  - classification,
  - term of periodic calibration (legal or intern),
  - date of first calibration,
  - performer of first calibration,
  - approval of the laboratory manager for the use of new equipment (signature)
- A field of periodic calibration contains:
  - serial number,
  - date of calibration
  - performer(s) of calibrations,
  - identification of a certificate,
  - person(s) who approved calibrations,
  - notes.
- Evidence sheets are issued by the user in the laboratory. The sheets are based on the protocol of acceptance.

- The evidence sheets are filed in the folder E 01.

10.2.2 Identification of measuring equipment

- The entire equipment is identified by inventory numbers. They are printed on metal or plastic plates that are attached to the equipment.

10.2.3 Instructions for keeping the equipment files

- The following equipment files are kept in the laboratory:
  - documents about authorization for using the equipment,
  - documents about the equipment used for calibration,
  - documents about the equipment used for measurement.

10.3 Issue and receipt

10.3.1 Procedures for supervision, issue and receipt of equipment

- Only manual measuring equipment that is not used for calibration (accredited or non-accredited) is allowed to be lent out,
- Equipment, which is lent (or brought) outside the laboratory, must be registered. A bond, issued for the issued equipment, should contain the following information:
  - address of the Laboratory for production measurement,
  - address and telephone number of the institution borrowing the equipment (if it is lent out),
  - location of the equipment during the period, when it is outside the laboratory,
  - bond number,
  - number of pieces of the equipment (if the equipment, carrying one inventory number, contains more parts, all parts must be quoted),
  - name of the equipment,
  - manufacture and inventory number,
  - date of issue, lending period, date of return,
  - name and signature of the person issuing (receiving) the equipment,
  - name and signature of the person borrowing (returning) the equipment.
- The bond is issued in two copies. The original is kept by the laboratory, whereas the second copy is given to the institution (person) borrowing the equipment.
- Bonds of issued and returned equipment are filed in the folder E 01.
- At the time of return the equipment must be checked (function and damages). When needed, precise equipment must be calibrated after return.
- Issue of equipment must be approved by the laboratory manager.

10.3.2 Rules for borrowing equipment from third parties

- We borrow only missing equipment for calibration and measurement. If borrowed equipment is not traceable, it is calibrated in the laboratory in accordance with the laboratory authorities.
- Bonds of borrowed equipment are filed in the folder E 01.

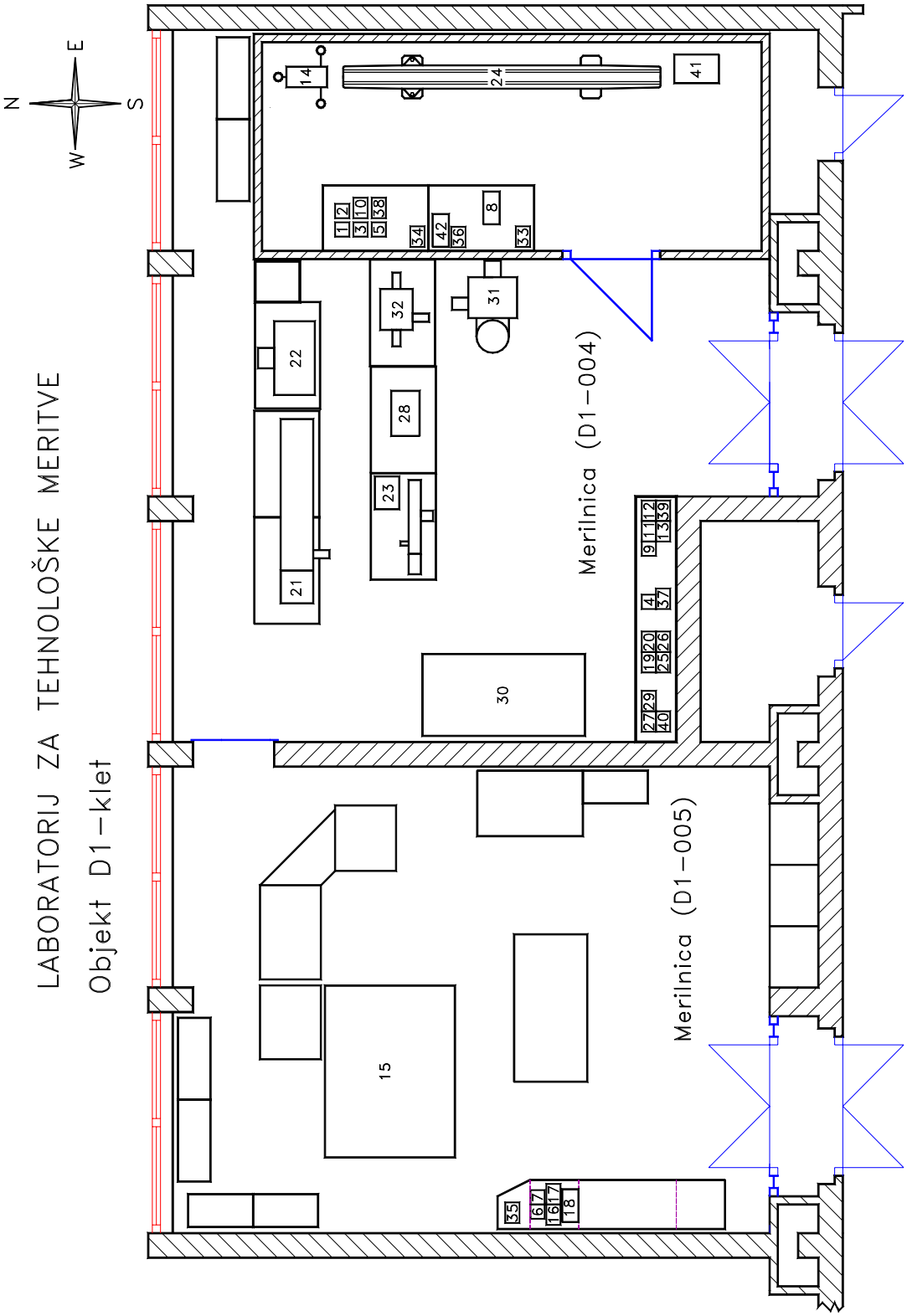
10.4 Authority

10.4.1 Rules regarding the authority to use the equipment

- Calibration equipment may be used only by properly qualified staff members.
- The following staff members are authorized for using the calibration equipment:
  - dr. Bojan Ačko,
  - ing. Jakob Žiljcov,
  - Miran Milfelner,
  - mag. A. Godina (with limitations, see personal map).
- Other persons can use the equipment only by special authorization of the laboratory manager. The authorization for the use of the equipment contains:
  - address of the laboratory,
  - authorization number,
  - list of equipment,
  - manufacture and inventory numbers,
  - period of authorized use of equipment,
  - name and signature of the user,
  - signature of the laboratory manager.
- The authorization is issued in two copies. The original is filed in the folder E 01, whereas the copy is given to the user.

