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## PECB ISO/IEC 42001:2023 Artificial Intelligence Management System Lead Auditor Exam Sample Questions (Q90-Q95):

### NEW QUESTION # 90

Scenario 7 (continued):

Scenario 7: ICure, headquartered in Bratislava, is a medical institution known for its use of the latest technologies in medical practices. It has introduced groundbreaking AI-driven diagnostics and treatment planning tools that have fundamentally transformed patient care.

ICure has integrated a robust artificial intelligence management system AIMS to manage its AI systems effectively. This holistic management framework ensures that ICure's AI applications are not only developed but also deployed and maintained to

adhere to the highest industry standards, thereby enhancing efficiency and reliability.

ICure has initiated a comprehensive auditing process to validate its AIMS's effectiveness in alignment with ISO/IEC 42001. The stage 1 audit involved an on-site evaluation by the audit team. The team evaluated the site-specific conditions, interacted with ICure's personnel, observed the deployed technologies, and reviewed the operations that support the AIMS. Following these observations, the findings were documented and communicated to ICure, setting the stage for subsequent actions.

Unforeseen delays and resource allocation issues introduced a significant gap between the completion of stage

1 and the onset of stage 2 audits. This interval, while unplanned, provided an opportunity for reflection and preparation for upcoming challenges.

After four months, the audit team initiated the stage 2 audit. They evaluated AIMS's compliance with ISO

/IEC 42001 requirements, paying special attention to the complexity of processes and their documentation. It was during this phase that a critical observation was made:

ICure had not fully considered the complexity of its processes and their interactions when determining the extent of documented information. Essential processes related to AI model training, validation, and deployment were not documented accurately, hindering effective control and management of these critical activities. This issue was recorded as a minor nonconformity, signaling a need for enhanced control and management of these vital activities.

Simultaneously, the auditor evaluated the appropriateness and effectiveness of the "AIMS Insight Strategy," a procedure developed by ICure to determine the AIMS internal and external challenges. This examination identified specific areas for improvement, particularly in the way stakeholder input was integrated into the system. It highlighted how this could significantly enhance the contribution of relevant parties in strengthening the system's resilience and effectiveness.

The audit team determined the audit findings by taking into consideration the requirements of ICure, the previous audit records and conclusions, the accuracy, sufficiency, and appropriateness of evidence, the extent to which planned audit activities are realized and planned results achieved, the sample size, and the categorization of the audit findings. The audit team decided to first record all the requirements met; then they proceeded to record the nonconformities.

Based on the scenario above, answer the following question:

Question:

Which clause did the audit team evaluate when assessing the appropriateness of the "AIMS Insight Strategy" procedure?

- A. Clause 5.2 AI policy
- **B. Clause 4.1 Understanding the organization and its context**
- C. Clause 4.3 Determining the scope of the AI management system

**Answer: B**

Explanation:

The "AIMS Insight Strategy" refers to ICure's method for identifying internal and external challenges, which maps directly to Clause 4.1.

\* ISO/IEC 42001:2023 Clause 4.1 requires organizations to determine external and internal issues relevant to the AIMS, including stakeholder needs and challenges.

\* The Lead Auditor Manual states: "Clause 4.1 focuses on environmental, regulatory, technological, and organizational factors that affect AI operations and should be addressed through strategic tools like insight strategies." Reference: ISO/IEC 42001:2023 Clause 4.1; Lead Auditor Study Guide Module 2.

## NEW QUESTION # 91

In which situations does an auditor have the right to decline the audit mandate?

- A. When technical experts have not been assigned to participate in the audit
- B. When clear problems exist related to the experience and language proficiency of the auditee's employees
- **C. When the allocated time for conducting the audit does not allow for a thorough assessment of the management system**
- D. When the auditee is unwilling to provide documented information in advance

**Answer: C**

Explanation:

Auditors have the right and responsibility to ensure that audits are conducted effectively. According to ISO 19011:2018 and ISO/IEC 17021-1:2015, if the audit time allocated is insufficient to conduct a comprehensive and thorough audit, the auditor may refuse or request modification of the assignment.

This helps maintain audit integrity, quality, and professional due care.

Reference:

ISO/IEC 17021-1:2015, Clause 9.1.4 - Audit duration

ISO 19011:2018, Clause 5.3.2 - Audit planning responsibilities

### NEW QUESTION # 92

Which aspect of the previous certification of VeridicAI is NOT correct? Refer to scenario 8.

