

Konformitätsbewertung

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Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis

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Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis

1 Introduction

The Directive 93/42/EEC concerning medical devices (MDD) contains possible conformity assessment procedures in order to CE mark devices. Up to now, there has been inconsistency in the way Notified Bodies (NB) have performed the assessment of technical documentations for Class IIa and Class IIb products following quality system conformity assessment routes.

The Directive 2007/47/EC, covering the revision of the MDD, includes additional requirements for review of technical documentation for all Class IIa and Class IIb medical devices covered by quality system assessment routes.

2 Scope

This guideline has been prepared for NBs on how to assess the technical documentation on a representative basis according to the Directive 2007/47/EC. Attention was given to the sampling size and depth of the assessment. It will also be useful for Designating Authorities in monitoring the performance of their NBs in this area.

3 Definitions

3.1 Device subcategory (Directive 2007/47/EC, Art. 2, Paragraph 1 (iii), point (l) and Directive 93/42 EEC Art 1 Paragraph 2 (l))

A set of devices having common areas of intended use or common technology.

3.2 Generic device group (Directive 2007/47/EC, Art. 2, Paragraph 1 (iii), point (m) and Directive 93/42 Art. 1 Paragraph 2 (m))

A set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

4 Directive Requirements

4.1 Class IIa devices

For Class IIa devices the requirements are covered in Directive 2007/47/EC at Annex II, Paragraph 2 (i), Paragraph 5 (f), and Paragraph 6 (e). The Directive 93/42/EEC is amended and Annex II 7.2, Annex V 6.2 and Annex VI 6.2, states that "For devices in Class IIa the notified body shall assess ... the technical documentation ... for at least one representative sample for each device subcategory for compliance with the provisions of this Directive."

4.2 Class IIb devices

For Class IIb devices the requirements are covered in Directive 2007/47/EC at Annex II, Paragraph 2 (i). The Directive 93/42/EEC is amended and Annex II 7.3 states that "For devices in Class IIb the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2 (c) for at least one representative sample for each generic device group for compliance with the provisions of this Directive."

4.3 Concept of the reviews

Directive 2007/47/EC, Recital (22) introduces the concept of the reviews of Class IIa and IIb devices: "... The depth and extent of this review should be commensurate with the classification of the device, the novelty of the intended treatment, the degree of intervention, the novelty of the technology or construction materials, and the complexity of the design and/or technology. This review can be achieved by taking a representative example of design documentation of one or more type(s) of devices from those being manufactured. Further review(s), and in particular the assessment of changes to the design that could affect conformity with the essential requirements, should be part of the surveillance activities of the notified body."

Directive 93/42/EEC is amended and in Annex II 7.4, Annex V 6.3 and Annex VI 6.3, there are rationales provided for the sampling: "In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken."

4.4 Requirements for surveillance assessments

Directive 2007/47/EC Annex II, Paragraph 2 (i), Paragraph 5 (f), Paragraph 6 (e) and Paragraph 6.4 introduces requirements for surveillance assessments. The Directive 93/42/EEC is amended and in Annex II 7.5, Annex V 6.4 and Annex VI 6.4 it is stated: "Further samples shall be assessed by the notified body as part of the surveillance assessment...".

5 Timing

Directive 2007/47/EC Article 4 states Member States "... shall apply those measures from 21 March 2010".

Following the adoption of Directive 2007/47/EC, from 21 March 2010 at the latest, for Class IIb devices following the Annex II assessment route and Class IIa devices following the Annex II, V or VI assessment route there is a specific requirement for technical documentation to be reviewed by the NB on a sample basis. At any rate and at the latest, the first surveillance following 21 March 2010 will need to address this element.

After the 21 March 2010 new certificates can be issued only according to the new requirements.

For existing certificates issued prior to this date please see "Interpretative document of the Commission's services Implementation of Directive 2007/47/EC amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC" [1] for details. In this document the Commission's services call upon the member states to require Notified Bodies to ensure that surveillance audits are performed **at least once a year** as specified in the standard EN ISO /IEC 17021 [2].

