Quality in the Supply Chain

A guide to what makes a 'good'
ISO 9001 audit from the perspective of the
customer and an organisation certified by
an accredited certification body

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Foreword

Making an accurate assessment of the capabilities of an organisation's Quality Management System (QMS) to consistently deliver customers' requirements is the auditor's primary role and accredited Certification Bodies (CBs) need to ensure that their auditors are equipped and trained, through suitable policies and competence processes, to fulfil this function.

This audit is relied on by many of the organisation's stakeholders both internal and external. This document discusses the components that lead to a successful audit of the QMS and the importance of the Certification Body and its auditors in meeting customer expectations. The document highlights those areas identified by stakeholders involved in Management Systems Certification and discusses best practice in how CBs (Red Text) and certified organisations should approach these areas during assessments.

This document is intended as a best practice guide, to inform those training auditors and organisations' Quality Managers so that they can deliver training material that is

relevant. It is also available as general reading for auditors and Quality Managers in support of their continual professional development..

This document was produced by a Stakeholder Group with the shared aim of enhancing purchaser confidence in the certification of their suppliers in terms of supplied product quality. The Stakeholder Group included representatives from procurement organisations, certification bodies, national and international trade bodies and regulators, and UKAS. This document details the agreed set of aspects and components of the certification process considered by the group to be crucial to achieving confidence in the certification process.

Introduction

From the perspective of the customer of an organisation certified by an accredited certification body, the certification process must be completed in a competent, thorough and transparent manner.

It is a fundamental principle that the customer needs to have confidence that the certificated organisation it is contracting with poses the least risk procurement option. This is based upon the premise that the organisation's management system has been audited by an independent certification body as capable of consistently delivering the customers' requirements. In other words, compared to contracting with a non-certificated organisation where the risks are significantly higher as its capability has not been assessed by an accredited independent body. As such, certification is a mitigation to the risk of poor or inconsistent quality.
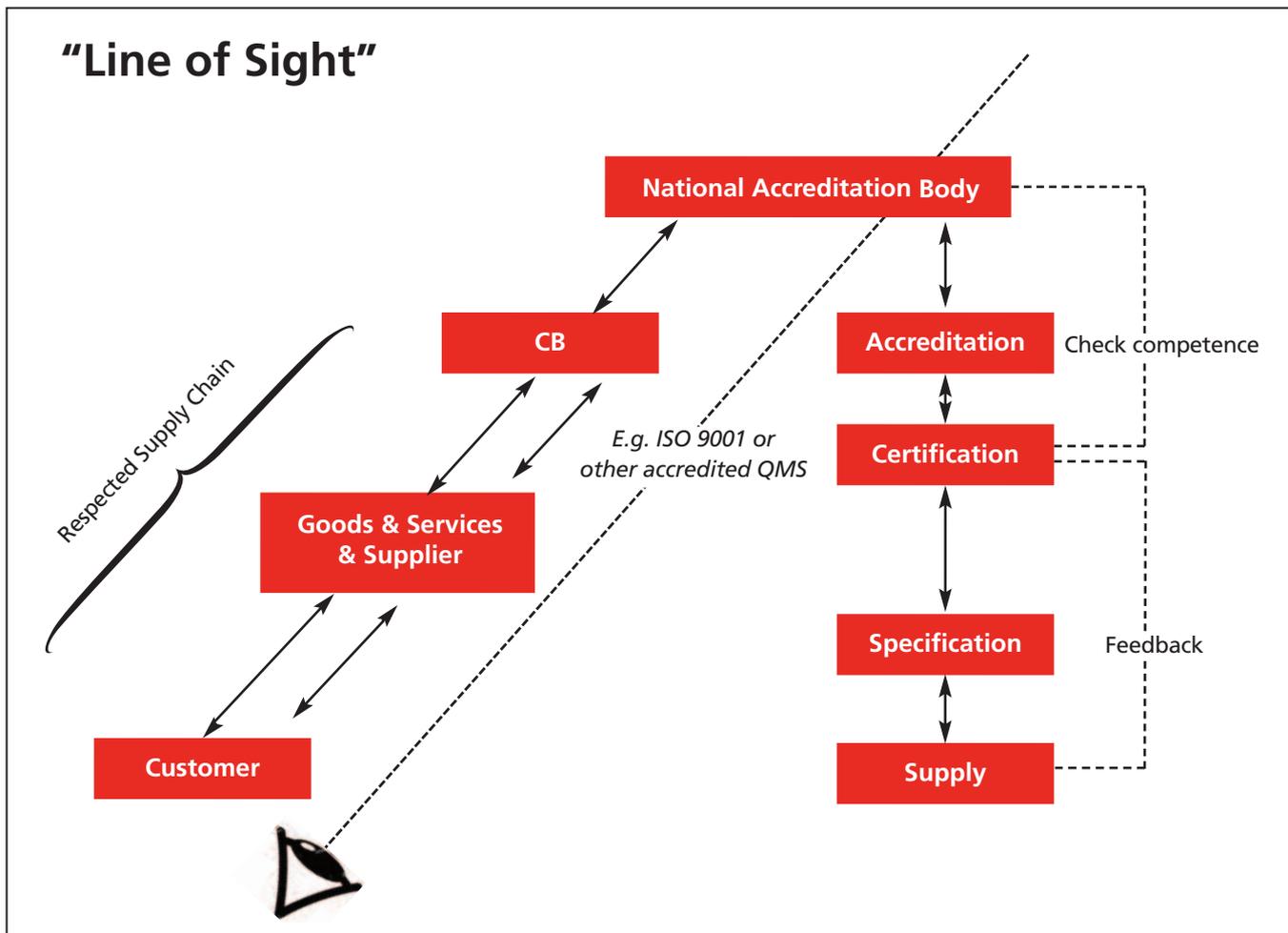

