European Federation of National Associations of Measurement, Testing and Analytical Laboratories

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Position Paper

First-, second- and third-party testing – how and when

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EUROLAB POSITION PAPER

FIRST-, SECOND- AND THIRD-PARTY TESTING - HOW AND WHEN?

Introduction

This paper intends to clarify the roles of first-, second- and third- party test laboratories and their specific roles in conformity assessment in context with European legislation. Testing[1] is to be understood today as part of "conformity assessment[2]". In that context testing plays a key enabling role for technology and trade.

There are various general and specific rules – issued for example by the European Legislators – stating when testing has to be performed by a first-, second- or third-party testing laboratory. For example the Low Voltage Directice 2014/35/EU bases its conformity assessment requirements on results obtained by the manufacturer wheras the Directive for Equipment used in potentially explosive athmospheres (ATEX Directive 2014/34/EU) requires for nearly all equipment testing performed by a third party notified body. In addition there are definitions for first-, second- and third-party conformity assessment bodies in ISO/IEC 17000. The standards of the ISO/IEC 17000 series contain the detailed requirements on these various bodies

This position paper has been written in order to create a common understanding when first-, second- and third-party testing should or shall be used.

[1] determination of one or more characteristics of an object of conformity assessment, according to a procedure [ISO 17000]
[2] demonstration that specified requirements relating to a product , process, system, person or body are fulfilled [ISO 17000]

Contents

1. Methodology of testing

1.1. Definition of first-, second- and third-party laboratories

Testing is defined according to ISO/IEC 17000[3] as "determination of one or more characteristics of an object of conformity assessment, according to a Procedure" where Procedure is defined as "specified way to carry out an activity or a process"

Different parties can be involved in testing activities and therefore it is distinguished between

- first-party[4] activities carried out by manufacturers and suppliers
- second-party[5] activities performed by buyers, users, retailers or consumers
- third-party[6] activities done by organisations independent of the above mentioned parties.

First-party testing is intensively applied in all sectors of the economy and comes in various forms. It is for example used as an internal quality control measure that the products, materials, items and services are up to the requirements expressed in legislation, standards, technical specifications and contracts with the clients. The manufacturers' declaration of conformity expressed by different ways of marking the product is often based also on the outcome of these tests.

Second-party testing is performed by the customer of the products, materials, items and services mainly in order to ensure that agreed requirements and specifications are fulfilled. Second-party testing is also often performed by retailers that sell OEM products under their own trade name. For consumers, testing can be performed by consumer interest organisations or buyer organisations of products. Because of its often very individual nature this type of testing is not considered in detail here.

Third-party testing is especially required, preferred or used if the results have a considerable influence or effect on public or societal issues, in particular related to health, environment, safety and large economic values. It is also applied when taking measures to reduce the possibility of cheating or when crucial risks of wrong or manipulated results exist. Third-party testing is expected to provide a nonbiased neutral and objective view and thus greater confidence in the test results. Third-party testing occurs also if testing is in general outsourced to third party laboratories with the special case when a manufacturer's laboratory (own first party) offers testing to other manufacturers as a service to perform the testing and issueance a test report.

In certain areas it may be difficult or not necessary to determine which party carries out the testing. The public sector often makes use of third-party testing to provide objective evidence and facts for studies, evaluations, analyses and technical support for decision making processes.

1.2. Quality in testing

The following aspects apply to most testing laboratories irrespective of whether they carry out first-, second- or third-party testing.

Testing is a specialised service based on requirements, the contents and objectives of which are determined by the needs of society, industry, authorities, consumers and other parties. Several factors influence the conditions governing the achievement of the expected quality, which is that needed or required by the parties involved. With respect to the methodology of testing, the following aspects are crucial in order to achieve that level of quality:

[3] ISO/IEC 17000 Conformity assessment - Vocabulary and general principles
[4] ISO/IEC 17000: first-party conformity assessment activity
conformity assessment activity that is performed by the person or organization that provides the object
[5] ISO/IEC 17000: second-party conformity assessment activity
conformity assessment activity that is performed by a person or organization that has a user interest in the object
[6] ISO/IEC 17000: third-party conformity assessment activity
conformity assessment activity that is performed by a person or body that is independent of the person or organization that provides the object, and of user interests in that object

- The laboratory must be able to choose and apply the test method that provides a technically correct answer to the problem.

- The testing must be performed efficiently, also in such a way that delivery times and cost can be met.

- The laboratory must be able to provide reliable results with an accuracy appropriate to the needs.

- The testing laboratory must have the necessary expertise available to be able to assist in the evaluation of the test results and to provide other relevant technical services of an advisory nature. The expertise may be in another organisational unit.

- The reports and presentations of the results must be clear and complete, and the recipient must be able to understand and apply them correctly.

