

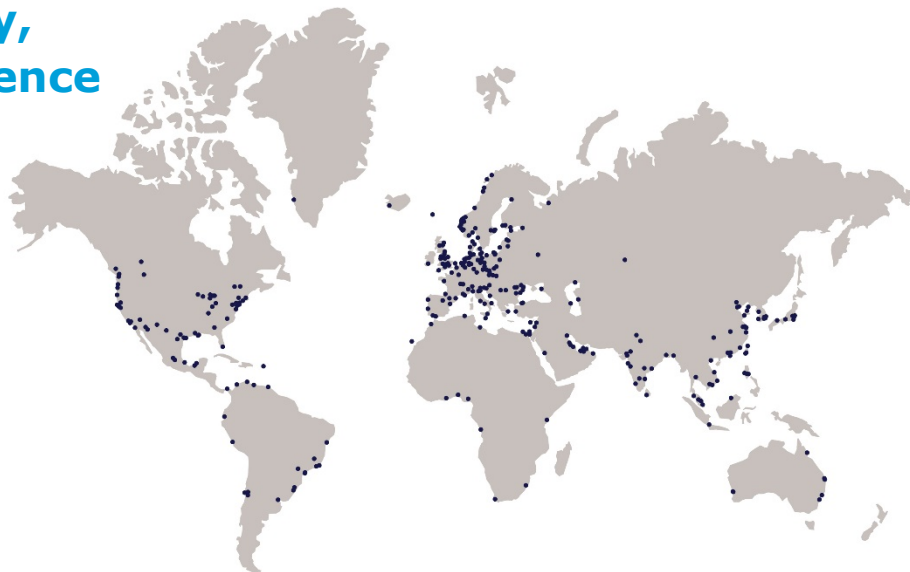
ISO 9001 Top 10 Finding in 2019: Practical Actions For The Future

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DNV GL Group: Who we are

Long history, Global presence



≈ 100,000

Customers



1864

Established



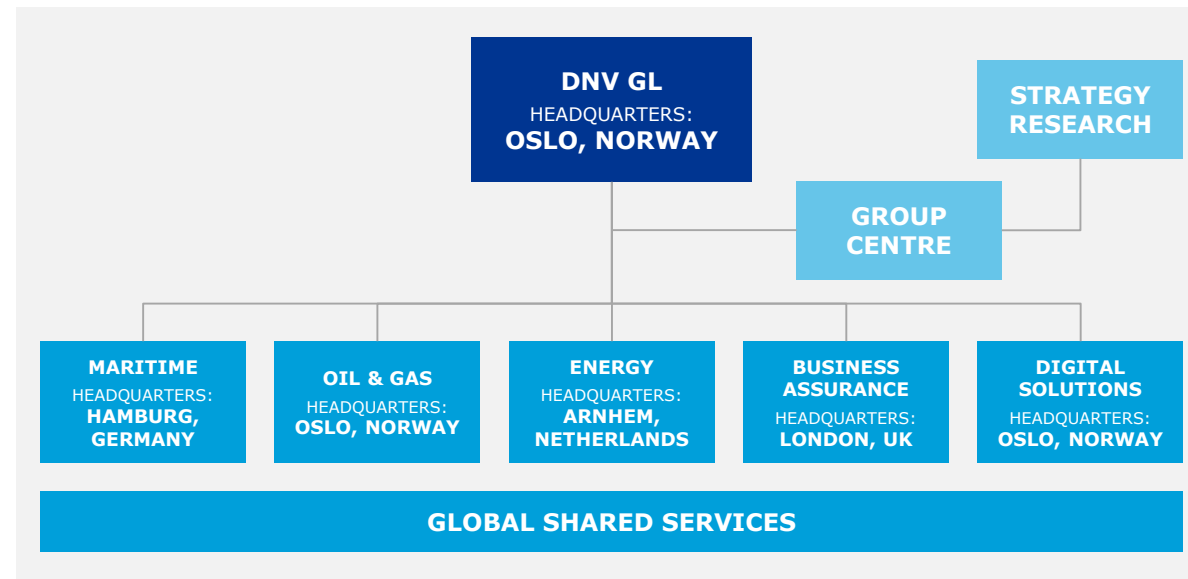
350

Offices Worldwide



100+

Countries



OUR PURPOSE

To safeguard life, property and the environment

OUR VALUES

WE CARE for each other, our customers, our planet, and we take care of ourselves.

