Common Nonconformities when Certifying to Management Systems Standards

State of Transitions 2018

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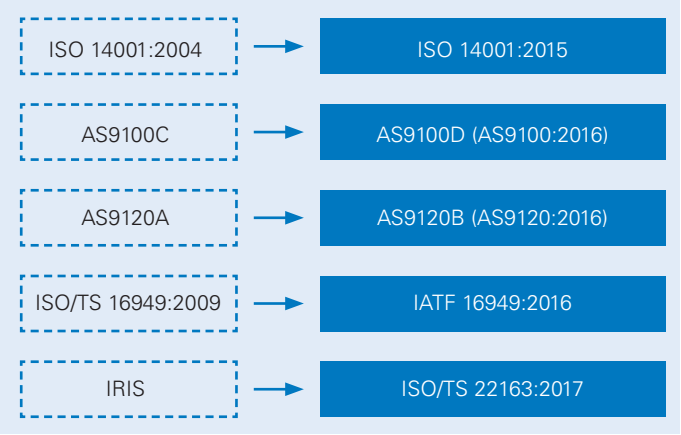
Executive Summary

2018 represents a major milepost within the Management System Certification spectrum, with changes to management system standards across all manufacturing and service industries including aerospace, automotive and railway manufacturers, as well as environmental management and occupational health and safety.

The most significant defining moment occurs on September 14, 2018, which marks the end of the three-year transition period from the ISO 9001:2008 standard to the 9001:2015 revision. After that date, ISO 9001:2008 certificates will no longer be valid. If your organization is currently ISO 9001 certified and has not transitioned to ISO 9001:2015 by then, you put yourself at risk of losing business and market access.

The transition date for 9001 casts a ripple effect across the entire sphere of quality management, as multiple standards are based on the ISO 9001:2015 structure and share the same transition deadline. These include:



All of these certificates likewise become invalid on Sept. 15, 2018 if you have not been certified against the most recent version of the standard.

At the same time, 2018 marks the beginning of wholesale changes in the world of occupational safety. An entirely new standard, called ISO 45001:2018, was published in March, 2018 to replace and supersede OHSAS 18001. The availability of ISO 45001 comes with its own three-year transition period, and there are many additional criteria you'll need to understand before making the switch.

This paper will provide you a summary of the most common nonconformities that may be holding organizations up as they make the transition to revised versions of QMS standards. We will also preview the upcoming planned obsolescence for OHSAS 18001.

Nonconformity Hotspots, Standard by Standard

As TÜV Rheinland continues to transition its clients to the new standards, a number of common nonconformities tend to catch organizations off-guard as they complete the transition ahead of the September deadline. We have identified the most common missteps below, broken out by specific standard, as well as efficient corrective actions your organization can take to put themselves in the best possible position to certify to the revision without undue delay.

ISO 9001

ISO 9001 was developed as an international standard of uniform requirements to assist any organization in any industry with establishing, maintaining, and continually improving a comprehensive quality management system (QMS) to better meet the needs of their customers. The standard provides guidance on defining policy and objectives, monitoring and measuring processes and product characteristics, specifying corrective and preventative actions, and encouraging continual improvement.

Organizations operating under ISO 9001:2015 tend to get hung up while attempting to conform with several of the key new clauses. Namely:

- Not addressing new requirements to a) identify and define interested parties and b) monitor and measure processes.
- Internal and external issues are missing from risk evaluations.
- Organizations are ineffectual at capturing organizational knowledge, including insufficient document control and records retention.
- There is inadequate inspection and ill-defined processes for approving and disqualifying vendors.
- Management review records do not include a list of actions taken to mitigate risk.

Self-checking can be as easy as a yes-or-no answer. To address the above issues, ask yourself the following questions before going into a certification audit and, if the answer is "no," do what needs to be done to turn the answer to "yes."

☐ YES ☐ NO Is the organization still maintaining Documented Procedures?

☐ YES ☐ NO Has the organization identified both internal and external issues and interested parties that are relevant to and/or support the strategic direction of the organization?

☐ YES ☐ NO When establishing the QMS and planning for change, have risks to achieving process objectives been identified?

☐ YES ☐ NO Is the organization using Key Performance Indicators (KPIs) to analyze the effectiveness of actions taken to address risks?

☐ YES ☐ NO Following corrective action, is there evidence that process risks have lessened?

☐ YES ☐ NO Have risks to achieving product or service conformity been:

- considered as part of the planning for operational control?
- considered when determining and reviewing customer requirements?

