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QUALITY ASSURANCE CRITICAL POINTS OF VERIFICATION LABORATORIES

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Abstract - In this work are analysed performance of quality assurance in the Estonian measuring instruments verification laboratories. During last 10 years had Estonia changed completely and this involves also activity on the metrology area. Basic change was case, that on the previous period the verification was mandatory for almost all measuring instruments, now shall it be replaced greatly by voluntary calibration. But verification stays highly required service. Verification area involves mainly measuring instruments which are used in affairs. New is also fact that now-a-days verification laboratories are more commonly private companies and public authorities carry out only market surveillance. To get stability of work laboratory shall implement quality system.

Above was ground for this work and analysed are the quality and competence assurance in the verification laboratories. Based on the accreditation data are analysed the critical points of quality assurance. In a summary is given conclusion of actions which can be used for restructuration of metrological infrastructure especially in measuring instruments verification area.

Keywords: verification, quality assurance, metrological infrastructure.

1. INTRODUCTION

To have correct measurement result the used measuring equipment must be controlled metrologically. In developed countries measuring instruments metrological control is carried out mainly in the form of calibration or verification. More preferable is to perform such control voluntary but in some cases mandatory form is required. Mandatory form is as rule verification. In practice verification is highly required procedure. Scope of verifications in Estonia involve such measuring instruments as weighing instruments, fuel dispensers, water meters, gas meters, heat meters, electrical energy meters, manometers, thermometers and length measuring instruments. Up to year 2003 from all controlled measuring instruments (65 ÷ 75) % were verified in Estonia. Advances of the verification are its results better clearness for customary client and its less cost.

In Estonia, during last 10 ÷ 15 years main change in metrology area was replacement of the state verification laboratories, with quite good verification level, with private metrological laboratories. This prescribed need to assure the verifications quality and need to carry out researches of this problem.

In practice, basic principle for competence assurance was the accreditation of verification laboratory on the basis of the standard EN ISO/IEC 17025 requirements. To have an accreditation all competence requirements given in EN ISO/IEC 17025 and some more specific requirements shall be guaranteed. There was possibility to use also standard EN 45004 requirements but EN ISO/IEC 17025 requirements were more strict in the technical area. Also EN ISO 9001:2000 modified requirements would be suitable to take account.

To assure the verification result exist some critical points. For quality assurance shall be taken account specific needs of measuring instruments verification laboratories. Such specific points were as follows: traceability of the measurement unit; relation of the uncertainties of standards and measurement equipment under control; verification procedures; proficiency testing; verification personnel competence and training; recording and confidentiality of verification results; conformity estimation and declaration, surveillance of activity and authorities influence.

Verification laboratories activity is deeply combined with legal acts regulations and after accreditation can verification laboratory seek from authorities the license for verification activity.

This research tackled with above problems. Those problems were solved in practice by 19 verification laboratories accreditation. This work gives some concrete recommendation which were used in Estonian verification laboratories quality assurance.

2. NEED FOR VERIFICATION OF MEASURING INSTRUMENTS

Verification is widely used in various countries, especially in Eastern Europe, but also in several Western-European countries. Verification stays highly required procedure in now-a-days Estonia. Verification is suitable in areas where users want only to know that measuring instrument is correct in the prescribed measurement range and the uncertainty of measurement and the correction are

not needed to document. Some researches [1] show that verification is fitting when the ratio between measuring istrument permissible error and measurement combined uncertainty is lower than 3 or 4.

Scope of verification involves such measuring instruments as weighing instruments, fuel dispensers, water meters, gas meters, heat meters, electrical energy meters, manometers, thermometers, measurement tanks and volume measures.

Need for the verification comparing to the calibration on the end of year 2002 in Estonia shows Fig. 1, where are given quantity of authorized verification and calibration laboratories (same laboratory can carry out both activities). From Fig. 1 can see that most needed is volume measuring instruments like water meters, capacity serving measures, measurement tanks verification laboratories and only few calibration laboratory do not carry out verifications.

In Table 1 is given accredited Estonian verification laboratories main metrological data. Verification laboratories can satisfy all need of infrastructure in Estonia.

