Maritime & Coastguard Agency

MARINE GUIDANCE NOTE

MGN 554 (M+F)

Marine Equipment - Marine Equipment Directive UK Applicant Notfied Bodies

Notice to all Conformity Assessment Bodies Seeking Designation by the Secretary of State as a Notified Body pertinent to the Marine Equipment Directive.

This notice should be read with The Merchant Shipping (Marine Equipment) Regulations 2016 and Merchant Shipping Notice 1874 (M+F)

Summary

This Note sets out the procedure for Conformity Assessment Bodies (CAB) to follow in seeking designation by the Secretary of State as a Notified Body for the Marine Equipment Directive (Directive 2014/90/EU).

It contains contact details for relevant parts of the Maritime and Coastguard agency which is the Notifying Authority in the UK for the Marine Equipment Directive and the United Kingdom Accreditation Service (UKAS). Further, it cites the standards and requirements to which a CAB must meet in order to be eligible for designation by the Secretary of State.

1. Introduction

1.1 This Note describes the requirements applicable in the United Kingdom for the assessment and appointment of notified bodies under the Merchant Shipping (Marine Equipment) Regulations 2016 ("The Regulations"), which implement the provisions of Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC ("The MED") into UK law. Notified bodies are designated by the Secretary of State under the Regulations, providing they comply with the requirements in Annex III of the MED.

1.2 This Note applies to all conformity assessment bodies (CAB) applying for designation as notified bodies under the Regulations.

1.3 The conformity assessment procedures (modules of conformity) under the Regulations consist of those listed within Annex II of the MED.

1.4 These modules require the involvement of third party conformity assessment bodies. These third party bodies are appointed by member/ EEA States of the EU. In the United Kingdom,

they are designated under regulation 4 of the Regulations. These third party bodies, once assessed for their competence and designated 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 its designation.

1.5 In the United Kingdom, the Maritime and Coastguard Agency, an executive agency of the Department for Transport, is responsible for appointing notified bodies (NB) on authority of the Secretary of State for Transport.

1.6 For the purpose of this Note, whenever the Secretary of State is mentioned it means the Secretary of State for Transport or the MCA acting on his/ her behalf; whenever the MCA is mentioned it means the MCA alone.

2. Criteria, Application and Designation

2.1 An organisation wishing to be designated as a notified body in the United Kingdom must meet the requirements set out in Annex III of the MED. 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 6 regarding insurance arrangements.

2.2 Applicants should in the first instance, 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 3 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 within the scope of the MED and applicants should indicate the particular product(s) in respect to which NB status is applied for. 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 must send a copy to the MCA (Marine Equipment Quality Assurance, Marine Technology Branch, MCA, 105 Commercial Road; SO15 1EG Southampton). This will provide the MCA, which acts on the authority of the Secretary of State with advance notice of the intention to apply for designation.

2.4 Once UKAS has completed the accreditation assessment, it will issue an accreditation certificate and schedule to the CAB. The CAB should then submit an application for designation to the MCA (at the address in 2.3 above). The application should describe the conformity assessment activities and the products for which the CAB wishes to be designated and should be accompanied by the accreditation certificate, schedule, final assessment report issued by UKAS and evidence of the applicant’s insurance cover (see 6 below). The Secretary of State may request further information from UKAS about the applicant’s accreditation, as required. The MCA 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 Regulations, the MCA will issue designation to the CAB.

2.5 The precise terms of designation will be set out in the individual designations, but they will include conditions that the applicant agrees:

- to take part in co-ordination activities at UK and European level;

- to audit annually or at intervals which are thought appropriate by the Secretary of State (newly appointed Notified Bodies may be required to undergo an initial surveillance after 6 months);

- to a full reassessment every four years or at intervals which are thought appropriate by the Secretary of State.

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

2.7 Surveillance and reassessment will be carried out on behalf of the Secretary of State by UKAS in line with usual accreditation practice and para 2.5 above. Surveillance and reassessment may also be carried out by the Secretary of State. UKAS will advise the Secretary of State of the outcome of annual surveillance, four yearly re-assessment and any other necessary monitoring in intervening periods in order for the Secretary of State to take any necessary decisions about the continuation of the designation. The Secretary of State may request further information about the surveillance and reassessment activities, as required. The Secretary of State or a representative of the Secretary of State may choose to accompany UKAS during the above mentioned visits.

2.8 To be eligible for designation as a UK notified body for the purposes of the Regulations, an applicant must be a legal entity in the UK, must exercise management control of the process, have technical capability and carry out its final assessment functions within the jurisdiction of the UK. It may conduct technical activities, or have technical activities conducted on its behalf, outside the jurisdiction of the UK.

2.9 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 Annex III of the MED by fulfilling the requirements of the ISO/IEC 17065:2012 and which contains 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 be subject to change.

