COMMON NONCONFORMITIES
IN
ISO9001:2015 3RD PARTY AUDITS

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WELCOME INTRODUCTIONS

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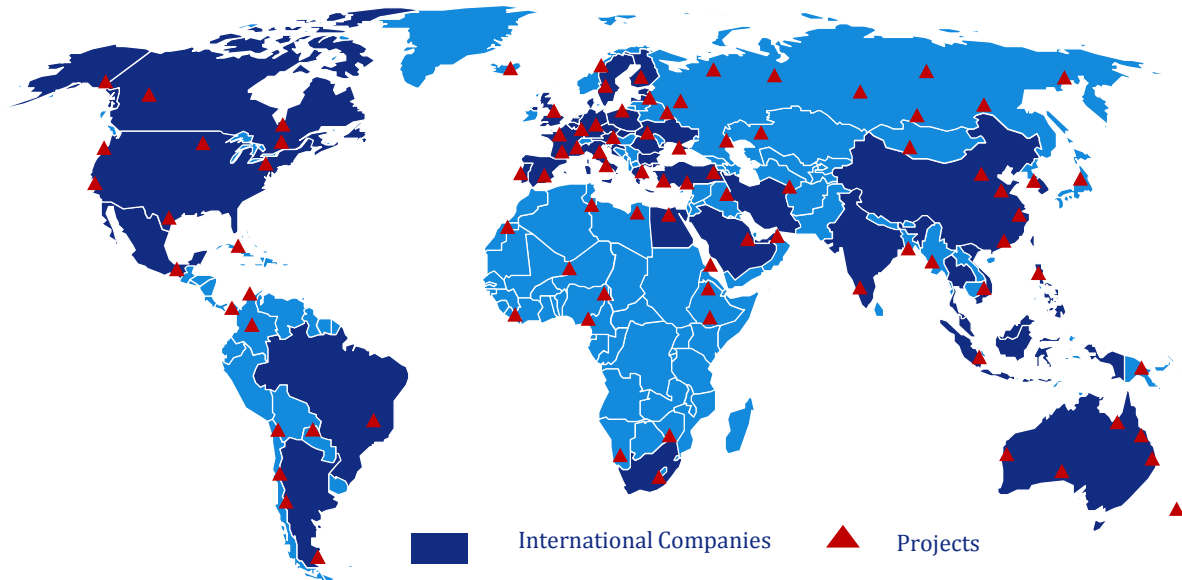
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GLOBAL PRESENCE:
TÜV NORD GROUP

(Ref.: 2016 reports)

Present in over 70 countries

40 subsidiaries

Turnover of more than EUR 1 billion

13,000 employees

40,000 customers in the field of system certification worldwide

63,000 certified systems

TÜV NORD

DMT

ALTER TECHNOLOGY

TUVIT ®

International Companies ▲ Projects

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TUV USA SERVICES & MAIN ACCREDITORS

Certification, Training

Inspection Services

Laboratory Services

Quality, Environmental and Health and Safety and Energy Management Systems	Food Safety	Medical Systems	IT/IS
ISO9001 IATF 16949 IRIS AS9100 AS9100-10-20 OHSAS18001 ISO50001 ISO29990 Etc.	BRC ISO22000 IFS Gluten-Free HACCP Global Gap Organic Certification Etc.	ISO13485 MDSAP Medical Device Directive MDD CMDCAS Etc.	ISO27001 BS10012 – PIMS Security4Safety General Data Protection Regulation (GDPR) ISO20000 Etc.

DAkkS
Deutsche Akkreditierungsstelle

ANAB ACCREDITED

Standards Council of Canada
Conseil canadien des normes

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AGENDA

1. Introduction to TUV NORD

2. Purpose / Outlines

3. *4.1 Understanding the organization and its context*

4. *4.2 Understanding the needs and expectation of interested parties*

5. *4.3 Determining the scope of the quality management system*

6. *6.1 Actions to address risks and opportunities*

7. *6.3 Planning of changes*

8. NCs count per subclause in 250+ audits

9. Frequency of NCs in 250+ audits

10. *7.1.5.1 General <Monitoring and measuring resources >*

11. *7.1.6 Organizational Knowledge*

12. *8.2.1 Customer communication*

13. *8.2.3.1 <void> <Review of requirements related to products and services >*

14. *8.4.1 general <Control of externally provided processes, products and services >*

15. *8.5.1 Control of production and service provision*

16. *9.2.2 <void> < Internal audit >*

17. How much has ISO 9001:2008 actually changed?

18. ISO 9001:2015 New requirements

19. Changed existing requirements

20. Some recommendations/ notes:

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PURPOSE/ OUTLINE

1. To share common failures in implementation of new / changed requirements
2. To make value for quality field activist through prevention of similar NCs
3. To make a robust understanding of the requirements
4. Not a training session but a friendly exchange of experiment

4.1 UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT

Common NCs:

- The organization does not have a mechanism to monitor its external and internal issues.

