SAT-2B.412-2-EM1-04

RAILWAY QUALITY MANAGEMENT SYSTEMS – PAST, PRESENT, AND FUTURE TRENDS

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Abstract: *The purpose of this paper is to highlight the recent trends in quality management systems, and in particular – the quality management systems in the railway sector. These systems are based on the popular ISO 9000 series of standards, and more specifically- on the requirements of ISO 9001:2015. The latest standard ISO 22163:2023 for quality management systems in the railway sector is the heir to ISO/TS 22163:2017 which was also based on ISO 9001:2015 and expanded it with industry-specific requirements. This paper presents the main changes between the two editions of ISO 22163 and outlines some key issues and opportunities to be considered when implementing quality management system requirements, methods, and tools in the railway sector.*

Keywords: *Quality Management Systems, Railway Sector, ISO 9001, ISO 9000 Series of Standards, ISO 22163*
JEL Codes: *L15, L62, L92, O31*

INTRODUCTION

Quality managements systems are an indispensable tool for the top management of any organization. They support the achievement of the organization's strategic direction, mission, vision, and quality policy. The international standardization of quality management systems dates back to 1987 when the first edition of ISO 9001 was published. Since then, this standard has undergone 4 revisions, and its latest edition is of 2015. In 2021 it has been confirmed as relevant to the current context and remains a valid model for establishing a quality management system. According to the latest results of the ISO Survey of management systems standards, the number of ISO 9001 certificates leads by a significant margin the certified organizations for compliance with ISO 14001 for environmental management systems, ISO 45001 for occupational health and safety management systems, and many other standards specifying requirements for management systems in various domains and sectors.

Two distinct approaches have been applied when this standard is adopted to various industry sectors:

- Adding supplementary requirements after the basic requirements of ISO 9001;
- Integrating the supplementary requirements within the text of the standard.

The approach selected for the railway sector and more specifically- ISO/TS 22163:2017, is to use the structure and requirements of ISO 9001:2015, and then to add specific requirements for the railway sector. Recently, the second edition of ISO 22163 had introduced more updates that define the true meaning of quality management systems in the railway sector.

EXPOSITION

The Past - Comparison of ISO 9001:2015 and ISO/TS 22163:2017

The structure of management systems standards introduced by Annex SL in 2012, and implemented in ISO 9001:2015 has been expanded in ISO/TS 22163:2017 (ISO, 2017).

Both standards have an identical introduction and normative references. The first difference is that ISO/TS 22163:2017 adds supplemental comments on the scope by highlighting the applicability to the railway sector, focusing on continual improvement, defect prevention and reduction, safety aspects, and also enhancing and sustaining quality.

On top of the typical quality management terminology, the Technical Specification ISO/TS 22163:2017 further details 42 terms and definitions for the rail sector, as well as 13 abbreviations with their explanation.

Clause 4 "Context of the organization" has just one supplementary element which is an expansion of the requirements of ISO 9001:2015 (ISO, 2015). This is a set of requirements for the minimum documentation of processes "in procedures, instructions, method descriptions, flowcharts or workflows etc., supported by application software and templates".

Clause 5 "Leadership" begins in the same way for both standards in chapter 5.1 "Leadership and commitment". There are two key additions to 5.2 "Policy":

- the requirement to address failure prevention and customer expectations in the quality policy, and
- the requirements to establish, implement, maintain and communicate a safety policy.

Clause 5.3 "Organizational roles, responsibilities and authorities" is expanded with requirements to appoint and empower process owners.

The only element of Clause 6 "Planning" that remains unchanged is 6.3 "Planning of changes". Chapter 6.1 "Actions to address risks and opportunities" further details the requirements with having a documented risk management process, possibly applying FMEA and/or FMECA, and also establishing a contingency plan upon evaluation of business risks. The safety policy, established in Clause 5.2.4 may serve as a basis for establishing safety objectives in Clause 6.2.3. A totally new element is Clause 6.4 "Business planning" which has to be documented and reviewed annually.

Clauses 7.1.2, 7.1.3, 7.1.4, and 7.4 are directly borrowed from ISO 9001:2015. However, there are supplemental requirements for the following clauses:

- 7.1.1 "General": a documented process for budget planning, approval and controlling;
- 7.1.5.3 "Monitoring and measuring resources — Supplemental": a documented process for verification or calibration, or both of monitoring and measuring resources;
- 7.1.6.1 "Organizational knowledge — Supplemental": additional requirements for return of experience, best practices and lessons learnt (learned), knowledge sharing, transfer, management and relevant software to be used;
- 7.2.1 "Competence — Supplemental": a documented process for competence management;
- 7.3.1 "Awareness — Supplemental": there is a requirement for awareness of the safety policy and objectives in addition of awareness of the quality policy and objectives;
- 7.5.3.3 "Control of documented information — Supplemental": a documented process for the control of documented information.

