

dti

## The Recreational Craft Regulations 2004

Guidelines for Organisations seeking Notified Body status to undertake inspection and certification of recreational craft and specified components - including conformity assessment for exhaust emissions from engines and noise emissions from such craft

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## CONTENTS

1.	Introduction	2
2.	Application and Appointment	3
3.	Scope of Appointment	5
4.	Meeting the Criteria	11
5.	Subcontracting	14
6.	Duties of a Notified Body	15
7.	Confidentiality	16
8.	Documents to be retained by the Notified Body	16
9.	Internal Audit and Periodic Review	16
10.	Misuse of Certificates and Identification Numbers	16
11.	Mutual Recognition Agreements	17

### **Annexes (found at the end of this document)**

- Annex 1 Minimum Criteria to be taken into account by Member States for the Notification of Bodies (Annex XIV of Directive 94/25/EC)
- Annex 2 Model Letter of Appointment
- Annex 3 Basis of Assessment for Appointment of Notified Bodies for the purpose of the Regulations
- Annex 4 Contact Details

## **1. Introduction**

1.1 This booklet is intended as a guide to potential applicants for UK Notified Body<sup>1</sup> status under the Recreational Craft Regulations 2004 ("the Regulations") which implement Directive 2003/44/EC<sup>2</sup> ("the amending Directive") amending the Recreational Craft Directive 94/25/EC ("the Directive"). It aims to provide guidance on the DTI's appointment criteria for such applicants and bring together into one booklet the information necessary for those interested in undertaking this work.

1.2 Directive 94/25/EC, containing essential safety requirements for the design and construction of recreational craft, came fully into effect in the United Kingdom on 16 June 1998. The Directive applies to recreational craft measuring between 2.5 and 24 metres in hull length, intended for sports and leisure purposes. On 12 October 2000, the European Commission presented a proposal for an amendment to the Directive, extending the scope to include personal watercraft and adding further essential requirements covering exhaust emissions from propulsion engines and noise emissions from craft. The proposal has since been adopted by the European Council and Parliament on 16 June 2003 as Directive 2003/44/EC.

1.3 Directive 2003/44/EC must be implemented in the UK by 30 June 2004, the regulation enabling Notified Bodies to be appointed in the UK will also come into force on that date but Notified Bodies will not be able to issue type-examination certificates until 1 January 2005

1.4 The Recreational Craft Regulations 2004 will consolidate the existing Recreational Craft Regulations 1996 (S.I. 1996 No. 1353) and the Recreational Craft (Amendment) Regulations 1998 (S.I. 1998 No. 116) with the amendments required by Directive 2003/44/EC. Subject to certain saving provisions, the 1996 Regulations (as amended) are revoked by the Regulations but applicants may still require knowledge about them.

1.5 Regulation 12 of the Regulations permits the Secretary of State to appoint such persons as she thinks fit to be Notified Bodies for the purposes of the Regulations. The Secretary of State for Trade and Industry has responsibility for appointing and notifying to the European Commission and other Member States the Notified Bodies to carry out these functions.

### **1.6 Purpose of these guidelines**

The Department of Trade and Industry ('the Department') is responsible for the appointment, or designation, of notified bodies to undertake duties as set out in the Regulations. An organisation wishing to be appointed as a notified body in the United Kingdom will need to meet the criteria in the Regulations and the requirements in these guidelines. These guidelines also provide information on how compliance with the criteria can be demonstrated by compliance with the relevant conformity assessment standards in the EN45000/17000 series for a specified scope of appointment.

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<sup>1</sup> A body approved by the Secretary of State for the purposes of carrying out the testing, certification and monitoring procedures laid down in the Recreational Craft Directive

<sup>2</sup> (Official Journal No. L214 of 26<sup>th</sup> August 2003) amending 94/25/EC ("the Directive") (Official Journal No. L146 of 30 June 1994)

## **2. Application and Appointment**

### **2.1 Eligibility and legal entity**

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.

### **2.2 Application to UKAS, copy application to DTI**

Application for assessment for the purposes of appointment should be made in the first instance to the United Kingdom Accreditation Service (UKAS) and copied to the Department of Trade and Industry at the addresses indicated on page 25. The copy application to the Department will form the application for appointment as a Notified Body. Applications to UKAS should be made using the forms obtainable from the UKAS contact (see page 25).

### **2.3 Overall process of assessment by UKAS**

UKAS will then carry out an assessment of the applicant body on behalf of the Secretary of State for Trade and Industry against the criteria set out in these guidelines, which may be updated from time to time.

### **2.4 Agreement on the use of subcontracted UKAS assessors**

UKAS will use suitably qualified assessors or assessment teams to undertake the assessment and make clear to applicant bodies when sub-contracted assessors are to be used and give applicant bodies the right to object to specific assessors, if there are concerns about potential conflicts of interest.

### **2.5 UKAS scale of charges**

UKAS will quote and charge applicants against its standard scale of charges for its assessment activities under the scope of the guidelines. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

### **2.6 Insurance (see paragraph 4.6 in meeting the criteria)**

The applicant body shall provide evidence of its insurance cover to UKAS and to the Department before any appointment is made. After appointment, the notified body shall provide evidence of insurance to UKAS at each annual surveillance.

### **2.7 Secretary of State's decision**

The Secretary of State will make a decision on the basis of the report from UKAS and any other relevant information. It should be noted that appointment is at the discretion of the Secretary of State and it should not be assumed that if an applicant body meets all the criteria then an appointment will automatically follow. However, if the Secretary of State is satisfied that the applicant body is suitable, and should be appointed, a letter of appointment will be issued to the applicant body. A copy of the letter of appointment will be provided to UKAS.

