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

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

Abstract

Testing is to be understood today as part of "conformity assessment" which is defined according to EN 45020 as "any activity concerned with determining directly that relevant requirements are fulfilled". 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 Commission – stating when testing has to be performed by a first-, second- or third-party testing laboratory. In addition there are requirements in the EN 45000 series standards referring to the criteria an organisation has to fulfil in order to be a third-party organisation or to be a notified body. However, there is a clear need to discuss the issue in further detail.

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

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1. Methodology of testing

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

Testing is defined according to EN 45020 as "technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure".

Different parties can be involved in testing activities and therefore one distinguishes between

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

First-party testing is a large sector. It is for example used as an internal quality control measure that the products, materials, items and services are up 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 receiver of the products, materials, items and services mainly in order to ensure that agreed requirements and specifications are fulfilled. For ordinary 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 eliminate the possibility of cheating and considerable misconduct or when crucial risks and consequences of wrong or manipulated results exist. Third-party testing is expected to provide a nonbiased view and thus a better confidence in the test results.

In certain areas it may be difficult or not necessary to distinguish clearly between the three categories of laboratories. For example in certain industrial fields (e.g., classification of ships) it has become a practice or an agreement between peers to use testing services independent of a single manufacturer. This has led to a de facto standard accepted by all parties.

The public sector prefers to use independent third-party testing laboratories to provide objective evidence and facts for studies, evaluations, analyses and technical support for decision making processes. The mandatory part of the public sector is clear cut; either the authorities require or the legislation demands that only results of third-party testing laboratories are accepted. Third-party involvement is also recommended when there is a risk of a major dispute or conflict of interest.

1.2 Quality in testing

The following aspects apply to most testing laboratories irrespective of their first-, second- or third-party status.

Testing is a specialised service, 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 right 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 the right quality:

- 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 can be met and costs and charges minimized.
- 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.

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 new standard EN ISO/IEC 17025 follows the philosophy of defining required technical competence and quality aspects of the testing laboratory. In addition it gives guidance to the laboratories. The aim of EN ISO/IEC 17025 is to obtain correct 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 EN ISO/IEC 17025 even verified by accreditation is, however, not always considered to be enough by the market or the public authorities especially when activities related to conformity assessment or professional judgement are concerned. The standard EN 45004 (inspection including testing) which explicitly includes professional judgement contains certain requirements for independent bodies.

Test and measurement results always have a certain experimental scatter of data expressed as "uncertainty" (sometimes small, sometimes large) due to technical and operational reasons. When additionally considering sampling, assessment and judgement linked to the testing, the "uncertainty" increases and there is a "grey zone", within which one cannot say for sure how valid the results are and for that reason one arrive at different conclusions although the underlying test results are identical. For example the laboratories involved can adopt different principles for selecting and taking the samples.

The situation that technical competence of the testing laboratory may not be enough at least partly resembles that of product certification and "traditional" inspection bodies, for which a third-party status with independence and impartiality requirements is imposed. For example, in EN 45011 and EN 45010 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.

2.2 Removing technical barriers to trade

Internationally and within Europe the tendency is to decrease or even remove the so called technical barriers to trade but still guarantee the safety of products and to create a level playing field and harmonised regulations for all competent bodies. Adequate activities of manufacturers as well as the involvement of independent organisations (authorities, third-party organisations) are needed in this respect.

It is not enough that the laboratory is technically competent. It must also have the requested first-, second- or third-party status especially when required by legislation or demanded by other requirements.

2.3 Marking of products

Concerning the CE-marking of products, the manufacturer has under prescribed conditions to affix the mark to his product. The CE-marking underlines the responsibility of the manufacturer. The manufacturer's declaration of conformity must be supported in certain product areas by market surveillance means because certain CE-marked products do not fulfil all requirements imposed on them. One reason may be poor standards and different interpretations of the requirements. It is up to the society and the public sector to decide where third-party testing involvement 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 must be given to authorities supported by third-party organisations.

2.4 Notified bodies

For notified bodies operating in the conformity assessment modules Aa, C and F of the new approach (EC directive 98/34) EN 45001 can also be the essential

standard to be followed. The notified bodies which are independent third-party organisations and follow EN 45001 shall in addition have the ability to decide on the conformity. The European Commission's guide to the implementation of directives based on the new and global approach (July 1999) 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.

