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ISO 9001 Auditing Practices Group Guidance on:

Auditing Climate Change issues in ISO 9001

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INTRODUCTION

As part of ISO's commitment to action on climate change, approved unanimously by all ISO Member Bodies in the so-called London Declaration, (https://www.iso.org/ClimateAction.html), amendments to over 30 of ISO's Management System Standards, including ISO 9001, have now been issued to include climate change considerations, as follows:

4.1 Understanding the organization and its context.

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its quality management system.

Added: The organization shall determine whether climate change is a relevant issue.

4.2 Understanding the needs and expectations of interested parties.

The organization shall determine:

- the interested parties that are relevant to the quality management system.
- the relevant requirements of these interested parties.
- which of these requirements will be addressed through the quality management system.

Added: NOTE: Relevant interested parties can have requirements related to climate change

The overall intent of the clauses 4.1 and 4.2 remains unchanged, as these clauses already included the need for the organization to consider internal and external issues that can impact the effectiveness of their management system (from ISO/IAF Joint Communiqué). These new inclusions are to ensure that climate change is firmly on the organization's radar screen and is given special attention as one of the external issues to be considered in the design and implementation of their quality management system.

The purpose of this paper is to provide auditors with guidance on auditing this amended requirement and note in the specific context of the ISO 9001 scope and its intended results, providing additional clarification on potential overlaps or confusion with other themes addressed by organizations and that are not directly related to quality management.

The amendments of the standard are publicly available. The guidance provided in this paper is intended for first, second and third-party audits. In what concerns third party certification, due to the nature of the amendment a specific transition program is not required, as timely communicated by IAF.

In some parts of the world climate change and its causes are controversial topics. Consistent with ISO 19011: 2018 Guidelines for auditing management systems, auditors are to maintain objectivity and neutrality when auditing climate change issues. They should not express personal beliefs relating to climate change. The role of the auditors is to assess whether the organization determined if climate change issues are relevant or not in relation to their QMS and its intended results and, if that is the case, then how it is addressed within the QMS.





This amendment does not require an organization to have climate change initiatives unless it has been identified as a relevant issue to achieve the intended results of the QMS.

CLIMATE CHANGE IN THE CONTEXT OF ISO 9001

Relevant Issues related to climate change, to be determined by the organization, if any, are those relevant to its purpose and strategic direction and that affect the organization's ability to achieve the intended results of the quality management system:

- the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements (ISO 9001, clause 1).

Relevance of these issues will vary significantly depending on the size and sector of the organization, the products and services provided, its position in the supply chain, its geography, the scope of the organization's quality management system, and potentially other factors. These may span the spectrum from no relevance to extremely relevant.

The inclusion of the new text in 4.1 requires organizations to consider climate change to determine if there are or not relevant issues that will need to be addressed. Although the text is new, auditors may find that some organizations are already considering and addressing issues related to climate change within the scope of the quality management system (e.g.: energy supplier invoices, stating the percentage of supplied energy coming from renewable sources; claims on carbon credit, on-product claims on energy consumption reduction, replacement of raw materials or consideration of eco-design of products to reduce climate change impact, etc.). Auditors will also find organizations that have already considered climate change and determined that it was not a relevant issue for their QMS. For other organizations, this may be a new consideration.

The note at 4.2 is a reminder that there may exist, currently or potentially in the future, requirements related to climate change dictated by customers and relevant interested parties.

A climate change issue can be relevant for different management system disciplines, such as environmental, health and safety, energy, finance, or other aspects of an organization's activities. While these may have ancillary significance, they are not generally addressed within the scope of the quality management system audit. If an organization has an integrated management system with other management system disciplines, it is likely that the same issue is analysed in different perspectives by the organization in a holistic manner. Auditors need to be aware of this and focus on the intended outcomes of the QMS and its processes, bearing in mind that there might exist overlaps in certain areas (e.g. design of product considering environmental aspects).





AUDITING CLIMATE CHANGE ISSUES WITH IMPACT IN THE QMS AND ITS RESULTS

- 1. Has the organization determined whether climate change is a relevant issue?
- 2. Does the organization's determination align with applicable statutory and regulatory requirements applicable to their products and services?
- 3. Does the organization's determination align with their contractual requirements?