WE DARE to explore, to experiment, to be different, and to be courageous, curious and creative.

WE SHARE our experience and knowledge. We collaborate with each other and our customers, and we continue to grow and develop as a result.

OUR VISION

A trusted voice to tackle global transformations

DNV GL - Business Assurance:
Americas in a nutshell



8

Offices



12,250+

Certificates



630+

Employees



500+

Hospitals Accredited

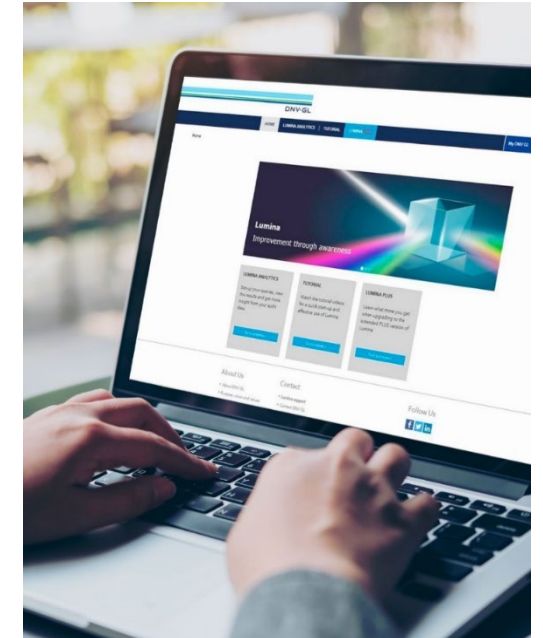
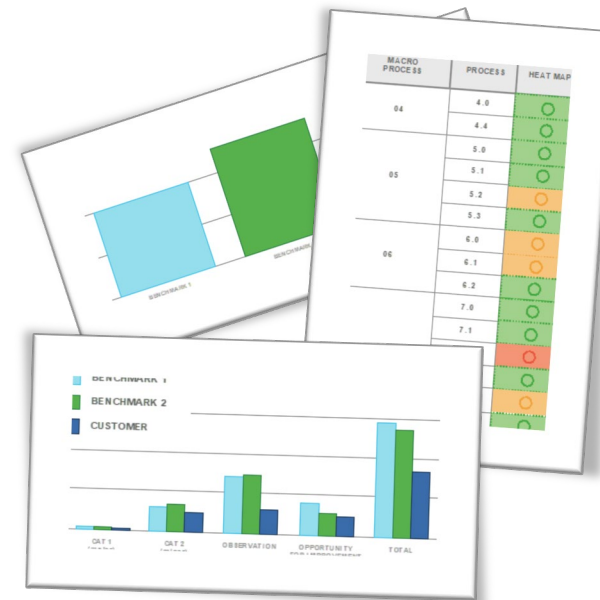


Improvement through awareness

Lumina app is our proprietary business intelligence benchmarking suite for analyzing data on the performance of thousands of companies' management systems.

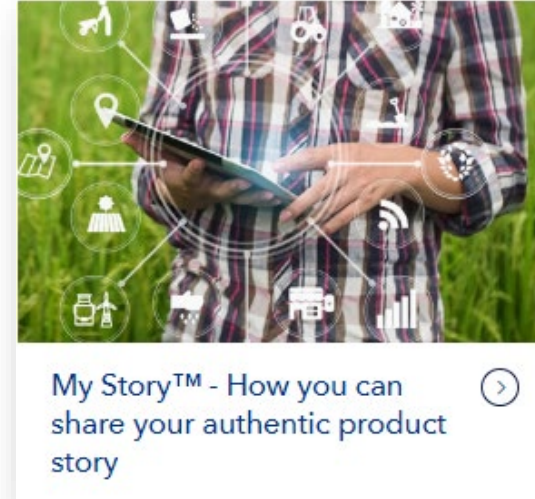
Lumina provides:

- ✓ **An objective measure** of the overall Management System's performance.
- ✓ **Benchmark analysis** against identified reference groups (e.g. industry peers, best performers, etc.).
- ✓ Extensive **internal benchmarking** among sites or business units.
- ✓ A **detailed planning** of the improvement path.
- ✓ **Definition of targets** at several levels in the organization and their measurement/follow-up.
- ✓ **Trend-line analysis** over time periods.



