Transition to IATF 16949

Understanding and Avoiding the Most Common Nonconformities

Auditing to Add Value

Presented by:

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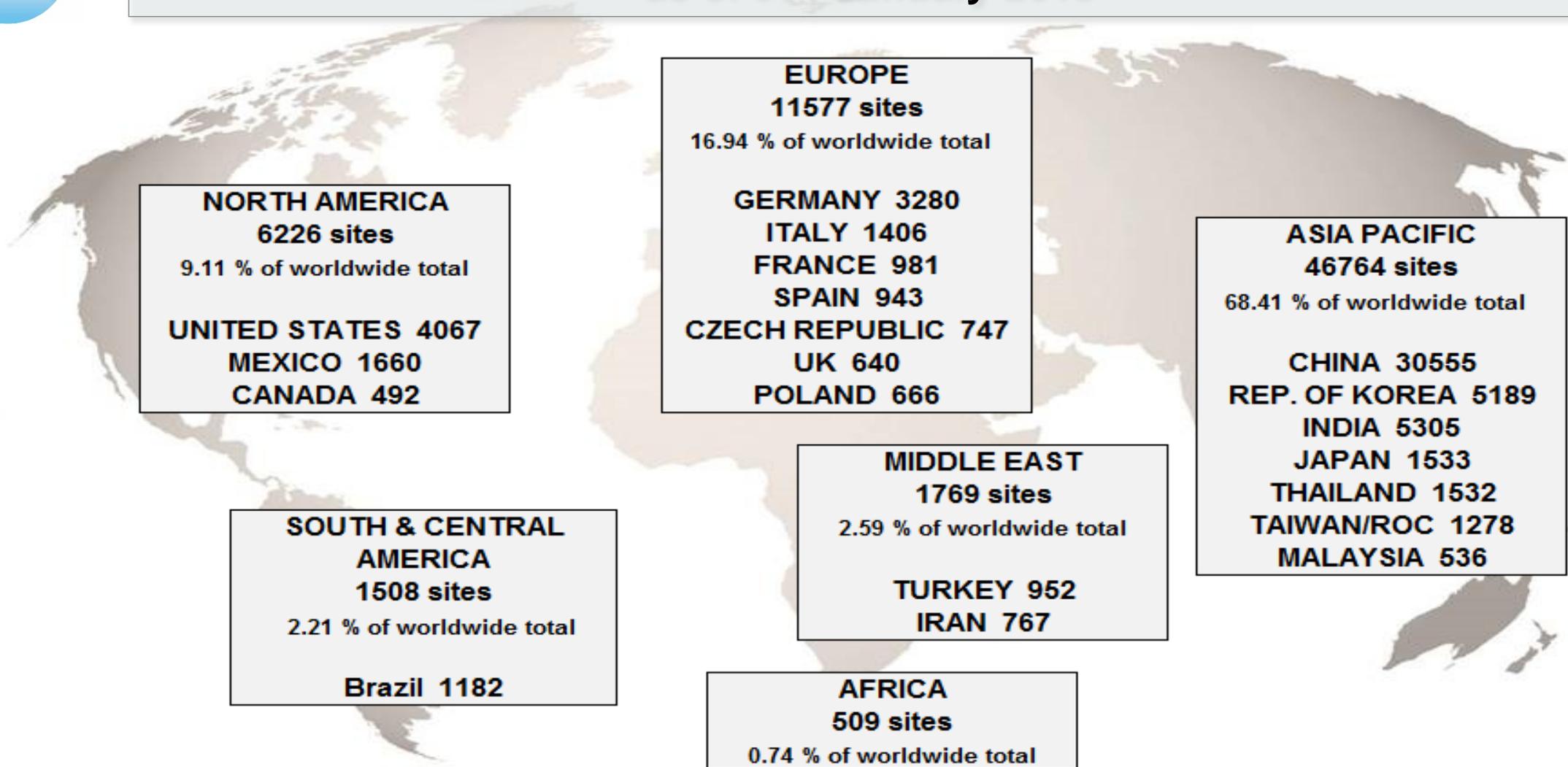
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Today's Topics

- Status of the Transition

- Most Common Major and Minor Nonconformities

- Understanding is Key to Prevention

- Auditing to Add Value

Status of the Transition

Distribution of the 68,355 ISO/TS 16949 and IATF 16949 certified sites as of 31st January 2018

