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National Accreditation Body Communication with National Regulators - Best Practice Guide

PURPOSE

Meeting the expectations of national regulators is an important function of EA national accreditation body members. The EU Regulation on accreditation and the Decision on marketing of products formalise the obligations on EA members in this respect and require close cooperation between EA and the Commission and national accreditation bodies and the national authorities. This Best Practice Guide is intended to assist the EA members in developing, maintaining or strengthening cooperation with the regulators, at the national level.

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1 INTRODUCTION

The European Commission published Regulation (EC) No 765/2008 with the aim to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interest such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Community harmonisation legislation or any other relevant Community rules.

In order to reach these objectives, it was necessary to establish an overall framework of rules and principles in relation to accreditation, conformity assessment and market surveillance.

Regulation (EC) No 765/2008 provides a comprehensive framework for accreditation and to lay down at Community level the principles for its operation and organization. The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements providing a high level of protection of public interest. Moreover, transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered by the national public authorities as the preferred means of demonstrating the technical competence of conformity assessment bodies (CABs).

In order to ensure that the European regulator takes recourse to accreditation, a close collaboration between EA and the European Commission is in place according the General Guidelines for the cooperation between EA and the European Commission, the European Free Trade Association and the competent national authorities, which are published in the Official Journal of the EU.

But it is important that the national accreditation bodies (NABs) collaborate with the national regulators, hence accreditation is used as the preferred means to demonstrate the competence of conformity assessment bodies.

This Best Practice Guide shall support the EA national accreditation bodies in the communication with the national regulators. Thereby, the following objectives shall be addressed:

- Investigate the present processes in the Member States for communication between national accreditation bodies and regulators and use this information to help members where this communication does not yet exist;
- Establish common goals for effective communication with regulators;
- Establish the opportunity for benchmarking between national accreditation bodies the effectiveness of their communications networks with regulators.

It should further be underlined that variations from country to country in the level and structure of cooperation between national authorities and NABs are a result of different cultures and approaches to the handling of public authority activities, and the cooperation differs even considerably between sectors within member states.

It is not the intention of this Guide to propose a uniform system for cooperation to be implemented throughout Europe. The cooperation between national authorities and NABs

should always be designed to fit the specific objective and take into account the culture and tradition within the country and sector in question.

2 BACKGROUND

National regulators use the accreditation system to assess the technical competence, impartiality etc. of conformity assessment bodies (CABs) performing specific conformity assessment activities¹.

National legislation may state that manufactures shall demonstrate compliance with requirements in the legislation by using services provided by accredited CABs e.g. testing or inspection. Alternatively, legislation may require that applicants shall present an accreditation certificate to support their application for registration / notification to provide specific services.

In both cases close cooperation between the national authorities and NABs is important to facilitate that the service delivered by the NAB and its accredited CABs is meeting the need and expectation of national regulators and authorities.

National regulators are further obliged to accept reports and certificates issued by CABs accredited by NABs who successfully has undergone peer evaluation of EA i.e. are signatories to the EA MLA². The EA MLA is recognised as a “stamp of approval” of NABs and for activities performed by their accredited CABs. NABs should inform the national authorities of the purpose and operation of the EA MLA to ensure that authorities have confidence in the EA MLA and in reports and certificates issued under the MLA by accredited CABs.

Cooperation between national regulators and NABs is especially important when draft legislation contains requirements for industry to use services provided by accredited CABs or for companies to be accredited as a precondition for operating in specific sectors or performing specific tasks.

When legislation is prepared at EU level, i.e. by the European Commission, close cooperation is even more important between national authorities, NABs and the European Commission as the implementation of requirements for assessment of CABs should be done in a harmonised way in all Member States. Therefore, it is important that the Commission, the national authorities and the NABs have a common understanding and approach to implementation of the requirements and thereby are facilitating that CABs are treated equally and facing the same requirements in all Member States.

The Guide is developed especially to support use of accreditation in the mandatory field where EU legislation authorises national authorities to appoint notified bodies. In Decision 768/2008 accreditation is considered as the preferred tool for the assessment of notified bodies. A successful application of this approach in existing and future legislation will require close cooperation between national authorities and the NABs.

¹ Conformity assessment activities include: calibration, testing, medical examination, certification, inspection as well as validation and verification.

² According to article 11,2 in Regulation 765/2008.

In some countries, cooperation is very close during the entire process i.e. in the preparation/discussion of EU legislations, national implementation of EU legislation, handling applications and assessment of applicants, notification and designation of notified bodies and supervision of notified bodies. In other countries, the national authorities require applicants to present an accreditation certificate to support their application for notification without any discussion with the NAB about scope of accreditation for a CAB or other requirements. Indeed, in some cases the NAB is not aware that accredited organisations are using their accreditations to support applications for notifications.

