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Accreditation Body Communication With National Regulators Best Practice Guide

PURPOSE

Meeting the expectations of national regulators is an important function of EA accreditation body members. The EU Regulation on accreditation and market surveillance 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 accreditation bodies and the national authorities. This Best Practice Guide is intended to assist the EA and the EA accreditation body members in developing, maintaining or strengthening cooperation with the Regulators, at the European and national level.

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The text may be translated into other languages as required. The English language version remains the definitive version.

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1 INTRODUCTION

In June 2006, the European co-operation for Accreditation (EA) established a development project to coordinate and undertake work involved in readying EA for the proposed new role for accreditation in the framework of the European Commission's project for a new horizontal legislative approach to technical harmonization in Europe.

As part of this work, a project group (PG3) was established to consider how communication between accreditation bodies and national regulators could be improved, with the following objectives:

- Investigate the present processes in the Member States for communication between 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 accreditation bodies the effectiveness of their communications networks with regulators.

The Best Practice Guide was the first step in addressing these three objectives.

The Guide is intended to assist EA and the national accreditation bodies (ABs) in handling the obligations transferred to the European accreditation system in the EU Regulation on accreditation and market surveillance and the Decision on marketing of products.

The Regulation contains the principles and criteria for the structure and operation of accreditation bodies in the member states and applies to accreditation in both the voluntary and the regulated field. The Decision has reinforced the principle that accreditation is the preferred tool for the assessment of bodies carrying out conformity assessment under EU legislation.

Meeting these obligations will require close cooperation between EA and the Commission and ABs and the national authorities. The European accreditation system will need to take on the responsibility to strengthen the cooperation as close contacts with the authorities are essential for the successful handling of the tasks transferred to the European accreditation system.

It should further be underlined that variations from country to country in the level and structure of cooperation between national authorities and ABs 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 the Guide to propose a uniform system for cooperation to be implemented throughout Europe. The cooperation between national authorities and accreditation bodies 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. test or inspection reports. 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 accreditation bodies (ABs) is important to facilitate that the service delivered by the AB 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 ABs 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 national ABs and for activities performed by their accredited CABs. ABs should inform the national authorities of the purpose and operation of the EA MLA to ensure that authorities has confidence in the EA MLA and in reports and certificates issued under the MLA by accredited CABs.

Cooperation between national regulators and accreditation bodies 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 EU Commission, close cooperation is even more important between national authorities, ABs and the EU 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 ABs 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 assessment of notified bodies. A successful application of this approach in existing and future legislation will require close cooperation between national authorities and the ABs.

EA has completed two surveys – in 2008 and 2010 – to gain information on the actual level of cooperation between national authorities and the ABs. In countries, cooperation is very close during the entire process i.e. in the preparation/discussion of EU directives, 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

¹ Conformity assessment activities include: calibration, testing certification and inspection.

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

applicants to present an accreditation certificate to support their application for notification without any discussion with the AB about scope of accreditation for a CAB or other requirements. Indeed, in some cases the AB is not aware that accredited organisations are using their accreditations to support applications for notifications.

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

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 AB and the regulators is not always guaranteed. In many cases where accreditation is a legal requirement, regulators rely on accreditation certificates without any detailed communication with the AB.

The recommendations for best practice that follow focus primarily on communications between ABs and national authorities in relation to the appointment of notified bodies under the New Approach Directives. However, it is the Commission's intention that the new legislative 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 New Approach 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 ABs 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 an AB's interests to other parts of government and can often open doors that would otherwise remain closed to an AB.

One option for ABs, in order to provide a clearer structure to the overall co-operation 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 AB in assessing against the general requirements"

An Advisory Committee as proposed would serve three functions:

- Be the national co-ordination point between public authorities and the accreditation body. The AB 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 co-ordination 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 directives; notified bodies; economic operators; and the AB.

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

Recommendation 1

National accreditation bodies should ensure that they have a recognised 'sponsor' within Government and develop a strong relationship with the sponsoring ministry

Recommendation 2

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

Recommendation 3

EA and national accreditation bodies should develop some information material to help ABs 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

Responses from ABs clearly demonstrate that the confidence of regulators in the national AB is 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

National accreditation bodies, 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

National accreditation bodies should ensure that their national regulators are informed of the outcome of their peer evaluation.

3.1.3 Contacts across the range of New Approach Directives

Replies from ABs suggested that communications between ABs and regulators are generally good and improving but, in some countries, are still patchy. This is supported by the results of the surveys completed and several ABs have mentioned difficulties convincing the medical sector of the benefits of relying on accreditation.

