

Guidance on legislation

## Requirements for UK notified bodies

November 2013

## Contents

<b>Introduction</b> .....	<b>3</b>
<b>1 General</b> .....	<b>4</b>
<b>2 Independence</b> .....	<b>4</b>
<b>3 Impartiality</b> .....	<b>5</b>
<b>4 Technical competence</b> .....	<b>5</b>
<b>5 Facilities</b> .....	<b>7</b>
<b>6 Confidentiality</b> .....	<b>7</b>
<b>7 Liability insurance</b> .....	<b>8</b>
<b>8 Subcontractors</b> .....	<b>8</b>
<b>9 Quality system</b> .....	<b>9</b>
<b>Appendix</b> .....	<b>11</b>

This document replaces Guidance Note 6 ‘Requirements for UK notified bodies’

### Revision history

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## Introduction

For the United Kingdom, designation of notified bodies under the medical devices directives<sup>1</sup> is by the Secretary of State acting through the Medicines & Healthcare Products Regulatory Agency, the UK competent authority for the regulations<sup>2</sup>. Each notified body will be designated to offer the services set out in one or more of the relevant annexes of the directives. To be designated, the applicant must be capable of taking responsibility for all procedures required of a notified body in any particular annex (see appendix).

Notified bodies seeking designation to carry out assessments under the regulations will themselves be subject to assessment audits against the requirements<sup>3</sup>. These audits may be conducted either by the competent authority or by its appointed agent.

This document specifies the audit criteria for judging a notified body's compliance with the requirements. Also, where appropriate, guidance is given on some particular aspects of the criteria.

Many of the requirements for a notified body under the regulations are similar to clauses found within the ISO/IEC 1702X series of standards 'Conformity assessment - Requirements for bodies providing audit and certification of management systems'. Formal accreditation against these standards may establish an applicant's basic competence. However, some aspects of the regulations are not covered by existing standards. Organisations accredited to the ISO/IEC 1702X series of standards will need to establish systems to ensure they comply also with these additional requirements.

Following designation, the notified body may expect to be monitored through surveillance audits, at intervals determined by the competent authority. The designating authority has a duty to withdraw designation should the notified body fail to meet the criteria. However, designation would be withdrawn only after discussion with the notified body and opportunity had been given for the organisation to refute the audit findings.

In addition it is expected that guidance documents produced at a European level should also be followed, eg the Designating Authorities Handbook - [http://www.nbog.eu/resources/da\\_handbook.pdf](http://www.nbog.eu/resources/da_handbook.pdf), produced by the Notified Body Operations Group (NBOG).

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1 Council Directive 90/385/EEC of 20<sup>th</sup> June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (referred to in this document as the AIMDD); Council Directive 93/42/EEC of 14<sup>th</sup> June 1993 concerning medical devices (referred to in this document as the MDD); and Council Directive 98/79/EC of 27<sup>th</sup> October 1998 on in vitro diagnostic medical devices (referred to in this document as the IVDMD).

2 The directives are transposed into UK legislation as regulations, and are published as a statutory instrument.

3 The requirements are originally set out in annex 8 of the AIMDD or annex XI of the MDD or annex IX of the IVDMD, and the associated responsibilities described in annexes 2, 3, 4 and 5 of the AIMDD and annexes II, III, IV, V and VI of the MDD and annexes III, IV, V, VI and VII of the IVDMD.

## 1 General

### Requirements

#### (A) Resources

The notified body shall provide the resources for the conformity assessment of medical devices as specified in the directives in a competent, transparent, neutral, independent and impartial manner.

#### (B) Legal status

The notified body shall be a legally defined entity and shall make available to the competent authority or its appointed agent on request:

1. documentation clearly identifying its legal status
2. a description of the means by which the notified body obtains financial support
3. documentation which clearly shows both the authority and the responsibility of individuals within, and the reporting structure of the notified body
4. documentation about the notified body's financial situation, including accounts
5. details about fees and financial conditions for the conduct of conformity assessment.

#### (C) Organisational structures

If the notified body is a legal entity which is part of a larger organisation, the links and relationship between the notified body and the larger organisation shall be clearly documented.