TABLE 1. Estonian verification laboratories main data up to 02.2003

Type of measuring instruments	Measure-ment range	Best accuracy
Mass measuring instrument: non-automatic weighing instruments, dynamic railway weighing instruments, weights	1 mg ÷ 200 t	I class
Length measuring instrument: rulers, measuring tapes and sticks	(0 ÷ 100) m	I class
Temperature and heat energy measuring instrument: thermometers, heat energy meters, thermocouples	(0 ÷ 650) ^{o}C	100 ^{o}C, U= =0,05 ^{o}C
Pressure measuring instrument: manometers, vacuum-meters	(-0,1÷250) MPa	0,02 %
Volume measuring instruments: fuel dispensers, water meters, measurement tanks, capacity servicing measures	min 1 ml	0,2 %
Electrical measuring instruments: electrical energy meters		0,1 class

3. ACCREDITATION OF VERIFICATION LABORATORIES

Measuring instruments verification laboratories were licensed by governmental authorities up to 1993 in Estonia. License requirements based mainly on Soviet Union Gosstandard regulations. Quantity of licensed laboratories was on the end ca 43 ÷ 45.

Verification laboratories competence assessment taking account new principles was began in 1993. At this time competence was estimated, named as recognition, on the bases of standard EN 45001 requirements, but those were on some extent simplified. Totally was recognised in such way 28 laboratories and activity was ended in 1999.

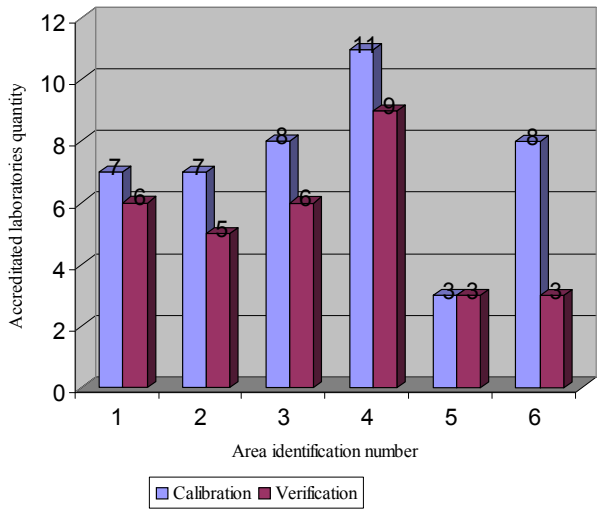

Fig. 1. Quantity of verification and calibration laboratories in areas.
Areas identification numbers are as follows: 1 – mass, 2 – pressure, 3 – electrical, 4 – volume, 5 – length; 6 – others.

In 2001 was began verification laboratories accreditation based on standard EN ISO/IEC 17025 [2] requirements.

In Fig. 2 is given growth of competence estimation of verification laboratories in Estonia during 10 last years. Total quantity of accredited verification laboratories was 19 up to 02.2003.

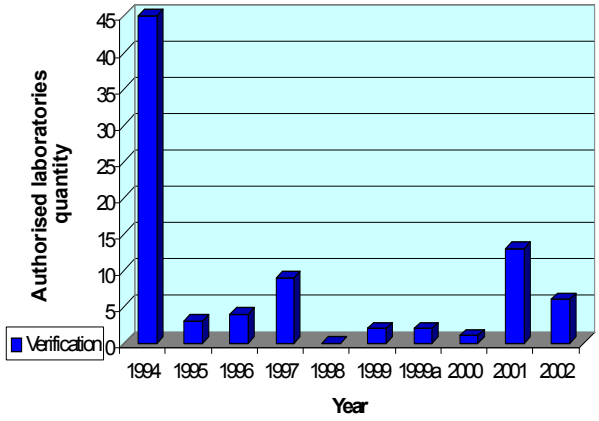

Fig. 2. Competence estimation of verification laboratories of measuring instruments.

Note for Fig.2: for 1994 is given total quantity of authorised verification laboratories, for 1999 is given quantity of recognised verification laboratories, for 1999a are given quantity of accredited laboratories.