## **2.8 Letter of appointment**

The precise terms and conditions of appointment will be set out in the individual letters of appointment, but it will be a standard condition that the applicant body agrees:

- to surveillance annually or at whatever intervals are thought appropriate by the Department (newly appointed bodies will undergo an initial surveillance after 6 months); and
- to a full reassessment every four years or at whatever intervals are thought appropriate by the Department.

A model appointment letter is attached at Annex 2 for general guidelines

## **2.9 Notification of the appointment to the European Commission and other Member States**

The Department will notify the appointment to the European Commission and other Member States. If the applicant body has not previously been assigned an identification number according to another EC Directive, the Department must ask the Commission to assign such a number prior to notification. The appointed body must not issue any certificates until the identification number has been assigned and it has received confirmation from the Department of its notification.

## **2.10 Reassessment and Surveillance of notified bodies by UKAS**

UKAS will carry out the reassessment and surveillance of the notified body referred to in paragraph 2.8 above and send a report to the Secretary of State. The information in the report will relate only to the notified body's activities as a notified body and will not include any other activity that is not relevant to the appointment. Reassessment and surveillance may also be carried out by the Secretary of State. UKAS will advise the Department if it believes that a notified body no longer complies with the terms of its letter of appointment, including compliance with the minimum criteria laid down in these guidelines.

## **2.11 Co-ordination of action between DTI and UKAS on suspension or withdrawal of accreditation and appointment**

In the case of a notified body that has been accredited for a scope within its scope of appointment as a notified body, UKAS will advise the Department if that accreditation is suspended, withdrawn, or reduced in scope. When an appropriate appeals procedure has been completed, UKAS will recommend to the Department whether this constitutes a failure to continue to comply with the minimum criteria laid down in these guidelines. UKAS will notify the Department when an accreditation that supports notification is re-instated following suspension, withdrawal or reduction in scope. The Department will advise UKAS if, for whatever reason, a notified body has its notification suspended or withdrawn.

### 3. The Scope of Appointment

The applicant body will need to specify the intended scope of its appointment in terms of the products and conformity procedures in the Regulations.

#### 3.1 Products

Assessment of a body will be related to the essential requirements and conducted against a specified range of activities to be known as the scope of approval. The scope will have regard to:

3.1.1 the category of recreational craft and where applicable their components as defined respectively in Schedules 1 and 2 to the Regulations, or in the case of propulsion engines, the type of engines and whether it relates to exhaust or noise emission as defined respectively in regulation 3 (1) (b) and (c) of the Regulations, plus any services or activities which are to be inspected, examined or approved. Applicants must state in respect of which product and conformity assessment module they wish to be appointed to approve on the basis of type-examination, product certification, quality assurance, or a combination of all three. An applicant for Notified Body status need not apply to be appointed for every design category of craft, every engine, or for noise and emission assessment, or for every conformity assessment module, which involves the services of a Notified Body. A body cannot however be appointed for part of an assessment module;

3.1.2 the standards, where applicable, to which those craft, services or activities are to be approved may include national or international standards, specific product standards or requirements of a more general nature. The criteria against which conformity assessment is to be made are those listed in Schedule 1A, 1B or 1C to the Regulations detailing the essential requirements for the design and construction of recreational craft, exhaust emissions from propulsion engines and noise emissions from craft respectively. The Directive also defines the role of 'harmonised standards' in Article 5, which is based on a mandate from the EC Commission to the European standards body, European Committee for Normalisation (CEN). This mandate authorises CEN to adopt / develop relevant standards from other organisations with a view to becoming harmonised European Standards. This states that where a national standard transposing a harmonised standard, the references of which have been published in the Official Journal of the European Communities (OJ), covers one or more of the essential requirements, recreational craft and the specified components constructed in accordance with that standard shall be presumed to comply with the relevant essential requirements;

3.1.3 applicants must be able to examine or inspect against such standards where appropriate. National or international standards which have not been published in the OJ will not give a presumption of conformity. In the absence of harmonised standards a Notified Body must be competent to judge the extent to which existing national or international standards, or in some cases a manufacturer's technical specification, can satisfy the relevant essential requirements of the Regulations;

3.1.4 the module(s) in respect of which the Notified Body wishes to be appointed relative to the manufacturer's choice of modules based on the design category of a craft, propulsion engines and description of components referred to in Schedules 1 and 2 to the Regulations. A description of the type-examination procedure is given in Schedule 7 to the Regulations. Under paragraph 4.1 of Schedule 7, a Notified Body will be expected to verify that a product has been manufactured in conformity with

the technical documentation as described in Schedule 13 to the Regulations and identify the elements which have been designed in accordance with the relevant provision of the standards referred to in Article 5 of the Directive.

3.1.5 inspection by the Notified Body may be conducted in-house or be sub-contracted. In the latter casework may only be sub-contracted on the clear understanding that the Notified Body employs the necessary professional expertise to oversee and take responsibility for the work of sub-contractors. A Notified Body cannot sub-contract the responsibility for making the necessary analytical technical judgements on which the decision as a Notified Body are made including whether or not to issue an EC type-examination certificate.

3.1.6 with the exception of a product conforming to module A, and to a lesser extent module Aa, all manufacturers of a product shall have access to the services of a Notified Body. There shall not be undue financial or other conditions imposed on the manufacturer. The procedures under which the Notified Body operates shall be administered in a non-discriminatory manner.

