ISO 9001 Auditing Practices Group

Guidance on:

AUDITING ISO 9001:2015 IN THE CONTEXT OF A DISRUPTIVE EVENT

Content

Introduction

The 2020 Covid 19 pandemic impacted society and the economy globally, forcing many organizations to adapt and change. For some the consequences were extremely disruptive; for others, there was little or no impact. The type, extent and consequences of the impact varied considerably among different organizations and sectors as well as their state of preparedness to deal with this event.

ISO 9001:2015 introduced the concept of risk-based thinking. It is not prescriptive in defining requirements for how organizations deal with issues related to emergency preparedness or business continuity. However, it does require risk-based thinking in the context of the products and services offered, continuity of processes for provision of products and services in accordance with statutory and regulatory requirements and fulfilment of customer specified requirements.

For third party ISO 9001:2015 audits, an immediate consequence was the need to change the audit program either by postponing the audits or using remote auditing techniques when feasible. Other changes also needed to be implemented such as those regarding safety protocols for auditors and people in the organization in face-to-face audits.

Auditors need to consider the impact of the pandemic in the organization and its quality management system and its processes. They should evaluate how the organization determined the changes needed and implemented the actions planned to ensure "their 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 9001:2015 – 1. Scope).

In this paper we revisit ISO 9001:2015, focusing primarily on the requirements that address risk-based thinking. We picked a few clauses related to areas of the organization where the implementation and management of change may have presented greater or more complex challenges. While looking at the standard in this perspective it is important to bear in mind that the audit shall always follow a process approach. Therefore, these issues should be analysed within the context of the respective processes.

The aim is to guide auditors to aspects of ISO 9001:2015 that might need to be explored in more detail or analysed in the light of a different perspective. This facilitates an auditor's ability to evaluate if the standard is being applied correctly and if it is effectively

implemented to support the organization's ability to deliver the expected outcomes of the QMS.

Furthermore, taking a value-added approach to audit, we point out aspects of the standard where we believe the audit may help to bring awareness to the organization of possibilities for improving its QMS.

1 Before starting
1.1 General

It is very important to define the approach needed for the audit in the context of a pandemic or other disruptive event, both during the emergency period and when dealing with the times that follow.

1.2 Focus on the expected outcomes of the QMS

COVID-19 may impact an organization at many levels: quality, health and safety, environment, finances, etc. Auditors will naturally be confronted with these multiple aspects. In many instances it may be difficult or impossible to differentiate them, as they relate to different disciplines equally. For example, the need to keep an environment safe in a shop, relates both to the safety of workers as to the safety of customers.

During the audit, the auditor should always bear in mind that it is organization's QMS and its processes conformity to ISO 9001:2015 requirements that are being evaluated.

1.3 The organization and its context

ISO 9001:2015 does not explicitly require an emergency or contingency plan.

Nevertheless, many organizations already have contingency plans in place that accommodate a different set of scenarios and actions to be taken when certain events happen. This will depend on many factors, such as the sector in which they operate, the statutory and regulatory requirements, customer requirements, level of maturity of the organization, application of other management system standards, among others.

Some examples of contingency plans that are directly related to the expected outcomes of the QMS are found in companies that are contractually obligated to provide public services that cannot be interrupted, like electricity and water supply, or health services. There are suppliers in certain supply chains that need to guarantee they will not interrupt supply.

Other organizations have already established contingency plans regardless of whether or not they are required to do so by customer or statutory requirements. There are many

organizations who do not have any contingency or emergency plans. They react to the disruptive event as best they can as things unfold.

Either acting according to a plan or in the absence of it, being more proactive or more reactive, more adaptative or more conservative, a certified organization should have a QMS in place that enables it to determine the risks and opportunities, make their decisions, determine, and plan the actions to take, monitor and take actions to improve.

1.4 Auditor mindset

The auditor needs to allow for flexibility to understand the evolving internal and external context, empathizing with the auditee, while at the same time evaluating conformity to ISO 9001:2015 requirements. The auditor's challenge is to gather adequate evidence to reach valid conclusions on the conformity of the QMS and its ability to continue to deliver the expected outcomes.

