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PECB ISO/IEC 42001:2023Artificial Intelligence Management System Lead Auditor Exam Sample Questions (Q165-Q170):

NEW QUESTION # 165
Scenario 4 (continued):
BioNovaPharm, a German biopharmaceutical company, has implemented an artificial intelligence management system AIMSbased on ISO/IEC 42001 to optimize various aspects of drug discovery, including analyzing extensive biological data, identifying potentialdrug candidates, and streamlining clinical trial processes. After having the AIMS in place for over a year, the company contracted acertification 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 plancorresponded to the scope and complexity of the audit. The team employed a ranking system for detailed audit procedures, prioritizingthose with the highest risk.
Once the stage 1 audit began, the audit team started reviewing the auditee's documented information. To assess whether BioNovaPharmcomplies with the legal and regulatory requirements related to incident communication, the audit team examined evidence provided bythe company's external legal office. The evidence confirmed that BioNovaPharm applies the requirements of the EU Al Act, whichmandates that providers of high-risk Al 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 theobservations of the audit team that could result in nonconformities during the on-site audit. However, the audit team leader, Emma, whowas overseeing the audit activities, observed that John failed to document significant observations related to the lack of transparency inthe Al 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 level of negligence did Emma observe regarding John's audit documentation failures?

- A. Fraud
- B. Ordinary negligence
- C. Gross negligence
- D. Minor error

Answer: B

Explanation:
Ordinary negligencerefers to a failure to apply the level of care that a reasonable auditor would exercise, without intentional misconduct.
* ISO/IEC 17021-1:2015 Clause 7.2.5 requires auditors todocument audit findings properly and completely.
* TheLead Auditor Study Guidedefines ordinary negligence as:"An auditor's unintentional oversight or failure to perform duties to expected professional standards, without evidence of deliberate wrongdoing." Reference:ISO/IEC 17021-1:2015 Clause 7.2.5; Lead Auditor Manual Chapter 6 ("Audit Team Behavior and Ethics").

NEW QUESTION # 166
Scenario 5 (continued):
Scenario 5: Aizoia, located in Washington, DC, has revolutionized data analytics, software development, and consulting by using advanced Al algorithms. Central to its success is an Al platform adept at deciphering complex datasets for enhanced insights. To ensure that its Al systems operate effectively and responsibly, Aizoia has established an artificial intelligence management system AIMS based on ISO/IEC 42001 and is now undergoing a certification audit to verify the AIMS's effectiveness and compliance with ISO/IEC 42001.
Robert, one of the certification body's full-time employees with extensive experience in auditing, was appointed as the audit team leader despite not receiving an official offer for the role. Understanding the critical importance of assembling an audit team with diverse skills and knowledge, the certification body selected competent individuals to form the audit team. The certification body appointed a team of seven members to conduct the audit after considering the specific conditions of the audit mission and the required competencies.
Initially, the certification body, in cooperation with Aizoia, defined the extent and boundaries of the audit, specifying the sites (whether physical or virtual), organizational units, and the activities for review. Once the scope, processes, methods, and team composition had been defined, the certification body provided the audit team leader with extensive information, including the audit objectives and documented details on the scope, processes, methods, and team compositions.
Additionally, the certification body shared contact details of the auditee, including locations, time frames, and the duration of the audit activities to be conducted. The team leader also received information needed for evaluating and addressing identified risks and opportunities for the achievement of the audit objectives.
Before starting the audit, Robert wrote an engagement letter, introducing himself to Aizoia and outlining plans for scheduling initial

contact. The initial contact aimed to confirm the communication channels, establish the audit team's authority to conduct the audit, and summarize the audit's key aspects, such as objectives, scope, criteria, methods, and team composition. During this first meeting, Robert emphasized the need for access to essential information that would help to conduct the audit.
Moreover, audit logistics, such as scheduling, access, health and safety arrangements, observer attendance, and the need for guides or interpreters, were thoroughly planned. The meeting also addressed areas of interest or concern, preemptively resolving potential issues and finalizing any matters related to the audit team composition.
As the audit progressed, Robert recognized the complexity of Aizoia's operations, leading him to conclude that a review of its AI-related data governance practices was essential for compliance with ISO/IEC 42001.
He discussed this need with Aizoia's management, proposing an expanded audit scope. After careful consideration, they agreed to conduct a thorough review of the Al data governance practices, but there was no mutual decision to officially change the audit scope.
Consequently. Robert decided to proceed with the audit based on the original scope, adhering to the initial audit plan, and documented the conversation and decision accordingly.
Based on the scenario above, answer the following question:
Question:
Based on Scenario 5, were all the recommended aspects covered during the initial contact with Aizoia?

