

# **GUIDELINES ON THE DESIGNATION OF UK NOTIFIED BODIES UNDER THE CONSTRUCTION PRODUCTS REGULATION (305/2011)**

**Issued by the Department for Communities and Local Government, July 2011**

## **1. INTRODUCTION**

- 1.1. These guidelines describe the requirements applying in the United Kingdom for the assessment, designation and notification of Notified Bodies under the EU Construction Products Regulation (305/2011). The text of the Regulation was adopted by the European Parliament and the Council on 9 March 2011 and published in the Official Journal No. L 088 on 4 April 2011, pages 5-43. The Regulation applies in the European Union and in other countries of the European Economic Area (EEA) who adopt the Regulation into their own national regulations.
- 1.2. The Regulation came into force in April 2011, but with most articles only applying from 1 July 2013. The Regulation applies directly in UK law, and so unlike a Directive, there are no transposing UK Regulations<sup>1</sup>.
- 1.3. Article 40.1 of the Regulation requires Member States to designate a notifying authority. In the UK this is the Department for Communities and Local Government. In accordance with Article 40.2, the United Kingdom Accreditation Service (UKAS) undertakes accreditation and monitoring of notified bodies in the UK.
- 1.4. These guidelines are designed to be consistent with the guidelines on notification under the other EU New Approach Directives and Regulations, and have been based on a template prepared by the Department for Business, Innovation and Skills. For information on the other New Approach Directives, see <http://www.bis.gov.uk/policies/business-sectors/environmental-and-product-regulations/product-regulation/ec-product-directives/new-approach-directives>. These guidelines are up to date as at the time of publication. They will be updated as and when necessary.

### **Designation and notification for construction product CE marking**

- 1.5. Designation and notification under the Construction Products Regulation is most commonly carried out in accordance with harmonised product standards. The harmonised product standards set the scope of CE marking under the Regulation, and from 1 July 2013 all products which fall under the scope of a published harmonised product standard will have to have a declaration of performance and be

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<sup>1</sup> Although there are no transposing Regulations, when it comes into force in full in July 2013, the Construction Products Regulation will be supported by a UK Statutory Instrument to replace the 1991 UK Construction Products Regulations (SI 1620) setting out arrangements for (among other things) enforcement of the Regulation's requirements.

CE marked in order to be put on the market in the UK. Until July 2013 this is voluntary.

- 1.6. Under the Regulation, a construction product means ‘any product or kit which is produced and placed on the [European Union] market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works’ (Article 2.1).
- 1.7. Annex V of the Regulation sets out five systems for attestation and verification of constancy of performance for construction products (hereafter called ‘systems’). All but one of these systems require the involvement of third party bodies. The Regulation specifies three types of body:
  - **Product certification bodies,**
  - **Factory production control certification bodies,** and
  - **Testing laboratories.**
- 1.8. As soon as a harmonised product standard is published in the Official Journal, bodies can be notified to carry out the relevant assessment tasks required by the standard, and manufacturers can apply to have their products CE marked.
- 1.9. Subject to Section 7 below, these third party bodies are notified by member/EEA states and by states with relevant Mutual Recognition Agreements. These third party bodies, once assessed for their competence and designated by the Secretary of State, are notified to the European Commission and become ‘Notified Bodies’.
- 1.10. The harmonised product standards and activities for which a Notified Body is designated and notified will be published on the Commission’s electronic information system (NANDO<sup>2</sup>) and updated as its scope of notification changes. Its initial scope of notification is also specified in the letter of designation. This also includes the test methods that a notified test laboratory has been initially designated as competent to carry out under a harmonised product standard. The Secretary of State for Communities and Local Government at present has the responsibility for designating Notified Bodies in the United Kingdom to carry out the functions referred to above and for notifying the designations to the European Commission and other member/EEA and MRA States.

### **CE marking for products not covered by harmonised product standards**

- 1.11. Under the Construction Products Regulation, CE marking is also a possibility (but not a legal obligation) for manufacturers of construction products which are not covered or not fully covered by a harmonised

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<sup>2</sup> The New Approach Notified and Designated Organisations (NANDO) Information System - <http://ec.europa.eu/enterprise/newapproach/nando/index.cfm>

standard (some innovative products, for example). The manufacturer of such a product can apply for a European Technical Assessment, which is another route to CE marking. European Technical Assessments are based on European Assessment Documents<sup>3</sup>. Both of these documents are prepared by Technical Assessment Bodies<sup>4</sup>.

