BIS | Department for Business Innovation & Skills

THE TOYS (SAFETY) REGULATIONS 2011

Guidelines on the appointment of UK notified bodies

AUGUST 2011

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GUIDELINES ON THE APPOINTMENT OF UK NOTIFIED BODIES

ISSUED BY THE DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS ON BEHALF OF THE SECRETARY OF STATE FOR BUSINESS, INNOVATION AND SKILLS

1. INTRODUCTION

1.1 These guidelines describe the requirements applying in the United Kingdom for the assessment and appointment of Notified Bodies under the Toys (Safety) Regulations 2011 which will implement the provisions of Directive (2009/48/EC) in UK law. These regulations replace in their entirety the Toys (Safety) Regulations 1995 (SI 1995/204) which implemented the previous Directive on the approximation of the laws of the Member States concerning the safety of toys (88/378/EEC) on the coming into force date for directive 2009/48/EC of 20 July 2011. Notified Bodies are appointed under, and operate according to the law which transposes the provisions of the Directive and any appointments under the old set of regulations will terminate automatically on that date. The text of the Directive was adopted by the European Parliament and the Council on 18 June 2009 and published in the Official Journal No. L170/1 of 30 June 2009, p.1. The Directive applies in the European Economic Area (EEA).

1.2 The Toys (Safety) Regulations 2011 will apply to those toys that are designed or intended (whether or not exclusively) for use in play by children under 14 years old which fall within the definition in Regulation 4.

1.3 The conformity assessment procedures under the Regulations will consist of the internal production control procedure set out in Module A (of Annex II to Decision No 768/2008/EC) where a manufacturer has applied harmonised standards covering all of the relevant safety requirements for the toy. In certain circumstances e.g. where harmonised standards do not exist then the toy must be submitted to EC type examination in accordance with the procedures set out in Module B (of Annex II of Decision No 768/2008/EC) together with the conformity to type procedure set out in Module C (of Annex II to Decision No 768/2008/EC).

1.4 One of the modules outlined above (Module B) requires the involvement of a third party conformity assessment body. Subject to paragraph 7 (below), these third party bodies are appointed by member/EEA States. In the United Kingdom, they are appointed under regulations 26-36 of the Toys (Safety) Regulations 2011. These

third party bodies, once assessed for their competence and appointed by the Secretary of State, are then notified to the European Commission and become "Notified Bodies". The scope of products within the Regulations which a Notified Body is authorised to assess will be published and will also be specified in the letter of appointment. The Secretary of State for Business, Innovation and Skills at present has the responsibility for appointing Notified Bodies in the United Kingdom to carry out the functions referred to above and for notifying the appointments to the European Commission and other member/EEA States.

2. CRITERIA, APPLICATION AND APPOINTMENT

2.1 An organisation wishing to be appointed as a notified body in the United Kingdom will need to meet the requirements set out in Regulation 40 (Article 26 of the Directive) . It should, however, be noted that meeting the requirements for appointment will not automatically lead to such an appointment as this remains at the discretion of the Secretary of State. Reference should also be made to paragraph 3.14 regarding insurance arrangements.

2.2 Applicants will be required in the first instance, to make an application for accreditation to the United Kingdom Accreditation Service (UKAS) which will undertake an assessment of the applicant against the relevant harmonised standard(s) (see paragraph 3.4 below) to ensure that the applicant complies with the requirements. Applications should be submitted using the relevant UKAS form (AC1 to AC4 - available to download from the UKAS website at www.ukas.com) dependent upon the standard against which accreditation is required. The scope of accreditation will be defined by reference to the specific products set out in the Regulations and applicants should indicate the particular product(s) (if not all) in respect of which they wish to be appointed. 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.

2.3 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 for Business, Innovation and Skills. This will represent formal notification to the Secretary of State of the intention to apply for appointment.

2.4 Once UKAS has completed its accreditation, it will issue an accreditation certificate and schedule to the CAB. The CAB should then submit an application for appointment to the Department. The application should describe the conformity assessment activities and the products for which the CAB wishes to be appointed and should be accompanied by the accreditation certificate and schedule issued by UKAS and evidence of the applicant's insurance cover (see paragraph 3.14). The Secretary of State will then make a decision on appointment on the basis of all of the evidence. If

satisfied that the applicant is fit for appointment under the Regulations, the Secretary of State will issue a letter of appointment.

2.5 The precise terms of appointment will be set out in the individual letters of appointment, 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 (newly appointed Notified Bodies may be required to undergo an initial surveillance after 6 months);

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

2.6 Reassessment and surveillance will be carried out on behalf of the Secretary of State, by UKAS in line with usual accreditation practice and para 2.5 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 re-assessment and any other necessary monitoring in intervening periods of Notified Bodies in order for the Department to take any necessary decisions about the continuation of a Notified Body's appointment. The information provided by UKAS to the Department will include supporting documentation such as a copy of the assessor's visit report, details of identified deficiencies and any agreed remedial action.

