applicable for ☒ AIMDD, ☒ MDD, and ☒ IVDD

2010-1

Guidance for Notified Bodies auditing suppliers to medical device manufacturers

1 Introduction

This document gives guidance to Notified Bodies on auditing of a manufacturer's purchasing controls, including when and to what extent audits of suppliers are necessary. It also serves as guidance to Designating Authorities assessing such Notified Body activities.

The manufacturer that is ultimately responsible for the device also has full responsibility for each element of the quality management system (QMS). The manufacturer cannot relinquish (contractually or otherwise) the responsibility of any or all functions within the quality management system relating to a particular device. This includes elements such as customer complaints handling and vigilance.

In effect, this means that the responsibility for complying with the QMS requirements cannot be delegated to any supplier of a product, and/or a service.

2 Definitions

2.1 Supplier

Organisation or person that provides a product, a service or information, and which is outside of the QMS of the manufacturer [1].

Examples of supplier: Producer, distributor, retailer or vendor of a product, or provider of a service or information

For the purpose of this document, the 'product' supplied may be a 'process', e.g. a supplier may provide a sterilisation process.

Note 1: For the purpose of this document, Note 1 of EN ISO 9000 3.3.6 does not apply

Note 2: The term supplier may refer to a 'contractor' or 'subcontractor'. For the purposes of the document the terms are regarded as synonymous.

2.2 Critical supplier

A critical supplier is a supplier delivering materials, components, or services that may influence the safety and performance of the device [2].

Note: In the context of the audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause a significant degradation in performance. This can include suppliers of services, which are needed for compliance with QMS or regulatory requirements, e.g. internal audit contractors or Authorised Representatives.

3 Legislative Basis for the requirements for suppliers – Quality assurance systems

Approvals of quality systems according to Annex II, V or VI of Directive 93/42/EEC, Annex 2 or 5 of Directive 90/385/EEC or Annex IV or VII of Directive 98/79/EC may only be issued if the Notified Body has verified and documented, i.e. evidence has been provided, that the quality system is able to ensure 'that the products conform to the provision of these Directives, which apply to them at every stage, from design to final inspection'.

The Notified Body shall include in its assessment all of the steps in the design and/or manufacture during product realisation of a medical device that are conducted by suppliers. This includes the provision of raw materials, components and services.

Annex II Section 3.2 (b) of Directive 93/42/EEC states 'where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party' must be included in the manufacturer's application for assessment to the Notified Body. Suppliers are examples of a 'third party'.

The Directives, e.g. Directive 93/42/EEC Annex II Section 3.3, state 'The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes'. The Notified Body therefore has to audit the activities and/or premises of suppliers linked to the specific medical devices (for further guidance please refer to section 5 of this document).

However, in the conformity assessment procedure the Notified Body should consider the results of tests, assessments and audits, which have already been conducted for the relevant products.

4 Audit of the purchasing system of the manufacturer

The manufacturer should establish and maintain documented procedures and records to ensure that products or services purchased from their suppliers meet the relevant regulatory requirements.

Purchasing controls will be first assessed by the Notified Body at the premises of the manufacturer. Hereby, the Notified Body normally should use section 7.4 of EN ISO 13485 [3] and applicable guidance from the GHTF [4, 6] (extract from document N30 [4] is reproduced below).

> "N30 7.6 Purchasing Controls Subsystem
>
> The Purchasing Controls subsystem should be considered a main subsystem for those manufacturers who outsource essential activities such as design and development and/or production to one or more suppliers.
>
> **Objective**: The purpose of auditing the purchasing control subsystem is to verify that the manufacturer's processes ensure that products, components, materials and services provided by suppliers, (including contractors and consultants) are in conformity. This is particularly important when the finished product or service cannot be verified by inspection (e.g. sterilisation services).
>
> **Major Steps**: The following major steps serve as a guide in the audit of the Purchasing controls Subsystem. [The examples listed below of objective evidence were drawn from the flow chart in GHTF SG3 N17 Guidance on the control of products and services obtained from suppliers [5] (see Appendix 1)]:

1. Verify that procedures for conducting supplier evaluations have been established. (ISO 13485:2003: 7.4.1)
    - Documented process/product controls for manufacturer and supplier
    - Supplier Management Procedures
2. Verify that the manufacturer evaluates and maintains effective controls over suppliers, so that specified requirements are met. (ISO 13485:2003: 7.4.1)
    - Supplier selection criteria & decision rationale
    - Competency of the selector of the supplier
    - Supplier agreements (see Appendix 2 for details)
    - Change Management Methodology and Records
3. Verify that the manufacturer assures the adequacy of specifications for products and services that suppliers are to provide, and defines risk management responsibilities and any necessary risk control measures. (ISO 13485:2003: 7.4.2)
    - Specifications, requirements, procedures & work instructions
    - Documented list of the risks identified for the products and services supplied, and linkage to design and planning
    - Quality Requirements documented
    - Capability assessment of the supplier
    - Contracts, Purchase Orders
4. Verify that records of supplier evaluations are maintained. (ISO 13485:2003: 7.4.1)
    - Audits Reports (1st, 2nd, & 3rd Party)
    - Correspondence (Supplier File; e.g. Change control, audits, CAPAs)
    - Minutes of Meetings with Supplier
    - CAPA relating to products and services supplied
    - Verification of incoming products
5. Determine that the verification of purchased products and services is adequate. (ISO 13485:2003: 7.4.3)
    - Acceptance procedures for incoming products
    - Specifications & Procedures
    - Documented process/product controls for manufacturer and supplier

Evaluate the Purchasing Controls subsystem for adequacy based on findings."

5 Criteria for audit of a supplier's premises

The Notified Body auditors should determine and document the need to audit at a supplier's premises depending on:

- the outcome of the audit of the manufacturer's purchasing process (as outlined in Appendix 1) and other processes, described above.

  The Notified Body should have predefined decision criteria, which they use to decide, based on audit outcome if an audit of a particular supplier is required.

  Information derived from the audit may include:

  - information of the product realisation processes, including data from incoming acceptance activities and production controls
  - whether the manufacturer performs an inspection on the product or service supplied
  - whether faults in the product supplied can be detected at some later stage in production

- whether the history/data relating to suppliers is sufficient
- whether there is third party certification of suppliers and whether this certification alone is adequate

– the criticality of the item or process being purchased, i.e. the effect the purchased product/service might have on the subsequent product realisation or the final product (GHTF SG3 N17/2008 [5], section 3.3.1).

  Critical items or processes may include:

  - Finished products
  - Primary packaging
  - Sterilisation
  - Contract laboratories (e.g. biocompatibility)
  - Services (Design, Distribution, Regulatory Compliance etc.)
  - Labeling
  - Other similar cases where the conformity of the finished medical device is significantly influenced by the activity of the supplier and the manufacturer cannot demonstrate sufficient control over the supplier via purchasing controls and incoming acceptance activities

  Note: It is the responsibility of the manufacturer to determine which are critical items or processes and how their purchase is controlled. This depends on the manufacturer's risk management activity. However, the auditing organisation may decide to visit suppliers deemed by the manufacturer to be non-critical.

– In response to post market information

  - Field Safety Corrective actions impacting on the supplier's processes or products
  - Complaints relating to the supplier's processes or products
  - Post-market information, e.g. clinical investigations, public information etc., relating to the supplier's processes or products

In principle, premises of critical suppliers should be audited. In cases where the manufacturer is not able to give satisfactory evidence to the Notified Body that purchase of critical products or services meet the specified requirements (e.g. relying solely on the supplier's certification to EN ISO 9001 or EN ISO 13485), the Notified Body needs to audit the control of processes on the premises of the manufacturer's suppliers (e.g. sterilisation suppliers). The Notified Body has to audit each of these suppliers unless there is enough evidence provided by the manufacturer demonstrating that sufficient controls have been established and implemented.

6 Audit at supplier premises

The objective of an audit at a supplier's premises is to:

– verify manufacturer's supplier control is effective to ensure the purchased product or service conforms to the specified requirements

– assess the supplier's ability to provide a product or service that consistently meets specified manufacturer requirements including quality requirements

An audit at a supplier should be carried out as part of the audit of the manufacturer's purchasing activity. It should not take the place of a Second Party[1] audit carried out on behalf of the manufacturer.

