Proposed Report Format Template (Based directly on the current draft of GD211)

Introduction

During discussions with the US Food and Drug Administration (FDA) regarding potential uses by FDA for Notified Body reports on ISO 13485 audits, audit reports FDA expressed a desire for greater uniformity in the reports submitted to them. AdvaMed offered to develop a format for the purpose. To accomplish that, AdvaMed assembled a Working Team of member company representatives and Notified Body representatives, who worked with FDA advisors to develop the following template.

The template is based almost entirely on a draft of Health Canada guidance with similar intent. The particular document used is a draft of Health Canada GD 211 (Specifically draft GD211 v. 4c) that was made available to the Working Group in mid-2009.

As the FDA is at this time the primary customer of this template, the document has been designed primarily with their concerns in mind. However, if there is interest, the Working Group intends the document to be adaptable to other regulatory regimes.

The Working Group assumes responsibility for any errors made in the adoption of the GD211 draft.

Template

The report shall be typed and shall be in a format that can be stored and transferred electronically. The format of the report should be electronically text-searchable and be in a widely available format.

The reports shall contain all the elements in section 1.0 in the order specified. The contents of the report should be organized along the broad categories identified below, namely information about the manufacturer (auditee), information about the audit, audit findings, and conclusions.

Finally, this document does not preclude the inclusion of other information or parts in the audit report.

Report Language

When submitted to the FDA, the report shall be in English. Otherwise, the report shall use the operating language of the registrar and shall be understandable by the auditee.
1.0 Report Content

1.1 Information about the Auditee

The audit report shall contain information which allows an unambiguous identification of the auditee being audited in terms of the name and physical locations of the auditee, the quality system being audited, and the medical devices that are part of the scope of registration. The following items shall be included in the report:

a) Auditee’s Name and Address

The name and address of the auditee subject to the conformity assessment procedure and that will appear on the registration certificate shall be included in the report.

b) Company Identification Number

Regulatory body establishment registration number (e.g., FDA, Health Canada).

c) Corporate Identity of the Auditee

When an auditee has multiple names or identities, these shall be clarified. This clarification also extends to any relationships with sister or parent companies, and daughter companies including subsidiaries, acquisitions, and business units. When writing this section, auditors should be mindful to frame the explanation in the context of the quality management system under audit and its associated scope of activities.

This item can be omitted from surveillance audit reports.

d) Description of the Auditee

A brief description of the auditee shall be included in the report. This description shall include the approximate number of employees and the number of shifts. The description shall also include an overview of the activities carried out by the auditee and the scope of the quality management system. Finally, where the conformity assessment procedure involves more than one physical site, all the sites shall be identified as in item “a” above and a description of the relationships between the sites and their relative role within the quality management system, including any shared functions, shall be included.

The description of the auditee can be limited to those parts that fall within the scope of the audit for surveillance audit reports.
e) **Scope of Certification**

The report shall include the scope of certification of the auditee under audit. This includes activities and a list of the generic medical device groups or families that are included in the scope of certification. Where the scope of certification is prohibitively long, it can be appended to the report and cited.

f) **Identification of Critical Suppliers**

The report shall include an identification of critical suppliers (name and address, product or service provided) that provide products or services used in the audited processes. Where the list is prohibitively long, the report may refer to an appendix.

This item can be integrated in the audit findings section of the report.

g) **Contact Person for the Quality Management System**

The name and contact information of the contact person for the quality management system shall be included in the report.

h) **Status of any Relevant QMS Certification**

If not apparent elsewhere in the audit report, the status of any relevant certification or registration of the quality management system of the auditee (including the one subject of the report) shall be listed.

i) **Exclusions and Non-Applications of Requirements in Quality Management System**

Where the auditee under audit has claimed an exclusion or non-applications of requirements found in ISO 13485:2003 in its quality management system, the report shall identify these. The report does not need to include the justification of these exclusion and non-applications.

1.2 **Executive Summary**

The Executive Summary shall include information about the locations and products covered by the audit. It shall also include a listing of the regulations and standards to which the facility was audited and any significant findings. Finally, it shall include a statement describing the state of compliance of the audited facility.