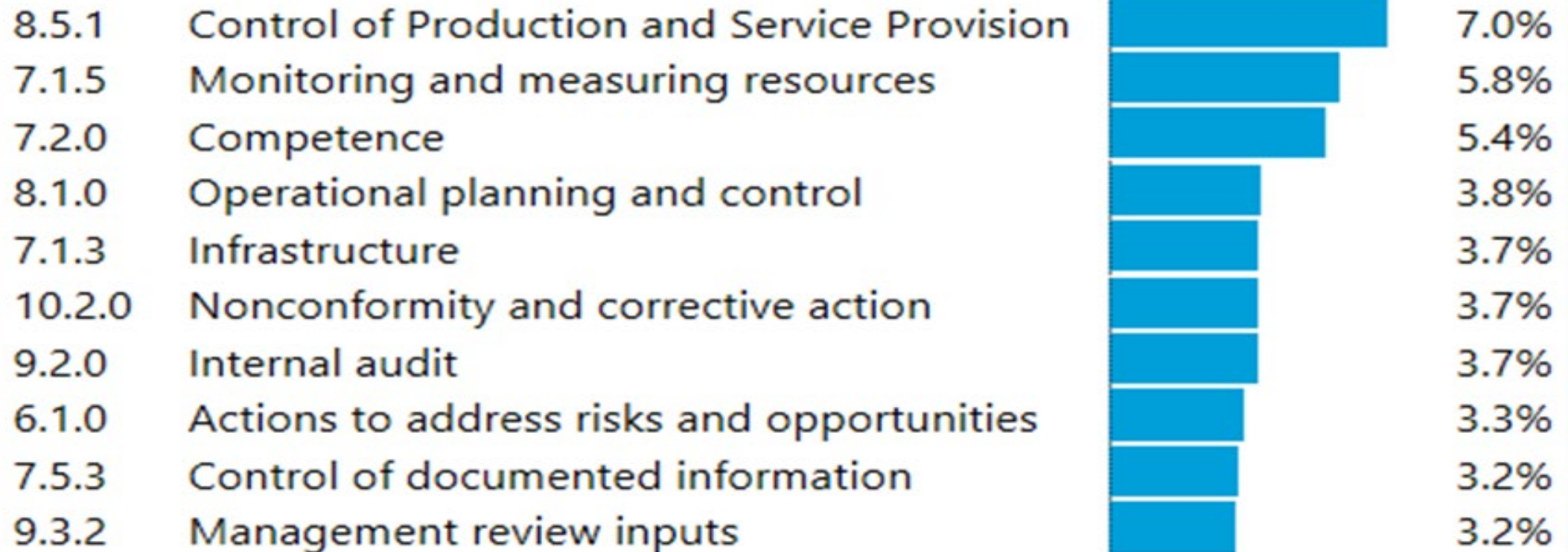
Digital Assurance and Transformation

- Blockchain Solutions – show origin, quality and social/environmental/ethical integrity of product to consumers displaying facts verified by DNV GL and immutably stored on VeChain platform.
- Since 2018, DNV GL's certificates are stored in a private BlockChain to improve security and transparency.
- Virtual Auditing and Witness Assessments (sit by the pool while you participate in the audit)



Top 10 Findings Issued in 2019: Practical Actions For The Future

Top 10 Findings (non-conformities)



