DESIGNATING AUTHORITIES HANDBOOK

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Glossary

(Note: Readers will wish to be aware that there may be other 'official' definitions for some of these terms in other documents/standards (e.g. Mutual Recognition Agreements (MRAs), ISO/IEC 17000, GHTF SG4 (98) 39, EN ISO 1900011 etc)

Designating Authority (DA)

National authority with responsibility for the designation, monitoring and control of national Notified Bodies.

Competent Authority (CA)

National authority with responsibility for implementing the relevant provisions contained in the specific new approach directives within their jurisdiction.

Notified Body Operations Group (NBOG)

Group consisting of members from EU Commission and nominees from the Member States Competent Authorities and/or DAs, representatives of the EFTA/EEA countries as well as the various PECA or Accession countries with the objective of improving the overall performance of Notified Bodies in the medical devices sector.

Notified Body (NB)

A Conformity Assessment Body authorized to perform defined conformity assessment activities within the scope of European Directives.

Auditor

Person employed by the NB for the purpose of assessing a manufacturer's conformity with one or more of the medical devices Directives conformity assessment annexes.

Assessor

Person employed by the DA for the purpose of assessing the initial and ongoing competence of a NB to perform the tasks it is designated for.

Preface

The Designating Authorities Handbook

Preface

It is a requirement of the various medical devices Directives that Member States (MS) each establish one or more Competent Authorities (CAs) within their jurisdiction to oversee the effective implementation and enforcement of the Directive's provisions as well as carrying out those functions specifically ascribed to the National Authorities. One of these functions is the designation and control of Notified Bodies (NBs). These are independent certification bodies that, as required, assess and confirm a manufacturer's compliance with the provisions of the relevant Directive prior to the device being affixed with the CE-mark.

Several MSs have retained responsibility for the designation and control of NBs within the CA. In some others these actions are carried out by separate Designating Authorities (DAs). The choice of where the function is situated is for the MS to decide. In any event, the effective designation and control, by close monitoring, of NBs is a key component in the effective operation of the European regulatory system for medical devices.

This Handbook provides guidance to assist authorities in the execution of their responsibilities for the designation, monitoring and control of NBs in the medical devices sector.

The Handbook has been produced by the Notified Body Operations Group (NBOG). It draws on a variety of guidance documents produced by various organisations as well as specific material produced by NBOG. It is designed to be an organic document. It will change from time to time as required. It is anticipated that, over time, existing sections will change or be deleted and new sections added. But most of all, the Handbook has been designed to be a practical aid for DAs and their staff. Accordingly comments upon it, plus suggestions for amendments or for new areas to be covered, will be welcomed by NBOG. These should be sent, in the first instances, to your national NBOG representative as shown in Annex 1 to Section 2.

The Handbook is organised into four sections as under:

Section 1: provides information on NBOG, its role, composition and working methods.

Section 2: describes the role and responsibilities of DAs. This includes descriptions of the skills and resources a DA will need if it is to function effectively in the key areas of designating and monitoring their national NBs. Additionally, the section describes an agreed "Communications Protocol" which should be used by DAs wishing to communicate effectively with each other.

Section 3: describes, and gives practical advice and guidance on, the designation process. The section covers both the initial designation of a NB with a prescribed scope and subsequent actions in relation to changing that scope, including suspension or withdrawal of designation.

Section 4: describes, and gives advice and guidance on, the monitoring of a NB's activities by the DA. This includes a description of the various ways in which the NB's activities can be monitored by regular DA assessments of the NB and gives advice on the assessment process itself.

SECTION 1

The Notified Body Operations Group (NBOG)

The Notified Body Operations Group

1.0 Introduction

1.1 This section describes the Notified Body Operations Group (NBOG), its role, membership and working methods.

2.0 Background

2.1 Member States (MSs) and the EU Commission agreed in July 2000 to set up NBOG. This was in response to widespread concern that the performance of Notified Bodies (NBs) in the medical device sector, and the Designating Authorities (DAs) responsible for them, was variable and inconsistent. Accordingly NBOG's terms of reference were agreed to be:

> ***"To improve the overall performance of Notified Bodies in the medical devices sector by primarily identifying and promulgating examples of best practice to be adopted by both Notified Bodies and those organisations responsible for their designation and control."***

2.2 NBOG first met in November 2000 and produced a suggested work programme that was endorsed by MSs in December 2000.

2.3 NBOG is chaired by a representative of a MS's Competent Authority (CA) and hosted by the Commission. It reports on its work to the twice yearly meeting of CAs and to the Medical Devices Experts Group (MDEG).

3.0 NBOG Membership

3.1 NBOG membership consists of the EU Commission, and nominees from the Member States CAs and/or DAs. Additionally, membership of the Group is open to representatives of the EFTA/EEA countries as well as the various PECA and Accession countries. On the whole, members of the Group are nominated by their national authorities on the basis of their expertise in the area of NB designation and control.

4.0 NBOG Working Methods

4.1 NBOG works primarily by the production of written guidance and advice. The usual working method is for one representative of the Group to take the lead in producing a draft of a required guidance paper. This is circulated electronically to the rest of the Group for comments. The process is repeated until the whole of the Group is able to endorse the document. Appropriate documents may be discussed at MDEG.

4.2 Additionally, NBOG is able to provide topic specific training events for DA assessors and NB auditors as well as organising and facilitating training opportunities for individual DA assessors under its Invitational Audit Programme.

4.3 In general NBOG meets twice a year.

4.4 For further information about the work of NBOG, comments on this Handbook, or suggestions for amendments to it, please contact in the first instance your national NBOG representative.

Section 2

Roles and Responsibilities of the Designating Authority

Roles and Responsibilities of the Designating Authority

1.0 Introduction

1.1 This section describes the role and responsibilities of the Designating Authorities (DAs) under the medical devices Directives for the designation, monitoring and control of Notified Bodies (NBs).

2.0 Background

2.1 The Active Implantable Medical Devices Directive (90/385/EEC), the Medical Devices Directive (93/42/EEC) and the *in-vitro* Diagnostic Medical Devices Directive (98/79/EC) all provide for the appointment of independent certification bodies called Notified Bodies (NBs). For devices other than those subject to self declaration, NBs are responsible for verifying the conformity of devices or the way in which they are manufactured with the relevant Directives provisions. Where appropriate a manufacturer cannot place a device on the EU market until they have been successfully assessed by a NB. Accordingly the NB provides a vital and critical link in the regulatory chain.

2.2 It is essential that NBs perform at a consistently high level of expertise and rigour. Failure to properly carry out the conformity assessment tasks for which they have been designated may result in harm to public health and safety and an erosion of public confidence in the system of medical device regulatory control.

2.3 Ultimately the DA is responsible for the performance of those NBs that it has designated. This remains the case even where the activities of the NB are outside of the DAs own geographical area.

3.0 The Designating Authorities Responsibilities

3.1 As the *Guide to the Implementation of Directives Based on New Approach and Global Approach* [1](page 36) makes clear:

> ***"Member states are responsible for their (the Notified Bodies) notification. They may choose the bodies they notify from the bodies under their jurisdiction, which continuously comply with the requirements of the directives and the principles laid down in Council decision 93/465/EEC."***

3.2 From this it is clear that DAs have the three main roles and responsibilities set out below.

3.3 First, DAs are responsible for designating as NBs only those organisations that meet the requirements of the particular Directive in question and the principles of 93/465/EEC. This requires the DA to carefully and thoroughly examine any request for designation to ensure that the applicant organisation has the necessary technical, scientific and medical competence and facilities to carry out the conformity assessment procedures in question for the specific device scope. In addition the DA

[1] http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm

must ensure that the applicant organisation can demonstrate the necessary levels of independence, impartiality and integrity. In designating an organisation as a NB, it is the DAs responsibility to ensure that the scope of activities ascribed to it (i.e. the particular conformity assessment activities or device types) are limited to those for which the necessary expertise and facilities have been clearly demonstrated.

3.4 Detailed guidance and advice for DAs on the designation of NBs is given in Section 3 of this Handbook.

3.5 Second, DAs are responsible for ensuring that designated NBs for whom they are responsible "continuously comply with the requirements of the Directives and the principles laid down in Council decision 93/465/EEC". Thus, DAs have a clear responsibility to subject the activities of their NBs to regular and structured surveillance. In practice this means subjecting NBs to a range of different types of assessment by properly trained and qualified DA assessors. The aim of these assessments is to confirm that the NB performs consistently at a high level of competence and within the scope of its designated activities.

3.6 Detailed advice and guidance for DA assessors involved in the assessment of NBs is given in Section 4 of this Handbook.

3.7 Third, the DA has a clear responsibility to act on the findings of its assessments of NBs. This involves communicating to the NB details of concerns about its performance obtained during periodic assessments of its activities, the results of enforcement activities, concerns passed to it by other Member States, etc. On the basis of these concerns the DA is responsible for agreeing or imposing actions for the NB to take designed to address them. Depending upon the seriousness of the concerns such actions can range from, for example, requiring that NB personnel are re-trained, audits are repeated, the NBs designated scope adjusted or, in cases of extreme or persistent poor performance, that the NB is de-designated.

3.8 Similarly, DAs are responsible for investigating allegations of poor performance made by other Member States (MSs). MSs have an agreed Communication Protocol that should be used in these cases. This is reproduced at Annex 1 to Section 2.

3.9 Further advice and guidance on the identification of problems, their grading into levels of seriousness and possible responses to them is given in Section 4 of this handbook.

3.10 Finally, DAs should, as applicable, aim to comply with relevant sector wide standards and guidance available for accreditation bodies. Of particular relevance in this regard is the forthcoming EN ISO/IEC 17011 standard "General Requirements for accreditation bodies accrediting conformity assessment bodies".

4.0 Designating Authority skill and resource requirements.

4.1 It is clear that for DAs to function effectively in the designation, monitoring and control of their NBs, they must be properly resourced. In particular they must have an adequate number of suitably trained and experienced staff to enable it to carry out its main responsibilities as described above.

4.2 It is for each DA to determine what skills and level of resource it needs to exercise its responsibilities correctly. However, experience suggests that it is possible to draw some general guidelines. Thus the number of assessors required to consider applications for designation and to conduct assessments of those organisations designated, will clearly depend upon the number of NBs the DA is responsible for and the number of clients those NBs have. However, experience has shown that an absolute minimum of two assessors are needed to provide flexibility and essential back up when scheduling and conducting assessments of NBs. Two assessors also help prevent the situation of a single assessor becoming too familiar with any particular NB, and provides an opportunity to quality assure each others work.

4.3 Experience also shows that DA assessors should ideally have certain core skills. Thus, for example, all DA assessors should be trained in the appropriate skills needed for assessing the effectiveness of NB auditors. Additionally, a broad and comprehensive knowledge of the various medical devices Directives, and the national laws that transpose them, is clearly an essential requirement. Ideally, they should also have knowledge and experience of medical devices manufacture and be familiar with the relevant standards. Like NB auditors , all DA assessors should be able to demonstrate a high level of integrity and impartiality.

4.4 In short, DA assessors should have the skills and expertise necessary to allow them to conduct meaningful, thorough and proficient assessments of NBs. This implies that DA assessors should have substantially the same mix of skills and experience as NB auditors. These are well described in the following extract from the Global Harmonisation Task Force Document "Guidelines for regulatory auditing of quality systems of Medical Device Manufacturers general requirements : 1999"[2].

> 10.2.3 Auditor qualifications, training and experience
>
> In addition to basic auditing skills the competencies specifically required for auditing medical device manufacturers may be achieved through a variety of means including a combination of one or more of the training or experience elements listed below.
>
> a) Qualification
>
> Auditor qualification is most likely to be in one or more of the following:
>
> i. Biology or microbiology;
> ii. Chemistry or biochemistry;
> iii. Computer or software technology;
> iv. Electrical, mechanical or bioengineering;
> v. Human physiology;
> vi. Medicine;
> vii. Pharmacy;
> viii. Physics or biophysics.

[2] http://www.ghtf.org/sg4/inventorysg4/99-28genreq.pdf

b) Training

Special programmes may be established for training technically qualified staff in the following:

i. Understanding the regulatory requirements and related laws/ordinances/statutes etc.;
ii. Auditing of medical devices manufacturers' quality systems;
iii. Understanding the design and manufacturing processes and the technologies involved;
iv. Safety aspects relating to the intended use of medical devices.

c) Experience

Auditor experience is most likely to be in the following:

i. Working in closely related industries and the workplace such as research and development, manufacturing;
ii. Working in the application of the device technology and its use in health care services and with patients;
iii. Testing the devices concerned for compliance with the relevant national or international standards;
iv. Conducting performance testing, evaluation studies or clinical trials of the devices.

5.0 Sub-contracting Designating Authority Functions

5.1 It can sometimes prove difficult for an individual DA to ensure that it has personnel "in house" with all the necessary skills, training and experience to effectively carry out its role in the designation and control of NBs. In such situations it is possible for the DA to sub-contract some of its functions to another DA or other independent/impartial body or expert with the required skills. An alternative option would be to obtain the necessary skills etc from another DA for a particular task or range of tasks. In both situations it is vital that the relationship, roles and respective obligations are clearly set out in written form before any work is undertaken. It is also the DAs responsibility to ensure that the person/body it is sub-contracting to has the necessary expertise, experience, training and facilities to do the job being sub-contracted. It is also important for the DA to assure itself that the sub-contractor meets the necessary requirements in terms of impartiality and independence.

5.2 While sub-contracting activities can be a useful way for the DA to ensure it carries out its responsibilities fully it is important to recognise that the primary responsibility for any work carried out remains with the DA.

ANNEX 1 to Section 2

COMMUNICATION PROTOCOL

Introduction

1. This paper sets out a standard communication protocol, in respect of Notified Body performance, to be adopted by Member States/Designating Authorities. The aims are:
    - to encourage examples of possible poor performance to be passed to the appropriate Member State/Designating Authority for investigation;
    - to improve Notified Body performance generally.

2. In addition, the named individuals listed below can be used as a contact point by anyone wishing to observe another Designating Authority's auditors auditing a Notified Body in order to develop their own expertise in this area. The contact will be able to advice on the availability of a suitable planned audit and help advise on other practical matters as appropriate.

Protocol

3. During its post market surveillance activities or investigations into reported adverse incidents involving medical devices, it sometimes happens that a Competent Authority, Designating Authority or others identifies possible examples of poor performance by the relevant Notified Body. Such "poor performance" could include, for example, failure to spot classification errors, the use of an incorrect conformity assessment procedure for the specific class of device, an inadequate assessment of the manufacturer's risk analysis, design dossier, or clinical data as appropriate, etc. It is important that such cases are brought to the attention of the appropriate Designating Authority who can then investigate and, if necessary, take action.

4. In practice, however, it is likely that such information will only be passed routinely where there is confidence that it will be acted upon. For that reason the following 3 step protocol has been agreed by Member States/Designating Authorities.

Step 1

- A Member State identifying possible poor performance by a Notified Body designated by another Member State or having queries about a Notified Body's designated scope, should pass all the relevant information, with a specific request for the matter to be investigated, to the named contact point (listed below) for the other Member State. The information passed should be as complete as possible and identify the specific problem identified with any supporting information. As a minimum, however, the query should contain, wherever possible, and as appropriate:

    the name and number of the Notified Body;
    the type and number of certificate (annex);

the name and address of the manufacturer;
the name of the device(s) involved:
the class of the device;
the applicable medical device Directive

together with a full description of the perceived problem. Copies of all relevant correspondence should also be provided where possible.

Step 2

- The receiving Member State should acknowledge receipt of the complaint within 5 working days of receipt, and, if possible, give an indicative timetable for its investigation.

Step 3

- At the conclusion of the investigation, the receiving Member State should reply to the complainant (and other Member States if appropriate) describing the outcome of the investigation. Where the complaint is upheld details should be given of remedial action taken or proposed to ensure the problem is not repeated.

Contact List: Reports of possible poor Notified Body performance should be addressed to the following named individuals.