The biggest number of additional requirements to the core elements of ISO 9001:2015 are introduced in Clause 8 "Operations". It may seem that only the clauses after 8.7 are new:

- 8.8 Reliability, Availability, Maintainability, Safety / Life Cycle Costing (RAMS / LCC);
- 8.9 First article inspection (FAI);
- 8.10 Obsolescence management;
- 8.11 Innovation management: this clause requires that the organization establishes a documented process to manage innovation of new products, services and technologies. A best practice and guidance for innovation management can be the ISO 56000 series of standards, and more specifically ISO 56002:2019 (ISO, 2019).

A more in-depth analysis uncovers additional requirements in:

- Clause 8.1 "Operational planning and control" which has been significantly expanded by adding to the original text of ISO 9001:2015 the following elements: 8.1.1 "Planning for the outsourcing or transfer of processes", 8.1.2 "Tender management", 8.1.3 "Project management" (containing 9 sub-chapters), 8.1.4 "Configuration management", and 8.1.5 "Change management";
- Clause 8.2 "Requirements for products and services" has supplementary requirements in 8.2.1.1 "Customer communication", 8.2.2.1 "Determining the requirements related to

products and services", and totally new sub-chapter 8.2.5 "Requirements for products and services — Supplemental";

- Similar is the case with Clause 8.3 "Design and development of products and services" for which supplementary requirements are included in: 8.3.1.1 "General", 8.3.2.1 "Design and development planning", 8.3.3.1 "Design and development inputs", 8.3.4.1 "Design and development controls", and 8.3.5.1 "Design and development outputs". Interestingly, elements typical for the design and development method "Advanced Product Quality Planning" and one of the "5 Core Tools" in the automotive industry are also included in Clause 8.4.3, i.e., 8.3.4.2 "Design reviews", 8.3.4.3 "Design verification", and 8.3.4.4 "Design validation";
- Many additional requirements are also added to Clause 8.4 "Control of externally provided processes, products and services". They are specified in: 8.4.1.1 "General — Supplemental" (including 8.4.1.1.1 "Classification of external providers and external provided products, process or service", 8.4.1.1.2 "Evaluation of external providers", 8.4.1.1.3 "Approval of external providers", 8.4.1.1.4 "External provider offer selection"), 8.4.2.1 "External provided products, process or service approval of release", 8.4.2.2 "External provided products, process or service verification after release", 8.4.2.3 "Monitoring of external provider performance, re-evaluation and ranking", and 8.4.3.1 "Information for external providers — Supplemental". An entirely new element to the requirements of ISO 9001:2015 is the Clause 8.4.4 "Supply chain management";
- The core process in any quality management system- Clause 8.5 "Production and service provision" has supplemental requirements in: 8.5.1.1 "Control of production and service provision" (including 8.5.1.1.1 "Controlled conditions", 8.5.1.1.2 "Verification of the process for production and service provision", and 8.5.1.1.3 "Validation of the process for production and service provision"), 8.5.2.1 "Identification and traceability", 8.5.3.1 "Property belonging to customers or external providers", 8.5.4.1 "Preservation", and 8.5.5.1 "Post-delivery activities". Entirely new are the clauses 8.5.1.2 "Special processes", 8.5.1.3 "Production equipment", and 8.5.7 "Production scheduling".
- There is one new sub-clause to Clause 8.6 "Release of products and services", namely 8.6.1 "Release of products and services — Supplemental";
- The last largely common element with ISO 9001:2015- Clause 8.7 "Control of nonconforming outputs" also has one addition- 8.7.3 "Control of nonconforming outputs — Supplemental".

Clause 9 "Performance evaluation" has supplemental requirements in: 9.1.1.1 "General", 9.1.2.1 "Customer satisfaction", 9.1.3.1 "Analysis and evaluation", 9.2.3 "Internal audit" (including 9.2.3.1 "Audit programme" and 9.2.3.2 "Auditors management"), 9.3.1.1 "General", 9.3.2.1 "Management review inputs", and 9.3.3.1 "Management review outputs". A set of new requirements is stated in 9.4 "Process reviews". The reviews for the mandatory processes shall be every 12 months and shall include review of KPI target achievement.

