

Guidelines for designating and monitoring notified bodies in Norway

The Ministry of Trade and Industry has also prepared a Norwegian version of these guidelines. Questions may be directed to postmottak@nhd.dep.no or see www.nhd.no for further information.

1. BACKGROUND

For a number of products the directives included in Annexes to the EEA Agreement require an independent third party, a notified body, to consider whether the product conforms with the basic safety and health requirements in the relevant product regulations. Responsibility for notification of competent bodies is vested with the competent ministry that has the main responsibility for implementing the relevant regulations. This will usually be the competent ministry that exercises the legal authority for the product regulations. If two ministries share responsibility for an area, they must have an agreement on a clear division of responsibility. The competent ministry is also responsible for monitoring the notified bodies under its remit. The bodies that are notified must be established in Norway.

Act No. 20 of 16 June 1994 concerning notified bodies whose task is to carry out conformity assessments (hereinafter the NB Act), provides legal authority to notify enterprises, public bodies and others as notified bodies. The Act also lays down a common framework for the notified body system in Norway. The Act is administered by the Ministry of Trade and Industry (NHD). The NB Act will be supplemented by regulations in each product area. The product regulations specify the functions the notified bodies shall have and sets qualifications required of the notified bodies. The Act concerning notified bodies regulates the relationship between the notifying authority and notified body.

To contribute to the consistent application of the act, NHD has developed these guidelines in addition to proposals for notification letters and certificates in English for designated notified bodies.

Other useful interpretation documents in connection with the implementation of the system of notified bodies are:

- *Decision No 768/2008/EC on a common framework for the marketing of products,*

- The European Commission's (the Commission's) Guide to the implementation of directives based on the New Approach and the Global Approach (also known as the “Blue Guide”)¹,
- Preparatory works for the NB Act, Proposition No. 47 (1993-1994) to the Odelsting, and
- Commission document “Commission communication in the framework of the implementation of the Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision 768/2008/EC of the European Parliament and of the Council, Regulation (EC) No 761/2001 of the European Parliament and of the Council (*Publication of titles and references of harmonised standards*) (2009/C 136/08)”².

2. APPLICATION

Institutions seeking notification as a notified body shall submit an application to notifying authorities in the country where they are established.

Authorities with responsibility for designating NBs (competent authorities), have a general duty to provide guidance to institutions that are considering applying for notification as a notified body. The competent authority shall provide information on current legislation and what requirements will be made of notified bodies, including requirements for documentation of competence. The notifying authority should also disclose that the Commission's NANDO database³ contains a list of NBs in the EEA. However, it is up to the individual institution to consider whether it wishes to use resources to be a notified body. Institutions seeking notification as a notified body shall submit a written application to the competent authority. The application must contain documentation that they meet the requirements the authorities make of the notified body.

3. REQUIREMENTS OF NOTIFIED BODIES

Requirements of notified bodies are listed in the product regulations in each area and by the NB Act. Competent authorities may impose additional requirements to the degree it is in accordance with the regulations and it is expedient in relation to the competence of the notified bodies or supervision of the notified bodies (cf. Proposition No. 47 (1993-1994) to the Odelsting, Chapter 3.7). The competent authority shall inform the applicants concerned about these additional requirements.

The requirements of notified bodies may vary from product to product, but the follow-

¹ See <http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/>

² See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:136:0029:0030:EN:PDF>

³ New Approach Notified and Designated Organisations Information System, see <http://ec.europa.eu/enterprise/newapproach/nando>

ing requirements are valid in most regulatory areas:

- The notified body shall be *independent* in relation to its customers and other involved parties. Under the New Approach directives the notified body shall ensure that the salaries of employees do not depend on the number of tests or their result. Staff are subject to the disqualification rules in the Public Administration Act. The notified body may take on assignments from the market surveillance authorities, but shall not carry out conformity assessments of products it itself has previously assessed (cf. Proposition No. 47 (1993-1994) to the Odelsting, Chapter 3.5).
- The notified body shall have the necessary staff and equipment available. In addition, it should have the technical *competence* necessary to perform the tasks arising from the relevant product regulations it is notified to certify. Under the New Approach directives the notified body must meet the minimum requirements laid down for designating notified bodies. The notified body must document that it has the necessary competence.
- The notified body shall participate in, or ensure that staff who carry out conformity assessments are informed about relevant standardisation activities. Section 6.3 of the Commission's "Blue Guide" states that notified bodies shall take part directly or be represented in European standardisation, or otherwise ensure that they know the situation of relevant standards.
- The notified body shall be *insured* to cover the conformity assessments it carries out. The state is its own insurer for activities of notified bodies that are directly under the central government, cf. Proposition No. 47 (1993-1994) to the Odelsting, Chapter 3.6.

Section 5 of the NB Act states that a notified body can take normal payment for conformity assessments. This means that the notified body may charge for its conformity assessments on a commercial basis, see special notes to Section 5 of Proposition No. 47 (1993-1994) to the Odelsting.