In a value-added approach to a third-party audit, the audit should provide useful information for the organization regarding:

- "it's ability to meet strategic objectives;
- identifying problems which, if resolved, will enhance the organization's performance;
- identifying improvement opportunities and possible areas of risk (…);
- enhancing the organization's ability to provide conforming products and services (…)" (Value added APG paper, adapted)

2 Exploring Standard Requirements
2.1 General

In this part of the paper we share our thoughts on the standard requirements that appear to require a particular or different focus. In the COVID 19 context (or comparable disruptive event) two factors warrant consideration:

- The requirements that define how an organization needs to address change
- The requirements related to activities and processes that are more likely to be impacted by the pandemic.

Response to these changes, if applied correctly, will support the organization in this period. It may also lead to additional organizational improvements. With this, we hope to inspire auditors rather than imposing a specific audit plan. And, by pointing to specific

clauses and requirements we are not abandoning the process approach. The starting point is understanding the organization's QMS and its processes.

2.2 Risk Based Thinking

Whether taken by surprise or reacting according to a plan, ISO 9001:2015 sets requirements to deal with context and its changes.

The risk-based thinking concept needs little explanation, as it is at the core of the changes introduced in the 2015 edition. The following picture displays an overview of the risk-based thinking while the second identifies main aspects to analyse within the different clauses of the standard.

Figure 1 - CIR: Context, Interested Parties, and Risks

Figure 2 – ISO 9001 approach to changing CIR circumstances

CONTEXT	Interested Parties	IMPACT ON THE ORGANIZATION AND ITS QMS	Planning Changes
• Changes in External context • Changes in Internal context	• New Interested Parties • Changes in Requirements • New Requirements	• New Risks • New Opportunities	• Consequences • Management System Integrity • Resources • Responsibilities and authorities

2.3 Context

Changes in Context will vary considerably. The following table highlights some of the most probable changes that organizations face in this context.
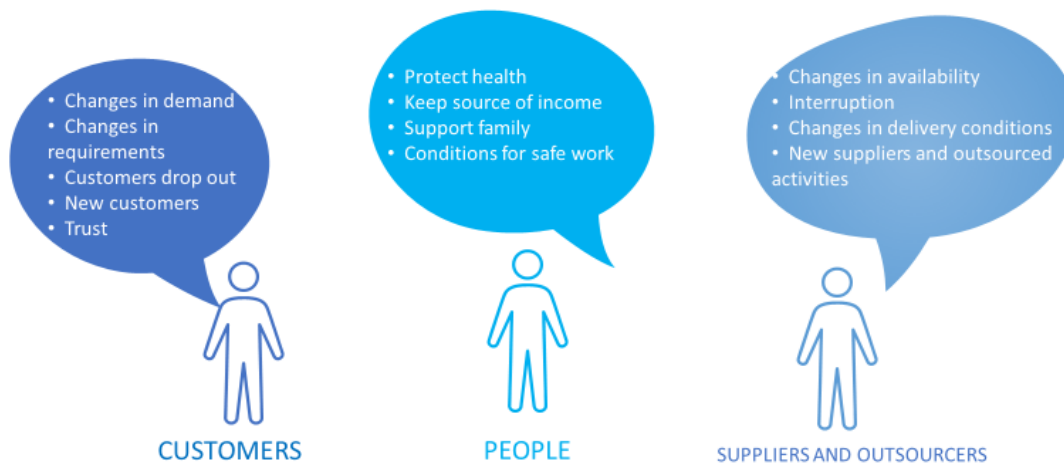
Table 1 – Probable Changes in Context due to COVID 19

External	Internal
• Level of uncertainty • Demand for products and services • Supply chain • Distribution chain • Statutory, regulatory or customer requirements	• Level of uncertainty • Absenteeism • Physical distance • Remote work • Constraints or changes to processes • Infrastructure & other resources • Competencies required

2.4 Needs and Expectations of Interested Parties

Besides changes in legal requirements that directly or indirectly affect the organization's ability to consistently provide its products and services, the auditor needs to evaluate how the organization identified changing needs and expectations from interested parties.