10.5 Drawings

10.5.1 Drawing of equipment installation



Equipment in the installation drawing:

	Standard/instrument	Manufacturer	Type	Identification	Inventory number	Remark
1	Gauge blocks 0,5-100/122	FRANK	DIN-Kl 00	9770	S 40160	
2	Gauge blocks 1-100/11	FRANK	11 delne	9771A,B	S 40104	
3	Gauge blocks 0,5-100/122	KOBA	1122M	86098	S 37221	
4	Gauge blocks 125-500/8	KOBA	1008M	35570	S 37676	mobile
5	Gauge blocks 600-1000/5	TESA-RSD	5 delne	103133	S 40119	
6	Gauge blocksa 2,5-25/10	MITUTOYO	516-156	952879	S 40097	
7	Gauge blocks 0,5-100/121	CARL ZEISS	121 delne	33009	S 7645	
8	Gauge block comparator	MAHR	826	1129/96	S 36993	
9	Glass roundness standard	Taylor Hobson	Ø50mm	112/43-721F	S 40436	
10	Optical plain (glass cylinder)	TESA	50mm	5Eg	S 40474	
11	Polygon	TESA-RSD	12 kotni	102868	S 40640	
12	Gauge rings	MITUTOYO	4-275mm	S 40851	S 40901	
13	2D scale plate	HEIDENHAIN	75x75mm	S 40901	S 40901	
14	Laser interferometer	HP	5528A	2532A02451	S 34428	mobile
15	CMM	ZEISS	UMC 850	74698	S 22547	
16	Micrometer-external 0-25	TESA	0-25mm/0.001	6P0004301	S 40651	mobile
17	Micrometer-externa 25-50	TESA	25-50mm/0.001	6F0024701	S 40652	mobile
18	Dial gauge comparator	MAHR	865E	9421	S 40743	
19	Measuring wires	TESA	0,17-3.20mm	S 40653	S 40653	mobile
20	Inductive probe	MAHR	1301	S 40475	S 40475	mobile
21	Optical division head	CARL ZEISS	P1	9338	S 7885	
22	2D measuring machine	CARL ZEISS	ZKM 1-300D	193	S 21095	
23	Universal 1D machine	CARL ZEISS	0-400mm	7060	S 41262	
24	Universal 1D machine	CARL ZEISS	0-3000mm	1376	S 7887	
	Militron	MAHR	1240	2997/99	S 41654	mobile
	Inductive prove	MAHR	1340	5313400	S 41655	mobile
	Inductive probe	MAHR	1340	5313400	S 41656	mobile
25	Electronic level Leveltronic	WYLER	A40	S 36992	S 36992	mobile
26	Electronic level Leveltronic	WYLER	A40	S 36992	S 36992	mobile
27	Electronic level system	Taylor Hobson	Talyvel 4	271	S 40852	mobile
28	Roundness measuring device	Taylor Hobson	Talyround 31c	S 40816	S 40816	
29	Granite square	WENZEL	300x500/0.001	S 39175	S 39175	mobile
30	Granite plate	PLANOLITH	DIN 876/000	12094	S 40115	
31	Profile projector	CARL ZEISS	MP 320	S 00116	S 00116	
32	Tool microscope	CARL ZEISS		13659	S 7888	
33	Temperature meas. system	ZEISS	TEMP 10G	930039	S 39327	mobile
34	Thermo-hygrograph	-	TH 252	495014	S 40056	
35	Thermo-hygrograph	-	TH 3015-3	9704157	S 40678	
36	Thermo-hygrograph	AHLBORN	Almemo	D97091918	S 40679	mobile
37	Gauge blocks 125-500+1000/9	KOBA	1008M	86226	S 41657/8	
38	Gauge block 500/1	KOBA	1 delna	86388	S 41248	
39	2D angular standard plate	HEIDENHAIN	0-360º	15198401	15198401	mobile
40	Electronic level system	WYLER	Levelt. NT	B0960/0961	S 41661	mobile
41	Video probing system Renishaw	RENISHAW	VP 2	P82787	P82787	mobile
42	Gauge block comparator	CARY	IVC-154	4191	S 41818	

10.6 Maintenance

10.6.1 Maintenance instructions

- The original instructions of manufacturers should be used for the maintenance of the equipment.
- Service periods are based on the recommendations of manufacturers. Reparations should be performed only by authorized services.
- Maintenance plans and addresses of authorized services are kept in the folder E 01.

10.6.2 Lists of spare parts

- Lists of spare parts are kept in the folder E 01.

10.7 Calibration

10.7.1 Procedures for calibration of the equipment

- A procedure for the calibration in the laboratory:
  - all measuring instruments and work standards are calibrated in the laboratory,
  - calibration should be performed in accordance with calibration procedures (Ch. 12.4) and work instructions,
  - calibration reports and certificates should be filed in the folder E 01,
  - dates of calibration should be noted on evidence sheets.
- A procedure for calibration outside the laboratory:
  - reference standards and other equipment used for assuring traceability of measurements and calibrations, which can not be calibrated in the laboratory, are calibrated in other institutions;
  - the head of the laboratory is responsible for choosing calibration laboratory;
  - the offers are collected by the quality manager and his deputy in accordance with procedures in Ch. 11;
  - the most important criterion for selecting a laboratory is its best calibration capability;
  - quality manager is responsible for the communication with calibration laboratories;
  - an order for calibration shall include the form of calibration results, the limits of measuring uncertainty, the period of calibration and reference to the order price;
  - quality manager is responsible for the transportation of the equipment. The transport is organized by the office (on the faculty level) which is co-operating with a forwarding agency (this agency also organizes the transportation);
  - suitable package shall be available for all standards and other equipment. Quality manager deputy is responsible for marking the package with all necessary data for transport (addresses, instruction for handling);

- when the equipment is returned from calibration, the user (the one who is in charge for it) shall check if and write a short record if significant changes are detected. The changes are analyzed by the quality manager and a warranty procedure is initiated if necessary.

10.7.2 Program for performing periodic calibrations

A register of equipment and calibration intervals are written in the folder E 01.