### Guidance

Where the notified body uses the services of a subcontractor, the notified body is responsible for all contracted actions of its subcontractor and shall be liable for them as if the notified body itself performed the actions. See also section 8.

## 2 Independence

### Requirements

#### (A) Involvement in manufacture

The notified body shall not be the designer, manufacturer, supplier, user or installer of devices within the product category for which the notified body has been designated, nor the authorised representative of any of those parties.

#### (B) Links with manufacturers

The directors, executives and personnel responsible for carrying out the evaluation and verification activities shall be independent of both the manufacturers for whom the notified body conducts assessments and the commercial competitors of those manufacturers, during their employment by the notified body for the product range it is notified for. They shall not have been directly involved in the design, construction, marketing or maintenance of the devices for which the manufacturer has approached the notified body.

#### (C) Consultancy

Notified body personnel shall not be involved in consultancy activities relating to the devices in question, their manufacturing control or test procedures, or their manufacturer. See also section 3.

## Guidance

- a) The notified body should have documented procedures for the identification, review and resolution of all cases where conflict of interest is suspected or proven. Records of such reviews and decisions should be kept.
- b) The notified body should require all staff acting on its behalf to declare any potential conflict of interest. Records of such declarations should be kept.
- c) If the notified body, or any part of a larger organisation to which it is linked, provides consultancy services, then the documented quality system of the notified body should include a policy statement and documented procedures ensuring that assessment and consultancy services are separated. The notified body should ensure, by means of a documented agreement, that its subcontractors are aware of this guidance.
- d) Marketing material produced by the notified body should not give any impression that consultancy and assessment activities are linked.
- e) The requirements of this section do not preclude exchange of technical information and guidance between a notified body and a company seeking their assessment.

## 3 Impartiality

### Requirements

#### (A) Remuneration

The notified body shall guarantee the impartiality of all inspection and evaluation personnel and ensure that the remuneration of personnel shall neither depend on the number of controls and verifications that they carry out, nor on the results of their activities.

#### (B) Documentation

The notified body shall ensure by implementation of documented procedures that personnel are free from pressures and inducements, particularly financial, which might influence their judgement during any assessment or inspection that they perform.

### Guidance

The notified body should document the means by which it ensures that the principle of impartiality is made known and safeguarded throughout its organisation.

## 4 Technical competence

### Requirements

#### (A) Knowledge and training of assessment staff

Assessment personnel shall possess satisfactory knowledge of the requirements relating to the assessments they are undertaking and be adequately experienced in their designated area of competence. This to cover the medical application, technology and performance of medical devices; and to cover the clinical utility, methodology/technology and performance of in vitro diagnostic medical devices.

**(B) Records**

Records shall be available to demonstrate that personnel have the appropriate experience and have received appropriate training relevant to the notified body's scope.

**(C) Auditors' experience**

Notified bodies carrying out assessments under annexes 2 and 5 of the active implantable medical devices directive, annexes II, V and VI of the medical devices directive and annexes IV and VII of the in vitro diagnostic medical devices directive shall require that such quality system audits are conducted by a team that includes at least one member who is experienced in the evaluation of the technologies used by the manufacturer.

**(D) Staff within the organisation**

The notified body must have sufficient scientific and technical staff **within the organisation**, with adequate experience and knowledge, in order to be able to handle the technical and administrative tasks such as allocation of appropriate assessment personnel, review of assessment output and to advise on certification for the specific tasks and products it has been designated to cover.

**Guidance**

- a) The management of the notified body should satisfy themselves that personnel who administer and perform evaluation and verification operations are competent to fulfil the tasks required of them.
- b) One or more members of an assessment team should be trained and/or experienced in each of the following skills that is relevant to the assessment being made:
  1. the production methods and test and verification procedures applicable to the various types of medical devices within the designated scope (relevant to all directives and annexes)
  2. the assessment of design documentation and clinical evaluation data (AIMDD and MDD) or performance evaluation data (IVDMDD) to determine that all aspects of the design are in compliance with the requirements of the regulations. Relevant to:  
annexes 2 and 3 of the AIMDD  
annexes III, IV and V of the IVDMDD  
annexes II and III of the MDD
  3. for sterile medical devices, microbiological assessment, including environmental control, and validation and routine control of sterilization processes (relevant to all directives and annexes)
  4. biocompatibility assessment. Relevant to:  
annexes 2 and 3 of the AIMDD  
annexes II and III of the MDD
  5. the assessment and evaluation of quality systems. Relevant to:  
annexes 2 and 5 of the AIMDD  
annexes IV and VII of the IVDMDD  
annexes II, V and VI of the MDD
  6. the application of statistical controls to device verification (relevant to all directives and annexes)
  7. clinical pathology applicable to the conditions or disease states assessed by the various types of products within the designated scope (relevant to annexes III, IV and V of the IVDMDD).