Figure 1: "Line of Sight" diagram showing the relationships and controls through the supply chain when using accredited certification.

Therefore, the Accredited Certification Body becomes a vital link in providing customers throughout the Supply Chain in increasing Confidence in the proven ability of the certified organisation.

a) Those seeking to procure products and services often prefer to contract with suppliers whose management system is appropriately certified. They do this in order to increase their confidence that the selected supplier will deliver. This in turn lowers risk.

b) For customers of certified organisations, it is vital that the certification audit of the quality management system is undertaken rigorously and impartially by auditors who are competent and who are given sufficient time to carry out the required audit activities against the requirements of the international standard. Certification can also lessen the customer's supply chain management overhead by reducing QA activities. The use of accredited certification bodies provides an additional level of confidence in the competence and capabilities of the supplier.

c) The importance of the supply chain in the delivery of projects today is very high. During the late 20th and into the 21st Century, supply chains have lengthened and become more complex, often like a web regularly crossing international boundaries. This has been particularly so with organisations supplying complex systems requiring their supply chains to be increasingly agile and innovative. These organisations have sought to outsource their manufacturing capability by buying in sub-systems and components for assembly placing greater emphasis on their supply chains to conduct product realisation. This has led to more organisations being involved in the realisation of projects and the requirement to manage an increasingly complex supply chain. In turn, this means confidence is required in more organisations thereby increasing the importance of robust certification of their quality management systems.

d) Those seeking to procure products and services often prefer to use tenderers and suppliers whose management system is appropriately certified. Once they become Customers they seek confidence that the product/service the organisation produces through its quality management system will be 'right' (i.e. satisfy customer and legal requirements). This continues for the duration of a contract and is especially for those of longer length and complexity. To give the required confidence to organisations' customers, auditors must collect objective evidence from a number of areas and use this to evaluate and conclude if the quality management system of the organisation is likely to deliver consistently, the product/service expected by their customers; only those that demonstrate this should be granted a certificate. As such, certification is a mitigation to the risk of poor quality.

e) To this end it is important that organisations seeking certification always contract with accredited certification bodies, ensuring that the accreditation covers the scope covered by the required certification. The accreditation assessment process of these CBs will ensure that they are considering the supply chain and that systems and procedures are aimed at fulfilling customer and supply chain requirements. It is also important that, when certified companies are found not to be consistently fulfilling customer requirements, the customer feeds this back to the Certification Body for investigation and then, if necessary, to the Accreditation Body so that the situation can be investigated, and necessary improvements instigated.