10.7.3 Analysis of calibration results

Results shall be analyzed after each calibration (in LTM or outside) according to the following procedure:

- the results from the last certificate are compared with the results on previous certificate(s).
- if the deviations are in limits of specified uncertainty res. it is found out that they do not increase the uncertainty of calibration or measurement for which the equipment is used, the head of the laboratory approves the use with a signature in the field "Periodic calibration" of the evidence sheet,
- if detected deviations could threaten trust in calibrations pr measurements for which the equipment is used, the technical commission (head of the laboratory, quality manager and a user of the equipment) analyses causes for such deviation(s) and checks a possibility that calibrations, which have already been performed, are not confident. I necessary, such calibrations are repeated,
- if causes can not be detected by the analysis, the equipment is recalibrated (if possible in other institution),
- a report of the analysis (including all conclusions) is written and filed into the folder E 01 after the evidence sheet of the respective piece of equipment,
- a "history" of equipment in a for of comparison table or graphs is managed for reference standards (filed in the folder E 01 after the evidence sheet of the respective piece of equipment,
- if it is necessary to change calibration values of a standard, it is done by the person responsible for standards and checked and approved by the head of the laboratory. The record on changing necessary data including the date and the signature of the head of the laboratory is a part of the report on the calibration data analysis.

10.7.4 Intermediate checks

Intermediate checks of reference standards, which are calibrated outside the laboratory, are not possible (no appropriate equipment is available). Such equipment can only be checked by means of interlaboratory comparisons. The person performing calibrations with this equipment shall check the results (if this is possible based on the results from the past) and the head of the laboratory shall be contacted in the case of suspicion in the correctness of the calibrated value(s). The head of the laboratory decides whether an extra (intermediate) calibration is necessary.

Intermediate checks of the equipment, which is calibrated in the laboratory, are only performed in cases of suspicion in the correctness of operation and in cases when greatest amounts of calibrations are performed with such equipment. Intermediate checks are performed according to the calibration procedures, but instead of a calibration certificate and hand written check report is made. Regular

intermediate checks for the equipment in the laboratory are not necessary (this statement is based on the equipment history and on properly defined calibration intervals). The results of intermediate checks shall be stored in the equipment files E 01 by the performer(s) of the checks.

10.8 Computer system

10.8.1 Documentation of the computer system

10.8.1.1 Computer system

The computer system consists of PC computers linked in a network.

The **users** in the network have equal priority and enable:

- data input,
- data manipulation.

The documentation of the computer system is divided into:

- hardware documentation (E 02)
- software documentation (E 03 + original software documentation - commercial)

10.8.2 Hardware documentation

Hardware documentation contents:

- all PCs of the computer system,
- network cards,
- printers and plotters,
- streamer (for back ups).

10.8.3 Software documentation

Software documentation contents operating instructions for:

- operation system,
- network,
- streamer,
- word processor,
- data base control system,
- data base for calibration (inspection).

10.9 Defective equipment

10.9.1 Instruction for removing defective equipment from use

If it is detected, that equipment:

- does not work,
- does not work properly or there is a doubt about improper functioning,
- gives uncertain results,
- has not been properly used (overloaded, damaged),
- has not been properly maintained or repaired in time,
- has not been calibrated in time

the following actions should be taken:

- portable equipment should be removed from working place and put in the place designated for defective equipment,
- fixed equipment should be equipped with a warning text NOT FOR USE - DEFECTIVE EQUIPMENT.

11 SUPPLIES AND SERVICES

11.1 Purchasing and contract service policy

Suppliers of new equipment (measuring equipment, computers, furniture, ...) and subcontractors (reparations, cleaning, painting, ...) are chosen in accordance with the following criteria:

- ability to fulfill exactly defined requirements,
- ability to deliver a product or to finish a service in the defined time period,
- quality and fast service,
- price.

A priority is given to the suppliers or subcontractors, with which we have had good experiences in the past, and to those with good reputation (especially suppliers of measuring equipment and standards).

Evaluation of suppliers and subcontractors is based on offers. The laboratory manager is authorized and responsible for choosing the best offers.

After we have got all the offers, we build a list of possible suppliers or subcontractors, which contains:

- type of the product or service,
- names and addresses of checked suppliers res. subcontractors,
- names of contact persons.

In the case of purchasing measuring equipment, we require a calibration certificate of an accredited laboratory. Other equipment (computers, furniture, ...) is inspected by the laboratory staff before installation (100 % inspection). If a purchased product does not meet the requirements, it is returned to the supplier and new equipment is required. If the supplier is not able to deliver suitable equipment, he is deleted from the list of suppliers. Very important criterion for evaluation of suppliers and performers of services is the period of warranty.

Contracts with performers of services should exactly define the requirements, time periods for performing services, prices, working conditions, supervision of services and performers of services, warranty and measures taken in the case of improper service (deleting from the list of subcontractors, indemnity, penalty, etc.).

11.2 Suppliers

11.2.1 Procedure for the assessment of suppliers

- Potential suppliers are selected from catalogues of domestic and foreign professional fairs, from advertisements in professional papers and magazines, by visits of professional stores, from web pages, Accreditation bodies' information, Euromet database, etc.
- The following three methods are used for the assessment of suppliers:
  - reputation of the supplier and experiences with the supplier in the past,
  - technical check of the suppliers' products/services at professional fairs,

- inspection and tests of purchased products/services.

- The assessment is performed by:
  - the laboratory manager,
  - the quality manager,
  - the personnel performing calibrations.
- The assessment procedure:
  - suppliers that are able to supply certain product(s)/service(s) with required characteristics are selected,
  - official offers are required from the selected suppliers,
  - potential suppliers are chosen among the selected suppliers on the base of their reputation and our experiences in the past,
  - the chosen suppliers are classified by the product/service price(s) and recorded in the list of approved suppliers.
- The described procedure should be carried out before each purchase and the existing list of approved suppliers should be considered.
- The list of approved suppliers is filed in the folder Z 02. It should contain the following data:
  - the type of the product/service,
  - names and addresses (telephone, fax) of the approved suppliers,
  - names of the contact persons at the suppliers.

11.2.1.1 Special procedure for evaluating performers of external calibrations

The performers of external calibrations can be exclusively European national institutes and the laboratories accredited by an accreditation body, which is a signatory of multilateral recognition agreement.

The quality of the external calibration performers is based on the records of calibration analysis (Ch. 10.7.3), which are stored in E 01. The evaluation is performed on a special form "Evaluation of the external calibration performers", which is in an annex of this document. Fulfilled form is stored in E 01.

The most important criteria for the evaluation are the following:

- best calibration capabilities (CMC),
- price,
- terms of performance,
- proper communication.
- transportation possibilities,
- results of performed calibration analyses.

11.2.2 List of approved suppliers

The list of approved suppliers is in the file Z 02. Special list of approved external calibration performers is in the file E 01.