The parts of the Executive Summary may be copied from other sections of the report, as the purpose of the Executive Summary is simply to collect in one location the highlights of the audit report.
1.3 Information about the Audit

The audit report shall describe in adequate detail the nature of the audit performed. It shall also identify the audit team. The following items shall be included in the report:

a) Audit Type

The report shall identify the type of audit performed (e.g., certification, surveillance, re-certification, etc.)

b) Audit Criteria

The audit criteria shall be listed in the report, e.g., ISO 13485:2003, applicable Medical Devices Regulations requirements, and the auditee's quality management system documentation.

c) Audit Objectives

The audit objectives shall be listed in the report. This includes as a minimum, the following:

i) the assessment of the conformity of the auditee's QMS to ISO 13485:2003, and

ii) the assessment of the capability of the quality management system to ensure compliance with any additional applicable requirements.

d) Audit Scope

The report shall include the audit scope. Particular attention should be placed on the physical locations and organizational units of the audit and, in the case of a surveillance audit, on the activities and processes that form the scope of the audit.

e) Audit Dates

The dates of the on-site audit shall be included in the audit report. This shall also include the number of auditor-days on-site.

f) Identification of the Audit Team

The report shall identify all members of the audit team and describe their respective roles (e.g., team leader, technical expert, etc.) Any observers present should also be listed. Finally, if interpreters are used, these shall be identified. The affiliation of interpreters shall also be indicated.
g) Audit Language

The language or languages used during the audit shall be indicated in the report.

h) Document Review Results

When a review of the auditee's quality management system documentation is performed prior to the audit, this shall be mentioned in the audit report and reference should be made to the report and to the results of such a review.

1.4 Audit Findings

The audit report shall include sufficient audit findings, both positive and negative, to support the audit conclusions made in the report. Audit findings shall always be framed in context through objective evidence and evaluated against the appropriate audit criteria. Because the audit report is a record of what was reviewed and the audit team's conclusions, omission of an aspect of the audit or of the auditee's quality management system in the report is taken as an area or function not audited.

a) Audit Summaries

Brief written summaries of the audit of each quality management system process or activity audited shall be included in the report. Examples of quality management system processes or activities include:

- management processes (management review, resource management, internal audits, organizational structure, training etc.)
- design and development
- production and process controls
- corrective and preventive action systems (relevant field actions, complaints, and event reporting)
- purchasing controls
- control of documents and records
- customer related processes.

Note: the above list is not intended to be all inclusive and is only included for illustrative purposes.

The audit summaries should be brief but nonetheless include the following information:

i. A description of the quality management system process or activity audited;
ii. the area (physical or organizational) of the site visited;
iii. the name and position of key management or 'process owner' interviewed;
iv. key documents reviewed (procedures, work instructions, etc)
v. type and number of records reviewed, including a qualitative statement of the sample size where appropriate;
vi. identification of products or components reviewed; and,

vii. statements regarding the conformity of the activity or process under audit to the normative criteria.

**Note:** the inclusion of clause numbers in the concluding statements can help demonstrate appropriate coverage.

Additionally, the audit summaries shall include the following where they are encountered:

**b) Description of Major Changes**

When the activity of process under audit has been subject to a major change, this shall be described in the audit report. This includes major changes to products or processes, changes to the organizational structure or ownership, as well as changes to key personnel and facilities and to the quality management system as a whole. The description of these changes can be included in the audit summaries or be included under a separate heading.

**c) Obstacles/Refusals**

Identification of any information that was requested and refused by the auditee shall be included in the report. This also includes the refusal of access. Any other obstacles encountered shall be identified in the audit report where these have the potential to impact the validity of the audit conclusions.

Alternatively, these obstacles can be described in section 1.4 d).

**d) Follow-up on Past Nonconformities**

Where the implementation of correction and corrective actions stemming from past nonconformities is verified, this verification shall be included in the audit report, either as part of the audit summaries or under a separate heading. If nonconformities from past audits cannot be closed, this shall be indicated.

**e) Nonconformities**

Registrars are free to use separate nonconformity reports or forms; however the audit report shall include, for each nonconformity, as a minimum, a statement of nonconformity and the normative criterion against which the nonconformity is raised. These items should be put into context and included in the appropriate audit summaries. This does not preclude further reporting on nonconformities in the report or elsewhere.

Where the auditee undertakes cause analysis, correction or corrective action before the end of the audit, a mention of this may be made in the report, however it does not eliminate the need to report the nonconformity.