The last Clause 10 "Improvement" basically remains identical to the same clause in ISO 9001:2015, with the only addition being Clause 10.2.3 "Nonconformity and corrective action — Supplemental" that requires the establishment of a documented process for managing nonconformities and corrective actions.

The Present - Comparison of ISO/TS 22163:2017 and ISO 22163:2023

The main changes of this standard are listed in the foreword of ISO 22163:2023 (ISO, 2023). In more detail they are:

- the terms and definitions have been expanded (from 42 to 64);
- the number of abbreviated terms has been increased from 13 to 19;
- Clause 4 "Context of the organization" has been augmented with 4.1.1 "Understanding the organization and its context - Supplemental" which now contains Clause 6.4 of ISO/TS 22163:2017 ("Business planning"), a new Clause 4.1.2 "Social responsibility", 4.3.1

"Determining the scope of the quality management system - Supplemental", and 4.4.3 "Quality management system and its processes - Supplemental";

- Most of Clause 5 "Leadership" remains unchanged. The previously listed 5.2.4 "Safety policy" is now integrated in 5.2.3 "Quality policy - Supplemental".
- In addition to the abovementioned change in the position of Clause 6.4, the main changes in Clause 6 "Planning" are the elimination of 6.1.4 "Contingency planning" from ISO/TS 22163:2017 and its replacement by 6.1.4 "Business continuity" in ISO 22163:2023. Clauses 6.2 "Quality objectives and planning to achieve them" and 6.3 "Planning of changes" are now identical with those in ISO 9001:2015, thus 6.2.3 "Safety objectives" has been removed from ISO/TS 22163:2017;
- Basically, the only structural changes to Clause 7 "Support" are the deletion of 7.3.1 "Awareness — Supplemental" and the addition of 7.4.1 "Communication – Supplemental";
- Clause 8 "Operations" has been subjected to many changes. Subclause 8.11 "Innovation management" from ISO/TS 22163:2017 has been brought to the forefront and now is 8.1.1.1 "Innovation management". The expanded view of 8.1.3 "Project management" in the railway sector is shown on Fig. 1 where 8.1.3.11 "Project review management" has been separated from the previous subclause 8.1.3.7 "Project communications management". Clause 8.1.4 "Configuration management and change control" now combines clauses 8.1.4 "Configuration management" and 8.1.5 "Change management" of ISO/TS 22163:2017. There is an added subclause 8.3.4.5 "Design verification and validation test requirements" to 8.3 "Design and development of products and services". Yet another addition to 8.4 "Control of externally provided processes, products and services" is subclause 8.4.2.1.2 "Approval of release for new or modified Externally provided products, processes and services (EPPPS) should consider". Clause 8.8 "Reliability, availability, maintainability, safety and life cycle costing" has been subdivided into: 8.8.1 "General", 8.8.2 "Reliability, availability and maintainability", 8.8.3 "Safety", and 8.8.4 "Life cycle costing". There are no major changes in the structure of Clauses 8.9 through 10.3;
- Three annexes have been added: Annex A "List of processes", Annex B "Subordinate concept of requirements for products and services" and Annex C "Performance indicators".