- c) Personnel involved in the assessment of quality systems (i.e. procedures according to annexes 2 and 5 of the AIMDD; annexes IV and VII of the IVDMDD; and annexes II, V and VI of the MDD) should be qualified in accordance with 'Guidelines for Regulatory Auditing of Quality Systems of Medical Devices Manufacturers: Part 1: General Requirements' ([GHTE SG4/N28R4:2008](#)). The management of quality systems assessment should be in accordance with these same guidelines.
- d) For each assessor, a record should include the following information:
1. name of assessor
  2. designated areas of competence and responsibility within the scope of activities for which the notified body has been notified
  3. educational and professional qualifications
  4. work experience (relevant to the activities being performed)
  5. details of training received relating to assessment activities, including training in the requirements of the directive(s), relevant standards, European guidance and other appropriate documents.

## 5 Facilities

### Requirements

#### (A) Extent

The notified body shall have available the appropriate facilities to enable it to carry out the assessment and verification activities for which it has been notified.

### Guidance

The facilities should enable the notified body to perform the technical and administration tasks connected with evaluation and verification, whether those tasks are carried out by the notified body itself or under its responsibility (see also section 8). If verification and testing procedures require use of technical equipment normally controlled and used by the manufacturer, the notified body should be able to demonstrate that it both had access to, and full control of, the equipment during the relevant procedures.

## 6 Confidentiality

### Requirements

#### (A) non-disclosure

The notified body shall have made adequate arrangements to ensure confidentiality of the information obtained in the course of carrying out its tasks under the regulations. These arrangements shall ensure that no details, records, results or information of any kind are disclosed to any other party except the competent authority and the manufacturer.

### Guidance

- a) Documented procedures should describe the means by which the notified body maintains confidentiality between itself and its clients. These should include the mechanism through which assessment personnel are made aware of confidentiality requirements. For example staff may be required to give a written undertaking not to divulge any information gained about clients to third parties.

- b) Section 6(A) does **not** relate to:
1. the provision of access to certification information requested by other notified bodies in accordance with the directives, or
  2. the requirement to communicate information relating to the issue, refusal, suspension or withdrawal of certificates to the competent authority, designating authority or other notified bodies, or
  3. information pertaining to devices that when correctly put into service and used in accordance with their intended purpose have been found to compromise the health and/or safety of patients or users.

## 7 Liability insurance

### Requirements

#### (A) Provision for misadventure

The notified body shall take out appropriate professional indemnity insurance to provide for claims and litigation in the event of misadventure. Evidence that adequate insurance cover has been arranged shall be provided.

### Guidance

- a) The scope and overall financial value of any liability insurance policy will be a matter for decision by the notified body, as guided by its own legal advisers.
- b) Under Directive 85/374/EEC, the manufacturer or importer remains responsible for product liability.

## 8 Subcontractors

### Requirements

#### (A) Contract requirements

Where tasks relating to conformity assessment are carried out on behalf of a notified body by external subcontract organisations or individuals, except as provided by sub-section (B), the notified body shall ensure that these subcontractors and their personnel conform to all the requirements of the regulations that would apply had the task been performed by its own personnel.

#### (B) Derogation

Sub-section 8(A) is not applicable to sub-section 2(A).

#### (C) Limitation to scope

The notified body shall not subcontract the overall responsibility for reviewing the outcome of assessment and verification activities, which are the essential tasks for which it was notified. Subcontractors shall fulfil only an objective role, that is, one which is restricted to factual reporting and/or supported recommendations, on the basis of which the notified body shall make assessments and judgements in relation to the requirements of the regulations.

