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Audit evidence	ISO 9001 Clause 8.3 extract
Half of all new products launched in the past 12 months were late. The NPD Manager explains he has not got enough people on his team to cope with the demand for new products.	"8.3.2 e) ... internal ... resource needs for the design and development of products ..."
The NPD Manager explains many changes are made to cosmetic formulations during product development owing to retailer feedback. Only when confirmed by the retailer is the agreed formulation documented on SWIFT.	"8.3.6 ... retain documented information ..."
The NPD Manager explains that the customer confirms their approval to proceed with a new formulation by email. These emails are kept on SWIFT.	"8.3.5 ... retain documented information ..."
The NPD Manager shows you evidence of consumer trials that are carried out for some new products prior to full-scale launch.	"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."
The NPD Manager explains that an approved external laboratory is used to perform shelf-life stability trials on some formulations during product development.	"8.3.2 e) ... external ... resource needs for the design and development of products ..."

To complete the table click on the blank section you want to complete so it is highlighted in red and then click on the ISO 9001 clause 8.3 extracts listed below. Alternatively, drag and drop each clause to the audit evidence that applies.

"8.3.2 e) ... internal ... resource needs for the design and development of products ..."

"8.3.2 e) ... external ... resource needs for the design and development of products ..."

"8.3.4 d) ... conducted to ensure that the design and development outputs meet ..."

"8.3.5 ... retain documented information ..."

"8.3.6 ... retain documented information ..."

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ISO-9001-Lead-Auditor - QMS ISO 9001:2015 Lead Auditor Exam Useful Valid Test Topics

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q44-Q49):

NEW QUESTION # 44

XYZ Corporation is an organisation that employs 100 people. As the audit team leader, you are conducting a certification audit at Stage 1. When reviewing the quality management system (QMS) documentation, you find that quality objectives have been set for every employee in the organisation except top management. The Quality Manager complains that this has created a lot of resistance to the QMS, and the Chief Executive is asking questions about how much it will cost. He asks for your opinion on whether this is the correct method of setting objectives.

How would you respond with the following options? Select three.

- A. Indicate that ISO 9001 requires a minimum of two quality objectives.
- B. Suggest that the Quality Manager obtains external consultancy on the use of quality objectives.
- C. Advise the Quality Manager that you will raise an opportunity for improvement if the quality objectives are not addressed properly.
- D. Suggest that all employees undertake a training course on ISO 9001.
- E. Advise the Quality Manager to read the ISO 9001 standard and interpret in relation to the organisation's requirements.
- F. Suggest asking the certification body for guidance on this matter.
- G. Inform the Quality Manager that you will comment on the subject in your audit report.
- H. Advise the Quality Manager that, as an auditor, you cannot provide advice to the organisation on how it should operate its QMS.

Answer: C,E,G

Explanation:

According to the ISO 9001:2015 standard, clause 6.2.1 requires organizations to establish quality objectives at relevant functions, levels, and processes needed for the quality management system. The quality objectives must be consistent with the quality policy and the strategic direction of the organization. The quality objectives must also be measurable, monitored, communicated, and updated as appropriate.

In this scenario, the Quality Manager of XYZ Corporation has set quality objectives for every employee in the organization except top management. This has created a lot of resistance to the QMS, and the Chief Executive is asking questions about the cost and the method of setting objectives. The Quality Manager asks for your opinion as an auditor on whether this is the correct method of setting objectives.

As an auditor, you cannot provide advice to the organization on how it should operate its QMS. Your role is to assess the conformity and effectiveness of the QMS against the requirements of the standard and the organization's own policies and objectives. Therefore, you should respond with the following options:

B: Advise the Quality Manager to read the ISO 9001 standard and interpret in relation to the organization's requirements: You can suggest that the Quality Manager should familiarize himself with the requirements of clause 6.2.1 and understand how they apply to his organization. He should also consider the context and the needs and expectations of interested parties when setting quality objectives. He should ensure that the quality objectives are aligned with the quality policy and the strategic direction of the organization.

C: Advise the Quality Manager that you will raise an opportunity for improvement if the quality objectives are not addressed properly: You can inform the Quality Manager that you will evaluate the quality objectives during the audit and check whether they meet the requirements of clause 6.2.1. If you find any gaps or weaknesses in the quality objectives, you will raise an opportunity for improvement to help the organization improve its QMS. You will also verify whether the quality objectives are monitored, communicated, and updated as appropriate.

D: Inform the Quality Manager that you will comment on the subject in your audit report: You can inform the Quality Manager that you will document your findings and observations on the quality objectives in your audit report. You will also provide a summary of the audit results and any recommendations for improvement.

You will also indicate the level of conformity and effectiveness of the QMS.

These three options would help you to maintain your impartiality and professionalism as an auditor and to provide constructive feedback to the organization

NEW QUESTION # 45

Who maintains ownership of the audit report?

- A. The auditee

- B. The audit team leader
- C. The certification body

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

According to ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting):

- * The certification body retains ownership of the audit report as it is responsible for the certification decision.
- * The auditee may receive a copy, but it does not own the report.
- * The audit team leader compiles the report but does not own it.

