

Presented for ASQ Section 304 North Jersey

By
Edwin May, ASQ CSSBB
New Jersey Director
Quality & Productivity Solutions

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At 7pm General Section Meeting
Presented via Zoom

38 slides



Before We Begin...

- Thank you for attending for this Zoom Event
- The presentation will last about 45 minutes
- It will be followed by 15 minutes of Q & A
- Please mute yourself when not speaking
- Attendees will be awarded ASQ Recertification units
- Email <u>koshy.sachariah@outlook.com</u>



Speaker Bio – Ed May

Ed May has served as the Director of Quality and Productivity Solutions in New Jersey since 2013. He personally teaches a number of Lean Six Sigma, Supply Chain, ASQ Body of Knowledge, and ISO Courses for QPS NJ. He supervises the teaching of Project Management, Agile and Scrum courses at QPS NJ.

Ed has over 30 years of experience in Industry and is an expert in several ISO Standards, Lean Thinking and Six Sigma.

Ed has trained organizations in various industries in Lean Six Sigma. He has championed the implementation of Lean Six Sigma projects at these organizations, leading to process improvements and increased customer satisfaction.

Ed is an ASQ CSSBB, CMQ/OE, CQA, CQE and CSQP as well as an Exemplar Global Master Black Belt. He is active in ASQ North Jersey Section, where serves as the Section Chair for the years 2021and 2022.

Ed earned his BE degree from Stevens Institute of Technology and his MBA from Harvard Business School.







A COMPARISON OF FIVE MANAGEMENT SYSTEM STANDARDS



This presentation explores the evolution, differences between and relationship of these five standards to each other. It will show how ISO 9001:2015 is the basis for the other four standards. Many organizations go beyond the generic Quality Management System Standard to address the needs of their Aerospace and Automotive customers, and to meet or exceed Environmental, and Health and Safety Requirements.



Justifications for the revisions and transitions include:

- Taking a more holistic approach
- Harmonization with other standards
- Standardization of clause numbers
- Making standards more relevant to services
- Taking into account technological changes
- Various global considerations.



Many companies have transitioned to the current revisions of five major Quality Management System Standards.

- ISO 9001:2008 superseded by ISO 9001:2015.
- AS 9100C:2009 superseded by AS9100D:2016.
- ISO/TS 16949:2009 superseded by IATF 16949:2016.
- ISO 14001:2004 superseded by ISO 14001:2015
- OHSAS 18001 superseded by ISO 45001:2018.

- ISO 9001:2015 "Quality Management System"
- AS 9100D:2016 "Aviation, Space and Defense"
- IATF 16949:2016 "Automotive"
- ISO 14001:2015 "Environmental"
- ISO 45001:2018 "Occupational Health and Safety"

ISO 9001:2015

"Quality Management Systems - Requirements" Maintained by ISO/TC 176 Quality Management and Quality Assurance

ISO 9001:2015 is appropriate for any organization producing goods and services. It is structured according to "Annex SL" which took this standard from 8 to 10 clauses. It added: Context of the Organization, Interested Parties, Risk Based Thinking, and Organizational Knowledge. It made the Process Approach more explicit. It limited exclusions. It added new definitions and changed old definitions. It no longer requires a Quality Manual, Management Representative or Preventive Actions. It is supported by ISO 9000:2015: Fundamentals and Vocabulary, ISO 9004:2018: Quality of an Organization - Guidance to achieve Sustained Success, and ISO 19011:2018 Guidelines for Auditing Management Systems.



AS 9100D:2016 "Quality Management Systems –

Requirements for Aviation, Space and Defense Organizations"
Released by Society of Automotive Engineers & European Association of Aerospace Industries

AS9100D:2016 is for organizations that design, develop and provide Aviation, Space and Defense products and services, and post-delivery activities, including maintenance, spare parts, and materials for their own product and services. This standard embraces ISO 9001:2015 but still requires a Management Representative and suggests use of a Quality Manual. It offers new and modified terms and definitions. It includes useful Notes and Examples. It adds separate clauses for Product Safety and Counterfeit Parts Prevention. It requires consideration of Human Factors when dealing with Nonconformances and Corrective Actions. It clarifies Configuration Management, enhances Awareness, and emphasizes Ethical Behavior. It is supported by AS 9100F Auditing, As 9102B First Article and AS 9120B Distributors.

IATF 16949:2016

"Quality Management System Requirements for Automotive Production and Relevant Service Parts Organizations" Published by the International Automotive Task Force (IATF)

IATF 16949:2016 is for Automotive Production and relevant service parts organizations. It embraces ISO 9001:2015, but Preventive Action is still required. It offers new and modified terms and definitions. It adds separate clauses for Product Safety and Warranty Management. It clarifies Manufacturing Feasibility and enhances the clause on Products with Embedded Software. It emphasizes Auditor Competency.

ISO 14001:2015 "Environmental Management Systems" Issued by ISO/TC 207/SC 1 Environmental management systems

ISO 14001:2015 is based on ISO 9001:2015 and sets out the criteria for an environmental management system that can be certified to. It maps out a framework that a company or organization can follow to set up an effective environmental management system. Designed for any type of organization, regardless of its activity or sector, it can provide assurance to company management and employees as well as external stakeholders, that environmental impact is being measured and improved. It is supported by ISO 14004 General Guidelines on implementation and ISO 14005:2019 Guidelines for a flexible approach to phased implementation.