NORTH AMERICA
6226 sites
9.11 % of worldwide total

UNITED STATES 4067
MEXICO 1660
CANADA 492

EUROPE
11577 sites
16.94 % of worldwide total

GERMANY 3280
ITALY 1406
FRANCE 981
SPAIN 943
CZECH REPUBLIC 747
UK 640
POLAND 666

ASIA PACIFIC
46764 sites
68.41 % of worldwide total

CHINA 30555
REP. OF KOREA 5189
INDIA 5305
JAPAN 1533
THAILAND 1532
TAIWAN/ROC 1278
MALAYSIA 536

SOUTH & CENTRAL AMERICA
1508 sites
2.21 % of worldwide total

Brazil 1182

MIDDLE EAST
1769 sites
2.59 % of worldwide total

TURKEY 952
IRAN 767

AFRICA
509 sites
0.74 % of worldwide total

Understand the IATF Transition Strategy

- Transition process applies to manufacturing sites and remote support functions/locations
- Read through the transition strategy to understand how the requirements affects/applies to your organization
- Be aware of subsequent changes to the strategy that are released by the IATF via the IATF Global Oversight website
- Direct any questions to your certification body

http://www.iatfglobaloversight.org

Before Your Transition Audit:

Conduct a full internal systems audit to IATF 16949 and a management review <u>prior to</u> the transition audit by the certification body

- Required to show the quality management system is in compliance to all IATF 16949 requirements
- For internal audits, this can be accomplished through a combination of previous internal system audits to ISO/TS 16949 and a supplemental internal system audit(s) to cover the additional requirements of IATF 16949
- For management review, this can be accomplished through a combination of a previous management review in compliance with ISO/TS 16949 requirements and a supplemental management review in compliance with the additional requirements of IATF 16949.

Key points about the transition audit process:

- Transition process includes the following steps:
  - Transition Audit
  - Nonconformity management
  - Certificate decision
  - Certificate issuance

- Transition audit starts a new 3-year audit cycle
- Transition audit is equivalent to a recertification audit which is a full systems audit covering all requirements of IATF 16949:2016 and ISO9001:2015.

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Some Good News…

IATF approved a deviation to allow the certification bodies to make a positive certification decision after the expiration date of the existing ISO/TS 16949 certificate as long as the decision is made within a maximum of 120 calendar days from the last day of the transition audit.

- This might result in a period where the client's ISO/TS 16949 certificate has expired and no valid certificate exists
- The obsolescence date of ISO/TS 16949:2009 is 14 September 2018.

Top Major and Minor Nonconformities Written During the Transition

IATF 16949 Top Major NCs (Jan 2018)

	Major NC
10.2.1	87
7.2.3	51
10.2.3	46
6.1.2.3	42
8.5.1	39
8.5.1.5	38
8.5.1.1	34
4.3.2	31
9.2.2	31
7.1.5.1.1	30
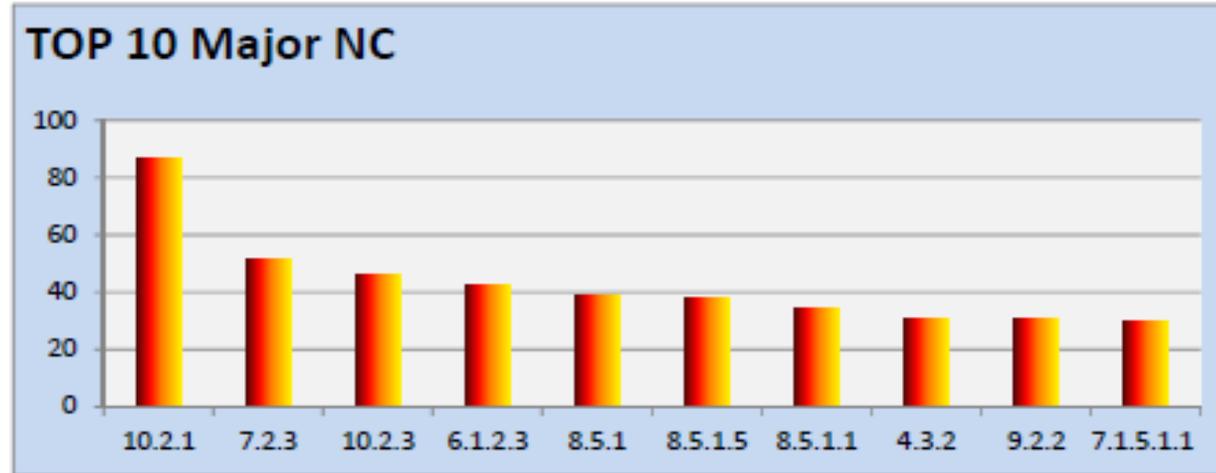
TOP 10 Major NC

Key areas within the Top 10 Major NCs:

