

June 8, 2011

NOTICE

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Re: Guidance Document *GD211: Guidance on the Content of Quality Management System audit reports*

Health Canada is pleased to announce the release of the guidance document *GD211: Guidance on the Content of Quality Management System Audit Reports*. A draft version of this guidance document was first released for consultation in January, 2011. No changes have been made from the draft version.

The implementation date of this guidance document is January 1, 2012. Once implemented, all audit reports prepared as part of certification procedures in support of an application for, or the maintenance of, a medical device licence are expected to be prepared in accordance with the guidance specified herein.

The purpose of this document is to provide guidance to Health Canada recognized registrars on the expectations for the content of Quality Management System (QMS) audit reports prepared as part of certification procedures in support of an application for, or the maintenance of, a medical device licence.

This guidance document is based on the work of Study Group 4 of the Global Harmonization Task Force (GHTF), and in particular on the technical content of GHTF document SG4/N33R16:2007 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports*. It was developed in consultation with stakeholders and regulatory partners in other jurisdictions.

This guidance document will also be used as part of the US Food and Drug Administration (FDA)'s Medical Devices ISO 13485:2003 Voluntary Audit Report Submission Pilot Program.* As part of this cooperative endeavour, the FDA's Centre for Devices and Radiological Health and Health Canada's Medical Devices Bureau have developed publicly accessible training resources to assist auditors and registrars in implementing this guidance document.

It is expected that the implementation of this guidance document will be an important step in the creation of a harmonised single audit program, initially involving Health Canada and the US FDA, and ultimately involving other regulators as well.

* see www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/default.htm for guidance on this initiative.

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GUIDANCE DOCUMENT

GD211: Guidance on the Content of Quality Management System Audit Reports

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Health Products and Food Branch

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Également disponible en français sous le titre : GD211: Directive sur le contenu des rapports d'audit de système de management de la qualité

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1 Introduction

1.1 Policy Objective

To establish the minimum content expectations of Quality Management System (QMS) audit reports prepared by Health Canada recognized registrars as part of certification procedures in support of an application for, or the maintenance of, a medical device licence, pursuant to paragraphs 32(2)(f), 32(3)(j), 32(4)(p), and as applicable, sections 34 or 43.1 of the *Medical Devices Regulations* (Regulations).

1.2 Policy Statements

All QMS certificates issued by Health Canada recognised registrars in support of an application for, or the maintenance of, a medical device licence pursuant to the Regulations are to be based on a certification procedure, including audits that are documented in an audit report. All such certification procedures, audits, and audit reports are expected to meet the requirements set out in ISO/IEC 17021:2006, ISO 19011:2002, and Health Canada's guidance documents GD210 and GD211.

1.3 Scope and Application

The scope of this guidance document is limited to the information that Health Canada requires in QMS audit reports for all audits, other than stage 1, performed as part of certification procedures in support of an application for, or the maintenance of, a medical device licence. The format of reports, as well as acceptable practices, are discussed.

The guidance in this document applies to all registrars recognised by Health Canada under section 32.1 of the Regulations.

Once this document is final, all audit reports prepared in support of a certification issued in support of an application for, or the maintenance of, a medical device licence are expected to be prepared in accordance with the guidance specified herein.

1.4 Background

This guidance document, *GD211: Guidance on the Content of Quality Management System Audit Reports*, is based on the work of Study Group 4 of the Global Harmonization Task Force (GHTF), and in particular on the technical content of GHTF document *SG4/N33R16:2007 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports*.

The purpose of this document is to describe Health Canada's expectations regarding the content of audit reports prepared by recognized registrars, in order to reduce variations in both the QMS conformity assessment procedures with respect to medical device manufacturers as well as the accreditation and recognition procedures with respect to registrars.

In order to comply with the applicable subsections of sections 32, 34 and 43.1 of the Regulations, a manufacturer must provide a valid QMS certificate to Health Canada. A valid certificate, as issued by a Health Canada recognised registrar, is an attestation on the part of the registrar that the QMS of the manufacturer has been audited against ISO 13485:2003 in accordance with Health Canada's requirements and has been found to be in conformity for the scope of activities as outlined on the certificate.

Whereas a certificate is an attestation of QMS conformity to requirements, the corresponding audit report represents a significant portion of the objective evidence of the implementation of the conformity assessment procedure. The audit report serves as a written record of the audit team's determination of the extent to which specified requirements have been fulfilled. It also serves to demonstrate that the rules of the registrar's conformity assessment scheme have been followed.