#### (D) Documented agreement

A documented agreement shall be drawn up between the notified body and the subcontractor reflecting these requirements, including confidentiality and the provision of access for the

competent authority. This agreement shall also prohibit subcontractors from further subcontracting their duties.

#### **(E) Subcontractor's documentation**

The notified body shall ensure that the subcontracted activities are carried out according to detailed documented procedures which are the same as, or judged by the notified body to be equivalent to, those followed by the notified body itself in the context of conformity assessment.

#### **(F) Register**

The notified body shall inform the competent authority of its intention to subcontract duties in relation to the scope for which it was appointed. The notified body shall keep an up to date register of all its subcontractors, which shall be provided to the Commission and the competent authority without delay and to other member states on request. The notified body shall maintain documentary evidence that the subcontractor has the necessary technical competence and facilities to carry out the subcontracted activities.

### **Guidance**

- a) A notified body which subcontracts duties in relation to the scope for which it was notified remains in all cases responsible for all activities covered by the notification. Subcontracting does not entail the delegation of powers or responsibilities. The subcontractor register maintained by the notified body should include the following information:
  1. the name of the subcontract organisation
  2. its legal status and details of any relationship with a parent company, group of companies, or any other organisation of which the subcontractor is a part
  3. names of staff carrying out the subcontracted activities and evidence that they are competent to do so (see also section 4)
  4. the precise duty performed by the subcontractor (e.g. quality system assessment, testing etc.) and details of the procedures used in carrying out the subcontracted duties.
- b) A notified body which subcontracts duties should document the means by which it ensures that the principle of impartiality is made know to subcontractors and safeguarded by the subcontractor's personnel carrying out assessment activities on behalf of the notified body.
- c) The conditions of this section apply to any subcontractor whether or not it is located on Community territory. Subcontractors are not necessarily resident in the Community but their activities are defined by contract which is interpreted under UK law.

## **9 Quality system**

### **Requirements**

#### **(A) Documentation**

The notified body shall establish and maintain up to date documented procedures and records which, together, demonstrate its compliance with the regulations and this document. As appropriate, this documentation shall include the following:

1. A description of the legal status of the notified body, including the links and relationship with parent organisations, if relevant.
2. Documentation showing the responsibilities and reporting structure of the notified body.

3. A rationale for defining the scope of the responsibilities for each of the assessment personnel.
4. The names of assessment personnel, both internal and subcontracted, their assessment responsibilities, and records of their relevant training and experience. (See also section 4).
5. A description of the application process by which manufacturers can obtain third party approval by the notified body. The document shall specify which languages are acceptable for submissions and correspondence from manufacturers relating to their demonstration of compliance with the requirements of the directives.
6. Procedures to review applications in respect to the manufacturer's classifications of his medical devices.
7. Procedures to review the completeness of applications against the details provided in the annex under which approval has been sought.
8. Procedures to evaluate and verify manufacturers' compliance with their chosen annexes.
9. Procedures detailing the rationale for fixing time limits for completion of evaluation and verification activities.
10. Procedures for the examination of clinical evaluations. Where data is derived from clinical investigations NBs should ensure that the conclusions drawn by the manufacturer are valid in the light of any submissions to competent authorities relating to that investigation (relevant to annexes 2/II and 3/III).
11. Procedures to take account of information on medical devices subject to pre-existing national law, regulations or administrative provisions.
12. Records to demonstrate the conclusions of the assessment including a reasoned evaluation of the manufacturer's compliance with the requirements of the relevant directive.
13. Procedures for the consideration of appeals against decisions made by the notified body regarding:
  - the interpretation of classification rules, including referral to the competent authority where necessary
  - a manufacturer's compliance with the requirements of the directives.
14. Procedures relating to the issue, modification, refusal, suspension, re-instatement and withdrawal of, or restrictions placed on, certificates, including action to be taken in the event of the notified body learning that a CE mark has been wrongly affixed to a device. These procedures shall include a requirement to inform the competent authority about all certificates refused, suspended, re-instated, withdrawn or having restrictions placed upon them.
15. Details of obligations regarding communications with other organisations, including competent authorities, the Commission and other notified bodies (i.e. about all certificates suspended or withdrawn and, on request, about certificates issued or refused and any additional relevant information). The documentation shall also include records of all communications with the Commission and action taken as a result of such communications. These records shall be made available to the competent authority on request
16. Procedures for assessing and monitoring the competence of subcontractors, if used.