2.7 To be eligible for appointment as a United Kingdom Notified Body for the purposes of the Regulations, an applicant must be a legal entity in the United Kingdom and carry out its assessment functions within the jurisdiction of the United Kingdom. It may, where necessary, conduct tests, or have tests conducted on its behalf, outside the jurisdiction of the United Kingdom.

2.8 Notified Bodies should ensure that they do not unreasonably restrict the access of manufacturers of products within the scope of the Regulations to their services. They must not place undue financial or other conditions upon such manufacturers. The procedures under which a Notified Body operates must be administered in a non-discriminatory manner.

3. MEETING THE CRITERIA

Accreditation

3.1 Applicants are required to demonstrate conformity with the requirements set out in the Regulations 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 As indicated in paragraph 2.2 and 2.4 (above), applicants will need to state for which products specified in the Regulations they wish to be appointed. The scope of accreditation and subsequent appointment will be determined by reference to the categories of product specified.

3.4 Accreditation will be carried out against either:

ISO/IEC 17025 (including the ability to decide on conformity);

ISO/IEC 17020 with ISO/IEC 17025 to be taken into account for testing; or

EN 45011 with ISO/IEC 17025 to be taken into account for testing.

In all cases, the 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[1].

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 conformity assessment bodies for notification purposes. The standards against which accreditation may be carried out for the purposes of the Toys (Safety) Regulations 2011 (as set out above) 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 Directive and of the implementing

[1] Available from the EA website at www.european-accreditation.org/n1/doc/EA-2_17.pdf

Regulations to be able to determine whether products offered for assessment satisfy the ESRs and the other relevant provisions.

Harmonised Standards

3.6 The Directive also defines the role of harmonised standards, which are produced in response to a mandate from the European Commission to the European standards organisation, the Comite European de Normalisation (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Products within the scope of the Directive produced in accordance with such standards will enjoy a presumption of conformity with the relevant ESRs (set out in Regulation 5 to the Regulations and Annex II to the Directive). Under the appropriate conformity assessment procedures, applicants will need to be able to examine or inspect against the ESRs and other relevant provisions directly. They will also need to be able to inspect against the CEN and CENELEC standards.

Quality System

3.7 An applicant will need to have a Quality System, usually specified in a Quality Manual and associated documented operational procedures, appropriate to the conformity assessment modules and types of product which it wishes to certify. 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 appointment and operation as a Notified Body.

Sub-Contracting

3.8 Where an applicant wishes to sub-contract testing, 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. 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.

3.9 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.

3.10 A Notified Body will at all times be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the implementing Regulations.

Insurance

3.11 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 appointed 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 Community, the European Economic Area (EEA), or, if the applicant intends to carry out work under the Directive 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 assess the conformity of the products which fall within the scope of its appointment, against the requirements of the Regulations. When a Notified Body assesses products as being in conformity with those Regulations, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations. This would include a type examination certificate stating that the product concerned complies with the terms of the Directive 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 conformity assessment 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 national and European agreement on interpretation and application of the Directive and the implementing Regulations can be sought from the Department, or through the national and European fora already in place for the exchange of views and discussion of interpretative issues in which prospective applicants are expected to fully participate.

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 and conformity numbers. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. will be dealt with 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 conformity assessment 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 conformity assessment body standard against which accreditation is held (e.g. EN 45011, ISO/IEC 17020 etc), with the requirements for notification and with the requirements in BIS publication 09/1090 'Conditions' document and any other requirements specified by UKAS.

7. CONTACT POINTS

7.1. Contact addresses are:

Tony Eden-Brown

Department for Business, Innovation and Skills

1 Victoria Street, London SW1H 0ET

Tel: 020-7215 0360

Email: tony.edenbrown@bis.gsi.gov.uk

Kevin Belson (or your usual Assessment Manager)

United Kingdom Accreditation Service

21 - 47 High Street

Feltham

Middlesex, TW13 4UN

Tel: 020-8917 8400

Fax: 020-8917 8500

Email: kevin.belson@ukas.com

Web: www.ukas.com

8. SOURCES OF RELEVANT DOCUMENTS

8.1. Copies of the Directive on the safety of toys are available from the Europa website at: http://ec.europa.eu/enterprise/sectors/toys/safety/index_en.htm

8.2. Copies of the Toys (Safety) Regulations 2011 may be obtained from:

The Stationery Office Ltd

PO Box 29

Norwich, NR3 IGN

Tel: 0870 600 5522

Fax: 0870 600 5533

Email: customer.services@tso.co.uk

Textphone: 0870 240 3701

Or from the Office of Public Sector Information website at www.opsi.gov.uk

Information on the EN 17000 and EN 45000 series of standards and the harmonised standards is available from:

BSI British Standards

389 Chiswick High Road

London, W4 4AL

Tel: 020-8996 9001

Fax: 020-8996 7001

Web: http://www.bsi.group.com

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URN 11/1263