1.3. The role of accreditation in testing

Accreditation of a laboratory is a formal attestation of its impartiality and competence to consistently perform tests according to its accredited scope, as assessed and confirmed by the accreditation body. This is monitored and assessed regularly during the accreditation cycle. . The validity of results of accredited first and second party laboratories are equivalent to those of third parties. In many cases, accreditation is requested by customers and/or mandatory by law. This „testing of the testers“ is a crucial instrument, based on international standards and European law, for safeguarding the quality of testing activities. More or less, accreditation has become the „state of the art“ for laboratories, irrespective of whether they are first-, second- or third-party laboratories.

Further information on the role of accreditation is given in the following Eurolab Position papers:

- ”What conformity assessment operators expect from accreditation”
- ”Accreditation bodies – national recognised bodies or market players?”

2. Testing in standards and legislation

2.1. General requirements

Product standards often contain technical requirements concerning testing procedures which can be applied during the manufacturing phase or to the final product. The requirements are generally such that all testing laboratories have to fulfil them.

The International standard ISO/IEC 17025 determines the general requirements for the competence, impartiality and consistent operation of the testing laboratories. The aim of ISO/IEC 17025 is to obtain technically correct test results from all testing laboratories irrespective of their first-, second- or third-party status. That is obvious as the status of the testing laboratory should not affect the technical results. Fulfilment of the requirements in ISO/IEC 17025, even when verified by accreditation, is however not always considered to be sufficient by the market, the public authorities, or as input for further conformity assessment services (e.g. certification body) especially when activities related to conformity assessment or professional judgement are concerned. The standard ISO/IEC 17020[7] (inspection including testing) which explicitly includes professional judgement contains certain requirements for independent bodies.

The situation that the technical competence of the testing laboratory may not be sufficient at least partly resembles that of product certification, for which a third-party status with specific independence and impartiality requirements is imposed.
For example, in ISO/IEC 17065[8] and ISO/IEC 17067[9] concerning bodies operating product certification systems and their assessment and accreditation, respectively, there are requirements concerning impartiality and independence. Accreditation is consequently covering also these aspects and gives a confirmation of the third-party status of the product certification body.

[7] ISO/IEC 17020 Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
[8] ISO/IEC 17065 Conformity assessment - Requirements for bodies certifying products, processes and services
[9] ISO/IEC 17067 Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes

2.2. CE Marking of products

Concerning the CE-marking of products, the manufacturer is obliged under prescribed conditions to affix the CE-marking to his product. The CE-marking expresses the overall responsibility of the manufacturer. It is up to the society, the public sector, customers or the manufacturer to decide where the involvement of third-party testing laboratories is needed and/or required and to what extent. However, it is quite clear that the manufacturer cannot perform market surveillance and associated testing which definitely is the task of authorities, possibly supported by third-party laboratories if it is ensured that there is no conflict of interest with notified bodies.

2.3. Notified bodies

For notified bodies operating under the conformity assessment modules A1/2, C1/2 and F of the New Legislative Framework (EUDecision 768/2008) ISO/IEC 17025 can also be the essential standard to be followed. The Union Harmonization Legislations do not stipulate which harmonized standard(s) have to be used. That means that Notifying Authorities and/or Notified Bodies may choose the appropriate harmonized standard for each of the Union Harmonization Legislations and the related modules. As a consequence thereof the conformity assessment bodies in different member states have to meet different requirements with the significant effects. To ensure a coherent level of outcome provided by conformity assessment bodies being accredited and notified by the Member State the accreditation by National Accreditation Bodies (NABs) should be conducted in a harmonized way throughout Europe. The aim of the project EA Accreditation for Notification (AfN) is the harmonization of the accreditation requirements used as basis for notification by defining the preferred harmonized standards for each Union Harmonization Legislation.
The notified bodies which follow ISO/IEC 17025 shall in addition have the capacity and procedures for judging and deciding on conformity. The European Commission's guide to the implementation of EU product legislation (Blue Guide 2016) stipulates that to be eligible as a notified body the organisation must be a third party. In addition to that, the testing laboratory operating as a notified body should have personnel with a broad competence profile. The personnel responsible for the opinions, interpretations and professional judgement should in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out also have

- relevant knowledge of the technology used for the manufacturing of the products, materials, items, services (etc.) tested, of the way they are used or intended to be used and of the defects or degradations which may occur during use or in service,
- knowledge of the general requirements expressed in the legislation and standards and,
- an understanding of the significance of deviations found in the products, materials, items, services etc. with regard to the normal use of them.

3. The role of first-party testing

3.1. General criteria

A distinction has to be made between manufacurers' laboratories that are run under the responsibility of the product developing unit or department and accredited manufacturers' laboratories which are independent of the department/business unit. The technical competence and impartiality of which have been evaluated by an accreditation body that also performs regular surveillance. Whereas the first type of manufacturers' laboratories is often used to support research and development and to perform routine test and quality control tests during manufacture, accredited laboratories perform tests within their accredited scope that are equivalent to tests by third parties.

