

01	☐ A	☐ B	☐ C	☐ D	☒ E
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31	☐ A	☐ B	☒ C	☐ D	☐ E
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35	☐ A	☐ B	☒ C	☐ D	☐ E
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37	☐ A	☐ B	☒ C	☐ D	☐ E
38	☐ A	☐ B	☐ C	☒ D	☐ E
39	☐ A	☐ B	☐ C	☐ D	☒ E

PRACTICE QUESTIONS

American Society For Quality (ASQ)

CBAEN2

Certified Medical Device Auditor

EDITION

Demo

QUESTIONS

9

FORMAT

Limited Edition PDF

Before you begin

What this is

9 practice questions for American Society For Quality (ASQ) CBAEN2 , each with its answer key and an explanation. Answer a question before you read its key — the explanation is worth more once you have committed.

If something looks wrong

Send us three things and we will check it:

- the exam code, CBAEN2
- the question number
- the email address on your order

Write to **support@mometrix.net**. We reply within one business day.

QUESTION 1

MULTIPLE CHOICE

During the opening meeting of a medical device audit, the auditee requests that the auditor share the audit checklist in advance so the audit team can prepare more effectively. Which of the following responses by the lead auditor align with ASQ auditing best practices? (Choose two.)

- ☐ **A** Provide the checklist because transparency with the auditee fosters cooperation and a smoother audit.
- ☒ **B** Decline to share the specific checklist questions, but explain the scope, criteria, and any process or product areas that will be examined.
- ☐ **C** Share the checklist but mark only the high-risk areas so the auditee can focus corrective actions before sampling begins.
- ☒ **D** Decline and explain that sharing the checklist in advance could compromise the integrity of objective evidence gathering and lead to staged records or rehearsed responses.

ANSWER B • D

WHY ASQ auditing guidance holds that the auditor shares the audit scope, criteria, and plan—not the specific questions or sampling approach, because doing so could lead to prepared or staged evidence. Declining while still explaining scope and criteria (B) preserves both transparency and independence. Declining with the explanation that pre-sharing risks evidence integrity (D) is the standard ASQ rationale. Sharing the full checklist (A) compromises audit independence, and sharing only high-risk items (C) is selective disclosure that biases the audit.

QUESTION 2

MULTIPLE CHOICE

An auditor is constructing a sampling plan for a sterile packaging process validation review and needs to decide between statistical and non-statistical sampling. Which of the following statements correctly describe characteristics of non-statistical sampling in an audit context? (Choose two.)

- ☐ **A** It allows the auditor to project results quantitatively to the entire population with a defined confidence level.
- ☒ **B** It relies on the auditor's professional judgment to select items most likely to reveal nonconformities.
- ☐ **C** The sample size justification is based on a probability theory formula such as the binomial distribution.
- ☒ **D** Findings apply only to the records examined, and the auditor cannot draw statistical inferences about the entire population from the sample.

ANSWER B • D

WHY Non-statistical (judgmental) sampling relies on the auditor's expertise to choose records most likely to disclose nonconformities (B), and conclusions apply only to the records sampled rather than being projected statistically to the whole population (D). Quantitative projection with a defined confidence level (A) and probability-based sample size formulas (C) are properties of statistical sampling, not non-statistical.

QUESTION 3

SINGLE CHOICE

Under 21 CFR Part 820 (U.S. FDA Quality System Regulation for medical devices), which requirement most directly drives the need for a documented Design History File (DHF)?

- ☐ **A** The requirement to establish and maintain a quality system appropriate to the design and complexity of the device.
- ☒ **B** The requirement that design controls be applied to the design of any Class II, III, or Class I device that contains software.
- ☐ **C** The requirement for a corrective and preventive action (CAPA) subsystem.
- ☐ **D** The requirement for management review of suitability and effectiveness of the quality system.

ANSWER B

WHY 21 CFR 820.30 (Design Controls) mandates design controls for Class II, Class III, and certain Class I devices, and it is the source of the Design History File (DHF) requirement under 820.30(j). Option A describes the general quality system requirement under 820.5. Option C is the CAPA system under 820.100. Option D is 820.20(c), management review. Only B specifically drives the DHF.

QUESTION 4

SINGLE CHOICE

According to ISO 14971, when a medical device manufacturer identifies a hazard that has been judged acceptable after risk control measures are applied, what additional action is required for residual risk to be considered acceptable overall?

- ☐ **A** The manufacturer must automatically reduce the risk further because any identified hazard disqualifies the device from market release.
- ☒ **B** The manufacturer must decide whether the residual risk is outweighed by the expected clinical benefit, particularly for risks that are not individually acceptable but contribute to the overall risk profile.
- ☐ **C** The manufacturer must publish the residual risk statement only in voluntary post-market surveillance reports and not in the risk management report.
- ☐ **D** The manufacturer must rerun the design verification tests for the affected risk control measures before declaring acceptability.