Scenario 8: VeridicAI, based in San Francisco, USA, specializes in market research using AI technologies to analyze customer behavior. Founded in 2023, the company employs natural language processing, machine learning, and predictive analytics to provide real time insights to a range of businesses. VeridicAI has implemented an artificial intelligence management system AIMS based on ISO/IEC 42001 to manage its AI technologies effectively. The AIMS scope includes select departments within the company, for which it has received a four-year certification against ISO/IEC 42001. Committed to transparency, VeridicAI publicly shares details of this certification.

As the certification nears its end, VeridicAI is preparing for an audit to renew its certification.

The audit process was led by Sharona, the audit team leader, who is a full-time employee of the certification body. Sharona and the audit team undertook all planned audit activities. Afterward, they organized the closing meeting with VeridicAI's management. During the meeting, Sharona and the team made a recap on audit objectives and scope, presented the audit findings and conclusions, presented identified nonconformities, and organized a session for questions and answers for the auditee.

VeridicAI received a conditional recommendation for certification, underscoring its compliance with the industry's standards.

Sharona confirmed that the company met the essential requirements but noted some identified minor nonconformities. In response, VeridicAI compiled and submitted a comprehensive action plan that addresses all identified nonconformities within a designated timeframe. Because of the comprehensive action plan, Sharona did not see the need for an additional on-site visit to verify the effectiveness of the action plan.

Sharona played an integral role in the certification decision process. Her thorough understanding of VeridicAI's operations, gained from the audit, guided the certification body towards a well-informed certification decision.

- A. The AIMS certification was valid for a four-year period
- B. The certification was issued for specific departments within the company
- C. The certification details were made public, allowing access to all interested parties

**Answer: A**

Explanation:

According to ISO/IEC 42001:2023 and ISO/IEC 17021-1:2015 (which governs certification bodies), the maximum validity for a certification issued by a certification body is three years. Therefore, a four-year certification period, as mentioned in the scenario, is not consistent with the standard certification lifecycle.

\* Clause 9.1.3 of ISO/IEC 17021-1:2015 specifies that certification is typically valid for a maximum of three years.

\* ISO/IEC 42001:2023 does not override this requirement and aligns with ISO certification cycles.

\* Clause 5.3 of ISO/IEC 42001 highlights the importance of the scope definition, allowing certifications to apply to specific departments, which is permitted.

\* Clause 10.3 emphasizes transparency - thus sharing certification status publicly is also correct and encouraged.

Therefore, the only incorrect detail is the certification duration of four years.

Reference:

ISO/IEC 17021-1:2015 Clause 9.1.3 - Certification Cycle

ISO/IEC 42001:2023 Clause 5.3 - Scope of the AIMS

ISO/IEC 42001:2023 Clause 10.3 - Communication

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### NEW QUESTION # 93

Which requirement of Clause 7 (Support) of ISO/IEC 42001 did OptiFlow NOT implement? Refer to Scenario 2.

Scenario 2: OptiFlow is a logistics company located in New Delhi, India. The company has enhanced its operational efficiency and customer service by integrating AI across various domains, including route optimization, inventory management, and customer support. Recognizing the importance of AI in its operations, OptiFlow decided to implement an Artificial Intelligence Management System (AIMS) based on ISO/IEC 42001 to oversee and optimize the use of AI technologies.

To address Clauses 4.1 and 4.2 of the standard, OptiFlow identified and analyzed internal and external issues and needs and expectations of interested parties. During this phase, it identified specific risks and opportunities related to AI deployment, considering the system's domain, application context, intended use, and internal and external environments. Central to this initiative was the establishment and maintenance of AI risk criteria, a foundational step that facilitated comprehensive AI risk assessments, effective risk treatment strategies, and precise evaluations of risk impacts. This implementation aimed to meet AIMS's objectives, minimize adverse effects, and promote continuous improvement. OptiFlow also planned and integrated strategies to address risks

and opportunities into AIMS's processes and assessed their effectiveness.

OptiFlow set measurable AI objectives aligned with its AI policy across all organizational levels, ensuring they met applicable requirements and matched the company's vision. The company placed strong emphasis on the monitoring and communication of these objectives, ensuring they were updated annually or as needed to reflect changes in technology, market demands, or internal processes. It also documented the objectives, making them accessible across the company.

To guarantee a structured and consistent AI risk assessment process, OptiFlow emphasized alignment with its AI policy and objectives. The process included ensuring consistency and comparability, identifying, analyzing, and evaluating AI risks.

