International Organization for Standardization

International Accreditation Forum

Date: 13 January 2016

ISO 9001 Auditing Practices Group Guidance on:

Audit Reports

1. Introduction

Clause 1 of ISO 9001 states that an organization should implement a QMS when it needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements. The audit report is an important tool in demonstrating that the organization satisfies the requirements of ISO 9001.

ISO/IEC 17021-1 "*Conformity assessment - Requirements for bodies providing audit and certification of management systems*" outlines the minimum requirements for reporting, but does not define a specific format for ISO 9001 management systems reports. However some sector schemes may require the use of specific report formats. The format and content of an audit report may be varied depending on the size and nature of the organization being audited. It also depends on the objectives and scope of the audit (e.g. whether it is an Initial certification audit, surveillance audit, etc.)

This paper aims to summarize a wide range of experience in preparing audit reports, to meet the needs of all interested parties.

2. Interested Parties and Their Needs

The following are examples of possible users of the information contained in audit reports:

- The Audit Client
  - Top management/ Board of Directors
  - Management Representative
  - Internal Auditors
- Accreditation Body
  - Accreditation decision Maker
- Certification Body
  - Certification Decision Maker
- Audit Team performing future certification audits
- Regulatory Body

Each user may require different information, so the structure of the audit report will need to be varied to meet these needs. The report should provide the required information, satisfy the needs of users in a balanced way, and add value to the audit.

An interested party might need to know:
- if the system conforms to the requirements
- any opportunities for improvement
- any nonconformities and areas of concern
- any strengths and weaknesses
- if the management system adequately addresses the risks associated with achieving and maintaining quality
- information for future audit planning
- areas that require follow-up
- additional information required for a decision regarding certification.

3. Outline for Audit Reports

An audit report can be a stand-alone document, or can be accompanied by, or make reference to, other types of documented information (documented procedures, data repositories, etc.). Not all of the topics listed below are applicable to every type of audit and the sequence of topics in individual audit reports can vary.

The following are suggested for inclusion in an audit report:

a) Introduction

This section of the report should reference the mandatory requirements of ISO/IEC 17021-1 (see clause 9.4.8) and the guidance given in ISO 19011 "*Guidelines for auditing management systems*"(see clause 6.5).

b) Executive Summary

This section should concentrate on giving a summary of the overall effectiveness of the quality management system (QMS), including information on:
- the strengths and weaknesses of the management system;
- continual improvement; and
- other key performance indicators.

Particular highlights of the audit should be commented upon, as well as an overview of any findings that represent nonconformity and/or significant 'areas of concern' (that could become a nonconformity unless satisfactorily resolved).

The conclusions of the audit regarding conformance of the organization's QMS to the standard being assessed against, and any recommendations, should be stated.

The organization should be thanked, as appropriate, for its hospitality, cooperation and openness.

c) Management commitment & leadership, objectives and targets:

This section should provide comment on the demonstration of Top management leadership and the organization's processes for determining, setting and

communicating policies and objectives. It should cover the monitoring, measuring, reporting and reviewing against key performance objectives. It should include appropriate comments regarding the progress the organization has made against its objectives since the last audit (however, for an initial certification, this section may need to acknowledge that the organization had not yet developed sufficient history of such achievement for auditing purposes) and, for a certification renewal audit, a review of the evolutions and achievements of the QMS over the previous audit cycle, as appropriate.

d) Actions taken on previous audit issues:

This section should provide comment on the organization's ability to determine the root causes of any previously identified quality problems, as appropriate, and on the effectiveness of the actions it has taken to correct such situations and prevent their recurrence. It should also comment on the sufficiency of the organization's formal processes for corrective action.

Where a nonconformity had been previously identified, it should also provide comment on whether confidence has been restored in the organization's own ability to identify potential nonconformities, and to prevent them from occurring.

e) Internal audit, management review, and continual improvement processes:

This section should provide comment on the timeliness and effectiveness of the internal audit, management review and continual improvement processes with regard to the risks associated with achieving and maintaining quality.