10.2.1 (ISO) under Nonconformity and Corrective Action

7.2.3 Internal auditor competency

10.2.3 Problem solving

6.1.2.3 Contingency plans

8.5.1 (ISO) Control of Production and Service Provision

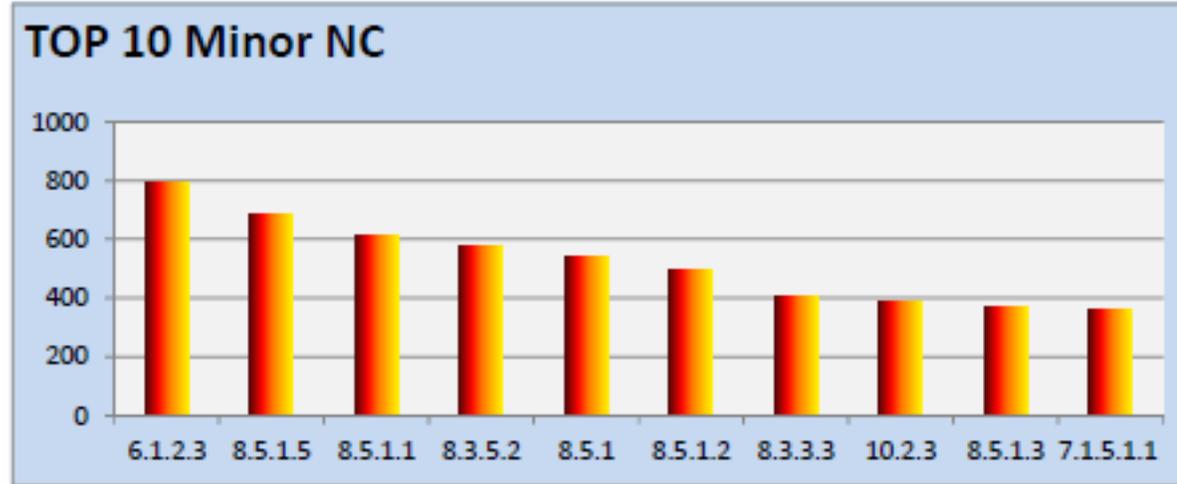8.5.1.5 Total productive maintenance

8.5.1.1 Control plan

4.3.2 Customer-specific requirements

9.2.2 (ISO) under Internal Audit

7.1.5.1.1 Measurement Systems Analysis

IATF 16949 Top minor NCs (Jan 2018)

	Minor NC
6.1.2.3	795
8.5.1.5	685
8.5.1.1	611
8.3.5.2	575
8.5.1	539
8.5.1.2	499
8.3.3.3	403
10.2.3	385
8.5.1.3	373
7.1.5.1.1	363

TOP 10 Minor NC

Key areas within the Top 10 minor NCs:

6.1.2.3 Contingency plans

8.5.1.5 Total productive maintenance

8.5.1.1 Control plan

8.3.5.2 Manufacturing process design output

8.5.1 (ISO) Control of Production and Service Provision

8.5.1.2 Standardized work – operator instructions and visual standards

8.3.3.3 Special characteristics

10.2.3 Problem solving

8.5.1.3 Verification of job set-ups

7.1.5.1.1 Measurement system analysis

Why do we see these NCs?

- 8.5.1.5 Total Productive Maintenance (see in both minor / Major NCs)

- 10.2.3 Problem Solving (see this in both minor / Major NCs)

- 6.1.2.3 Contingency Plans (again, see this in both minor / Major NCs)

- 8.5.1 (ISO) Control of Production and Service Provision (ditto)

- 8.5.1.1 Control Plan (ditto)

- 7.1.5.1.1 Measurement systems analysis (ditto)

Revelation that many of the common minor / Major NCs are not new to Quality Management Systems; however, for those with expanded / new requirements (ex: 8.5.1.5 TPM) IATF has issued SIs and FAQs to further expand / clarify the requirements.

Understanding is Key to Prevention

10.2.1 Nonconformity and Corrective Action

- Interestingly, this is a fundamental ISO 9001:2015 requirement.
- These majors likely result from repeat third party audit findings. May also result from poor problem solving in response to customer issues or in other areas.
- Issues may arise from organizations not taking action at all in response to a nonconforming situation.
- Issues may arise from organizations doing a poor job when they do take action. Remember!
  - Containment and correction should address the symptoms of the problem. Needs to include an extent analysis.
  - Root cause should answer the question, "What in the system failed such that the problem occurred?"
  - Corrective action should address the root cause.

7.2.3 Internal Auditor Competency

- A documented process is required. List of internal auditors is required.
- Different requirements for management system, process and product auditors.
  - Management system auditors need to understand: automotive process approach to auditing, CSRs, ISO 9001 and IATF 16949, applicable core tools and fundamental audit skills.
  - Manufacturing process auditors need to understand the process they are auditing and associated documents – the control plan and FMEA.
  - Product auditors need to understand the product requirements and associated measurement equipment.

7.2.3 Internal Auditor Competency

- If the organization's personnel provided training to meet these competency requirements, documented information regarding the trainer's competency must be maintained.
  - Sanctioned Interpretation #4

10.2.3 Problem Solving

- A documented process is required. Ensure conformance with any customer-specified requirements.
- Watch for common pitfalls:
  - Correction not including an extent analysis
  - Root cause is a re-statement of the finding, not a true root cause
  - Corrective action re-states correction or does not address root cause
  - Failure to review/update associated documents, e.g. the "living" control plan and FMEA.

