

MINISTRY OF TRADE AND INDUSTRY

Proposals for design of decision and information letter after designation of notified body

Version 13 December 2010

Relevant text replaces the text in square brackets. We have used the following abbreviations:

NN = Notifying Authority and XX = Notified Body.

Questions about the Act concerning notified bodies may be directed to the Ministry of Trade and Industry Ministry at postmottak@nhd.dep.no or see information posted on nhd.no.

There is also a Norwegian version of this letter template.

[Letter template of the notifying authority]

DECISION ON NOTIFICATION OF [XX] AS A NOTIFIED BODY

Pursuant to Act No. 20 of 16 June 1994 concerning notified bodies whose task is to carry out conformity assessments (Act concerning notified bodies) and acts/regulations concerning [the relevant Norwegian product regulations], [NN] has decided to designate [XX] as a notified body under Directive No. [.../...../ EU] on [.....]. We refer to the enclosed notification to the other Member States parties of formal notification of [XX] as a notified body. The notice gives further information about the functions [XX] is designated to perform. [Notification applies until [specified date]].

1. TECHNICAL TASKS ASSIGNED TO [XX]

[XX should receive accurate information about the tasks XX is designated to perform. This should include reference to the relevant Norwegian regulations. The regulations can be attached to the notification letter, which should also contain a web link to the regulations and a reference to the Commission's NANDO database.]

2. REQUIREMENTS FOR ACTIVITIES PURSUANT TO THE PUBLIC ADMINISTRATION ACT

Pursuant to the Act concerning notified bodies, the activities of the notified body are subject to the Act of 10 February 1967 relating to procedure in cases concerning the public administration (Public Administration Act), Chapter II - VI when performing conformity assessments. The other rules in the Public Administration Act will also apply in cases where individual decisions are made, cf. Section 1 of the Public Administration Act.

Some of the most important rules are presented below.

2.1. Impartiality

An individual executive officer [XX] must not handle cases where the person in question is considered disqualified under Section 6 of the Public Administration Act. The individual must assess their own impartiality.

2.2. Access and duty of confidentiality

Act No. 16 of 19 May 2006 relating to public access to documents in the public administration (Freedom of Information Act) is a document that relates to individual decisions even if the decision is made by a legal entity other than a public authority, cf. Section 2, first paragraph, litra b. Staff are nonetheless obliged to prevent others from gaining knowledge about what they learn about technical facilities and procedures in connection with their work. The confidentiality obligation does not prevent the information from being made known to other relevant parties, including the notifying authority. See also Section 13 et seq. of the Public Administration Act.

2.3. Duty to provide guidance

Under Section 11 of the Public Administration Act notified bodies have a general duty to provide guidance. For instance, through its guidance the technical body shall point out any defects and deficiencies in the product so that the manufacturer can bring the product into compliance with regulatory requirements. The manufacturer is responsible for finding the specific technical solutions.

2.4. Justification of refusal

If the notified body has found deficiencies in the product and these are not satisfactorily remedied, the body shall refuse the application for a certificate of conformity. The manufacturer shall be notified of the refusal. At the same time, the manufacturer shall receive a written justification for the decision and information about the appeals process and how he can get access to documents in the case. Information shall also be provided that the manufacturer may not apply for a certificate of conformity from another notified body unless the product has been modified in the meantime.

2.5. Appeal of any refusal

Any appeal of the decision of the notified body must be sent to the body no later than three weeks after the manufacturer received notification of the decision. The notified body shall perform the examinations arising from the appeal and may revoke or modify the decision. The notified body may also reject the appeal if the conditions for handling it are not met. If no decision is taken the documents in the case shall be sent to an appeals body. Any appeals will be finally decided by the administrative agency that is the closest superior notified body, or special appeals body where it exists. See also Chapter VI of the Public Administration Act.

2.6. Costs

Pursuant to Section 5 of the Act concerning notified bodies, the notified body may charge regular prices for its services. This means that the notified body may charge for its conformity assessments on a commercial basis.