In 2009, Health Canada initiated a pilot project to determine whether the application of GD211 would standardize minimum audit report content, reduce variability in report content amongst registrars, and increase the usefulness and reliability of audit reports. The results from report evaluations and feedback obtained from auditors, certifiers, and registrar representatives indicated that the GD211 would successfully standardize the minimum content of audit reports and facilitate the preparation of more useful and reliable audit reports.

1.5 Definitions

Certificate, Valid

Means a certificate that :

- has been issued by a Registrar that has been recognized by Health Canada under sections 32.1 - 32.7 of the *Medical Devices Regulations*;
- contains the information described in guidance document "*GD207: Guidance on the Content of ISO 13485 Quality Management System Certificates issued by Health Canada Recognized Registrars*"; and
- is valid for the period, not exceeding three years, specified in it.

Manufacturer

Means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Registrar

Organization that assesses and registers or certifies the quality management systems of manufacturer with respect to published standards.

Registrar, CMDCAS Recognized

Registrars that are recognized by Health Canada through the accreditation by the Standards Council of Canada (SCC). A list of Canadian Medical Devices Conformity Assessment System (CMDCAS) recognized Registrars is on the Health Canada website.

Registrar, Health Canada Recognized

Includes both CMDCAS recognized Registrars and Registrars that are directly recognized by Health Canada under section 32.1 of the Regulations.

Supplier, Critical

A supplier delivering materials, components, or services, that may influence the safety and performance of the product.

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. (SG4N84:2010).

In addition to the definitions above, the definitions found in the following documents applies:

ISO 9000:2005 Quality management systems - Fundamentals and vocabulary

ISO/IEC 17000:2004 - Conformity assessment - Vocabulary and general principles

2.0 Guidance for Implementation

2.1 Report Format

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

Registrars are free to use reporting formats that meet their needs. However, the reports produced should contain all the elements in section 2.3 of this document. The contents of the report should be organised along the broad categories identified below, namely information about the manufacturer, information about the audit, audit findings, and conclusions. Preference is given to the order presented herein.

The information required to appear in the audit report, as delineated in section 2.3, should be presented in a single document wherever possible. Reference to other documents as primary sources of information should be avoided in most cases. This does not preclude the use of supporting documents as appendices to the report. Appendices should be identified and referenced in the report.

Other information may be included in the audit report.

2.2 Report Language

The language of the report is subject to the operating language of the registrar and should be understandable by the manufacturer, however, all audit reports for conformity assessment procedures performed under the Canadian Medical Devices Conformity Assessment System (CMDCAS) must be available in either French or English, or be made available in either language upon request.

2.3 Report Content

2.3.1 Information about the Manufacturer

The audit report should contain information that unambiguously identifies: the name and physical locations of the manufacturer being audited; the quality management system being audited; and the medical devices that are part of the scope of registration. The following items should be included in the report:

a) **Manufacturer's Name and Address**

The name and address of the manufacturer subject to the conformity assessment procedure, as it will appear on the registration certificate, should be included in the report.

b) **Company Identification Number**

The manufacturer's 'Company ID' number assigned by Health Canada should be obtained from the MDALL website (<http://www.mdall.ca>) and included in the audit report in association with the manufacturer's name and address. Where a company has no licensed devices, no Company ID number will exist. In such a case, a notation of 'N/A' or 'not applicable' should be made.

c) **Corporate Identity of the Manufacturer**

When a manufacturer has multiple names or identities these should be clarified.

This clarification also extends to any relationships with sister, parent, and daughter companies, including subsidiaries, acquisitions, business units, and joint ventures. When preparing this section, auditors should be mindful to frame the explanation in the context of the QMS being audited and its associated scope of activities and devices.

This item can be omitted from surveillance audit reports.

d) Description of the Manufacturer

A description of the manufacturer should be included in the report. This description should include the approximate number of employees and associated number of shifts. The description should also include an overview of the activities and processes carried out by the manufacturer at the audited location(s) as well as identification of key outsourced activities. The name and title of senior management of the location(s) audited should be included in the description.

Where the conformity assessment procedure involves more than one physical site, all sites should be identified [as in a) above] and a description of the relationships between the sites and their relative role within the QMS, including any shared functions, should be included.

The description of the manufacturer can be limited to those parts that fall within the scope of the audit for surveillance audit reports.

e) Scope of Certification

The report should include the scope of certification of the manufacturer being audited. 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 may be referred to in an appendix.

f) Identification of Critical Suppliers

The report should identify the name, address, and product or service of critical suppliers that provide products or services used in the audited processes. The involvement of a supplier can be through an outsourced process such as sterilisation or software development. 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 QMS

The name and contact information of the contact person for the QMS should 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 QMS of the manufacturer should be listed.

i) Exclusions and Non-Applications of Requirements in the QMS

Where the manufacturer being audited has claimed an exclusion or non-application of requirements of ISO13485:2003 in its QMS, these should be identified in the report. The report need not include the justification of these exclusions and non-applications.