6.1.2.3 Contingency Plans

- This is not a new requirement, but it is a significantly enhanced one.
- Important additions:
  - C) prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see Section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; **cyber-attacks on information technology systems;** labour shortages; or infrastructure disruptions;
  - E) periodically test the contingency plans for effectiveness (e.g., simulations , as appropriate);
  - F) conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team, including top management, and update as required.
- SI #3

8.5.1 Control of production and service provision

- This is an ISO 9001:2015 requirement.
- New requirements:
  - E) the appointment of competent persons, including any required qualification;
  - G) the implementation of actions to prevent human error;

8.5.1.5 Total productive maintenance

- This is a significantly enhanced requirement. Requirements previously related to preventive maintenance. Emphasis is now on TPM as a way of improving the integrity of production through equipment, processes and employees that add value.
- New requirements:
  - C) provision of resources for machine, equipment and facility maintenance;
  - F) documented maintenance objectives… shall form an input to management review;
  - G) regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
  - J) periodic overhaul.

8.5.1.1 Control plan

- Some new requirements, but the most common nonconformity is the lack of agreement between the control plan and execution of physical processes on the floor.

- New requirements:
  - Verification of job set-ups
  - First-off/last-off part validation
  - Control plans need to be reviewed at a set frequency based on a risk analysis, not only when any change occurs.

4.3.2 Customer-specific requirements

- Although the need to fulfill and satisfy customer-specific requirements was already mentioned throughout the whole ISO/TS 16949 document, in IATF 16949 this requirement specifically addresses the need to evaluate the customer specific requirements and include them where applicable in the organization's quality management system.

- This means that the supplier would need some sort of process to evaluate each of their customer's customer-specific requirements and determine exactly how (and where) it applies to their organization's QMS, as applicable.

9.2.2 Internal audit

- Not much new when compared to ISO/TS 16949:2009.

7.1.5.1.1 Measurement systems analysis

- Studies shall be conducted on each type of equipment identified in the control plan.

- FAQ #6: Are studies required on each instrument or device?
  - No. A complete statistical study on each single piece of equipment is not required. Instruments with the same characteristics (e.g. measurement range, resolution, repeatability, etc.) can be grouped and a sample instrument (representative of the gauge family) can be used for the statistical study.

- Adhere to customer-specific requirements, i.e. reference manuals.

- Maintain records of customer acceptance of alternative methods/results.

8.3.5.2 Manufacturing process design output

- List of manufacturing process design outputs is expanded:
  - B) special characteristics for product and manufacturing process
  - C) identification of process input variables that impact characteristics
  - D) tooling and equipment for production and control, including capability studies of equipment and process(es);
  - F) capacity analysis;
  - H) maintenance plans and instructions;

8.5.1.2 Standardized work – operator instructions and visual standards

- IATF 16949 strengthens the requirements for standardized work, including the requirement to address specific language needs.

- Standardized work documents need to be clearly understood by the organization's operators and should include all applicable quality, safety, and other aspects necessary to consistently perform each manufacturing operation.

8.3.3.3 Special characteristics

- Clarification provided in SI #6:

- The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

- a) documentation of all special characteristics in the **product and/or manufacturing documents drawings** (as required), **relevant** risk analysis (such as **Process** FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are **cascaded through each of these documents; documented in the manufacturing documents which show the creation of, or the controls required, for these special characteristics;**

8.5.1.3 Verification of job set-ups

- Clarify that the organization shall verify job changes that require a new set-up; maintain documented information for set-up personnel; perform first-off/last-off part validation, as applicable, including retention and comparison; and retain records of process and product approval following these validation actions.

Auditing to Add Value

Industry Goal

- The automotive industry is trying to drive on-time, on-quality performance through IATF 16949, customer-specific requirements and the automotive process approach to auditing.

- Internal audits are a critical tool to drive this level of performance.

- The audit process should change as an organization's management system and quality culture become more sophisticated.

Maturity Zones

Terminology

- Management Culture –
  - degree of awareness
  - commitment
  - collective attitude and behavior of the organization with regard to quality or Base standard objectives
- Conformity to Management Systems–
  - maturity of organization's MS
  - Extent to which it meet the requirements of the MS
- Conformance versus effectiveness