3. OTHER REQUIREMENTS RELATING TO ACTIVITIES

3.1. Independence

It must be ensured that the staff who will be conducting the assessment of conformity are completely independent in relation to their customers and other involved parties. The notified body under the New Approach directives shall ensure that the salary of individual staff members does not depend on the number of tests that are performed or the results of tests. Impartiality rules in the Public Administration Act provide further guidelines for how to ensure that the assessments of conformity are performed in an impartial manner.

As the competent body [XX] can take on assignments from [the authority in charge of market surveillance]. To avoid problematic dual roles, [XX] should normally not assess products it has previously assessed. However, it is up to the authority in charge of market surveillance to assess whether [XX] can perform such assignments in a satisfactory manner in special cases.

3.2. Requirements of subcontractors and subsidiaries:

[XX] is fully responsible for the tasks [XX] is designated to carry out even if parts of them are performed by subcontractors or subsidiaries.

When carrying out inspection tasks, [XX] may by agreement with the client use subcontractors or subsidiaries to perform tasks of a technical nature where the procedures are clearly defined (e.g. testing or certification of quality management system). However, it is only [XX] which may make discretionary assessments or establish procedures for conformity assessments where harmonised standards do not exist.

In cases where [XX] uses subcontractors or subsidiaries, agreements shall be signed with them that the subcontractor or subsidiary shall comply with the same requirements as [XX] concerning its activities. This applies also in relation to independence and competence. The standards and procedures the subcontractor or subsidiary will use shall be clearly defined.

If these conditions are met, there are no obstacles to using subcontractors or subsidiaries in other countries.

3.3. Assessment of conformity without harmonised standard

In the event of an assessment of conformity where there are no harmonised standards, [XX] shall ensure the development of an appropriate testing program and an appropri-

ate reporting form to assess conformity with the basic safety requirements in the relevant directive.

3.4. Standardisation

Technical bodies must consider whether the products satisfy the general safety and health requirements in the product regulations, operationalised by harmonised standards or other satisfactory specification. In order to carry out a satisfactory assessment, [XX] is required to be involved in European standardisation work with direct relevance to its own area of work¹. This means that the notified body shall take part directly or be represented in European standardisation, or otherwise ensure that they know the situation of relevant standards.

3.5. Issuing certificates of conformity

The certificate of conformity shall be issued in Norwegian unless the product regulations or other considerations suggest the use of other languages².

3.6. Cooperation with other notified bodies

[XX] is obliged to cooperate with other notified bodies to ensure uniform application and common understanding of the regulations. [XX] shall cover the costs of this cooperation.

3.7. Liability

[XX] shall carry liability insurance to cover the conformity assessments it carries out. [The state is its own insurer for the activities of notified bodies that are directly under the central government.]

4. DUTIES VIS-À-VIS NOTIFYING AUTHORITY

4.1. Reporting requirements

[XX] shall submit an annual report to [NN] by the end of the 1st quarter of the following year. The report shall review all aspects of operations that may be relevant to the authorities' supervision of the activities and competence of the notified body. The body shall specifically address what it has done to maintain satisfactory competence in its own field.

The report shall contain a list of conformity assessment applications that have been received and processed. The types of tasks performed by the notified body shall be described. The report shall include an overview of any appeals and refusals of applications for certificates, and any withdrawal of certificates. It shall also provide a briefing about any changes in [XX]'s competence. [Private notified bodies must submit evidence that

¹ Through its special competence, notified bodies have much to add to standardisation work. Participation in standardisation work also provides early information about new standards, knowledge of test methods, etc. which are necessary in inspection work. It simultaneously provides an opportunity to meet potential buyers of services from the notified body.

² Must be adapted to the Norwegian regulatory requirements.

they carry adequate liability insurance.]