Country	Name	Address and other Contact Details
Austria	Wolfgang Ecker	Federal Ministry for Health and Women Radetzkystr.2 1031 Vienna Austria Tel: + 431 71100 4206 Fax: + 431 71100 4217 e-mail: wolfgang.ecker@bmsg.gv.at
Belgium	Philippe Bauwin	SPF Sante Publique CAE Quartier Vegale Brussels Belgium Tel: +32 2 2104899 Fax: +32 2 210 4901 e-mail: meddev@health.fgov.be

Denmark	Helle Sandager-Jorgensen	Ministry of the Interior and Health Slotsholmsgade 10-12 1216 Copenhagen K Denmark Tel : +45 33 92 32 20 Fax : +45 33 92 48 88 e-mail : has@im.dk
Finland	Petri Pommelin	National Agency for Medicines and Medical Devices Mannerheimintie 166 00301 Helsinki Finland Tel :+358 9 473 341 Fax: +358 9 4733 4266 e-mail : petri.pommelin@nam.fi
France	Isabelle Tordjman	AFSSAPS 143-147 Boulevard Anatole France 93285 Saint Denis France Tel : +33 1 5587 3745 Fax : +33 1 5587 3742 Email isabelle.tordjman@afssaps.sante.fr
Germany	Rainer Edelhaeuser	ZLG – Zentralstelle der Laender fuer Gesundheitsschutz bei Arzneimitteln und Medizinprodukten Sebastianstr. 189 D-53115 Bonn Germany Tel : +49 228 97794 0 Fax : +49 228 97794 44 e-mail: zlg@zlg.nrw.de
Greece	Nicolos Pallikazakis	EOF/INBIT Stadiou Street PSP Platani Patras Greece Tel : +30 2610 99750-81 Fax : +30 2610 992496 e-mail : nipa@inbit.gr

Ireland	Maria Carleton	Irish Medicines Board Earlsfort Terrace Dublin 2 Ireland Tel : +353 1 6343424 Fax : +353 1 6767836 e-mail: ann.oconnor@imb.ie
Italy	Mrs Marcella Marletta	Ministerio delle Sanita Piazza Industria, 20I-00144 ROMA Italy Tel : 00390 659942464 Fax :00390 659942111 e-mail: m.marletta@sanita.it
Luxembourg		No information available
Nederlands	Jos Kraus	Healthcare Inspectorate Parnassusplein 5 2511 The Hague Netherlands Tel : 0031 70 340 6150 Fax: 0031 70 340 7159 e-mail: j.kraus@igz.nl
Norway	Ingeborg Hagerup-Jenssen	Directorate for Health and Social affairs PO Box 8054, dep N-0031 Oslo Norway Tel : +47 2416 3000 Fax: +47 2416 3021 e-mail:ingeborg.hagerup-jenssen@helsetilsynet.dep.no
Portugal	Maria Judite Neves	Infarmed Parque de Saude de Lisboa Av. Do. Brasil 1749-004 LISBOA Portugal Tel:00351 21 7987 290/92 Fax:00351 21 7987 890 e-mail: judite.neves@infarmed.pt

Spain	Carmen Abad	Ministerio de Sanidad y Consumo Paseo del Prado, 18-20 28014 Madrid Spain Tel : +34 91 596 43 47 Fax : +34 91 596 44 00 e-mail : cabad@msc.es
Sweden	Lars Johansson	Medical Products Agency Box 26 SE-75103 Uppsala Sweden Tel : +46 18 172651 Fax : +46 18 503115 e-mail : lars.olsson@swedac.se
Switzerland	Markus Zobrist	Swissmedic Erlachstrasse 8 CH-3000 Bern 9 Switzerland Tel: +41 31 324 9181 Fax: +41 31 322 76 46 e-mail: markus.zobrist@bog.admin.ch
United Kingdom	Rob Higgins	Medicines and Healthcare products Regulatory Agency (MHRA) Hannibal House Elephant & Castle London SE1 6TQ Tel : +44 20 7972 8185 Fax : +44 20 7972 8112 e-mail: rob.higgins@mhra.gsi.gov.uk

Section 3

THE DESIGNATION PROCESS

The Designation Process

1.0 Introduction

1.1 The Guide to the implementation of directives based on the New Approach and the Global Approach[3] (Vade Mecum) states that Member States (MSs) take final responsibility for the actions of the Notified Bodies (NBs) under their jurisdiction even where their activities are outside the Designating Authorities (DAs) own geographical area. Therefore, it is essential that DAs verify that organisations seeking to become NBs meet all the designation criteria specified in the medical device Directives, national regulations transposing the Directives and other relevant documents.

1.2 DAs considering the designation of any organisation as a NB in the medical devices sector should use as its primary reference document Meddev 2.10-2 "Designation and Monitoring of Notified Bodies within the framework of the EC Directives of Medical Devices". Meddev 2.10-2 gives excellent guidance on the designation criteria to be adopted and the designation process overall. This section of the Handbook is thus supplementary to the Meddev. It seeks to add practical guidance and advice to that given in the Meddev.

1.3 This section describes the designation process. It is divided into the following subsections

- Designation Criteria
- Application Process
- Assessment Process
- Designation Decision
- Amendment to Scope

2.0 Designation Criteria

2.1 The medical device Directives set out the criteria organisations seeking designation as NBs must meet as under:

- Active Implantable Medical Device Directive 90/385/EEC (esp. Article 11, Annex 8)
- Medical Device Directive 93/42/EEC (esp. Article 16 and Annex XI) and Directive 2003/32/EC which introduce detailed requirements with respect to medical devices manufactured utilising tissues of animal origin.
- In vitro diagnostic medical device Directive 98/79/EC (esp. Article 15 and Annex IX)

[3] http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm

2.2 In general, these criteria cover:

- Availability of personnel, equipment and test facilities (including sub-contractors)
- Independence and impartiality
- Technical, scientific, and medical competence of NB personnel both in relation to the conformity assessment procedures and to the medical devices in question
- Professional confidentiality and integrity of the NB and the staff it employs
- Civil liability insurance, unless covered by the state under national law

2.3 This is very similar to how the designation criteria for NBs in the medical devices sector is given in Meddev 2.10-2 "Designation and Monitoring of Notified Bodies within the framework of the EC Directives of Medical Devices" (see Appendix 1)[4] i.e.:

- General – These are general requirements covering the resources, legal status and organisational structures of NBs.
- Independence – The independence requirements are intended to ensure that the NB, and the personnel it uses, have no conflict of interest with manufacturers (eg financial or based on consultancy) which could prevent, or be thought to prevent, the NB conducting a thorough, honest and impartial audit of the medical device manufacturers activities.
- Impartiality – Like the requirements for independence, this requirement is aimed at ensuring that NB audits and decisions are not affected by any improper pressure or inducements, particularly financial.
- Competence – This covers the experience and training requirements for the personnel employed by the NB – especially those used as auditors. Experience has shown that this is a critical requirement and additional guidance on this specific aspect is provided below.
- Facilities – This covers the requirement to have appropriate facilities for the NB to carry out the relevant tasks for which it is designated.
- Confidentiality – This requirement ensures the need for the NB and its staff to respect the confidentiality of any information obtained as a result of carrying out their tasks.
- Liability Insurance – This covers the requirement to have appropriate liability insurance (unless covered by the state under national law).

[4] Amendment to include the IVDMDD in progress

- Subcontracting – This covers the requirements (including the need for proper documented agreements or contracts between the NB and the sub contractor) for those situations where NBs use subcontractors to carry out specific functions on its behalf.

- Internal Quality System – This requires that the NB has an appropriate quality system to cover their operations. The requirements identify the areas that the system has to cover including document control and ensuring that it is being effectively implemented.

2.4 Overall, however, it is vital for DAs to understand that the requirements for a NB in the medical devices sector fall into two broad categories: those that are generic to all NBs under the New Approach, and those which are specific to the medical devices sector. Both sets of requirements must be fulfilled to warrant designation.

2.5 The EN 45000 (ISO/IEC 17000) series of standards provides a means of assessing compliance with the generic requirements for all sectors. An accreditation against any standards in the EN 45000 / ISO/IEC 17000 series may be used to demonstrate compliance with basic (horizontal) requirements. **Of itself, however, accreditation under the EN 45000 series or equivalent is not sufficient to justify designation as a NB under any of the medical devices Directives.**

2.6 This is because the medical devices Directives impose specific requirements for NBs. These stem partly from the nature of the products covered and partly from the particular requirements of the Conformity Assessment Annexes contained in the Directives. Hence the DA should give particular care to ensuring that any organisation applying for NB designation (the applicant) has sufficient knowledge and expertise to cover the products and Conformity Assessment Annexes in the Scope of designation being applied for.

Specific staff competency requirements for the medical devices sector

2.7 It is absolutely essential that before designating any organisation as a NB, that the DA pays particular attention to the skills of the staff the applicant intends using as auditors. This, perhaps more than any other single point will help ensure that, as stated in Annex XI of Directive 93/42/EEC and Annex IX of Directive 98/79/EC "The Notified Body and its staff … carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices …".

2.8 The Directives and Meddev 2.10-2 all give advice on the skills and expertise NB staff should have. The following is therefore intended to supplement and expand upon that advice. Ideally, therefore, experience has shown that NBs auditing personnel should have:

- Successfully completed a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering

- Substantial relevant experience in e.g. the diagnostic, medical devices or pharmaceutical industries, the health care professions, medical laboratories, or test institutes,

- Proven knowledge of medical devices Directives and other relevant Directives, national transpositions, and relevant guidance documents

- Proven knowledge of quality management procedures, especially of relevant standards[5] acquired through successful participation in relevant training courses and/or practical experience

- Knowledge of the current status of applicable and relevant product-related standards, Common Technical Specifications (CTS) and monographs in pharmacopoeias

- Technical knowledge and experience of the design, manufacture, and quality control of medical devices and in vitro diagnostics

- Risk assessment and management as applied to medical devices, including relevant standards

2.9 In addition, and depending on the scope of designation being applied for in respect to device types and conformity assessment annexes, the applicant may need to show that the people it intends using as NB auditors have additional specific expertise in other relevant areas, e.g.:

- Sterile devices: where auditors will need to be able to assess technologies and methods used by manufacturers, e.g. for making sterile medical devices, the evaluation of sterility data, including environmental control, and the validation and routine control of sterilization processes (Meddev 2.10.2 Rev 1 Attachment 4 provides additional information)

- Assessment of medical devices against specific essential requirements, where auditors will need to be able to, for example:

    - Evaluate the biological and medical functionality and performance of medical devices

    - Evaluate devices containing animal tissues in line with Directive, 2003/32/EC

    - Evaluate devices containing human blood derivatives in line with Directive 2000/70/EC[6], and have knowledge of the biological and medical functionality and performance, including an up to date knowledge on relevant blood borne infectious agents and their epidemiology;

[5] esp. EN 46001/2/3, EN ISO 13485/88, EN 724, EN 928, EN 50103

[6] As modified through Directive 2001/104/EC

- Evaluate bio-compatibility data and clinical data used by manufacturers to demonstrate compliance with the Essential Requirements

- Evaluate the electrical safety of medical devices

- Evaluate software used in medical devices

- Knowledge of, and the ability to apply, relevant standards as applicable.

2.10 In addition an applicant seeking designation under the IVD Directive will need to demonstrate that it has suitably qualified/experienced staff in the following key areas:

- The evaluation of performance characteristics of IVDs (guidance is in preparation for inclusion in Meddev 2.10-2 Rev 1)

- The assessment of the complexity and variability of biological test systems

- The development and use of standard methods for the evaluation and assessment of IVDs mentioned in Annex II Lists A and B and devices for self-diagnosis as stated in Directive 98/79/EC

- Experience in the development and use of reference methods, reference materials and standards used in batch testing

- Experience/training in the batch testing of those IVDs listed in Annex II of Directive 98/79/EC including application of the Common Technical Specifications (CTS) 2002/364/EC

- Knowledge of the complexity and variability of pathogens in so far as they affect the performance of those IVD's listed in Annex II List A of Directive 98/79/EC (HIV 1 and 2, HTLV-1 and II, hepatitis B, C and D)

2.11 For applicants wishing to be designated for devices incorporating Animal Materials as covered by Directive 2003/32/EC technical experts designated to assess systems to minimise the risk of infection should be able to demonstrate they have the following specialist skills and knowledge:

- experience and/or training in the application of the standard EN12442

- evidence of a structured program to keep up-to-date on relevant issues

- knowledge of the requirements and interpretation of the medical devices Directives, including Commission Decisions and any guidance documents for this subject area.

- Knowledge of risk analysis/management

The type of experience and background likely to be relevant to a technical expert's ability to assess measures to reduce/eliminate risk are most likely to include some of the following:

- several years industrial experience in medical device technology using tissues or derivatives
- a sound knowledge of the fundamental principles behind the sourcing controls and validation of inactivation methods described in the standard EN12442
- knowledge of the biological materials available to the healthcare market
- assessment experience of medical devices containing animal origin
- participation in the development of relevant standards or Steering Committees
- contribution to European committees on medical devices for these product types
- experience in presenting at National or International regulatory conferences on relevant issues

3.0 Application

3.1 The designation process normally begins with a formal application for designation from the potential NB to its DA. There is no standard format in which this application must be made, but the DA should define what information has to be submitted. Whatever format of application is used, however, it should ideally contain the following information:

Applications for designation should contain the following information:

Applied scope for designation

- Details of which medical devices Directive, National Regulation transposing the Directive and Conformity Assessment Annexes (modules) the organisation is applying to be designated under, and whether it is already designated under any other Directives (esp. medical devices Directive)
- Range of products or technologies to be covered by designation

Organisation – General information on organisation and structure

- Name, address and contact point
- Description of the legal status of the applicant, including links and relationship to parent and/or related organisations, if any
- Details of the applicant's liability insurance
- Organisational chart of the applicant

- Job descriptions of the applicant's key personnel and auditors
- Statements with respect to independence and impartiality. If another part of the applicant's organisation provides consultancy services[7], details should be provided showing how these would be separated from the applicant's activity as a NB
- Name of "most responsible individual" or certification manager that would be responsible for the applicant's NB activities should designation be granted
- Details of how the NB activities being applied for would fit into the applicant's current structure and be financed
- A written undertaking that, if designated, the applicant will meet the requirements of the relevant national regulations transposing the relevant medical devices Directive, the relevant medical devices Directive themselves and any European Commission Guidelines

Quality management (internal)

- The applicant's internal Quality Manual
- Details of the applicant's document control procedures
- The applicant's procedures for corrective and preventive actions including complaint handling
- The applicant's procedures regarding internal audits and management review

Personnel (internal and external)

- Comprehensive details of existing expertise held within the applicant organisation (e.g. authorisation matrix). This should include the names of experts, their Curriculum Vitae (CVs) and details of the medical products or manufacturing processes for which they are experienced
- Names and CVs of any sub-contractors the applicant proposes to use for specific technical expertise or as general quality systems assessors and details of products or processes to be covered
- Procedure(s) for authorisation and monitoring of assessment and verification staff
- Overview of training programmes provided by the applicant, or to be provided, to ensure personnel are familiar with medical devices directives requirements, ISO 13485/ EN46001, etc
- Procedures to ensure the avoidance of conflicts of interest and ensuring confidentiality

[7] Not allowed within the medical devices area

Facilities (in-house and subcontractors)

- If application covers product testing, details of relevant in-house facilities and any sub-contractors the applicant proposes to use, including any relevant accreditations held by either the applicant or the sub-contractor.

- Terms of agreements with any sub-contractors the applicant proposes using.

Process – Conformity assessments

- Copies of any documentation (eg General terms and conditions, marketing materials, application forms and contracts) the applicant would propose sending to potential new clients if designated

- Procedures to assess clients' conformity with the appropriate Directive's Conformity Assessment Annexes and Essential Requirements, including as applicable, those procedures specific to: Design Dossier reviews; the assessment of clinical and bio-compatibility data , devices containing animal tissues, sterile devices; and other specialised technologies; and the clinical pathology aspects of IVDs; etc

- Procedures to take account of existing certifications and registrations, eg from other NBs, or medicines licensing authorities

- Details of procedures to ensure conformity assessment certificates are only issued after a full assessment of all relevant information and that this assessment is subject to an independent check

- Procedures aimed at ensuring the independence and impartiality of assessments and certification decisions

3.2 DAs may wish to consider providing applicants with a detailed questionnaire and/or application form. At the least however it should provide detailed guidance to applicant organisations on the type and depth of information to be provided by them. A suggested format for an application form is attached at Annex 1 to this section. In whatever format the application is made however it is important that it be signed and dated by the applicant.