3.1.7 for the purposes of understanding the conformity assessment modules referred to above, applicants for Notified Body status should refer to the provisions in the Regulations, in particular Schedules 7 to 12, 15 and 16.

## **3.2 Conformity assessment procedures**

3.2.1 Under the appropriate conformity assessment procedures it will be the duty of the Notified Body to assess accurately the conformity of a product with the provisions of the Directive (as implemented by the Regulations). Having concluded that the product and/or quality assurance system (as the case may be) is in conformity, they should issue the appropriate conformity assessment documentation as specified in the Schedule to the Regulations which lays down the relevant procedure.

3.2.2 Applicants for Notified Body status should thoroughly familiarise themselves with the Regulations, the 1996 Regulations (as amended) and the Directive (as amended) and, in particular, with the relevant Essential Requirements laid down in Schedule 1 A, B, and C to the Regulations and the conformity assessment procedures in respect of which they seek appointment.

3.2.3 The conformity assessment system under the Directive is based on the modular approach (as set out in Council Decision 93/465/EEC of 22 July 1993, Official Journal No. L220, 30.08.1993, page 23 - concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives). This gives the manufacturer a number of options from which to make a selection. For the purposes of understanding the conformity assessment modules and procedures referred to above (involving a Notified Body), applicants for Notified Body status should refer in particular to Schedules 5 to 12, 16 and 17 to the Regulations

3.2.4 In accordance with regulation 7(2)(b)(i) and regulation 10 of the Regulations, the manufacturer or his authorised representative established in the Community shall carry out the following procedures for boat design categories A, B, C and D as referred to in Schedule 1 to the Regulations

### 3.2.5 For categories A and B:

For boats from 2.5 metres to 12 metres hull length; the internal production control plus tests (module Aa), which is set out in Schedule 6, or the EC type-examination (module B), which is set out in Schedule 7, supplemented by conformity to type (module C) which is set out in Schedule 8, or any of the following modules: B + D, or B + E, or B + F, or G or H;

For boats from 12 metres to 24 metres hull length: the EC type-examination (module B), which is set out in Schedule 7, supplemented by type conformity (module C), which is set out in Schedule 8, or any of the following modules: B + D, or B + E, or B + F or G or H;

### 3.2.6 For category C:

(i) for boats from 2.5metres to 12metres hull length:

Where the harmonised standards relating to sections 3.2 and 3.3 of Annex I.A are complied with, the internal production control (module A), which is set out in schedule 5, or internal production control plus tests (module Aa), which is set out Schedule 6, or the EC type-examination (module B), which is set out in Schedule 7, supplemented by conformity to type (module C), which is set out in Schedule 8, or any of the following modules: B + D, or B + E, B + F, or G, or H,

(bb) where the harmonised standards relating to sections 3.2 and 3.3 of Annex I.A are not complied with, the internal production control plus tests (module Aa), which is set out in Schedule 6, or the EC type-examination (module B), which is set out in Schedule 7, supplemented by conformity to type (module C), which is set out in Schedule 8, or any of the following modules: B + D, or B + E, or B + F, or G, or H;

(ii) for boats from 12m to 24m hull length: the EC type-examination (Module B), which is set out in Schedule 7, followed by conformity to type (module C), which is set out in Schedule 8, or any of the following modules: B + D, or B + E, or B + F, or G or H;

### 3.2.7 For category D:

For boats from 2.5 metres to 24 metres hull length, the internal production control (module A) referred to in Annex V, which is set out in Schedule 5, or the internal production control plus tests (module Aa), which is set out in Schedule 6, or the EC type-examination (module B), which is set out in Schedule 7, supplemented by conformity to type (module C), which is set out in Schedule 8, or any of the following modules: B + D, or B + E, B + F or G or H;

3.2.8 For personal watercraft, the internal production control (module A) referred to in Annex V, which is set out in Schedule 5, or the internal production control plus tests (module Aa), which is set out in Schedule 6, or the EC type-examination (module B), which is set out in Schedule 7, followed by conformity to type (module C), which is set out in Schedule 8, or any of the following modules:

B + D, or B + E, or B + F, or G or H; and

3.2.9 For components, any of the following modules: B + C, or B + D, or B + F, or G or H

### 3.2.10 With regard to exhaust emissions:

For products referred to in Article 1(1)(b) of the Directive (as amended), the engine manufacturer or his authorised representative established in the Community shall apply the EC type-examination (module B), which is set out in Schedule 7, followed by conformity to type (module C), which is set out in Schedule 8, or any of the following modules:

B + D, or B + E, or B + F, or G or H

### 3.2.11 With regard to noise emissions:

(a) for products referred to in Article 1(1)(c)(i) and (ii) of the Directive (as amended), the boat manufacturer or his authorised representative established in the Community shall apply:

- (i) where tests are conducted using the harmonised standard EN ISO 14509 for noise measurement: either internal production control plus tests (module Aa), which is set out in Schedule 6, or unit verification (Module G), which is set out in Schedule 11, or full quality assurance (module H), which is set out in Schedule 12
- (ii) where the Froude number and power displacement ratio method is used for assessment: either the internal production control (module A), which is set out in Schedule 5, or the internal production control plus tests (module Aa), which is set out in Schedule 6, or unit verification (module G), which is set out in Schedule 11, or full quality assurance (module H), which is set out in Schedule 12.
- (iii) Where certified reference boat data, established in accordance with point (i) is used for assessment: either internal production control (module A), which is set out in Schedule 5, or internal production control plus supplementary requirements (module Aa), which is set out in Schedule 6, or unit verification (module G), which is set out in Schedule 11, or full quality assurance (module H), which is set out in Schedule 12.