- The organization Is not reviewing its external and internal issues in a timely manner.

- The organization has not planned to review and monitor its external and internal issues.

Key notes:

Context : the circumstances that form the setting for an event, statement, or idea, and in terms of which it can be fully understood and assessed.

SWOT weaknesses: static in time, too far external environmental factors

Review ISO3100:2009- Risk management, principles and guidelines

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4.2 UNDERSTANDING THE NEEDS AND EXPECTATION OF INTERESTED PARTIES

Common NCs:

- The organization is not reviewing information about its interested parties – relevant to its QMS- and their relevant requirements in a timely manner.

- The organization has not planned to review and monitor information about its interested parties –relevant to its QMS- and their relevant requirements.

- The organization –producer of low pressure gas flow meter- has not determined Measurement Canada as its interested party and therefore its requirements are not recognized by its QMS processes.

Key notes:

Any party that can make your product/service provision inconsistent is one of your organization interested party

Meaning of consistency : the same behavior in time

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4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

Common NCs:

- The organization has excluded its product design activities whereas its strategic direction (came out of its external and internal issues review), its customer delegated authorities to change product specifications –except assembleability requirements-, record of the last five product changed and validated design required its QMS to include product design.

Key notes:

Strives to make the scope *very* specific

Makes it more difficult to justify an exclusion for Design, if the organization actually performs a design function, for example.

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6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

Common NCs:

- The organization has developed a risk mitigation plan in which all actions are notes "out of company control". ☹

- In some cases, the organization actions against identified risks are not effective to mitigate risk. For instance, Risk : packaging staff are not competent to pack brittle models of glasses, Action: Train operators WHEREAS no operator is good in English language and training was held in English.

- The organization has not planned actions to address its identified opportunities.

Key notes:

Uncertainty : Predictability : Confidence : ….

Risk: A state of uncertainty where some possible outcomes have an undesired effect or significant loss.

Intelligent system

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

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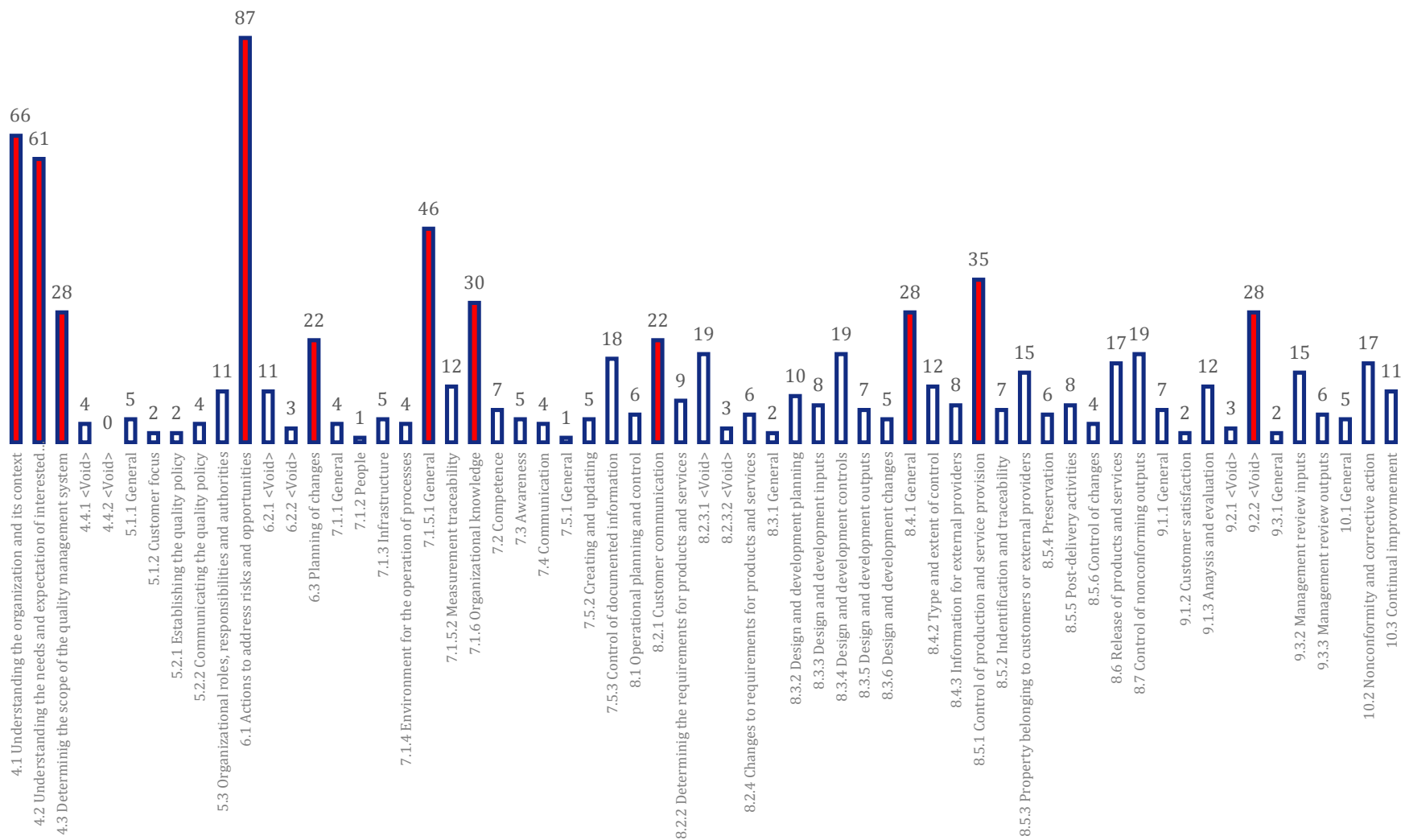TÜV NORD GROUP