4.0 Assessment

4.1 The DA is responsible for checking the application and supporting data thoroughly to ensure the applicant meets the Criteria for the Designation and Operation of Notified Bodies set out in the relevant Annexes of the Directives and as explained in more detail in Meddev 2.10-2 Rev 1.

4.2 It is essential that this is done thoroughly. To help DAs in this vital task, NBOG has produced a detailed checklist of the criteria, taken from MEDDEV 2.10-2, that needs to be satisfied. DAs may find it useful to use this checklist as an aide as they review the application. The checklist is reproduced as Annex 2 to this section.

4.3 The extent to which the applicant satisfies the designation criteria should be capable of being verified by a paperwork check of the documentation supplied with

the application. (But experience has shown that the DA should also consider visiting the applicant at its premises to assess the way in which its procedures are implemented and applied to any existing business).

4.4 The DA's review of the documentary evidence may well identify various issues that it will want to discuss with the applicant or where it feels that further information is required. In practice it may be necessary for the DA to go back to the applicant for further information or clarification several times before a decision can be made. The review process is therefore iterative. It is important that any changes made to the applicant's systems during this review of its application should be updated.

4.5 The review of the application may also result in aspects of the applicant's own operating systems or procedures being updated and altered as potential problems or shortcomings are identified. Where changes are made it is important that these are documented by the applicant and sent to the DA, so that it has an up to date set of documents supporting the application for designation.

Assessment of expertise of Applicant by scrutiny of CVs

4.6 A key part of any application for designation will be the information provided on any auditing staff that the applicant proposes using. As stated in para 3.1 the application should contain detailed CV's of these personnel (whether directly employed or not). It is essential that the DA carefully studies these CVs to re-assure itself that the applicant will have the necessary skills to perform the tasks for which it is seeking designation. Thus, for example, if an individual is to be used as an auditor they must have audit experience in the relevant area, unless the applicant undertakes to use them only in conjunction with a suitable qualified generalist auditor. Audit experience can be gained by working within a designated NB in conjunction with a suitably qualified auditor.

4.7 There is no standard format for the provision of NB personnel's CVs and DAs are free to request this information in any format that they choose or alternatively leave this to the applicant's discretion. However, a suggested format is given in Attachment 1 to Meddev 2.10-2 Rev 1. (Currently, Attachment 1 only relates to the AIMD Directive and the Medical Devices Directive. But, MEDDEV 2.10 is in the process of being revised to incorporate the IVD Directive and Attachment 1 will be updated as part of this exercise. In the meantime, however, and to assist DAs who wish to prescribe a format for applicants to use a suggested format is provided at Annex 3 to this section).

4.8 Nevertheless, whatever the format of the CVs submitted by the applicant to the DA for scrutiny they should cover the following:

- Education and qualification: this should be in a scientific or technical subject which can be readily related to the scope of the medical devices, processes or technology in which they will work
- Work experience: this should be relevant to current safety and performance aspects of the medical devices with which they will work
- Training or professional development: this may be either in features related to relevant medical devices (their manufacture, safety or use) or to auditing

against the regulatory requirements of the Directives and the requirements of the EN 46001 / ISO 13485

- Standards knowledge: this provides the link between academic and other knowledge and medical devices or technologies

- Special processes: as defined in ISO 9000, these are processes whose effectiveness cannot be verified by subsequent testing so that they have to be properly validated and closely controlled. The most common example is sterilisation which is sufficiently important to merit its own set of special rules in Meddev 2.10-2 Rev 1

4.9 DAs should use the CV's to help it verify the suitability, expertise and capability of the personnel the applicant proposes using to cover the range of products or/and processes covered by the application.

Assessment of applicant's ability to cover the Conformity Assessment Annexes applied for

4.10 The conformity assessment annexes in the medical devices Directives broadly follow the modules specified for the New Approach Directives. However, there are additional responsibilities for the NBs under the medical devices Directives. They are described in detail in Attachment 3 to Meddev 2.10-2 Rev 1 and summarised in the table below. DAs must ensure that the applicant has systems to ensure that it can carry out all the responsibilities under the various conformity assessment Annexes covered in the scope applied for, i.e.:

- Under the full quality assurance annexes, NBs must approve the manufacturer's quality system, including design control, and where applicable carry out design dossier approvals

- Under the partial quality assurance annexes, NBs must approve the manufacturer's quality system as defined in the relevant Conformity Assessment Annex

- Under the Type Examination Annex, NBs must specify in advance the tasks to be carried out (test protocol) and need adequate facilities (internal or sub-contracted) to carry out inspections and tests to verify that products meet the Essential Requirements

- Under EC Verification Annex, NBs must specify in advance the tasks to be carried out (test protocol) and need adequate facilities (internal or sub-contracted) to verify that each batch or unit meets the Essential Requirements

- For IVDs in List A of Annex II of Directive 98/79/EC the NB must verify each batch of manufacturer's product.

4.11 Appendix A of the NBOG designation checklist (see Annex 2) lists procedures that NBs must be able to check and thus ensure that manufacturers meet their

responsibilities under the various Conformity Assessment Annexes of the medical devices Directive. The DA will need to check that this is the case for all applicant organisations. These procedures shall ensure that the applicant:

- has appropriate personnel
- can deal with manufacturing or design changes made by the device manufacturer
- can identify devices with medicinal products and has procedures to consult with the relevant drug regulatory authority
- has appropriate laboratory facilities (preferably accredited for the scope applied for) either themselves or sub-contracted
- has procedures to carry out surveillance audits at suitable intervals
- can implement any necessary statistical sampling regimes

Assessment of applicant's proposed use of sub-contractors

4.12 Depending on the scope of designation applied for, the applicant may propose obtaining the necessary specialist facilities or specialist staff skills or expertise needed (and briefly described above) by "buying in" those facilities from sub-contractors. In such cases the DA must assure itself of the suitability of the sub-contractor facilities or staff in exactly the same way as it assesses the suitability of the applicant. In addition, the DA will need to check that, where the applicant chooses to cover any aspects of its work by sub-contracting, it nevertheless has sufficient in-house expertise to judge the quality of the sub-contractor's work. It is the NB and not any sub-contractor used that retains the ultimate responsibility for decisions on certification.

4.13 When assessing an application for designation from an organisation that proposes using sub-contractors, the DA may find it helpful to keep the following factors firmly in mind:

- A NB may sub-contract any of its functions except:
    - initial contract review: this includes the assessment by the NB as to whether the proposed job is within its scope and whether it has the necessary resources and expertise to carry it out properly
    - final decision to issue a certificate of conformity: this includes an assessment of all the information derived from audits, tests or design dossier reviews; it must be carried out by appropriate personnel within the NB who has sufficient knowledge and experience to come to a reasoned judgement of the information present and the authority to make that decision
- The applicant NB must therefore have sufficient in-house expertise to:

- enable it to decide whether to take on a particular contract
- to assess the expertise of its sub-contractors, and to control their work
- to assess and make judgements based on the work of its own employees and of its sub-contractors.

o The applicant NB must ensure that its sub-contractors have the expertise necessary and are free from conflicts of interest. All sub-contractors must be covered by proper contracts with the NB covering these requirements.

5.0 Designation Decision

5.1 The DA should only agree to the designation of the applicant when it has clearly demonstrated that it has the structure, expertise and systems to fulfil all the relevant requirements set out in Meddev 2.10-2 Rev 1. Ideally, given that the Member States (MS) take final responsibility for the competence of its NBs, the decision to designate should be taken at a senior level within the DA.

5.2 To facilitate the decision making process, and provide an assessment trail following best practice, DAs may find it useful for the person or persons who assess the application to prepare a report on their findings for the person or persons who will take the final decision on the application. This report should contain a recommendation to:

- Agree to designate for the full scope requested
- Agree to designate but for a more restricted scope from that requested
- Refuse designation

5.3 Where the final decision is to agree to designate (either wholly or in part) experience has shown that the DA should clearly describe the designated scope it is agreeing to and thus avoid any possible future confusion or doubt as to which products or technologies are covered. In particular, the scope should not imply the inclusion of technologies for which the applicant has not demonstrated sufficient expertise. For example, a designated scope including “heart valves” is unclear as the expertise needed for metal heart valves is different from that needed for animal-derived valves. Care also needs to be taken when describing medical devices, for example arterial stents should be distinguished from urinary stents.

5.4 As part of the decision to designate the applicant, the DA may wish to impose conditions placing specific restrictions or obligations on the NB. Such conditions should be designed to allow the DA to gain confidence in the new NB’s operational ability in specific areas where small doubts may still exist after the assessment of the application. Examples of conditions applied by DAs in the past include, for example:

- informing the DA of any changes to the NBs staff or to the staff of its sub-contractors

- getting prior approval from the DA before accepting any job, or jobs involving a particular Conformity Assessment Annex or with a particular group of products or technologies

- information of conformity assessments planned to allow the DA to carry out observed audits or witness tests

- submission of test-plans for EC-Type Testing or EC Verification to the DA prior to carrying out these assessments

- informing the DA of any certificates issued or refused to allow the DA to review files

5.5 The DA should discuss the proposed scope and any conditions with the applicant to ensure that they are clearly understood and agreed. Both the scope and any conditions imposed should be fully documented.

5.6 Notification of the DAs' final decision on designation to the Commission and the other MS is discussed below. However the DA should make it clear to the applicant that they cannot operate as a NB until the required notification is made.

6.0 Notification

6.1 Once the DA [8] has decided to designate the applicant it should convey its decision to the European Commission and the other MS via its Permanent Representative in Brussels using the Notification Form attached as Annex 4 to this Section. The European Commission will publish the Notification in the Official Journal and in the NANDO database.

7.0 Amendment to Scope

7.1 The NB, once designated, will sometimes wish to alter or extend its scope of designation. The process of submitting an application for this proposed change in scope to the DA for review follows an identical pattern to that for an initial designation. In such cases however the DA should already have a good knowledge of the basic organisational structure, facilities and expertises available to the NB as well as detailed experience of the way it has performed in practice. In assessing the application for change therefore, the DA should require confirmation from the NB that these aspects are unchanged and still meet the requirements of Meddev 2.10-2 Rev 1 . It can then concentrate on assessing the NBs capabilities for performing the additional tasks being applied for.

8.0 Limitation of scope, suspension and de-designation

8.1 Where a NB no longer meets the requirements for designation, or where its performance falls below the consistently high standards demanded, the DA must take action to correct the situation. In extreme cases this may require the DA to amend its designated scope or to remove temporarily or permanently the NBs designation.

8.2 Illustrations of issues which may lead the DA to consider limiting the NB's scope or withdrawing it completely are listed in Section 4 of the handbook. Where the DA is considering taking action that will amend or remove the NBs designated scope it

[8] In MEDDEV 2.10/2 also called the Competent Authority responsible for designation

should ideally first hold an internal meeting to review all the relevant factors and information available to it about the performance of the NB. Following this internal review of evidence the DA may then consider it sensible to meet with the NB to see if there are any factors of which the DA is unaware and which could therefore influence its final decision.

8.3 Where nevertheless, the DA decides to de-designate (either in part or completely) it should inform the NB giving its reasons. Depending upon the specific laws in a particular MS a period in which the NB may appeal against the DAs decision may also have to be provided.

8.4 Where the decision to remove or restrict designation is upheld, the DA should advise other MSs and the European Commission of their decision.

ANNEX 1 to Section 3

APPLICATION FOR DESIGNATION, RE-APPLICATION* OR SCOPE EXTENSION* AS A NOTIFIED BODY UNDER THE AIMDD, MDD, OR IVDD.

**Note: - This form should also be used for making applications for re-applications and extensions to scope (e.g. Annex and products). Provide only relevant information*

1. **Please state here the name of the organization applying, the full postal address, telephone number, fax number and where available the E-Mail address.**

Organization Name:	
Address :	
Telephone number:	
Fax number:	
E-Mail address:	

2. **Who are the key contacts concerning this application?**

Name	*Position*	*Tel*	*E-Mail*

3. **Under which medical devices Directive is this application being made?**

Please tick one. Use a separate Application Form for each.

tick

1. [ ] Active Implantable Medical Devices Directive (90/385/EEC)

2. [ ] Medical Devices Directive (93/42/EEC)

3. [ ] In Vitro Diagnostic Medical Devices Directive (98/79/EEC)

4. **Under which Annex(es) of the appropriate EEC Directive does your organization intend to provide a conformity assessment and certification service?**

Please list all that will apply.

5. **What is the range of products for which your organization seeks designation?**

Please list product types / families, if possible also by reference to GMDN.

Product Type/Family	GMDN Code	Product Type/Family	GMDN Code

If space is insufficient, please attach an addendum.

6. **Is your organization already designated as a Notified Body under any other EC Directive?**

Yes [ ] No [ ]

7. If [Yes] to Question 7, under which Directive(s)?

Please list all.

8. If [Yes] to Question 7, what is your organization's identification number?

ID Number:	

Application for Designation
List of supporting documentation

Please submit the following documents with your application for designation

1 Organisation	pages	date/revision
2 Description of legal status		
1.		
3 Proof of liability insurance		
1.		
4 Organisational chart		
1.		
5 Job descriptions, including that for the "most responsible individual" or certification manager for the medical devices directives or equivalent		
1.		
6 Statements with respect to independence and impartiality		
1.		
7 Details of how the Notified Body activities being applied for would fit into the organisations current structure and be financed		
1.		
8		
1.		

9 Quality management (internal)	pages	date/revision
10 Quality manual		
1.		

11 Lists of related documents (procedures, SOPs, forms, etc.)		
1.		

12 Control of documents and records/data		
1.		

13 Nonconformities, corrective and preventive actions, complaint handling		
1.		

14 Internal audits, audit plan, management review		
1.		

15		
1.		

16 Personnel (internal and external)	pages	date/revision
17 Authorisation matrix		
1.		

18 Procedure(s) for authorisation, training and monitoring of assessment and verification staff		
1.		

19 CVs, forms “Qualification of Personnel” for all personnel, both internal and external, identifying the products/processes/technologies they have been authorised to cover based on their qualifications, training and experience		
1.		

20 Employment contract (sample), list of contracted personnel		
1.		

21 Agreements with external auditors/experts, list of external personnel		
1.		

22 Conflict of Interest procedure(s) and statements		
1.		

23 Confidentiality procedure(s) and statements		
1.		

24 Training programme , further education		
1.		

25 Facilities (in-house and subcontractors)	pages	date/revision
26 In-house testing facilities		
1.		
27 List of subcontractors		
1.		

28 Contracts		
1.		

29 Procedure for subcontracting		
1.		

30 Certificates of accreditation (including attachments)		
1.		

31 Process – Conformity assessment	pages	date/revision
32 General terms and conditions, testing and certification regulations, prices		
1.		

33 Quotations (sample), application forms, marketing materials, including procedures to take into account any existing certifications		
1.		

34 Contract (with manufacturer)		
1.		

35 Procedures for conduct and follow up of each conformity assessment annex, including surveillance, evaluation of risk assessments, clinical data, validation of sterilisation processes etc.		
1.		

36 Check lists		
1.		

37 Reporting (samples of audit/assessment reports)		
1.		

38 Certificates of conformity (samples)		
1.		

39	**Conditions for issuing, maintaining, extending, reducing, suspending and withdrawing certificates of conformity, including independent review and impartiality of decisions**		
	1.		

40	**Procedures for changes of certification requirements**		
	1.		

Note
For submission please use a numerical register. Amendments and supplements should always be referenced to the numbers above. Please send this list both as signed hardcopy and as electronic file.