OptiFlow prioritizes its AIMS by allocating the necessary resources for its comprehensive development and continuous enhancement. The company carefully defines the competencies needed for personnel affecting AI performance, ensuring a high level of expertise and innovation.

OptiFlow also manages effective internal and external communications about its AIMS, aligning with ISO/IEC 42001 requirements by maintaining and controlling all required documented information. This documentation is meticulously identified, described, and updated to ensure its relevance and accessibility.

Through these strategic efforts, OptiFlow upholds a commitment to excellence and leadership in AI management practices.

To comply with Clause 9 of ISO/IEC 42001, the company determined what needs to be monitored and measured in the AIMS. It planned, established, implemented, and maintained an audit program, reviewed the AIMS at planned intervals, documented review results, and initiated a continuous feedback mechanism from all interested parties to identify areas of improvement and innovation within the AIMS

- A. Ensure that changes are carried out in a planned manner
- B. Ensure that individuals under their control are informed about the AI policy
- C. Ensure that employees are competent on the basis of appropriate education

**Answer: A**

Explanation:

Clause 7 of ISO/IEC 42001 (Support) outlines key requirements related to:

- \* Resources
- \* Competence
- \* Awareness
- \* Communication
- \* Documented information

According to the scenario:

- \* OptiFlow defines competencies required for personnel and allocates necessary resources (covers A).
- \* It manages internal/external communication, and documentation practices (covers C).
- \* However, there is no mention of planning and controlling changes - a key requirement under Clause 7.5.6 and also reflected in Clause 8 (Operational planning and control), which often ties into Clause 7 for support readiness.

Thus, Option B - "Ensure that changes are carried out in a planned manner" - was not evidenced in the scenario and is the correct answer.

Reference:

- \* ISO/IEC 42001:2023, Clause 7.2 (Competence), 7.3 (Awareness), and 7.4 (Communication)
- \* Clause 7.5.6 - Control of changes
- \* PECB AI Lead Auditor Training Guide, Section 7 - Support functions in AIMS

## NEW QUESTION # 94

Scenario 4:

BioNovaPharm, a German biopharmaceutical company, has implemented an artificial intelligence management system AIMS based on ISO/IEC 42001 to optimize various aspects of drug discovery, including analyzing extensive biological data, identifying potential drug candidates, and streamlining clinical trial processes. After having the AIMS in place for over a year, the company contracted a certification body and is now undergoing an AIMS audit to obtain certification against ISO/IEC 42001.

Adopting a risk-based approach, the audit team focused on risk throughout their activities. The level of detail outlined in the audit plan corresponded to the scope and complexity of the audit. The team employed a ranking system for detailed audit procedures, prioritizing those with the highest risk.

Once the stage 1 audit began, the audit team started reviewing the auditee's documented information. To assess whether BioNovaPharm complies with the legal and regulatory requirements related to incident communication, the audit team examined evidence provided by the company's external legal office. The evidence confirmed that BioNovaPharm applies the requirements of the EU AI Act, which mandates that providers of high-risk AI systems report serious incidents to relevant authorities.

Following the completion of the stage 1 audit, John, an audit team member, documented the stage 1 audit outputs, including the observations of the audit team that could result in nonconformities during the on-site audit. However, the audit team leader,

Emma, who was overseeing the audit activities, observed that John failed to document significant observations related to the lack of transparency in the AI decision-making processes of BioNovaPharm. Considering that Emma observed John's lack of competence in undertaking some audit activities, a disciplinary note was recorded for John.

Question:

What type of evidence did the audit team obtain to assess BioNovaPharm's compliance with legal and regulatory incident reporting requirements?

- A. Analytical
- B. Technical
- C. Confirmative
- D. Observational

**Answer: C**

Explanation:

The audit team obtained Confirmative evidence.

\* ISO/IEC 42001:2023 Clause 9.2.2 specifies that during audits, objective evidence such as certifications, legal opinions, or official documentation that confirms compliance must be collected.

\* Confirmative evidence specifically refers to validated information from independent sources (in this case, external legal advice).

\* The Lead Auditor Training Manual also defines Confirmative Evidence as: "Evidence that provides verification of conformance through reliable independent sources." Reference: ISO/IEC 42001:2023 Clause 9.2.2; Lead Auditor Study Guide Chapter 7 ("Evidence Gathering Techniques").

## NEW QUESTION # 95

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