6.3 PLANNING OF CHANGES

Common NCs:

- In some cases, the organization has not reviewed consequences of changes on its QMS within planning of change implementation. For instance, consequences of material ordering method change on warehouse available space
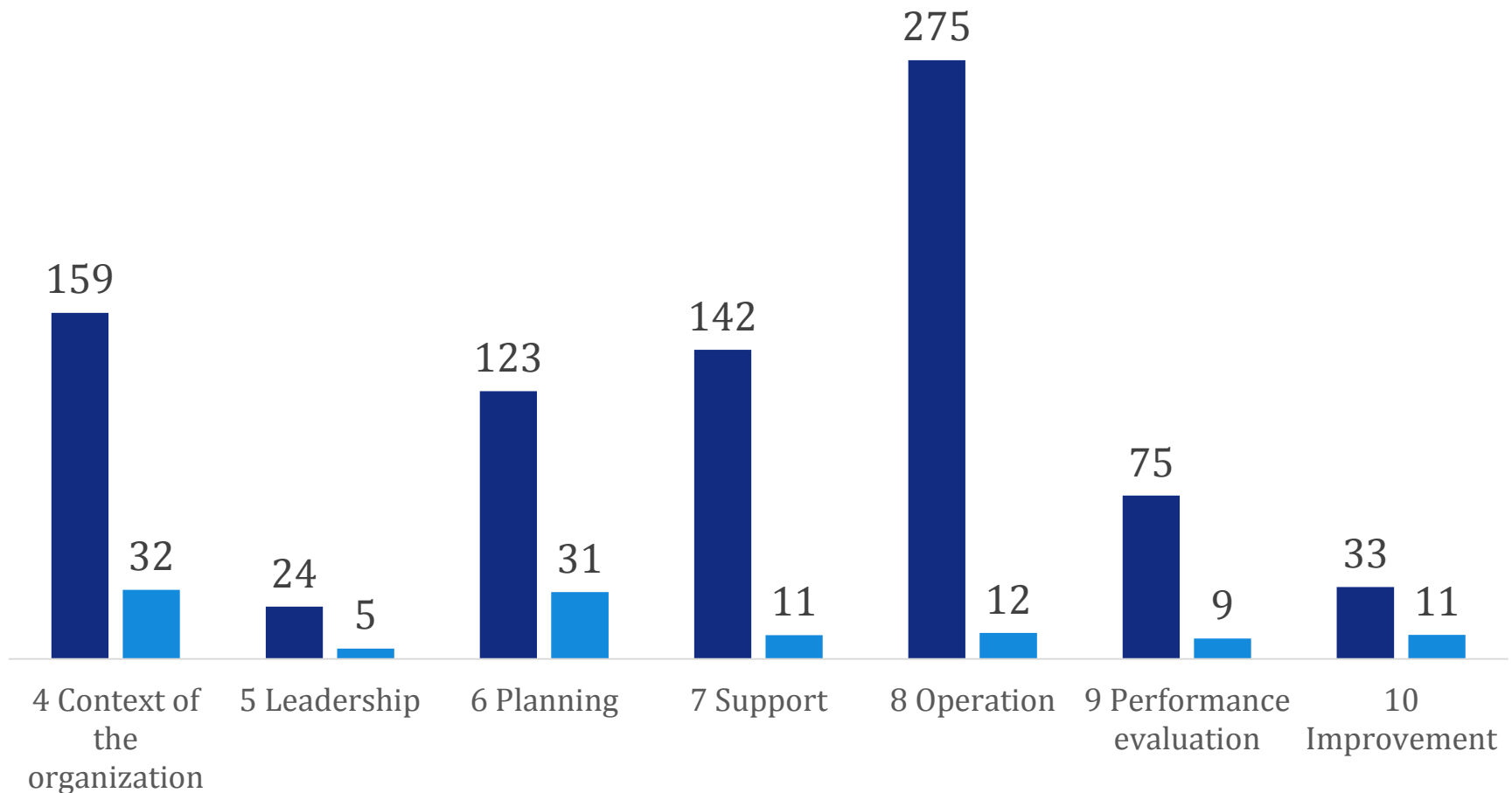
Key notes:

None

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NCs count per subclause in 250+ audits

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Frequency of NCs in 250+ audits

■ # of NCs ■ # of NCs per subclause

Category	# of NCs	# of NCs per subclause
4 Context of the organization	159	32
5 Leadership	24	5
6 Planning	123	31
7 Support	142	11
8 Operation	275	12
9 Performance evaluation	75	9
10 Improvement	33	11

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7.1.5.1 GENERAL <MONITORING AND MEASURING RESOURCES >

Common NCs:

- In some cases, measurement results are not reliable. E.g: measurement of extruded rubber compound by a Vernier. Result of 3 continuous measurements proves unreliable output.

- In some cases, the organization is not using suitable measurement device to control a specification. E.g: Vernier with resolution of 0.1 mm to measure a width dimension 24 ± 0.1 mm.

Key notes:

Data quality

Repeatability and reproducibility

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7.1.6 ORGANIZATIONAL KNOWLEDGE

Common NCs:

- The organization has not have a knowledge base to maintain its internal and external knowledge.

- The organization knowledge base in not accessible for related users. E.g: process engineer does not have access to the libraries on SharePoint to review current knowledge when planning a change

Key notes:

Knowledge management cycles : Zack, Bukowitz & William, McElroy, ….

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8.2.1 CUSTOMER COMMUNICATION

Common NCs:

- The organization has not developed and communicated specific requirements for contingency actions against the only paint blending machine failures with its customer.

Key notes:

None

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8.2.3.1 <VOID> <REVIEW OF REQUIREMENTS RELATED TO PRODUCTS AND SERVICES >

Common NCs:

- The organization has been committed to its customer to supply cherry fruit fly but record of reviewing its ability before making commitment does not show that it has determined and reviewed its ability to meet CFIA (Canadian Food Inspection Agency) requirements

Key notes:

Database of statutory and regulatory requirements

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8.4.1 GENERAL <CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES >

Common NCs:

- The organization has not determined criteria for external providers evaluation based on their ability to meet requirements. Current criteria that classifies external providers is the duration they have cooperated with the organization.

Key notes:

None

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8.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

Common NCs:

- In some cases, the organization has not implemented actions to prevent human errors. During the audit of SMD process, it was found that gas release button and machine shut down button are both at the same size and red very close to each other. It has the risk of operator error on pushing the wrong button.