17. Procedures describing the means by which assessment and consultancy services are separated, whether these services are carried out by the notified body or any part of a larger organisation to which it is linked, or its subcontractors.
18. Details of record keeping facilities including means to ensure security and confidentiality
19. Procedure for the provision of information in relation to the EUDAMED database.

### **(B) Control**

A system shall be maintained to control all quality system documentation and to ensure that current issues of procedures are available at all relevant locations.

### **(C) Implementation**

The notified body shall ensure that the defined quality system procedures are effectively implemented.

## **Guidance**

The description of the application process (sub-section 9(A) 5) may be the 'description of the certification system' required to be made available in published form by the ISO/IEC 17021 standard.

## **Appendix**

The following additional requirements relate to the specific annexes under which notified bodies offer their services. Further details can be found in the relevant annexes of the particular directives.

## **A1 Annex 2 of the AIMDD, Annex II of the MDD and Annex IV of the IVDMDD**

### **(A) Quality system**

1. Notified bodies shall ensure that personnel (whether directly employed or subcontracted) carrying out quality assurance audits are appropriately trained and experienced in the application of relevant harmonised standards.
2. Notified bodies and/or their subcontractors shall have appropriate facilities for conducting quality systems audits on manufacturers' premises. They shall ensure that the outcome of the evaluation, notified to the manufacturer after the inspection, includes a reasoned evaluation.
3. Notified bodies shall have documented procedures for drawing up client technical file sampling plans for class IIa and IIb devices, and for carrying out assessments of the files in accordance with the plans,
4. The notified body shall have documented procedures for dealing with notifications from manufacturers of proposed changes in their certified quality systems or the product range covered. They shall ensure that manufacturers are advised as to whether the modified quality system would meet the requirements of the relevant directive. This decision shall include a reasoned evaluation.

### **(B) Design dossier**

1. The notified body shall have procedures and facilities for the examination of design dossiers, relating to active implantable medical devices, class III medical devices or Annex II List A in vitro diagnostic medical devices and in vitro diagnostic medical devices for self-

testing. Examination of design dossiers shall be carried out by appropriately qualified personnel.

2. For dossiers covering devices which incorporate a medicinal product acting in a manner ancillary to that of the device, the notified body shall have procedures to identify such devices and, in consideration of the application, enable consultation with the relevant authority for medicinal products (e.g. MHRA in the UK). The notified body shall ensure its final decision is communicated to the authority consulted. For devices containing human blood derivatives this consultation should be with the EMA.
3. For dossiers covering devices utilising tissues of animal origin as referenced in [Directive 2003/32/EC](#), the notified body shall have procedures to identify such devices and to follow the procedure referenced in that Directive.
4. The notified body shall have procedures for the production of EC design examination certificates. The certificates should include their conditions of validity, the data needed for identification of the approved design, and (where appropriate) a description of the intended use of the product
5. The notified body shall have procedures for checking the significance of changes to the design dossier notified by the manufacturer. This shall include an evaluation of whether appropriate changes have been made to the manufacturer's quality system. Approval shall be given in the form of an addendum to the EC design examination certificate

**Note:** it is envisaged that a single design dossier may cover several variants of one model of device or even a range of models. A manufacturer need not inform the notified body of any subsequent design change, new model or variant which remains consistent with the existing approved design dossier and quality system.

### (C) Surveillance

The notified body shall have procedures which define how and when surveillance inspections and evaluations of manufacturer's quality systems are to be carried out and how unannounced visits to manufacturers are to be conducted. Manufacturers shall be supplied with evaluation reports following all inspections.

**Note 1:** the decisions taken by the notified body shall be valid for a maximum of five years and may be extended on application for further periods of up to five years (design dossiers).