_____
place, date

_____
name and signature of an authorized representative of the applicant

ANNEX 2 to Section 3

CHECKLIST FOR DESIGNATING AUTHORITIES DESIGNATION OF NOTIFIED BODIES (NB's)

1.0	**General requirements**	Complies?		Comments
		Yes	**No**	
a)	Does the NB have the facilities / resources to perform conformity assessments of medical devices as specified in the directives in a competent, transparent, neutral, independent and impartial manner?			
	Does the NB have the competence and ability to take full responsibility for all tasks required of a NB in relation to the Annexes of the NB application?			
	Post designation, does the NB have a system to inform the Competent Authority of any change regarding the availability of resources including sub-contractors that may have an implication on the designation and assignment of tasks?			
b)	Is the NB a legally defined entity? The following to be reviewed:			
	- *documentation of the NB legal status*			
	- *documentation which clearly shows both the authority and the responsibility of individuals within, and the reporting structure within the NB.*			
	- *documentation of the financial status of the NB*			
c)	If the NB is a legal entity, which is part of a larger organisation, is there clear documentation of the links and relationship between the NB and larger organisation?			
	Where the NB engages the services of a subcontractor does the NB retain the responsibility of all actions undertaken by subcontractors as if the Notified Body itself performed the tasks?			

2.0	**INDEPENDENCE REQUIREMENTS**			
a)	Are the NB or assessment / verification staff involved in the design, manufacture, servicing or supply, construction , marketing, installation or use, or the authorised representative of: medical devices under assessment medical devices within the scope of the audit the quality system under assessment			
	Are assessment and verification staff including subcontractors impartial and free from engagements and influences, which could affect their objectivity?			
b)	Do NB or subcontracted personnel have links with the manufacturer or a competitor manufacturer of the medical devices under assessment?			
	Is this Documented?			
c)	Have the NB or subcontracted personnel been involved in consultancy activities with the manufacturer, supplier, authorised representative or a commercial competitor of the medical devices under assessment within the last 5 years?			
	Does marketing material for the NB give the impression that consultancy activities are offered?			
	Does the NB have documented procedures for the identification, review, resolution and prevention of conflicts of interest where conflicts of interest are suspected or proven (including subcontracted personnel)?			
	Does the NB keep records of such reviews and decisions?			
	Does the NB require all staff acting on its behalf to declare any potential conflict of interest?			
	If the Notified Body is linked to an organisation that provides consultancy services, is there a documented policy/ procedure to ensure that the assessment and consultancy services are separate?			
	Does the Notified Body offer markings that may confuse the meaning of the CE mark?			

3.0	**IMPARTIALITY REQUIREMENTS**			
a)	Does the NB have documented procedures to ensure the impartiality of all assessment and verification staff and that this is made known and safeguarded throughout the organisation?			
	Does the NB implement documented procedures to ensure that the remuneration of internal and subcontracted staff is free from pressures and inducements and not dependent on the number or outcome of inspections/ verifications carried out, or the result of their activities?			
4.0	**COMPETENCE REQUIREMENTS**			
a)	Does the NB employ within its organisation the necessary administrative, technical, medical and scientific personnel, which possess satisfactory knowledge and experience relating to: the medical devices technologies conformity assessment procedures assigned to them			
	Can the NB demonstrate that the assessment and verification staff including subcontractors have knowledge and experience in the following areas as necessary for the tasks undertaken:			
	-regulatory requirements and enforcement policies			
	-European and international standardisation activities			
	-methodology of risk analysis and risk management regarding relevant medical technology, production methods and the applicable verification procedures; the personnel shall be capable of assessing the medical function and performance of devices and the processes to determine compliance with the essential requirements especially for those cases where no specific standards are available.			
	-clinical evaluation, conduct of clinical investigations and normal conditions of use of relevant medical devices.			

		Yes	No	Comments
b)	Does the NB document the competence and training requirements for assessment and verification staff including subcontractors? Records shall be available to demonstrate that personnel have the appropriate experience and have received appropriate training relevant to the NBs scope.			
c)	Does the NB participate in co-ordination activities at European and/or national level in order to attain maximum coherence in performing conformity assessment?			
d)	Does the NB carrying out Quality Assessments ensure that at least one member of the assessment team is experienced in the technologies used by the manufacturer?			
	Does the NB ensure that at least one member of the assessment team is trained and experienced in the following skills, as relevant to the assessment being made including:			
(i)	*-the assessment of design documentation and clinical evaluation data to determine that all aspects of design are in compliance with the requirements of the regulations;*			
(ii)	*-for sterile medical devices, microbiological assessment, including environmental control, and validation and routine control of sterilisation process according to harmonised standards or equivalent guidelines where harmonised standards are not applied by the manufacturer, with a rationale that demonstrates that the process meets the Essential Requirements.*			
(iii)	*-for devices that are in contact with the human bodies, biocompatability assessment according to harmonised standards);*			
(iv)	*-for devices containing animal tissues, assessment of all aspects of the raw material, processing and inactivation/elimination of transmissible agents;*			
(v)	*-for active devices: assessment of safety and performance of programmable electronic systems including software;*			
(vi)	*-the application of statistical controls to device verification;*			

		Yes	No	Comments
(vii)	***-medicinal products***			
	Does the NB ensure that the Personnel involved in the assessment of quality systems are qualified and capable of functioning in accordance with "Guidelines for regulatory auditing of quality systems of medical device manufacturers: Part 1 general requirements 1998" (see MEDDEV. 2.5/2)?			
	Does the NB ensure that the management of quality systems assessments be in accordance with "Guidelines for regulatory auditing of quality systems of medical device manufacturers: Part 1 general requirements 1998" (see GHTF/SG, 4(98))?			
	Does the NB maintain an up to date record for each assessor that includes the following information?			
	- name of assessor;			
	- designated areas of competence and responsibility within the scope of activities for which the NB has been notified;			
	- educational and professional qualifications, skills, languages;			
	- work experience (relevant to the activities being performed);			
	- audits conducted;			
	- details of training received relating to assessment activities, including training in the requirements of the directive(s), relevant standards and other appropriate documents			
5.0	**INTERNAL PROCEDURES AND FACILITIES**			
a)	Does the NB have appropriate structures and procedures to ensure that conduct of conformity assessment and issuing of certificates is subject to a review process? Relevant procedures shall in particular address: obligations and responsibilities in relation to suspension and withdrawal of certificates, the imposition of corrective measures on manufacturers, reporting to Competent Authorities.			

		Yes	No	Comments
b)	Does the NB have available the appropriate facilities to enable it to carry out the assessment and verification activities for which it has been designated?			
	Does the NB have access to / full control of appropriately maintained testing equipment normally used by the manufacturer during testing and verification procedures?			
	Do the facilities enable the NB to perform the technical and administrative tasks connected with evaluation and verification, whether assessment and verification activities are carried out by the NB itself or under its responsibility?			
	Does the NB apply appropriate procedures of quality control in relation to the services provided?			
6.0	**CONFIDENTIALITY REQUIREMENTS**			
a)	Does the NB have documented procedures to describe adequate arrangements between the NB, involved subcontractors and the manufacturer that ensure the confidentiality of information obtained in the course of carrying out its tasks? (Consult MEDDEV 2.10/2).			
	Do the procedures describe the mechanism through which assessment personnel are made aware of confidentiality requirements? (Consult MEDDEV 2.10/2).			
7.0	**LIABILITY INSURANCE**			
a)	Does the NB have appropriate liability insurance to provide for claims and litigation in the event of misadventure? (Consult MEDDEV 2.10/2).			
	Does the Notified Body have procedures for notifying the manufacturer of the liability insurance on request?			
8.0	**SUBCONTRACTING**			
a)	Where subcontractors carry out specific tasks relating to conformity assessment, does the NB ensure that these subcontractors conform to the same requirements (including documentation requirements) that would apply if the task had been performed by its own personnel?			
	Is the manufacturer’s approval obtained before activities are subcontracted?			

		Yes	No	Comments
b) + c)	Does the NB have a documented agreement to ensure that it will not subcontract the overall responsibility for reviewing the outcome of assessment and verification activities, which are the essential tasks for which it was designated, and ensure that subcontractors are restricted to factual reporting and/or supported recommendations? Does the agreement include confidentiality and make provision for access of the Designation Authority?			
	Does this agreement prohibit subcontractors from further subcontracting their duties?			
d)	Does the NB ensure that the subcontracted activities are carried out according to detailed documented procedures, which are the same as, or judged by the NB to be equivalent to, those followed by the NB itself in the context of conformity assessment?			
e)	Does the NB inform the Competent Authority of its intent to use subcontractors in relation to the scope for which it was appointed?			
	Does the NB maintain documentary evidence that the subcontractor has the necessary technical competence and facilities to carry out the subcontracted activities?			
	Does the NB maintain an up to date register of all its subcontractors, which shall be provided to the Designating Authority on request and which includes the following information:			
(i)	*- the name of the subcontractor*			
(ii)	*-the legal status and details of any relationship with a parent company, group of companies, or any other organisation to which the subcontractor is linked,*			
(iii)	*- names of staff carrying out the subcontracted activities and evidence that they are competent to do so;*			
(iv)	*- the precise duty performed by the subcontractor (e.g. auditing, testing, etc.) and details of the procedures used in carrying out the subcontracted duties;*			

		Yes	No	Comments
9.0	**NOTIFIED BODY'S QUALITY SYSTEM**			
a)	Does the NB have established and maintained up to date, documented procedures and records which, together, demonstrate its compliance with the regulations? As appropriate, this documentation shall include the following:			
(i)	*- description of the Notified Body's legal status, organisation, reporting structure, and links with a parent organisation if relevant;*			
(ii)	*- documentation showing the responsibilities and reporting structure of the NB,*			
(iii)	*- a rationale for defining the scope of the responsibilities for each of the assessment personnel,*			
(iv)	*- record of the names of assessment personnel, both internal and subcontracted, their assessment responsibilities and records of relevant training and experience;*			
(v)	*- procedures for the identification, review and resolution in cases where a conflict of interest is suspected or proven;*			
(vi)	*-a description of the application process by which manufacturers can obtain third party approval by the NB. (Consult MEDDEV 2.10/2).*			
(vii)	*- procedures to review applications in respect to the manufacturers classifications of his medical devices*			
(viii)	*- procedures to review the completeness of application against the details provided in the annex under which approval has been sought,*			
(ix)	*- procedures to evaluate and verify manufacturers' compliance with their chosen annexes,*			
(x)	*- procedures detailing the rationale for fixing time limits for completion of evaluation and verification activities,*			
(xi)	*- procedures for demarcation between Medical Devices and other Directives such as 65/65/EEC,*			

		Yes	No	Comments
(xii)	*- procedures for the assessment of clinical data ensuring that where applicable the conclusions drawn by the manufacturer from clinical data are valid in the light of the submission to the Competent Authority relating to that investigation.*			
(xiii)	*- procedures to take account of information on medical devices subject to pre-existing national law, regulations or administrative provisions,*			
(xiv)	*- records to demonstrate / communicate the conclusions of the assessment including a reasoned evaluation of the manufacturers compliance with the requirements of the relevant directive. For quality assessments, records should be available which provide a discernible audit trail (e.g. procedures, processes, records, products etc… that were assessed);*			
(xv)	*- 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 if necessary), and manufacturers compliance with the requirements of the Directives.*			
(xvi)	*-procedures relating to the issue, withdrawal and suspension of certificates, including action to be taken in the event a CE mark that has been wrongly affixed to a device (including informing the Competent Authority). (Consult MEDDEV2.10/2).*			
(xvii)	*-details of obligations regarding communications with other organisations, including Competent Authorities, the Commission and other NBs. (Consult MEDDEV2.10/2).*			
(xviii)	*- procedures for assessing and monitoring the competence of subcontractors, if used;*			
(xix)	*- details of NB record keeping facilities including means to ensure security and confidentiality,*			
(xx)	*- details about liability insurance,*			
(xxi)	*documentation about its financial situation, including* *accounts,*			
(xxii)	*- details about fees and financial conditions for the conduct of conformity assessment,*			
(xxiii)	*- procedure for the transfer of information to the EUDAMED database.*			

		Yes	No	Comments
b)	Does the NB maintain a system to control all quality system documentation and to ensure that current issues of procedures are available at all relevant locations?			
c)	Does the NB ensure that the defined quality system procedures are effectively implemented?			
	Does the NB have procedures to inform the CA of any changes/ additions to personnel, facilities or subcontractors, which might effect their designation scope?			

The following checklist is intended for Competent Authority assessment of Notified Bodies against their Annexes of designation (refer to Appendix A of MEDDEV2.10/2)

A2	**FULL QUALITY ASSURANCE ANNEXES**			**Comments**
		Yes	**No**	
a)	When auditing Quality System Assessments does the NB cover the following:			
(i)	ensuring that medical devices conform to the provisions of the relevant Directive at every stage, from design to final inspection; review of technical documentation; the elements, requirements and provisions adopted by the manufacturer in fulfilment of the essential requirements of the relevant Directive. Is the documentation sampled?			
(ii)	-ensure that personnel performing quality audits are appropriately trained and experienced in the application of the Medical Devices Regulations and relevant harmonised standards (refer to section 4d(vii)).			
(iii)	- ensure that NBs have appropriate facilities for performing quality system audits;			
	- ensure that a reasoned outcome of the assessments is notified to the manufacturer;			
(iv)	-check that the NBs have documented procedures for the processing of notifications of changes from certified manufacturers to their quality system, and evaluating its compliance with the Directives assessed; Does the CA ensure that a reasoned evaluation has been undertaken?			
	Does the Competent Authority ensure that a reasoned evaluation has been undertaken?			
b)	**DESIGN DOSSIER REVIEWS**			
	When carrying out Design Dossier Examinations does the NB cover the following:			

		Yes	No	Comments
(i)	-ensure that the NB has procedures, sufficient expertise and facilities for the examination of design dossiers;			
	-ensure that design dossier reviews are performed by appropriately qualified personnel;			
(ii)	-NBs procedures for the identification of medical devices incorporating a medicinal product acting in a manner ancillary to that of the device, and consultation with the relevant authority for medicinal products; The NB should ensure that its final decision is communicated to the authority consulted (MED DEV 2.1/3);			
(iii)	-NBs procedures for the production of EC design examination certificates.			
(iv)	-NBs procedures for checking the significance of notifications by the manufacturer changes to the design dossier, including whether appropriate changes have been made to the quality system; NB approval should be given in the form of a new certificate or an addendum to the EC design-examination certificate;			
c)	-ensure that NBs have procedures defining the method and frequency of surveillance inspections and evaluations of manufacturers quality systems, and how unannounced visits are to be conducted;			

A3	**TYPE EXAMINATION**			
a)	When carrying out Type Examinations does the NB cover the following:			
(i)	- carry out inspections and tests to verify whether the solutions adopted by the manufacturer meet the relevant harmonised standard(s) and essential requirements of the Directive; All relevant and critical parameters should be verified by the NB or subcontractor under its responsibility;			
(ii)	-suitability of NB/ subcontractor facilities and procedures for the examination and evaluation of documentation to verify that the type has been manufactured in accordance with the documentation, and for performing appropriate inspections and tests to verify compliance with the essential requirements, including risk analysis, of the relevant Directive;			

		Yes	No	Comments
(iii)	- procedures for the issue of EC type-examination certificates to manufacturers where the type meets the provision of the relevant directive. (Consult MEDDEV2.10/2).			
(iv)	- procedures for the identification and communication with the Competent Authority where medical devices incorporate a medicinal product acting in a manner ancillary to that of the device. (Consult MEDDEV 2.1/3).			
(v)	- documented procedures for reviewing changes to the approved product. (Consult MEDDEV 2.1/3).			

