P008

Designation of notified bodies within the framework of the 'New Approach' Directives

Amendments: Full document review

South Lane Tower I
1, avenue du Swing
L-4367 Belvaux
Tél.: (+352) 2477 4360
Fax: (+352) 2479 4360
olas@ilnas.etat.lu
www.portail-qualite.lu

Checked by Monique Jacoby

Approved by Dominique Ferrand

1. Aim

The aim of this procedure is to set the rules for conformity assessment bodies with regard to obtaining, maintaining or amending (restriction, suspension or withdrawal) a notification within the framework of the 'New Approach' Directives and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products. It also sets out the rules to be applied should certain modules be subcontracted.

2. Introduction

In order to guarantee a high level of safety for industrial products placed on the market or made available on the market, and to facilitate free movement thereof, the Commission adopted a legislative technique with regard to standardisation in 1985, known as the 'New Approach' (Council Resolution of 7 May 1985 – OJEC No C 136 of 4.6.1985). These directives set out the essential requirements in terms of safety, health, environment and consumer protection.

The 'New Approach' Directives define the products which must comply with these essential requirements to obtain CE marking, a mandatory requirement in order for them to be placed on the European market.

For a certain number of these products, the conformity assessment procedures prescribed by Community legislation require the involvement of conformity assessment bodies (CABs). In order to be authorised to carry out said conformity assessment procedures, these CABs must first be notified to the European Commission and the other Member States.

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 stipulates that the Member States must designate a notifying authority to assume responsibility for setting up and carrying out the necessary procedures for the assessment and notification of CABs and monitoring of notified bodies. This decision also states that these tasks may be delegated to the national accreditation body.

Article 7 of the law of the 4th July 2014 on the reorganisation of ILNAS appoints OLAS as the notifying authority within the framework of the Luxembourgish legislation transposing European Union harmonisation legislation.

3. Definitions

The definitions given hereafter are from the law of the 4th July 2014 and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008.

Conformity assessment

Process demonstrating whether specified requirements relating to a product, process, system, person or body have been fulfilled.

Notified body

Body appointed by a Member State to carry out third-party conformity assessment tasks within the framework of the European Union harmonisation legislation on product marketing.

Notifying authority

OLAS is the notifying authority within the framework of the Luxembourgish legislation transposing European Union harmonisation legislation.

Notification of bodies

Procedure whereby the European Commission and the other Member States of the European Union are informed of the designation OLAS of a body which fulfils the conditions laid down in the European harmonization legislation for carrying out assessment of conformity with the requirements set out in said directives.

Harmonised standards

A standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC.

CE marking

Marking by which the manufacturer indicates that the product conforms to the applicable requirements set out in Community harmonisation legislation providing for its affixing.

Placing on the market

The first time a product is made available on the Community market.

4. Notification procedure

4.1 General requirements for all notifications

In accordance with article 7 of the law of the 4th July 2014, any CAB applying for notification shall be established in Luxembourg, shall have legal personality and shall be accredited in the legal matter for which the notification is requested.

In order to be notified, the CAB shall offer the necessary guarantees of professional qualification, integrity, independence and confidentiality which are evaluated in the context of accreditation granted on the basis of national and European legislation in force, referring to:

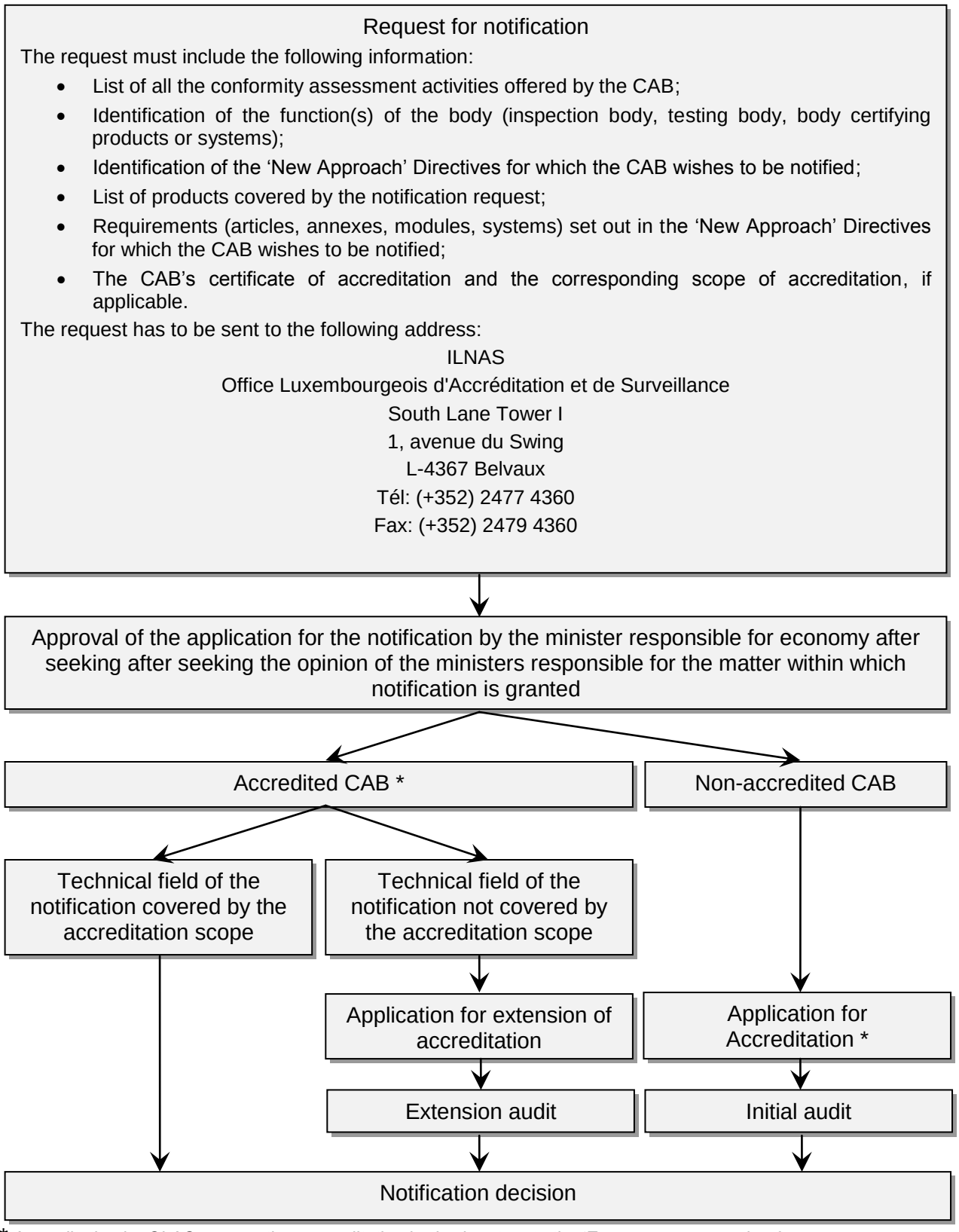
- National, European and international standards and other normative documents applicable as regards accreditation and any other document from European and international departments and bodies active in the accreditation field;
- Minimum requirements set out in the 'New Approach' Directives.