4. QUALITY SYSTEMS REQUIREMENTS

In real conditions the quality system in the verification laboratories can be implemented on:

a) EN ISO/IEC 17025 requirements;
b) EN 45004 requirements;
c) ISO 9001 requirements;
d) prescribed by legal acts requirements.

The quality system based on EN ISO/IEC 17025 requirements can excellently define regulations for almost all activities having connection with the verification like equipment, personnel, laboratory structure, archiving, methods, subcontracting, traceability and proficiency testing, but conformity assessment is not deeply involved.

The quality system based on EN 45004 requirements can define regulations for the verification activities like equipment, personnel, laboratory structure, archiving, methods, subcontracting, traceability and conformity assessment. Worst is case for proficiency testing and for metrological specific procedures.

The quality system based on EN ISO 9001 requirements can define regulations for the activities connected with verification like laboratory structure, document control, archiving, procedures and services. Worst is case for metrological specific procedures, equipment calibration, verification methods, conformity assessment and proficiency testing.

Through legal acts conformity assessment policies and verification permissible errors can be appointed. Requirements for the specific person, who shall be responsible for the declaration of conformity and knew deeply verification legal requirements and verification permissible errors can be described. Difficult is to express the methods and the quality system.

Each above quality system has positive factors but they do not solve properly verification all needs. Best result can be achieved if one system is taken as bases and added are some specific required points. For verification laboratories accreditation activity is suitable to issue special regulation document where are described summarily all requirements, in Estonia was issued [3].

5. SPECIFIC POINTS OF QUALITY ASSURANCE

5.1 Findings

To become aware of the critical points of quality assurance were analysed findings of the accreditation process. Results of 19 Estonian laboratories accreditation are given in Fig. 3. Included are laboratories which deal also with calibration and shown non-compliances have influence for the both, calibration and verification, activity. In Fig. 3 are given standard EN ISO/IEC 17025 articles and quantity of non-compliances in this area. Accreditation assessments were carried out during 1999 up to 2002.

5.2 Document control system

Large quantity of non-compliances was found in the document control system (Fig. 3 art.4.3). For verification laboratories have importance various norms, regulations and legal acts and they must be up to date. Assessment shows that laboratories not included such documents to control procedure. Was not issued a master list identifying the current status and distribution verification documents.

5.3 Review of requests and contracts

Also often exist non-compliances in review of contracts (art.4.4). There was not evidence that contract was acceptable for both to the laboratory and the client. Were not recorded reviews and pertinent discussions with a client. Often was misunderstood by client what is required – calibration or verification and laboratory did not had concrete policy how to solve such problem.

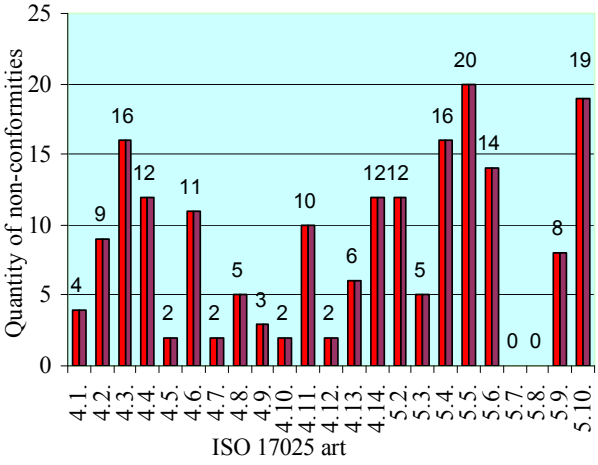

Fig. 3. Quantity of non-compliances in relation with EN ISO/IEC 17025 articles found by accreditation

5.4 Purchasing services and supplies

Verification laboratories use various consumable materials relevant for verifications (cleaning materials, measurement liquids and so on). Purchasing documents were not reviewed and approved for technical content prior to release. Exist cases where was obtained wrong auxiliary measuring equipment (art.4.6).

5.5 Preventive actions and management review

Verification laboratories used some kind of preventive actions but this activity was not documented and not planned. Verification laboratory's executive management did not conduct periodically a review of the quality system to ensure the verification suitability and effectiveness (art.4.11 and art 4.14).

