Journal of Thermal Analysis, Vol. 56 (1999) 1405-1412

QUALITY ASSURANCE IN TESTING LABORATORIES

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Abstract

General criteria for the operation of testing laboratories according to standards series EN 45000 and quality assurance under ISO series 9000 are discussed, and other quality management systems too are presented. The important elements of quality assurance as concerns measurements, tests and investigations are pointed out.

Keywords: accreditation, quality assurance

Introduction

More than 10 years ago, it became fashionable to speak about quality assurance, and 'quality managers' were appointed in companies. The major incentive came from the production industry, but after a short time it was clear that quality assurance is necessary in other areas too, e.g. in service sections such as testing laboratories. The best-known quality system in Europe is the European standard ISO 900 series [1–5]. These standards represent a general model for quality assurance.

We have often heard from scientists and testing engineers such statements as 'We deliver good quality, we are working according to different standards, instructions, operation procedures, etc., and it is our job to control the measuring results, to look at each deviation and to report all conditions.' In general, this is the case, as many elements of quality assurance exist in testing laboratories. This provides a good basis, but it is not sufficient for a complete quality assurance system, which must comprise the total organization.

The quality system applies to and interacts with all the activities pertinent to the quality of a product. It involves all the phases in the life cycle of a product and the necessary processes. In our case, the product is the measurement and the measured data. Quality management has therefore changed from a product-oriented to a process-oriented way of thinking, and we have to look at the complete measuring procedure and all its aspects.

General considerations

For service and testing laboratories, it is very important to have accreditation for their measuring methods. The basis for this is the EN 45000 standards series [6–8]. Quality assurance is a necessity for this, and so we should consider the conditions of

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1418–2874/99/ $ 5.00

Akadémiai Kiadó, Budapest
Kluwer Academic Publishers, Dordrecht

accreditation too if we wish to discuss quality assurance for such laboratories. The members of the European community are interested in harmonizing and conforming conditions for the mutual acceptance of results obtained by different testing laboratories. Various federations for laboratories exist, such as EUROLAB and EUROCHEM, organizations to look after problems of chemical, mechanical, physical, etc. testing laboratories. WECC (Western European Calibration Cooperation) and WELAC (Western European Testing Laboratory Accreditation Cooperation) have united to become EAL (European Accreditation for Laboratories). EAL and EAC (European Accreditation of Centrification) have joined to form EA (European Accreditation). The aims of this organization are to

- achieve a uniform approach to accreditation throughout Europe,
- achieve universal acceptance of accredited certificates and reports,
- achieve traceability of measurements,
- support the harmonized implementation of accreditation standards.

Requirements for the competence of testing laboratories and accreditation have been described in much detail, [9, 10]. An important prerequisite for obtaining accreditation is the operation of a quality system, but it is not defined which system should be used. For testing laboratories, different quality assurance systems have been in operation for many years; GLP and GMP are well known.

GLP [11] (Good Laboratory Practice) is designed for laboratories which test chemicals that could be dangerous for human health and for the environment, in particular toxic materials.

GMP [12] (Good Manufactoring Practice) is primarily a guide line for validation and tests of the sterilization of medical equipment by ionizing radiation.

Both systems are very strict in their details and should be used only for the defined materials and laboratories, where this is necessary. The international trend, and that in the European Community too, is in the direction of ISO 9001. Accordingly, it is advisable to use this system.

Figure 1 depicts the quality circuit [5] according to the ISO 9000 series and the relation to a testing laboratory. The influence of all activities and their interaction is shown. All elements addressed in Fig. 1 have to be considered in context with quality assurance, and examples are given concerning the relation to a testing laboratory which carries out measurements.