8.5.1 Control of Production and Service Provision

Common Implementation

- Process requirements affecting quality are **usually defined in work instructions**, such as engineering drawings, specifications, routers, or work orders. These documents often contain critical parameters and may also include or reference process equipment. It is important that operating personnel be familiar with the critical parameters, which have been defined.
- Where the achievement of desired levels of process control is dependent upon the consistent and stable operation of process equipment and essential materials, the organization **should include and define** the amount and extent of maintenance of such process equipment and essential materials and how they apply within the scope of the quality management system.
- Work instructions or specifications need to be clear and understandable and provide the necessary information to ensure that the product or service conforms to the specified requirements. However, it should be noted that it is **not necessary to write a detailed instruction** containing all the steps which a competent worker would be expected to know. For example it would not be necessary to provide a written instruction to a trained machine tool operator on how to operate the machine tool.



8.5.1 Control of Production and Service Provision (Cont.)

- **Controls** to prevent human error would vary based on the service or product type. It is very common in some industries that an employee can only work a specific number of hours before being “forced” off-duty. It could also be fixtures that are put in place or only the necessary tools being available in a work cell.
- **Process monitoring and measuring** instructions may be in various formats, such as:
 - Process sheets
 - Inspection and laboratory test instructions
 - Shop travelers
 - Test procedures
 - Standard operation sheets
 - Other similar documents used by the organization which meet the same intent
- The **validation methods** employed by the organization should include, as applicable, such things as:
 - Defined criteria for review and approval of the processes
 - Approval of equipment and qualification of personnel
 - Use of specific methods and procedures
 - Requirements for records, and
 - Revalidation



7.1.5 Monitoring and measuring resources



Common Implementation

- Documented information is frequently retained in a calibration database, spreadsheet, or through certificates. This documented information should include reference to the standards used, the results of any calibration or verification as well as when the resource is found not to be valid.

7.2.0 Competence

Common Implementation

- Some examples of information that an organization may use in determining **competence needs** may include the following:
 - An annual assessment, which takes into account changes in technology, annual business objectives, and organizational changes
 - Individual's performance appraisal results
 - Corrective action requests (e.g., from audits)
 - Customer complaints
- **Competence requirements** for individuals should be determined and may appear in departmental procedures, job descriptions or similar documents.
- The organization may select whomever it deems appropriate for a position; however, personnel selected **must meet defined criteria**. The Standard requires the organization to take action to satisfy identified competence needs. There are numerous methods for accomplishing this requirement. Competence needs should be defined for new employees as well as existing employees. Consideration should also be given to competence of temporary/subcontract employees where appropriate. Regardless of the method used, **documented information must be retained**.

7.2.0 Competence (Cont.)

- The organization must retain **appropriate personnel qualification** documented information which can include education, experience, and training information. The following list includes examples.
 - Signed application
 - Resume/Curriculum Vitae
 - Signed affidavit
 - Copies of certificates
 - Diplomas
 - Attendance sheets from training
 - Learning management systems



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8.1.0 Operational planning and control

Common Implementation:

- Most organizations have existing facilities, processes, documentation, and other resources. When a new product or service is to be introduced, or an existing product is to be modified, consideration should be given to the need for new processes and resources, or the modification of existing processes and resources to fit the **needs of the specific product**. Where the product manufacturing or service delivery involves highly repetitive routine activities, planning may be performed initially when documenting the quality system. If the nature of the activities is not routine, then separate planning for each new

order or contract may be needed. The risks and opportunities that were determined in clause 6 must also be addressed. This **could be done through methods such as FMEAs or control plans**. The output of the planning process is often referred to as a “Quality Plan”, “Project Plan”, or similar terminology. However, the specific format for the planning is up to the organization.

