

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec6
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Title:	Renewal of EC Design-Examination and Type-Examination Certificates
Chapter:	2.5.1 Conformity assessment procedures; General rules

Text:	<u>AIMD</u> Article 9.8 “Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of five years.” <u>MDD</u> Article 11.11 “Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of five years.” <u>IVDD</u> Article 9.10 “Decisions taken by the notified bodies in accordance with Annexes III, IV, and V shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of up to five years.”
Key words:	Conformity Assessment, validity period EC Certificates, extension of certificates, renewal

1. Introduction

The Directives do not specify the details of the procedure the manufacturer and Notified Body must follow in order to renew EC Design-Examination or Type-Examination certificates for further periods of up to 5 years.

2. Purpose

The purpose of this Recommendation is to describe the procedure for renewal of EC Design-Examination Certificates or Type-Examination Certificates, so as to avoid the following extremes:

- automatic renewal

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	Article/ Annex:	Reference to standards:
AIMD	Annex: 2.4, 3	
MDD	Annex: II.4, III	
IVD	Annex: III.6.2, IV.4.3, V.5	

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- repeating the complete previous product assessment without due recognition of previous Notified Body approvals (both original and for substantial changes).

3. Scope

The renewal of

- a) AIMD/MDD Annex 2.4/II.4 EC Design-Examination Certificates and Annex 3/III EC Type-Examination Certificates issued under either Directive 90/385/EEC or Directive 93/42/EEC
- b) IVDD Annex III.6.2 and IV.4.3 Design-Examination Certificates or Annex V.5 Type-Examination Certificates issued under Directive 98/79/EC.

4. Renewal procedure

- 4.1 The design-examination performed in accordance with Annex 2.4 (AIMD), II.4 (MDD) or IV.4.3 (IVDD) is an integral part of Notified Body conformity assessment in the course of the certification of a quality system; the same Notified Body must assess compliance with all requirements of the relevant Annex.
- 4.2 The manufacturer should provide the Notified Body with, as a minimum, the following information:

Note: The manufacturer may achieve this by means of a written application to the Notified Body.

- (a) the name and address of the manufacturer,
- (b) where the manufacturer is not resident within the EEA, the name and address of the authorised representative,
- (c) details of existing certificate(s), for example, reference number(s), date(s) of issue, expiry date(s) etc.,
- (d) identification of the device(s) and accessories(s) (catalogue number/generic name/trade name if applicable) for which a certificate renewal is required,

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- (e) a list of all the changes to the approved design or type,

Note: The manufacturer is obliged to obtain Notified Body approval for 'substantial' changes to the approved design or type; changes which are not 'substantial' do not require further Notified Body approval - see NB-MED/2.5.2/Rec2. Successive minor changes, however, may cumulatively mean the design or type differs significantly from that originally approved.

- (f) the identity of any other Notified Body(ies) involved in conformity assessment for the device(s) concerned, together with reference to any certificate(s)
- (g) the current conclusion of the manufacturers risk management on the continued compliance with the Essential Requirements, taking into consideration:
- experience gained in the post-production phase
 - additional knowledge on both already-recognized and emerging hazards and the acceptability of associated risks having due regard to changes in the generally acknowledged 'state of the art'
 - new regulatory developments
- (h) manufacturing site(s) location(s) and reference to any EC Quality System Certificate(s) concerned.

The above, together with the results of surveillance audits by the Notified Body during the validity period of the current certificate with regard to minor changes and the manufacturers post market surveillance system, will be the base upon which the validity period of the EC Design Examination and EC Type Examination Certificates can be extended for a period of up to five (5) years.

The certificate can be renewed prior its expiration date.

- 4.3 The Notified Body shall assess the continued compliance of the device(s) concerned with the Directive in accordance with the conformity assessment procedure selected.

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Rev 1: Notified Body Meeting, Brussels, March 3. & 4. 1998:

Mr. Gianoglio gave an introduction to document NBM/10/98; the background is: What will happen with the certificate when a new issue of EN-Standard is published?