11.3 Documentation

11.3.1 Procedure for drafting, checking and approval of purchasing documents

- The quality manager deputy prepares an order, which contains the following information:
  - product/service specifications (name, number of pieces, required tolerances, measuring uncertainty, traceability, service contents, etc.),
  - referring offer,
  - date of delivery specified in the offer,
  - price specified in the offer,
  - exact address of the laboratory and the name of the responsible person.
- The laboratory manager checks and approves the documentation. After that he prepares and sends an application to the executive committee of the Faculty of mechanical engineering. The committee checks the financial state of the laboratory and approves res. rejects the purchase.
- After the purchase has been approved, the laboratory manager sends the order to the supplier. The copy of the order is filed into the records about supplies and services (Z 02).

11.4 Receipt and inspection

11.4.1 Procedure for the receipt and inspection of purchased products

- The laboratory manager, the quality manager and the staff performing calibrations are authorized and responsible for the receipt of the ordered product(s).
- The staff performing calibrations is authorized and responsible for inspection and testing of purchased product(s).
- If the product is imported, the legal activities (duty etc.) are carried out by the authorized person at the Faculty of mechanical engineering.
- When the product arrives to the Faculty of mechanical engineering, one of the responsible staff members (or the person, quoted on the package) is informed by the faculty post office (the procedure is laid down in the job descriptions of the faculty).
- After the receipt an authorized person unpacks the product. The assembly and installation (if required) are carried out by one or more authorized staff members.
- After the installation the product is inspected (tested) by an authorized person according to the instructions in next chapter. A 100% inspection of product and its components is required.

- If the product meets all the requirements specified in the order, it is accepted and the documentation is signed. In the case of detected defects the supplier is informed immediately.
- In a discussion with the supplier it is stated whether the product is defected or a mistake has been made during the inspection (test). In that case the inspection (test) should be repeated.
- In the case of a defect the product is returned to the supplier or a suitable service is required.
- After the inspection (test) a report should be written by the person performing the inspection (test) and checked by the quality manager. The report is filed into the equipment file (E 01),
- The use of new equipment must be approved by the laboratory manager (signature on the evidence sheet).

11.4.2 Inspection instructions for incoming products

- The purchased product should first be unpacked and placed in the working position.
- It should be checked if the package is complete in accordance with the specification of components included in the package.
- The specifications of the product should be checked by using the documentation (e.g. measuring range, measuring uncertainty, calibration certificates, proof of traceability, ...)
- The instructions for installation, assembly (if necessary) and use should be collected.
- The product should be assembled. Possible visible damages should be detected during the assembly. If the product is assembled by the manufacturer, one of the authorized staff members should supervise the assembly.
- The product should be installed (if necessary) and the correctness of operation according to the working instructions should be established.
- In the case of measuring or calibration equipment, a calibration with reference standards of measurement should be performed.

11.5 Service check

11.5.1 Procedure and instructions for checking services

- The following staff members are authorized and responsible for checking services:
  - the laboratory manager,
  - the quality manager,
  - the quality manager deputy.
- After the service has been completed it is checked in a qualitative (e.g. cleaning, replacement of windows, electrical installations, computer service...) or in a quantitative (e.g. service of measuring and calibration equipment, service of the air conditioner,...) way;
  - in the case of a qualitative check the suitability of the service is checked according to the requirements specified in the contract,

- in the case of a quantitative check a set of measurements is performed (measurements using standards of measurement, temperature measurements, humidity measurements,...) and the quality of the service is evaluated by using the measuring results.

- If the service is evaluated as improper or incomplete, the performer is informed and some corrective actions are required.
- After the service check a report must be written and filed into the records about supplies and services (Z 02). If a service of measuring equipment is checked, the report should be also filed into the equipment file (E 01).

11.6 Storage

11.6.1 Procedures for receipt, storage and issue of products, for stock control and for checking products on stock

Only consumer goods (paper, cleaning fluids, etc.) are on stock in the laboratory. Therefore, no special procedures are required for receipt, storage, issue and stock control.

12 PERFORMANCE OF THE WORK

12.1 Review of requests, tenders and contracts

The procedure for performing service (calibration, inspection, measurement, verification) is the following:

- the client's request which can be in written or in verbal form can be accepted by the permanent performers of calibrations, by the quality manager or by the laboratory manager;
- the request is responded by the quality manager or his deputy with a written offer contenting quality description of the service, term of performance and the price; in special cases can the offer be given in verbal form (on client's request, usually for a smaller extent of work). The offer is based on the valid price list approved by the laboratory manager. Before the offer is written, it is checked whether proper equipment, methods, personnel, instructions and standards or client's specifications are available. The capacities shall be checked, too;
- the client sends us an official order, in which he:
  - exactly specifies the contents and the extent of the work,
  - specifies the time period for the performance of the work or accepts our suggestion regarding the time period,
  - confirms an agreement with our offer,
  - specifies special requirements and standards (if necessary),
  - the order is filled in accordance with the procedure in Ch. 12.2; the order (original) stays in the LTM until sending it to the accounting department of the faculty together with the invoice, where is being archived.
- in the case of insufficient capacities, a subcontractor is involved in accordance with the policy in Ch. 14.1;
- the work is performed in accordance with the procedure in Ch. 15 and the invoice is sent to the client;
- if deviations from the agreed procedure appear during the performance of work, the client shall be informed and shall agree (written or verbal agreement) with the changes. Deviation(s) shall be recorded and records shall be stored among the order records.

If a calibration is ordered, we should be aware that we are accredited for the specific type of calibration. When we perform calibrations we are not accredited for, we should issue no certificate with the logotype of the accreditation services.

If ordered work has already been performed in the past, we should use the same working methods. If certain work is accepted for the first time, we should precisely check our capacities and abilities.

The following persons are authorized and responsible for the acceptance of new work:

- laboratory manager,
- quality manager,
- quality manager deputy.

No contracts are written for calibration, inspection and verification work. Contracted services are

only performed on the Faculty level in research and education fields.