4.1 New Requirement: The organization shall determine whether climate change is a relevant issue.

Auditing considerations for climate change impacts from external and internal issues can include:

- Changes in statutory or regulatory requirements such as restriction on the use of certain materials, product circularity, product life cycle, product origin, claims, etc.
- Use of bio-based, renewable materials.
- Potential impacts on the products and services or on the QMS processes, by changes
 determined in other management system disciplines, e.g. need to reduce energy consumption,
 reduce waste, reuse or recycle materials.
- Extended lifetime of products, post-delivery services and assistance
- Requirements to move to carbon neutral products and services.
- Issues impacting the processes and infrastructure, due to energy and other considerations.
- Vulnerability of the organization to deliver its products and services due to more frequency of storms, waterflows, fires, drought, that may imply shortages in the supply or difficulties in distribution.
- Concerns related to overall knowledge and control of the supply chain in issues related to climate change.
- Market trends on sustainability of products and services and related information and claims
- Competing products and services with potential better performance in climate change related issues.





4.2 NOTE: Relevant interested parties can have requirements related to climate change

Has the organization determined the existence of applicable requirements related to climate change from relevant interested parties?

Audit examples of relevant interested party requirements for climate change can include:

- Statutory and regulatory, environmental or climate change requirements for the product or service provided, and those that affect the organization's ability to provide that product or service.
- Customer requirements regarding climate change, zero discharge, or carbon neutrality of the products.
- Parent company policies and strategies.
- Requirements related to product information on aspects related to climate change (sustainability of the origin, reuse, recyclability, end of life, embedded carbon, "greenwashing labelling" etc.), including product claims and associated existing legal, statutory, and other requirements.
- Industry codes and standards changes related to climate change.
- Environmental agreements with community groups or non-governmental organizations.
- Permits, licenses, or other forms of environmental authorization.
- Climate change related requirements on processes such as packaging, manufacturing, servicing, logistics, among others.

ADDRESSING ISSUES DETERMINED AS RELEVANT BY THE ORGANIZATION

If the organization has determined there are relevant issues or customer and other interested parties' requirements related to climate change, the next step for the auditor is to evaluate how these are addressed in the QMS, which simply follows the paths of any other issues. Below are presented some non-exhaustive examples of questions and related aspects for the auditor to evaluate how the organization is addressing these issues.

4.3 Determining the scope of the QMS

Do these relevant climate change issues impact the QMS scope or change the applicability of certain requirements? Is there a need to change the scope of the QMS?

Relevant examples:

The organization considered to move location due to the higher risk of flooding in its current location.

The organization is provided different products and services.

The organization did not apply development of product but changes in raw materials or processes, determined the need for its applicability.





6.1 Actions to address risks and opportunities.

Has the organization considered these issues to determine risks and opportunities?

Relevant examples:

- Do these issues lead to changes in support, such as infrastructure, monitoring and measuring equipment, knowledge, communication or other?
- · Are there relevant changes in operational processes?
- · Changes in what needs to be monitored and measured?
- What are the risks that need to be addressed?

Has the organization determined new opportunities?

- New product and services or changes in the existing offerings:
 - Financing opportunities for changes in its infrastructure and processes
 - Communication related to products and services addressing climate change related issues.
 - New markets for its products and services
- Has the organization determined how the determined risks and opportunities impact the intended results of the QMS?
- What are the planned actions for these risks and opportunities?

6.3 Changes

Do potential risks and opportunities determined or changes in scope, imply changes in the QMS and its processes? Do planned actions considered all the items referred in 6.3 a) to d).?

7.1 Resources

If climate change issues have been deemed relevant, then how does this impact resources to achieve conformity of products and services?

Relevant examples:

- How do climate change considerations impact on the environment for the operation of processes (7.1.4)?
- How does the organization determine an appropriate source of knowledge on which to base their decisions (7.1.6)?





8. Operations

If climate change issues have been determined as relevant and do not imply changes in the QMS, nor on its QMS scope, are they already being handled within the dispositions of the current QMS?