A4	**EC VERIFICATION**			
	When carrying out EC Verification does the NB cover/have the following:			
(i)	- carries out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive. (Consult MEDDEV2.10/2).			
(ii)	- suitability of NB/ subcontractors facilities and procedures for the examination and testing of products to verify that they conform to the requirements of the relevant Directive;			
(iii)	- examine and test products on a statistical sampling basis or, on an individual product basis as appropriate, and draw up a written declaration of conformity related to the tests conducted;			
(iv)	-NB procedures to ensure that any product or batch of products rejected is prevented from being placed on the market, and in the case of frequently rejected batches to suspend statistical verification;			

A5	**PRODUCTION/PRODUCT QUALITY ASSESSMENTS**			
a)	When auditing such Quality Systems does the NB cover the following:			
(i)	approval of manufacturers quality systems for the manufacture and/or final inspection of products;			
	-ensure that those medical devices conform to the type described in the EC type-examination certificate or technical documentation, respectively. The NB should review the elements, requirements and provisions adopted by the manufacturer including those in relation to fulfilling the essential requirements including the risk analysis. Sample appropriate documentation and processes based on the risks associated with the intended uses of the devices, the complexity of the manufacturing technologies, the range of devices produced and post-market surveillance data.			
(ii)	-ensure that personnel (whether directly employed or subcontracted) performing quality audits have been appropriately trained and experience in the application of the Medical Devices Regulations and relevant harmonised standards;			
(iii)	- suitability of NB facilities for performing quality system audits;			
	- ensure that a reasoned outcome of the assessments is notified to the manufacturer;			
(iv)	- documented procedures for the processing of notifications of changes from certified manufacturers to their quality system, and evaluating its compliance with the Directives assessed; Does the CA ensure that a reasoned evaluation has been undertaken?			
b)	- procedures defining the method and frequency of surveillance inspections and evaluations of manufacturers quality systems, and how unannounced visits are to be conducted;			

ANNEX 3 to Section 3

Qualification of personnel

I General information

1 Personal data
Title, Name, First name **Date of birth** **Nationality** **Languages** *Note* The Designating Authority declares that any data is used only in relation with the designation process.
2 Field of operation

The above named person is

- ❑ full-time/part-time employee of the applicant
- ❑ employee on freelance-basis
- ❑ subcontractor

and is appointed as

- ❑ auditor
- ❑ lead auditor
- ❑ technical expert in an auditing team
- ❑ expert in ‘testing’
- ❑ expert in ‘design dossier/type examination’ evaluation
- ❑ expert in ’certification’

in the area

- ❑ conformity assessment procedures according to the medical device Directives
  - ❑ 93/42/EEC
  - ❑ 90/385/EEC
  - ❑ 98/79/EC

  and their national transpositions
- ❑ certification of quality management systems according to EN 46000 series, EN ISO 13485/13488

3 Education

From – to	College/university	Subject(s)	Degree/qualification

Additional qualifications (especially quality management, conformity assessment according to EC directives 93/42/EEC, 90/385/EEC and 98/79/EC)

From – to	Training organisation	Title of course	Degree/qualification

4 Curriculum vitae			
From - to	**Employer**	**Department/position**	**Responsibilities with respect to products/ technologies/quality management**

5	**Description of the current working activities in quality management and/or with respect to the products mentioned below** **Explanation of the experience in technologies**

6	Other experience
6.1	**Participation in national and international standardisation organisations**
6.2	**Participation in committees of the European Commission, Designating Authorities, scientific societies, and other organisations working with medical devices, other special fields or quality management**
6.3	**Own relevant publications**

7 Participation in external audits/testing/technical review within the last two years

Date and duration	Audited company/products	Lead auditor (LA) or auditor (A) or tester or reviewer	Basis of the audit (e.g. ISO 9000, EN 46000, EN ISO 13485/13488, MDD, GMP, ...)/standards applied

8	**Activity as auditor**
8.1	**Total number of audits** **Until now, ……external audits** **with a total number of ….. audit days at the manufacturer's facilities have been performed.**
8.2	**Total number of audits according to directive 93/42/EEC or 90/385/EEC** **Until now, ……external audits according to directive 93/42/EEC or 90/385/EEC** **with a total number of …. audit days at the manufacturer's facilities have been performed.**
8.3	**Total number of audits according to directive 98/79/EC** **Until now.....external audits according to directive 98/79/EC** **with a total number of..... audit days at the manufacturer's facilities have been performed.**
8.4	**Date of appointment as lead auditor** **Prior to the appointment as a lead auditor on**[9] **…… a total number** **of..... external audits with a total number of..... audit days at the manufacturer's facilities have been performed.**

9	**Consultation of companies**	
From - to	**Company**	**Type of consultation**

[9] ddmmyy

II Specific information

Area MDD/AIMD

Scope of technical expertise for non-active medical devices	Production	Product/ Application
Implants		
Orthopaedic implants	❑	❑
Soft tissue implants	❑	❑
Functional implants	❑	❑
Cardiovascular implants	❑	❑
Surgical instruments[10]	❑	❑
Anaesthetic devices, devices for emergencies and intensive care[11]	❑	❑
Orthopaedic and rehabilitation devices	❑	❑
Non-active medical devices with a measuring function	❑	❑
Devices for wound care		
Bandages and wound dressings	❑	❑
Suture material and clamps	❑	❑
Other medical devices for wound care	❑	❑
Dental devices and accessories		
Dental equipment and instruments	❑	❑
Dental materials	❑	❑
Dental implants	❑	❑
Disposable medical devices (others)	❑	❑
Contraceptive devices	❑	❑
Ophthalmologic devices	❑	❑
Devices for injection, infusion, transfusion, dialysis	❑	❑
Devices for disinfecting, cleaning, rinsing	❑	❑
Others[12]		
Medical devices containing medicinal substances	❑	❑
Medical devices derived from/made from animal tissue	❑	❑
Medical devices with derivatives of human blood	❑	❑
	❑	❑
	❑	❑

[10] including disposables
[11] including disposables
[12] please specify

Scope of technical expertise for active medical devices	Production	Product/ Application
Monitoring devices	❑	❑
Devices for extracorporal circulation, infusion und haemopheresis	❑	❑
Respiratory devices, devices for oxygen therapy and inhalation anaesthesia	❑	❑
Surgical devices	❑	❑
Devices for imaging		
Devices utilizing ionizing rays	❑	❑
Devices utilizing non-ionizing rays	❑	❑
Devices for radiotherapy		
Devices utilizing ionizing rays	❑	❑
Devices utilizing non-ionizing rays	❑	❑
Devices for stimulation	❑	❑
Ophthalmologic devices	❑	❑
Dental devices	❑	❑
Devices for disinfection and sterilisation	❑	❑
Rehabilitation devices and active protheses	❑	❑
Devices for patient positioning and transport	❑	❑
Medical supply units	❑	❑
Active implantable medical devices		
for stimulation	❑	❑
delivering drugs or other substances	❑	❑
substituting or replacing organ functions	❑	❑
others[13]	❑	❑
	❑	❑
Others[14]		
	❑	❑

[13] please specify
[14] please specify

Special non-scope related knowledge

- ❑ Conformity assessment procedures according to the medical device law and the Directives
  ❑ 93/42/EEC ❑ 90/385/EEC ❑98/79/EC
  and their national transposition
- ❑ Quality management systems, in particular of standards EN 46000 series, EN ISO 13485/13488, EN 724, EN 928, EN 50103, etc
- ❑ Risk analysis and risk management, including evaluation of side effects
- ❑ Chemical testing and evaluation
- ❑ Physical testing and evaluation
- ❑ Biological testing and evaluation
- ❑ Clinical testing and evaluation, biometrics
- ❑ Interaction with medicinal products/substances
- ❑ Microbiology, hygiene, cleaning, disinfection and sterilisation
- ❑ Environmental control
- ❑ Cleanroom manufacturing
- ❑ Aseptic processing
- ❑ Processing, preservation, testing and treatment of tissues, cells and substances of animal origin
- ❑ BSE/TSE
- ❑ Processing, preservation, testing and treatment of tissues, cells and substances of human origin
- ❑ Derivatives of human blood
- ❑ Measuring techniques
- ❑ Telemetry
- ❑ Protection against radiation
- ❑ Electromagnetic compatibility
- ❑ Labelling and instructions for use
- ❑ Product and packaging stability
- ❑ Ergonomics
- ❑ Maintenance
- ❑ Disposal
- ❑ Patent affairs
- ❑ Material and manufacturing techniques
- ❑ Thin and thick film technology
- ❑ Precision mechanics and optics
- ❑ Welding and bonding techniques
- ❑ Manufacturing techniques for ceramics
- ❑ Polymer processing (extrusion, injection moulding,...)
- ❑ Metal processing (prototyping, reshaping, ...)
- ❑ Textile/fiber processing, weaving technologies
- ❑ Process techniques
- ❑ Packaging technologies

Area IVDMDD

Scope of technical expertise for *in-vitro* diagnostic medical devices	**Production**	**Product/ Application**
Reagents and reagent products, including related calibrators and control materials for the determination and/or detection, confirmation and quantification of		
markers of HIV infection **(HIV 1** and **2), HTLV I** and **II,** and **hepatitis B, C and D**	❑	❑
the following blood groups: **AB0-System, Rhesus (C,c,D,E,e), anti-Kell-, anti-Duffy-** and **anti-Kidd-System**	❑	❑
irregular **Anti-Erythrocytic Antibodies**	❑	❑
the following HLA tissue groups: **HLA -DR, -A, -B**	❑	❑
Rubella, Toxoplasmosis, Cytomegalovirus and Chlamydia	❑	❑
Phenylketonuria	❑	❑
tumoral markers: **PSA**	❑	❑
Trisomy 21 (including the software designed specifically for evaluating the risk of)	❑	❑
Devices for self-diagnosis for		
clinical chemistry incl. endocrinology	❑	❑
haematology	❑	❑
immunology	❑	❑
pregnancy and ovulation	❑	❑
the measurement of **blood sugar**	❑	❑
Specimen receptacles	❑	❑
Others[15]		
	❑	❑
	❑	❑
	❑	❑

[15] please specify

Special non-scope related knowledge

- ❑ Conformity assessment procedures according to the medical device Directives 93/42/EEC 90/385/EEC 98/79/EC and their national transpositions
- ❑ Quality management systems, in particular of standards EN 46000 series, EN ISO 13485/13488, EN 724, EN 928, EN 50103, etc
- ❑ Clinical chemistry and haematology
- ❑ Haemostaseology
- ❑ Serology
- ❑ Endocrinological testing
- ❑ Toxicology
- ❑ Immunology
- ❑ Immunogenetics
- ❑ Immunohaematology
- ❑ Histocompatibility testing
- ❑ Microbiology, hygiene and sterilisation
- ❑ Serology of infectious diseases
- ❑ Parasitology
- ❑ Molecular biology, molecular biological and nucleic acid amplification techniques (NAT)
- ❑ Biochemistry : Purification of proteins, labelling of proteins, fixation of enzymes, peptides synthesis, synthesis of nucleic acids
- ❑ Transfusion, especially blood group analysis
- ❑ Genetics, especially hereditary diseases and genetics analysis
- ❑ Recombinant DNA technology
- ❑ Pathology
- ❑ Forensic medicine
- ❑ Virology
- ❑ Serological determination of virus infections
- ❑ Tumor marking
- ❑ Cell biology
- ❑ Failure, risk and effect analysis, risk management
- ❑ Evaluation of risks and side effects
- ❑ Biological testing and evaluation
- ❑ Chemical and physical properties
- ❑ Stability studies
- ❑ Infection and microbial contamination
- ❑ Measuring techniques
- ❑ Protection against radiation
- ❑ Electromagnetic compatibility
- ❑ Ergonomics, especially requirements for devices for self-testing
- ❑ Evaluation of labelling and instructions for use of IVD medical devices
- ❑ Verification of batches
- ❑ Batch release criteria (acceptance and rejection criteria)
- ❑ Performance evaluation of IVD medical devices
- ❑ Biometrics, statistics

Special non-scope related knowledge

- ❑ Common technical specifications (cts) for products defined in Annex II List A (where necessary List B) of directive 98/79/EC for the detection, confirmation and for determining of
  - ❑ the following blood groups: ABO system, rhesus (C, c, D, E, e), anti-Kell, anti-Duffy and anti-Kidd
  - ❑ Markers of HIV infection HIV (1 and 2), HTLV I and II, and hepatitis B, C and D
- ❑ Software validation
- ❑ Design and manufacturing of IVD medical devices
- ❑ Material and manufacturing techniques
- ❑ Processing, preservation, testing and treatment of tissues, cells and substances of human/animal origin
- ❑ Cleanroom manufacturing
- ❑ Environmental control
- ❑ Contact with infectious material
- ❑ Aseptic processing
- ❑ Sterilisation procedures
- ❑ Inactivation procedures
- ❑ Product and packaging stability
- ❑ Packaging technologies

ANNEX 4 to Section 3

TECHNICAL HARMONIZATION DIRECTIVE

Date:

From:
Permanent Representation to the European Communities

To: **The European Commission**
Enterprise Directorate-General
DG ENTR/G/1
Rue de la loi, 200
B-1049 Bruxelles
Other Member States

1. References: Directive / /(E)EC

2.A. Name of body, acronym, address, telephone/fax

Telephone: Fax:

2.B. Identification number of the body: ☐

3. Period of validity of the notification

☐ Unlimited

☐ Valid until: Subject to annual audit

4. Body's technical responsibilities (accreditation or other reasons)

Meets the requirements specified in annex

Accreditation/assessment in accordance with:

☐ EN 45001

☐ EN 45004

☐ EN 45011

☐ EN 45012

☐ Others (specify):

Note: The standards indicated must meet the requirements of the relevant conformity assessment procedures.

Tasks performed by the body

Product/product range	Procedures/Modules	Annexes/Articles of the legislation
	EC Declaration of Conformity (Full Quality Assurance)	
	EC Type-Examination	
	EC Verification	
	EC Declaration of Conformity (Production Quality Assurance)	
	EC Declaration of Conformity (Product Quality Assurance)	

Section 4

Designating Authority Monitoring of Notified Bodies

Designating Authority Monitoring of Notified Bodies

1.0 Background

1.1 Designating Authorities (DAs) are responsible for ensuring that those Notified Bodies (NBs) it has designated "continuously comply with the requirements of the Directives and the principles laid down in Council decision 93/465/EEC". Thus, DAs have a clear responsibility to subject the activities of their NBs to regular and structured surveillance. In practice this means subjecting NBs to a range of different types of assessment conducted by fully trained and qualified DA assessors. The aim of this is to confirm that the NB performs at a consistently high level of competence and within the scope of its designated activities.

1.2 This section describes and gives practical advice and guidance on the monitoring of NBs. In particular it:

- describes the different types of assessments that can be undertaken
- provides advice on how to prepare to conduct an assessment
- provides advice on conducting assessments
- provides advice on follow up activities resulting from the assessments.

2.0 Different Types of Assessment

2.1 Assessments of NBs by the DA can be grouped into one of four generic types. These are:

- Initial assessments
- Surveillance assessments
- Observed audits
- Others

2.2 Further details on each can be found in Section III 3 of MEDDEV 2.10-2. However brief details are also supplied in the following paragraphs.

Initial Assessments

2.3 An initial assessment is the first assessment performed at the NB's premises (and those of any sub-contractors). It is intended to let the DA examine all the specific operational activities set out in section II and the relevant Appendices of MEDDEV 2.10-2. It has the ultimate aim of verifying that the NB's own systems and procedures meet relevant requirements and that it is applying them in practice.

2.4 An initial assessment can either be carried out as part of the designation process, or immediately following the designation – see Section 3 of the Handbook.

Surveillance Assessments

2.5 Like the initial assessment a surveillance assessment is performed at a NB's premises and those of any sub-contractors. Also like the initial assessment, it is primarily intended to cover specific operational activities set out in Section II and the relevant Appendices of MEDDEV 2.10-2. The aim is to allow the DA to check the NB's continuous compliance with the Directive/Regulations/Standards and its own internal procedures.

2.6 The DA need not necessarily assess subcontractors that are solely carrying out a testing function provided they have relevant accreditation for those tests. Nevertheless the DA may still decide to assess such sub-contractors if it feels this is warranted for whatever reason. However, the DA should always ensure as part of its regular programme of surveillance assessments that the NB is exercising appropriate control over any sub-contractors that it uses.