(b) for products referred to in Article 1(1)(c) (iii) and (iv) of the Directive (as amended), the personal watercraft/engine manufacturer or his authorised representative established in the Community shall apply: internal production control plus supplementary requirements referred to in Schedule 6 (module Aa) or module G or H.

### 3.2.12 As stated in Annex XVII of the Directive (Schedule 16 to the Regulations):

“For verifying the conformity of an engine family, sample of engines is taken from the series. The manufacturer shall decide the size (n) of the sample, in agreement with the notified body.

The arithmetical mean X of the results obtained from the sample shall be calculated for each regulated component of the exhaust and noise emission. The production of the series shall be deemed to conform to the requirements (“pass decision”) if the following condition is met:

$$X + k \cdot S \leq L$$

S is standard deviation, where:

$$S^2 = \sum (x - X)^2 / (n - 1)$$

X = the arithmetical mean of the results

x = the individual results of the sample

L = the appropriate limit value

n = the number of engines in the sample

k = statistical factor depending on n (see table)

n	2	3	4	5	6	7	8	9	10
k	0,973	0,613	0,489	0,421	0,376	0,342	0,317	0,296	0,279
n	11	12	13	14	15	16	17	18	19
k	0,265	0,253	0,242	0,233	0,224	0,216	0,210	0,203	0,198

If  $n \geq 20$  then  $k = 0,860 / \sqrt{n}$ ."

### 3.2.13 Post-Construction Assessment:

In the case of post-construction assessment for recreational craft, if neither the manufacturer nor his authorised representative established in the Community fulfils the responsibilities for the product's conformity to the Regulations, these can be assumed by any natural or legal person established within the Community who places the product on the market and/ or puts into service, under his own responsibility. In such a case, the person who places the product on the market or puts into service must lodge an application for a post construction report with a Notified Body. The person who places the product on the market and/or puts it into service must provide the Notified Body with any available document and technical file referring to the first placing on the market of the product in the country of origin. The Notified Body shall examine the individual product and carry out calculations and other assessment to ensure its equivalent conformity with the relevant requirements of the Directive. In this case, the Builder's Plate described in Annex I, 2.2 of the Directive shall include the words (Post-construction certificate). The Notified Body shall draw up a report of the conformity concerning the assessment carried out and shall inform the person who places the product on the market and/or puts into service of his obligations. That person shall draw up a declaration of conformity and affix, or cause to be affixed, the CE mark accompanied by the distinguishing number of the relevant notified body on the product.

It is anticipated that this procedure will only be used to assess the conformity of individual craft that have already been constructed and not a type of craft. If the applicant wishes to be involved as a Notified Body in post construction assessment, this should be specifically stated in any application; in any event, Notified Bodies will be expected to be familiar with and be able to demonstrate technical competence to satisfy the requirements of this procedure.

### 3.2.14 Technical Documentation to be supplied by the Manufacturer

As stated in Schedule 13 to the Regulations:

"The technical documentation referred to in Annexes V, VII, VIII, IX, XI and XVI<sup>(a)</sup> must comprise all relevant data or means used by the manufacturer to ensure that components or craft comply with the essential requirements relating to them.

<sup>(a)</sup> These Annexes are respectively set out in Schedules 5, 7, 8, 9, 11 and 15

The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of this Directive.

The documentation shall contain so far as relevant for assessment:

- a general description of the type;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to fulfil the essential requirements when the standards referred to in Article 5 have not been applied;
- results of design calculations made, examinations carried out etc.;
- test reports, or calculations namely on stability according to section 3.2 of the Essential Requirements on buoyancy according to section 3.3 thereof (Annex I.A),<sup>(a)</sup>
- exhaust emissions test reports demonstrating compliance with section 2 of the Essential Requirements (Annex I.B)
- sound emissions test reports or reference boat data demonstrating compliance with section 1 of the Essential Requirements (Annex I.C)."

Schedule 5 to the Regulations (Annex V of the Directive) referred to above is not relevant to this document as it relates to the self certification procedure by the manufacturer which does not require the involvement of a Notified Body.

### 3.2.15 Type-Examination and Certification Procedures

The Notified Body is required to have documented procedures covering the type-examination, product certification and testing of craft as specified in the Annexes to the Directive (as implemented in the relevant Schedules to the Regulations) on conformity assessment procedures. Complementary documented staff instructions should be listed in the quality manual referred to in section 7 of EN 45004 and described in sufficient detail for their essential features to be identified. UKAS will assess the adequacy of the internal organisation and procedures adopted to give confidence in the quality of its services.

The basis of certification given should be clearly defined in the scope quoted on each certificate. Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or otherwise a certificate of EC type-examination, the Notified Body is required to have procedures for achieving common standards in such matters in its own operations. Guidance for achieving wider national and international agreement on the application of the Directive will be provided by the Department of Trade and Industry.

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<sup>(a)</sup> The Essential Requirements in Annex 1 are set out in Schedule 1

The procedures for EC type-examination are set out in Schedule 7 to the Regulations. Paragraph 6 requires the manufacturer to inform the Notified Body of any modifications made, or planned to be made, to the recreational craft or the specified components. The Notified Body will then be required to examine those modifications to ascertain whether or not the certificate remains valid.