**f) Areas not Audited**
When areas within the scope of the audit (as defined in the audit plan) are not audited or not sufficiently covered, this shall be noted in the audit report.

1.5 Conclusions

The audit report shall provide clear conclusions about the conduct of the audit and its overall outcome and results. The conclusions provided in this section shall relate to the quality management system as a whole and shall cover the following:

a) Conformity with Audit Criteria

A brief summary and conclusion regarding the conformity of the quality management system as it is implemented with each set of normative audit criteria in 1.3 b) above shall be included in the report. The conclusions shall be unambiguous as to the conformity (or nonconformity) of the quality management system.

b) Effectiveness

The report shall include a brief summary and conclusion regarding the effectiveness of the quality management system in meeting quality objectives.

Alternatively, items a) and b) above can be combined.

c) Confirmation of Audit Objectives

The report shall confirm that all audit objectives in 1.3 c) have been met where any of the audit objectives have not been met, an explanation should be provided.

d) Reliability of Audit

The report shall outline any factors encountered that may decrease the reliability of the audit. This may include such factors as a shortfall in auditor time or the absence of a needed technical competence.

e) Recommendations

The audit team’s recommendations shall be included in the report. Recommendations shall be made with regard to:

i) any follow-up actions by the registrar, changes to the audit programmed, or changes to the number of auditor-days; and,

ii) the initial or continuing certification of the quality management system, together with any conditions or observations.