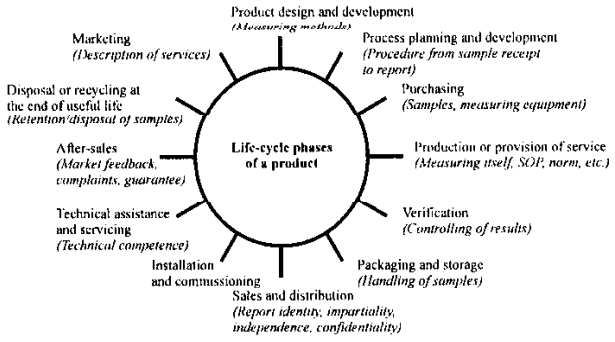

Fig. 1

The requirements of the quality system according to the 20 elements of Chapter 4 of ISO 9001 in relation to testing laboratories are the following:

4.1 Management responsibility

– The management must define and document its policy for quality, including its objectives and its commitment to quality.
– Responsibility, authority and the interrelation of personnel, which influence quality, must be defined.
– Resources, including trained personnel, must be provided.
– A quality manager must be appointed.
– The quality system must be reviewed at defined intervals.

4.2 Quality system

– A quality system must be established and maintained.
– A quality manual must be prepared.
– Quality system procedures must be documented.
– The preparation of quality plans is necessary.

4.3 Contract review

– Documented procedures must be established.
–Requirements must be defined and documented. It must be ensured that the requirements of verbal orders are agreed before acceptance.
– Before submission of a tender or acceptance of a contract, the capability of carrying it out must be controlled. Typical topics in this respect are: What kind of samples are to be investigated? Can be a reaction between samples and equipment? Is anything dangerous? In what range must measurements be made? What accuracy is needed? How many samples can be delivered? Is there a standard (norm), SOP (standard operation procedure) or any other guide line? What happens with the tested samples?
– Records of contract reviews must be maintained.

4.4 Design control – Description of measuring methods, development of new methods of measurements under customer-defined conditions

– Plans must be prepared for each design and development activity.
– Personnel assignment must be defined.
– Organizational and technical interfaces between different groups must be defined.
– Design input requirements must be identified.
– Design reviews must be carried out in appropriate stages.
– Design verification must be performed in appropriate stages.
– Design output must be documented and expressed in terms that can be verified and validated *vs.* design input requirements.

4.5 Document and data control

– Documented procedures must be established and maintained to control all documents.
– Documents and data must be reviewed and approved by authorized personnel.
– invalid or obsolete documents must be promptly removed from all points of use and suitably identified.

– Each measuring method must be based on a standard, device manual, instruction, guide line or SOP (standard operation procedure), this must be documented, and the responsible operator must receive this document.
– Calibration intervals, service instructions, etc. must be documented.

4.6 Purchasing: Equipment: devices and materials for the measurement and reference standards. Subcontractors

– Documented procedures must be established and maintained to ensure that purchased products conform to specified requirements.
– Purchasing documents must contain data clearly describing the product ordered.
– It must be controlled that the used materials are qualified for the given measurement.
– Reference material should, if possible, be purchased only with a certificate (many discussions are under way on this subject).
– Subcontractors must be evaluated.

4.7 Control of customer-supplied products: in rare cases, these are materials, chemicals or devices; usual samples are meant in the case of testing laboratories

– Documented procedures must be established and maintained for the control of verification, storage and handling of customer-supplied products.
– A circular (sample information sheet) must be drawn up to identify each material and specimen to be tested. The exact description and name, the number of samples, the receipt control, the desired measuring method with all conditions, the preparation, all necessary information, such as interactions with the environment, delivery time, etc. must be written on this document. The name and signature must indicate which operator is responsible for the relevant measurements.
There must be clear rules concerning the retention and disposal of samples. If possible, it is advisable to store parallel samples for later control measurements, but often the customer wishes to receive all samples back.

4.8 Product identification and traceability

– Documented procedures must be established and maintained for identification of the test report and the samples by suitable means, from receipt and during all stages of testing, and the test conditions. This is usually guaranteed through the sample circular.
– Through the documentation of all parameters relating to the measurements, the performance of sufficient test measurements, and regular recalibrations, the results obtained must be traceable to national or international reference materials.

4.9 Process control

– Documented procedures must define the manner of production and servicing.
– Criteria must be defined for workmanship, which must be in the clearest practical manner.
– Suitable equipment and working environnment must be described.
– Compliance with reference standards/codes, quality plans and documented procedures.

4.10 Inspection and testing ·

– Receiving inspection: incoming samples must be controlled.
– In-process inspection and testing, as required by the quality plan or documented procedures.

– Final inspection, control of the measurement result, with literature data, calculations, plausibility.
– Records must be established and maintained which provide evidence that the above inspections were carried out.