☐ YES ☐ NO Has the organization established criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?

ISO 14001

The ISO 14001 international environmental management system standard provides a systematic approach to assist organizations with identifying, controlling, and preventing potentially hazardous incidents, reducing the risk of legal liabilities. This standard provides clear, operational sequences and responsibilities for a functional environmental management system, balancing an organization's economic and environmental interests.

For ISO 14001, organizations seem to struggle most with two key matters:

- Providing sufficient evidence of leadership involvement; and
- Failing to include suppliers and regulatory agencies within the "Context of Organization"

In the march toward your 14001:2015 certification audit, you must not only ensure an answer of "yes" to the following questions, but also be prepared to provide evidence proving conformity.

☐ YES ☐ NO Has the organization determined the list of internal and external issues relevant to its purpose, including environmental conditions affected by or capable of affecting the organization?

☐ YES ☐ NO Has the organization determined which interested parties are relevant to the Environmental Management System (EMS), including the relevant needs and expectations of these parties it will adopt as compliance obligations?

☐ YES ☐ NO Is the strategic direction and context of the organization used as an input across the Management Review processes for Environmental Policy, Objectives, Addressing Risks and Opportunities, and Planning?

☐ YES ☐ NO Are environmental objectives and intended outcomes incorporated into business processes? Are they being properly monitored and controlled, and updated in response to changes?

☐ YES ☐ NO Does the organization have a closed loop process from the corrective action process back to risk identification and review?

AS9100

The aerospace industry includes three separate AS91xx standards to cover all sectors of the industry. AS9100 is the main quality management system standard for aerospace products and services. AS9120 focuses on distribution only and AS9110 is for aircraft maintenance organizations. Certification to any of the above standards requires registration to the OASIS database (Online Aerospace Supplier Information System) of the International Aerospace Quality Group (IAQG).

The great majority of nonconformities found during AS9100:2016 transition audits seem to fall within four main categories, namely:

- Incomplete implementation of risk-based thinking;
- Inadequate understanding of how to treat interested parties and external providers;
- Inadequate attention to product safety; and
- Procedural mistakes during internal audits and management review

Organizations in the midst of transition should pay particular attention to these new clauses and requirements and make sure their QMS processes address these issues.

NEW CLAUSES AND REQUIREMENTS

4.4.2 – Failure to define Interested Parties, as well as the needs and expectations of Interested Parties.

4.4.2 – Scope of QMS does not define the physical boundaries.

4.4.1 g – QMS processes are not being measured for performance against established targets, and actions are not being taken when planned results are not achieved.

6.1.2 – Actions to address Risk and Opportunities are not adequately determined or planned.

6.2.2 – Quality Objectives are well-defined, but specific actions to achieve them do not address requirements of the clause.

8.1.3 – Product Safety is not adequately defined and implemented in QMS.

8.4.1 – External providers evaluation and selection process is only partially effective. The criteria that's established is not risk based and/or not effectively implemented.

8.4.2 – When incoming material is accepted based on test reports, the verification process fails to evaluate test results against product requirements.

8.4.3 – Purchasing information to external providers does not include all Aerospace standard requirements.

8.7.1 – Process for control of non-conforming output does not adequately define responsibility and authority for the review and disposition. Additionally, the process does not define a method for approving appropriate personnel to make these decisions.

9.2.1 a.2 – Internal Audit planning and reporting do not adequately demonstrate conformity to AS9100 rev.D.

9.3.2 – Management review input does not demonstrate reviews included in new AS9100 Rev.D criteria such as c-7, d or e.

9.3.3 – Management review process outputs do not show how decisions and actions relate specifically to the identified risks.

IATF 16949

The International Automotive Task Force (IATF) created the harmonized international automotive supply chain standard ISO/TS 16949, providing a framework for reducing defects and waste in the industry through continuous improvement. Any supplier who provides a component or system that ends up in an automobile must be certified, along with any automotive supplier who is contractually required by an automotive OEM to be certified.

As we enter the final stretch to the Sept. 14 deadline for transition to IATF 16949:2016, major nonconformities are most commonly found in the areas of:

- Risk-based thinking
- Understanding what total productive maintenance means
- Understanding the implications of control plan
- Addressing contingency plans
- Internal audit procedures

Specifically, organizations in the midst of transition to IATF 16949:2016 tend to:

- Lack a structured approach to risk management, and more specifically fail to produce evidence of actions taken to address risks where identified;
- Inadequately address the clause for repair and rework controls and the reuse of sub components;
- Only partially address the contingency planning clause, with a lack of evidence showing proper testing and prioritization based upon risk to the customer; and
- Misunderstand the supplier management and development clause, especially where and when second party audits shall be performed.