Zone 1: (Low maturity of "management system culture"; immature MS, not conforming to ISO base standard)
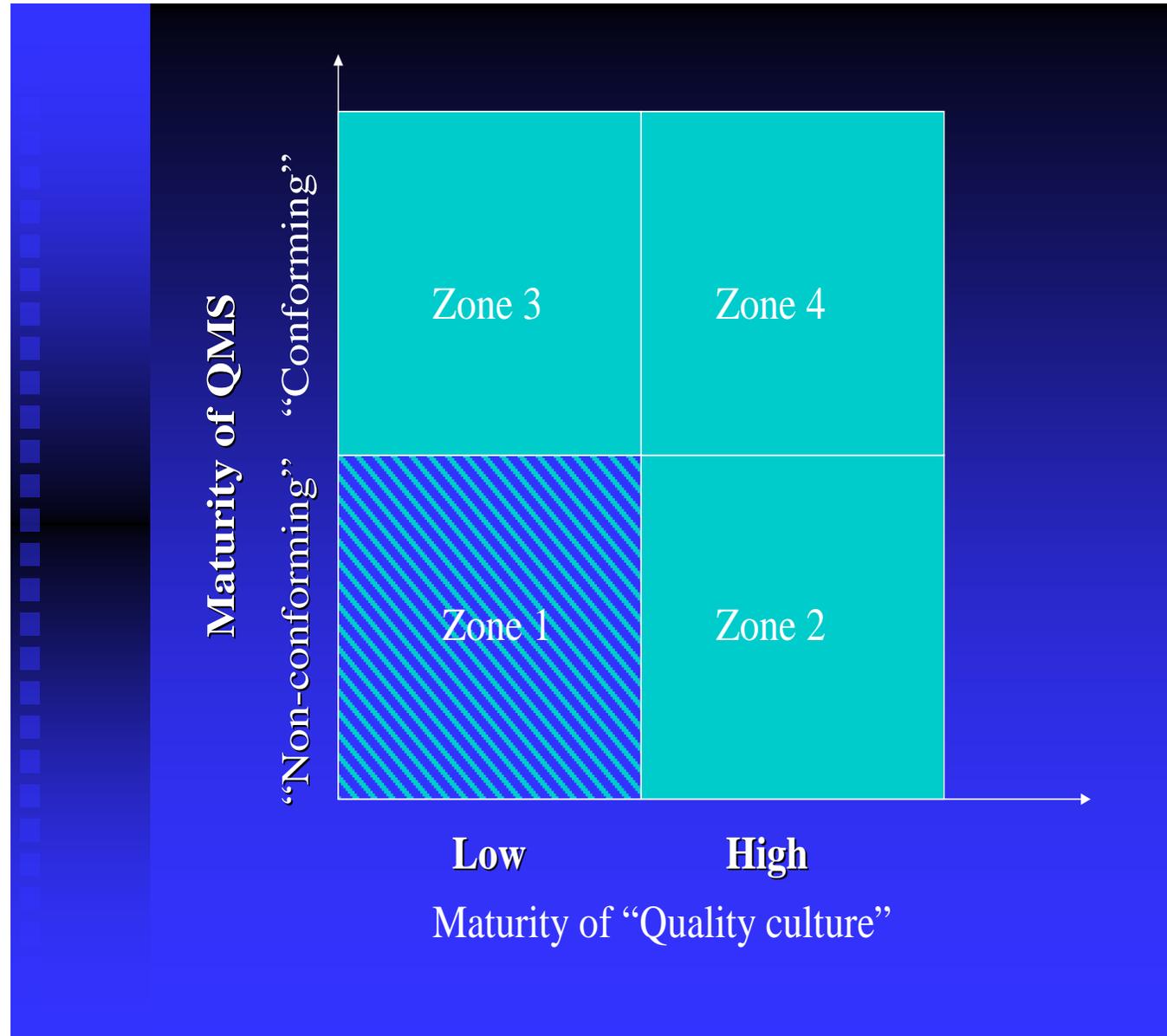
Zone 1

What an auditor can do:

- ensure that whenever non-conformities are encountered, the auditee has a clear understanding of **what** the standard requires, and **why** the non-conformity is being raised.

- If the organization can recognize that resolving these nonconformities will lead to improved performance, then it is more likely to believe in and commit to the process.

- It is important, however, that all identified non-conformities **are** reported, so that the organization clearly understands **what** needs to be done in order to meet the requirements of standard.