Section 8 (above) indicates the conformity assessment procedures involving a Notified Body based on the modular approach comprising type-examination plus conformity to type, or an approved quality system, which implement the relevant harmonised standards. Alternatively, conformity assessment by a Notified Body can be determined by module G (unit verification) involving examination and tests referred to in the appropriate harmonised standard.

It will be the duty of a Notified Body appointed to operate under the quality assurance modules accurately to assess and approve a manufacturer's quality system for the manufacturer of the craft or specified components for which it is approved against the requirements of the implementing Regulations, in accordance with the modules for which it has been appointed. In assessing quality systems against the requirements of a quality assurance module, Notified Bodies must presume compliance with these requirements in respect of those elements of the quality system which conform to the relevant harmonised standard (the relevant standard from the BS EN ISO 9000 series) When a Notified Body assesses a manufacturer's quality system as conforming with the requirements, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations.

#### **4. Meeting the Criteria**

##### **4.1 The minimum criteria for the appointment of notified bodies**

Organisations wishing to become Notified Bodies for the purposes of the Regulations must meet in full the minimum criteria set out in Annex XIV of the Directive (attached as Annex 1). UKAS will undertake an assessment of the applicant body against the criteria and other requirements in these guidelines and report to the Secretary of State on that assessment.

##### **4.2 Accreditation to an appropriate scope to one or more standards in the EN45000 series**

The Council Decision 93/465/EEC provides that applicant bodies wishing to be appointed as notified bodies may demonstrate compliance to the minimum criteria by means of the standards in the EN45000 series that contain specifications for bodies issuing certificates, performing inspections, or conducting tests.

##### **4.3 Policy on accreditation**

Accreditation to a relevant standard in the EN45000 series to an appropriate scope provides a presumption of conformity to the minimum criteria but accreditation is not mandatory. It is a principle of the New Approach that standards are voluntary and secondly some of the requirements in the standards are not relevant or justified by the minimum criteria in the Directives.

#### 4.4 Assessment

Applicant bodies that are not accredited will nevertheless be assessed to the relevant requirements of the appropriate standard in the EN45000 series and will need to demonstrate equivalent levels of ability in terms of competence, resources, organisational arrangements, policies and all other relevant matters.

The standards against which accreditation or assessment of Notified Bodies is carried out are shown, with the corresponding conformity assessment procedures, in Annex 3. Where more than one standard is provided as an option for a particular procedure, the applicant body will have the choice of deciding which standard to be accredited against.

If an applicant body includes more than one conformity assessment procedure in its scope of appointment it may choose to base its systems on one selected core standard and deal with the relevant requirements of the other standards as additions to its base system.

#### 4.5 Specific requirements that must be met in addition to the criteria in the standards

All bodies, whether accredited to one of the EN45000 series of standards or not, will need to meet the additional requirements set out in these guidelines. An applicant body will need to demonstrate with respect to the scope of appointment for which it has applied:

- a thorough technical understanding of the products concerned;
- the ability to undertake the duties of a notified body set out in the conformity assessment procedures;
- a thorough knowledge of the Directive and the Regulations.

4.5.1 Applicants will therefore need to state for which recreational craft and specific components and for which conformity assessment activities they wish to be appointed as referred to in Section 3 above. The scope of assessment by UKAS and any subsequent appointment by the Secretary of State will be determined by reference to the modules and activities described in the Regulations and the specified craft, components and engines. Applicants will be required to demonstrate the capability fully to undertake the functions defined by a particular module or activity for the relevant types of recreational craft, components and engines (this requirement does not preclude the possibility of sub-contracting).

#### 4.6 Insurance

A notified body's activities under the directive, must be covered by the following types of insurance:

- **Public liability insurance** – shall cover the legal liability of the notified body to third parties (i.e. members of the public) in respect of accidental bodily injury to any person or accidental loss of or damage to property happening in connection with its business as a notified body. (The notified body will not

necessarily be in a contractual or any direct relationship with the third party.)  
The territorial limits of the public liability insurance must include all countries in the European Economic Area (EEA).

- **Professional indemnity insurance** – shall indemnify the notified body against any claim for damages for breach of professional duty due to any negligent act or omission, to those to whom the notified body is under contract, or to others to whom it has provided professional advice and owes a duty of care. The policy must provide this cover for the EEA and for other countries in which its clients are based, or wherever the notified body carries out its work. The policy may however include a restriction on jurisdiction that limits any such claims for damages to a specified court.

The applicant must send copies of its public liability and professional indemnity insurance policies to the Department and UKAS, prior to any appointment as a notified body. They may be submitted when the organisation makes an application or, at the latest, when UKAS has completed its assessment with a recommendation that the applicant body should be appointed. If the former, it may be necessary to ensure that the insurance arrangements are still in place at the time of any appointment. Thereafter, as one of the conditions of appointment, the Notified Body must provide UKAS with written evidence of insurance at each annual surveillance visit.

The Secretary of State will not under any circumstances cover any liability of a notified body and the provision of evidence of insurance to either UKAS or the DTI should not be construed as either party's confirmation of the adequacy of such insurance, as this is the responsibility of the notified body. The Department may however ask the notified body to explain the basis on which the amount of insurance has been determined, and it reserves the right to refuse or withdraw the appointment if the issue cannot be resolved to the Department's satisfaction.

#### **4.7 Testing and inspection facilities**

Where an applicant body operates its own testing facilities these and their associated activities, will need to conform to the relevant requirements of BS EN ISO/IEC 17025:2000 and continue to do so during the period of appointment as a notified body, though accreditation is not mandatory. Similar requirements apply in the case of inspection facilities and BS EN 45004:1995.

