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## 問題集

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**Exam** : **ISO-9001 Lead Auditor**

**Title** : QMS ISO 9001:2015 Lead Auditor

**Version** : DEMO

1.DRAG DROP

Below are four of the seven principles on which ISO 9000 series are based. Match a potential benefit to each of the quality management principles (QMP).

**Quality management principles**

Customer focus		<input type="text"/>
Engagement of people		<input type="text"/>
Improvement		<input type="text"/>
Evidence-based decision-making		<input type="text"/>

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the options below. Alternatively, drag and drop each of the following potential benefits to a QMP.

Enhanced trust and collaboration throughout the organisation	Improved operational effectiveness and efficiency
Better communication between levels and functions of the organisation	Increased revenue and market share
Increased ability to demonstrate effectiveness of past actions	Enhanced drive for innovation
Common understanding of objectives and values among interested parties	

**Answer:**

**Quality management principles**

Customer focus		Increased revenue and market share
Engagement of people		Enhanced trust and collaboration throughout the organisation
Improvement		Enhanced drive for innovation
Evidence-based decision-making		Increased ability to demonstrate effectiveness of past actions

**Explanation:**

According to the ISO 9000:2015 document, the seven quality management principles are:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

For each principle, the document provides a statement, a rationale, key benefits, and actions you can take to apply the principle in your organization.

Based on the document, here is a possible way to match a potential benefit to each of the four quality management principles you mentioned: Table

Quality management principle Potential benefit

Customer focus Increased revenue and market share

Engagement of people Enhanced trust and collaboration throughout the organization

Improvement Enhanced drive for innovation

Evidence-based decision making Increased ability to demonstrate effectiveness of past actions

## 2.DRAG DROP

Match the process descriptions below to the process names:

The process by which the accuracy of test equipment is checked against a known standard. |

The process by which a product or service is visually examined to determine conformity to requirements. |

The process by which data is examined in detail to reach a specific answer or answers. |

The process by which a parameter of a product or service is examined to determine a specific value. |

To complete the table click on the blank section you want to complete s it is highlighted in red and then click on the applicable text from the options below. Alternatively you may drag and drop each of the following process names to the descriptions;

<input type="button" value="Sampling"/>	<input type="button" value="Calibration"/>	<input type="button" value="Evaluation"/>	<input type="button" value="Monitoring"/>	<input type="button" value="Analysis"/>	<input type="button" value="Measurement"/>
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### Answer:

The process by which the accuracy of test equipment is checked against a known standard. |

The process by which a product or service is visually examined to determine conformity to requirements. |

The process by which data is examined in detail to reach a specific answer or answers. |

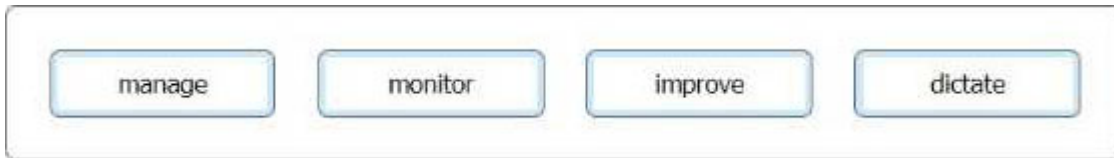
The process by which a parameter of a product or service is examined to determine a specific value. |

## 3.DRAG DROP

Select the word that best completes the sentence:

"The purpose of a management system standard is to  the performance of an organisation."

To complete the sentence with the best word, click on the blank section you want to complete so it is highlighted in red and then click on the applicable text from the option(s) below. Alternatively drag and drop the option(s) to the appropriate blank section.



**Answer:**

"The purpose of a management system standard is to  the performance of an organisation."

**Explanation:**

According to the ISO - Management system standards page, the key benefits of an effective management system include improved operational effectiveness and efficiency, improved risk management and protection of people and the environment, and enhanced drive for innovation. The Integrated Use of Management System Standards (IUMSS) handbook also states that the purpose and objectives of management system standards are to help organizations improve their performance by specifying repeatable steps that organizations consciously implement to achieve their goals and objectives.

Therefore, the complete sentence is:

"The purpose of a management system standard is to improve the performance of an organization."

4. Select the term that best describes the purpose of retaining documented information in a quality management system to ISO 9001.

- A. To facilitate auditing for proof of conformity to the standard.
- B. To provide confidence in the effectiveness of the quality management system.
- C. To safeguard the integrity of the quality management system.
- D. To support the operation of the processes of the quality management system.

**Answer: B**

**Explanation:**

According to ISO 9001:2015, clause 4.4, an organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are under control. The purpose of retaining documented information is to provide evidence of conformity to the standard, communicate information in the organization, maintain organizational knowledge, trace back changes or measurement used, and keep reference for improvement<sup>1</sup>.

Reference: Guidance on the requirements for Documented Information of ISO 9001:2015

Maintain Documented Information in ISO 9001:2015 – NIIX Quality Management System Software

Documented Information Required by ISO 9001:2015 - 9000 Store

Quality Systems - Records required by ISO 9001:2015

A Quality Management System Based on ISO 9001 | PECB

5. Which two of the following are the key expected results of a quality management system that conforms to the requirements of ISO 9001:2015?

- A. Decreased number of nonconforming products in all stages of the manufacturing cycle
- B. Decreased number of management system nonconformities
- C. Consistently provide products that meet customers' requirements
- D. Increased profits

E. Decreased number of warranty claims

F. Enhanced customer satisfaction

**Answer:** CF

**Explanation:**

According to the ISO 9001:2015 document, the key expected results of a quality management system that conforms to the requirements of ISO 9001:2015 are:

- the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
- the enhancement of customer satisfaction.

These results are derived from the quality management principles of customer focus and process approach, which are the basis of the ISO 9000 family of standards<sup>1</sup>. Customer focus means understanding and meeting customer needs and expectations, as well as exceeding them when possible<sup>1</sup>. Process approach means managing activities as interrelated processes that function as a coherent system, which leads to consistent and predictable results<sup>1</sup>. Therefore, the correct answer is C and F.

Reference: 2: ISO 9001:2015 - Quality management systems — Requirements 1: ISO - Quality management principles