[1] According to EN ISO 17000 Conformity assessment – Vocabulary and general principles, clause 2.3

An audit at a supplier assesses the implementation of the requirements placed upon the supplier by the manufacturer as documented in the agreement between the two parties. The adequacy of this agreement, including its scope, should be assessed as part of the audit of the manufacturer.

Although EN ISO 13485 or an annex of the relevant directive may be used to assist in the assessment of the suitability and implementation of the agreement, the audit of a supplier does not necessarily assess the supplier against the whole of EN ISO 13485 or an annex of the relevant directive.

Any nonconformity identified in the supplier audit will normally be documented as a non-conformity against the manufacturer.

7 Reporting

Audits at supplier's premises need to be adequately documented. This can be done either in the audit report of the manufacturer's quality system or in separate report(s). If a separate report is written, the Notified Body should make clear the reason for the audit of the particular supplier and should address the audit report to the manufacturer and not to the supplier.

It is the manufacturer's responsibility to discuss the reported findings of the NB audit with the supplier and to follow up on any nonconformity raised. However, if agreed by all parties, the results of the audit at the supplier may also be made available to the supplier for information.

The Notified Body's rationale for auditing a particular supplier should be documented either in the audit report or in a separate document generated as part of the preparation for the audit.

References: Directive 93/42/EEC*, Directive 90/385/EEC*, Directive 98/79/EC*, *as amended

Sources:

[1] EN ISO 9000 : 2005 Quality management systems – Fundamentals and vocabulary, Clause 3.3.6

[2] GHTF SG4/N33R16 : 2007: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports

[3] EN ISO 13485 : 2003 + AC : 2009 Medical devices – Quality management systems – Requirements for regulatory purposes

[4] GHTF SG4/N30R20 : 2006 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy

[5] GHTF SG3/N17/2008 Quality management system – Medical devices – Guidance on the control of products and services obtained from suppliers

[6] GHTF SG4(WD)N84R12 : 2009 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 5: Audits of manufacturer control of suppliers