Relevant examples:

- 8.2.1 a) Is the organization providing information related to products and services?
- 8.2. b) If there are any claims on products and services related to climate change, the organization demonstrates it can meet them?
- 8.2.1 e) Is the organization establishing specific requirements for contingency actions related to determined risks in the provision of the products and services?
- 8.2 a) and 8.2.3 Is the organization considering climate change related requirements when determining or reviewing the requirements related to products and services?
- 8.2.4 Are changes in the requirements of products and services being documented and relevant persons made aware?
- 8.3 Is the organization addressing requirements related to climate change in product and service design and development?
- 8.4 Do requirements related to climate change for externally provided products, services, and processes that the organization needs to control, include consideration of the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements? If so, what has been determined by the organization in terms of type and extent of control and information for external providers?
- 8.5 Do issues related to climate change indicate the need for specific controls of production and service provision?

Relevant examples:

- unique identification and traceability of products to sustainable sources of raw materials,
- appointment of competent persons, including required qualifications,
- post-delivery activities, such as recycling and final disposal,
- evidence of conformity to acceptance criteria,
- · Control of non-conforming outputs,
- etc.





9. Performance evaluation and Improvement

If relevant issues related to climate change have been determined by the organization, these may have specific monitoring and measurement needs, eventual implications on monitoring and measuring customer satisfaction or changes to the audit program.

Relevant examples:

- Reliable sources of information and data, either external or internal
- Monitoring and measurement of organizational impact, results of the introduced changes

It is also expected that management review inputs consider any changes related to this context issue, and outputs of management review may include related decisions, including opportunities for improvement.

SPECIFIC CONCERNS

It is up to the organization to determine if and how climate change issues impact the QMS and its intended results.

For auditors, special attention is necessary for product and service claims related to climate change issues, as with other claims made on products, as the organization shall demonstrate that it ensures it can meet the claims (8.2.1 b).

Many of these claims may imply specific methodologies for monitoring and measurement, may require additional third-party verification or be subject to statutory and regulatory requirements. Auditing the methods used to determine these claims may be outside the objectives of an ISO 9001 audit. However, auditors are to be aware of the requirements related to these claims to enable them to evaluate if the organization can demonstrate the claims can be met or if there is a risk to the integrity of the quality management system, in particular for third party certification audits.

SUMMARY AND CONCLUSIONS

Climate change issues are one of many issues that organizations are to consider when analysing their internal and external context and determining requirements from customers and other relevant interested parties. In its communiqué ISO and IAF considered that this is an external factor that is important enough for our community to require organizations to consider it now.

The amendment to ISO 9001:2015 has been published on 23 February 2024. Auditors will have to evaluate how the organization demonstrates it has determined if climate change is a relevant issue, in the context of the quality management system and its intended results. In practice, auditors need to perform the audit to processes related to context, relevant issues and relevant requirements as usual, but evaluating specifically how climate change issues were considered





While some organizations may already address climate change issues, others will be considering it for the first time. Auditors are to be aware that implications of climate change issues and related legal, customer and other interested party requirements, may vary.

If relevant climate change issues are determined by the organization, these will need to be addressed within the QMS. This implies determination of risks and opportunities, planning of changes to the QMS, changes in scope or simply addressing related requirements within the other requirements of the QMS. Auditors should look for evidence that the organization has considered the issues and is addressing them within the scope of the organization's quality management system.

Auditors are to evaluate if the organization has identified any contractually agreed customer requirements or statutory and regulatory requirements with climate change relevance that are applicable to its products and services and whether these are being acted upon.

Auditors are to be particularly careful evaluating if there are any existing product and service claims related to climate change. If so, organizations need to demonstrate that they ensure these claims can be met, as this may pose a risk to the integrity of the QMS.





BIBLIOGRAPHY AND FURTHER READINGS

ISO/IAF Joint communiqué on addition of climate change considerations to MSS

IAF Final decision following 30 days consultation addition of climate change notes to the management system standards

Auditors also may find useful the following documents:

ISO/TS 9002:2016 Quality management system. Guidelines for the application of ISO 9001:2015

ISO 9001 APG Context

ISO 9001 APG Statutory and Regulatory Requirements

Please access our websites at <u>ISO 9001 Auditing Practices Group</u>, or at <u>Accreditation and Assessment Practices - IAF</u>, where you can find information about ISO 9001 Auditing Practices Groups, download Introduction, the other ISO 9001 APG and AAPG papers.

Feedback from users is welcomed by APG/AAPG and will be used to determine the need for additional guidance documents, as well as for the revision of the current ones.

In case you wish to provide your feedback, the Group Secretary contact details are also available on these sites.

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