Additionally, it should provide comment about the organization's progress:
- in its planned actions aimed at continual improvement, and
- in monitoring information relating to customer satisfaction and customers' perceptions of the organization's performance relating to quality.

f) Impact of significant changes (if any):

This section could apply to any type of audit; however it is more likely to be applicable at surveillance and re-certification audits rather than initial audits. The details that should be recorded include the impact of changes in, for example: ownership; facilities and equipment; key personnel; management systems; scope of certification etc.

g) System requirements and interrelationships, functions, processes, areas audited:

The heading (or sub-headings) of this section in a report may need to be individually customised to refer explicitly to specific functions, areas, processes etc., for example "Sales", "Warehouse", "Training and Competence", "Customer Perception/ Satisfaction" etc.

The following should be identified in this section:
- the quality management standard being used as the basis for the audit (e.g. ISO 9001, ISO/TS 16949 etc.)
- the situation that is being audited.
- the key documents and records used during the audit, such as:
  - Observations sheets

- Audit plans
- Audit history
- Audit trails

This section can be used to give comments about the conformance of (a part of) the organization's management system to the 'System requirements', i.e. a clause or specific requirement of the quality management system standard.

Similarly, it can be used to provide comment about 'System interrelationships', i.e. the way in which different aspects of the organization's QMS work together (either in synthesis or separation) with their respective positive or negative impacts on the ability of the QMS to deliver its intended outputs.

Such comments should be focussed on the effectiveness of the links between the standard's requirements, and factors such as the organization's policy, performance objectives, any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data, or internal audit findings and conclusions.

The comments on 'Processes' will probably account for most of the report, as a QMS is generally audited 'process by process'. The report should address the applicable requirements in the QMS standard for each process being covered e.g. planning, process objectives, control of documents and records, responsibility and authority, competence and awareness, identification, traceability, measuring, monitoring, calibration, control of nonconformity, process improvement etc., and should focus on the process factors that assist or hinder consistency and / or improvement of the outputs.

h) Site inspection

This section should provide comments on the condition of the site that was audited, and should highlight any adverse conditions or unusual sightings or observations made.

i) Compliance evaluation of legal, statutory, regulatory and other requirements; and communication:

This section should provide comments about:
- the organization's systems for the identification of the legal / regulatory or industry specific requirements pertinent to its activities,
- on its methodology for the periodic evaluation of such requirements, and
- its systems for the communication of any changes to them.

j) Continuing effectiveness of the management system:

This section should provide an overall assessment of the continuing effectiveness of the organization's QMS, and should comment on whether the "scope of its certification" continues to be relevant, suitable and applicable, after taking into account any pertinent internal and external changes that have may have occurred since the last audit. (Note, this section will not be applicable for initial audits).

k) Use of marks and/ or any other reference to certification:

This section should record the ways in which the organization uses certification or

accreditation body marks (e.g. on stationary, in promotional literature, on its vehicles), and should highlight any concerns about the way in which they are being used.

l) Issues requiring further attention:

This section should record any issues that require further attention, and (where applicable) dates for the completion of planned actions, e.g. nonconformities, residual issues that remain following the closure of an NCR, other areas of concern etc.

m) Disclaimer

The report should include a disclaimer statement to say that auditing is based on a sampling process of the available information and that consequently there will always be an element of uncertainty present in auditing evidence, which may be reflected in the audit findings. Those relying or acting upon the audit results and conclusions should be aware of this uncertainty.

It should also advise that the recommendations from the audit will be subject to review, before any final decision is made concerning the awarding or maintenance of certification.

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: *Introduction to the ISO 9001 Auditing Practices Group*

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsigroup.com.

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

www.iaf.nu
www.iso.org/tc176/ISO9001AuditingPracticesGroup

Disclaimer

This paper has not been subject to an endorsement process by the International Organization for Standardization (ISO), ISO Technical Committee 176, or the International Accreditation Forum (IAF).

The information contained within it is available for educational and communication purposes. The *ISO 9001 Auditing Practices Group* does not take responsibility for any errors, omissions or other liabilities that may arise from the provision or subsequent use of such information.