#### **4.8 Quality management system**

An applicant body shall have a quality system that is based on a relevant standard in the EN45000/17000 series appropriate to the scope of appointment. It shall have a quality manual and associated documented operational procedures that shall ensure that all the requirements of the relevant standard(s) in the EN45000/17000 series are met plus any further requirements for accreditation (if appropriate) and criteria for appointment and operation as a Notified body. The quality system documentation shall contain policies and procedures to include:

- a) a statement on the training of staff engaged in the conformity assessment process;
- b) details of the documented procedures for assessing initial and audit product testing
- c) a general statement on the range of testing and inspection facilities appropriate to its activities;

- d) details of documented procedures for the surveillance of a manufacturer's quality system;
- e) a list of sub-contractors and details of the documented procedures for assessing and monitoring their competence;
- f) details of appeals procedures and the procedure for ensuring that complaints to the Notified body are investigated to ensure that any shortcomings of the certification activities are revealed;
- g) a list of staff members responsible for investigating complaints and those having the authority to take remedial action;
- h) a copy of instructions to staff on confidentiality;
- i) a copy of the written undertaking by staff not to divulge any information gained about the client to a third party;
- j) a copy of the provisions in all sub-contracts to maintain confidentiality.

## **5. Subcontracting**

The following text should be read in conjunction with the terms and conditions in the model letter of appointment in Annex 2

### **5.1 Definition of subcontracting**

A contract with a different legal entity to carry out supporting activities related to its scope of appointment.

### **5.2 Activities that may be contracted**

The notified body can subcontract those parts of a conformity assessment procedure that are limited to well-defined, discrete technical operations that are used to determine information on which an assessment would be based. Typically this would involve carrying out tests or examinations but not the assessment of those results, not making any decisions on conformity.

### **5.3 Documented evidence for the competence of subcontractor**

The Notified body shall possess documented evidence to demonstrate the competence of the subcontractor. Compliance with the relevant EN45000/17000 standards entails a presumption of conformity with most of the requirements but accreditation is not mandatory.

### **5.4 Competence of the notified body to assess subcontracted work**

The Notified body shall have staff with the necessary expertise to monitor the performance and assess the work of subcontractors.

### **5.5 Register of subcontractors**

A register of all subcontractors used by the Notified body shall be maintained; the quality manual may include the register or shall state where it is to be found. The register shall include:

the name of the external body;

its legal status and details of any relationship with a parent company, group of companies or any other organisation of which the external body is a part;

- a) names and qualifications of all staff engaged in relevant technical work;
- b) functions performed by the external body.
- c) results of any assessments performed to check compliance with the requirements of BS EN ISO/IEC17025:2000 or BS EN45004:1995.

## **5.6.....Overall responsibility for subcontracting rests with the notified body**

The responsibility for undertaking the conformity assessment in accordance with the requirements of the Regulations and liability for failing to do so, always rests with the notified body itself, irrespective of whether it makes use of the services of any subcontractors.

The agreements and the register should be available for scrutiny at any time on request by the Secretary of State or such other person as may be appointed by the Secretary of State Register of subcontractors.

## **6. Duties of a Notified Body**

### **6.1 Access to the services of a notified body and equal treatment**

Notified bodies shall ensure that they do not unreasonably restrict access to their services or place undue financial or other conditions upon manufacturers. The procedures under which a notified body operates must be administered in a non-discriminatory manner.

### **6.2 Carry out conformity assessment**

The most important function of a notified body is to carry out conformity assessment on products, or quality assurance systems, according to the conformity assessment procedures in the Regulations. The basis of the conformity assessment certification should be clearly set out in the scope quoted on each certificate.

### **6.3 Procedures to ensure consistency**

Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the notified body is required to have procedures for achieving consistency in such matters in its own operations. Guidance for achieving wider national and European agreement on interpretation and application of the Regulations will be provided by the DTI.

### **6.4 Participation in co-ordination activities**

Notified bodies are required to participate in the notified body co-ordination activities at the national and European level. Notified bodies should demonstrate active participation by a record of frequent attendance at UK meetings and they should also show that they have an effective means of providing input and making themselves aware of the outcome of co-ordination at the European level.

## **6.5 Circumstances in which a notified body shall contact the Department**

Notified Bodies are requested to inform the Department without delay of:

the withdrawal of an EC type-examination certificate by the notified body;

of any changes which, in any way, have a bearing upon its status as a notified body, or its ability to perform the duties and functions in its scope of appointment;

with details of any defective standard and, if relevant, an inappropriate application of harmonised standards. (Defective standards are those which do not fulfil the mandate issued to the European Standards organisations by the Directive 98/34 Article 5 committee, and/or do not allow the essential requirements of the Regulations to be met).

## **7. Confidentiality**

**7.1** Subject to any arrangements in respect of the release of information to other Notified Bodies in accordance with the relevant conformity assessment procedures, the Notified Body shall have adequate arrangements for ensuring confidentiality of information obtained in the course of its certification activities between itself and its clients. This should include:

- (a) a copy of the instructions to staff on confidentiality;
- (b) a copy of the written undertaking that staff are required not to divulge any information gained about the client to third parties;
- (c) a copy of the provisions in all sub-contracts to maintain confidentiality

## **8. Documents to be retained by the Notified Body**

**8.1** The Notified Body is required to maintain an up to date record of recreational craft and their components for which it has issued a type examination or quality assurance certificate, and to name the company to which a certificate has been issued. The records shall be made available, on request, to the Secretary of State or such other person as may be authorised by the Secretary of State.