Manufacturers design and manufacture products with a view of placing them on the market. In the pertinent European legislation, there are obligations on manufacturers (or their authorised representatives) to draw up an EU declaration of conformity before a product is placed on the market. Depending on the type of the product the manufacturer's declaration of conformity states that the product satisfies the essential requirements of the applicable legislative acts. In some cases the product has to be in conformity with the type for which a type-

examination certificate has been issued. First-party testing under the responsibility of the manufacturer may be applied in order to determine whether one or more characteristics of a given product fulfil the essential requirements. It may also be applied in connection with the obligation of manufacturers to draw up technical documentation containing information to demonstrate the conformity of products to the applicable requirements.

3.2. Why first-party testing?

In the fulfilment of conformity assessment requirements, for example those of the European legislation, manufacturers must take all measures necessary to ensure that the manufacturing process assures compliance of the products with the type, to affix the CE marking to the product and to establish a technical documentation. For the purpose of complying with the related conformity assessment modules the manufacturer must ensure that a quality system is implemented. In this context, first-party or outsourced to third party testing may be supportive in aspects such as:

- providing input into the development and design of products,
- performing inspection and tests of incoming materials and unfinished components,
- measuring and controlling production processes and finished products, using preferably methods which are identified in agreed standards,
- checking quality objectives in order to deliver products with expected properties, performance, environmental compatibility, etc.,
- ensuring quality records, like test data, inspection reports and calibration data suitable to ensure the fulfilment of the applicable essential requirements.

It is obvious that first-party testing is supportive in various aspects of the manufacturer's declaration of conformity, but its role depends on the product under consideration.

3.3 Responsibility of first-party laboratories

The responsibility of a first-party testing laboratory – if it is operated directly or indirectly by the manufacturer of the product to which the testing is applied – is inevitably connected with the overall responsibility of the manufacturer for the pertinent product. Therefore, first-party testing may be a measure to ensure that a product intended to be placed on the market is safe and otherwise in conformity with relevant requirements. First-party testing may be performed with respect to finished products as well as with respect to ready-made parts or components.

4. The role of third-party testing

4.1. General criteria

If the laboratory wishes to be recognised as a third-party laboratory, it must be able to demonstrate that it is independent and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. Procedures shall be implemented to ensure that persons or organisations external to the testing laboratory cannot influence the results of tests carried out.

Third-party testing laboratories shall be independent to the extent that is required with regard to the conditions under which they perform their services:

- The third-party testing laboratories and their staff responsible for carrying out the tests shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the items which they test, nor the authorised representative or a subsidiary of any of these parties.
- The third-party testing laboratories and their staff shall not engage in any activities that may conflict with their independence, judgement capability and integrity in relation to their testing activities. In

particular they shall not become involved in the design, manufacture, supply, installation, use or maintenance of the items tested, or similar competitive items.

4.2. Why third-party testing?

There are several different reasons why testing is done by a third-party organisation:

- The manufacturer or buyer of products orders third-party testing services.
- The contracting parties agree to use a third-party testing laboratory.
- Both the first- and second-party laboratory perform the testing and in case of divergent results, the dispute is solved by a third-party laboratory.
- It is the common practice in the sector (field) to utilise third-party testing organisations.
- It is required due to certain conformity assessment services, e.g. product certification schemes.
- It is a mandatory legislative requirement.
- In legal court proceedings test results from unbiased third-party laboratories have a high level of acceptance.

4.3. Responsibility of third-party laboratories

Testing laboratories produce test results that are used as a basis for decisions and judgements on conformity. The testing laboratory should not take any responsibility for the product, material, item, or services being tested. That responsibility belongs solely and unlimited to the manufacturer. The third-party testing laboratory may perform the testing for or requested by the authorities. Although the laboratory in these cases executes tasks of an authority character the laboratory can neither in this case be hold responsible for the product, material, item or service.

5. In summary

Conformity assessment and testing are crucial enabling factors for technology and trade. To improve the common understanding, laboratories should indicate in a clear and transparent way whether they act as a first-, second- or third-party testing laboratory. They also should define their competence and the scope of their activities.

The volume of first-party testing is very large. Additionally, there are a number of cases either in the regulated, public or in the non-regulated sector where third-party testing is needed and/or useful. In principle, it is the laboratories' clients who decide on the extent of the third-party involvement. The client can either come from the private sector - and the situation is then clear-cut - or from the public sector. In the latter case the customership is often an indirect one and the third-party testing laboratory involvement is originating from requirements in legislative documents.

In the mandatory part of the public sector, the European Commission must together with the Member States and the national authorities define when third-party testing is necessary. The general principles have been described in the New Legislative Framework and they may be further detailed in the EU legislation as well as in the modules providing for the involvement of notified bodies. Also the national legislation must clearly express if a third-party testing laboratory service is needed or if the first- (and second-) party testing is considered to be satisfactory.
The question of the requirements on and responsibilities of first-, second- and third-party organisations has been addressed in the development of the ISO/IEC 17000 series of standards.
For further conformity assessment services relying on testing agreements, statutes or guidelines of relevant organisations such as certification bodies define the extent of involvement of first-, second- or third-party testing laboratories.