This document identifies the depth of assessment that a user of accredited certification can expect to have taken place at their certified suppliers.

Where examples are included in the sections below, these are intended to highlight possible system and/or process weaknesses which are to be avoided.

The Certification Body's Steps that lead to a Good Audit (see below)

- **Contract Review** process ensures the scope and context of the certification are fully understood.

- Sufficient **Time** allocated to allow for a full and effective audit process.

- **Competence** of the team matches the client's scope and organisational context. For auditors to make the required evaluation and draw valid conclusions on compliance or otherwise, they must be competent. It is for certification bodies to determine the competence criteria necessary to undertake the audit and then ensure that the auditor(s) have demonstrable competence before deployment. Supply chain diversity makes this a challenging process requiring certification bodies to have a broad competence base at their disposal. Whether the auditors are employees, contracted-in or sub-contracted is acceptable but they must be demonstrably competent.

- **Intended Outcomes** of the QMS are fully understood.

- Stage 1 audit confirms all of the above.

- **Risks** associated with the organisation and its QMS are fully understood.

- Audit is **process based** taking into account relationships, processes, leadership and organisational context.

- **Report** shows the ability of the QMS to achieve intended results i.e. will the QMS be effective?

- Clear **conclusions** reached and reported with any nonconformities clearly stated.

- **Feedback**, all stakeholders in quality management system certification can contribute to an effective certification process through the provision of feedback.

Factors to Take into Account

Understand the Organisation and its Context

"Organisation SHALL determine external and internal issues that are relevant to its purpose and affect its ability to achieve **intended outcomes.**" Understanding why the organisation exists, its purpose, who are its stakeholders, their requirements and their impact on the organisation is essential and is the starting point for the audit.

Typical areas to investigate are:

- What is the purpose of the management system?
- What are the intended outcomes of the management system?
- What are the external and internal issues that may be factors?
- Which of these external and internal issues are relevant and can have an impact on the organisation's ability to meet intended outcomes?

Position of the organisation. An organisation does not operate in a vacuum – many internal and external factors affect their operation. Typical areas to investigate are:–

- Who they are? Are they a single entity, part of a group, a site in a multi-national organisation or even just a department within an organisation?
- What they do? Manufacturer, distributor, service organisation, what are their products/services?
- Who they do it for? Who are their "Interested parties"? – these can be their customers, their regulators, the public, the list can be long depending on the sector in which they operate.
- Where do they do it? Geographic locations can one of the key factors in the organisations management system's ability to deliver on its purpose.

Auditors need to see how this information is gathered, evaluated and acted upon by the company. Where this is done poorly it is likely to lead to an organisation producing unacceptable outcomes.

It is also important to ascertain that all the staff of the organisation within the QMS, understand the organisational context and how their job affects the ability to meet the expected outcomes. Where staff are unclear on this it is likely to lead to an organisation producing unacceptable outcomes.

Auditors need to think about intrinsic cultural aspect connected to geographical locations.

Example: The CB auditor fails to identify that the organisation is manufacturing items without a clear understanding of where and how the products will be used, and without understanding the impact that not meeting expectation can have within that sector.

Factors to Take into Account

Audit Preparation and Conduct

Contract Review and Stage 1 audits should ensure that the organisational context is fully understood, so that the correct audit team can be allocated in terms of competence and understanding and so that any questions can be clarified up-front.

Sufficient time must be allocated – Remember –

"For each client the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's management system." (ISO/IEC 17021-1: 2015 clause 9.1.4.1)

Understanding the organisational context is a vital consideration in the determination of audit time. Therefore, it is important that all personnel involved in the contract review process have the ability to understand what is being requested and the ability of the certification body to deliver this.

Knowledge of client's business sector and Knowledge of client products, processes and organisation is a vital input into the contract review process, so as to ensure that technical aspects are considered.

