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Nordic Innovation Centre

POSITION PAPER

POSITION PAPER ON THE SIMPLIFICATION OF THE CONFORMITY ASSESSMENT PROCESSES AND THE EN 45000 SERIES STANDARDS

Position paper 4
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1. Introduction

Many organizations are involved in conformity assessment activities and they are categorised in different ways.

There are testing laboratories as well as inspection and certification bodies. The EU and EFTA Member States notify to the Commission the bodies they consider competent to undertake the responsibilities arising from the new approach legislation and directives. In addition, there are sectorial arrangements covered by special rules and requirements as well as international conventions. The technical and administrative requirements relating to the notification process seem to differ from one country to another.

The situation becomes even more complex as many organizations have multiple roles. For example, organizations performing testing can be found under the headings: testing laboratories, inspection bodies, product certification bodies, GLP-laboratories, notified bodies etc. Some can be considered to be 1st party organizations, i. e. representing the manufacturer or vendor, others are 2nd party organizations, i.e. representing the buyer (purchaser) and, finally, there are 3rd party organizations independent of the above mentioned parties.

As one organization can carry out many tasks in the conformity assessment process and the different operations are governed by different rules, a clear definition and description of tasks and responsibilities is needed. Unfortunately there are no overviews or general policies identifying similarities and differences. The existing rules seem to have emerged more from single interest groups than from a coordinated approach. The conformity assessment system developed by the European Commission has not been able to eliminate the partial confusion that exists and to outline clear policies in the way the European system should be built up.

The EN 45000 series covers not only testing, inspection and product certification but also certification of quality systems and personnel. These two subjects are only indirectly discussed in this position paper.

2. Need for improvement

There are many issues under discussion and they are all reflections of the problems encountered in the conformity assessment process:

- The structure of the EN 45000 series standards must be revised.
- All conformity assessment processes should be defined from the same few basic (generic) elements.
- Rules for third party involvement in the regulated sector must be drawn up.
- There is a need to have a clear correspondence between the use of the different modules in the directives and the specific EN 45000 series standards.
- Technical and administrative requirements relating to the notification process must be defined.
- The overlap between the concepts testing, inspection and certification in the existing EN 45000 standards creates some confusion which should be eliminated. Requirements and responsibilities do not clearly distinguish between the different roles of different organizations.
- Cost-effectiveness of the conformity assessment processes should be improved, balancing the quality of the conformity assessment services towards the industry and economy at large against the price they have to pay for the services. (In this context quality means improved safety and reliability of products, less risk to health and environment etc.)

There are no clear-cut answers or even policies for the solution of these problems. Therefore this policy paper has been drawn up.

3. The way forward

All parties agree that the aim of the conformity assessment operations is to ensure that certain minimum requirements must be fulfilled by the products, installations etc. at reasonable cost to the clients as well as to the operators and in a mutually accepted way.

The development during the last decade has led to a relatively heavy system with increased bureaucracy and paperwork. The aim of this has been to be able to ensure transparency in demonstrating technical competence. The processes of accreditation, certification and notification have introduced an external assessment of competence and capabilities as well as of organizational and administrative matters. The question, however, remains whether we have been able to achieve the intended goals and objectives. There are diverging views expressed by the different organizations

involved.

It is proposed that an independent evaluation of the European conformity system with related legislation, rules, requirements and standards is carried out. The evaluation should end up in a proposal for the direction of the development of conformity assessment in Europe and be used as a policy guideline for future development.

The present modular structure is relatively fine faceted and the modules partly overlap. The possibility of simplifying the modular structure should therefore also be discussed. The modular structure is not used in the old directives and is not applied in a uniform and consistent way in the new directives.

4. What is the possible solution?

There are too many types of organizations in the field of conformity assessment and the tasks of these organizations overlap. There is also a large variety of regulations and standards relating to the conformity assessment operations as well as to products. The present standards and requirements give the false impression that good harmonization exists in Europe. However, the implementation of the standards and requirements is different in different countries.