2.3.2 Information about the Audit

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

a) Audit Type

The report should identify the type of audit performed (for example [e.g.] certification, surveillance, re-certification, etc.)

b) Audit Criteria

The audit criteria should be listed in the report. For audits performed under the CMDCAS programme, this would normally include, as a minimum, ISO 13485:2003, the applicable regulatory requirements as stated in the Regulations, and the manufacturer's QMS documentation.

c) Audit Objectives

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

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

- ii) the assessment of the capability of the QMS to ensure compliance with applicable regulatory requirements. The applicable regulatory requirements should be clearly identified in the objectives.

d) Audit Scope

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

f) Identification of the Audit Team

The report should identify all members of the audit team and describe their respective role (e.g. team leader, technical expert, etc.). Any observers present should also be listed. Where interpreters are used, they should be identified. The affiliation of interpreters should also be indicated.

g) Audit Language

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

h) Document Review Results

When a review of the manufacturer's QMS documentation is performed prior to the audit, this should be mentioned in the audit report and reference to both the report and the results of the review should be made.

2.3.3 Audit Findings

The audit report should include sufficient audit findings, both positive and negative, to support the audit conclusions made in the report. Audit findings should 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 manufacturer's QMS in the report is taken as an area or function not audited.

Report authors should refrain from providing opportunities for improvement, including providing specific advice, instructions or solutions towards the development and implementation of a QMS. However, as an important component of a complete and accurate record of the audit, observations and findings should be reported. Observations can include situations which appear to be non-conforming but where insufficient audit evidence was collected.

a) Audit Summaries

Written summaries of the audit of each QMS process or activity audited should be included in the report. Examples of QMS 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;
- purchasing controls;
- control of documents and records; and
- customer related processes.

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

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

- i) description of the QMS process or activity audited;
- ii) area (physical or organizational) of the site visited;
- iii) name and title of persons 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 audit criteria.

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

Audit summaries should also include the following when applicable:

b) Description of Major Changes

When the activity or process being audited has been subject to a major change, this should 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 QMS as a whole. The description of these changes should include a discussion of their relevance and impact on regulatory requirements and submissions to regulators. The description can be included in the audit summaries or under a separate heading.

c) Obstacles

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

Alternatively, these obstacles can be described in section 2.3.4 d) - Reliability of Audit.

d) Follow-up on Past Nonconformities

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

e) Nonconformities

Registrars are free to use separate nonconformity reports or forms, however the audit report should include, for each nonconformity: a statement of nonconformity; the criterion against which the nonconformity is raised; and the

supporting objective evidence. 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.

Any unresolved objections by the manufacturer to the issued nonconformities should be recorded.

Where the manufacturer 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 should be noted in the audit report.

2.3.4 Conclusions

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

a) Conformity with Audit Criteria

A brief summary and conclusion regarding the conformity of the QMS as it is implemented with each set of audit criteria in 2.3.2 b) above should be included in the report. The conclusions should be unambiguous as to the conformity or nonconformity of the QMS.

b) Effectiveness

The report should include a brief summary and conclusion regarding the effectiveness of the QMS in meeting quality objectives. One of these quality objectives includes compliance with applicable regulatory requirements.

c) Confirmation of Audit Objectives

The report should confirm that all audit objectives in 2.3.2 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 should outline any factors encountered that may decrease the reliability of the audit. This may include such factors as a shortfall in auditor time, the absence of a needed technical competence, or any obstacle not mentioned under 2.3.3 c).

e) Recommendations

The audit team's recommendations should be included in the report. Recommendations should be made with regards to:

- i) any follow-up actions by the registrar, changes to the audit programme, 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.

2.3.5 Identification and Dating

The final audit report should include the name(s) of the author(s) of the report. The report should also be dated on its final date of issue and include version control information where necessary.

3.0 Bibliography

Medical Devices Regulations SOR/98-282 (latest consolidated version)
<http://laws.justice.gc.ca/en/F-27/SOR-98-282/>

GD207: Guidance on the content of ISO 13485 quality management system certificates issued by Health Canada recognized registrars

GD210: ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars

ISO/IEC 17021:2006 - Conformity assessment - Requirements for bodies providing audit and certification of management systems

ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing

SG4/N33R16:2007 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports

SG4/N84:2010 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers Part 5: Audits of Manufacturer Control of Suppliers