[XX] shall immediately report circumstances that are material to notifying authorities. There shall be continuous reporting about³:

- Refusal of an application for a certificate.
- Restriction, suspension or withdrawal of a certificate⁴.
- Any circumstances affecting the scope of and conditions for notification.
- Any request for information which they have received from market surveillance authorities regarding conformity assessment activities.
- On request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

Notified bodies shall provide the other bodies notified under the same rules carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4.2. Storage of documentation

Certificates of conformity with technical attachments shall be kept in accordance with the requirements of [the relevant product regulations - specific reference to the relevant regulations must be entered here] and as a rule for 10 years⁵. Upon request, the documentation should be put at the disposal of [NN] and the designated appeals body. Upon request, relevant documents showing the notified body's assessment of the qualifications of the subcontractor or subsidiary, and documents related to tasks performed by subcontractors or subsidiaries shall be made available to the notifying authority.

4.3. Market surveillance⁶

Under paragraph 3.1 above, tasks in connection with public market surveillance are discussed. Public market surveillance shall ensure that regulatory requirements are met by all involved actors, including manufacturer, notified body, importers and dealers. [XX] is encouraged to inform the authority in charge of market surveillance if, in connection with its activities, it discovers violations of product regulations, such as improper use of the CE marking.

4.4. Providing support to the authorities in professional issues

Within its field and based on its experience [XX] shall support the authorities in issues related to the development and implementation of the regulations.

³ This overview must be in accordance with the specific information requirements of the relevant product regulations.

⁴ Some directives require reporting to Member States and the Commission or EFTA Surveillance Authority (ESA) with the reason for the refusal or withdrawal of the certificate of conformity. In other areas it must be assessed whether such reporting is appropriate in light of the appeals scheme and annual reporting.

⁵ The text must be adapted to the specific requirements of the regulations.

⁶ The section may be removed if it does not apply.

5. INSPECTION AND WITHDRAWAL

5.1. Controls

The authorities shall ensure that the notified body is competent to perform the tasks it has been designated to carry out. The notifying authority can inspect the activities of the body directly and through access to reports from the notified body. See also paragraph 4 on duties vis-à-vis notifying authority.

5.2. Withdrawal

If [XX] does not meet the requirements of [specific reference to the relevant product regulations] or other requirements imposed on [XX], [NN] may pursuant to Section 4 of the Act concerning notified bodies, issue remedial orders by a specified deadline or withdraw the body's status as a notified body. In other words [NN] will reconsider the notification on the basis of serious violations of procedural rules, unsatisfactory development of competence or deficient reporting to the authorities. Complaints from involved parties and the EFTA Surveillance Authority (ESA) can likewise provide a basis for reconsideration of the notification.

5.2. Voluntary termination of status as a notified body

[XX] shall inform [NN] should [XX] no longer desire its status as a notified body. In consultation with the Ministry of Industry and Trade [NN] 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, [XX] must remain listed in NANDO even after the notification is withdrawn.

6. OBLIGATIONS OF THE NOTIFYING AUTHORITIES

[NN] shall notify [XX] of changes in the technical regulations related to its activities as a notified body. However, it is the responsibility of [XX] to keep up to date in relation to the guidance document, technical standards and other documentation relevant to its work.

[NN] shall assist in the interpretation of the technical regulations.

[NN] shall distribute information about other notified bodies in the field and contribute to the establishment of contact between the notified bodies.

Sincerely

[Signature by authority]

[Countersignature]

Cc: Ministry of Trade and Industry
C/O Economic Policy Department, EEA and Internal Market Affairs

Distribution:

Ministry of Children, Equality and Social Inclusion,
C/O Department of Consumer Affairs

Ministry of Health and Care Services
C/O Administration Department

Ministry of Justice and the Police
C/O Legislation Department

Ministry of Justice and the Police
C/O Rescue and Emergency Planning Department

Ministry of Local Government and Regional Development
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Ministry of Transport and Communications
C/O Department of Civil Aviation, Postal Services and Telecommunications

Ministry of Transport and Communications
C/O Department of Public Roads and Rail Transport

Cc:

Confederation of Norwegian Enterprise
Innovation Norway, C/O Enterprise Europe Network
Norwegian Accreditation
The Norwegian Electrotechnical Committee
Standards Norway