## **9. Internal Audit and Periodic Review**

**9.1** The Notified Body shall undertake internal audits and management reviews as required by the particular EN 45000 standards to which it is working. Audits and reviews shall include checking compliance with the criteria for appointment as a Notified Body and checking that the certification process is correctly and effectively implemented.

## **10. Misuse of Certificates and Identification Numbers**

### **10.1 Policy and procedures for the control of the identification number**

The quality manual should state the notified body's policy and procedure for controlling the use of its certificates and identification numbers. Incorrect references to the certification system or misleading use of information found in advertisements,

catalogues etc. must be dealt with by suitable means including for example corrective action, publication of the transgression or, if necessary, legal action. The Notified Body should have documented procedures covering the control and use of its identification number with guidelines on action to be taken in case of misuse. These should be described briefly in the quality manual and the reference numbers of the documentation listed.

## **11. Mutual Recognition Agreements**

**11.1** It should be noted that ten new members are due to become member States on 1 May 2004. Protocols on European Conformity Assessment (PECAs) have been signed with some of the acceding countries and generally all EU Notified Bodies appointed for the specific sectors covered by such Agreements have been included in the relevant lists of notified bodies.

**11.2** Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, EC Notified Bodies may be eligible to perform conformity assessments as required by these key trading partners' laws. If a notified body has been designated under an MRA with a third country their insurance arrangements must meet the legal requirements of that country. Similarly, those trading partners' equivalents to EC Notified Bodies may be eligible to perform conformity assessments under EC Directives. A Notified Body should inform the Department if it wishes to be considered for appointment under the MRAs.

**11.3** Switzerland is not in the EU but an MRA has been agreed to provide free movement and all EU Notified Bodies appointed for the specific sectors covered by the MRA will automatically be included in the relevant lists of Notified Bodies. The Swiss MRA, however, does not currently cover the recreational craft sector.

**MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES (Annex XIV of Directive 94/25/EC)**

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of boat or components which they inspect, nor the authorised representative of any of these parties. They shall not become either involved directly or as authorised representatives in the design, construction, marketing or maintenance of the said products. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.
4. The staff responsible for inspection shall have:
  - sound technical and professional training;
  - satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;
  - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except *vis-à-vis* the competent administrative authorities of the State in which its activities are carried out) under the Directive or any provision of national law giving effect to it.

## Model Appointment Letter

020 7215 ----

2004

**[APPOINTMENT OF {NAME OF COMPANY} AS A NOTIFIED BODY UNDER REGULATION xxxx OF THE xxxx REGULATIONS]**

I am writing to inform you that the Secretary of State hereby *appoints* [name of company] (the *Company*) as a *Notified Body* under regulation xxxx of [The xxxx Regulations] (the Regulations) which implement the provisions of Council Directive [number of Directive] (the Directive) on [title of Directive] subject to the conditions set out in this letter.

2. The *Company* is *appointed* for the purposes of [conformity assessment procedures/modules], in relation to the following:

[list product(s)/range of products for which company is appointed]

3. This *appointment* shall remain in force until [such time as it is withdrawn by the Secretary of State pursuant to clause 5 below] or after the elapse of a period of [xx days] after the *Company* has notified the Secretary of State in writing that it wishes the *appointment* to be terminated pursuant to clause 6 below.

4. This *appointment* is subject to the following specific conditions:

- a) the *Company* shall at all times carry out the duties and functions of a *Notified Body* under regulation xxxx of the Regulations to the satisfaction of the Secretary of State;
- b) the Secretary of State continues to be satisfied as to the *Company's* suitability - including its status and competence - to be a *Notified Body*; in connection with this, the *Company* shall, in some circumstances and at the Secretary of State's request, submit to immediate reassessment of its suitability for *appointment*;
- c) the *Company* shall submit itself annually for surveillance for the purposes of ascertaining that the *Company* is performing its duties and functions in accordance with its appointment; [in connection with this, the first surveillance shall take place no later than six months after the date of acceptance of this *appointment*]; provided always that the Secretary of State may require more frequent surveillance.
- d) the *Company* shall submit itself every 4 years for a full reassessment for the purposes of the Secretary of State satisfying himself that the *Company* remains suitable for appointment;
- e) for the purposes of reassessment and surveillance an assessment shall normally be carried out on behalf of the Secretary of State by the

United Kingdom Accreditation Service (UKAS), which will submit a report to the Secretary of State; Provided always otherwise or in addition, such assessment may be carried out by or on behalf of the Secretary of State as he in his absolute discretion thinks fit;

- f) the *Company* shall fulfil and comply at all times with the “minimum criteria” specified in Schedule [xx]/Annex [xx] of the Directive (which is set out in Appendix 1 to this letter);
- g) It is the responsibility of the Company to provide annual evidence of adequate insurance cover taking into account all relevant circumstances in relation to the scope of the Company’s activities;
- h) the Company shall follow the relevant conformity assessment procedures as stated in regulation xxxx of the Regulations (these are the procedures mentioned or referred to in Article [x] of the Directive);
- i) [where the *Company*, in accordance with regulation [xxxx] of the Regulations, is minded to refuse to issue an *EC type-examination certificate* it shall:
  - i) give notice in writing to the applicant of the reasons why it is minded to do so; and
  - ii) give the applicant the opportunity of making representations within a reasonable period of the notice being given as to why it should not be refused;]
- j) the sub-contracting of work by the *Notified Body*, shall be subject to certain conditions guaranteeing:-
  - i) the competence of the establishment operating as sub-contractor by meeting the relevant requirements of the [EN 45000 series] of standards; and
  - ii) its ability to exercise effective responsibility for the work carried out under sub-contract; and
  - iii) any other matter required in guidelines issued by the Secretary of State in respect of the sub-contracting of work [(these appear at Appendix ? to the current issue of the guidelines)].