6 Depth of Assessment

The assessment of each set of technical documentation selected, **as a minimum**, should consist of a review of

- the intended use including confirmation that the product is a medical device and its correct classification,
- the validity of the essential requirements checklist, especially when harmonized standards have not been applied in full,
- risk management file,
- pre-clinical data (studies in animal models, biocompatibility, technical performance tests etc.),
- clinical evaluation in accordance with 93/42/EEC Annex X (Note the NB review should be as per MEDDEV 2.7.1 [3]),
- information supplied by the manufacturer (label, instructions for use),
- declaration of conformity or the draft thereof,
- other technical documentation based on risk,
- and should be done according to the respective parts of NBOG BPG 2009-1 [4].

Consequently, there will be one part of the assessment performed within the normal course of the audit but in addition, file reviews will be necessary.

The time spent on the review and the level of expertise used should be proportionate to the risk and complexity of the devices in question. For the more complex devices this may require a detailed technical review. If such an in depth assessment is not considered necessary then a justification should be available.

Depending on the risk and complexity of the device(s), different experts may be involved. Therefore, NBs may not be able to perform the complete assessment on site.

7 Reporting

For those elements covered the report produced for each technical documentation reviewed should be in line with the NBOG guidance on Design Dossier Report Content [4]. This could be either as part of the audit report or separately as a supplement.

Nonconformities/Corrective Action Requests should be raised in the normal manner, including those raised against technical documentation under conformity assessment procedures according to Annex V or Annex VI.

8 Sampling

For **initial audits** of devices in **Class IIb** the Directive states that the NB shall assess the technical documentation for at least one representative sample for each generic device group (i.e. a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics). This is the same description as for “generic device groups” in EN ISO 15225 [5], which specifies the GMDN system.

For **initial audits** of devices in **Class IIa** the Directive states that the NB shall assess the technical documentation for at least one representative sample for each device subcategory (i.e. a

set of devices having common areas of intended use or common technology). Since no similar description exists for subcategory/ies like for "generic device groups", the grouped collective terms described in NBOG BPG 2009-3 [6], which define scope expressions for NBs, could be used for this.

However, in practice it is expected that the NB identifies the complete range of Class IIa and IIb products manufactured and define a suitable sampling plan for initial audits. This should be done based on the numbers of generic device groups and grouped collective terms.

It is considered that if large numbers of samples are required to be taken then the following plan should be used:

For **Class IIa** devices: a sample of each group of scope expressions according to NBOG BPG 2009-3 [6].

For **Class IIb** devices: a sample of generic device groups, referenced by different GMDN preferred terms, to the following plan:

Up to 2 groups: a sample from each group

Up to 10 groups: a sample from 3 of these groups

Up to 20 groups: a sample from 5 of these groups

Up to 30 groups: from 7 groups a sample

N > 30 groups: from $N/10 + 5$ groups a sample

For **surveillance audits** the NB should identify the complete range of Class IIa and IIb devices and group them according to preferred terms and grouped collective terms (scope expressions). For each certification period, and at least every 3 years, the NB should identify the technical documentations to be reviewed in line with the above sampling plan. As long as there is still a technical documentation not yet reviewed, at least one technical documentation should be sampled each year. This activity may or may not be done in conjunction with routine surveillance assessments. During subsequent certification periods appropriate plans should be drawn up to ensure that in the long run the majority, if not all, of the technical documentations will be assessed.

9 Changes/New Devices

Manufacturers introducing a new subcategory of Class IIa device or a new generic Class IIb device need to inform their NB who need to review relevant technical documentation prior to the products being placed on the market. For changes to existing designs the normal change requirements apply.

Reference Directive 93/42/EEC Annex II, V and VI
 Directive 2007/47/EC

Sources [1] Interpretative document of the Commission's services:
 [Implementation of Directive 2007/47/EC amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC](#), 5 June 2009

- [2] EN ISO/IEC 17021 : 2006 Conformity assessment – Requirements for bodies providing audit and certification of management systems
- [3] [MEDDEV 2.7/1](#) Evaluation of clinical data – a guide for manufacturers and notified bodies
- [4] [NBOG BPG 2009-1](#) Guidance on Design-Dossier Examination and Report Content
- [5] EN ISO 15225 : 2000/A1 : 2004 Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange
- [6] [NBOG BPG 2009-3](#) NBOG Guidance for Designation Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessments

Keywords conformity assessment, device subcategory, generic device group, sampling basis, technical documentation

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