4.11 Control of inspection, measuring and test equipment

– A responsible operator must be named for each measurement or test equipment.
– Documented procedures must be established and maintained to control, calibrate and inspect measuring and test equipment.
– The measurements to be made and the accuracy required must be defined, and the appropriate measurement equipment capable of the necessary accuracy and precision must be selected.
– If the test or calibration interval is not stated in the manual of the device, this must be defined.
– Calibration records for inspection, measuring and test equipment must be maintained.
– Relevant incidents relating to the measurements, must be documented in the protocol book of the measurement or test equipment.

4.12 Inspection and test status

In each stage of the complete procedure, the state of the sample, measured or not measured, must be clear. In some cases, this is to seen, e.g. samples after melting tests or in mechanical tests such as bending tests. However, if the status is not visible, the sample or container must be marked clearly.

4.13 Control of non-conforming product

There are well-defined rules for the handling of a non-conforming product, but in addition the following points describe necessary actions:
– If the product (measurement outcome) does not agree with the expected result. all points of the procedure must be tested and, if possible, controlled by an other measuring method.
– If the suspect result originates from the measuring equipment, this instrument or parts of its must be taken out of service and clearly labelled and, after repair, it must be shown by test or calibration that its function is satisfactory.
– Measurements are to be repeated and the effects of the defect on the previous tests are to be examined.
– The method must be laid down in documented procedures, and all effects concerning equipment are to be documented in the relevant protocol book.

4.14 Corrective and preventive action

– If the deviation of the results of parallel measurements is higher than defined, steps according to 4.13 must be carried out. The analysis of quality records, data acquisition and calculations must be controlled.
– If an error is found in the procedure, the SOP must be corrected and a better procedure must be tested.
– The customer must be informed if there were errors in the storage or handling of the samples.
– Controls must be applied to ensure that effective corrective action is taken.

– Procedures for preventive action must include the use of appropriate sources of information, such as audit results, quality reports, service reports, etc.

4.15 Handling, storage, packing, preservation and delivery

– In a testing laboratory, data and reports are usually delivered. The work carried out must be covered by a report which clearly, accurately and unambiguously presents the test results and all other relevant information.

– In-process data, calculations, records and protocol books with information about the customer and his samples must be stored safely.

– All results are confidential and belong only to the customer.

– The testing laboratory must observe terms and conditions to provide for the confidentiality and security of all information concerning the material, processes, measuring results and all data relating to the customer.

4.16 Control of quality records

– Documented procedures must be established and maintained for the identification, collection, indexing, access, filling, storage, maintenance and disposition of quality records.

– The retention times of all quality records must be established (usually 10 years) and recorded.

– Where agreed contractually, quality records must be made available for evaluation by the customer.

– Records may be in the form of any type of media, such as hard copy or electronic media. However, records must be readable throughout the whole retention time.

4.17 Internal quality audits

– Internal audits must be carried out at defined intervals by independent personnel.

– Follow-up audit activities must verify and record the implementation and effectiveness of the corrective action taken.

4.18 Training

–Documented procedures must be established and maintained for the identification of training needs and for the provision of the training of the personnel.

– Personnel must be qualified on the basis of appropriate education, training and experience.

– Education in special measurement methods is sometimes possible in courses from the instrument producer, but often the operator must learn by himself.

– Qualification can be documented through participation in conferences and workshops and by publications.

4.19 Servicing

– Here the contacts between the testing laboratory and the customer after delivery of the results are relevant.

– Reaction, if the customer has additional questions.

– Complaints stemming from late delivery: clarification of the reason, and activities to avoid this in future.

– Complaints through suspect measuring results: Control of all steps of the procedure according to 4.13, and then corrective action.

– All complaints and subsequent action must be documented.

4.20 Statistical techniques

– Different standards exist for sampling, depending on the nature of the material, liquid, solid, powder, etc. and the desired measurement. The statistical methods must be described. This point is necessary if the test laboratory performs the sampling; in this case, the method must be described. However, the testing laboratory usually receives a number of prepared samples.

– Several parallel samples are usually measured, to obtain a good average value of the result, as demanded from the standard or SOP. Methods for the expression of the uncertainty are described in different publications [13, 14]. The calculation method with the statistics used must be documented in the report.