In the majority of countries, however, the cooperation is very good in most of the fields while in some areas the national authorities does not rely on accreditation and cooperation with the NAB does not take place at all. This pattern appears to be the same regardless of the public or private status of the NAB.

It is also of interest to note the relatively high number of countries that have a legal requirement for notified bodies to be accredited. However, it appears that, even where this is the case, good communication between the NAB and the regulators is not always guaranteed. In some cases where accreditation is a legal requirement, regulators rely on accreditation certificates without any detailed communication with the NAB.

The recommendations for best practice that follow focus primarily on communications between NABs and national authorities in relation to the appointment of notified bodies for the product harmonisation legislations. However, it is the Commission's intention that the new legislative framework (NLF) approach should apply to all EU legislation that contains requirements for conformity assessment and it is considered that these best practice recommendations can be applied to address legislation outside the NLF as well as within and also for national legislation adopted for national purposes only.

3 BEST PRACTICE

Against this general background, a number of specific points emerged along with a number of specific recommendations for best practice (shown in italics).

3.1 General contacts with regulators

3.1.1 Need for good central contact point/sponsor department

A number of NABs commented that a strong relationship with a central coordinating point within Government can help greatly to improve communication with regulators across Government as a whole. A Government 'sponsor' can represent a NAB's interests to other parts of government and can often open doors that would otherwise remain closed to a NAB.

One option for NABs, in order to provide a clearer structure to the overall cooperation with national authorities, might be to establish an Advisory Committee for their activities relating to notified bodies. Terms of Reference for this committee might be:

"To define the overall administrative and national requirements notified bodies shall meet and advise the NAB in assessing against the general requirements".

An Advisory Committee as proposed would serve three functions:

- Be the national coordination point between public authorities and the national accreditation body. The NAB should plan the work programme for the committee to facilitate increased confidence in the accreditation system with public authorities;
- Inform public authorities on the technical work and the peer evaluation system of EA to demonstrate that the European accreditation system constitutes the professional technical community for assessment of CABs;
- Be a coordination forum between national authorities, who could benefit from sharing experience in implementation of European legislation at the national level as well as exchange of experience in assessment, notification and designation of notified bodies.

The composition of an Advisory Committee on notified bodies may vary from country to country but might include representatives of the Ministry responsible for general policy on accreditation and notified bodies, the ministries responsible for the individual legislations, notified bodies, economic operators and the NAB.

The proposed committee should not deal with technical issues at sectoral level; the NAB should have Technical Advisory Committees dealing with specific technical issues.

Recommendation 1

NABs should ensure that they have a recognised ‘sponsor’ within Government and develop a strong relationship with the sponsoring ministry

Recommendation 2

NABs should consider establishing an Advisory Committee for their activities relating to notified bodies.

Recommendation 3

EA and NABs should develop some information material to help NABs develop a strong relationship with a central coordinating point within Government, where this does not yet exist.

3.1.2 Peer evaluation information – sharing with regulators

The confidence of regulators in the NAB will be improved with greater knowledge of the peer evaluation process. An Advisory Committee for notified body activities might be a good tool for collection of information on the needs of public authorities for increased understanding and acceptance of the EA MLA system and dissemination of information on the actual peer evaluation process and system.

Recommendation 4

NABs, with appropriate assistance from EA, should ensure that national regulators are well informed about the purpose and function of the peer evaluation process.

Recommendation 5

NABs should ensure that their national regulators are informed of the outcome of their peer evaluation.

Note: According Regulation (EC) No 765/2008 Article 12 (3), the NAB shall regularly make information concerning the results of its peer evaluation publicly available.

3.1.3 Contacts across the range of product harmonization legislations

Replies from NABs suggested that communications between NABs and regulators are generally good and improving but, in some countries, are still patchy.

The good cooperation between national authorities and the NAB is in a number of countries due to the fact that the national legislation has assigned well-specified tasks to the national accreditation body, i.e. the cooperation is based on the national legislation. In other countries, the involvement of the NAB in the process is not regulated by legislation but built on confidence in the accreditation system and on the technical competence of the national accreditation body.

Confidence can be improved by nominating a specialist contact person for notified body issues and even for specific legislations. Where NABs do not have access to technical expertise relating to specific legislations, it might be possible to secure assistance from a NAB that does have this expertise.

The NLF supports and encourages EA and NABs to cooperate with national regulators at sectoral level and require regulators to give greater consideration to the use of accreditation where legislation requires conformity assessment.

However, it is important that NABs consider carefully the tasks to be transferred to them and the resources needed within NABs to manage the new activities and obligations. It will be critical that sufficient financial and technical resources are available for NABs otherwise they will not be able to manage the function as advisor for public authorities in technical issues and coordinate assessment of notified bodies.

Recommendation 6

NABs should develop good relationships with officials responsible for the implementation and operation of each of the product harmonisation legislations.