Accreditation is also necessary for all CABs notified prior to 1 June 2008, date of entry into force of the law of 20 May 2008 on the creation of a Luxembourg Institute for standardisation, accreditation, safety and quality of products and services abrogated by the law of the 4th July 2014 on the reorganisation of ILNAS.

Notification may only be granted for the fields listed in the scope of accreditation of the certificate of accreditation.

NB : Before launching the notification procedure, each application has to be approved by the minister responsible for economy after seeking the opinion of the ministers responsible for the matter within which notification is granted. Accreditation in itself does not therefore guarantee a favourable notification decision.

4.2 Notification process



* Accreditation by OLAS or any other accreditation body signatory to the 'European co-operation for Accreditation' mutual recognition agreements if OLAS is not capable of proceeding with the accreditation.

For notification under directive 90/385/EEC on active implantable medical devices and directive 93/42/EEC on medical devices, the CAB shall use the form provided in annex II of the regulation (UE) n°920/2013 for its notification request.
Please find hereafter some examples from the NANDO information database (http://ec.europa.eu/enterprise/newapproach/nando/) which will give you a better understanding of how to complete your application:

88/378/EEC Safety of Toys

Products	Procedures	Articles/annexes
Toys referred to in Article 1	EC-type examination	Art. 10

95/16/EC Lifts:

Products	Procedures	Articles/annexes
Lift	Final inspection	Annex VI

96/98/EC Marine equipment:

Products	Procedures	Articles/annexes
Fire protection	Production quality assurance	Art. 10.1 (i) (b), Annex B - Module D

89/106/EEC Construction products:

Decision	Product family, product/planned usage	Conformity certification system	Harmonised technical specification	Function of the body
96/577/EC	Fire alarms/fire detection equipment, fixed firefighting equipment, products for firefighting and smoke control and explosion protection products (1/1): • smoke, heat and flame detectors (fire protection)	System 1	EN 54-10:2002 EN 54-10:2002/A1:2005 EN 54-5:2000/A1:2002 EN 54-7:2000/A1:2002 EN 54-7:2000/A2:2006	Testing laboratory

For Regulation (EU) No 305/2011 – Construction products, the information to be supplied is quite different from that for the other directives. Please consult the NANDO database for a better understanding.

5. Amendments to an existing notification (Article R25 – Decision 768/2008/EC):

Should it be ascertained (following an audit or through information provided by the body itself) that a notified body no longer meets the requirements or is failing to fulfil the obligations which led to it being notified, the notification may be restricted, suspended or withdrawn, as appropriate.

In the event of restriction, suspension or withdrawal of notification or where the notified body partially or entirely ceases its activities, it must inform its customers thereof so that they may seek another notified body to take over the processing of their file.

The files concerned must be made available to OLAS or to the competent market surveillance authorities on request.

6. Rules applying to subcontracting of a module

A notified body may subcontract all or part of a module of a 'New Approach' Directive to a subcontractor (or subsidiary) on condition that the latter is accredited for the tasks being assigned to it or meets the requirements in Article R17 of Decision 768/2008/EC (the relevant documents proving said compliance must be made available to OLAS during the accreditation audit).

However, in order for subcontracting to be accepted, the notified body (or body applying for notification) must first be in possession of at least one of the following accreditations:

- accreditation in accordance with standard ISO/CEI 17020 to cover all or part of the conformity inspections carried out on the equipment in question and/or,
- accreditation in accordance with standard EN 45011 or ISO/CEI 17065 to cover the conformity assessment procedure relating to the 'EC' type examination for the products concerned and/or,
- accreditation in accordance with standard ISO/CEI 17025 to cover all or part of the tests carried out on the products in question.
- accreditation in accordance with standard ISO/CEI 17021 to cover all or part of the assessment of quality assurance systems applied to the products or to production and/or,

Should a notified body call upon the services of a subcontractor (or a subsidiary), it must inform OLAS thereof.

Before having any conformity assessment activities carried out by a subcontractor (or a subsidiary), the notified body must first request the agreement of the customer.

The notified body shall be entirely responsible for the tasks carried out by a subcontractor (or a subsidiary). In this regard, it must have qualified internal staff who are able to interpret the results provided by the subcontractor (or subsidiary).

A body cannot be notified (or maintain a notification) for a directive for which it has no customers.