In the legislation there are in many areas the requirement that the testing must be performed by a third-party organisation.

2.5 Restructuring the EN 45000 series

A joint CEN-ISO working group has been established in order to revise the EN 45000 series of standards and corresponding ISO standards and guides. The outcome of this working group should be a recommendation for a new "function oriented" structure of this series of standards. It may contain clear requirements as an integral part concerning the functions and/or tasks of first-, second- and third-party organisations.

2.6 The transatlantic business dialogue

The transatlantic business dialogue (TABD) suggests for certain product areas the principle "approved once, accepted everywhere". In the present TABD action programme the following principle is accepted for specified product sectors by both the EU and US Governments: "one standard, one test, with suppliers' declaration of conformity accepted". However, concerning market surveillance, authority as well as third-party testing and inspection involvement is still required. In any case, a balance has to be found between reducing costs and time to market on one hand and the fulfilment of obligations such as product safety on the other hand.

3. The role of first-party testing

3.1 General criteria

Manufacturers are designing and manufacturing products with a view of placing them on the market on their own behalf. In the pertinent European directives,

there are, however, obligations on manufacturers (or their authorised representatives) to draw up a declaration of conformity when a product is placed on the market. Depending on the type of the product the manufacturers declaration of conformity must ensure that the product satisfies the essential requirements of applicable legislative directives. 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 conformity 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 directives, manufacturers must take all means necessary to ensure that the manufacturing process assures compliance with the prototype, to affix the CE marking to the product and to establish a technical documentation. For the purpose of complying with the related modules the manufacturer shall ensure that a quality system is implemented according to pertinent standards. In this context, first-party testing means may be supportive in aspects such as:

- providing input to the development and design of products,
- performing receiving 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 manufacturers 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. This responsibility originates from the directive on product liability. Therefore, first-party testing has an obligation to ensure that a product intended to be placed on the market is safe. In case, the products falls within the scope of a New Approach Directive it has to be ensured that it is designed and manufactured and its conformity assessed to the essential 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

Whereas there are various approaches and answers to the question when third-party testing laboratory involvement is needed, it is not difficult to define the criteria it has to fulfil.

In the revising of EN ISO/IEC 17025, the third-party testing laboratory issue has been conditionally addressed in the following way. If the laboratory wishes to be recognised as a third-party laboratory, it should be able to demonstrate that it is impartial 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.
- The procedures under which the third-party testing laboratories operate shall be administrated in a non-discriminatory manner. There shall not be undue financial or other conditions.

4.2 Why third-party testing?

There are several different routes, which result in the situation that the testing has to be 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 product certification schemes (product marking).
- It is a mandatory legislative requirement.
- In legal court proceedings test results from third-party laboratories are decisive.

In summary, the public at large is expected to have a high degree of confidence in results obtained by third-party testing laboratories.

4.3 Responsibility of third-party laboratories

The main characteristics of a third-party testing laboratory is that whatever the test results are, they should not in an undue way influence the assessment or judgement the laboratory makes based on these results.

Testing laboratories produce test results and use them also as a basis for decisions and judgements. The responsibility of the third-party testing laboratory must be limited to the responsibility for correct test results and its decisions or recommendations made thereupon. 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 if they are a first-, second- or third-party testing laboratory. They also should define their competence and the scope of their activities. Accreditation bodies may upon request from the laboratory be able to express the status of the laboratory in the accreditation certificate.

The volume of first-party testing is very much larger than that of third-party testing laboratories. However, 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 one can say that 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 should be described in the global and new approach documents and they should be further detailed in the EU directives as well as in the modules for notified bodies. Also the national

legislation must clearly express if a third-party testing laboratory intervention is needed or if the first-, (and second-) party testing is considered to be satisfactory. When developing national legislation, a certain European harmonisation is required.

In the discussion on the restructuring of the EN 45000 series and the corresponding ISO/IEC standards and guides, the question of the requirements on and responsibilities of first-, second- and third-party organisations must be addressed.

In the non-regulated sector, agreements, statutes or guidelines of relevant organisations such as certification bodies shall define the extent of involvement of first-, second- or third-party testing laboratories.