4. DOCUMENTATION OF COMPETENCE

4.1 Introduction

Pursuant to Section 2 of the NB Act a condition for notification is that the applicant may prove that it has satisfactory competence. This means that applicants must have a satisfactory quality management system. According to Decision 768/2008/EC⁴ applicants

⁴ Decision 768/2008/EC contains reference rules for future harmonised rules on the product. These reference rules shall be evaluated when new rules are prepared. The reason for any other rules that are proposed shall be explained.

shall be considered competent if they meet the requirements of the relevant product regulations. If notification is not made on the basis of accreditation, the notifying authority shall submit documentation of the competence of the notified body and the arrangements that will ensure the supervision of the body and that it still meets the requirements applicable for notification.

To ensure confidence in the Norwegian notified bodies, it is desirable that the Norwegian notified body not only prove that it is competent, but also verify its competence as soon as practically possible by accreditation (cf. Proposition No. 47 to the Odelsting, Chapter 3.6). The Ministry notes that accreditation is not mandatory and that competence may be documented in other ways. Although accreditation is voluntary, the notifying authority may in some cases find it appropriate to require accreditation, e.g. if it would be unreasonably costly to establish competence in other ways.

4.2 Accreditation carried out by Norwegian Accreditation

Applicants who approach the notifying authority should be made aware that Norwegian Accreditation is the body in Norway that conducts accreditation. If the applicant is already accredited for the area applied for, such accreditation can support the application. Norwegian Accreditation has application forms for accreditation and other information about accreditation schemes. This can also be downloaded from: www.akkreditert.no.

If the applicant meets the accreditation requirements, Norwegian Accreditation will issue an accreditation certificate and accreditation documents to the applicant. When applying for notification as a notified body, the Norwegian accreditation documents shall provide sufficient documentation of professional competence according to regulatory requirements. Further documentation of competence may still be requested as needed.

5. NOTIFICATION OF NOTIFIED BODIES

Reference is made to Proposition No. 47 (1993-1994) to the Odelsting, Chapter 3.6 regarding requirements of notified bodies and Chapter 3.7 for notification of notified bodies.

The notifying authority is responsible for ensuring that the notified bodies that are designated meet the competency requirements in the regulations. It must be documented to the EFTA Surveillance Authority (ESA) or the EFTA Court that Norwegian notified bodies meet the requirements. Inadequate documentation therefore provides sufficient basis for refusing applications for notification as a notified body.

A time-limited notification may be appropriate in some cases. The individual notifying authority is free to set such a time limitation upon notification. Even if the notification has taken place without time limitation, the notifying authority will in any case be able to request documentation on the competence of an NB at any given time.

If the applicant can demonstrate that it meets the requirements for notified bodies the notifying authorities shall grant the application without undue delay and send notification of designation to NHD:

Ministry of Trade and Industry
Economic Policy Department, EEA and Internal Market Affairs
P.O. Box 8014 Dep.
0030 OSLO
E-mail: postmottak@nhd.dep.no.

The notified body is now formally designated in Norway. For the notification to have legal effect throughout the European Economic Area the notification must also be reported to the Commission.

Based on the information in the notification letter and a special form (attached), NHD enters the information into the Commission's NANDO database. The information then goes to the Commission which checks to see that everything is filled in correctly. The Commission then publishes the information and an automatic e-mail is sent saying that the change has taken place. NHD may send forms and detailed information about notification procedures, or it can be downloaded from NHD's homepage. The notified body is formally registered as of the date NHD sends the information to the Commission. NHD then sends a letter back to the notifying authority that the information is publicly available in NANDO.

Formal notification of notified bodies is to be understood as an individual decision under the Public Administration Act. It is therefore necessary to give notice of the decision with a briefing on the rights and obligations arising from notification as a notified body. NHD has prepared proposals for the wording of the decision letter (attached).

We propose that the decision letter provide the designated notified body a briefing on:

- The basis for the decision
- Requirements concerning competence and activities
- Obligations to authorities
- Inspection procedures
- Circumstances that may lead to withdrawal of status as a notified body
- If the notification is time-limited: How long it is valid.

NHD can send an electronic version of the notification letter, which can also be downloaded from NHD's homepage www.nhd.no.

Applicants may appeal the decision on notification to the notifying authority. It follows from the Public Administration Act that the decision may be appealed to a superior authority.

Lists of notified bodies in the EEA are published in the Official Journal of the European Union (Official Journal). In addition, this information may be found in the Commission's

NANDO database⁵.

Nevertheless, a need has arisen for confirmation that the Norwegian notified bodies have been formally designated. NHD has therefore prepared the attached certificate in English that notifying authorities are encouraged to provide to designated notified bodies. NHD can send an electronic version of the certificate, which can also be downloaded from: www.nhd.no.

6. MONITORING AND INSPECTION

6.1 Background

The competent ministry shall ensure that the notified body is competent to perform the tasks it has been designated to carry out. It is up to each competent ministry to decide how to conduct its supervision, but the ministry should have access to the information that is necessary for it to be able to perform its supervisory tasks, cf. Section 3 of the Act concerning notified bodies.

