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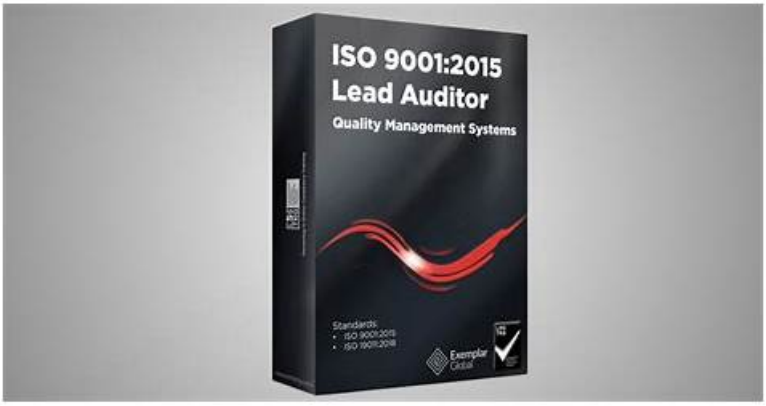

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PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q198-Q203):

NEW QUESTION # 198
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 # 199
You are conducting a third-party audit to ISO 9001 and the next item on your audit plan is 'internal auditing'.
When reviewing a sample of audit records up to 5 years previously, you find that many contain non-conformance reports and no actions have been taken. You interview the Quality Manager.
You: "I have noted that many of the older files contain non-conformances that have not had any corrective action taken." Quality Manager: "Because the business is always changing, the departmental managers tell me that the non-conformances are no longer applicable. I made a decision that any non-conformance over 3 years old is automatically closed" You: "Do you obtain any confirmation beforehand from the appropriate departments that the non-conformances are no longer applicable." Quality Manager: " No, because they are so old I consider that they are no longer appropriate. Please remember that we take a risk-based approach which means we audit where and when it is considered important to do so.
Select one course of action you would now take from the options.

- A. Interview relevant Departmental managers to assess whether the older non-conformances are still valid.
- B. Review all non-conformances reports related to clause 9.2 of ISO 9001
- C. Interview Top management to determine whether they were aware of and agreed the actions of the Quality Manager
- D. Raise a non-conformance report against clause 9.2.2.e of ISO 9001

Answer: D

Explanation:
According to ISO 9001:2015, clause 9.2.2.e, the organization is required to retain documented information as evidence of the implementation of the audit programme and the audit results. This includes the records of the nonconformities identified during the internal audits and the corrective actions taken to address them. The organization is also required to verify the effectiveness of the corrective actions, as per clause 10.2.2.
Therefore, in the scenario given, the Quality Manager's decision to automatically close any nonconformance over 3 years old without obtaining any confirmation from the relevant departments or verifying the effectiveness of the corrective actions is a clear violation of the requirements of clause 9.2.2.e. This indicates a lack of control and follow-up of the internal audit process, as well as a potential risk of recurrence or occurrence of the nonconformities in other areas. This also undermines the credibility and value of the internal audit programme, as well as the risk-based approach claimed by the Quality Manager.
Hence, the best course of action to take is D, to raise a nonconformance report against clause 9.2.2.e of ISO 9001, and to communicate the audit findings to the relevant management. The other options are either insufficient or irrelevant to address the issue, as they do not directly relate to the noncompliance with clause 9.2.2.e.
References:
ISO 9001:2015(en), Quality management systems - Requirements, clause 9.2.2 and 10.2.2 ISO 19011:2018(en), Guidelines for auditing management systems, clause 6.4.4 and 6.7.2 ISO 9001 Lead Auditor Training Course | IRCA Certified | BSI, section "Learning objectives" ISO 9001 Lead Auditor Course Material | 3FOLD Education Centre, module 5 and 6

NEW QUESTION # 200
You are conducting an audit at a single-site organisation seeking certification to ISO 9001 for the first time.
The organisation manufactures cosmetics for major retailers and the name of the retailer supplied appears on the product packaging. Sales turnover has increased significantly over the past five years You are interviewing the new Product Development Manager. You note that a software application called SWIFT is used to help control the product development process.
You have gathered audit evidence as outlined in the table. Match the ISO 9001 clause 8.3 extracts to the audit evidence.