- 1.12. Technical Assessment Bodies are also designated by Member States and notified to the Commission, to ensure their competence to carry out these third party assessment activities. However, these bodies are subject to different criteria (in Annex IV of the Regulation) and a slightly different process of assessment, accreditation and designation.
- 1.13. If you have queries on the process for designation as a Technical Assessment Body please contact [construction.products@communities.gsi.gov.uk](mailto:construction.products@communities.gsi.gov.uk).

## **2. CRITERIA, APPLICATION AND DESIGNATION**

- 2.1. An organisation wishing to be designated as a notified body in the UK will need to meet the requirements set out in Chapter VII (in particular article 43) of the Construction Products Regulation. It should, however, be noted that meeting the requirements for designation will not automatically lead to such a designation as this remains at the discretion of the Secretary of State. Reference should also be made to paragraph 3.13 of this guidance regarding insurance arrangements.
- 2.2. To be eligible for designation as a UK Notified Body for the purposes of the Regulation, an applicant must be a legal entity in the UK. An applicant must exercise management control of the process, have technical capability and carry out its final assessment functions within the jurisdiction of the United Kingdom. It may conduct technical activities, or have technical activities conducted on its behalf, outside the jurisdiction of the United Kingdom.

### **Applying to UKAS**

- 2.3. Applicants will be required, in the first instance, to make an application for accreditation to UKAS.
- 2.4. Applications should be submitted using the relevant UKAS form (AC1 to AC4 - available to download from the UKAS website at [www.ukas.com](http://www.ukas.com)) dependent upon the standard against which accreditation is required. Applicants should indicate the particular activities for which they wish to be designated. UKAS will quote and charge applicants against its standard scales of charges for its accreditation activities under the provisions of these guidelines. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

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<sup>3</sup> See Articles 19-26 of the Regulation.

<sup>4</sup> See Articles 29 and 30 and Annex IV of the Regulation.

- 2.5. At the same time as it submits its application for accreditation to UKAS, the applicant will be required to send a copy to the Department. This will provide the Secretary of State with advance notice of the intention to apply for designation.

### **Applying to DCLG for notification**

- 2.6. Once UKAS has completed its assessment and accreditation, it will issue an accreditation certificate and schedule to the notified body. The notified body should then submit an application for designation to the Department. The application should describe the systems, activities and products for which the notified body wishes to be designated and should be accompanied by the accreditation certificate and schedule and final assessment report issued by UKAS and evidence of the applicant's insurance cover (see para 3.13). The Department may request further information from UKAS about the applicant's accreditation, as required.
- 2.7. The Secretary of State will then make a decision on designation on the basis of all of the evidence. If satisfied that the applicant is fit for designation under the Regulation, the Secretary of State will issue a letter of designation.
- 2.8. The precise terms of designation will be set out in the individual letters of designation, but they will include conditions that the applicant agrees:
- to take part in co-ordination activities at both UK and European level;
  - to surveillance annually or at whatever intervals are thought appropriate by the Department;
  - to a full reassessment every four years or at whatever intervals are thought appropriate by the Department.

Once acceptance of the conditions of the letter of designation has been received, the Department will notify the European Commission and the other member/EEA and MRA States of the designation. The designation will become effective two weeks after the notification provided that no objections are raised by the European Commission or member/EEA and MRA states and will be confirmed at that point.

- 2.9. Reassessment and surveillance will be carried out on behalf of the Secretary of State by UKAS in line with usual accreditation practice and para 2.8 above. A report on the reassessment and surveillance will be sent to the Secretary of State. Reassessment and surveillance may also be carried out by the Secretary of State. UKAS will advise the Department of the outcome of annual surveillance, four yearly reassessment and any other necessary monitoring in intervening periods in order for the Department to take any necessary decisions about the continuation of the designation. The information provided by UKAS to the Department will include supporting documentation such as a copy of the assessor's visit report, an updated schedule of accreditation,

details of identified deficiencies and any agreed remedial action. The Department may request further information about the assessment and surveillance activities, as required.