5.6 Personnel

Verification personnel shall be qualified and competent and verification laboratory shall give evidence that its personnel have sufficient experience, skills and qualification, knew deeply verification legal requirements and verification permissible errors. Laboratory did not had policy for the satisfactory confirmation of the qualification (art.5.2).

As result of corrective actions was decided that satisfactory confirmation of the professional metrological skills is verifies ability to carry out in given measurement area measuring instruments verifications and also

calibrations, make conformity assessment and record correctly results and they shall take part in verification personnel specific qualification courses which are carried out by competent metrological firms at least once in 5 years period. Satisfactory confirmation of the experience is at least 10 verifications per year in given measurement area. For the verification activity shall be appointed general responsible person and specific person(s) who is/are responsible for the declaration of conformity.

5.7 Verification methods

Verification procedures (art.5.4) are issued by various international institutions for various measuring instruments, but they are mainly very general. In Estonia were used previously GOST methods. Laboratories did not had correctly documented and confirmed methods.

As result of corrective actions was decided that was need to work out the harmonised Estonian verification methods. For the period when such methods do not exist, method shall be issued by laboratories and it shall be confirmed by authorities. The verification methods shall based, if exists, on EU directives or/and international organisations documents, as OIML, IEC or/and European standards (EN). Procedures shall be separated for the initial and subsequent verification and shall include specific parts where shall be given specific requirements:

- which concretised control of type approval or/and legal acts requirements fulfilment;
- for the verification acceptance and errors criteria;
- for the relation between accuracy parameters of used standards and accuracy class of the controlled measuring instruments.

5.8 Equipment and calibration

By the applicants verification laboratories was not maintained record for some item of equipment significant to the verification and for some cases was not assured traceability (art.5.5).

As result of corrective actions was decided next. Traceability must go up to the international reference standards except if such achievement has to much high price. Estonian verification laboratories reference standards the traceability chain is not controlled in noise and in some rare physical-chemical standards mainly on reasons that there is not enough economical resources. In Estonian verification laboratories relation of the uncertainties of standards and measurement equipment under control shall be at least 3.

5.9 Proficiency testing

To carry out specific 'interverifications' were very problematic. Set up was requirement that verification laboratory must participate periodically on intercalibrations as calibration laboratory in the area where they carry out verifications, if possible (art.5.9).

5.10 Reporting of the verification results and conformity estimation and declaration

Verification reports to not include all important data about verifications, especially identification of the document were normative value was given (art.5.10). By the verification laboratories were not described policy of conformity declaration and did not given treatment of values which lies on the prescribed permissible error limits. As result of corrective actions was decided next.

In Estonia, verification permissible errors were established by legal act. For finding and modelling verification permissible errors were used the calculation method which based on the uncertainty estimation. The calculated result was corrected using existing practice data and existing norms. Such limits shall be as small as possible but do not cause exaggerated financial pressure.

The verification result acceptance estimation principles are needed to establish by the legal act. Especially shall be known evaluation principles when result situates on errors limit values. Up to now do not exist general acceptance estimation principles for verification given by legal acts in Estonia. As general principles are suitable to use like are given in ISO 4259, but this shall be modified for the verification activity. Above standard is valid for petroleum product parameters conformity assessment. Petroleum product quality parameters limit values estimation, given in the general rule in ISO 4259 is as follows. In case of dispute when single results are obtained in two laboratories and their difference is less than or equal to repeatibility R, the two results shall be considered as acceptable and their average, rather than either one separately, shall be considered as the estimation value of the measured property.

6. CONCLUSION

During last 10 years was modernised metrological structure in Estonia. Results of measuring instruments verification system modernisation and competence assurance were as follows:

- verification laboratory can be private company and for its quality assurance can use standards EN ISO/IEC 17025 principles;
- competence of verification laboratories can successfully estimated using accreditation;
- for settle up mandatory requirements some legal acts shall be issued;
- by the accreditation shall be taken account specific requirements for verification, especially for verification methods and for conformity estimation.

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