

	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/2.5.2/Rec1
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Title:	Subcontracting - QS related
Chapter:	2.5.2 Conformity assessment procedures; Quality assurance

Text:	The manufacturer's responsibility for the quality of the subcontractor's performance of quality of their products.
Key words:	subcontractors, audit, supplier

According to MDD Annex II, item 3.3, Annex V, 3.3 and Annex VI, 3.3 or IVDD Annex IV, item 3.3 and Annex VII, item 3.3 an inspection on the premises of the manufacturer's subcontractor will take place in duly substantiated cases.

When contemplating the necessity of such an inspection, the inspection team shall take into account the manufacturer's obligation on the evaluation of subcontractors as laid down in article 4.6.2 of EN ISO 9001.

The two main issues a Notified Body should address when reviewing subcontractors are:

- a) Whether the subcontractor has a substantial involvement with the design and/or production of the device.
- b) Whether the subcontractor is undertaking the supply of a part, material or service, which may affect the compliance of the device with the essential requirements.

If the answer to both a) and b) above is NO, no further action is required.

If the answer to a) or b) above is YES, then the Notified Body must evaluate whether there is sufficient evidence provided of the competence of the subcontractor to undertake supply of the part, material or service in relation to the medical device(s) in question. The evaluation will consider various matters including the control exercised

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

Reference to Directives:	Article/ Annex:	Reference to standards:
AIMD	Annex: 2	
MDD	Annex: II-3.3, V-3.3, VI-3.3	EN 46001/2
IVDD	Annex: IV-3.3, VII-3.3	

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by the manufacturer over the subcontractor and the certification held by the subcontractor.

The circumstances where the Notified Body should be expected not to consider an audit of the subcontractor are where it can be demonstrated that another Notified Body competent in relation to the evaluation of the part, material or service has undertaken an assessment of the subcontractor in relation to the part, material or service and has attested to the competence of the subcontractor in relation to the part, material or service. In all other circumstances, the Notified Body must be allowed to review the relevance or criticality of the subcontractor to the medical device and, if not satisfied by the evidence available from the manufacturer, undertake an audit/assessment of the subcontractor or require the manufacturer to undertake a re-evaluation of the subcontractor.

Note: For the purpose of this recommendation the term “subcontractor” is used to designate both “subcontractor” and “supplier” as used in the directives.

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	<u>Rationale and history sheet</u> to NB-MED/2.5.2/Rec1
Title:	Subcontracting - QS related	

Rationale

This document is developed to establish the principles to be taken into account when assessing manufacturers control of subcontractors.

History

Rev 1: NB Draft Recommendation 2.5.2/R1 was prepared on 03.08.95

Meeting of NBR Group, Essen, April 03. & 04. 1997:

The draft recommendation was considered together with a document tabled at the meeting.

It was decided to replace the draft recommendation with a modified version of the document tabled at the meeting.

NBRG agreed 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 June 1997.

New revision no: 1

Confirmed to be at Stage: 2

Rev 2: Notified Body Meeting, Brussels, June. 24 & 25. 1997:

It was decided to add a footnote concerning the use of „subcontractor“ and „supplier“ and to do some minor additions.

Confirmed to be at Stage: 3

Meeting of NBR Group, Brussels, June 26. & 27. 1997:

Respectively the results of the NB-MED plenary meeting the recommendation was revised by NBRG.

New revision no: 2

Confirmed to be at Stage: 3

Meeting of NBR Group, Essen, September 29 & 30 1997:

It was decided to fit the document in the new *recommendations nomenclature system* (chapter **2.5.2 Conformity assessment procedures; Quality assurance**). Therefore the recommendation gets the new number **NB-MED/2.5.2/R1**. The old number will be retained for a transitional period.

Rev. 3: Medical Devices Expert Group Meeting, Brussels, February 9/10, 1998:

The stage 3 document was presented to the Medical Devices Experts Group and fully accepted.

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Meeting of NBR Group, Brussels, April 20 & 21, 1998:

One minor (editorial) change was made by the NBRG (not only in „according to MDD Annex II, item 3.3, but also to Annex V, 3.3 and Annex VI, 3.3 an inspection on the premises of the manufacturer's subcontractor will take place in duly substantiated cases.“).

On occasion of the next NB-MED meeting on June the new document will be presented.

Confirmed at stage 4

New revision no: 3

Notified Body Meeting, Brussels, June 9 & 10, 1998:

NB-MED agreed with above proposed changes and this document will stay a stage 4 document because it was fully accepted at the Medical Devices Experts Group meeting on February '98.

Confirmed at stage 4

Rev. 4: Notified Body Meeting, Brussels, November, 2 & 3, 1999:

The NBRG was asked to rework the NB-MED Recommendations in light of the IVD-directive.

Meeting of NBR Group, Cologne, February 3, 2000:

The work results of a small task force (task: reworking the Recommendations) were presented to that NBRG-meeting.

The tabled revised Recommendation was discussed and NBRG agreed that the document, as discussed and revised, should be presented for adoption at the February/March NB-MED Plenary meeting. Only some editorial changes were made.

Revision no: 4

stage 2

Notified Body Meeting, Brussels, February 29 & March 1, 2000:

The document (NBM/37/00) was approved by the NB-MED plenary.

Confirmed at stage 3.

Revision no: 4



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