Recommendation 7

NABs should have a designated contact person for notified body issues and, depending on the size of the organisation, should have designated contact persons for each of the legislations or groups of legislations.

Recommendation 8

EA and NABs should develop some information material to help convince national regulators in specific sectors that accreditation can be relied upon. This information should draw on the work of EA for harmonization of the assessment process published in EA-2/17 “EA Document on Accreditation for Notification Purposes”.

3.2 Preparation of legislation

3.2.1 Involvement at an early stage

The use of accreditation and relationship with regulators will be strengthened by involvement at the earliest possible stage in the development of legislation. In some cases, NABs are consulted at the point that legislation is being negotiated by the Council and European Parliament. This gives NABs the opportunity to ensure that the legislation produced makes the appropriate references to the use of accreditation and that the national regulators make good use of accreditation in the implementation stage.

Involvement at the national implementation stage gives NABs opportunity to ensure that they have the relevant technical expertise to carry out the required functions and to reassure other interested partners that they have the capability to do so.

Recommendation 9

NABs should ensure that they have close cooperation with national authorities from the very beginning in the negotiation of draft legislation. The cooperation may be based on national legislation or national practice based on confidence in the accreditation system.

3.2.2 Role for EA to provide information on new proposals

To strengthen cooperation with national authorities, EA may have a role to play by informing NABs on new areas, where the use of accreditation is an option e.g. new legislations being developed. To deal with this task, EA could collect information from members and members could forward information to EA on new areas being discussed with national authorities or with the Commission. Collecting and distributing this information may be useful for members to have in designing and improving their communication with national authorities.

To ensure that the work of EA will have the effect that EA and the national NABs are involved at an early stage in drafting European legislation, EA members will need to be prepared to deal with situations where national authorities may have an approach to an assessment activity different from the approach taken by EA. EA members will need to be committed to convince national authorities of the advantages of using a harmonized approach to the assessment activities, otherwise confidence in the EA MLA may be at risk.

By improving communication with authorities and NABs being involved in discussion at the national level of the EU legislation, provisions in the legislation on assessment of technical competence may be better defined and adjusted to the accreditation concept and thereby improving the NABs ability to deliver the service needed in the specific field.

EA also has an important role in representing the interests of NABs to the Commission as new proposals are developed.

Recommendation 10

EA should provide information to member NABs relating to new legislative proposals developed at EU level that could have the potential to use accreditation.

Recommendation 11

NABs should provide to EA any information received about the development of new legislative proposals so that this information can be disseminated to EA members.

Recommendation 12

EA should communicate with the Commission as new legislative proposals are developed in order to secure a harmonized approach to the use of accreditation in EU legislation.

3.2.3 Technical guidelines

As required in the EU Regulation on accreditation technical guidelines will be developed to assist and guide the accreditation of notified bodies under the different legislations. It is considered to be extremely important for NABs to be involved in this process at European or national level. The objective must be for the technical guidelines to be consistent with general accreditation practice and understandable by all parties involved in the process.

Recommendation 13

EA should ensure that technical guidelines are developed in cooperation with the European Commission and the Member States, to aid the accreditation of notified bodies under the individual directives, consistent with general accreditation practice.

Recommendation 14

NABs should support national authorities in the preparation of technical guidelines to aid the accreditation of notified bodies under individual directives and should ensure consistency with general accreditation practice.

3.3 The assessment of conformity assessment bodies for notification

3.3.1 Involvement of NABs in the assessment process

The structure differs considerably across Member States regarding cooperation between national authorities and NABs during the assessment of applicants for notification, from NABs handling the assessment on its own to close involvement of national authorities in the assessment process.

In the majority of countries, the NAB has the role of assessing the technical competence of the applicant and based on the NABs decision on technical competence (accreditation certificate) the national authorities take the decision on notification and designation of the applicant.

In some countries, the NAB is given the task of assessing all aspects of an applicant's suitability for notification i.e. organisational and administrative aspects as well as technical competence.

In some cases, the national authorities carry out the assessment process themselves without reference to the NAB.

Variations in the procedure used occur across technical sectors as well as from country to country.

Recommendation 15

EA and NABs should work to ensure that assessment of the technical competence of applicants for notification should be based on accreditation.

Recommendation 16

The degree of involvement of the national authorities in monitoring/witnessing the process should be determined at the national level focusing on the need for national authorities to keep confidence in the work of the NAB.

EA may have a coordinating role to play in securing a harmonised approach by the NABs in their assessment activity within the technical field in question. The EA role may vary from drafting guidance documents to training of assessors and facilitating exchange of experience among the members.