Zone 2: Mature "management system culture"; immature MS, not conforming to the MS
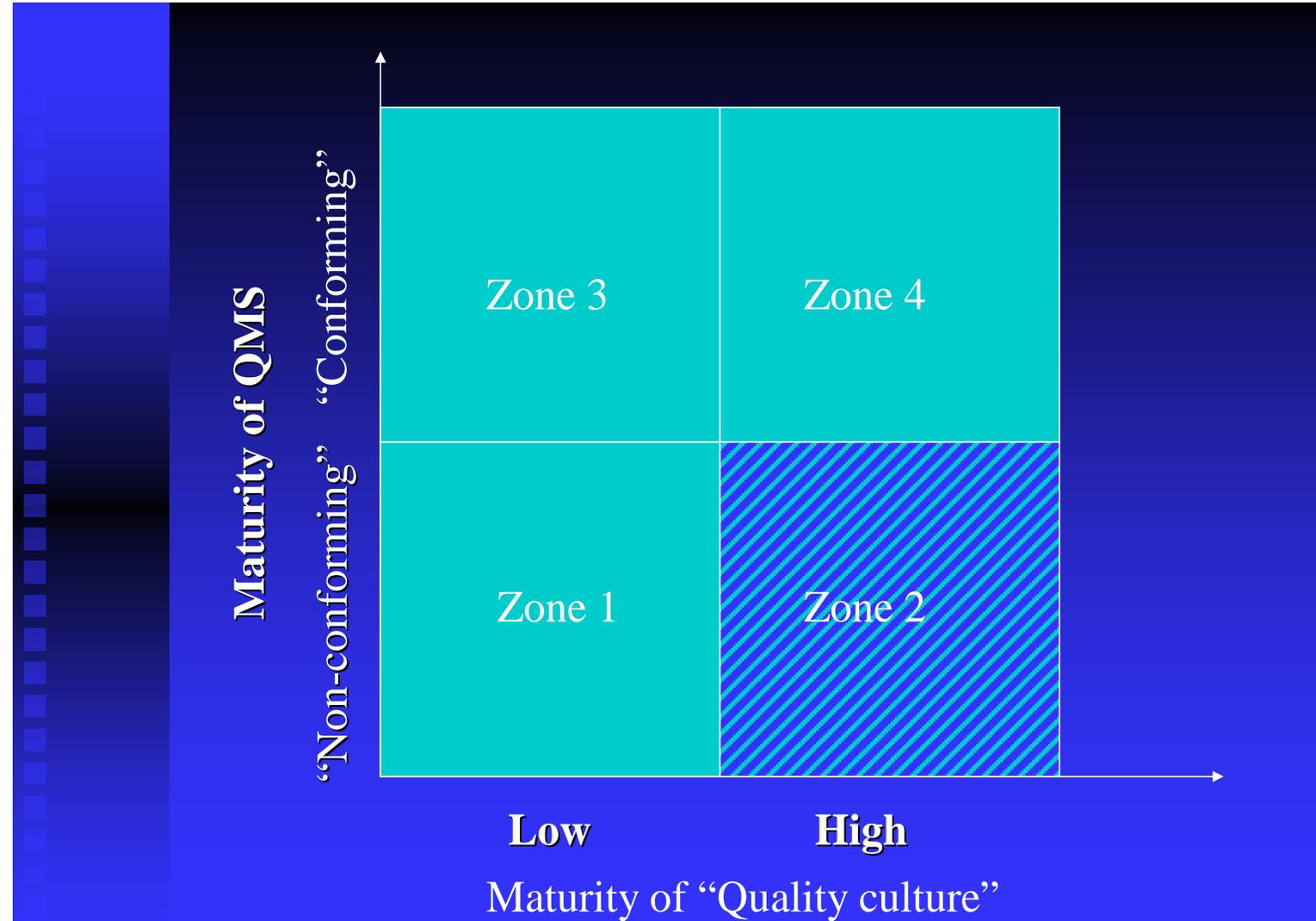
Zone 2

- Auditor has to understand the way in which the organization's existing practices meet the requirements of ISO standard.

- Do not insist that the organization redefine its processes and documentation to align to the clause structure of the standard.

- Auditor should, at a minimum, be aware of the organization's methodologies, and be able to see to what extent they are effective in meeting the requirements of the standard.

Zone 2

- It is also important that the auditor not be "intimidated" by the organization's apparent high degree of sophistication.
- While the organization may be using these tools as part of an overall management philosophy, there might still be gaps in the way the tools are being employed.
- Therefore, the auditor must be able to identify any systematic problems and raise the appropriate non-conformities.
- In these situations, the auditor might be accused of being pedantic or even bureaucratic, so it is important to be able to demonstrate the relevance of the non-conformities that are being raised.