12.2 Performing the work

The following procedure is used for planning the work (calibration and inspection):

- We should check whether we are authorized and qualified to perform the work.
- Each order should be analyzed in order to find out:
  - if all requirements regarding the work are clear,
  - if necessary standards, guidelines and work instructions are available,
  - if the client agrees with using non standard procedures in the case of absence of standard procedures.
- Necessary work should be specified in detail before beginning of work.
- We should check the availability of sufficient, suitable equipment.
- The work should be assigned to the best qualified person(s). If more persons should be involved, we should appoint a team leader. The decision about subcontracting work is taken in accordance with the Ch. 14.
- Every calibration is filled using the program Kalibracija. Instructions for filling data is in folder "Računalniška programska oprema – E 03".
- Every inspection is filled using the program Kalibracija. Instructions for filling data is in folder "Računalniška programska oprema – E 03".
- After the calibration first page of the calibration certificate is created by option "Kalibracija meril" and saved as pdf (filename and location are defined in Ch. 5).
- Following pages of the certificate are created from calibration results (as defined in corresponding SOP) and afterwards transformed to pdf, merged to the file with firs page and saved. Therefore certificate in electronic form is completed.
- When performing verification, after the finished inspection first page of the verification certificate is created by option "Overjanje" and saved as pdf (filename and location are defined in Ch. 5).
- All records from calibration, inspection or verification, are treated as defined in Ch. 6.2.
- Certificate is printed from file *.pdf and handed over for signature.

12.3 Policy regarding design and development activities

New methods or procedures are developed when no standard procedures res. methods are available and when a client is not able to provide us with his own or already used methods and procedures.

A new measuring procedure (method) must assure a correct result of a calibration/inspection.

We should get an agreement from the client before using a new non-standard procedure or method. If the client has any objections, the new procedure should not be used.

New methods and procedures are designed and developer by the staff performing calibrations/inspections and by the staff developing new measuring methods and devices. A new procedure or method should be approved by the laboratory manager or by the quality manager before use.

12.4 Calibration procedures

The list of the available calibration procedures is in the folder Spiski (see Ch. 5.1).

12.5 Inspection and verifications

12.5.1 Legal acts

Laboratory is performing all activities in the field of legal metrology in conformance with the Metrology law and in accordance with the »Provision of the notification for performing compliance testing procedures, regular and extraordinary verification of measures « No. 306-13/2004 (Ur.l. RS 87/04).

All contracts, agreements, authorizations etc. in connection with legal metrology are kept in the folder "Zakonsko meroslovje: predpisi, veljavni certifikati, pooblastila".

12.5.2 Cooperation with MIRS

Additionally to the requests from the contract, mentioned above, to MIRS are to be send also:

- a copy of each issued Certificate of conformance,
- every year before October: a request for verification labels for the next year.

12.5.3 SOP's for inspection and validation

The inspection and validation are performed in accordance to the procedures based on the metrology guidelines for certain types of measures, which are listed in the accreditation scope for ISO 17020 in Ch. 8. The procedures describe check and metrology test of measures as well as the criteria for evaluating conformance with the metrological guidelines. They are identified in the same way as calibration procedures (SOP xx) and stored, as stated in Ch. 5.1. The list of these procedures is in the folder Spiski (see Ch. 5.1). Metrology guidelines are stored in the folder "Zakonsko meroslovje: predpisi, veljavni certifikati, pooblastila".

Rules for personnel, traceability of measurement equipment, premises and other technical aspects are the same as for calibrations.

12.5.4 Handling with verification labels

- For verification three different types of labels are used: for the first and regular verification and protective label. For the use in LTM all label have characteristic number 344. Labels are kept in the folder "Overjanje: nalepke, potrdila o skladnosti in zahteve za overitev" together with the receipt with stated types and amounts of the labels being delivered.
- In the case of running short of the labels, additional are requested from MIRS. This can have different characteristic number.
- When a label is damaged (by sticking on, falsely used and then ripped off,…), the label is kept beside unused labels and later returned to MIRS.

12.6 Validation of the software used for calibration and inspection

Entire software used for calibration/inspection must be validated using the following procedure:

- values calculated by the software are compared with the manually calculated values. Manual calculation is based on the values given by the measuring device (e.g. read from the display) for the smallest, middle and the greatest measuring value.
- the calibration procedure must be followed precisely when calculating manual values,
- proper validation method is created for every calibration procedure,
- procedure, calculations and the results of the validation for every calibration procedure are archived,
- the revision numbers of validated software must be kept in the records.

12.7 Quality control of performed work

Quality manager and his deputy are responsible for the quality control of the performed work.

The control is performed in the following way:

- results in calibration certificates are checked,
- performance of work is checked during internal audits,
- client's responds are checked (complaints and remarks),
- best measurement capabilities of calibration procedures are regularly checked by:
  - intercomparisons on national and international level,
  - research in the field of equipment, procedures and environmental influences,
- accredited calibration procedures are checked by expert assessors of accreditation bodies (evaluation of measuring uncertainty, suitability of the procedures, performance of calibrations, calibration certificates, environmental conditions).

12.7.1 Intercomparisons

Intercomparisons are the most important parameter of detecting quality of performed measurements and calibrations. Therefore the laboratory is participating at all intercomparisons organized by national accreditation body, European accreditation or EUROMET. The aim of the laboratory is also to take part in other bilateral or multilateral intercomparison schemes in the limits of its financial possibilities and to organize and conduct such intercomparisons in the frame of research projects.

12.8 Work instructions

12.8.1 List of available work instructions

A list of available work instructions is in the folder Spiski (see Ch. 5.1).

12.8.2 Documentation

Work instructions are stored in the folder “Work instructions”, which is located in the calibration room (room D1 004 - Microclimatic chamber).

12.9 Security

12.9.1 Protection against unauthorized entering the measuring rooms

The procedure is specified in the Ch. 9.

12.9.2 Instructions on how to act in the case of emergency

In the case of natural accidents and fire the following instructions should be taken into consideration:

- A fire extinguisher HL-3 for extinguishing all kinds of fire (types B, C and E) should be used in the case of fire breaking out (e.g. caused by electricity or inflammable fluids). One extinguisher is located in each laboratory room. The extinguishers should be checked periodically - each year (the maintenance service of the Faculty is responsible for periodic checks).
- The person detecting fire or other accident should immediately inform the Faculty management and the maintenance service (phone numbers are in the internal phonebook). After that he (she) should try to help in the accident.
- If fire is to strong and/or if people are hurt, we should immediately call a fire brigade (phone No. 112) and/or rescue service (phone No. 112).

12.9.3 Instructions for the use of personal safety equipment

12.9.3.1 Protecting clothes

In air-conditioned rooms we should wear clothes, suitable for laboratory and not for the outside conditions.

The following protecting means enable safety use of the equipment:

- protecting coats (white color),
- protecting cotton gloves (white color),
- protecting plastic gloves.

12.9.3.2 Additional safety measures

The following safety guidelines should be concerned when working with the equipment:

- Proper lifts and transportation means should be used for transportation in order to enable safe and effective work.

➢ Illumination of measuring rooms should fulfill the requirements in the chapter 9 - Facilities.