Answer:

Explanation:

Explanation:

The table below shows the possible matching of the ISO 9001 Clause 8.3 extract to the audit evidence.

Table

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.

"8.3.5 ... 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.

"8.3.6 ... 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 resulting products and services meet the requirements ..." 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 ..."

NEW QUESTION # 201

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).

Answer:

Explanation:

Explanation:

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 According to the Quality management principles document published by ISO, each quality management principle has a statement, a rationale, key benefits, and actions you can take to apply it. Based on these descriptions, the potential benefits can be matched to the corresponding principles as follows:

Customer focus: The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations. The key benefits of this principle include increased customer value, customer satisfaction, customer loyalty, repeat business, reputation, customer base, revenue and market share.

Engagement of people: Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value. The key benefits of this principle include improved understanding of the organization's objectives and values, increased involvement in improvement activities, enhanced personal development, increased motivation and empowerment, enhanced trust and collaboration, and increased recognition and rewards.

Improvement: Successful organizations have an ongoing focus on improvement. The key benefits of this principle include improved organizational capabilities, alignment of improvement activities at all levels, increased ability to anticipate and react to opportunities and threats, enhanced drive for innovation, and increased levels of satisfaction.

Evidence-based decision-making: Decisions based on the analysis and evaluation of data and information are more likely to produce desired results. The key benefits of this principle include improved decision-making processes, increased ability to demonstrate the effectiveness of past decisions, increased ability to review, challenge and change opinions and decisions, and increased ability to improve performance.

NEW QUESTION # 202

In the context of a management system audit, identify the sequence of a typical process for collecting and verifying information. The first one has been done for you.

To complete the sequence 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 the options to the appropriate blank section.

Answer:

Explanation:
Explanation:
Identifying the source of information
Sampling available data
Gathering audit evidence
Verifying objective evidence
Evaluating evidence against the audit criteria
Making audit conclusions
Evaluating against the audit criteria
According to ISO 19011:2018, clause 6.4, the process of collecting and verifying information during an audit involves the following steps1:
Identifying the source of information: The audit team should identify the sources of information that are relevant to the audit objectives, scope and criteria. These sources may include documents, records, personnel, processes, activities, facilities, equipment, etc. The audit team should also determine the methods and tools for accessing and collecting the information, such as interviews, observations, document review, sampling, etc.
Sampling available data: The audit team should select a representative sample of the available data to verify the conformity and effectiveness of the management system. The sample size and selection method should be based on the audit objectives, scope and criteria, as well as the level of confidence and risk. The audit team should also consider the validity, reliability, relevance and sufficiency of the data.
Gathering audit evidence: The audit team should use the methods and tools identified in the previous step to collect audit evidence, which is the records, statements of fact or other information that are relevant to the audit criteria and verifiable. The audit team should record the audit evidence in a clear, concise and objective manner, using notes, checklists, photographs, audio or video recordings, etc.
Verifying objective evidence: The audit team should verify the accuracy, completeness and authenticity of the audit evidence collected. This may involve cross-checking different sources of information, confirming the identity and authority of the persons providing the information, examining the original documents or records, etc. The audit team should also identify any discrepancies, inconsistencies or gaps in the audit evidence.
Evaluating evidence against the audit criteria: The audit team should compare the audit evidence with the audit criteria to determine the extent of conformity and nonconformity. The audit team should also identify any opportunities for improvement, best practices, positive aspects or potential risks. The audit team should use professional judgement and apply the principles of auditing when evaluating the audit evidence.
Making audit conclusions: The audit team should consolidate the audit findings and evaluate the overall performance and effectiveness of the management system. The audit team should also consider the audit objectives, scope and criteria, as well as the context and expectations of the auditee and other interested parties. The audit team should provide a clear, concise and objective statement of the audit conclusions, which may include the degree of conformity, the achievement of the intended outcomes, the need for corrective actions, the suitability for certification, etc.
Evaluating against the audit criteria: The audit team should review the audit conclusions and ensure that they are consistent with the audit criteria and supported by sufficient and appropriate audit evidence.
The audit team should also ensure that the audit conclusions are communicated to the auditee and other relevant parties in a timely and effective manner, using the agreed audit report format and distribution method.
References: ISO 19011:2018(en), Guidelines for auditing management systems

NEW QUESTION # 203
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