In any case the *Notified Body* remains entirely responsible for the work carried out under the sub-contract.

- k) the Company shall authorise, at any reasonable time, access by or on behalf of the Secretary of State to:
  - i) all documentation arising out of its duties and functions under this *appointment* and shall comply with any reasonable request



6. This *appointment* shall be terminated in accordance with regulation [xxxx] of the Regulations at the request of the *Company* upon [xx] days' notice in writing to the Secretary of State.

7. This *appointment* is subject to the following additional conditions in the event of it being withdrawn or terminated:

- a) the *Company* shall prepare and submit to the Secretary of State within three calendar months of the date on which the termination of the *appointment* takes effect or, if appropriate, of the date of withdrawal, a report in writing on the exercise of its duties and functions under the Regulations; this report shall contain such information as may have been agreed in writing between the Secretary of State and the *Company*;
- b) the *Company* shall transfer to the Secretary of State or to such person or company as the Secretary of State shall direct, without charge, all records, information and other things, whether stored manually by computer or by any other means whatsoever, arising out of the performance of its duties and functions under the Regulations as the Secretary of State may specify.

8. Your attention is drawn to Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation Directives.

9. You should note that *Notified Bodies* are to be encouraged to apply the modules without unnecessary burdens for applicants.

10. The Secretary of State will notify the European Commission and other *EEA* States of this *appointment* to act for the purposes stated above and it will be made public.

11. If the above terms and conditions of *appointment* are acceptable to you, you should signify your *Company's* consent by signing, or arranging for the signature of, the attached copy of this letter, dating and returning it to: **[name and address of DTI contact]**. The appointment shall take effect upon receipt of your *Company's* consent and you will receive formal confirmation of this.

Rob Brightwell  
for and on behalf of the Secretary of State

On behalf of **[name of Company]** I hereby accept the *appointment* of **[name of Company]** as a *Notified Body* on the terms and conditions set out in this letter.

Signed.....  
(duly authorised to sign in that behalf)

Name in Capitals.....

Position.....

Dated.....

**Basis of assessment for appointment of Notified Bodies for the purpose of the Directive 94/25/EC and the Regulations**

Table 6/2 from the New Approach Guide, published by the European Commission, provides guidance on the use of the EN 45000 series of standards in support of the assessment of notified bodies under New Approach directives. It has been revised in the version below to take account of the replacement of EN 45001 by BS EN ISO/IEC 17025:2000. For convenience, references to BS EN ISO/IEC 17025:2000 will be shortened to EN 17025 throughout this document.

Module	Conformity Assessment Standard(s) Applicable
Aa	EN 17025 (including the ability to evaluate and decide on conformity), or EN 45004 (EN 17025 to be observed for testing required), or EN 45011 (EN 17025 to be observed for testing required)
B	EN 45004 (EN 17025 to be observed for testing required), or EN 45011 (EN 17025 to be observed of testing required)
C	EN 17025 (including the ability to evaluate and decide on conformity), or EN 45004 (EN 17025 to be observed for testing required), or EN 45011 (EN 17025 to be observed for testing required)
D	EN 45012 (+ product related knowledge)
F	EN 17025 (including the ability to evaluate and decide on conformity), or EN 45004 (EN 17025 to be observed for testing required), or EN 45011 (EN 17025 to be observed for testing required)
G	EN 45004 (EN 17025 to be observed for testing required), or EN 45011 (EN 17025 to be observed for testing required)
H	EN 45012 (+ product related knowledge)

**Note:**

Notified Bodies assessed to EN 17025 are considered to be acting in a testing, as opposed to a calibration mode and are required to be third parties described in Note 2 to clause 4.1.4 of that standard.

Notified Bodies assessed to EN 45004 are required to be Type A bodies as described in clause 4.2.1 of that standard.

Contact Points
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**Applications:**

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 Standards & Technical Regulations  
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 Website: <http://www.dti.gov.uk/strd>

Information on the EN 45000/ISO 17000 series of standards and the harmonised standards being developed in support of the Recreational Craft Directive is available from:

British Standards Institution (BSI)  
 389 Chiswick High Road  
 London  
 W4 4AL

Tel: 020 8996 9001  
 Fax: 020 8996 7048 / 7001

Website: <http://www.bsi-global.com>

**Assessment/Accreditation:**

United Kingdom Accreditation Service (UKAS)  
 21-47 High St  
 Feltham  
 Middlesex TW13 4UN  
 E-mail [info@ukas.com](mailto:info@ukas.com)  
 Tel: 020 8917 8400  
 Fax: 020 8917 8499

**Availability of texts:**

The complete text of the Directive 94/25/EC has been published in the Official Journal of the European Communities (No L146 of 30 June 1994). Copies of this text are generally available from the European Information Centres and European Documentation Centres.

The Regulations are available from:

The Stationery Office  
 PO Box 276  
 London SW8 5DT

Tel: 020 7873 9090  
 Fax: 020 7873 8200