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Nordic Innovation Centre

# POSITION PAPER

## **PROFESSIONAL JUDGEMENT AND TESTING LABORATORIES**

Position paper 6  
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## **1. Summary**

The aim of this position paper is to discuss to what extent testing laboratories can apply professional judgement in their work and when presenting their results. The main conclusion is that professional judgement should be made by the organisation which has the best technical expertise. Consequently, the testing laboratories are very well suited to give their opinions and interpretations of test results and, based on them, a conformity assessment judgement of the results with regard to regulations, technical standards and requirements as well as contractual specifications.

## **2. Background**

Professional judgement is the ability of a single person or a team to draw conclusions, give opinions and make interpretations based on experiments, measurements, observations, knowledge, experience, literature and/or other sources of information. In this definition, professional judgement is based on facts and objective evidence as well as experience, which includes some subjectivity. However, professional judgement should not be based on political or societal opinions. Professionalism refers to skill and competence of a degree definitely above average.

The terminology "professional judgement" is used in this position paper, although the term "expert judgement" is analogous. Both terms refer to a technical judgement made by a highly skilled, knowledgeable and experienced person or group of persons.

## **3. The importance of professional judgement**

Professional judgement relates mainly to non-routine operations (e.g. research, product development) and it is expressed as:

- opinions on the technical results (merits and drawbacks),
- interpretation of results, and recommendations for how to use them, and
- guidance for improvement.

Professional judgement can also be an element of the conformity assessment activities. However, in several cases conformity assessment is such a straight forward process that real professional judgement is not necessary. The term "conformity assessment judgement" is used in the following to describe the assessment activities, which, for example, relate to accredited operations and the modular approach. The outcome of the conformity assessment judgement is generally expressed as:

- opinions on the conformity of results and performance with the requirements,
- fulfilment of contractual specifications, and
- representativeness of the results.

The issue of professional judgement and testing has recently become current due to two simultaneous developments.

Firstly, in the revision of ISO/IEC DIS 17025, the drafting group included a subsection dealing with professional judgement in relation to testing and calibration. The comments received rejected the incorporation of such a subsection and the reasons referred to were:

- Professional judgement is too subjective and open to a wide range of interpretations.
- Professional judgement is an integral part of some testing activities (e.g. failure analyses, metallographic studies, noise and vibration analyses, finite element analyses, and non-destructive testing) and thus that subject need not to be addressed separately.

- Accreditation can only be provided for the competence to perform tests and calibrations, not for offering professional judgements, opinions and interpretations based on the results obtained.
- It will be difficult to require and assess that the personnel have the applicable theoretical and practical background and recent experience to qualify them for being able to make professional judgements.

These arguments are partly contradictory. Further, they do not reflect what can be achieved by following EN 45004 or EN 45011 (see below), according to which the capability to perform professional judgement is covered in the accreditation process. Secondly, in recent working documents (CERTIF 97/5 EN, 15.9.97; Note to SOGS 14.10.97) issued by the European Commission, the conformity assessment procedures (modules) of the global approach have been reconsidered. Both documents end with the proposal to drop the possibility to use EN 45001 for assessing the competence of the notified bodies. This especially refers to the modules Aa and C. The reason for dropping the reference to EN 45001 was that all modules involve evaluation, auditing and determination of conformity in the design and production phases. It has been argued that notified bodies making the assessment according to EN 45001 do not have the capability of and procedures for judging and deciding based on the test results, if the essential requirements are fulfilled and/or harmonised standards have been applied. As a corollary

of this, the conformity assessment procedure should basically involve evaluation and determination of the conformity of products according to the standards EN 45004, EN 45011 and EN 45012 according to the requirements of the modules.

After the above mentioned documents had been issued the Commission reiterated its position (see working document CERTIF 97/5 EN Rev. 1; 24.3.1998) and again included EN 45001 for demonstrating the capability to carry out operations within the modules Aa, C and F. As will be shown later, this definitely is the correct direction, because otherwise it would imply that fulfilment of EN 45001, the normal standard for testing laboratories, does not suffice. Further, it is not efficient for enhancing European competitiveness if the Commission should disregard the competence and expertise of several thousands of European third-party laboratories. Neither would it be a relevant standpoint when considering the introduction of ISO/IEC 17025.

Several organisations have reacted because they want to secure the position of those testing laboratories that possess such competence that they could make professional judgements based on their results. In particular, multidisciplinary (testing) laboratories are indeed considered able to make professional judgements within their field of expertise. Experience even shows that, in many cases, the testing laboratories are even better off than certain product certification and inspection bodies, who get plain test results from a testing laboratory. Especially when something goes wrong, only the test performer can straighten out the problems. The testing laboratories are best aware of the limits and restrictions of the tests.