– Statistical methods can also be applied to prevent failures, e.g. if the results of a statistical method indicate a significant shift of a zero-point deviation, a significant increase in the uncertainty, etc.

For accreditation according to EN 45001, some other additional points are very important:

– Legal identity: the laboratory must be legally identifiable.

– Impartiality, independence and integrity: the organizational and financial independence of the personnel who manage, perform and verify measurements.

– Competence: the laboratory must be competent to perform the tests concerned. It must be organized in such a way that each member of the personnel is aware of both the extent and the limitations of his area of responsibility. A technical manager who has overall responsibility must be defined.

– Premises and environment: the laboratory must be furnished with all items of equipment required for correct performance of the tests and measurements. The environment must not influence the results. Access to and use of all test areas must be controlled in a manner appropriate to their designed purpose, and conditions of entry by external persons must be defined.

– Equipment: all equipment must be properly maintained. Records must be kept of each item of measurement equipment. The content of this record is exactly defined, e.g. controlling, inspection and calibration. Reference standards for measurements must be used for calibration only. Where traceability to national or international standards of measurement is not applicable, the laboratory must provide satisfactory evidence of the correlation or accuracy of test results (e.g. participation in interlaboratory comparisons).

– Test methods and procedures: the laboratory must have documented instructions of all equipment, on the handling and preparation of test items and standard testing techniques, SOP, etc. All instructions, standards, manuals and reference data must be maintained up-to-date. All measurements, calculations and data transfers must be subject to appropriate checks.

– Test reports. The content is exactly described; it must not include any advice or recommendation arising from the test result.

– Records: the record system must retain all original observations, calculations and derived data, calibration records and the final report for an appropriate period. It must contain sufficient information to permit repetition of the test and should include the identity of the personnel who carried out the work.

– Handling of the test samples: is clearly defined in the standard.

– Confidentiality and security: this must be guaranteed.

– Subcontracting: the testing laboratory must ensure and be able to demonstrate that the subcontractor is competent to perform the services with the same criteria as the testing laboratory. The testing laboratory must advise the customer of its intention to subcontract. The subcontractor must be acceptable to the customer.

– Cooperation with customer: affording the customer access to relevant areas of the testing laboratory. The testing laboratory must have a defined complaint procedure.

– Cooperation with bodies granting accreditation: is described exactly in the standard, e.g. affording access, witnessing of tests, checks to verify the testing capability. Participation in round-robin-tests.

– Cooperation with other laboratories and bodies producing standards and regulations: testing laboratories are encouraged to participate in the drawing-up of national or international standards. Exchange of information with other laboratories having activities in the same field.

– Duties resulting from use of accreditation: are defined exactly in the standard.

Quality assurance cannot avoid errors, but it helps to minimize them and to reduce uncertain results in future. The advantages for the test laboratory, user and customers are the clear description and traceability of all steps, procedures and instructions. The managing director of the testing laboratory must define and document its policy for quality, including its objectives and its commitment. Provision must be made for premises, equipment and the necessary education, training, technical knowledge and experience of sufficient personnel.

References

1 ISO 9000 Quality management and quality assurance standards – guidelines for selection and use.
2 ISO 9001 Quality systems – Model for quality assurance in design/development, production, installation and servicing.
3 ISO 9002 Quality systems – Model for quality assurance in production and installation.
4 ISO 9003 Quality systems – Model for quality assurance in final inspection and test.
5 ISO 9004 Quality management and quality system elements – guidelines.
6 EN 45001 General criteria for the operation of testing laboratories.
7 EN 45002 General criteria for the assessment of testing laboratories.
8 EN 45003 General criteria for laboratory accreditation bodies.
9 ISO 17025 General requirements for the competence of testing and calibration laboratories (draft).
10 QS No 4 The European Quality Assurance Standards (EN ISO 9000 and En 45000) in the Community's new approach legislation. The European Quality Promotion Policy, EC DG III.
11 OECD No 1 OECD Principles of Good Laboratory Practice.
12 EN 552 Sterilisation of medical devices – validation and routine control of sterilisation by irradiation.
13 DKD-3 Ermittlung von Meßunsicherheiten, PTB.
14 WECC Doc19 Expression of the Uncertainty of Measurements in Calibration.