Thus, C is the correct answer.

Reference:

ISO 17021-1:2015, Clause 9.4.8 (Audit Reporting)

NEW QUESTION # 46

Scenario 5: Mechanical-Electro (ME) Audit Stages

Mechanical-Electro, better known as ME, is an American company that provides mechanical and electrical services in China. Their services range from air-conditioning systems, ventilation systems, plumbing, to installation of electrical equipment in automobile plants, electronic manufacturing facilities, and food processing plants.

Due to the fierce competition from local Chinese companies and failing to meet customer requirements, ME's revenue dropped significantly. In addition, customers' trust and confidence in the company decreased, and the reputation of the company was damaged.

In light of these developments, the top management of ME decided to implement a quality management system (QMS) based on ISO 9001. After having an effective QMS in place for over a year, they applied for a certification audit.

A team of four auditors was appointed for the audit, including Li Na as the audit team leader. Initially, the audit team conducted a general review of ME's documents, including the quality policy, operational procedures, inventory lists, QMS scope, process documentation, training records, and previous audit reports.

Li Na stated that this would allow the team to maintain a systematic and structured approach to gathering documents for all audit stages. While reviewing the documented information, the team observed some minor issues but did not identify any major nonconformities. Therefore, Li Na claimed that it was not necessary to prepare a report or conduct a meeting with ME's representatives at that stage of the audit. She stated that all areas of concern would be discussed in the next phase of the audit.

Following the on-site activities and the opening meeting with ME's top management, the audit team structured an audit test plan to verify whether ME's QMS conformed to Clause 8.2.1 (Customer Communication) of ISO 9001.

To do so, they gathered information through group interviews and sampling. Li Na conducted interviews with departmental managers in the first group and then with top management. In addition, she chose a sampling method that sufficiently represented customer complaints from both areas of ME's operations.

The team members were responsible for the sampling procedure. They selected a sample size of 4 out of 45 customer complaints received weekly for electrical services and 2 out of 10 complaints for mechanical services.

Afterward, the audit team evaluated the evidence against the audit criteria and generated the audit findings.

According to general principles of sampling procedure, did the audit team select a valid sample for electrical services?

- A. Yes, the selected sample size is proportionate to the population.
- B. No, the selected sample size is high compared to the population, as for a population from 13 to 52 the minimum sample size should be 10.
- C. No, the selected sample size is low compared to the population, as for a population from 13 to 52 the minimum sample size should be 5.

Answer: C

Explanation:

Comprehensive and Detailed In-Depth Explanation:

The audit team selected 4 out of 45 customer complaints for electrical services, which is too low based on standard statistical sampling methods. According to ISO 19011:2018 (Guidelines for Auditing Management Systems), for a population size between 13 and 52, a minimum sample size should be 5 to achieve a reasonable level of confidence.

This means the selected sample (4 complaints) was insufficient and did not align with standard sampling procedures. Therefore, the correct answer is A.

Reference:

ISO 19011:2018, Clause 6.4.5 (Sampling Methods in Auditing)

NEW QUESTION # 47

You are carrying out an annual audit at an organisation that offers home security services. You are interviewing the Quality Manager (QM) You: "Would you tell me about your management review process?" QM: "The senior management team plans to review the management system every six months. The review follows a set agenda and records are maintained." You: "May I see the records from the last two management reviews?" Narrative: The Quality Manager gives you the latest record, which shows the last management review took place nine months ago.

The Quality Manager then gives you the previous management review record, which took place one year before the latest review.

You: "Are there any other review reports in the last two years?"

QM: "No, these are the only ones."

Answer:

Explanation:

Explanation:

Nonconformity report

ISO 9001 Clause Number: 9.3.1 Nature of problem: Management review has not been conducted at the defined frequency. ISO 9001 requirement that has not been fulfilled: ISO 9001 - "Top management shall review the organization's quality management system at planned intervals." Evidence: The last management review took place nine months ago, and the previous one took place one year before the latest review. The planned interval is six months.

NEW QUESTION # 48

Select the words that best complete the sentence:

Answer:

Explanation:

Explanation:

According to the ISO 19011:2018 document, the audit plan should provide the basis for agreement regarding the conduct and scheduling of the audit activities. The amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives¹. The scope of the audit refers to the extent and boundaries of the audit, such as the audit criteria, the audit objectives, the organizational and functional units, and the processes to be audited¹. The complexity of the audit refers to the degree of difficulty or intricacy of the audit, such as the number and diversity of the auditees, the audit criteria, the audit methods, and the audit team composition². The risk of not achieving the audit objectives refers to the possibility that the audit may fail to provide reliable and sufficient audit evidence to support the audit conclusions and report¹.

Therefore, the complete sentence is:

In the context of a third-party audit, the amount of detail provided in the audit plan should reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives.

References: 1: ISO 19011:2018 - Guidelines for auditing management systems 2: Audit Complexity - an overview | ScienceDirect Topics

NEW QUESTION # 49

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