Observed Audits

2.7 This is where the DA witness a NB conducting a Quality Assurance audit on a manufacturers premises or a design dossier review or where it is witnessing (type/verification) testing being conducted. Observed audits allow the DA to directly check the quality and thoroughness of individual NB auditors and their knowledge of the various Directives, national Regulations and Standards, etc. Crucially they allow the DA to check the NB auditors ability to check that the manufacturer is complying with these and, indeed, that the NB auditor is complying with his own organisations internal procedures.

Other

2.8There may be circumstances where a DA might choose to carry out variations on the above assessments. An example would be a 'Follow Up' assessment to ensure that corrective actions agreed with the NB following previous assessments has been correctly implemented.

3.0 Frequency of Assessments

3.1 It is for the DA to decide upon the frequency with which it will assess its NBs and the nature and type of those assessments. However it is possible to set out some general guidelines and this is done below**.**

Initial and Surveillance Assessments

3.2 The following guidelines with regard to frequency are taken from MEDDEV 2.10-2 (Section III 3. A.):

Initial assessments are the first assessments performed by the DA

Surveillance assessments at the NB site should take place at least every 18 months unless the NB has performed no audits since the previous surveillance. However such audits could be brought forward if considered necessary for example :

- Major problems found at initial or previous surveillance audit
- Extension to scope (being requested by the NB)
- Significant vigilance or regulatory compliance cases arising for a particular manufacturer covered by the NB
- Complaints received about a particular NB's work
- Large volume of work conducted by the NB

3.3 As stated above surveillance assessments should ideally be carried out at least every 18 months. However, experience has shown that surveillance assessments should be carried out at least annually for Notified Bodies having more than about 150 clients.

3.4 Where the NB has performed no audits since the previous surveillance activity the DA may wish to consider its continued designation. In particular it should consider verifying that the NB continues to have the required systems and expertise to perform to the required standard.

Observed Audits

3.5 The following, based on MEDDEV 2.10-2 (Section III 3. B.), provides useful guidance when considering the frequency of observed audits and suggests that they take place at least every 18 months.

3.6 When considering when to schedule an observed audit MEDEV 2.10-2 suggests that the following circumstances/factors should be taken into consideration:

- The timing of one of the NBs first Quality Assurance audits following designation.
- the number of certificates granted since the last audit (frequency of audit should be increased if a large amount of work is being undertaken)
- where relevant an observed audit could be scheduled in conjunction with, or as a result of, an initial or surveillance audit, especially where there is an indicated problem
- following an extension to scope in order to assess competence in this new area
- where there has been a significant number of vigilance or regulatory

compliance cases affecting a particular manufacturer covered by the notified body

- where the CA/DA has received complaints about a NB's performance

- where the NB is due to carry out testing on devices [or a design dossier review]

- where the NB's workload is significantly growing such that they are employing new personnel, holding new training events etc

- where the NB is significantly changing its working practices.

3.7 Experience has shown that observed audits should be carried out at least annually for NB having more than about 150 clients.

4.0 Scheduling of assessments/audits

Initial and Surveillance Assessments

4.1 For initial and routine surveillance assessments NBs need to be given good notice of a DAs intention to carry out an assessment. It is recommended that this notice is around 8 weeks. This will enable the NB to confirm dates and provide relevant information (e.g. a list of certifications and a copy of current procedures) needed by the DA assessor to prepare.

4.2 MEDDEV 2.10-2 recommends that the duration of Initial and Surveillance assessments be a minimum of 3 man days for initial assessments and a minimum of one man day for surveillance assessments. The actual duration, however, will depend on the amount and complexity of work that the NB is designated for and has undertaken. Experience has shown that 1 man day is sufficient for an NB that has undertaken only a handful of audits since the last assessment whereas up to 12 man days may be required for an NB with a large number of clients (e.g. 400 +), or where a wide range of Design Dossier/Type Examinations have been undertaken since the last assessment.

Observed Audits

4.3 NBs need to be given sufficient notice of a DA's intention to conduct an Observed Audit. This will allow the NB time to provide dates and details of forthcoming audits for the DA to select the most appropriate one to attend. Because of the logistical difficulties in setting up observed audits, DAs may well find it useful to consider asking NBs to routinely keep them informed of their future audit programmes.

4.4 When selecting an appropriate NB audit to observe, the DA should take the following factors into consideration:

- The risk classification of the devices manufactured at the facility being audited

- The type of audit being conducted by the NB (eg It would be preferable to observe an initial or re-certification audit)

- Type of conformity assessment audit the NB is due to conduct (e.g. Annex II (preferable), V or VI under the MDD)

- Location of the audit

- The identity of the NB auditors to be used (i.e. have they been previously observed in action by the DA?)

- Manufacturing processes and technology being used (i.e. has the NB already been observed auditing similar manufacturers?)

- Known problems with the manufacturer or the devices being audited from, for example, vigilance and post-market surveillance data

5.0 Preparation

5.1 The key to a successful assessment is preparation.

5.2 This means being clear as to what aspects of the NB's operations, procedures or performance the DA wants to examine in depth and in ensuring that the assessor is properly prepared in terms of familiarity with relevant documentation, standards, and technology, etc. The following paragraphs provide some additional guidance on preparing for each of the normal types of assessment undertaken.

Initial and Surveillance Assessments

5.3 Before the start of an assessment the NB should be asked to provide the DA with all relevant information. In the case of initial and surveillance assessments examples of the types of information that could be requested include:

- any change in the NB's organisational structure or legal status. (An up to date organisational chart should always be provided)

- updated list of the NB's own internal procedures, if applicable, highlighting any changes made since the last assessment.

- updated list of subcontractors (and list of subcontracted activities) used by the NB

- updated list of personnel used by the NB. (This should include both full time employees of the NB as well as any external experts employed for particular functions)

- current list of certifications issued by the NB since the last DA assessment

- updated lists of accreditation held by the NB and its employees

- details of all relevant activity between the NB and other CA/DAs since the last assessment

5.4 The DA should select appropriate personnel to conduct the assessment. Particular care needs to be taken to ensure that people with the necessary expertise are included in the assessment team. This is of particular importance if any design/type examination cases undertaken by the NB are to be reviewed.

5.5 Before the assessment the DA should draw up a detailed assessment plan. This should be sent to the NB prior to the assessment. The plan should provide details of the DAs assessment team, the expected time and duration for each major audit activity (covering the selected requirements of MEDDEV 2-10.2), and the schedule for relevant meetings between the DA assessors and the NB auditors (i.e. opening/closing meetings and daily briefings). If possible, the major assessment activities should take place during the normal working hours of the NB. An example of an assessment plan is attached at Annex 2 to this Section of the Handbook.

5.6 At the beginning of the assessment, the DA should select appropriate cases for review. Possible criteria for selection could include:

- The Product Range covered by the NB Certification
- Conformity Assessment Annexes followed by the NB
- Manufacturers' locations
- Information derived from Vigilance/User Reports
- Compliance Reports/Complaints held by the CA/DA
- Reported Clinical Investigations
- Special processes (e.g. sterilisation) involved in the manufacturing of the devices
- Products or processes affected by the withdrawal / and re-issue of a certificate by the NB
- Regulatory non-conformities by a manufacturer, evaluated by the NB, observed during a CA enforcement/compliance inspection
- Re-classification/Classification/Borderline issues

5.7 DA assessors may also find it helpful to prepare, before starting the assessment, a detailed brief, to act as an aide memoir, which they can refer to during the assessment. This could include details of corrective actions from any previous assessments, details of cases to be audited and notes of the particular aspects of the NB's Quality System elements that need to be examined during the assessment.

5.8 DA assessors should also assemble, before the assessment begins, all relevant reference documentation likely to be needed during the assessment. Such documentation could include:

- The Assessment Plan
- The Assessors brief, if prepared
- Copies of the relevant national Regulations
- A copy of the relevant Directive(s)
- A copy of MEDDEV 2.10-2
- The NBOG Checklist for Audit of Notified Bodies (attached as Annex 1 to this section of the Handbook)
- The NBOG Checklist Regarding NB Review of Clinical Data (in course of preparation)
- Copies of previous assessment reports on the NB
- Copies of corrective actions agreed by the DA/NB resulting from previous assessments (including those from observed audits)
- Relevant vigilance, compliance and clinical investigation information
- Copies of current Quality Assurance standards (ISO 9001, EN 46001, ISO 13485)
- List of Harmonised Standards
- Copies of relevant Common Technical Specifications (CTSs)

Observed Audits

5.9 To fully prepare for an observed audit, it is essential that the DA fully understands the devices and technologies to be audited by the NB as well as the precise nature of the conformity assessment it intends to carry out. To enable the DA to do this it should, as a minimum, ask the NB to supply it with the following information.

(This should be requested sufficiently in advance of the audit to allow the DA to ensure it has the correct skill mix within its assessment team, to allow the DA assessors time to study it in detail and to allow the DA time to prepare its assessment plan properly to ensure that all relevant areas are covered by the NB during the audit):

- Description of the Product Range under assessment (indications for use, device classification, etc.)

- The Conformity Assessment Annex to be followed

- Scope of the audit

- Details of any subcontractors to be audited by the NB

- Copy of any QS documentation review along with the manufacturer's Quality Manual, procedures and organisation chart

- Travel and accommodation information

- The NB Audit Plan

- Any previous NB audit reports on the manufacturer including details of non-conformities raised and corrective actions agreed

- Details of the NB Audit Team to be deployed, including details of their competencies, experience, training, impartiality/independence and whether they are internal/external employees of the NB.

5.10 Before conducting an observed audit, the DA should take particular care in selecting appropriate personnel to form its assessment team. They should have relevant medical device experience with regard to the products/processes under assessment by the NB. Consequently more than one DA assessor may be necessary. If a review of design dossiers or device testing is to be undertaken by the NB during the audit, then device specialists with specific knowledge of the devices involved may be required.

5.11 Before an Observed audit, it is imperative that the DA assessors fully familiarise themselves with the manufacturers' product range to be assessed by the NB. This involves ensuring that they have up to date knowledge about all relevant standards and the production processes and testing regimes that will be encountered. It is essential that the critical design features of any products, critical elements of the manufacturing process and details of any expected product testing that the NB auditor should be covering are identified and considered by the DA assessor in advance.

5.12 The DA assessors should assemble all relevant documentation for reference during the assessment. Such documentation could include in addition to that supplied by the NB:

- Copies of relevant national Regulations

- Copies of relevant Directives and any guidance notes relating thereto

- A copy of the GHTF Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers

- Copies of previous NB audit reports of the manufacturer

- Copies of corrective actions agreed by the NB and manufacturer from the previous audit

- Relevant vigilance, compliance and clinical investigation information relating to the manufacturer

- Copies of current QA standards and Guidance (ISO 9001, EN 46001, ISO 13485, EN724, EN50103, EN928)

- List of Harmonised Standards

- Copies of relevant standards applicable to the manufacturer's devices subject to the NB audit

6.0 Conduct of the Assessment

Initial and Surveillance Assessments

6.1 For initial and surveillance assessments, the DA assessor(s) should ideally follow the usual format for conducting audits set out, for example, in Section 6.5 of ISO 19011 Guidelines for Quality and /or Environmental Management Systems Auditing. Key features of the standard include:

- An Opening Meeting

The purpose of the opening meeting is to allow the DA assessment team to:

- introduce themselves to the NB personnel

- review the scope and objectives of the audit

- provide a short summary of the methods and procedures to be used to conduct the assessment

- confirm that the resources, facilities and members of the NB's staff needed by the assessment team to conduct the assessment are available

- confirm the time and date for the closing meeting and any interim meetings

- clarify any unclear details

- The Assessment

The assessment is considered to be the examination of relevant procedures and records at the NB premises to:

- determine compliance of the NB's documented system with the regulatory requirements;

- confirm the accurate and effective implementation of the NB's procedures by its staff; and to

- verify the effectiveness of the NB's quality system

- Closing Meeting

  The main purpose of the closing meeting is to present any issues of concern to the NB to ensure that they are understood in order for appropriate corrective actions to be taken.

6.2 The Checklist for Assessment of NBs (Annex 1 to this section of the Handbook) can be used by the DA assessors as the basis for the review of the NB's system, including a review of case files. Following the checklist will provide a useful aide memoire and help ensure that all key items are assessed. For initial assessments the full checklist can be used. During surveillance assessments selected elements of the checklist only may be used. The DA assessor should make detailed notes throughout the assessment. These should detail all the procedures, records and other documentation reviewed and any conclusions reached by the assessor.

6.3 At the closing meeting, at the end of the assessment, the DA assessors should tell the NB of any concerns they have as a result of the assessment. Any non-compliances with the Directives/Regulations/Standards, etc should similarly be revealed, discussed and (ideally) agreed. (DA assessors may find it helpful to group their concerns into Major, Minor or Observations categories as described in para 8.0 et seq below). It is good practice for the DA assessors to provide a written list of their concerns at this meeting. It is particularly important that, before leaving the site, the DA assessor should make clear to the NB whether he has found any issues of concern so serious that the DA may wish to re-consider the NB's designation or scope.

6.4 Either at the closing meeting, or shortly thereafter, the NB should be asked to provide the DA with a detailed Corrective Action Plan (CAP). This should describe actions the NB proposes taking to address the concerns raised during the assessment. The CAP should be formally agreed by the DA. Implementation of the CAP by the NB should be checked by the DA during future assessments.

6.5 Finally, where the initial or surveillance assessment has raised serious concerns about the ability of the NB to perform to an acceptable standard, the DA should consider suspending or ending the NB's designation or amending its designated scope.

Observed Audits

6.6 When conducting an Observed audit, it is recommended that the DA assessors use the GHTF Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers as their basic reference document.

6.7 During the Observed audit, the DA assessors should take care not to interfere in any way with the audit being conducted by the NB. In particular, they should not discuss issues with the NB auditor that may alter the way in which he carries out the audit of the manufacturer. Such interference could easily affect the performance of the NB auditor making it more difficult to assess his understanding of the relevant Regulations/Directive, the product range(s) under assessment and his compliance with his own organisational procedures. Rather, the DA assessor should take detailed notes throughout the assessment. These should fully cover the areas, procedures and records reviewed by the NB auditor, any non-conformities and observations raised by

him, together with the DA assessors conclusions on the effectiveness of the NB auditor reached as a result of the assessment.

6.8 Experience has shown that key items for the DA assessor to look at during an observed audit include the following;

- Confirmation of annexes, product range and audit plan (this is best done in the opening meeting)

- That the NB auditor has adequately challenged all relevant elements of the manufacturer's Quality System

- That all Regulatory elements contained in the appropriate Directive have been adequately covered by the NB auditor

- That all identified critical elements are covered by the NB auditor (see para 5.11 above)

- That the NB auditor has selected and assessed an appropriate sample of processes and device types, including the technical files for selected devices

- That the auditor is following NB procedures

- That the NB auditor demonstrates an adequate understanding of : the regulatory requirements of the Directives, national Regulations, manufacturing processes and technology used by the manufacturer and the medical devices under assessment

- That the NB auditor identifies correctly any non-conformities and assigns to them an appropriate level of seriousness when reporting back to the manufacturer at the closing meeting.

6.9 At the end of the Observed audit the DA assessor should hold a closing meeting with the NB auditors. At this the NB auditors should be told of any concerns about their performance or level of relevant knowledge demonstrated during the audit. Ideally problems identified should be referenced against the appropriate section of the relevant source reference documents, e.g. Directives, national transpositions, MEDDEV 2.10-2, standards, GHTF documents, etc. Additionally, DA assessors may find it helpful to group problems found into Major, Minor or Observation categories (see paras 8.0 et seq below).

6.10 Details of any problems found during the observed audit should either be given to the NB auditor in writing at the closing meeting or sent to the NB shortly thereafter. In either case the NBs response to the DA assessors findings should be requested together with proposals for action by the NB - a Corrective Action Plan (CAP) - to ensure that such problems are dealt with and are not repeated in future. The CAP should be formally agreed by the DA and its implementation checked during subsequent assessments. In cases where the DA assessor has identified serious concerns about the NB's ability to carry out its designated functions, it may well have to consider amending or ending the NBs designation or amending its designated scope.