Zone 3: Low maturity of "management system culture"; mature MS, conforming to the MS
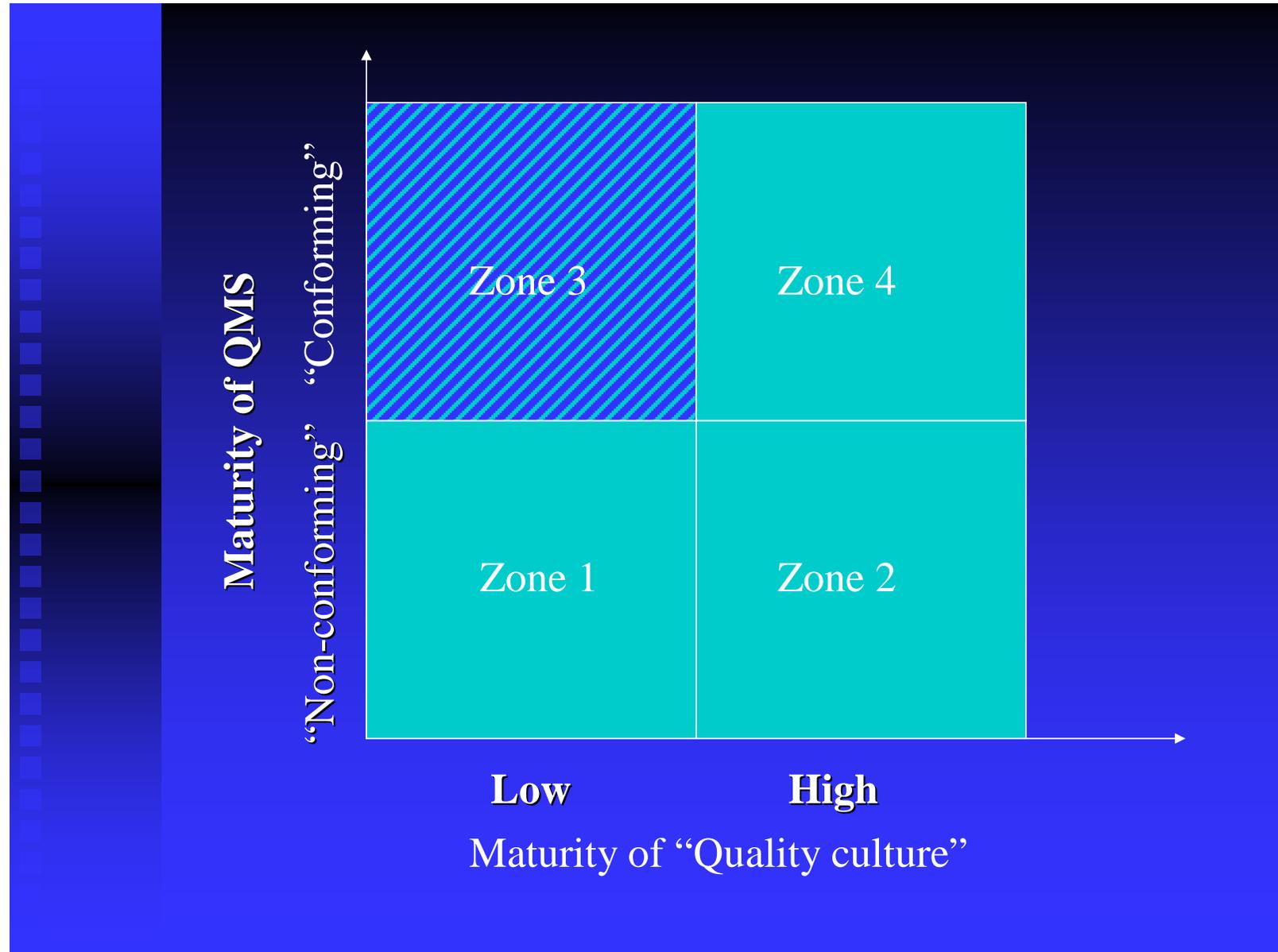
Zone 3

- An organization that has been certified to one of the MS standards for a significant period of time might be able to demonstrate a high level of conformity to the MS, but at the same time not have truly implemented a "MS culture" throughout the organization.

Zone 3

- Typically, the MS might have been implemented under pressure from customers, and built around the requirements of the standard, rather than on the organization's own needs and expectations.

- As a result, the MS, may be operating in parallel with the way the organization carries out its routine operations, generating redundancy and inefficiency.

Zone 3

- Primary objective of the auditor should be to act as a catalyst for the organization to build on its Standard-based management system, and to integrate the system into its day-to-day operations.

- It is a good practice to **encourage** and **stimulate** (but not **require!**) the organization to go **beyond** the requirements of the standard.

Zone 3

- The questions the auditor asks (and the way he or she asks those questions) can provide valuable insights for the organization into how the MS could become more efficient and **useful**.

- Identification of "Opportunities for Improvement" by the auditor should include ways in which the effectiveness of the MS might be enhanced, but could also address opportunities for improved **efficiency**.