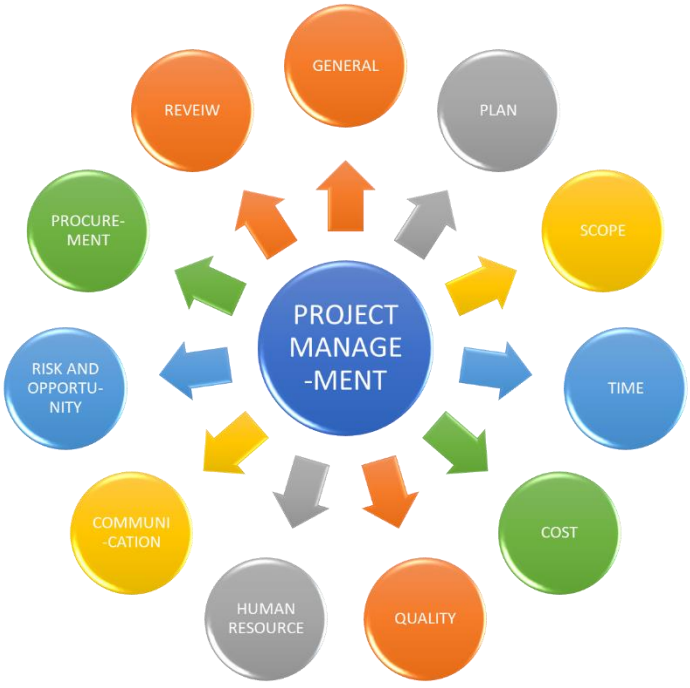

Fig. 1. Project management in the railway sector

The future – Integrating ISO 22163:2023 with other management systems standards

The standard ISO 22163:2023 continues the tradition of ISO 9000:2015 (ISO, 2015) and ISO 9001:2015. As such, it is bound to seek coherence with ISO/TS 9002:2016 (ISO, 2016) and ISO 9004:2018 (ISO, 2018). The maturity model proposed in Annex A "Self-assessment tool" needs to be carefully analyzed for similarity between ISO 9001:2015 and ISO 22163:2023 processes. For the outstanding differences, best practices in the railway sector have to be scanned and adapted, or even reimagined and invented, to match the 5 maturity levels used in ISO 9004:2018 (Babekova et al, 2022). When this is successfully done, the reports from such maturity analysis will be used as inputs for top management reviews and for further improvement of the quality management system in the railway sector.

Another expected development is to adapt the guidance from the standards ranging from ISO 10001 to ISO 10020 to the railway sector:

- ISO 10001 through ISO 10004, and ISO 10008 for customer satisfaction;
- ISO 10005 for quality plans;
- ISO 10006 for quality management in projects;
- ISO 10007 for configuration management;
- ISO 10009 for quality tools and their application;
- ISO 10010 for quality culture;
- ISO 10012 for metrology (ISO, 2003);
- ISO 10013 for documented information;
- ISO 10014 for financial and economic benefits;
- ISO 10015 for competence management and people development;
- ISO 10017 for statistical tools (ISO, 2021);
- ISO 10018 for people engagement;
- ISO 10019 for the selection of quality management system consultants and use of their services;
- ISO 10020 for change management, etc.

CONCLUSION

Chronologically, quality management systems in the railway sector are based on ISO 9001:2015. The paper has successfully highlighted the main additions to the requirements of ISO 9001:2015 in ISO/TS 22163:2017, which represent an expansion from 29 to 69 pages of the core text of the standard. Attention is drawn to the key differences between the 2017 edition and the latest revision of ISO 22163 published in 2023. Furthermore, some supporting standards can be used to improve the quality of measurement equipment, the use of statistical tools, the innovation processes and other important elements of a quality management system. It is suggested that there is a need to develop a self-assessment framework for the maturity level of the quality management system in the railway sector.

REFERENCES

Babekova, N., Gueorguiev, T., Vitliemov, P. (2022) A Maturity Model as a Tool for Sustainable Development of Organizations. 8th International Conference on Energy Efficiency and Agricultural Engineering (EE&AE), Ruse, Bulgaria, 2022, pp. 1-4, doi: 10.1109/EEAE53789.2022.9831414.

International Organization for Standardization [ISO] (2015) *ISO 9000:2015 Quality management systems — Fundamentals and vocabulary*, ISO.

International Organization for Standardization [ISO] (2015) *ISO 9001:2015 Quality management systems — Requirements*, ISO.

International Organization for Standardization [ISO] (2018) *ISO 9004:2018 Quality management — Quality of an organization — Guidance to achieve sustained success*, ISO.

International Organization for Standardization [ISO] (2003) *ISO 10012:2003 Measurement management systems — Requirements for measurement processes and measuring equipment*, ISO.

International Organization for Standardization [ISO] (2021) *ISO 10017:2021 Quality management — Guidance on statistical techniques for ISO 9001:2015*, ISO.

International Organization for Standardization [ISO] (2023) *ISO 22163:2023 Railway applications — Railway quality management system — ISO 9001:2015 and specific requirements for application in the railway sector*, ISO.

International Organization for Standardization [ISO] (2003) *ISO 56002:2019 Innovation management — Innovation management system — Guidance*, ISO.

International Organization for Standardization [ISO] (2016) *ISO/TS 9002:2016 Quality management systems — Guidelines for the application of ISO 9001:2015*, ISO.

International Organization for Standardization [ISO] (2017) *ISO/TS 22163:2017 Railway applications — Quality management system — Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector*, ISO.