7.0 Assessment Follow Up

7.1 Following the assessment (of whatever type) the DA assessor should write a report detailing any issues of concern or observations, ideally split between Major or Minor non-conformities or Observations (see Para 8 et seq below). Additionally, the report should contain details of any corrective action plan put forward by the NB for consideration by the DA and any recommendations from the assessor for further action.

Initial and Surveillance Assessment Reports

7.2 The following elements may be considered appropriate to be included by the DA assessor in his report:

- Names and titles of the NB representatives/DA assessors involved
- Scope of assessment (Directives, Annexes, product scope)
- References used
- Review of issues/corrective actions previously raised
- areas assessed in the current assessment
- description of the means by which compliance was demonstrated
- records/files examined
- a clear description of each area of concern raised (supported by relevant information).
- Summary (including issues raised at opening and closing meetings)

Observed Audits Reports

7.3 The following elements may be considered appropriate to be included by the DA assessor in his report:

- Names and titles of the NB auditors/company representatives/DA assessors/NB Representatives involved
- scope of audit being undertaken by the NB
- references used
- audit plan
- areas audited by the NB auditors
- a clear description of each area of concern raised (supported by relevant information).
- Summary (including discussions held at the debrief meeting)

7.4 Experience suggests that the DA should hold an internal review of the assessment report, corrective action plan and any recommendations made by the DA assessor as soon as possible after the assessment. Ideally, a competent person, independent from the assessment team, should carry this out. This review should in particular consider the corrective action plan (CAP) put forward by the NB and either agree it or seek amendments. In addition, it should identify any issues of a serious nature (see below) and consider taking immediate and appropriate action against the NB if necessary. Immediate actions that could be applied to a NB will obviously depend upon the nature of the problems found. However they could include:

- Suspension of specific activities (eg design dossier reviews).
- Suspension of the use of certain auditors
- Increased control and surveillance by the DA
- Additional conditions imposed upon the NB
- Requiring an audit to be repeated urgently where concerns about the correctness of any certifications issued have been identified such that the safety of devices may be questioned.
- Where possible breaches of the national Regulations are identified passing this information to the relevant regulatory authority
- Consideration being given to either suspending or amending the NB's designated scope or removing it entirely.

7.5 Where no serious problems have been identified routine follow up should take place. The follow-up of an observed audit process could also include :

- review of NB audit report
- review of NB analysis of the manufacturer's corrective actions
- review of NB preparation of the recommendation for issuing (or not)/renewing the certificates
- issue of certification

7.6 In all cases a written report of the internal review described in para 7.4 above should be prepared. This should contain a summary of the discussions and, if necessary, details of any actions taken, the reasons for them, and any decisions made regarding further actions to be taken by the DA in relation to the NB.

Close Out

7.7 When the DA has completed its study of the assessment report, agreed - if necessary - a corrective action plan with the NB, and decided upon any further actions to be taken, it should write formally to the NB advising it of the DAs position. If any conditions are to be placed upon the NBs activities it is essential that these are

set out clearly in the letter. Equally, when a DA assessment has found no problems with a NB's performance it should write formally confirming that this is the case.

8.0 Non-Compliances identified during DA assessment of NB

8.1 In general, areas of concern identified during a DA assessment, of whatever type, of a NB will relate to either:

a) the competence and expertise of the NB's auditor(s), its facilities or its internal control mechanisms (including its control of sub-contractors), or a failure by it to operate within its designated scope; or

b) the quality of the NB's work in relation to a specific audit or audits of its customers.

8.2 In all cases however it is possible to group these concerns into:

- Major non-compliances
- Minor non-compliances
- Observations

8.3 It is essential that all matters of concern identified during a DA assessment are brought speedily to the attention of the NB and that a Corrective Action Plan (CAP) is agreed in respect of all major or minor non-compliances. The DA should monitor implementation of the CAP. Failure by the NB to implement an agreed CAP will itself constitute a major non-compliance.

Major Non-Compliances

8.4 A major non-compliance can be defined as a situation where a NB's ability to carry out its designated activities to an acceptable standard is brought seriously into question. This could include:

a) the NB no longer meeting the designation criteria set out in Annex XI of the MDD or Annex 8 of the AIMD or Annex IX of the IVDMDD; or

b) where the NB or its auditor(s) has failed to address or implement requirements as stated in the relevant Articles and Annexes of the relevant Directives, including the Conformity Assessment Annexes; or

c) any situation where a NB has issued a certificate of conformity based on an inadequate/improper assessment.

8.5 It is imperative that all major non-compliances are dealt with immediately by the DA and the NB. Failure to do so means that non-conforming devices may be placed, or continue to be placed, on the EU market with possibly serious harm to public health and safety.

8.6 The following table provides some examples of issues that would generally be regarded as constituting major non-compliances. The list is illustrative only.

Additionally, while each case should be considered on its own merits, the table provides some suggestions as to possible corrective actions the DA may wish to consider taking. There are however no hard and fast rules that can be applied. Nevertheless, in each of the situations listed below it is clear that the DA should take some action to both deal with the immediate situation and to ensure that it is not repeated.

Problem	Possible Designating Authority Action
Failure to continue to meet the designation criteria set out in the relevant Directive, eg: a) loss of key personnel b) loss of major sub-contractor c) loss of impartiality d) breach of confidentiality requirements e) lack of liability insurance	The DA should consider either suspension, amendment to scope or de-designation, as appropriate. (Suspension and amendment to scope may be applicable while the NB addresses major non-conformities relating to skill shortages by, e.g. recruiting suitably trained and experienced staff or sub-contractors.)
NB failing to operate its own internal control mechanisms by, for example: a) failing to ensure appropriately trained auditors are allocated to particular audits; b) audit reports inadequately assessed before Certificate of Conformity issued c) Certificate of Conformity issued with significant non conformities outstanding d) failing to operate within its designated scope e) failing to ensure auditors competence and training is regularly updated through appropriate training f) failing to provide suitable control of sub-contractors g) undertaking inappropriate or	a) – g) In such situations there is a high potential danger of Certificates of Conformity being inappropriately issued. DAs should consider suspension or removal of designation or amending the NB's designated scope. Other possible actions could include requiring the NB to repeat audits where, for example, an inappropriate auditor had been used.

inadequate conformity assessment route, including as a result of incorrectly classified devices. h) Failure to comply with conditions of designation i) Inadequate internal audits	h) Severity of action to be taken depends on the nature of the failure. i) Severity of action to be taken depends on the nature of the inadequacy.
NB auditor failing to undertake audit of an acceptable standard eg a) inadequate scrutiny of clinical data b) failing to consult with pharmaceutical regulatory bodies where required c) failing to follow up non-compliances identified in previous audits d) failure to identify manufacturer's non-compliance with his own quality systems e) failure to take into account design changes f) non-conformities wrongly classified as minor when they were major g) no performance testing carried out during EC Verification process (ie Annex IV) h) Inadequacies with Initial QS assessments eg full range of product types and processes or all the elements of the QS standard not assessed i) failure to identify the correct	In all the examples listed, there is a real chance of unsafe devices being incorrectly certified. All the examples below normally constitute major non-compliances. Corrective actions could include • de-designation or restriction of scope, • requiring particular conformity assessment procedures to be undertaken only by specified auditors, requiring auditors to be re-trained in specific matters, requiring amendments to be made to the NBs own internal operating procedures, etc. In all circumstances however the DA should consider requiring the NB to suspend the certificate and, if the DA believes the NB is capable, to repeat the audit as a matter of urgency. (If the DA does not believe the NB is capable then de-designation is the only possible response). Additionally increased surveillance of the NB by the DA may be required.

classifications	

8.7 Guidance for DAs considering suspending, limiting or withdrawing a NBs designation is provided in Section 3 of this Handbook.

Minor Non-Conformities

8.8 Minor non-conformities may be defined as problems which, of themselves, may not necessarily result in the issue of an inappropriate Certificate of Conformity. However such failings will result in a general loss of confidence in the ability of the NB or its auditors, to perform as required.

8.9 All non-compliances identified by the DA assessor must be brought to the attention of the NB and corrective action (a Corrective Action Plan or CAP) agreed. Implementation of the CAP must be monitored by the DA. Failure by the NB to implement a corrective action programme once agreed will automatically constitute a major non-compliance.

8.10 The table below lists examples of items which, inter alia, could constitute minor non-conformities. The list is not exhaustive. Also, while the DA will need to consider each case on its merits, the table provides some examples of the types of remedial actions that may be considered appropriate.

Problem	Possible remedial action
Certificates of Conformity imprecisely defined	In all the examples the DA should consider requiring the NB to review its own internal control procedures. Additionally consideration will be needed to re-training of staff.
Audit reports poorly written	
Audit reports not signed or dated	
Incomplete training records of NB staff	
Audit poorly planned	

Comments/Observations

8.11 Comments or Observations are findings or statements by the DA assessor following an assessment which constitute in the DA's opinion an opportunity for improvement in the performance or procedures of the NB. They are intended to add value to the system and operations under assessment, eg

- Minor inconsistencies within the documented quality system
- The need for more frequent assessor meetings
- The need to ensure that companies subject to Design Dossier renewals are contacted in sufficient time.

8.12 While the DA should not necessarily insist that the NB act on any Comments/Observations it is always sensible to discuss them and, where possible, agree a process of implementation.

Annex 1 to Section 4

CHECKLIST FOR DA ASSESSMENT OF NOTIFIED BODIES

This checklist can be used as a guide and record when performing assessments of Notified Bodies at their offices

MEDDEV **2.10/2**		COMMENTS – procedures and documents sampled
	GENERAL REQUIREMENTS	
1a 5	Review the appropriateness of the NB facilities to undertake its tasks? Infrastructure: Building Test house Staffing level *This will become apparent during the course of the audit.*	
	Review the NB procedure for notifying the CA of personnel changes affecting their designation activities? Have notifications been made?	
	ORGANISATION OF THE NOTIFIED BODY	
2a + c	Review the role/ tasks undertaken by the NB. Ensure that the NB is not the designer, manufacturer, supplier, installer of medical devices, or acting as a consultant for devices / quality systems under assessment. *Review NB marketing material.*	
1b	Review a statement of the NB's legal status	
	Review the financial status of the NB e.g. previous annual report	
7.0	Review and retain a copy of the current liability insurance of the NB.	

1b/c	Review the organisation chart of the NB to include authority, responsibility and reporting structure within the NB, identifying links with any parent organisation. This may take the form of: -Organisational chart - Individual job descriptions - Individual statements - Individual procedures * *Is there consistency between the above and responsibilities documented in the NB's Quality Manual/ working procedures?*	
a, b, c 3a +b 5a 9(A) v	What is the means by which the NB ensures the independence and impartiality of staff? *Review and assess whether the procedure adequately addresses issues of independence, impartiality, and the declaration and resolution of conflicts of interest.*	
6a	Review the procedure by which the NB ensures confidentiality of information obtained during the course of the NB's activities.	
	PERSONNEL	
1a 4a	Review the adequacy of staffing levels of administrative support staff, lead and generalist assessors, and technical experts within the organisation to cover the designated activities of the Notified Body.	
	Confirm the attendance of the Notified Body at European (or at least National) co-ordination activities.	
2 a, b, c 3a +b 5a 6a	***the following requirements also apply to subcontractors (see subcontracting below)** *Review staff contracts. Do they address the issues of independence, impartiality, confidentiality, and the declaration and resolution of conflicts of interest?* *Review a sample of the contracts of administrative, quality system, device and technology specialist assessors.* *This should confirm that staff are not involved in the design, construction, marketing, maintenance or consultancy of devices or quality systems under assessment.* *Staff remuneration should not depend on their activities.*	

	Have NB staff declared potential conflicts of interest? *Have staff signed up to the confidentiality requirements?*	
4a, b, c	Review the procedure for specifying the educational, training and experience required for different roles within the organisation. - *Ensure that all roles within the organisation are defined.*	
4d 9A ii, iv	Review the procedure defining the rationale by which the tasks of assessment staff are allocated. *Review a "Competency Matrix" where available, is this current?*	
4a,c, d	The NB should ensure that assessment staff are appropriately trained/ experienced in the following where relevant: Regulatory requirements Assessment of device conformity with the essential requirements European and international standards Risk analysis and risk management Evaluation of clinical data The review of design dossiers Biocompatability evaluation Assessment of devices containing animal tissues Safety and performance assessment of electronic systems/software Devices containing medicinal products The assessment of special processes Statistical sampling methods used for product verification *This should include knowledge of Harmonised Standards where available.* *Sample training records to determine compliance with the above.*	
	Review the adequacy of training records. *This should include their areas of competence/ responsibility, educational and professional qualifications, skills, work experience, audits conducted, training in the Directives and Harmonised Standards, declaration of conflicts of interest.*	

	Are quality system assessors trained in the application of GHTF/SG, 4 (98) Guidelines for regulatory auditing of quality systems of medical device manufacturers? - *Sample training records of Quality System assessors to determine compliance.* - *Are training records up to date?*	
4d	Review the procedure for the selection of the assessment team. The assessment team should comprise team members with expertise in the technology, device type and regulatory requirements of the assessment. *Client files should be sampled to ensure the appropriate selection of assessment staff.*	
4a	How is the competence of assessors evaluated? *Sample records of evaluation.*	
guidance 5	Where the testing of medical devices is undertaken at the manufacturers premises, does the NB: Have full access to and control of equipment? Ensure the calibration of test equipment used?	
	SUBCONTRACTING	
8a, c, d, 2 a, b, c 3a +b 5a	CONTRACTS Review the responsibilities of subcontractor and NB as defined in the contract indicating that: 1. Subcontractors' assessments will be performed in the same way as those by in-house NB staff. 2. The NB retains the overall responsibility for the assessment (subcontractors activities should be limited to factual reporting).	

	3. The role of subcontractor may not be further subcontracted. 4. Issues of independence, impartiality, and the declaration and resolution of conflicts of interest have been addressed. 5. Subcontractors are free from inducements that may affect their objectivity. 6. Subcontractors have declared any potential conflicts of interest. 7. Confidentiality of information gained during the course of an assessment. 8. Provision is made for Competent Authority access to information gathered during assessments. *Notes: Subcontracted staff should not be involved in the design, construction, marketing, maintenance or consultancy of devices or quality systems under assessment.* *Contracts may exist between a subcontracted organisation or individuals.* - *Sample a range of subcontractor agreements including organisations and individuals.*	
8f	Review the following for subcontracted individuals/ organisations: 1. Legal status including links/ relationship with a parent organisation. 2. Procedure for the allocation of subcontracted assessment staff. 3. The procedure for the task allocation of subcontracted staff (e.g. a competence matrix). 4. Evidence of subcontracted staff to undertake tasks allocated.	
8f	Review the NB procedures for the control of subcontractors with respect to: 1. Informing the CA of their intent to use subcontracted staff for assessments (including the scope of assessment activities). 2. Notifying the CA of changes to subcontracted personnel affecting the NB's scope of designation. 3. A register of subcontracted staff.	

	Review the procedure for the training of subcontractors in in-house NB procedures. *Review document control to ensure that subcontractors are issued with **current** NB procedures.* *Procedures issued should detail the activities performed by the subcontractor.*	
guidance 5	Where the testing of medical devices has been subcontracted, does the NB: Specify the test plan? Ensure the calibration of test equipment used?	
4a, 9 xviii	Is the competence of subcontracted assessors evaluated? Are subcontractor assessments shadowed? *Sample records of evaluation.*	
	OTHER QUALITY SYSTEM PROCEDURES	
9 (A)	Obtain overview of NB's Quality System. Review of the NB's Quality System ensuring that the NB has up date procedures and records that demonstrate their compliance with the regulations. *This will become apparent during the course of the assessment.*	
9 (A) vi, ix, x, xi, xii, xiii, xiii, xiv	Review the content and implementation of the following procedures: (Consult MEDDEV 2.10/2) Manufacturers application procedure. Device classification.	