Discussion: *N. A. stated that if there is a new standard the old product is not unsafe per se, but nevertheless the question of moving to the new standard opens up the question whether a product is still fitting with the state of the art or not; this could fall together with the decision of prolongation of certificate. If things have evolved over time, this question in the context of prolongation of certificates needs to be addressed. R. V. added that risk benefit ratio is the key for the acceptability of risk compared to the state of the art, compared to what is achievable with the state of the art. M. F. advised that there is no stringent ground to say that with changing of standards the devices will become unsafe and that there should be a redesign depending the change; but manufactures must be aware of the state of the art and if there is safety implications at the time of review of certification.*

*In light of the importance of the discussion (before information on other sectors of the new approach directives will be made or pronounced) NB-MED agreed to bring this subject "Renewal of type certificates" forward in a NB-MED Recommendation via **NBRG**. Also the proposal made by Gianoglio was not shared by everybody. The **member of NB-MED** were asked to send their comments to the Technical Secretariat. Two main aspects should be:*

- a) change of state of the art; change of standards which may be considered as a reflection of the change of the state of the art*
- b) their impact for the certification process; end of certificate in particular annex III and II.4; what kind of procedure should be met.*

Meeting of NBR Group, Dublin, February 1 & 2 1999:

A draft document NB-MED Recommendation 2.5.1/Rec6 „Renewal of EC Design-Examination and Type-Examination Certificates“ – made by David Barrow/EUCOMED and Mr. Roelofs-Heyrmans/IAPM - was delivered to NBRG for further discussion on its meeting on 01./02.02.99.

Some changes were made for clarification. It was also decided to send the revised document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in March 1999.

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Rev 2: Notified Body Meeting, Brussels, March 2. & 3. 1999:

Dr. Holland presented the results of the meeting of the NBRG on 02./03.02.99 (NBM/26/99 and the rationale & history sheet).

Discussion: J. P. mentioned that - in his first view – the document needs more clarification on the differences between "renewal of a certificate" and "new certificate". "Renewal of EC Design-Examination and Type-Examination Certificates" is a problem that the Commission is facing in all sectors not only medical devices; it is almost automatic in the sense that it is a procedural aspect. The basic element in renewal is that the product as it is today - if it would be presented today - can be approved (without full new procedure). A product that needs modifications to be approved today at the actual state of the art situation needs also a "new approval" what is not a "renewal"; made changes or made modifications are the key aspects. Concerning the wording "experience gained in the post-production phase" J. P. explained if the post-production phase just says the product is perfect the process of "renewal" is indicated. In case of founded differences or modifications a new product has to be considered and a new certificate must be given, but the Notified Body has to consider all the elements that are appropriate and still valid today that have been certified five years ago. Often this is more a formal aspect than a technical discussion. R. V. added that a product - "new" or "old" – must also be considered against its external aspects may have changed in the meanwhile e. g. new knowledge about hazards than five years ago. So not only the possible change of the product should be considered but also a possible change of the environment. It was proposed to check the document against a clear distinguishable use of "renewal of a certificate" and "new certificate". The NB-MED agreed that this rework of wording will be made within the **NBRG**. **Mr. R.-H.** mentioned that he will present a revised draft document (as stage 1 document) at the NBRG meeting on 10./11.05.99.

Meeting of NBR Group, Brussels, March 4, 1999:

The comments made by the plenary were very detailed discussed. The following change was made under chapter 4.2, note (g):

"... continued compliance with the Directive Essential Requirements, taking ..."

It was agreed that with this change and the detailed rationale & history all made comments are covered by this Recommendation.

Revision no: 2

stage 2.

Notified Body Meeting, Brussels, June 8. & 9. 1999:

Dr. Holland presented the results of the meeting of the NBRG on 04.03.99 (NBM/76/99 and the rationale & history sheet) based on some comments made by the Commission on occasion of the last plenary meeting on 02./03.03.99.

The NB-MED adopted the revised draft Recommendation document with this presented change.

Confirmed at stage 3

revision no: 2 (not changed)

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Rev. 3: Notified Body Meeting, Brussels, November, 2 & 3, 1999:

The NBRG was asked to rework the NB-MED Recommendations in light of the IVD-directive. The work results of a small task force (task: reworking the Recommendations in light of IVDD) were presented to the Technical Secretariat for dissemination to NBRG (doc. NBRG/207/00).

Revision no: 3

Rev 4: Meeting of NBR Group, Berlin, September 4 & 5, 2000:

The work results of that small task force were presented to that NBRG-meeting. The tabled revised working document (NBRG/207/00) was discussed and some criticism was made (e.g. some written comments by Mr. Bellwinkel were tabled). After the discussion it was agreed that all comments were considered and that some text of the older version should be remain because it was the intention only to make changes in light of IVDD-relevance.

NBRG agreed that the document, as discussed and - during the meeting - revised, should be presented for adoption at the November NB-MED Plenary meeting.

Revision no: 4

stage 2

Notified Body Meeting, Brussels, November 7 & 8, 2000:

The document (NBM/81/00) was approved by the NB-MED plenary.

Confirmed at stage 3.

Revision no: 4



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