ISO 45001:2018

"Occupational Health and Safety Management Systems – Requirements with Guidance for Use"

Issued by ISO/TC 283 Occupational health and safety management systems

ISO 45001:2018 is based on ISO 9001:2015 and is for organizations that are serious about improving employee safety, reducing workplace risks and creating better and safer working conditions. ISO 45001 is a milestone. It is the world's first International Standard dealing with health and safety at work. It offers a single, clear framework for all organizations wishing to improve their Occupational Health and Safety Performance. Directed at the top management of an organization, it aims to provide a safe and healthy workplace for employees and visitors. To achieve this, it is crucial to control all factors that might result in illness, injury, and in extreme cases death, by mitigating adverse effects on the physical, mental and cognitive condition of a person. It is supported by ISO/PAS 45005:2020 Genera Guidelines for safe working during the COVID-19 pandemic.

Clause by Clause Comparison of the Five Management System Standards

ISO 9001:2015 is numbered as per Annex SL.

The other 4 standards based on ISO 9001:2015 are actually based on **Annex SL**.

Clause by Clause Comparison

of the management system standards.

AS 9100D:2016 "Aviation, Space and Defense" accepts ISO 9001:2015 verbatim:

- adds words to a few dozen clauses, sub-clauses and sub-sub-clauses
- and adds several sub-clauses and sub-sub-clauses.

IATF 16949:2016 "Automotive" accepts ISO 9001:2015 verbatim:

- adds dozens of sub-clauses, sub-sub-clauses, and sub-sub-sub-clauses.
- changes some of the clause and sub-clause titles.

Clause by Clause Comparison

of the management system standards.

ISO 14001:2015 "Environmental":

- adds some sub-clauses
- changes "Quality" to "Environmental" throughout.

ISO 45001:2018 "Occupational Health and Safety":

- adds some sub-clauses
- changes "Quality" to "Occupational Health and Safety" throughout.

4 Context of the Organization

Aerospace adds:

- Customer specific requirements
- Statutory and Regulatory requirements

Automotive adds:

- Customer specific requirements
- Conformance of Products and Services
- Product Safety



4 Context of the Organization

Environmental:

Focuses on Environmental Context

OH&S:

Focuses on OH&S Context

5 Leadership

Aerospace adds:

- On-Time delivery requirements
- Action taken if planned results are not achieved.

Automotive adds:

- Corporate responsibility
- Process effectiveness and efficiency
- Process owners
- Responsibility and authority for product requirements, and corrective actions.

5 Leadership

Environmental cites:

Environmental Policy.

OH&S cites:

- OH&S Policy
- Consultation and participation of workers.

6 Planning

Aerospace adds nothing.

Automotive adds:

Risk Analysis, Preventive Action, Contingency Plans.

Environmental adds:

- Environmental Aspects
- Compliance Obligations
- Environmental Objectives
- Actions to achieve Environmental Objectives.



6 Planning

OH&S adds:

- Actions to address risks and opportunities
- Hazard Identification
- Assessment of risks and opportunities
- Assessment of OH&S risks and other risks to the OH&S management system
- Determination of legal and other requirements
- OH&S Objectives and how to achieve them.

7 Support

Aerospace adds:

- Register of monitoring and measurement equipment
- Periodic review of competence
- Awareness of ethical behavior
- Protection of data.

7 Support

Automotive adds:

- Plant, facility and equipment planning
- Measurement System Analysis
- Auditor competency
- Employee motivation and empowerment.

7 Support

Environmental adds:

Internal & external communication.

OH&S adds:

Internal & external communication.

Aerospace adds:

- Operational Planning and Control which includes many requirements.
- Personal and product safety.
- Embedded software.
- Foreign objects.
- Recycling or final disposal of product.
- Statistical techniques.
- On-time delivery of product and services.
- Operational risk management.
- Control of software, tools, software programs.
- Validation and control of special processes.
- Product process verification plan.

Aerospace also adds:

- Configuration management.
- Product safety.
- Prevention of counterfeit parts.
- Specific requirements in Design & Development of products and services.
- Specific requirements in Control of external process, products & services.
- Risks associated with the external provision
- Register of its external providers.
- Conformity and on-time delivery of suppliers.
- Suppliers must implement a quality management system.
- Provide access to supply chain.
- Product safety.
- The importance of ethical behavior.

Automotive adds:

- Confidentiality.
- Organizational manufacturing feasibility.
- Products with embedded software.
- Prototype program.
- Product approval process.
- Directed Buy.
- Supplier Quality Management System Development.

Automotive also adds:

- Standardized work.
- Total productive maintenance.
- Production scheduling.
- Statutory and regulatory conformity.
- Control of suspected product.
- Control of reworked product.
- Control of repaired product.
- Nonconforming material disposition.

Environmental adds:

Emergency preparedness and response.

OH&S adds:

- Eliminating hazards and reducing OH&S risks
- Procurement
- Contractors / Outsourcing
- Emergency preparedness and response.

9 Performance Evaluation

Aerospace adds:

- On-Time Delivery performance metric
- Identification of risks.

9 Performance Evaluation

Automotive adds:

- Monitoring & measuring of manufacturing processes
- Statistical tools and concepts
- Prioritization
- Internal Audit program
- Quality Management System audit
- Manufacturing process audit
- Product audit.

9 Performance Evaluation

Environmental adds:

Internal Audit Program.

OH&S adds:

Internal Audit Program.

10 Improvement

Aerospace adds:

- Flow down of requirements to external providers
- Specific actions when corrective actions not achieved
- Monitoring of improvement activities
- Evaluation of effectiveness of results.

10 Improvement

Automotive adds:

- Problem solving
- Error Proofing
- Warranty management
- Customer complaints and field failure test analyses.

10 Improvement

Environmental adds nothing.

OH&S adds nothing.







PLEASE ASK QUESTIONS





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LAST SLIDE

A Comparison of Five Management Standards