	Demarcation between the Medical Devices and other Directives such as 65/65/EEC. Annexes of the assessment (refer to appendix documents). Completeness of the application/Contract Review. NB method of assessing manufactures compliance with the chosen annexes within a specified time frame. Procedure for NB evaluation of clinical data. Ensure NB procedures take account of the compliance of products/ systems with existing national regulations/ administrative provisions. Adequate detail of reporting.. *Sample NB Records (see appendices) :*	
9(A) xv	Review NB procedure for the appeal of NB decisions regarding the classification of devices and the outcome of assessments. *Sample any appeals to ensure compliance with the above procedure.*	
9(A) xvi	Review the procedure relating to the issue, withdrawal and suspension of certificates, wrongly affixed CE marks. *(Consult MEDDEV2.10/2).* *Certificates should be sampled to ensure that the procedure has been followed (see Appendices).*	
	Ensure the NB procedure for communications with other regulatory authorities (NB's, CA's and the European Commission) conforms to the requirements of MEDDEV2.10/2. *Sample communications with Regulatory Authorities.*	
9(A) xix	Review record keeping facilities with regard to security and confidentiality.	
9(A) xxii	Review NB fees structure for the conduct of conformity assessment.	

9(A) xxiii	Review the procedure for the transfer of information to the EUDAMED database.	
9 (b)	Review Document Control procedure Does the NB ensure that current NB procedures are available to all relevant staff, including subcontractors. *Sample the availability of NB procedures, including their issue to subcontracted staff.*	
(c)	Review the NB procedure for evaluating the effectiveness/ internal audit of the Quality System. Review the following: Internal audit schedule – ensure audits are conducted as planned. Procedure for internal audit – to ensure it is fully implemented. Review the most recent internal audit to determine: Whether CA's are closed out from the previous audit. Independence and training of auditors in the conduct of an internal audit. Ensure the audit covers all areas of the Notified Body's Quality System, including review of case files. Is the output of internal audits reported at a Management Review? *Correctives actions plans should be sampled to ensure they have been appropriately closed out in a timely manner.*	

	APPENDIX A: **ANNEX SPECIFIC REQUIREMENTS**	
	Case files should be sampled and reviewed to demonstrate compliance with the above procedures and the Medical Devices Directives (see Appendices B, C, D and E : Case File Reviews).	
	FULL QUALITY ASSURANCE / PRODUCTION / PRODUCT QUALITY ASSURANCE ANNEXES	COMMENTS – procedures /documents assessed
	FULL QA ANNEX (2 AIMDD, II MDD) Assess the Notified Body procedures for the review of information provided by the manufacturer in the following areas: Design Control NB review of changes to manufacturers product range / quality system. Document control Post market surveillance and vigilance Internal audit Labelling (labels, IFU, DoC's). Review of manufacturing processes to include: Manufacturing procedures / process validation. Equipment maintenance and calibration. Special processes (for sterile/ measuring devices). In process and final release criteria. Control of non-conforming product. Procedure for the sampling to Technical Files (according the product range and classification of devices within the manufacturers scope). NB procedure for the in-depth sampling of different areas of manufacturers technical file to assess compliance with the Essential Requirements (Class IIa and IIb devices). Procedure for the review of clinical data (Class IIa+b) Procedure for the review of Design Dossier (see separate section). PRODUCTION QUALITY ASSURANCE ANNEXES (ANNEX 5 AIMDD, V MDD) *Review points 2 to 8 in the above section related to production quality system assessments.* Review the following additional elements Assessment of manufacturing processes to ensure they conform to that of the Type certificate/Technical File. PRODUCT QUALITY ASSURANCE (ANNEX VI MDD) *Review points 2 to 6 and 8 in the above section related to product quality system assessments.* Review the following additional element NB procedure for the review final inspection and testing at the manufacturers' premises. **All:** Review NB's procedure for assessing significant changes to manufacturers' product ranges and Quality Systems. **All:** Review NB's procedure for production of Assessment Reports (for manufacturers) and trails.	

	TYPE EXAMINATION ANNEX (3 AIMDD, III MDD)	COMMENTS – procedures /documents assessed
	Review Notified Body procedures for the review of technical information and manufacturing procedures for the device type, to determine compliance with the Essential Requirements and relevant Harmonised Standards. This should include the review of the following. Compliance with the essential requirements and relevant harmonized standards Review of clinical data Biocompatability/electrical safety testing data where applicable. Methods of Manufacture Review of process validation where applicable. Risk analysis and Risk benefit analysis of the device. Sterilisation validation where appropriate. Review of Specifications including test regimes Medicinal products, animal tissues, stable derivatives of human blood plasma contained in the device where applicable. Labelling and Instructions for Use Review NB's procedure for determining appropriate test and inspection protocols to define the device "type". Review NB's testing procedures (to demonstrated compliance of the type with Harmonised Standards/ Essential Requirements). Production of Notified Body report assessing overall compliance of the technical information provided with Harmonised Standards/ Essential Requirements and the results of the testing.. Review NB's procedure for assessing changes to products issued with an EC-Type certificate.	

	VERIFICATION ANNEXES (ANNEX 4 AIMDD, IV MDD,)	
	Assess the Notified Body procedures to cover the following areas: Manufacturers sampling plan for the testing of a homogenous batch (to include a statistical rationale), if relevant. Notified Body procedure for either testing each device/ sampling plan (to include the rationale). Procedure for identifying the tests/data required to demonstrate that the device has been manufactured to conform with the technical documentation / Essential Requirements. Procedure for determining test protocols including pass/fail criteria Procedure for the review of test data. Control of non-conforming product	

	DESIGN DOSSIER REVIEW (Annex II section 4 MDD)	COMMENTS – procedures /documents assessed
	Assess the Notified Body procedures for **Design Dossier** review to include the following requirements: Review of technical information (compliance with Harmonised Standards / the Essential Requirements). Review of clinical data, verifying conclusions drawn by the manufacturer. Biocompatability/electrical safety testing data where applicable. Risk analysis/ Risk benefit analysis. Sterilisation validation of sterile devices. Notified Body assessment of medicinal products, animal tissues, stable derivatives of human blood plasma components of the device where applicable. Labelling and Instructions for Use Notified Body report assessing overall compliance of the device with Harmonised Standards/ Essential Requirements. Changes Procedures for the Renewal of Certification	

APPENDIX B CASE FILE REVIEW **(Separate sheet to be used for each case reviewed)**

FULL QA ASSESSMENT (Annex 2 AIMDD, II MDD)
PRODUCTION QA ASSESSMENT (Annex 5 AIMDD, V MDD)
PRODUCT QA ASSESSMENT (Annex VI MDD)

INITIAL/RENEWAL AUDITs: The Notified Body should assess all elements of the relevant Quality System, including regulatory aspects.
SURVEILLANCE AUDIT: The NB should sample different elements of the Quality System and ensure that all of the Regulatory requirements continue to be appropriately addressed.

NOTIFIED BODY	

MANUFACTURER NAME		File Reference:
LOCATION		
SCOPE OF ASSESSMENT(product range)		

Assessment Type	Date(s)	Assessor(s)

		Procedures/records Reviewed
1.	Review manufactures application for assessment. Note the terms and conditions of the signed contract (signed/ dated?) with NB (not local office) Confirm device(s) classification and scope of the assessment. Review appropriateness of the conformity assessment route. Application review (depending on the NB's procedure)	
2.	Identify and review the NB assessor(s) allocated : Accordance with the Notified Body's procedure Competence of the assessor for the scope of the assessment	
3.	Review the audit schedule (NB Surveillance assessments only) to ensure that surveillance audits took place on time, and all aspects of the quality system and product range had been addressed over time.	

4.	Review the audit output ensuring that the NB addressed all of the Regulatory Aspects eg: **Post market surveillance and vigilance** **Changes to the product range / Quality system** Regulatory input for design (Full QA only) Technical Files, including DoCs, and processes sampled appropriately Did the audit output, including the manufacturer's report, demonstrate that the assessment addressed all required areas of the relevant Quality System? Was the audit output of sufficient detail providing a clear audit trail? Were non-conformities raised at the appropriate level where applicable? Did the accepted corrective actions address the issues raised? Was any appropriate action taken by the NB?	
5.	**Review output of the certification review according to the NB procedure to cover the following where applicable:** technical / scientific review of the audit output close of out corrective actions raised prior to certification *Note the personnel involved in the certification review.*	Date of Review: Personnel:
6.	**Check that the details recorded on the certificate are correct (to include issue date and version, and expiry date).** ***Ensure the scope on certificate matches that of the application, audit, and of the technical certification review.***	Date: Certificate Number: Issue Number and date: Expiry Date: Scope:
7.	Check that any changes have been appropriately handled.	

Any additional comments :	

CA ASSESSOR		DATE	

APPENDIX C CASE FILE REVIEW (Separate sheet for each case reviewed)

DESIGN DOSSIER REVIEW (Annex 2 section 4 AIMDD, II Section 4 MDD)

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NOTIFIED BODY	
NB ASSESSOR(S)	

MANUFACTURER NAME		File Reference:
LOCATION		Date of review:
PRODUCT SCOPE		

	ITEM	**COMMENTS – procedures / documents**
	Review the following documents for compliance with NB procedures and the Medical Devices Directives:	
1	Confirm that the product is within the scope of the Directive.	
2	Review the completeness of Design Dossier	
3	Review the appropriateness of the conformity assessment annex chosen (ie Class III product only)	
4	Review compliance of the manufacturers technical information with the essential requirements and any relevant Harmonised Standards to include : Compliance with Harmonised Standards / the Essential Requirements. Clinical data, verifying conclusions drawn by the manufacturer. Biocompatability/electrical safety testing data where applicable. Risk analysis/ Risk benefit analysis. Sterilisation validation of sterile devices. Aspects regarding any medicinal products, animal tissues, stable derivatives of human blood plasma components of the device where applicable. Labelling and Instructions for Use	
5	Review the Notified Body's assessment of the technical documentation and compare to ensure that all relevant aspects have been appropriately addressed.	
6	Ensure that any issues raised by the Notified Body have been satisfactorily resolved.	
7	Verify the conclusions drawn by the Notified Body assessor(s).	

8.	**Review output of the certification review according to the NB procedure to cover the following where applicable:** technical / scientific review of the assessment output close of out any corrective actions required prior to certification *Note the personnel involved in the certification review.*	Date of Review: Personnel:
9.	Review the Design Certificate to contain the identification of the device, Annex of assessment, issue date, version number and expiry date.	Issue number and date Version number Scope Expiry date
10.	Confirm that any changes have been appropriately handled.	
11.	Review the Design Certificate schedule to ensure that all re-certification assessments were conducted on time.	
12.	Identify and review the NB assessors allocated : Accordance with the Notified Bodies procedure Competence of the assessor for the scope of the assessment	

Any Additional Comments:

CA ASSESSOR	Date

APPENDIX D CASE FILE REVIEW (Separate sheet for each case reviewed)

TYPE EXAMINATION REVIEW (Annex 3 AIMDD, III MDD)

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NOTIFIED BODY	
NB ASSESSOR(S)	

MANUFACTURER NAME		File Reference:
LOCATION		Date of review:
PRODUCT SCOPE		

	ITEM	**COMMENTS – procedures / documents**
	Review the following documents for compliance with NB procedures and the Medical Devices Directives:	
1	Confirm that the product is within the scope of the Directive.	
2	Review the completeness of the Technical Information provided	
3	Review the appropriateness of the conformity assessment annex chosen ie Class IIa or III products.	
4	Review compliance of the manufacturers technical information with the essential requirements and any relevant Harmonised Standards to include : Compliance with Harmonised Standards / the Essential Requirements. Clinical data, verifying conclusions drawn by the manufacturer. Biocompatability/electrical safety testing data where applicable. Risk analysis/ Risk benefit analysis. Sterilisation validation of sterile devices. Aspects regarding any medicinal products, animal tissues, stable derivatives of human blood plasma components of the device where applicable. Labelling and Instructions for Use	
5.	Review test and inspection protocols prepared to define the device “type”.	
6.	Review results of NB testing and that it was undertaken in accordance with the protocols.	
7.	Review the Notified Bodies assessment of the technical documentation to ensure that all relevant aspects have been addressed.	
8.	Ensure that any issues raised by the Notified Body have	

	been satisfactorily resolved.	
9.	Verify the conclusions drawn by the Notified Body assessor(s).	
10.	**Review output of the certification review according to the NB procedure to cover the following where applicable:** technical / scientific review of the assessment and test output close of out any corrective actions required prior to certification *Note the personnel involved in the certification review.*	Date of Review: Personnel:
11.	Review the Type Examination Certificate for adequacy	Issue number and date Version number Scope Expiry date
12.	Confirm that any changes have been appropriately handled	
13.	Review the Certificate schedule to ensure that all re-certification assessments were conducted on time.	
14.	Identify and review the NB assessors allocated : In accordance with the Notified Bodies procedure Competence of the assessor for the scope of the assessment	

Any Additional Comments:

CA ASSESSOR	Date

APPENDIX E CASE FILE REVIEW

(Separate sheet for each case reviewed)

EC VERIFICATION ANNEX
(Annex 4 AIMDD, IV MDD)

NOTIFIED BODY	

MANUFACTURER NAME		File Reference:
LOCATION		
SCOPE OF ASSESSMENT(product range)		

	ITEM	**COMMENTS – procedures / documents**
	Review the following for compliance with NB procedures and the Medical Devices Directives:	
1.	Review manufactures application for assessment. Note the terms and conditions of the signed contract (signed/ dated?) with the NB (not a local office) Confirm device classification and scope of the assessment. Review appropriateness of the conformity assessment route. Application review (depending on the NB's procedure)	
2.	Review the appropriateness of the Notified Body's test facilities	
3.	That the NB has an approved protocol which has been drawn up based on the information provided by the manufacturer.	
4.	Review the NB assessment of any technical and manufacturing information required to be supplied by the manufacturer to ensure that the products meet the agreed criteria.	
5.	Review NB test records for the following: -Review the statistical basis of the batch sample size, if relevant Tests performed comply with those specified. Ensure that the batch/ devices meet the specifications. Where specifications have failed, review the NB action to prevent product being placed on market and their review of the sample size (including rationale), if relevant.	
6.	Ensure that the NB/ subcontracted personnel performing and signing off tests were acting within their scope.	

7.	**Review output of the certification review according to the NB procedure to cover the following where applicable:** technical / scientific review of the assessment/test output close of out any corrective actions required prior to certification *Note the personnel involved in the certification review.*	Date of Review: Personnel:
8.	Review the batch release certificates to ensure the relevant information is present (identification of the device type, serial/lot numbers, issue etc…).	Certificate Number: Issue Number and date: Scope:

Any Additional Comments:

CA ASSESSOR		DATE	

ANNEX 2 to Section 4

Example Assessment Plan **(Note : This is an example of type of plan that might be given to an NB prior to assessment and is not intended to be restrictive)**

NOTIFIED BODY : **Contact :**

Dates : **Expected time of arrival :**

Assessment Type :

Assessment Team

Details of the members of the Team and dates of their attendance

Member 1	(Team Leader) attending throughout
Member 2	(Trainee) attending throughout
Member 3	(Team Member) attending on *xx*

The proposed assessment program is as follows:

Day 1 (Member 1 & 2)

Introduction and opening meeting

Follow-up of observations raised at the previous surveillance audit

Follow up of observations raised at the previous witnessed audit

Organisation and structure - changes - review of specific documentation

Lunch

Independence, Impartiality, Confidentiality, Liability Insurance

Subcontractors, Document Control, Internal Audit

End of day feedback

Day 2 (Member 1,2 & 3)

Facilities, subcontractors and subsidiaries (Members 1,2 & 3)

Assessment Processes (Member 1,2 & 3)

Specific QS Assessments (Members 1 and 2)

Design Dossier Examinations (Member 3)

Lunch

Continuation of specific QS Assessments (Members 1 and 2)

Batch Verifications (Member 3)

End of day feedback

Day 3 (Members 1, 2 & 3)

Technical Competence – Personnel – Auditor competency – maintaining expertise

Aspects of issuing certificates

Finish assessment and prepare for closing meeting

Closing Meeting and Assessment Team's Observations

Reference Documents:

National Transposition

Medical Devices Directives

Meddev 2.10-2 “Designation and Monitoring of Notified Bodies within the framework of the EC Directives of Medical Devices”

NBOG Handbook

Applied Standards