Keywords: auditing, critical supplier, Notified Body, supplier, subcontractor

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Appendix 1

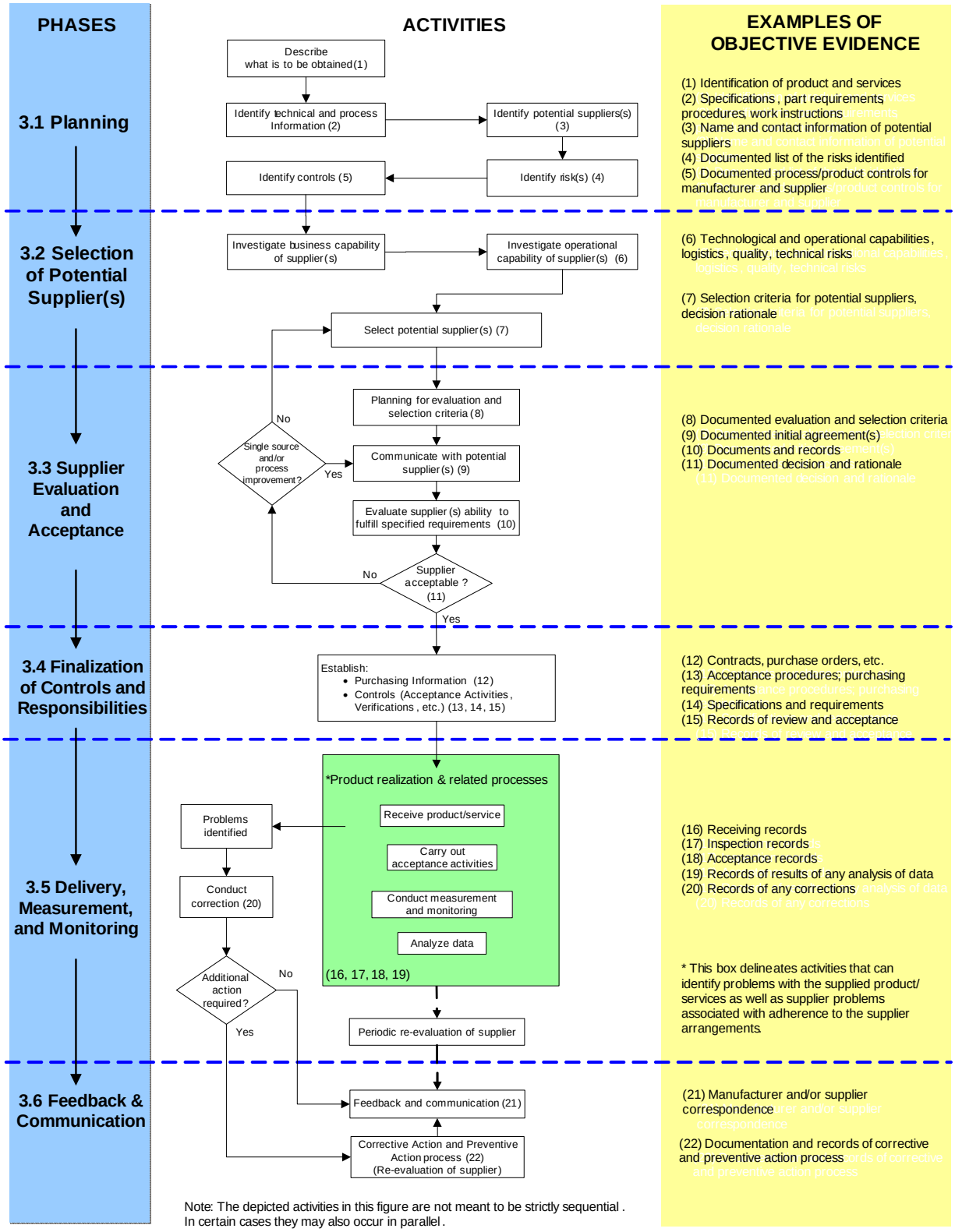

Figure 1 (excerpt from GHTF SG3/N17/2008 Guidance on the control of products and services obtained from suppliers [5])

Appendix 2

Agreements with suppliers

The medical device manufacturer must provide evidence of detailed agreements with their suppliers to the Notified Body. In these agreements, precise provisions must be made concerning conformity with all the requirements of the relevant Medical Device Directive and of any applicable national law, which the manufacturer cannot demonstrate themselves.

The items below will be checked and assessed by the Notified Body:

- Scope of agreement(s) (devices/device groups concerned, activities)
- Procedures by which manufacturer maintains effective controls over all suppliers and subcontractors
- Period of agreement(s) validity and in the case where the validity has expired, relevant provisions to ensure the required post market activities are completed
- Detailed specifications for the devices/activities concerned
- Details of who is responsible for each piece of documentation (e.g. quality/production records, including language and retention periods, also in case of termination of the agreement(s))
- Traceability of raw material/components
- Details of the process for, the documentation of, and the parties responsible for the design of the device should be reviewed and it should be ensured that the overall responsibility for the design of the device rests with the manufacturer
- Procedure by which changes to the device or supplied components or activities and/or the manufacturing process are initiated, released, implemented, documented and communicated between all the relevant parties e.g. manufacturer and subcontractor
- The right to access to the supplier technical documentation and records by the manufacturer, the Notified Body assessing the product and the relevant Competent Authority if required
- Procedures governing collaboration between supplier and manufacturer in the case of incidents/mandatory notifications/recalls
- Procedures and criteria for managing, communicating and following up on customer complaints, post-market issues and corrective and preventive actions between the relevant parties e.g. supplier/manufacturer, and procedures for assessment of the impact that any such issues, from any stage in the product realisation, have on the product
- Procedures governing access of manufacturer, Notified Body and Competent Authorities to the premises of supplier(s) if required
- Obligation to provide information to the manufacturer and Notified Body where there are changes to the status of the supplier certificates that affect the status of the device
- Where relevant, a responsibility matrix
- Full data relating to medicinal substances, human blood and plasma derivatives, and tissues of animal origin held by suppliers must be available to the manufacturer and the Notified Body