Needs and Expectations of Interested Parties

"organisation shall determine the interested parties that are relevant to the QMS, and the requirements of these interested parties".

An "interested party" (stakeholder) is any person or organisation that can affect, be affected by, or perceive itself to be affected by a decision or activity of the organisation. "Many of these interested parties are related directly or indirectly to the internal and external issues related to organisational context."

For example:

- Customers
- Regulators
- Competitors
- Suppliers (parts and services)

Typical areas to understand are:

- Where the company sits in the Supply Chain (for example tier 1, tier 2, tier 3 etc.?)
- What the next step is for the product being supplied, is it the final product or is it going for further processing or assembly?
- That the organisation has identified all of the interested parties and evaluated how they can meet their needs and expectations, and that Risks have been fully addressed.
- The typical contractual interfaces in terms of tenders, contracts, purchase requirements, and corresponding risks associated with these.

Example: Where, following the stage 1 visit, generic audit plans are issued with no reference to specific client processes and no consideration of what was audited on the previous visit(s).

Example: Contractual requirements placed at the Tier 1 level that have not been correctly applied to the lower tiers.

Factors to Take into Account

Risk Based thinking

Highlighted in ISO 9001 as a key element in the development and operation of the management system. Typical areas to investigate are:

- Is Risk-Based Thinking embedded into the organisations culture and processes including the organisation's **leadership,** do top management promote Risk-Based thinking?
- Does the organisation's risks and opportunities processes reflect its **organisational context?**
- Does the organisation implement actions to address risks and opportunities interested parties?
- Is **customer-focus** apparent in the organisation's operations?
- Are risks and opportunities covered within the internal audit and management review processes?

The standard does not specify any specific methodologies for risk analysis and risk-based thinking, auditors should be open-minded as to the type of processes used but the processes must be effective and intrinsic within the management system.

In sectors where specific risk-based methodologies are used (for example Automotive, Defence and Aerospace), the audit team must be competent in the use and interpretation of these methods.

Leadership

Leadership is a difficult area to audit; the organisation's leadership need to be truly taking the lead in terms of understanding the purpose of the management system and the factors that lead to its success in meeting the **expected outcomes.**

Typical factors to confirm leadership are:

- Communication of quality policy and strategy, supported by measurable objectives, monitoring of key performance indicators, etc.
- Identification, measurement and reporting everything that matters and review actions needed to improve, simplify, eliminate to ensure ongoing effectiveness and capability.
- Demonstrated, Pro-active involvement of management and supervisors.
- Effective resource management especially for high risk operations. Including training, mentoring, and independent checks and balances where necessary.
- Ensuring Personnel are confident in their roles, attitude to achieving goals — actions when things go wrong,
- Ensuring the correct culture exists within the organisation, a right first-time approach, support to colleagues, correct knowledge base regarding the company product/service and implications if not correct, appreciation of their contribution and implications on final product/service if not correct.
- Fair approach to blame culture when things go wrong.
- Analysis and corrective actions which prevent reoccurrence, and checks in place to confirm the effectiveness of the corrective actions.

Example: Where a non-conforming item has been allowed to reach the customer (by concession) without the risk having been suitably evaluated, resulting in problems further along the production process.

Example: Where the organisation's leadership paints a picture of the organisation's performance that is not reflected in the evidence gathered during the audit.

Factors to Take into Account

Design

Audit of the design process has been shown to be effective when the auditor again has a good appreciation of the context of the organisation, client base and especially product knowledge to appreciate the type of controls expected for the total design process from planning through auditing the design input/output methodology.

The design processes should be understood in terms of:–

- design reviews.
- design verification.
- design validation.
- design approvals– overall confirmation that the design quality planning is well established and implemented accordingly.
- controls pertinent to design changes and configuration management.

Auditors with the required knowledge of the product design process are able to confirm, or challenge, the arrangements for establishing the correct design inputs and outputs and the information suitable for planning the in-house activities to produce the final product supported by the relevant detailed information for outsourced work — the start of the procurement activity.

Also, auditors will need knowledge of the regulatory and sector specific aspects of design and typical statistical tools such as FMEA, design of experiments etc. as used in the sector concerned so as to challenge their proper and effective use.