Interested parties themselves might change, as new customers arrive while others interrupt demand. Changes in requirements for the products and services, packaging, or delivery methods are likely to occur that can lead to new suppliers (e.g. delivery by post office, alternative routes, new suppliers). Requirements from statutory and regulatory interested parties also need to be considered.

Figure 3 - Needs and Expectations from Interested parties

CUSTOMERS
- Changes in demand
- Changes in requirements
- Customers drop out
- New customers
- Trust

PEOPLE
- Protect health
- Keep source of income
- Support family
- Conditions for safe work

SUPPLIERS AND OUTSOURCERS
- Changes in availability
- Interruption
- Changes in delivery conditions
- New suppliers and outsourced activities

2.3 Dynamics in Context, Interested Parties, and Risks

Changes due to a pandemic can evolve dynamically and necessitate that organizations frequently monitor their context to determine new risks and opportunities.

Auditors should also be aware that, as Covid-19 is a disruptive global event, it is likely that some organizations will feel the need to enlarge the scope of their analysis, far beyond the usual environment in which they operate, e.g. to look at trends, new markets, new products, different applications of their products and services.

As stated in the Introduction of ISO 9001:2015 "Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation, and re-organization."

When analysing the impact on the organizations' QMS it might be interesting to explore how the organization is determining the impact of changes to the QMS at different time horizons:

Short term – immediate consequences of the pandemic, reaction, adaptation to circumstances, changes in operations, keeping integrity of the QMS;

Medium to long term – moving out of the pandemic, changes introduced or going back to previous "normal", changes in the strategic direction, structural changes in the organization, lessons learned from the event and improvements in the QMS. Was the QMS prepared for this? Does it support the organization? If not, what has the organization missed? How can it be improved? Although it might be too soon to evaluate possible changes in the longer term, for a value-added perspective of auditing a QMS, it might be interesting to explore how the organization is anticipating changes and looking at how its quality management system can help deal with the changes.

3 Dealing with changes

Dealing with changes is addressed in several clauses of the standard but it is in 6.3 *Planning of changes* that organizations are required to carry out changes in a planned manner, and points to the main issues to be considered. Of particular significance is the guidance in 6.3 (b) to consider the integrity of the quality management system.

Table 2 indicates which other clauses besides 6.3 Planning of Changes, where control of changes is addressed. This can help the auditor to evaluate the organization's QMS by indicating where more changes are expected.

Table 2 – ISO 9001:2015 clauses addressing the control of changes

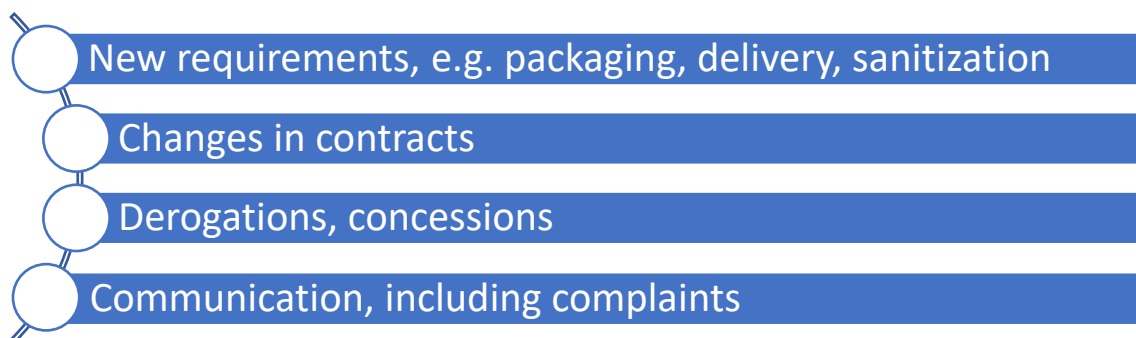| Clause	Issue
4.4.1 Quality management system and its processes g)	Change processes when needed to ensure they can achieve the intended results
5.3 Organizational roles, responsibilities, and authorities	Assignment of responsibilities and authorities to ensure integrity of the QMS when changes are planned and implemented
6.3 Planning of Changes	Implement changes in a planned manner (see risk-based thinking)
7.5.3.2. Control of documented information	Control of changes in documented information
8.1 Operational planning and Control	Control planned changes, review consequences of unintended changes and take action to mitigate any adverse effects