6.2 Key reporting points

As a main rule the notification letter shall lay down requirements for annual reporting on activities to the notifying authority by the 1st quarter. The following reporting points should be adapted and supplemented if necessary in relation to the requirements of the product regulations:

- The report should contain a list of conformity assessment applications that have been received and processed.
- It should be clear from the report what types of tasks have been performed by the notified body, document storage, type examination, type approval, etc.
- An overview of any refusals of applications for certificates of conformity, appeals, and any withdrawals of certificates of conformity.
- The report should explain what has been done to maintain satisfactory competence in the body's own field.
- Private notified bodies must prove that they carry adequate liability insurance.

6.2 Reporting on significant and relevant circumstances

All significant and relevant circumstances must be promptly reported to the notifying authority. Besides agreements entered into with subcontractors, relevant circumstances may be significant changes in the notified body's organisation or competence. In some regulatory areas there are also special requirements concerning, e.g., continu-

⁵ See: ec.europa.eu/enterprise/newapproach/nando/

ous reporting to the authorities and the Commission on the rationale for refusal or withdrawal of a certificate of conformity. These requirements must be listed in the notification letter.

The notified body is expected to be competent to perform the tasks for which it has been designated. Even so it may be unclear how the current regulations are to be interpreted. Technical issues can be clarified between the notified bodies, but the interpretation of the regulations is a task for the authorities and ultimately a task for the EFTA Court. There may therefore be a need for some guidance and follow-up at a professional level by the authorities, initially by the agencies.

Notified bodies shall normally not conduct market surveillance, cf. also the Commission's "Blue Guide", section 8.1 (cf. also section 6.3) which states that notified bodies should, basically, be excluded from the responsibility of market surveillance activities. There may still be a need for the NB to carry out tasks in individual cases. This should in any case be made clear in the notification letter, cf. section 4.3. Furthermore, there should be a general reporting requirement in cases where the NB learns of circumstances that are relevant to market surveillance activities of the competent authorities.

7. ACCREDITATION AS DOCUMENTATION OF PROFESSIONAL COMPETENCE

The notifying authority shall supervise the notified bodies. If the notified bodies are accredited or evaluated by Norwegian Accreditation this process will be simplified since regular follow-up has already been established by Norwegian Accreditation. In connection with annual reports from notified bodies to notifying authorities, the result from Norwegian Accreditation's follow-up is satisfactory documentation of the professional competence of the notified body. In that case the notifying authority may limit its supervision to matters that are not covered by accreditation.

Any desire by the notifying authority to have Norwegian Accreditation examine special conditions not covered by accreditation must be clarified as a special task between the two parties.

8. UNSATISFACTORY CONDITIONS

8.1. Background

Section 4 of the Act concerning notified bodies states that if the notified body does not meet the requirements of the respective product regulations or other requirements laid down upon notification, orders for remedial action by a deadline may be issued or its status as a notified body may be withdrawn. A decision on withdrawal of status as a notified body may be appealed in the usual manner to the superior authority (see paragraph 4 above).

For example, the notifying authority may learn about unsatisfactory conditions during the inspection conducted by the authorities of the activities of the notified body or complaints from the parties involved. It may also learn of this through market inspections of products that have been assessed by the notified body. It would also be unsatisfactory if the notified body has not had sufficient assignments to maintain professional competence.

8.2. Consequences in relation to the accreditation of the notified bodies

Notified bodies shall immediately notify the notifying authorities about significant changes in their competence. This means, for example, that if an accredited notified body's accreditation is suspended or withdrawn, the body shall immediately inform the notifying authority about this. In the event of a withdrawal of accreditation, the notifying authority shall reconsider the notification.

If unsatisfactory conditions are uncovered during monitoring of an assessed notified body that is not accredited, the body shall also promptly notify the notifying authority about this.

If the notifying authorities uncover identifying unsatisfactory conditions at a notified body accredited or evaluated by Norwegian Accreditation, the authorities shall inform Norwegian Accreditation about the situation and the measures that are initiated. Norwegian Accreditation will decide whether there are grounds for a notice of suspension and, ultimately, whether there are grounds to withdraw the accreditation, alternatively, to recommend measures to the notified body that has been assessed.

9. VOLUNTARY TERMINATION OF STATUS AS NOTIFIED BODY

A body that no longer wants to have a status as a notified body shall inform the notifying authority about this. In consultation with the Ministry of Trade and Industry the notifying authority will be able to provide further information about the practical effects of this. It will have to be evaluated from case to case whether for the sake of the validity of the conformity assessments already carried out, the notified body in question must remain listed in NANDO even after the notification is withdrawn.

10. VALIDITY

NHD will revise these guidelines as needed. Notifying authorities are therefore requested to provide continuous feedback on their experience with the NB Act and input if they see a need for further clarification in notification letters and guidelines.