Potential Failure	Severity Ranking 1 to 10 (10=most severe)	Occurrence Ranking 1 to 10 (10=most likely to occur)	Detection Ranking 1 to 10 (10=no advance warning)	RPN Severity x Occurrence x Detection
Failure 1	7	1	3	21
Failure 2	10	8	8	640
Failure 3	2	10	5	100
Failure 4	7	8	6	336
Failure 5	4	7	10	280

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7.1.3 Infrastructure

Common Implementation

- Considerations for **infrastructure** may include such things as:
 - Offices, production facilities, warehousing, and distribution centers
 - Access to infrastructure such as highways, railroads, and airports may also be an important part of the equation
 - Maintaining production machinery, measuring equipment, and handling and conveying equipment
 - Any information technology required to accomplish the tasks should be identified, including hardware and software
- **Supporting services** may include such things as building maintenance, maintenance of production machinery, transportation, communication or information technology support.

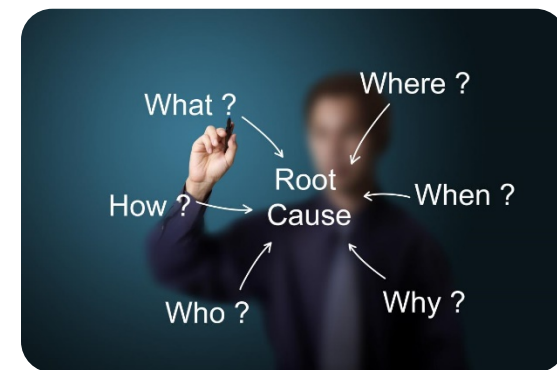


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10.2.0 Nonconformity and corrective action

Common Implementation

- It is DNV GL’s interpretation, as well as our Accreditation Bodies, that “cause” as stated in this clause of The Standard is **“root cause”**. In response to nonconformity, it is expected that containment (immediate action) is done. That is followed by a root cause analysis, and a subsequent plan to eliminate the nonconformity from happening again. Of course, there should be sufficient time to allow the implementation of the corrective action with a follow-up to determine if the action(s) were effective.
- For multi-site certifications, it is expected that any nonconformity found, no matter what the source, that the nonconformity and subsequent root cause analysis **include all sites covered by the certificate**. All sites are required to investigate, and where appropriate, implement the corrective action.

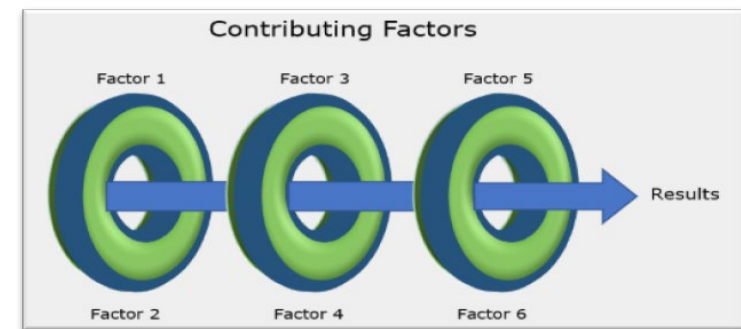


MDA 3

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10.2.0 Nonconformity and corrective action (Cont.)

- To achieve effective corrective actions, a company needs to **establish robust methods**. It is equally important that employees in the organization understand these methodologies. Many organizations choose to train some or all of its employees in the methods they use to ensure that corrective actions are adequately responded to. When training is not possible, some organizations assign a person responsible for reviewing the corrective actions for consistency.
- The **importance of fully investigating the cause**, making educated decisions about, and acting on the sources of problems is well understood. Without good information regarding the true source or cause of a problem, a great deal of effort can be expended with no beneficial results. The organization may find itself fighting the same fires again and again.





9.2.0 Internal audit

Common Implementation

- DNV GL’s interpretation is in general that the **internal audit system needs to be fully operational and be shown to be effective**. This means that a program covering all parts of the company and all elements of the management system is established. A major part of this program must have been executed at the time of certification, especially areas with most significant aspects. Additionally, evidence of follow-up need to be shown.
- There is no requirement on audit frequency in absolute terms. DNV GL’s interpretation is that the audit program should be **based on**

criticality and ensure that all parts of the company are audited at least once within a 3-years period. Critical areas should be audited annually, and again, frequency increased based upon the importance of the processes and changes to the organization, and the results of previous audits.