Key notes:

Refer to 8.3.3 and 8.3.4

9.2.2 <VOID> < INTERNAL AUDIT >

Common NCs:

- The audit program of the organization has not considered importance of the processes and the results of previous audits to determine frequency of the audits. Previous audit (Jun) of HR shows no NC but 5 NCs for maintenance process. Previous 6 months internal performance results shows that OEE was less than 75% in Sep, Oct, Nov and slightly over it in Dec. HR process KPIs were all at a good behavior in the previous 6 months. Audit program shows that next audit of maintenance process is not planned for Jan but HR process is planned to be audited that month.
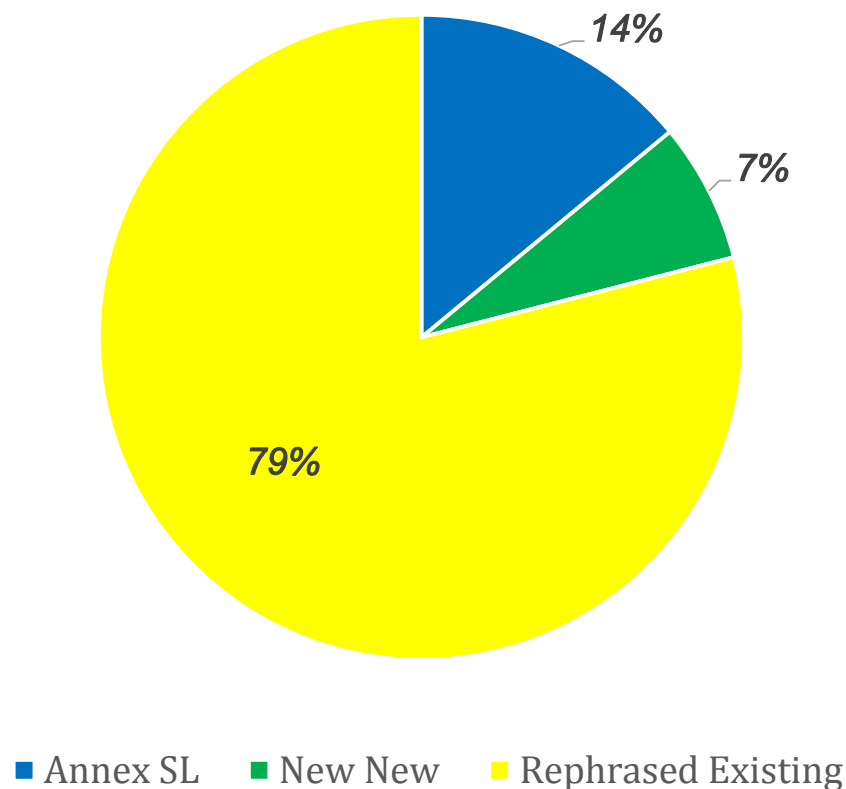
Key notes:

Risk based audit program

Performance based audit program

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HOW MUCH HAS ISO 9001:2008 ACTUALLY CHANGED?

ISO 9001:2015 vs. ISO 9001:2008

14%

7%

79%

■ Annex SL   ■ New New   ■ Rephrased Existing

ISO 9001:2015 NEW REQUIREMENTS

4.1 "Understanding the Organization and its Context"

4.2 "Understanding the Needs and Expectations of Interested Parties"

4.4 "Quality Management System and its Processes"

5.1 "Leadership and Commitment"

6.1 "Actions to address Risks and Opportunities"

6.3 "Planning of Changes"

7.1.6 "Organizational Knowledge"

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CHANGED EXISTING REQUIREMENTS

1. Scope of the quality management system
2. Control of Documents
3. Management Commitment
4. Customer Focus
5. Management Review
6. Human Resources
7. Customer Property
8. Corrective Action
9. Preventive Action

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SOME RECOMMENDATIONS/ NOTES:

1. Think risk-based in each and every activity in your QMS
2. Use supportive standard guides such as ISO3100:2009
3. ISO9001:2015 helps you more than before to align QMS with your business
4. Don't go very deep and don't be too superficial with requirements
5. Collaborate and share your best practices about ISO9001:2015 with TUV NORD

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TUV USA ACADEMY

Training Schedule USA

ISO 9001:2015 Internal Auditor Training
- March 13-14 – Chicago, IL Area
- May 17-18 – Salem, NH

Food Safety Trainings

Implementing SQF Systems Ed. 8
- February 26-27 – Orlando, FL
- March 29-30 – Chicago, IL (Area)

PCQI Human Food
- March 26-28 - Chicago, IL (Area)
- April 2-4 – Boston, MA (Area)
- May 22-24 – Orlando, FL

Training Schedule Canada

ISO 9001:2015 Transition Training
- March 16 – Mississauga, ON

IATF 16949 Transition Training
- March 8-9 – Mississauga, ON
- May 24-25 - Mississauga, ON

Food Safety Trainings

PCQI Human Food
- April 19-20 – Mississauga, ON

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Thank you for attending

Technical or Quotation questions please contact mnmovahed@tuv-nord.com

Questions regarding Training Courses contact klehoullier@tuv-nord.com

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