Procurement

The procurement process has a number of interlocking stages which does indeed require a process audit from the design or planning (if no design) through purchasing/buying to receipt inspection.

It has been shown that this is best achieved by the same auditor undertaking the end to end process audit, or, alternatively by very well managed communication between audit team members to ensure the process audit approach is maintained.

The auditor with the product knowledge and industry process knowledge is able to confirm the client has fully specified the requirements for the outsourced item Including the flow down of information from their purchaser relevant to any regulations, end use, critical aspects etc.

AND —

in addition, can establish/confirm the client has considered the impact (risk) of the outsourced item on their product being supplied, i.e

- consideration of the criticality of the items or service being purchased, and the risks involved in failure to meet specification, including risk of counterfeit fraudulent suspect (CFS) items.
- adopting a graded approach (8.4.2) to specifying/applying the necessary controls to their suppliers, for example, requirement for manufacturing/inspection plans, approval of personnel and documents, inspection stage requirements (first, second and/or third party, intermediate and release).
- and the corresponding internal controls at goods receipt, for example, inward inspection checks and tests which takes into consideration where the outsource originates and whether there is a risk to counterfeit/suspect product requiring greater diligence on their part.

The procurement process is also supported by the evidence of confidence in the supplier being used, the process capability, competence, resources, management system culture etc and evidence of monitoring the performance of suppliers.

Example: Where the importance of the design process for the client concerned has not been identified and therefore sufficient time has not been allocated for a full assessment of it.

Example: Where the purchase order requirements have not been fully and clearly stated such that the supplier is not fully aware of all requirements.

Factors to Take into Account

Auditing of Manufacturing/Assembly

Auditors with a **demonstrated knowledge** of the processes involved in producing the product, and the corresponding high-risk areas, are able to conduct effective process audits by **establishing audit trails** which test the inputs and outputs (and the corresponding checks) of the various established processes of the organisation to confirm an integrated and complete system is in place. This approach confirms the organisation fully understands all the customer's specification and associated requirements and has the management systems and controls to produce/assemble and test the product, or provide the service, and meet the contract requirements IN FULL, including the identification. traceability, documentation, records required, to support the finished item/completed service.

Audit team members that have sufficient knowledge of a business sector, including contractual requirements, demonstrate their ability to identify and sample contracts and follow effective audit trails accordingly as part of the process audit, fully testing/challenging the systems and confirming the required controls are in place and confirming that the organisation can meet the customer requirements and deliver the product/service consistently utilising the management system.

Auditors will need to understand the use of statistical processes and techniques for the sector concerned and should have the ability to investigate and challenge their effective use.

Reporting

The audit report must have enough objective evidence to stand on its own as a complete record. Audit reports shall provide an accurate, concise, and clear record of the audit to enable an informed certification decision.
ISO/IEC 17021-1: 2015 clause 9.4.8.2 specifies information to be contained or referred to including audit findings (summarising conformity and detailing non-conformity), reference to evidence and conclusions consistent with the requirements of the type of audit.

In addition, ISO/IEC 17021-1: 2015 clause 9.4.8.3 requires the report to contain:–

a) a statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to:
   – **the capability of the management system to meet applicable requirements and expected outcomes;**
   – the internal audit and management review process;

b) a conclusion on the appropriateness of the certification scope;

c) confirmation that the audit objectives have been fulfilled.

The certification body shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. (9.4.10).