The present situation creates so much documentation work that the real quality as well as the service to the customers are sometimes forgotten in the process.

4.1. Identifying the different operations

Whatever the conformity assessment process is called, there are the basic elements:

- clients "and authorities" requirements
- investigations to be carried out i.e. measurements, tests, analyses, calculations, observations etc.
- judgements, which can be based on facts, comparisons, experts' views, statements etc.
- criteria arising from regulations and requirements in standards as well as from practice; the criteria can be specific or general.

At present the investigation area is relatively well developed. Testing including measurements, analyses etc. is carried out to provide facts. It is, however, not always clear today how a judgement based on these facts is to be made.

The part of the conformity assessment process that is not defined is judgement. There are no guidelines as to the way in which judgement shall be exercised, nor is there any unambiguous requirement that the personnel should be able to make judgements. Inspection and certification cover judgement in relation to general or specific criteria. The inspection and certification of products may also include the supervision of the manufacturing process. When the criteria are specific there is in principle no problem in comparing the facts from the investigations with the requirements.

The concept of professional judgement is not very clear and therefore harmonization in that area will take a very long time. All efforts to clarify the concept are welcomed. When the process of judgement is clearly understood it becomes much easier to differentiate between testing, inspection and certification. Consequently, this understanding will influence the future structure of the EN 45000-series.

The comparison with existing requirements can be made on the basis of a few test results or in relation to more general requirements on the products. In some areas the requirements are not detailed enough, which means that acceptance or rejection cannot be based on fully qualified information. General knowledge and the experience of the personnel will have a more pronounced role in these cases. The follow up of the manufacturing process and related quality measures can also provide additional confidence in the acceptability of the products or services.

All the activities which occur are either

- a technical investigation, with a varying but defined use of methods, equipment and judgement or
- a conformity assessment procedure including a statement about the outcome of the technical investigation; also this procedure requires control or assurance of competence, methods, decision making etc.

The technical investigation also includes inspection elements i.e. visual control, operational or trial control of equipment etc. The aim of the conformity assessment procedure is to link facts and

observations to conformity declaration statements, which are based on comparison with existing requirements and professional judgement.

There is really no reason why the two above mentioned actions should be fragmented into so many types of standards and requirements, except historical ones and the fact that many old organizations want to keep up their volume of activity. The subdivision is in conflict with efforts to rationalize the conformity assessment process, and to improve the competitiveness of European industry.

4.2. A structure for a new EN 45000 standard

As all processes in conformity assessment are based on technical operations, these should form the core of the solution. There should be a document (resembling the revised ISO Guide 25) describing the quality systems and the management of the organizations as well as the technical requirements relating to the operations being carried out. It should further include a section describing the way judgements are made. This core should be independent of what the operations are called. The general requirements may be complemented with branch specific requirements (e.g. toxicology from the present GLP). The elements (e.g. handling of equipment, calibration, sampling, validation, internal audits, document control, records, subcontracting etc.) should be made identical.

The implications of the principles described above would be as follows. The qualification system should be the same for all conformity assessment operators. This means that e.g. the technical competence, use of test methods, calibration, equipment etc. should be the same for the same technical operations irrespective of whether they are used for "testing", "inspection", "certification", "notification" etc. purposes. It is then up to the authorities and the interested parties to agree upon the status and use of the results. For the judgement part a new well structured approach is needed. In this, the relationship between responsibilities, competence and legislation must be clarified.

The organizations involved in the technical operations of market surveillance shall also fulfil the core requirements. It is important to underline that the decisions relating to the conformity assessment procedures should be taken as close as possible to or preferably in the organization or a part thereof where the technical competence exists. This will underline the harmonization and trust in the technical and not the administrative part of the conformity assessment.

What is the consequence of the above proposal? Certainly an outcry of distress from many "interest organizations" as we do not need the large variety of different organizations. Many administrators will not be needed any more, although the technical work will not disappear. The operations will be streamlined and more cost-effective to the benefit of the customers. The legislation can be simplified and the number of standards and regulations reduced considerably.

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NORDTEST

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