

Certified Quality Auditor Body of Knowledge 2019

The topics in this body of knowledge (BOK) include additional detail in the form of subtext explanations and cognitive level. These details will be used by the Exam Development Committee as guidelines for writing test questions, and are designed to help candidates prepare for the exam by identifying specific content within each topic that may be tested. The subtext is not intended to limit the subject-matter or be all-inclusive of what might be covered in an exam, but is intended to clarify how the topics relate to a Quality Auditor's role. The descriptor in parentheses at the end of each entry refers to the maximum cognitive level at which the topic will be tested. A more comprehensive description of cognitive levels is provided at the end of this Primer Section.

Case Studies for the CQA Exam

The CQA examinations will continue to present a number of case studies. Each case study will include a brief scenario outlining critical details about an audit situation. In addition, each case study will be supported by related audit documents. The documents will be contained in a separate booklet "Confidential Audit Documents – CQA Case Studies" that will be part of the test materials distributed at the examination. Approximately 15-20% (25-30 questions) of the test will be devoted to these case studies. Although the questions related to these cases will use the same four-choice answer format as the rest of the test, the use of scenario details and sample documents will allow the candidates to apply their critical thinking skills in evaluating realistic situations and accompanying documents,

I. Auditing Fundamentals (28 Questions)

A. Types of quality audits (Analyze)

1. Method (Analyze)

Define, differentiate, and analyze various audit types by method: product, service, process, desk, department, function, element, system, management, and integrated (combined and joint).

2. Auditor-auditee relationship (Analyze)

Define, differentiate, and analyze various audit types by auditor-auditee relationship: first-party, second-party, third-party, internal and external.

CQA BOK (Continued)

- 3. Purpose (Analyze)**
Define, differentiate, and analyze various audit types by purpose: verification of corrective and preventive action (CAPA), risk-based, accreditation (registration), compliance, surveillance, and for-cause.
 - 4. Common elements with other audits (Apply)**
Identify elements such as audit purpose, data gathering techniques, and tracing, that quality audits have in common with environmental, safety, financial, and other types of audits.
- B. Purpose and scope of audits**
- 1. Elements of purpose and scope (Apply)**
Describe and determine how the purpose of an audit can affect its scope.
 - 2. Benefits of audits (Analyze)**
Analyze how audits can be used to provide an independent assessment of system effectiveness and efficiency, financial risks, cybersecurity risks, and other organizational measures.
- C. Criteria to audit against (Analyze)**
- Define and distinguish between various audit criteria, such as external (industry, national, international) standards, contracts, specifications, quality awards, policies, internal quality management system (QMS), sustainability, social responsibility, etc.
- D. Roles and responsibilities of audit participants (Apply)**
- Define and describe the functions and responsibilities of various audit participants, including audit team members, lead auditor, client, auditee, etc.
- E. Professional conduct and consequences for auditors**
- 1. Professional conduct and responsibilities (Apply)**
Define and apply the ASQ Code of Conduct, concepts of due diligence and due care with respect to confidentiality and conflict of interest, and appropriate actions in response to the discovery of illegal activities or unsafe conditions.

CQA BOK (Continued)

- 2. Legal consequences (Apply)**
Identify potential legal and financial ramifications of improper auditor actions (carelessness, negligence, etc.) in various situations, and anticipate the effect that certain audit results can have on an auditee's liability.
- 3. Audit credibility (Apply)**
Identify and apply various factors that influence audit credibility, such as auditor independence, objectivity, and qualifications.

II. Audit Process (42 Questions)

A. Audit preparation and planning

- 1. Elements of the audit planning process (Evaluate)**
Evaluate and implement the basic steps in audit preparation and planning: verify audit authority; determine the purpose, scope, and type of audit; identify the criteria to audit against such as, customer specific requirements, applicable standards and regulations (laws), and identify the necessary resources, including, the size and number of audit teams, and documentation requirements.
- 2. Auditor selection (Analyze)**
Identify and examine various auditor selection criteria, such as education, experience, industry background, subject-matter or technical expertise, and independence from the activity being audited.
- 3 Audit-related documentation (Analyze)**
Identify the sources of pre-audit information and examine audit-related documentation, such as audit criteria references and results from prior audits. Recognize situations where evaluation of data integrity, electronic documents and records, and/or use and control of computerized systems (cybersecurity) is appropriate to include in the audit.
- 4. Logistics (Analyze)**
Identify and organize audit-related logistics, including travel, safety and security considerations, the need for escorts, translators, confidentiality agreements, clear right of access, and facility accommodations such as internet access, printers, work space, and personal protective equipment (PPE).

CQA BOK (Continued)

- 5. Auditing tools and working papers (Create)**
Identify the sampling plan or method and procedural guidelines to be used for the specific audit. Select and prepare working papers (checklists, log sheets, and forms) to document the audit and the method of documentation (manual or electronic).
- 6. Auditing strategies (Apply)**
Identify and use various tactical methods for conducting an audit, such as forward and backward tracing, discovery, etc.
- 7. Audit plan (Create)**
Create an audit plan using information obtained during the audit planning process, provide plan to the client and/or auditee, and distribute the plan to defined stakeholders.

