EUROPEAN COMMISSION
DG ENTERPRISE
Directorate G
Unit 4 - Pressure Equipment, Medical Devices, Metrology

MEDICAL DEVICES : Guidance document

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GUIDELINES RELATING TO THE APPLICATION OF :
THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES
THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

SUBCONTRACTING – QUALITY SYSTEMS RELATED

According to MDD Annex II, item 3.3, 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.

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 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.

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