ANSWER B

WHY ISO 14971 requires that, after applying risk control measures, the manufacturer evaluate whether each residual risk is acceptable. If individual residual risks are not acceptable when viewed against criteria in the risk management policy, the manufacturer must apply the benefit-risk analysis described in the standard, weighing overall residual risk against expected clinical benefit (B). Option A is incorrect because identified hazards do not automatically disqualify a device. Option C misrepresents disclosure requirements—residual risk disclosures belong in the risk management file and accompanying documents. Option D confuses risk control verification with acceptability judgment.

QUESTION 5

SINGLE CHOICE

Which of the following is required to appear in a compliant ISO 19011-style audit report for a medical device audit?

- ☐ A Personal opinions of individual auditors about the auditee's management competence.
- ☒ B The agreed-upon audit objectives, scope, criteria, the audit team identification, and the dates and locations of on-site activities.
- ☐ C A complete restatement of every regulatory clause that may apply to the device, regardless of scope.
- ☐ D The audited organization's corporate financial performance over the prior fiscal year.

ANSWER B

WHY Per ISO 19011 reporting guidance, an audit report must contain the agreed audit objectives, scope, and criteria, identification of the audit team, the dates and locations where audit activities were performed, and the audit findings and related conclusions. (B) reflects these elements. Personal judgments (A) violate objectivity, restating all regulations (C) exceeds scope, and financial performance (D) is unrelated to conformity audit reporting.

QUESTION 6

SINGLE CHOICE

During an audit follow-up, the auditee presents evidence intended to address a major nonconformity. Which standard professional principle requires the lead auditor to verify whether actions have actually been implemented and are effective, rather than accepting the auditee's plan?

- ☐ A Confidentiality
- ☐ B Due professional care
- ☐ C Independence and objectivity
- ☒ D Evidence-based approach

ANSWER D

WHY The evidence-based approach principle requires auditors to use verifiable evidence as the basis for findings. Accepting a plan or stated commitment without verification would violate this principle. Due professional care (B) describes the diligence expected but the specific requirement to verify implementation and effectiveness of corrective actions is rooted in the evidence-based approach, used to confirm closure of nonconformities. Confidentiality (A) and independence (C) are different principles.

QUESTION 7

SINGLE CHOICE

A device manufacturer receives a complaint that a previously implanted orthopedic device fractured in vivo. Under 21 CFR Part 820, what is the manufacturer required to do first upon receipt of this complaint?

- ☐ **A** Immediately notify the FDA Office of Compliance via Form 483 and suspend all production.
- ☒ **B** Review, evaluate, and investigate the complaint in accordance with written procedures and document the activity.
- ☐ **C** Initiate a software regression test plan and update the design history file.
- ☐ **D** Update the device master record and then determine whether the change constitutes a redesign.

ANSWER B

WHY 21 CFR 820.198 (Complaint Files) requires manufacturers to establish and maintain procedures for receiving, reviewing, and evaluating complaints, and to investigate complaints in accordance with those procedures. The complaint handling process mandates review, evaluation, investigation, and documentation (B). Form 483s are issued by FDA to a manufacturer after inspection—manufacturers do not file them (A). Software regression testing (C) and design changes (D) are unrelated to the immediate complaint-handling obligation.

QUESTION 8

SINGLE CHOICE

Which ISO 14971 concept describes a chain of events that begins with a hazard and culminates in harm to the patient or user?

- ☐ A Risk control measure
- ☐ B Risk benefit-risk analysis
- ☒ C Hazardous situation
- ☐ D Hazard

ANSWER C

WHY In ISO 14971, a hazardous situation is the circumstance in which a person, property, or the environment is exposed to one or more hazard(s)—it is the link in the chain between hazard and harm. A hazard (D) is the potential source of harm; a risk control measure (A) reduces risk; benefit-risk analysis (B) evaluates overall acceptability.

QUESTION 9

SINGLE CHOICE

When preparing an audit plan for a multi-site medical device manufacturer, which of the following is the most appropriate approach for selecting which sites to visit?

- ☐ A Randomly select sites without regard to risk so the manufacturer cannot claim bias.
- ☐ B Sample only the headquarters site because the quality system should be identical everywhere.
- ☒ C Use a risk-based approach considering process significance, prior audit results, complaint history, regulatory issues, and complexity at each site.
- ☐ D Visit only sites flagged in current marketing materials where the latest devices are produced.

ANSWER C

WHY A risk-based audit selection process evaluates each site's contribution to quality, prior audit performance, complaint and CAPA signals, complexity, and any regulatory concerns. This aligns with ISO 19011 guidance on planning. Pure randomness (A) ignores risk; sampling only headquarters (B) ignores site variation; selecting only marketed-device sites (D) ignores other high-risk processes.