### **3 MEETING THE CRITERIA**

#### **Assessment and accreditation**

- 3.1 Applicants are required to demonstrate conformity with the requirements set out in the Regulation by being accredited to the appropriate scope of one, or more, of the relevant EN 45000 and ISO 17000 series of standards, which contain requirements for bodies issuing certificates, performing inspections or conducting tests.
- 3.2 All applicants, as part of the accreditation process, will need to meet any additional requirements set out in these guidelines which may change from time to time.
- 3.3 Applicants will need to state for which harmonised product standards, systems and activities they wish to be designated. UKAS will undertake an assessment of the applicant against the relevant harmonised standard(s) to ensure that the applicant complies with the requirements and has the necessary product knowledge and capability to carry out the relevant activities. The scope of accreditation and subsequent designation will be determined by reference to the product standards and systems specified.
- 3.4 In all cases, the accreditation standards will be applied in accordance with EA 2/17 – Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes<sup>5</sup>.

**Note that consideration is being given at both national and European level to the use of the various EN 45000 and ISO/IEC 17000 standards for the accreditation of notified bodies for notification purposes. The standards against which accreditation may be carried out for the purposes of designation in accordance with these guidelines may change depending on the outcome of this work.**

- 3.5 All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of the Regulation.

#### **Assessment of capability**

- 3.6 In notifying a body to the Commission, or extending the notification scope of an existing body, the Department must ensure that the body has the necessary specific product knowledge and assessment (certification and/or testing) capability. This is demonstrated by accreditation to the relevant EN 45000 and ISO 17000 series

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<sup>5</sup> Available from the EA website at [www.european-accreditation.org/n1/doc/EA-2\\_17.pdf](http://www.european-accreditation.org/n1/doc/EA-2_17.pdf)

standards and reference to the title(s) and scope(s) of harmonised European product standards.

- 3.7 Harmonised product standards are produced in response to a mandate from the European Commission to the Comité Européan de Normalisation (CEN). Notification is only possible once the reference to the standard has been published in the Official Journal of the European Union.

### **Quality system**

- 3.8 All applicants will need to have a Quality System, usually specified in a Quality Manual, and associated documented operational procedures, appropriate to the systems and harmonised technical specifications which it wishes to certify or test to. The Quality System will need to ensure that all of the relevant requirements of the appropriate standards in the EN 17000 and 45000 series are met plus any further requirements for designation and operation as a Notified Body.

### **Sub-Contracting**

- 3.9 Where an applicant wishes to sub-contract, the body must comply with Article 45 of the Regulation and will at all times be responsible for ensuring that the assessment is carried out in accordance with the requirements of the Regulation. The Quality Manual of the applicant will need to describe the procedures to be followed by the applicant to ensure compliance by the sub-contractors with the relevant requirements and to demonstrate that the sub-contractor is competent to carry out the task for which it has been engaged.
- 3.10 Such competence will include, but is not limited to, the ability fully to conform to the requirements that are placed on the applicant itself in respect of the task contained within the subcontract. The applicant will need to maintain documented procedures for the assessment and monitoring of sub-contractors, and a list of sub-contractors and the facilities used by them to carry out work packages on behalf of the applicant. The list will need to form part of the Register specified in the next paragraph.
- 3.11 An applicant will need to have fully documented agreements with its sub-contractors. A Register of all sub-contractors which may be used by the applicant will need to be maintained; the Quality Manual will either contain the Register or will state where the Register is to be found. The agreements and the Register will need to be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed on behalf of the Secretary of State for that purpose.
- 3.12 A Notified Body will at all times be responsible for ensuring that the assessment is carried out in accordance with the requirements stated

for notified bodies within the Regulation and the harmonised technical specification.

## **Insurance**

- 3.13 All applicants will be required to demonstrate that they have adequate public liability and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted to UKAS and to the Department at the point at which a body makes an application to be designated as a Notified Body. Thereafter, the Notified Body should make available to UKAS evidence of insurance at each annual surveillance undertaken by UKAS. Such cover should extend to the whole of the European Union, the EEA, or, if the applicant intends to carry out work under the Regulation outside these areas, world-wide. The Secretary of State will not in relation to any case or circumstance cover a Notified Body's liability.