- A. No, the negotiation of the final audit fee and payment schedule was not covered
- B. Yes, all the required aspects were covered during the initial contact
- C. No, the agreement with the auditee regarding the extent of the disclosure and the treatment of confidential information was not confirmed

Answer: C

Explanation:
The scenario does not mention addressing confidentiality agreements, which is mandatory during the initial contact.
* ISO/IEC 17021-1:2015 Clause 9.2.3.1 and ISO 19011:2018 Clause 6.4.3 both require that agreements about confidentiality, access rights, and data protection must be confirmed before starting the audit.
* The Lead Auditor Manual highlights: "Initial contact meetings must establish the treatment of confidential information and audit-related disclosure agreements." Reference: ISO/IEC 17021-1:2015 Clause 9.2.3.1; ISO 19011:2018 Clause 6.4.3.

NEW QUESTION # 167
Question:
During which phase of the certification process is confirmation of registration performed?

- A. Before the initial audit
- B. After surveillance audits
- C. Beyond the initial audit
- D. During the initial audit

Answer: C

Explanation:
Confirmation of registration (certification) is performed beyond the initial audit, specifically after successful completion of the Stage 1 and Stage 2 audits and review by the certification body's decision committee. ISO
/IEC 17021-1:2015 (referenced in ISO/IEC 42001 certification processes) explains this clearly.
Reference: ISO/IEC 17021-1:2015, Clause 9.5 (Certification decision).

NEW QUESTION # 168
Scenario 4 (continued):
BioNovaPharm, a German biopharmaceutical company, has implemented an artificial intelligence management system AIMSbased on ISO/IEC 42001 to optimize various aspects of drug discovery, including analyzing extensive biological data, identifying potentialdrug candidates, and streamlining clinical trial processes. After having the AIMS in place for over a year, the company contracted acertification 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 plancorresponded to the scope and complexity of the audit. The team employed a ranking system for detailed audit procedures, prioritizingthose with the highest risk.
Once the stage 1 audit began, the audit team started reviewing the auditee's documented information. To assess whether BioNovaPharmcomplies with the legal and regulatory requirements related to incident communication, the audit team examined evidence provided bythe company's external legal office. The evidence confirmed that BioNovaPharm applies the requirements of

the EU Al Act, whichmandates that providers of high-risk Al 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 theobservations of the audit team that could result in nonconformities during the on-site audit. However, the audit team leader, Emma, whowas overseeing the audit activities, observed that John failed to document significant observations related to the lack of transparency inthe Al 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:
Based on Scenario 4, is the decision of the top management representative not to provide theadditional evidence requested by the audit team justifiable?

- A. Yes, because audits are based purely on interview evidence
- B. Yes, because the top management representative determined that the answers from the interviews could be corroborated by interviewing different employees
- C. No, because it is not recommended to conduct interviews with different employees to verify segregation of roles and responsibilities within the organization
- D. No, because verbal evidence is less reliable than the other types of evidence and requires additional supporting evidence

Answer: D

Explanation:
Verbal evidence alone is consideredless reliable.
* ISO/IEC 42001 Clause 9.2.2 states that"auditors shall corroborate interviews with documented information or other tangible evidence whenever possible."
* TheISO 19011:2018 Guidelines for Auditing Management Systems(adopted for auditing principles) Clause 6.5.6 also clearly specifies:"Interview results should be verified with other forms of evidence because interviews alone are insufficient."
Reference:ISO/IEC 42001:2023 Clause 9.2.2; ISO 19011:2018 Clause 6.5.6.

NEW QUESTION # 169
What does the 'Human-Centered Design' core element prioritize in AI development?

- A. Designing AI systems that prioritize human needs and values
- B. Maximizing profit
- C. Increasing automation
- D. Minimizing user interaction

Answer: A

Explanation:
Human-Centered Designfocuses on designing AI systems thatrespect and enhance human well-being, align withuser needs and values, and promoteinclusive and accessible technologies.
According toISO/IEC 42001:2023 - Clauses 4.2 and 6.1.2, and highlighted throughout thePECB Lead Auditor Guide - Domain 1, AI systems should beusable, inclusive, and ethically aligned, especially when intended for diverse or vulnerable user groups.
This principle ensures thathumans remain in control and benefitfrom the capabilities of AI.
Reference: ISO/IEC 42001:2023 - Clause 4.2 (Needs of interested parties), Clause 6.1.2 (Ethical impact and risk analysis) PECB Lead Auditor Guide - Domain 1: "Human-Centered Design and Trustworthy AI"

NEW QUESTION # 170
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