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PECB ISO-9001-Lead-Auditor 시험요강:

| 주제 | 소개 |
|------|---|
| 주제 1 | <ul style="list-style-type: none">Conducting an ISO 9001 audit: It evaluates your skills to conduct a QMS audit. |
| 주제 2 | <ul style="list-style-type: none">Managing an ISO 9001 audit program: This topic evaluates your abilities to establish and managing a QMS audit program. |
| 주제 3 | <ul style="list-style-type: none">Fundamental principles and concepts of a quality management system: The main objective of this domain is to evaluate your skills of explaining and applying ISO 9001 principles and concepts. |
| 주제 4 | <ul style="list-style-type: none">Fundamental audit concepts and principles: Questions about interpreting and applying the main concepts and principles related to a QMS audit appear in this topic. |

- Preparing an ISO 9001 audit: This topic covers sub-topics related to preparing a quality management system audit.

최신 ISO 9001 ISO-9001-Lead-Auditor 무료샘플문제 (Q112-Q117):

질문 # 112

Which two of the following may be changed once a Stage 2 certification audit has commenced?

- A. Audit plan
- B. Audit checklist
- C. Increase of audit duration
- D. Agreed standard for the audit criteria
- E. Agreed language of the audit
- F. Audit scope

정답: A,C

설명:

Comprehensive and Detailed In-Depth Explanation:

Once a Stage 2 certification audit has commenced, certain logistical or planning-related elements may still be adjusted, while others are fixed by prior agreement and cannot be changed.

C. Audit Plan:

The audit plan is a document that outlines the scope, objectives, criteria, and logistics of the audit. According to ISO/IEC 17021-1:2015 (the standard for bodies providing audit and certification of management systems), clause 9.2.3.3 allows for modification of the audit plan based on real-time conditions during the audit - such as availability of auditees or changes in process access.

F. Increase of Audit Duration:

Audit duration is generally determined during audit planning based on factors like employee count, risk, complexity, etc. However, if during Stage 2 it is found that more time is needed (e.g., due to additional processes, scope not fully covered, or significant findings), auditors are permitted to extend the audit. This ensures full coverage of all required areas as per ISO/IEC 17021-1 clause 9.1.4 and IAF MD 5.

A. Agreed Language of the Audit:

This is determined and agreed upon in the contract and audit planning stages. Changing it during Stage 2 would create communication and documentation issues, especially in multi-site or multi-national audits.

B. Audit Scope:

The audit scope is defined in the contract and certification agreement based on clause 4.3 of ISO 9001:2015.

Changing it mid-audit would invalidate planning, required competencies, and potentially even the certification basis.

D. Agreed Standard for the Audit Criteria:

Changing the standard (e.g., from ISO 9001 to ISO 13485) is fundamentally altering the purpose and contractual basis of the audit and is not permissible once Stage 2 has started.

E. Audit Checklist:

The checklist is a tool prepared by the auditor as part of audit preparation and is based on the audit plan and standard requirements. While it may be adapted during the audit (e.g., if new risks arise), it does not constitute a formal change like duration or scope.

Relevant References:

- * ISO/IEC 17021-1:2015 Clause 9.2.3.3 (Audit Plan Modification)
- * IAF MD 5:2019 (Duration of QMS Audits)
- * ISO 9001:2015 Clause 4.3 (Scope of the QMS)
- * ISO/IEC 17021-1:2015 Clause 9.1.4 (Audit Duration)

질문 # 113

You are an auditor from a construction organisation who is conducting a second party audit to ISO 9001 at a steel rolling mill producing structural steelwork. When auditing the rolling process, you find that the operator who is unloading the furnace does not use the adjacent infrared pyrometer to measure the appropriate product temperature in readiness for the next production stage.

You: "How do you tell when the billet is ready for the rolling stage?"

Operator: "I've done this job for 20 years. I can tell by the bright red colour." You: "What happens if the colour is wrong?"

Operator: "The billet goes back into the furnace." You: "Is the pyrometer ever used?" Operator: "Only in borderline cases." You continue to interview the operator and find that around 25% of the billets are sent back to the furnace.

This includes 80% of the borderline cases.

Select three options that would provide evidence of conformance with clause 9.1.1 of ISO 9001.