➢ After the work all tools, instruments and auxiliaries used should be cleaned (oiled, if necessary) and put into their places.

➢ A device LAMBRECHT, type TH-252 with monthly print -out for continuing registration of important physical values (temperature, air pressure, humidity) is placed in the measuring room.

12.10 Objects of calibration

12.10.1 Procedures for receipt, storage and issue of calibration objects

Objects of calibration/inspection should be checked at the time of receipt:

- identification numbers on items must be the same as those on the order,
- number of items must be the same as the specified number on the order,
- all detected damages must be registered using the form "Obr 04-Zapis o neustreznosti merila.doc" in the folder Obrazci (see Ch. 5.1).
- the documentation must be complete.

Reception of the objects is recorded using a software program Kalibracija or Kontrola, using an option "Sprejem meril" (reception of the measure). Instructions for using the software are in the folder "Računalniška programska oprema – E 03".

Thereby generated record "Prevzem merilnega orodja" is saved in electronic form, as defined in Ch. 5.1.

12.10.2 Identification system for calibration/inspection objects

Before a calibration/inspection object is stored, it should be equipped with a yellow label containing the following information:

- client,
- order number of calibration/inspection,
- number of calibration/inspection,
- date of receipt,
- signature of the person receiving the calibration/inspection object.

The label is attached to the object of calibration or to the box containing the object of calibration.

Small items are identified by writing the identification number by means of waterproof pencil.

12.10.3 Handling of calibration/inspection objects

The following instructions regarding handling of items should be followed:

- Objects of calibration should be handled in such a way, that their characteristics are not changed during the calibration. The changes of characteristics can be caused by mechanical damages, overloading, corrosion, contamination etc.
- If objects are damaged, lost etc. during the calibration, the client should be informed immediately and a protocol about damage should be written.

The following instructions regarding disposal of objects of calibration should be followed:

- Objects should be properly packed and protected in the case of sending by mail.
- Proper transportation means should be chosen.
- All mails and personal receipts of calibrated objects should be registered.

12.10.4 Procedures for storing objects of calibration/inspection

- After the receipt and identification objects of calibration should be cleaned and put on a special place designated for objects that are not yet calibrated (in the room D1 005).
- If the calibration/inspection is not performed on the day it was received, objects should be properly protected against the environment influences. If the objects have been in an original package, we do not unpack them. If the objects have not been properly packed, we should oil them with special oil and put into cardboard boxes.
- We should handle the objects with special care during packing and classifying in order to avoid mechanical damages. Objects should be packed separately.
- A calibration/control procedure can be started after the temperature of the object has reached the reference value (20 ºC). No chemical methods (fluid nitrogen bath, etc.) are allowed for cooling objects of calibration and no intensive heating is allowed for warming up objects of calibration. Intensive cooling and heating can cause permanent deformations.
- Work instructions should be followed precisely during calibration.
- We should take care that the work conditions are within the prescribed limits.
- After calibration/inspection, objects should be oiled again (if appropriate) and packed in order to avoid mechanical damages.
- Calibrated/inspected items are put on the designated place (in the room D 005).
- Objects of calibration/inspection can be handled only by authorized staff members (laboratory manager, quality manager, staff performing calibrations). Other persons are not allowed to touch the objects.

12.10.5 Procedures for delivering objects of calibration/inspection

At handing over/delivery following rules apply:

- when delivering by mail objects have to be properly packed in order to avoid mechanical damages,
- when delivering by mail both the letter (form) "Obr 13-Spremni dopis za pošiljanje meril.doc", stored in the folder Obrazci (see Ch. 5.1), and the list of the objects (Prevzem merilnega orodja) are to be included. If not all objects from the list are send, all redundant are to be strike through.
- when objects are handed over to the client, he/she confirms a completeness of the list of the objects with a signature on the list. The signed list is kept for the time of complaint, as stated on the list.
- all mail delivery must be registered.

12.11 Software for calibration /inspection

12.11.1 Procedure for maintaining and up-dating software for calibrations /inspection

- software for calibrations /inspection can be:
  - bought with a measuring device,

- made in the laboratory;

- the list of software is kept in the folder "Computer software – E 03";
- instruction for use of software are kept in the folder "Computer software – E 03";
- all software used for calibrations/inspection shall be validated before first use in accordance with the policy in Ch. 12.6. Records of validations are kept in the folder "Validacija programske opreme za kalibracije (kontrole)";
- original of a valid software version (floppy disc, CD or other medium) is stored in the microclimatic chamber in D1 004, except for the CMM, which is kept near the device;
- the user uses a copy of original software;
- quality manager is responsible for managing lists of software;
- software is up-dated (a new version of commercial software is purchased or self-developed software is changed) in a case, when a user detects that the old version is not suitable any more (because equipment is renewed or calibration demands change);
- the head of the laboratory decides to change or up-date of software after an initiation of user or after a distributor has informed us about issuing a new version.

12.11.2 Procedure for filing changed (old) versions of calibration software

- an obsolete version of software, which was replaced with a new one, is filed in the archive of documentation (case F in the room D1 004);
- software carrier (floppy disc, CD, ...) shall be marked with a yellow label "Invalid version";
- the obsolete version shall be stored for five years after the last use;
- quality manager is responsible for filing obsolete versions.

13 CALIBRATION/INSPECTION ON SITE

13.1 Quality policy

Quality policy for all calibrations/inspection on site is equal to the policy for in the laboratory. Appropriate procedures must be established for all calibrations/inspection on site. These procedures should include all specific instructions for calibration/inspection on site. Measuring uncertainty should be evaluated concerning conditions of calibration /inspection on site. Therefore, special attention is paid to measurement and records of calibration/inspection conditions. Responsible and authorized personnel for calibration/inspection on site are the same as for calibration in the laboratory. The personnel must be precisely informed about the regulations stated in this document. No hired personnel or subcontractors are involved in calibration on site. Quality manager includes the review of calibration on site in regular audits of the quality system. Client who orders calibration on site has the same rights and possibilities (e.g. possibility of complaint, presence at calibration) as the one who orders calibration in our laboratory.

The laboratory manager is personally responsible for the insurance of the personnel and the equipment during the period of transport and calibration on site.

Quality policy was defined by the laboratory manager and approved by the dean of the Faculty of Mechanical Engineering. Signed original is in Z 09.

13.2 Organization

13.2.1 Organization scheme

There is no special scheme for calibration/inspection on site. Calibrations are performed by the personnel from the department "Measurement, calibrations", inspections from the department "Inspection and verification" (see organizational scheme of the laboratory in Ch. 3.1).