The report provides evidence to demonstrate that an effective process-based audit has been carried out consistent with the scope of certification.
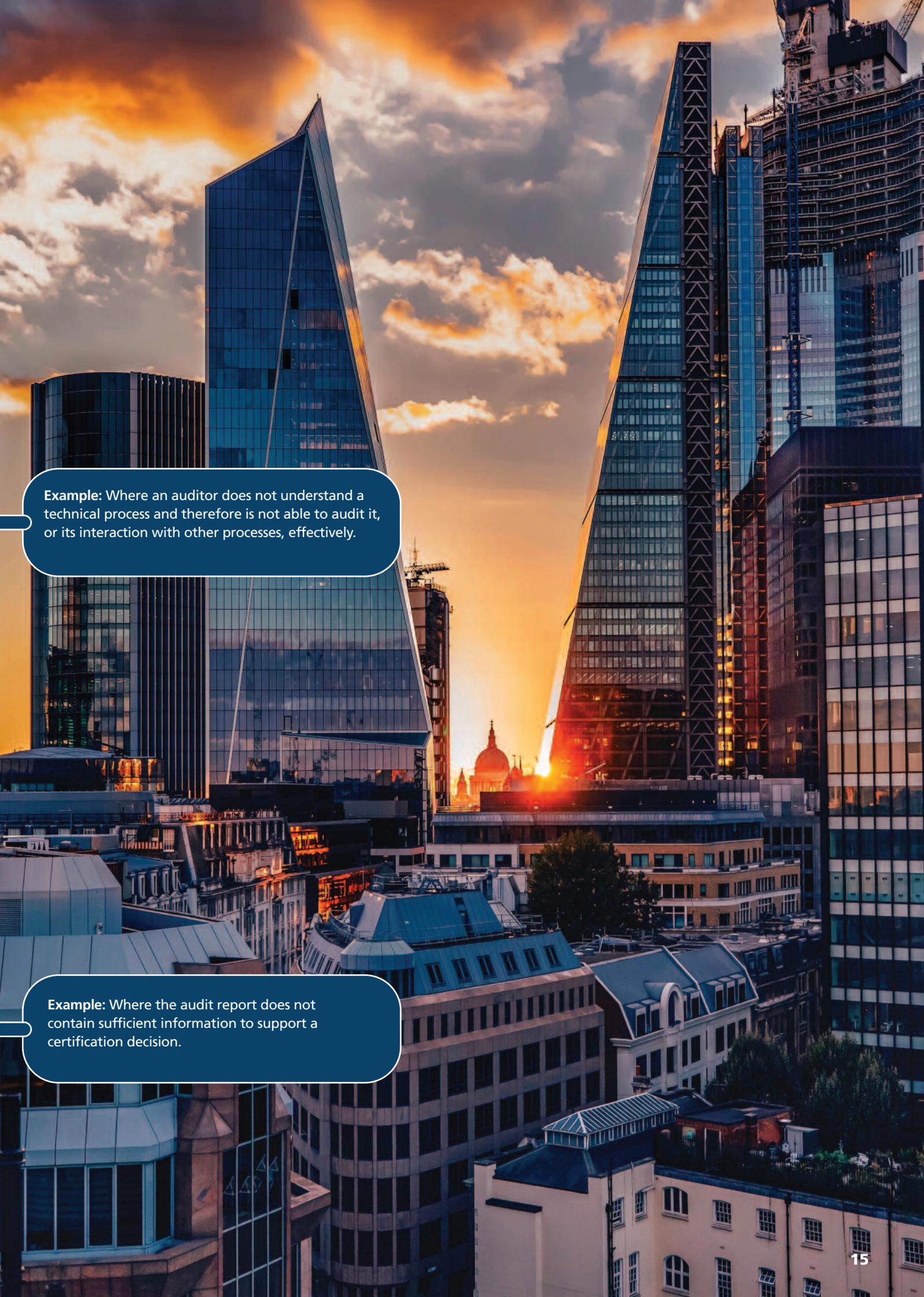
Example: Where an auditor does not understand a technical process and therefore is not able to audit it, or its interaction with other processes, effectively.

Example: Where the audit report does not contain sufficient information to support a certification decision.

Further Reading – Related and Referenced Documents

Expected Outcomes for Accredited Certification to ISO 9001

ISO/IEC 17021-1: 2015 – Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 1: Requirements

ISO/IEC 17021-3: 2017 – Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems

ISO 9001: 2015 – Quality management systems Requirements

ISO 19011: 2018 – Guidelines for auditing management systems

ISO 19443: 2018 – specific requirements for the application of ISO 9001 and IAEA GS-R, requirements by organisations in the supply chain of the nuclear energy sector.

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