3.3.2 Application

In some countries, applications for notification are made direct to the NAB, in others to the national authorities and some countries require applications to be sent to both the NAB and the national authority. The initial point of application is not considered to be important but it is important that the NAB and the national authorities are informed of applications received. This is so that any immediate problems can be discussed. For example, the national authorities could decide that they do not wish to appoint any more notified bodies in a particular sector and so any effort on the part of the NAB would be wasted. On the other hand, it could be that the NAB has information relating to the applicant of which the national authorities need to be aware.

Recommendation 17

Arrangements should be made so that NABs and national authorities have sight of all applications received. Any difficulties identified should be discussed and resolved by the NAB and the national authorities in co-operation.

3.3.3 Communication during the assessment process

In many cases, problems emerge during the course of the assessment process that cannot be resolved by the NAB alone. These could relate to issues such as technical competence, facilities, independence and impartiality. In these cases, NABs will need to have good channels of communication to be able to discuss and resolve these issues with the national authorities. It is good practice, in any case, to keep the national authorities informed of progress on assessments especially if they are likely to take some time to complete.

However, the exchange of some information on applicants or CABs may put a NAB into conflict with the confidentiality provisions in ISO/IEC 17011. To avoid this, NABs should consider asking for information from applicants if the accreditation is sought with the purpose to become notified body for a specific legislation. If this is the case, the NAB should ask for permission to transfer information on the applicant to the national authority responsible for notification process with the argument that transfer of information will facilitate the smooth and effective notification process.

Recommendation 18

NABs should keep in close contact with their national authorities during the assessment process to resolve any difficulties that arise and to keep the national authorities informed of progress.

Recommendation 19

NABs should consider if existing confidentiality arrangements are in conflict with the need to exchange information with public authorities on applicants and notified bodies and obtain acceptance from applicants and notified bodies to the transfer or exchange of information with the national authorities.

3.3.4 The appointment process

It is an established principle that, whatever the NABs involvement in the assessment process, it is the national authorities that make the final decision on designation and notification. In most countries where the NAB is involved, this decision is based upon an accreditation certificate issued by the NAB. In other countries, the decision is based on a 'letter of recommendation' that covers not only the technical accreditation issues but also the more general administrative and organisational requirements.

Recommendation 20

NABs should clearly communicate the results of the assessment process to the national authorities. The national authorities should make the final decision on designation and notification, taking into account the recommendations from the NAB.

3.4 Supervision of notified bodies

3.4.1 The assessment cycle

In the majority of countries, the supervision of notified bodies follows the assessment cycle for accredited bodies. In some countries NABs report to the national authorities the result of the assessment visit while in other countries reporting is only required if the accredited status of the notified body is changed. In any case, NABs needs to be able to communicate with the national authority if problems are identified with the notified body during the course of the assessments e.g. personnel or organisational changes that put into question the ability of the notified body to continue to meet the requirements. NABs will be able to resolve many of these questions themselves but arrangements need to be in place to discuss issues with the national authorities if necessary.

Recommendation 21

The goal for EA and the NABs should be to have surveillance intervals for notified bodies in line with the national rules for assessments of accredited bodies.

Recommendation 22

NABs should keep the national authorities informed of assessment visits carried out but at least report to the national authorities in case the accredited status of the notified body is changed.

Recommendation 23

NABs should discuss and resolve with the national authorities any difficulties that emerge during the assessment process that they cannot resolve themselves.

3.4.2 Exchange of information on latest guidelines, interpretation etc

Meetings between national authorities and the NABs are held with different intervals in the countries. In some countries there are regular meetings while in other countries meetings are only convened to solve problems and questions identified by the parties.

In any case, arrangements need to be made so that NABs are kept informed of the latest guidelines or interpretations issued at national or EU level.

Recommendation 24

NABs should ensure that arrangements are in place so that the national authorities keep them informed on the latest guidelines or interpretations issued at national or EU level.

3.4.3 National co-ordination meetings

In many countries it is the practice for the national authorities or the notified bodies themselves to organise meetings of notified bodies for a specific legislation in order to discuss issues of common interest. These can include questions of interpretation of the technical requirements, questions relating to the operation of the modules or even questions relating to the assessment of notified bodies. In some countries, NAB representatives attend these meetings and they are considered to be an effective way of keeping in contact with the national authorities and notified bodies and resolving any difficulties between the parties.

Recommendation 25

NABs should attend national co-ordination meetings of notified bodies where they are held and where they are permitted to do so.

3.4.4 European co-ordination meetings

Periodically, the European Commission organises co-ordination meetings for notified bodies for a specific legislation in order to discuss questions of interpretation and common practice. In order for NABs to have a good understanding of the way that notified bodies are expected to operate, it is considered to be useful for a representative of EA to attend these meetings and report back to NABs involved in the assessment of notified bodies for the specific legislation under discussion.

Recommendation 26

Representative(s) of EA should attend European notified body co-ordination meetings and should report back to NABs.