To correct these deficiencies, IATF 16949 organizations should take the following actions:

- Read the standard in its entirety.
- Confirm that your risk process follows through with a full Plan-Do-Check-Act (PDCA) cycle.
- Pay particular attention to the repair and rework clause so that all internal parties understand its implications.
- Prior to the certification audit, deploy your contingency test plan and have evidence of its effectiveness in place.
- Read Chapter 4 in its entirety on supplier management and development and confirm that all the “shall statements” in the various clauses are addressed. Chapter 4 is somewhat disjointed because it not only includes concepts introduced in ISO 9001:2015, but also combines all-new issues unique to the automotive supply industry, so it must be read very carefully.

ISO/TS 22163

As of September 14, 2018, the railway industry's management standard IRIS is replaced by ISO/TS 22163:2017 as a way to make processes faster, more effective, and more cost-efficient for companies that develop or manufacture railway products, perform maintenance work on railway vehicles or work with signaling technology.

Specific benefits of ISO/TS 22163:2017 certification include:

- A QMS specifically designed to address railway sector nuances
- Enhanced ability to fulfill requirements for supplier approval
- Increased quality standards
- Gain competitive advantage in international markets with an internationally recognized certificate
- Systematically ensure customer satisfaction
- Reduce liability risks
- Replace multiple, costly certifications with a single certification
- Increase chances of being awarded a tender
- Addition to the IRIS database to improve international recognition/exposure

Importantly, all organizations with an existing IRIS registration must transition to ISO/TS 22163:2017 by September 14, 2018, and certifications can only be granted by independent certification bodies such as TÜV Rheinland.

From OHSAS 18001 to ISO 45001 - What does ISO 45001 mean for safety leaders?

On March 12, 2018, the International Organizations for Standardization published an entirely new standard, ISO 45001, which outright replaces and supersedes OHSAS 18001. Here's what you need to know.

Similar to most standard transitions across the ISO landscape, there will be a three-year transition period for conversion to ISO 45001, making the transition deadline March 11, 2018 based on the initial publication date.

ISO 45001 borrows from upstream updates to ISO 9001, which engender a more proactive approach to risk control. In this way, 45001 leaves the more reactive approach of OHSAS 18001 behind. One can most clearly see this outdated feature in 18001's reliance on delegating tasks like hazard control to safety management personnel, rather than integrating the responsibilities into the overall management system of the company. This is a key change of pace.

The new standard also focuses much more intently on managerial ownership, with commitment from top management being central to the standard's effectiveness and integration. It all starts by incorporating employee health and safety mechanisms into the overall management system, and members of an organization's C-Suite will be compelled to play an active role to ensure protection of their workers, as well as performance improvements, under the new ISO 45001.

By the same token, ISO 45001 provides broader latitude for workers themselves to implement and continuously improve an organization's safety management system (SMS). Under the standard, employees will be trained and educated to spot safety risks and participate in remediation activities. Safety management more clearly belongs to everyone in the organization with ISO 45001.

BENEFITS OF ISO:45001:2018 CERTIFICATION

- Demonstrate commitment to occupational health and safety with an internationally recognized certificate, securing a competitive advantage among interested parties
- Increase safety awareness and engagement among employees
- Systematically reduce occupational hazard incidents
- Prevent business disruptions and unnecessary downtime
- Improve your brand image among clients, authorities, and investors
- Increase confidence in the fulfillment of legal and other compliance requirements
- Achieve closer alignment with other ISO standards and business systems, streamlining both inter- and intra-organization communication

TÜV Rheinland is your Transition Partner for Management Systems Certifications

2018 is a critical year for companies with Management System Certification. TÜV Rheinland is a globally-recognized leader in independent inspection services, with over 500 locations around the world. Our audits are not about just identifying nonconformities — we offer additional services to help companies prepare for the changes or to become certified for the first time.

TÜV Rheinland's partnership-approach to audits include pairing auditors with clients based on industry experience. Our auditors do more than point out gaps in your Management System, sharing industry best-practices to give you every opportunity for improvement. We understand that there is a difference between how a small- or medium-sized business operates and how a large organization with several locations and hundreds of employees operates, and we tailor every audit experience accordingly.

To contact your TÜV Rheinland representative for a quote, or for more information, call 1-888-743-4652 or send an email to info@tuv.com.

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