- A. Maintenance plan for the furnace.
- B. Certification of conformance to national standards from the manufacturer of the pyrometer.
- C. A procedure that provides instruction in taking billet temperature.
- D. Planning for monitoring and measuring the billet temperature.
- E. A quality objective to achieve lower recycle rates for billets.
- F. Periodic analysis of the results of temperature checks.
- G. Annual review records for furnace operators.
- H. An increase in the use of the pyrometer by operators.

정답: C,D,F

설명:

According to ISO 9001:2015, clause 9.1.1, the organization is required to determine what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results, and when the monitoring and measuring shall be performed. The organization is also required to retain appropriate documented information as evidence of the results.

Therefore, in the scenario given, the organization should have planned for monitoring and measuring the billet temperature, as it is a critical factor for the quality of the product and the process. The organization should also have established a procedure that provides instruction in taking billet temperature, using the pyrometer or other suitable methods, to ensure consistency and accuracy. The organization should also have performed periodic analysis of the results of temperature checks, to identify trends, problems, and opportunities for improvement.

Hence, the options that would provide evidence of conformance with clause 9.1.1 of ISO 9001 are A, E, and F, as they are aligned with the requirements of the clause. The other options are either irrelevant or not directly related to clause 9.1.1, as they do not pertain to the monitoring and measurement of the billet temperature.

References:

ISO 9001:2015(en), Quality management systems - Requirements, clause 9.1.1 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

질문 # 114

Scenario 4:

TD Advertising is a print management company based in Chicago. The company offers design services, digital printing, storage, and distribution. As TD expanded, its management recognized that success depended on adopting new technologies and improving quality.

To ensure customer satisfaction and quality improvement, the company decided to pursue ISO 9001 certification.

After implementing the QMS, TD hired a well-known certification body for an audit. Anne Key was appointed as the audit team leader. She received a document listing the audit team members, audit scope, criteria, duration, and audit engagement limits.

Anne reviewed the document and approved the audit mandate. The certification body and TD's top management signed the certification agreement.

Before contacting TD, Anne reviewed the audit scope and noticed that TD made changes to it due to the adoption of new printing equipment. However, Anne disagreed with the changes, stating they would affect the audit timeline. She considered withdrawing from the audit.

Scenario 4 mentions that Anne received a document that contained the audit scope, criteria, duration, and the limits to the audit engagement. What did Anne receive in this case?

- A. The audit offer.
- B. The audit mandate.
- C. The audit plan.
- D. The certification agreement.

정답: A

설명:

Comprehensive and Detailed In-Depth Explanation:

Before conducting an audit, the certification body must provide an audit offer, which outlines the audit scope, criteria, and duration. Clause References:

* ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning: Requires the certification body to communicate key audit details before finalizing the audit process.

Why is the Correct Answer C?

- * The audit offer includes scope, criteria, duration, and engagement limits before the certification agreement is signed.
- * The certification body sends this to the auditee before finalizing the contract.

Why are the Other Options Incorrect?

- * A (Certification Agreement) # This is the contract signed after the audit offer is accepted.
- * B (Audit Plan) # The audit plan details the day-to-day audit schedule and is created after the agreement.
- * D (Audit Mandate) # This is an internal document for the certification body.

Reference:

ISO/IEC 17021-1:2015, Clause 9.1.2 - Audit Planning

질문 # 115

You work as an external quality consultant for an organisation, 'A', which provides packaged food to the public. You are asked to lead a team (you as the leader and two other auditors) to audit a supplier, 'B', to ISO

9001 which provides packaging materials to your organisation. It is 4 pm and the audit is close to an end; you are having an internal meeting with the team to decide what will be presented to the auditee during the Closing meeting. The Closing meeting was scheduled at 5 pm

You, as Audit Team Leader, audited top management. You explain to the audit team that you identified two nonconformities:

a. There is no documented information on Top Management Reviews, as required in clause 9.3 of ISO 9001: 2015.

b. There is no evidence of Top Management Commitment as required in clause 5.1 of ISO 9001:2015. (e.g., not ensuring the availability of resources to operate the QMS, not ensuring the establishment of objectives, no promotion of improvement, no promotion of the process approach).