Customers (especially the SMEs) of the testing laboratories have a real need for opinions and interpretations, i.e. the professional judgement they get from the laboratory as they do not have the expertise themselves.

In summary, there is a clear and real need that testing laboratories as well should be empowered to make professional judgements within their field of competence. Consequently, the accreditation process should be further developed so that the laboratories are not subjected to multiple assessments, for example, for technical competence according to EN 45001 and professional judgement according to EN 45004.

#### **4. Requirements referring to professional judgement**

Professional judgement has been covered in EN 45004 in the following way:

"The staff responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of requirements of the inspections to be carried out. They shall have the ability to make professional judgement as to conformity with general requirements using examination results and to report thereon. They shall also have relevant knowledge of the technology used for the manufacturing of the products inspected, of the way in which products or processes submitted to their inspections are used or are intended to be used, and of the defects which may occur during use or in service. They shall understand the significance of deviations found with regard to the normal use of the products or processes concerned. The inspection body shall establish a documented training system to ensure that the training of its personnel in the technical and administrative aspects of the work in which they will be involved, is kept up-to-date in accordance with its policy. The training required shall depend upon the ability, qualifications and experience of persons involved."

The subclause 2.1. of EN 45004 has been commented on by the inspection bodies in the following way:

"The definition of inspection overlaps with that of testing and product certification where these activities have common characteristics. However, an important difference is that many types of inspection involve professional judgement to determine acceptability against general requirements and thus the inspection body will have to demonstrate that it has the necessary competence to perform the task. Generally, inspection involves direct determination of the conformance with specifications of unique - often complex or critical - products or small series of products, whereas product certification primarily involves indirect determination of the conformance of products manufactured in long series. While inspection of products in use (in-service inspection) is a well-established discipline, certification (EN 45011) of products in use does not occur."

In the ISO/IEC DIS 17025 the requirements on personnel are not very far from those in EN 45004, especially when one considers that personnel must be able to evaluate results and that the experience requirement may also cover knowledge in manufacturing and behaviour of products and materials.

#### **5. Can the relevant requirements concerning professional judgement be applied also for testing?**

Testing is becoming more complex and directed also towards the evaluation of the properties of new products and processes. The personnel in laboratories are becoming more qualified. In order to use this asset rationally and efficiently, and to enhance the introduction of new technology, it is sensible to add professional judgement, however named, to the services of testing laboratories.

Industrial customers, not least the great number of SMEs, require and have a real need for testing which provides optimum value for money and the right input in their product development as regards safety, function, performance and environmental impact as well as product acceptance. They need simple access to all competence, including the competence of testing laboratories. Consequently, the capability of the laboratory staff to make professional judgements must be utilised.

In the argumentation it has been said that professional judgement cannot be covered by accreditation after EN 45001. The opposing argument is how that can be achieved by following EN 45004, as the personnel competence requirements de facto are very similar to their contents. The debate should be more focused on the competence area that can be covered by the expert team or organisation. The area is of course dependent on the education, experience, training and other qualifications of the staff.

The professional judgement can in principle refer to all organisations or experts. However, very often the concept is related to third-party involvement, resulting in opinions and interpretations by an organisation independent of the designer, manufacturer, supplier, installer and user of the products, items and materials. The third-party organisation must operate in an impartial way. As ISO/IEC DIS 17025 is written for all testing and calibration laboratories and their technical performance, the third-party laboratories could easily demonstrate, in addition to their technical competence, their impartiality and independence to the same depth as required in EN 45004, EN 45011 and EN 45012. In this respect the main principle is that the organisation cannot accept its own work.

When talking about professional judgement the concept very often refers to the capability of individuals. However, in many cases it is the collective expertise of the whole organisation that is decisive in the organisation's capability to perform assignments that require professional judgement. Consequently, an individual can definitely cover a much smaller scope than a large multidisciplinary organisation. In the present system there can be a situation in which a testing laboratory produces a test result, sends the plain result to an inspection or certification body, which then makes a professional judgement. Does the inspection or certification body in all cases have such a superior expertise and knowledge that they are more competent than the testing laboratory to make the professional judgement? It is difficult to reach any other conclusion than: the organisation that has the best technical expertise should make the professional judgement.

There are differences in Europe with respect to responsibilities and liabilities in making professional judgements. In the Nordic countries it is the companies and organisations that bear the responsibilities, whereas in certain other European countries responsibilities rest on the individual employees (experts). Here there is a need for further harmonisation.