**Note 2:** if the notified body's scope includes Annex II list a products under the IVDMDD, see also appendix A6.

## A2 Annex 3 of the AIMDD, Annex III of the MDD and Annex V of the IVDMDD

### (A) Type examination

1. Notified bodies and/or their subcontractors shall have suitable facilities and procedures to examine and evaluate the documentation, to verify that the type has been manufactured in accordance with the documentation, and for performing the appropriate inspections and tests to verify compliance with the essential requirements of the relevant directive.
2. The notified body shall make provision to issue an EC type-examination certificate to the manufacturer where the type meets the provisions of the relevant directive. It shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved.

3. For devices that incorporate a medicinal product acting in a manner ancillary to that of the device, the notified body shall have procedures to identify such devices and, in consideration of the application, enable consultation with the relevant authority for medicinal products (e.g. MHRA in the UK). The notified body shall ensure its final decision is communicated to the authority consulted. For devices containing human blood derivatives this consultation should be with the EMA.
4. For devices utilising tissues of animal origin as referenced in Directive 2003/32/EC, the notified body shall have procedures to identify such devices and to follow the procedure referenced in that Directive.
5. The notified body shall have documented procedures for reviewing changes to the approved product. When the change is considered to be satisfactory, they shall issue to the manufacturer a supplement to the initial EC type examination certificate.

**Note:** the decisions taken by the notified body shall be valid for a maximum of five years and may be extended on application for further periods of up to five years.

### **A3 Annex 4 of the AIMDD, Annex IV of the MDD and Annex VI of the IVDMDD**

#### **(A) Verification**

1. Notified bodies and/or subcontractors shall have suitable facilities and procedures for examination and testing of products to verify that they conform to the requirements of the relevant directive.
2. The notified body shall make provision for examining and testing products on a statistical sampling basis for each homogeneously produced batch or, in addition for the medical devices directive and in vitro medical devices directive, on an individual product basis, and draw up a written certificate of conformity relating to the tests carried out.
3. The notified body shall have procedures to ensure that any rejected product or batch of products is prevented from being placed on the market and, in the event of frequent rejection of batches, to suspend statistical verification.

### **A4 Annex 5 of the AIMDD, Annex V and VI of the MDD and Annex VII of the IVDMDD**

#### **(A) Quality system**

1. Notified bodies shall ensure that personnel (whether directly employed or subcontracted) carrying out quality assurance audits are appropriately trained and experienced in the application of relevant harmonised standards.
2. Notified bodies and/or their subcontractors shall have appropriate facilities for conducting quality systems audits on manufacturer's premises. They shall ensure that the outcome of the evaluation, notified to the manufacture after the inspection, includes a reasoned evaluation.
3. Notified bodies shall have documented procedures for drawing up client technical file sampling plans for class IIa devices, and for carrying out assessments of the files in accordance with the plans,
4. The notified body shall have documented procedures for dealing with notifications from manufacturers of proposed changes in their certified quality systems. They shall ensure that manufacturers are advised as to whether the modified quality system would meet the requirements of the relevant directive. This decision shall include a reasoned evaluation.

**(B) Surveillance**

The notified body shall have procedures which define how and when surveillance inspections and evaluations of manufacturers' quality systems are to be carried out and how unannounced visits to manufacturers are to be conducted. Manufacturers shall be supplied with evaluation reports following all inspections.

**Note:** if the notified body's scope includes Annex II list A products under the IVDMDD see also appendix A6.

**A5 Annex III of the IVDMDD****(A) Design dossier for devices for self-testing**

Please see A1 (B) Design dossier requirements (I), (III) and (IV) above and Section 6 of Annex III of the In Vitro Diagnostic Medical Devices Directive.

**A6 Special provisions for Annex II list A products under Annexes IV and VII of the IVDMDD****(A) Verification**

1. Notified bodies and/or their subcontractors shall have suitable procedures for the examination and evaluation of the relevant test reports provided by the manufacturer for each manufactured device or batch of devices without delay.
2. The notified bodies and/or their subcontractors shall have suitable facilities and procedures for performing appropriate tests to verify compliance of each device or every batch, as necessary.
3. The notified body must give its decision on the acceptability, or otherwise, of the device or batch within the agreed timeframe but not later than 30 days of receipt from the manufacturer of the documentation and any samples.