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 designated. The scope of accreditation and subsequent designation will be determined by reference to the categories of product specified.

3.4 All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of the MED and of the Regulations to be able to determine whether products offered for assessment comply with the applicable international conventions and testing standards as referred to in the MED.

4 Quality System

4.1 All applicants 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 issue certification. The Quality System will need to ensure that all of the relevant requirements of ISO/IEC 17065:2012 are met and any further requirements for appointment and operation as a Notified Body, in accordance with the MED and the Regulations.

5 Sub-Contracting

5.1 Where an applicant wishes to sub-contract any part of the assessment process, 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 to fully conform to the requirements that are placed on the applicant itself in respect of the task contained within the subcontract. The applicant must 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 must form part of the Register specified in the next paragraph.

5.2 An applicant must have fully documented agreements with its sub-contractors. A Register of all sub-contractors which may be used by the applicant must 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.

5.3 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 Regulations and will remain solely responsible for the activities carried out by subcontractors on its behalf, and notify UKAS and the MCA (using the contact details in 11 below) of such subcontracting arrangements in accordance with Article 20 of the MED.

6 Insurance

6.1 All applicants must demonstrate that they have adequate public liability and professional indemnity insurance for the activities they wish to carry out. Evidence of this must be submitted to UKAS and to the Secretary of State at the point at which a body makes an application to be designated as a Notified Body. Thereafter, the Notified Body must make available to UKAS evidence of insurance at each annual surveillance activity 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.

7 Duties of Notified Bodies

7.1 It will be the duty of a Notified Body to assess the conformity of the products or quality systems, which fall within the scope of its designation, against the requirements of the Regulations and relevant parts of Annex II of the MED. When a Notified Body assesses products as being in conformity with those requirements, it must issue the appropriate conformity assessment documentation as specified in the Regulations. This includes a type examination or quality assurance certificate stating that the product or quality system concerned complies with the terms of the MED.

7.2 An applicant must 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 judgement or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the applicant must have procedures for achieving consistency. Guidance for achieving wider national and European agreement on interpretation and application of the MED and the implementing Regulations can be sought from the Secretary of State, 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.

7.3 A notified body must 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.

7.4 A notified body must 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, but is not limited to, any change in its status, ownership, location, key personnel, technical competence, facilities etc.

8 Misuse of Certificates and Conformity Numbers

8.1 The Quality Manual must 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.

8.2 A Notified Body must 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 must be contained or referenced within the Quality Manual.

9 Use of UKAS Symbols

9.1 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.

9.2 Certificates bearing an accreditation symbol must comply with the requirements of the conformity assessment body standard against which accreditation is held (i.e. ISO/ IEC 17065:2012), with the requirements for notification and with the requirements in BIS publication URN BIS/16/25'Conditions' document and any other requirements specified by UKAS.

10 Mutual Recognition Agreements

10.1 Applicants should note that the European Union aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, Notified Bodies may be eligible to perform conformity assessments as required by the third country's laws and, similarly, those trading partners' equivalents to Notified Bodies may be eligible for appointment to perform conformity assessments under EU Directives. If an applicant organisation wishes to be considered for appointment under MRAs, it should inform the MCA.

11 Contact Points

11.1 Contact addresses are:

Marine Equipment Quality Assurance,
Maritime and Coastguard Agency,
Marine Technology Branch,
Spring Place,
105 Commercial Road,
Southampton,
Hampshire SO15 1EG
Email: marine.technology@mcga.gov.uk

John Carter (or your usual accreditation manager)
United Kingdom Accreditation Service
2 Pine Trees,
Chertsey Lane,
Staines-upon-Thames,
TW18 3HR

Tel: 01784 429000
Tel: 01784 428855
Email: john.carter@ukas.com

12 SOURCES OF RELEVANT DOCUMENTS

12.1 Copies of the 2014/90/EU Directive are available from the Europa website at www.europa.eu

12.2 Copies of the Merchant Shipping (Marine Equipment) Regulations 2016, 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
www.tsoshop.co.uk

Or from the National Archives website at www.legislation.gov.uk

12.3 Information on ISO/ IEC 17065:2012 standard and the harmonised standards are 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

More Information

Marine Equipment Quality Assurance
Marine Technology Branch
Maritime and Coastguard Agency
Bay 2/27
Spring Place
105 Commercial Road
Southampton
SO15 1EG

Tel : +44 (0) 203 817 2000
e-mail: MEQA@mcga.gov.uk

Website Address: www.gov.uk/government/organisations/maritime-and-coastguard-agency

General Inquiries: infoline@mcga.gov.uk

File Ref: MS 195/007/0001

Published: November 2016
Please note that all addresses and
telephone numbers are correct at time of publishing

Safer Lives, Safer Ships, Cleaner Seas