All agreed to present these two nonconformities. They went to meet the Top Management of 'B' and noticed that the General Manager and three other managers (Production, Human Resources, and Sales) were present in the meeting room.

Considering the seriousness of the two nonconformities to Top Management, as audit team leader, from the following select the best option:

- A. Present the nonconformities to the managers, inform them that the report will be sent within 10 days, close the meeting and leave the site.
- B. **Present the nonconformities to the whole group and analyse with them how to overcome this situation.**
- C. Ask the General Manager to have a private conversation in which you present the nonconformities only to him because of their sensitive nature.
- D. Present the nonconformities to the whole group and inform that you will recommend your company to remove them from the approved suppliers list.

정답: B

설명:

According to the guidance on conducting the audit closing meeting¹, the audit team leader should provide a summary of the audit findings and conclusions, invite discussions, and agree on timelines for any corrective actions. The audit team leader should also be respectful, constructive, and objective when presenting the nonconformities, and avoid any personal or emotional comments. The audit team leader should also consider the impact of the disruptive event (such as the Covid-19 pandemic) on the auditee's context, interested parties, and risks², and acknowledge any good practices or improvements observed during the audit. Therefore, option D is the best option, as it follows the best practices for the closing meeting and allows the auditee to understand the nonconformities and their implications, and to participate in the analysis and resolution of the issues. Option A is not correct, as it is not respectful, constructive, or objective, and it does not invite any discussion or feedback from the auditee. It also assumes that the audit team leader has the authority to recommend the removal of the supplier from the approved list, which may not be the case. Option B is not correct, as it does not provide enough information or explanation to the auditee, and it does not allow any discussion or feedback from the auditee. It also does not follow the best practices for the closing meeting, such as providing a summary of the audit, acknowledging any good practices, and agreeing on timelines for corrective actions. Option C is not correct, as it does not involve the other managers who are responsible for the functions or processes that were audited, and who may have valuable input or information to share. It also does not follow the best practices for the closing meeting, such as providing a summary of the audit, inviting discussions, and agreeing on timelines for corrective actions. References: 1: Conducting the Audit Closing Meeting: Sharing the Results2: Auditing ISO 9001:2015 in the Context of a Disruptive Event.

질문 # 116

Scenario 2:

Bell is a Canadian food manufacturing company that operates globally. Their main products include nuts, dried fruits, and

confections. Bell has always prioritized product quality and has maintained a good reputation for many years. However, the company's production error rate increased significantly, leading to more customer complaints.

To increase efficiency and customer satisfaction, Bell implemented a Quality Management System (QMS) based on ISO 9001. The top management established a QMS implementation team comprising five middle managers from various departments, including Leslie, the quality manager.

Leslie was responsible for assigning responsibilities and authorities for QMS-related roles. He also suggested including a top management representative in the QMS team, but top management declined due to other priorities.

The team defined the QMS scope as:

"The scope of the QMS includes all activities related to food processing." Leslie established a quality policy and presented it to the team for review before top management approval

. Top management also proposed a new strategy for handling customer complaints, requiring biweekly customer surveys to monitor customer perceptions.

Which of the following indicates that Bell has defined its quality objectives?

- A. Establishing a new strategy for handling customer complaints and requests
- B. Implementing a QMS to increase efficiency in the manufacturing process and customer satisfaction
- C. Assigning responsibilities for QMS roles
- D. Establishing a QMS implementation team of middle managers from various departments

정답: A

설명:

Comprehensive and Detailed In-Depth Explanation:

ISO 9001:2015, Clause 6.2 (Quality Objectives and Planning to Achieve Them) states that an organization must establish measurable and relevant quality objectives to improve QMS effectiveness.

Bell's strategy for handling customer complaints aligns with this requirement because it includes specific, measurable goals (biweekly customer surveys) to enhance customer satisfaction and service quality.

Other options are not directly related to defining quality objectives:

- * Option B (Implementing a QMS) refers to the overall system, not specific objectives.
- * Option C (Creating a QMS team) is an implementation step, not an objective.
- * Option D (Assigning responsibilities) is necessary for QMS but does not define objectives.

Reference:

ISO 9001:2015, Clause 6.2 - Quality Objectives and Planning to Achieve Them

질문 # 117

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