## **6. EN 45001 and the modules**

In the quest for correspondence between the EN 45000 standards and the modules, the major issue is how competence and adequacy of professional judgement are assessed and surveyed, and to what they should be applied. Typically, a notified body will be faced with one or several of the following situations where it will have to apply professional judgement:

- deciding to which product category a product belongs in order to determine which Directives and testing and/or performance standards are applicable;
- sampling of products to be examined for type evaluation;
- determining a test programme, and deciding to what extent technical data and test results previously produced can be used;
- interpreting test results and technical data to determine compliance to the essential requirements of the Directives, even when the notified body applies harmonised standards.

It is clear that the building and maintenance of professional judgement in this context requires that the notified body keeps abreast with the development of a technical jurisprudence for the implementation of the Directives. If the correspondence between the EN 45000 standards and the modules is sought in order that accreditation may be used as the preferred mechanism for assessing and surveying notified bodies, then the competent authorities and the Commission must spell out and harmonise more precisely what they expect from notified bodies. Large economic interests are at stake. However, it should not be the conformity assessment operators only who make the rules of the game but their customers must have a say when determining what is the optimal solution for Europe.

In the Directives it is required that the notified bodies have at their disposal the necessary personnel and possess the necessary facilities to enable them to perform their tasks properly. They must also have access to the equipment required. These requirements disqualify "paper organisations" with no facilities or equipment. Testing laboratories fulfil almost by definition these requirements within their scope of operation.

EN 45001 is currently the most widely used standard for assessing the competence of notified bodies and it is indeed the one which addresses most specifically this competence through the examination of the competence of staff, the existence, adequacy, operation and maintenance of testing and measuring equipment and the sampling procedures. The right to make professional judgement in determining the compliance of tested items to requirements should also be possible to give to testing laboratories.

## **7. Suggestions and recommendations**

As can be seen from the discussion above, the spectrum of professional judgements can be broad, i.e. from comparing a single test result to a predetermined requirement, through combining several measurements and test results with more general requirements to making the judgement without any facts (e.g. test results, calculations etc.). Further, the professional judgement can be related to the conformity assessment process as well as to technical (expert) evaluations and interpretations. Professional judgement is generally considered to be a third-party activity although there may even be superior experts within the first and second-party sector. In this position paper, it is assumed that certain facts are available, otherwise one should not talk about professional judgement at all.

Professional judgement can also be discussed from the utilisation of outcome, which is either used in the mandatory field or in the voluntary field. The mandatory area relates to safety, health and environmental issues, i.e. issues of public interest, and in this area professional judgement can and should be covered by the ordinary accreditation. In the voluntary field it is the market that determines the "acceptability" of professional judgements. There are no guarantees that the free market is going to accept the accreditation of professional judgement capabilities. In many industrial sectors voluntary agreement schemes, which also cover professional judgement type activities, have been and are in use.

Comparing a single test result to the requirement or several test results to corresponding requirements is a straight forward process and there is no reason why testing laboratories should not be able to make that judgement. Then there is the case in which the professional judgement is based on test results and derived attributes (e.g. material properties and strength calculations). If the laboratory, for example, is accredited to perform materials testing and strength calculations, is it not as competent as an inspection body with the same qualifications to make the judgements on mechanical components? How is it with an accredited NDT-laboratory having certified NDT-operators? Is that laboratory technically less suited to judge the quality of the welds than an organisation fulfilling EN 45004?

The area, in which there are some facts but also many unspecified issues (e.g. safety of a large industrial plant), is such that a pure testing laboratory is not well suited to assess safety. For these purposes, inspection bodies are better off.

One subject which is underdeveloped in the whole conformity assessment process is the involvement of third-party conformity assessment organisations. When is a third-party intervention needed and how deep should that involvement be? The ISO/IEC DIS 17025 is developed for all laboratories and incorporates requirements relating to their technical competence. It is the public authorities and legislation that must determine what the depth of an independent third-party involvement should be and what the

corresponding requirements are on the independence and impartiality of the third-party organisation performing the work. Such a clarification is urgently needed and it should be drawn up irrespective of what the organisation calls itself (testing laboratory, certification body, inspection body, etc.).

Independent of the character of the organisation, there is a need to specify the capability of an organisation to perform professional judgements. There could in principle be different categories of professional judgement complexity and for each category "requirements" on the organisation performing the professional judgement should be defined. If an organisation, whatever it may be called, fulfils these requirements it should be considered competent to make the corresponding professional judgements. That competence could be assessed during an ordinary accreditation or authorisation visit and included in the given certificate. The general requirements relating to education, training, experience, etc. are easily expressed on an overall level but are very difficult if not impossible to define in detail because the possibilities and cases are numerous. Therefore, it seems practical to turn the problem around and ask the organisation asking for recognition to perform professional judgement to present their case and it would then be up to the accreditation or authorisation bodies to determine if that organisation is competent enough to perform the professional judgements.

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## NORDTEST

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