The good cooperation between national authorities and the AB 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 co-operation is based on the national legislation. In other countries, the involvement of the national AB in the process is not regulated by legislation but built on confidence in the accreditation system and on the technical competence of the accreditation body.

Confidence can be improved by nominating a specialist contact person for notified body issues and even for specific directives. Where ABs do not have access to technical expertise relating to specific directives, it might be possible to secure assistance from an AB that does have this expertise. EA has established a network for directives with the purpose of dealing with specific technical issues and AB are encouraged to join and use the networks.

The New Legislative Framework supports and encourages EA and national ABs 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 ABs consider carefully the tasks to be transferred to them and the resources needed within ABs to manage the new activities and obligations. It will be critical that sufficient financial and technical resources are available for ABs otherwise they will not be able to manage the function as advisor for public authorities in technical issues and co-ordinate assessment of notified bodies.

Recommendation 6

ABs should develop good relationships with officials responsible for the implementation and operation of each of the New Approach Directives.

Recommendation 7

ABs 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 directives or groups of directives.

Recommendation 8

EA and national accreditation bodies 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 Guidance on the horizontal requirements conformity assessment bodies for notification purposes” and from the directives networks. EA should consider if certain sectors should be given priority to remove obstacles or problems identified during the survey on the use of accreditation.

3.2 Preparation of legislation

3.2.1 Involvement at an early stage

A number of ABs commented that the use of accreditation and relationship with regulators was strengthened by involvement at the earliest possible stage in the development of legislation. In some cases, ABs are consulted at the point that legislation is being negotiated by the Council and European Parliament. This gives ABs 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 ABs 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

National accreditation bodies 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 ABs on new areas, where the use of accreditation is an option eg new directives 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 ABs 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 ABs 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 ABs ability to deliver the service needed in the specific field.

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

Recommendation 10

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

Recommendation 11

National accreditation bodies 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 and Market surveillance technical guidelines will be developed to assist and guide the accreditation of notified bodies under the different directives. It is considered to be extremely important for ABs 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 co-operation 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

ABs 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 ABs in the assessment process

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

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

In some countries, the AB is given the task of assessing all aspects of an applicant's suitability for notification ie 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 AB.

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

Recommendation 15

EA and the national accreditation bodies 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 accreditation body.

EA may have a coordinating role to play in securing a harmonised approach by the national ABs 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 AB, in others to the national authorities and some countries require applications to be sent to both the AB and the national authority. The initial point of application is not considered to be important but it is important that the AB 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 AB would be wasted. On the other hand, it could be that the AB has information relating to the applicant of which the national authorities need to be aware.

Recommendation 17

Arrangements should be made so that ABs and national authorities have sight of all applications received. Any difficulties identified should be discussed and resolved by the AB 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 AB alone. These could relate to issues such as technical competence, facilities, independence and impartiality. In these cases, ABs 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 an AB into conflict with the confidentiality provisions in ISO/IEC 17011. To avoid this, ABs should consider asking for information from applicants if the accreditation is sought with the purpose to become notified body for a specific directive. If this is the case, the AB

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

ABs 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

ABs 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 ABs involvement in the assessment process, it is the national authorities that make the final decision on designation and notification. In most countries where the AB is involved, this decision is based upon an accreditation certificate issued by the AB. 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

ABs 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 AB.

3.4 Supervision of notified bodies

3.4.1 The surveillance cycle

In the majority of countries, the supervision of notified bodies follows the surveillance cycle for accredited bodies. In some countries ABs report to the national authorities the result of the surveillance visit while in other countries reporting is only required if the accredited status of the notified body is changed. In any case, ABs needs to be able to communicate with the national authority if problems are identified with the notified body during the course of the surveillance eg personnel or organisational changes that put into question the ability of the notified body to continue to meet the requirements. ABs 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 national ABs should be to have surveillance intervals for notified bodies in line with the national rules for surveillance of accredited bodies.

Recommendation 22

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

Recommendation 23

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

3.4.2 Exchange of information re latest guidelines, interpretation etc

Meetings between national authorities and the ABs 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 ABs are kept informed of the latest guidelines or interpretations issued at national or EU level.

Recommendation 24

ABs 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 directive 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, AB 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

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

3.4.4 European co-ordination meetings

Periodically, the European Commission organises co-ordination meetings for notified bodies for a specific directive in order to discuss questions of interpretation and common practice. In order for ABs 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 or a member AB to attend these meetings and report back to other

ABs involved in the assessment of notified bodies for the specific directive under discussion.

Recommendation 26

Representatives of ABs should attend European notified body co-ordination meetings and should report back to other ABs.