Zone 4: Mature "management system culture"; mature MS, conforming to the MS
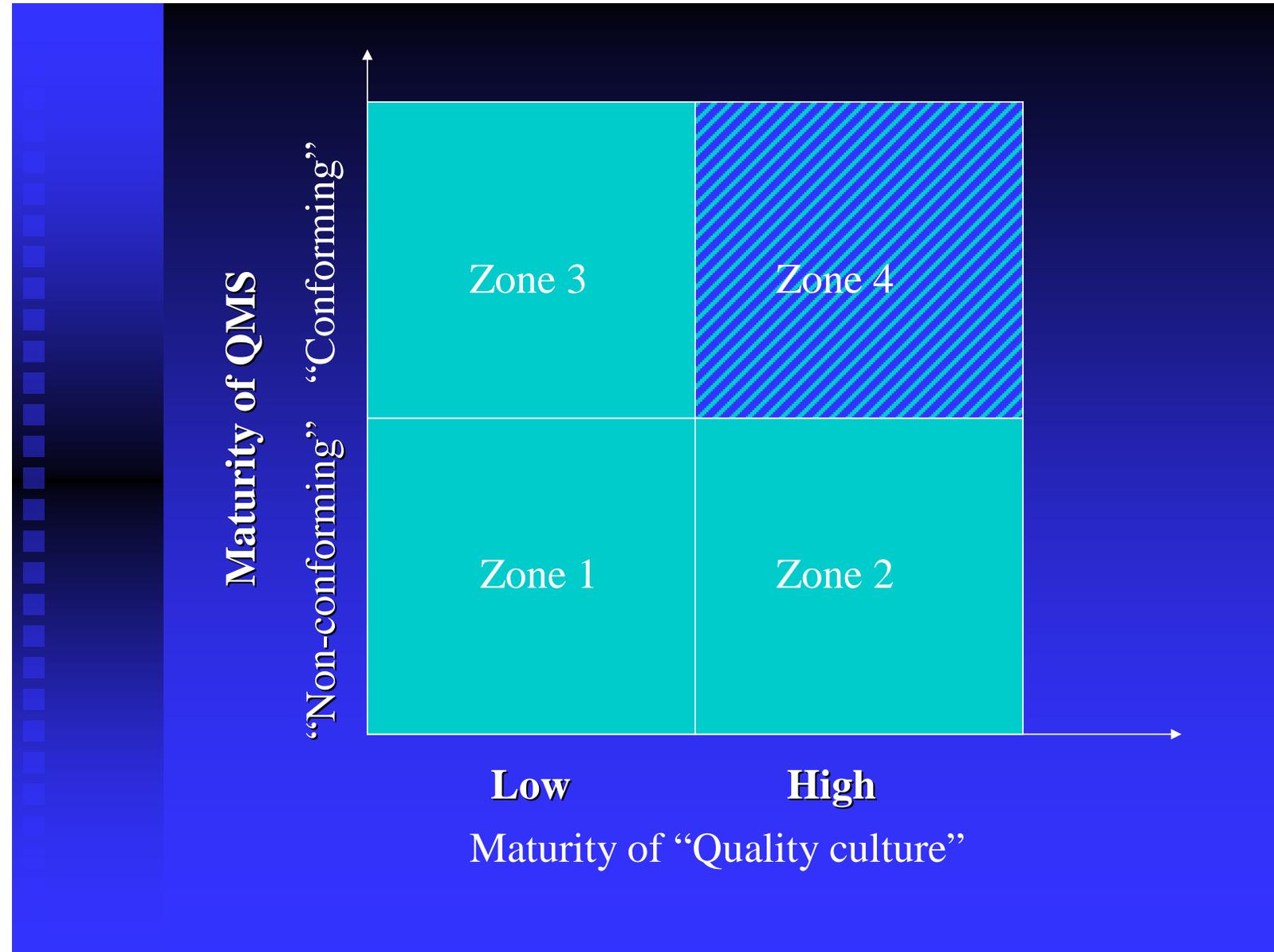
Zone 4

- For an organization that has a mature "MS culture", and has been certified to one of the MS standards for a significant period of time, the expectation of how an audit might add value will be the most challenging for an auditor.

- A common complaint among this kind of organization is that the "routine internal audits" by the auditor may be superfluous, and do little to add value in the organization's eyes.

Zone 4

- Top management becomes an important customer of the audit process.
- It is therefore important for the auditor to have a clear understanding of the organization's strategic objectives, and to be able to put the MS audit within that context.
- The auditor needs to dedicate time for detailed discussions with top management, to define their expectations for the MS, and to incorporate these expectations into the audit criteria.

Okay, so how do we do this?

- Audit Planning
- Audit Technique
- Analysis and Decision

Audit Planning

- Understand your organization's expectations/corporate culture
- Any specific concerns to be addressed (output from previous audits)?
- Pre-evaluation of statutory/regulatory requirements
- Appropriate assessment team selection to achieve assessment objectives
- Adequate time allocation

Audit Technique

- Focus more on the process, and less on procedures.
- **Some** documented procedures, work instructions, check-lists etc. may be necessary in order for the organization to plan and control its processes.
- Driving Force should be process performance.

Audit Techniques

- Focus more on results and less on records. In a similar fashion, **some** records may be necessary in order for the organization to provide objective evidence that its processes are effective (generating the planned results) but in order to add value, the auditor should be aware of and give credit for other forms of evidence.

Audit Techniques

- Remember the 7 [Quality Management Principles](#) for QMS assessments.

- Use the "Plan-Do-Check-Act" approach to evaluate the organization's process effectiveness.

  - Has the process been planned?

  - Is it being carried out according to plan?

  - Are the planned results being achieved?

  - Are opportunities for improvement being identified and implemented?

    - By correcting non-conformities
    - By identifying root causes of problems and implementing corrective action
    - By identifying trends, and the need for preventive action
    - By innovation

Audit Technique

- Adopt a "holistic" approach to evidence gathering throughout the audit, instead of focusing on individual clauses of the standard being assessed.

Analysis and Decision

- Put the findings into perspective (Risk assessment / "common sense").

- Relate findings to the effect on the organization's ability to provide conforming product and/or achieving objectives/continual improvement.

- Analysis of Process KPI's.

Summary

- The main objective of adding value via the audit process is to provide confidence that the output (expected outcomes – on-time, on-quality performance) of the IATF 16949 certified organization will be met.

Acknowledgements

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Thank you!

Questions/Answers/Cheers/Jeers