applicable for ☒ AIMDD, ☒ MDD, and ☒ IVDD

2010-2

Guidance on Audit Report Content

1 Introduction

This NBOG guidance document is the European implementation of the GHTF SG4/N33R16 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports [1] and highlights best practice that should be applied by Notified Bodies under the Medical Devices Directives. The document is limited to the "Main points of a Regulatory Audit Report", Chapter 8 of the GHTF document. For further background information on audit reports, see source documents [1-3].

Notified Bodies should implement reporting procedures, which are in compliance with the requirements defined in [2]. The audit report should comprise the documented evidence of a regulatory audit. It should contain sufficient information to identify the scope of the audit conducted, the type of audit, the audit objectives, the audit criteria, what was specifically covered during the audit, the audit findings, the evaluation of the manufacturer's compliance status, the effectiveness of the implementation of the quality management system (in particular its ability to achieve the desired quality of design and production of manufactured medical devices, including control of products which fail to conform), and the conclusions reached by the auditor. It should be suitable to allow for exchange of audit reports between regulators and/or auditing organisations.

As a minimum requirement, the items contained in chapter 3 should be included in the audit report. Preferably, the report should be structured in sections as defined below.

2 Scope

This document is intended to provide best practice guidance to Notified Bodies and regulatory authorities on the compilation of a report following audit by a Notified Body.

3 Main points of a Regulatory Audit Report

The report should be typed and may be in a format that can be stored and transferred electronically. The language of the report should be agreed upon between the manufacturer and the Notified Body[1] prior to the start of the audit. In many cases, the ultimate use of the report will dictate the language of the report.

3.1 Data concerning manufacturer

The audit report should document the following information relating to the manufacturer:

- Manufacturer's name, address
- Management representative responsible for the quality management system and key contact person(s) (if different from management representative) for
  - Arranging the audit

[1] See e.g. 93/42/EEC Art. 11 (12): "The records and correspondence relating to the procedures referred to in paragraphs 1 to 6 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body."

- Receiving the final audit report
- Receiving regulatory correspondence

– Description of the manufacturer and, if different, the auditee

  Size: approximate number of employees (total) and covered by the audit scope

  Structure: corporation details, organisation chart

  Operations: kind of operations (e.g. design and development, production, … of [listing of device categories], device name(s) and, where possible, estimated number or percent of device(s) exported, listed by country), hours of operations, shifts, and any seasonal variations

  Facilities: If a facility other than the main site of the manufacturer exists and/or is being audited, then the relationship of that site to the main site should be given. In case that the main site has additional facilities which contribute to the overall certification scope, the responsibilities and activities of these facilities including their audit status needs to be addressed and justification provided if these facilities are not subject to an audit

  Critical suppliers[2]: name, location and activity of critical suppliers, if applicable, including justification if critical suppliers are not subjected to audit

  Management system: exclusions and non-application of requirements in the quality management system

  Changes: if any since last audit(s)

  Others: Language(s) of operation

– Status of any relevant certification
– Information from previous audits including date, type of audit, name of auditing organization, name of auditor(s), audit criteria, subsystems covered and result, if applicable
– Additional information regarding compliance history of the manufacturer, if relevant

3.2 Data concerning audit

– Type of audit (e.g. initial, surveillance, special audit)
– Audit scope, objectives, and criteria against which the audit was conducted (EC directive(s) and standard(s)) including clear indications if sections of the audit report only apply to specific parts of audit scope, objectives, and criteria
– Product scope/product families and classifications covered by the audit (using an applicable nomenclature system, e.g. Global Medical Device Nomenclature (GMDN), where feasible
– On-site audit dates and time
– Total audit time (auditor days)
– Identification of the Notified Body and audit team members (including technical experts) and their roles and responsibilities
– Language(s) of the audit
– Identification of interpreter(s), if applicable
– Observer(s) and their organization, if applicable
– List of documentation reviewed prior to the audit (e.g. previous audit reports and technical assessments), including document identification and revision status, document review results

[2] See NBOG BPG 2010-1 Guidance for Notified Bodies auditing suppliers to medical device manufacturers [6] for further explanation

3.3 Audit trail

This section should cover a description of activities covered during the audit. It should contain a summary of the key elements for each of the subsystems[3] audited:

- Management (including the methods of monitoring the efficient operation of the quality system)
- Design and Development (describe the project(s) reviewed)
- Product Documentation (including justification for sampling of Technical Documentations; for the results of the review of Technical Documentation(s) separate reports may be used; see [5] for further guidance)
- Production and Process Controls (describe product and process/es reviewed)
- Corrective and Preventive Actions (report data sources available for review, and which ones were reviewed)
- Purchasing Controls
- Documentation and Records
- Customer Related Processes

The subsystem summary(ies) should include:

- Areas (e.g. organizational or functional units) of the site visited (e.g. incoming inspection, manufacturing areas, quality control laboratories) and, where relevant, persons interviewed
- Activities and processes evaluated, including, if a variety of activities and processes needs to be covered in the audit, the reason for their selection
- Documents reviewed, including document number, revision etc., if not recorded elsewhere, e.g. in checklist
- Specific references to records reviewed, e.g. complaints files, batch records
- Specific references to products reviewed, e.g. work in progress, components
- Statement concerning compliance with the regulation(s) and, when applicable, harmonized standard(s) being audited, e.g.
  - conforming
  - comments for improvement, if applicable
  - nonconformity (including major nonconformities)

  If a comment for improvement is recorded in the audit report, which suggests non-compliance but does not lead to a nonconformity, it should be clear why a nonconformity was not raised.

If a checklist without any further information is used to demonstrate coverage in a particular area then this should be described in the written narrative report.

The audit report should further contain:

- Description of field safety corrective actions and recalls or product removals or replacements (not deemed safety related by the manufacturer) since the last audit, if applicable
- Description of major changes to products or significant changes to processes, organisational structure, ownership, key personnel and quality management system since the last audit

[3] These are the subsystems in GHTF/SG4/N30, Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy [4]

- Description of any follow-up on specific complaints or adverse event reports performed by the manufacturer
- Identification of any requested information that was refused and any obstacles encountered that could compromise the reliability of the audit findings and conclusions
- Identification of nonconformities, including:

  i) details of each nonconformity

  ii) the audit criterion or the specific regulatory requirement to which it applies

  iii) the relative significance with respect to regulatory requirements

  iv) the date for submission of any corrective action plans

  v) details or evidence where the nonconformity was found

  vi) details of any corrective action(s) taken during the audit

  Note: When a nonconformity is found, a record of this should be completed even if the manufacturer corrects the nonconformity during the audit.
- Verification of effective implementation of corrective action(s) from previous audit
- Description of any items or comments for improvement not given in list of nonconformities, if applicable
- The proposed time frame for responding to the nonconformities, if applicable
- Follow-up items for the next audits
- Details of information provided during the closing meeting, including manufacturer's responses
- Unresolved diverging opinions between audit team and manufacturer
- Any areas not audited although within the audit scope

3.4 Conclusion

- Summary and conclusions regarding the conformity of the manufacturer's quality management system with each set of audit criteria
- Summary and conclusions regarding the effectiveness of the quality management system in meeting quality objectives
- Auditor's recommendation to the Notified Body (as applicable):

  a) Follow up action(s) including proposed time schedule(s)

  b) For the initial or continued certification
- Confirmation that audit objectives have been met or an explanation as to why not

3.5 Signature and dating of report

- Date of the audit report
- Audit team members' names, titles and organisations (signature of at least the lead auditor)

3.6 Attachments (used to support the content of the report)

- Audit plan(s)
- Attendance sheet for opening and closing meetings (if applicable)
- Evidence available to support the nonconformities (if applicable)
- Checklists used by the auditors (if applicable)
- Nonconformity reports if issued separately

References	Directive 93/42/EEC*, Directive 90/385/EEC*, Directive 98/79/EC*, *as amended
Sources	[1] GHTF SG4/N33R16 : 2007 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports
	[2] GHTF SG4/N28R4 : 2008 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements
	[3] EN ISO 19011 : 2002 Guidelines for quality and/or environmental management systems auditing
	[4] GHTF SG4/N30R20 : 2006 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy
	[5] NBOG BPG 2009-4 Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis
	[6] NBOG BPG 2010-1 Guidance for Notified Bodies auditing suppliers
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