1.6 Identification and Dating
The final audit report shall include the name(s) of the author(s) of the report, including a form of authentication. The report shall also be dated on its final date of issue and include version control information where necessary.
<table>
<thead>
<tr>
<th>Type</th>
<th>Term</th>
<th>Recommendation</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obs Use Process</td>
<td>Adverse event:</td>
<td>An “Adverse Event” is either a malfunction or a deterioration in the characteristics or performance of a sold medical device [including accessory(s) and labeling] or use error, which either has caused or could have caused or contributed to death, or serious injury to health of patients or other persons.</td>
<td>SG4 N33 R16</td>
</tr>
<tr>
<td>Process</td>
<td>Audit</td>
<td>Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 19011:2002 and ISO 9000:2005).</td>
<td>GD210</td>
</tr>
<tr>
<td>Process</td>
<td>Audit Conclusion</td>
<td>Outcome of an audit, provided by the audit team after consideration of the audit objectives and all audit findings</td>
<td>ISO 19011</td>
</tr>
<tr>
<td>Process</td>
<td>Audit Criteria</td>
<td>Set of policies, procedures or requirements</td>
<td>ISO 19011</td>
</tr>
<tr>
<td>Process</td>
<td>Audit evidence</td>
<td>Records, statements of fact or other information, which are relevant to the audit criteria and verifiable</td>
<td>ISO 19011</td>
</tr>
<tr>
<td>Process</td>
<td>Audit findings</td>
<td>Results of the evaluation of the collected audit evidence against audit criteria. Note: Audit findings can indicate either conformity or nonconformity with audit criteria.</td>
<td>SG4 N33 R16</td>
</tr>
<tr>
<td>Process</td>
<td>Audit followup</td>
<td>Conclusions of the audit may indicate the need for corrective, preventive or improvement actions, as applicable. Such actions are usually decided and undertaken by the auditee within an agreed timeframe and are not considered to be part of the audit. The auditee should keep the audit client informed of the status of these actions.</td>
<td>ISO 19011</td>
</tr>
<tr>
<td>Process</td>
<td>Audit Objectives</td>
<td>The audit objectives define what is to be accomplished by the audit</td>
<td>ISO 19011</td>
</tr>
<tr>
<td>Process</td>
<td>Audit Scope</td>
<td>Extent and boundaries of an audit. The audit scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period covered.</td>
<td>GD210</td>
</tr>
<tr>
<td>Definition</td>
<td>Audit team</td>
<td>One or more auditors conducting an audit, supported if needed by technical experts</td>
<td>ISO 19011</td>
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<tr>
<td>Definition</td>
<td>Auditee</td>
<td>Organization being audited</td>
<td>ISO 19011</td>
</tr>
<tr>
<td>Type</td>
<td>Term</td>
<td>Recommendation</td>
<td>Source</td>
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<tr>
<td>Definition</td>
<td>Auditor</td>
<td>Person with the competence to conduct an audit</td>
<td>ISO 19011</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Compliance</td>
<td>The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement or a recognized standard.</td>
<td>GD210 &amp; GD211</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Conformity</td>
<td>Fulfillment of a requirement (ISO 9000:2005)</td>
<td>GD210 &amp; GD211</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Correction</td>
<td>Action to eliminate a detected nonconformity.</td>
<td>GD210 &amp; GD211</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Corrective Action</td>
<td>Action to eliminate the cause of a detected nonconformity or other undesirable situation</td>
<td>ISO 2000:2005</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Major nonconformity</td>
<td>This term will be used when an auditor/assessor finds evidence of a system failure (e.g. required elements of the quality system have not been implemented or although implemented, there is a lack of compliance to the requirement). Therefore, the following observations constitute a “major” nonconformity: 1) any unjustifiable exclusion from medical device report /medical device incident (MDR/MDI) requirements; 2) the failure of the Manufacturer to address one or more applicable clause or process of the QMS standards or regulatory requirements; 3) there is a failure to comply with any of the “shall” requirements of an assessment standard / regulatory requirement 4) non-compliance with regulatory requirements or if customer requirements are not being met. 5) There is a total absence or breakdown of control or maintenance with respect to a provision of an assessment standard / regulatory requirement. 6) a number of minor nonconformities against a clause or process of the QMS standards or regulatory requirements that indicates a trend or absence of control; 7) failure to implement effective corrective action and/or effective preventive action when an investigation of the feedback system indicates a pattern of product defects;</td>
<td>Edited includes elements of GD210, UL &amp; LRQA</td>
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<tr>
<td>Type</td>
<td>Term</td>
<td>Recommendation</td>
<td>Source</td>
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<tr>
<td>Conclusion</td>
<td>Minor nonconformity</td>
<td>This term will be used when an auditor/assessor finds a sporadic lapse (deviation) in compliance with quality system requirements. Auditors/assessors shall raise this grade where: 1) there is evidence that the quality system element is implemented, but application of the requirement is not consistent, such that if not corrected could be at risk of becoming a major nonconformity, i.e., if failure to implement long-term corrective action with respect to such lapses, or any further deterioration of control could reasonably be considered likely to result in the system becoming ineffective. 2) Observations that do not raise significant doubt as to the ability of a medical device or a manufacturing process to satisfy the Manufacturer’s specified requirements.</td>
<td>Edited: includes elements of GD210 &amp; LRQA</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Noncompliance</td>
<td>A state of nonconformity with a specific requirement of the Act or Regulations.</td>
<td>GD210</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Nonconformity</td>
<td>Non-fulfillment of a requirement</td>
<td>ISO 9000:2005</td>
</tr>
<tr>
<td>Process</td>
<td>Objective evidence</td>
<td>Data supporting the existence or verity of something</td>
<td>ISO 14971</td>
</tr>
<tr>
<td>Process</td>
<td>Observation</td>
<td>An isolated or non-systemic finding detected during an audit that requires action to bring the system or any clause into compliance.</td>
<td>UL, SG4 N33 R16</td>
</tr>
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<td>Type</td>
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<tr>
<td>Conclusion</td>
<td>Opportunity for Improvement</td>
<td>This term will be used by assessors to indicate ways in which the system or business improvement can be achieved by your organization. You can choose to act on these suggestions and there will be no automatic follow up by the assessor.</td>
<td>LRQA</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Preventive Action</td>
<td>Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.</td>
<td>ISO 9000:2005</td>
</tr>
<tr>
<td>Definition</td>
<td>Quality Management System (QMS)</td>
<td>The organization structure, responsibilities, procedures, processes, and resources for implementing quality management.</td>
<td>21 CFR Part 820 (Quality System)</td>
</tr>
<tr>
<td>Process</td>
<td>Regulatory audit:</td>
<td>The audit of a quality management system to demonstrate conformity with quality management system requirements for regulatory purposes.</td>
<td></td>
</tr>
<tr>
<td>Conclusion</td>
<td>Significant Change</td>
<td>Means a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following: (a) the manufacturing process, facility or equipment; (b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture; (c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and (d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry date.</td>
<td>GD210</td>
</tr>
</tbody>
</table>