## **4 DUTIES OF NOTIFIED BODIES**

- 4.1 It will be the duty of a Notified Body to carry out the tasks associated with the assessment and verification of constancy of performance which fall within the scope of its designation, in accordance with the systems set out in Annex V of the Construction Products Regulation. Once a Notified Body has assessed a product, it will be required to issue the appropriate documentation as specified in the Regulation. This can include documentation of type test(s), type calculation(s), tabulated values, product description(s), initial inspection(s) of the manufacturing plant and factory production control, further inspection(s) of factory production control, audit test(s), and/or certificate(s) stating that the product or factory production control quality system concerned complies with the terms of the Regulation which apply to it and has been assessed as such.
- 4.2 An applicant will be required to have documented procedures covering all aspects of its work relating to the activities for which it seeks approval. As part of the accreditation process, an assessment will be made of the adequacy of the internal organisation and the procedures adopted to give confidence in the quality of the applicant's services. Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the applicant will be required to have procedures for achieving consistency. Guidance for achieving wider European agreement on interpretation and application of the Regulation can be sought from the relevant Group of Notified Bodies Sector Group for specific product issues, or via the UK National Mirror Group at Group of Notified Bodies Advisory Group meetings for general or horizontal issues.
- 4.3 A Notified Body will be required to maintain an up to date record of any certification which it has issued, and to whom it has been issued. The records will need to be made available on request to the Secretary of

State or such other person as may be authorised by the Secretary of State.

- 4.4 A Notified Body will be required to inform the Secretary of State and UKAS immediately of any changes within itself which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any change in its status, ownership, location, key personnel, technical competence, facilities etc.

## **5 MISUSE OF CERTIFICATES AND CONFORMITY NUMBERS**

- 5.1 The Quality Manual should state the Notified Body's policy and procedure for controlling the use of its certificates. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. will be dealt with by the Notified Body by suitable means including corrective action, publication of the transgression and, if necessary, legal action.
- 5.2 A Notified Body will need to have documented procedures for the control and use of its identification number complete with guidelines on action to be taken in cases of misuse. The procedures will need to be contained or referenced within the Quality Manual.

## **6 USE of UKAS SYMBOLS**

- 6.1 Notified Bodies may make reference to UKAS Accreditation or include the relevant National Accreditation Symbol on certificates issued where the work reported is included within the scope of accreditation of the Notified Body.
- 6.2 Certificates bearing an accreditation symbol must comply with the requirements of the relevant standard against which accreditation is held (e.g. EN 45011, ISO/IEC 17021 etc), with the requirements for notification and with any other requirements specified by UKAS.

## **7 MUTUAL RECOGNITION AGREEMENTS**

- 7.1 Applicants should note that the European Union aims to reach Mutual Recognition Agreements with key trading partners. Under these agreements, Notified Bodies may be eligible to perform assessments as required by the third country's laws and, similarly, those trading partners' equivalents to Notified Bodies may be eligible for designation to perform assessments under the Construction Products Regulation. If an applicant organisation wishes to be considered for designation under Mutual Recognition Agreements, it should inform the Department.

## **8 CONTACT POINTS**

Building Regulations and Standards Division  
Department for Communities and Local Government



Eland House, Bressenden Place, London SW1E 5DU  
[construction.products@communities.gsi.gov.uk](mailto:construction.products@communities.gsi.gov.uk)

United Kingdom Accreditation Service  
21 - 47 High Street  
Feltham  
Middlesex, TW13 4UN  
020 8917 8400  
[info@ukas.com](mailto:info@ukas.com)

## **9 SOURCES OF RELEVANT DOCUMENTS**

The Construction Products Regulation: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0005:0043:EN:PDF>.

The Construction Products Directive (which will be repealed from 1 July 2013): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0106:EN:HTML>.

EU Commission Guidance Papers on implementation of the Directive: [http://ec.europa.eu/enterprise/sectors/construction/documents/guidance-papers/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/construction/documents/guidance-papers/index_en.htm).

UK Construction Products Regulations (which are due to be replaced by 2013): <http://www.legislation.gov.uk/ukxi/1991/1620/contents/made>.

Information on the EN 17000 and EN 45000 series of standards and product standards: <http://www.bsi.group.com>.

The Group of Notified Bodies webpage (Advisory Group and Sector Group approved guidance, including position papers, meeting minutes and details of forthcoming meetings): [www.gnb-cpd.eu](http://www.gnb-cpd.eu).