13.2.2 Personnel

The personnel involved in calibration/inspection on site have the same authority, duties and responsibility as for calibration/inspection in the laboratory. Requirements for the personnel performing calibration on site are the same as for personnel performing calibrations in the laboratory.

13.2.3 Equipment

For calibrations/inspection on site we use the same equipment (also standards) as for calibrations/inspection in the laboratory. The equipment should always be transported in proper packages for the protection against damages. No special requirements for transportation means or conditions are necessary. Equipment used for calibration/inspection on site is marked in the equipment list in E 01.

13.2.4 Procedures

SOP's including specific instructions for calibration/inspection on site are used. General procedures and instructions for planning, performing and activities after calibration/inspection on site are defined in chapters 13.3, 13.4 and 13.5.

At the loading of calibration/inspection equipment the form "Obr 14-Dovolilnica za iznos opreme iz laboratorija.doc" is to be fulfilled and signed by the head of the laboratory. This document is written in two copies. One of them is kept by the head of the laboratory; another copy must remain at personnel until returning the equipment to the laboratory. This document also defines the responsibility for the equipment for the time of it staying out of the laboratory.

13.3 Planning of calibration/inspection

- When an official order is received, the client is asked for the following data:
  - data about the equipment to be calibrated and the drawings of the equipment if necessary for making special fixtures etc.,
  - the most appropriate term of calibration/inspection according to the stability of the conditions in the room, where calibration will be performed,
  - possibilities for accessing place of calibration/inspection (access by car and transport of equipment),
  - if device to be calibrated/inspected requires specially educated operator (e.g. coordinate measuring machines with different software), the client should make an operator available for the time of calibration/inspection.
- If necessary, it is agreed with the client about the machining of special fixtures (at his or at our place) and about additional expenses for these fixtures.
- Term of calibration/inspection is planned and agreed with the client.
- Person, who received an order (authorized and responsible persons for receiving orders are the same as for calibrations/inspections in the laboratory), informs the head of the laboratory about the planned calibration/inspection.
- The head of the laboratory (or the deputy in his absence) defines the person (s) who will perform the calibration/inspection and approves all necessary costs (travel costs, insurance, additional costs for performing work, hotel, etc.).
- Before the calibration/inspection the client is required to send written and approved order stating the equipment to be calibrated.
- Person who will perform the calibration/inspection create the list of necessary equipment that will be taken out of the laboratory. The copy of the list stating the period, when the equipment will be out of the laboratory, is filed in Z 01 together with records about calibration/inspection.
- Before leaving the laboratory the equipment should be checked and protected against possible damages by the person who will perform the calibration. The head of the laboratory arranges proper insurance for the equipment.

13.4 Performance of calibration/inspection

- Performer(s) of calibration/inspection must bring an official document (travel order) and his identification document with him.
- Performer(s) should know the contact person of the client who will arrange documents for bringing the equipment in and out of client's premises.

- Before performing calibration/inspection the performer should check the equipment to be calibrated and auxiliary equipment together with the responsible person of the client in order to detect existing defects, damages or malfunction.
- The performer fills the form "Obr 07-Zapisnik o stanju merilne opreme pri kalibr. na terenu.doc" about the condition of the equipment.
- The equipment that is not in proper condition is not calibrated.
- The performer of calibration/inspection checks the room and writes the conditions into the calibration/inspection record. During the calibration/inspection temperature and other important conditions should be measured and recorded (at least before and after the calibration/inspection). Therefore, calibrated sensors should be brought on site (if it is calibrated with laser interferometer, included sensors are used, in other cases temperature is measured using system TEMP 10).
- Calibration/inspection is performed in accordance with the calibration/inspection procedure, which should be available to the performer on site.
- Before the calibration/inspection the equipment (instruments, standards) used for calibration/inspection should be thermally stabilized. The time and the manner of stabilization depend on the equipment used and are described in calibration/inspection procedures that describe calibration/inspection on site.
- If special operator (client's personnel) should operate the calibrated device, detailed information about measurement strategy (measuring points - positions, measurement force, number of repeated measurements in measurement positions, contents of measurement protocol, ...) should be provided to him by the performer of calibration/inspection.
- During the calibration/inspection the conditions should be observed on their stability and deviations. The performer should tell the personnel of the client not to open doors or windows unless it is really necessary and the number of persons in the room should be as low as possible. The attention should be paid to the transportation means (if calibration/inspection is performed in production room) which should be avoided in the surrounding of calibrated device.
- Calibration/inspection record should be written during calibration/inspection using appropriate forms.
- After the calibration/inspection equipment should be packed and the number of pieces should be checked according to the list of equipment.
- The condition of calibrated equipment is checked again together with the authorized person of the client and the record is signed by both persons.
- Calibration certificate is not written on site. It is written after the calibration in the laboratory following common procedure for writing calibration certificates.

13.5 Activities after calibration

- After a calibration/inspection the equipment should immediately be returned to the laboratory even if the performer returns very late (in no case it should be carried home or let in a car).
- The performer of calibration/inspection is personally responsible for the equipment that was not returned immediately.

- When the equipment is returned to the laboratory, the performer should check completeness according to the list. After that the equipment should be properly protected (oiled, packed etc.) and placed back to its usual place.
- Calibration after returning is not foreseen (because of the nature of the equipment used on site it is not necessary). However, it can be suggested by the performer of the calibration if he thinks it is necessary because of special reasons (it was drooped or hit, ...).
- The performer of the calibration/inspection completes the order (all necessary documents are written and objects of calibration/inspection are recorded in accordance with the ordinary rule for calibration/inspection in the laboratory) and writes a calibration certificate/inspection report, which is than sent to the client.

13.6 Audit and review

13.6.1 Audit of performance of calibration/inspection on site

Quality of calibrations/inspections on site is audited once a year by the head of the laboratory. The audit is not included in the annual plan, but the most convenient calibration/inspection is chosen regarding to received orders. The report written using the form "Obr 09-Poročilo o interni presoji.doc" in the folder Obrazci (see Ch. 5.1).

13.6.2 Management review

Calibrations/inspections on site are treated by management review in the same way as the calibrations/inspections performed in the laboratory. We should evaluate conformity of the performance with written procedures and policy, and adequacy of the procedures in respect with experiences and remarks of the performers of calibrations/inspections.

14 SUBCONTRACTING

14.1 Policy regarding subcontracting

Calibrations are subcontracted only in a case of equipment defect that can not be repaired in a proper time period (calibration schedule can not be followed).

Subcontractors must be accredited.

Calibrations can be subcontracted only in agreement with clients (written and signed agreement).