- For multi-site companies where DNV GL uses a sampling approach, it is required that **all sites have been subject to internal audit at the time of certification**. This is also required by the IAF Mandatory Document.

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6.1.0 Actions to address risks and opportunities

Common Implementation

- A well-established approach already implemented by many organizations is the use of **risk registers**, which if properly managed and implemented, can effectively manage risks and opportunities across a wide range of areas and issues. The depth and complexity of approach will depend significantly on the size and complexity of the organization, as well as other factors which could include the level of external regulation, existing requirements for public reporting, shareholder interests, public profile, numbers and types of customers, range and types of suppliers. There could

be a range of approaches which will be appropriate for the wide spectrum of organizations.

- Auditors will not automatically raise non-conformities if a documented formal risk assessment is not provided. However, the client must be able to explain that risks and opportunities have been determined and that actions have been evaluated.



6.1.0 Actions to address risks and opportunities (Cont.)



- While verifying the determined risks and opportunities it is important to keep in mind:
 - The scope of this standard: “organization needs to demonstrate its ability to consistently provide product or service that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.” and
 - The interested parties that are relevant to the quality management system and the requirements of these interested parties that are relevant to the quality management system (see 4.2).

7.5.3 Control of documented information

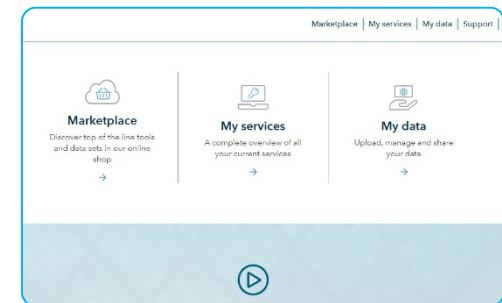
Common Implementation

- Organizations have available systems for retrieving documented information.

Consideration should be given to access of this information when individuals in the organization are working in the field such as sales people or a delivery person. These individuals in the organization should know where to get the information. If not every person is granted access, then the individuals need to know how and from whom to get this information.

- In some organizations where electronic access is not provided to everyone, there is posted information (e.g. documented standardized work).

- In these cases, there needs to be structure in ensuring that the posted documented information is correct.
- Protection for electronic information frequently comes in the form of employees not being able to revise documented information through read-only files. Access to information can also be given by the login rights of specific employees. Some employees might have read-only access while other employees have revision authorities.



9.3.2 Management review inputs

Common Implementation

– **Sufficient information must exist** to determine, whether the quality management system is suitable in meeting the requirements of the standard. Items that may be reviewed which are helpful during management reviews could also include the following:

- Process performance metrics
- Results of the improvement activities
- Results from audits of the quality management system including internal, customer, and third party audits
- Self-assessment of the organization
- Customer satisfaction measurements
- Measurements of fulfillment of the needs and expectations of other interested parties
- Market place evaluation including the performance of competitors
- Results of benchmarking activities
- Performance of suppliers
- Changes in original assumptions, arising from new technologies, outputs of research and development, quality concepts, financial, social, environmental conditions and legislative or regulatory changes

9.3.2 Management review inputs (Cont.)

- Needs or opportunities for improvement
- Status of achieving the quality objectives identified throughout the organization
- Where there is a multi-site certificate, the organization must determine if each site will perform their own management review and the main site (HQ) will review the summary, or will one management review be performed encompassing all sites. There is no requirement for a formal meeting. There is, however, a **requirement for documented information to be retained.**
- For items such as results of audits, nonconformities and corrective actions, there is no requirement for management to read every single nonconformity or audit report. Management is interested in **trends and high priority/risk items** to be highlighted.



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Polling Questions

What type of guidance do you feel you need?

Consulting

Training

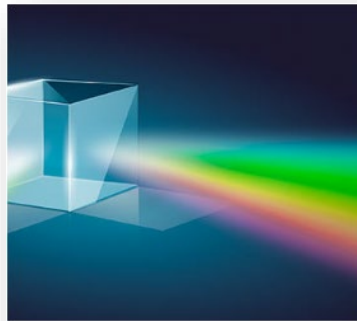
Certification

None

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