8.2.3 Review of the requirements for products and services (8.2.3.2)	Retain documented information on any new requirements for the products and services
8.2.4 Changes to requirements for products and services	Amend relevant documented information and make relevant people aware
8.3.6 Design and development changes	Identify, review and control changes to ensure there is no adverse impact on conformity to requirements
8.5.6 Control of changes (of Control of production and service provision)	Need to review and control changes in the production and service provision

4 Customers, products, and services

Customer requirements may change as a consequence of the pandemic and auditors will need to evaluate how they were addressed. The conditions for the provision of products and services by the organization may also change, which implies a need to communicate with customers and agree on new requirements and conditions.

During emergency situations, and even after them, with changes in order and delivery methods, complaints might increase or reveal inefficiencies in the organization's processes. The way the complaints are addressed by the organization, both in their treatment and for the analysis of any underlying potential nonconformities or need for improvements, will provide valuable information about the organization's QMS.

Figure 4 – Customers & requirements for products and services

New requirements, e.g. packaging, delivery, sanitization

Changes in contracts

Derogations, concessions

Communication, including complaints

5. External Providers

During pandemics or other disruptive events, there are also likely to be problems for the organization's suppliers or other eternal providers. This will affect the provision of products and services to the organization and impact its ability to provide its own products and services. Consequently, the processes related to purchasing and outsourcing need to be audited carefully. Auditing the requirements of clause 8.4 *Control of externally provided processes, products and services* will provide a good insight for a thorough analysis of changes due to this issue.

6 Resources: People, work environment, infrastructure

The measures taken to protect people from COVID-19 are likely to be ones that impact almost all organizations: safety and travel restrictions, closing operations, remote work, reorganization of working teams (e.g. fixed shifts where people do not rotate, to prevent the probability of cross contamination), etc. These often imply changes in the infrastructure and work environment, either by changes in the workplace or by application of remote work.

The impact on operations and the ways organizations adapt while delivering the expected outcomes of the QMS needs to be evaluated. Resources tend to be evaluated thoroughly at initial and reassessment audits and on a sample basis along the audit program, but in such situations, it is important to evaluate if any changes introduced impacted the QMS.

In a crisis situation with a lot of uncertainty, and as a lot of work is now being done remotely, with many people now working from home or other remote locations, the physical and psychological factors of the work environment might need specific consideration.

6 Competence

An auditor should determine whether the disruptive event has caused any changes in competence requirements for the organization's people. If applicable, were they prepared to do remote work? Do they need specific training? Did the organization identify opportunities for the development of competencies?

7 Design and development and possible scope changes

As requirements for products and services may change (and need to be communicated, agreed with the customer and documented, as stated in 8.2 *Requirements for products*

and services), this may require changes in the design and development of the organization's existing offerings.

There have been numerous examples during the Covid 19 crisis of organizations making significant changes in their product offerings, e.g. textile companies changing to producing masks or other safety equipment for hospitals, or automotive companies changing to producing medical ventilators. Such major changes in product offerings, involving considerable changes in design and development, needs to be examined carefully. Particular focus should be given to examining the determination and application of legal requirements for the new offerings, or on whether the organization has changed or not fully applied its existing design and development processes. This may also lead to a change in the organization's scope for its QMS that needs to be evaluated.

8 Production and Service Provision

As changes in requirements, supply chains, or contractors might have occurred, control of product and service provision needs to be carefully audited, to evaluate that production and service provision is being performed under controlled conditions and according to any changes introduced. This will include a look at the control of nonconforming outputs.

Special consideration should be given to property belonging to customers or external providers. This is especially important if the organization needs to outsource production and service provision, or if remote work poses a challenge for ensuring data protection.

9 Lessons learned and Improvement

The Covid 19 pandemic poses a challenge for many organizations to change and adapt to the new circumstances, address new risks, or pursue opportunities. Ultimately, auditors need to evaluate how organizations capture the lessons learned (both from what went right and what went wrong) and improve their QMS.

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.

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