Only the original report (certificate) issued by the subcontractor is allowed to be given to the client. The results of the subcontractor are not allowed to be used for issuing our own certificate(s).

14.2 Policy regarding subcontracting inspection

No inspection activities shall be subcontracted.

14.3 Procedure for subcontracting calibrations

- The laboratory manager decides whether subcontracting calibration is necessary and chooses a subcontractor. Only accredited subcontractors can be chosen.
- The laboratory manager calls the subcontractor and makes sure that the subcontractor has sufficient free capacities available and that he is capable of performing the calibrations in the defined time.
- The quality manager calls the client in order to get the agreement with subcontracted calibrations.
- The laboratory manager prepares a contract in which he exactly defines the price of the calibration, the time for completing the calibration, required measuring uncertainty and the contents of the calibration report. The contract is checked by the legal service of the Faculty of mechanical engineering.
- The objects of calibration should be properly marked and sent to the subcontractor together with necessary documentation.
- After the calibration has been completed, we go to the subcontractor to get the objects, the calibration reports, and the documentation (we never use mail service to get these items).
- The client gets the original report/certificate issued by the subcontractor.
- The calibration reports written by subcontractors should be filed (Z 06). The subcontractor is required to give us entire documentation of the calibration (including calculation, notes etc.).
- The following procedure is the same as by usual calibrations.

14.4 List of accredited subcontractors

The list of accredited subcontractors is in Z 06.

14.5 List of subcontracted calibrations

The register of subcontracted calibrations is in Z 06.

15 COOPERATION WITH CLIENTS

15.1 Visits in the laboratory and communication with clients

- The client should get the opportunity to:
  - enter the laboratory and control the calibrations,
  - get the data about the conditions, methods and results (including calculations) of the calibrations/inspections performed for them,
  - communicate with the staff performing calibrations/inspections and with the responsible staff (explanations etc.).
- Electronic correspondence with clients is saved in its original format (.eml) immediately after receiving or sending a message (see Ch. 5.1).
- Clients can get copies only upon written request. Copies are sent by registered mail to get client's receipt.
- The laboratory manager, the quality manager, and the staff performing calibrations/inspections are authorized and responsible for the communications with clients.
- The staff should introduce itself before each communication with a client.
- The client should get the name of the person to whom he (she) can mail the post or send a fax (orders, documentation, requirements, complaints, etc.).
- Clients should be informed about the changes of the address, phone number, fax number, etc.
- When communicating with clients we should consider their requirements, wishes, and suggestions. However, some limitations regarding our quality policy, work plans etc. should be respected.

15.2 Evaluation of client's satisfaction

Questionnaires about satisfaction (Obr 24) are sent to selected clients at latest one month after performing service (calibration, inspection). Clients are selected on the basis of certificate numbers. If certain client has already been selected in the last annual period, the next client on the list is selected.

The frequency of sending questionnaires is defined by the quality manager. He also appoints staff for sending the questionnaires.

The questionnaires are sent together with prepayed envelope containing the address of the Laboratory.

The quality manager analyses collected answers and presents them at the management review.

16 COMPLAINTS AND APPEALS

16.1 Procedure for dealing with complaints and appeals

- A person receiving a complaint or appeal should note the following data:
  - the name and the address of the client and the name of the contact person,
  - date,
  - service to which the complaint/appeal is referring,
  - date of performance of the service,
  - contents of the complaint/appeal.
- Appeal (against the result of the inspection) must be in written. Client who wants to give notice on appeal by the phone is instructed to write it and send it to the LTM. Complaints about other mistakes of the inspection body (such as wrong measuring tool data, overcharge, delay,…) are not appeals.
- The noted data are given to the quality manager.
- The quality manager writes a report about the complaint/announcement of an appeal and informs the laboratory manager.
- The laboratory manager should be informed about the complaint/appeal on the day it was received. In his absence all necessary actions are taken by the quality manager.
- The laboratory manager sends a written confirmation of receiving the complaint/appeal containing a short description of the complaint/appeal to the customer.
- The laboratory manager analyses the complaint/appeal in cooperation with the quality manager and the person performing the service, and defines a procedure for handling it. The analysis and the procedure for handling the complaint/appeal should be added to the report about the complaint/appeal.
- The quality manager calls the client and explains him the decision of the laboratory management regarding the complaint/appeal.
- When the appeal is rejected by the management of the inspection body, client is referred to the official body, which appointed inspection body.
- Management of the inspection body can, after closely examine the appeal, take a decision to pass the appeal to the official body, which appointed inspection body.
- If it is necessary to repeat or complete the service, it is done on our own expenses (including expenses of transport, mail, etc.) in the time period agreed with the client.
- The expenses regarding a complaint/appeal should be precisely specified and included into the report about the complaint/appeal.
- The report about a complaint/appeal is sent to:
  - the client,
  - the laboratory manager,
  - the quality manager,

- the documentation file of the laboratory(Z 07).

- If a quality system deficiency is detected during the analysis of a complaint/appeal, a corrective action should be taken immediately.

16.2 Instructions for keeping the register of complaints/appeals

The register of complaints/appeals (Z 07) is maintained by the quality manager. The following information should be included in the register for each complaint/appeal:

- name and address of the client,
- date of the complaint/appeal,
- service the complaint/appeal is referred to,
- date of the service completion,
- all correspondence with client,
- report about the complaint/appeal,
- analysis of the complaint/appeal,
- decision whether the service should be redone,
- detected quality system deficiency,
- corrective actions.

17 COOPERATION WITH ACCREDITATION BODIES

Procedure for cooperation with accreditation bodies

- responsible person: laboratory manager,
- contact person: quality manager and laboratory manager,
- documentation sent to the accreditation body:
  - quality manual,
  - calibration procedures (SOP).
- documentation available to the accreditation body during assessment or surveillance visit:
  - entire laboratory documentation, records, etc. without exceptions,
- access to the spaces and equipment:
  - unlimited access, accompanied by at least one member of the permanent laboratory staff,
- availability of information about the laboratory to the accreditation body:
  - laboratory management will sent to the accreditation body all the required information necessary for the maintenance of accreditation (questionnaires, telephone information, ...),
- arrangements of assessments and surveillance visits:
  - dates of visits will be agreed concerning the possibilities of the laboratory and the accreditation body.

18 SCOPE OF ACCREDITATION ACCORDING TO ISO 17025

Scope of accreditation is on the SA web page:

http://www.gov.si/sa/teksti-1/doc/cal/LK003.pdf

19 SCOPE OF ACCREDITATION ACCORDING TO ISO 17020

Scope of accreditation is on the SA web page:

http://www.gov.si/sa/teksti-1/doc/kontrol/K027.pdf