B. Audit performance

- 1. On-site audit management (Analyze)**
Interpret situations throughout the performance of the audit to determine whether time is being managed well and when changes need to be made, such as revising planned audit team activities, reallocating resources, adjusting the audit plan, and communicating audit status and potential findings and observations to the auditee on a timely basis.
- 2. On-site audit management for the auditee (Analyze)**
Identify and apply techniques for managing and facilitating the audit process on behalf of the auditee organization such as, serving as liaison between auditee management and the auditing organization, accompanying the auditor through the data-collection portion of the audit, providing clarifying information, and confirming or denying the existence of observations, nonconformities, and findings.
- 3. Opening meeting (Apply)**
Manage the opening meeting of an audit by identifying the audit's purpose and scope, describing any scoring or rating criteria that will be used during the audit, creating a record of the attendees, reviewing the audit schedule, and answering questions as needed.

CQA BOK (Continued)

- 4. Audit data collection and analysis (Evaluate)**
Use various data collection methods to capture information: conducting interviews, observing work activities, taking physical measurements, examining documents, etc. Evaluate the results to determine their importance for providing audit evidence.
- 5. Establishment of objective evidence (Analyze)**
Identify and differentiate characteristics of objective evidence, such as observed, measured, confirmed or corroborated, and documented.
- 6. Organization of objective evidence (Evaluate)**
Classify evidence in terms of significance, severity, frequency, and level of risk. Evaluate the evidence for its potential impact on product, process, system, cost of quality, etc., and determine whether additional investigation is required to meet the scope of the audit.
- 7. Exit and closing meetings (Apply)**
Formally manage these meetings: reiterate the audit's purpose, scope, and scoring or rating criteria, and create a record of the attendees. Present the audit results and obtain concurrence on evidence that could lead to an adverse conclusion. Discuss the next steps in the process (follow-up audit, additional evidence-gathering, etc.), and clarify who is responsible for performing those steps.

C. Audit reporting

- 1. Report development and content (Create)**
Group observations into actionable findings of significance, and identify the severity and risk to the client and the auditee. Use appropriate steps to generate the audit report: organize and summarize details, review and finalize results, emphasize critical issues, establish unique identifiers or codes for critical issues to facilitate tracking and monitoring.
- 2. Effective reports (Create)**
Develop and evaluate components of effective audit reports, including background information, executive summary, prioritized results (observations, findings, opportunities for improvement, etc.). Use graphical tools or other means of emphasizing conclusions, and develop a timeline for auditee response and/or corrections.

CQA BOK (Continued)

- 3. Final audit report steps (Apply)**
Obtain necessary approvals for the audit report and distribute it according to established procedures. Identify the contents of the audit file and retain the file in accordance with established policies and procedures.

D. Audit follow-up and closure

- 1. Elements of the corrective action process (Evaluate)**
Identify and evaluate various elements: assignment of responsibility for problem identification; the performance of root cause analysis and recurrence prevention.
- 2. Review of corrective and preventive action (CAPA) plan (Evaluate)**
Evaluate the acceptability of proposed CAPA and schedule for completion. Identify and apply strategies for negotiating changes to unacceptable plans.
- 3. Verification of corrective and preventive action (CAPA) (Evaluate)**
Determine the adequacy of CAPA taken by verifying and evaluating new or updated procedures, observing revised processes, and conducting follow-up audits.
- 4. Follow-up on ineffective corrective action and preventive action (CAPA) (Create)**
Develop strategies to use when corrective actions are not implemented or are not effective, such as communicating to the next level of management, reissuing the corrective action request, and re-auditing.
- 5. Audit closure (Apply)**
Identify and apply various elements of, and criteria for, audit closure.

III. Auditor Competencies (25 Questions)

A. Auditor characteristics (Apply)

Identify characteristics that make auditors effective: interpersonal skills, problem-solving skills, attention to detail, cultural awareness and sensitivity, ability to work independently as well as in a group or on a team, etc. In addition, apply lead auditor characteristics including: negotiation skills and the ability to direct an audit team by balancing strengths and weaknesses of the team members.

CQA BOK (Continued)

B. On-site audit resource management (Apply)

Identify and apply techniques for managing audit teams, scheduling audit meetings and activities, making logistical adjustments, etc.

C. Conflict resolution (Analyze)

Identify typical conflict situations (mild to vehement disagreements, auditee delaying tactics, interruptions, etc.) and determine appropriate techniques for resolving them: clarifying the question or request, reiterating ground rules, intervention by another authority, cool-down periods, etc.

D. Communication and presentation techniques (Evaluate)

Select and use written, oral, and electronic communication techniques for presentations made during audits for opening, closing, ad hoc meetings, etc. Use technical and managerial reporting techniques, including graphs, charts, diagrams, and multimedia aids in various situations: domestic, global, in-person, and multiple sites, etc.

E. Interviewing techniques (Apply)

Select and use appropriate interviewing techniques and methodologies.

1. Use open-ended or closed question types.
2. Use active listening, paraphrasing, and empathy.
3. Recognize and respond to non-verbal cues: body language, the significance of pauses and their length, etc.
4. Determine when and how to prompt a response: when supervisors are present, when interviewing a group of workers, when using a translator, etc.

CQA BOK (Continued)

F. Team dynamics

(Apply)

Define, describe, and apply various aspects of team dynamics.

- 1. Team-building: clarifying roles and responsibilities for participants and leaders to ensure equitable treatment for all team members, providing clear direction for deliverables, identifying necessary resources and ensuring their availability, etc.**
- 2. Team facilitation: providing coaching and guidance, defusing clashes between members, eliciting input from all, cultivating objectivity, overseeing progress, encouraging diverse views and consensus, etc.**
- 3. Stages of team development: forming, storming, norming, and performing.**

IV. Audit Program Management and Business Applications (30 Questions)

A. Audit program management

- 1. Senior management support (Understand)**
Identify and explain management's role in creating and supporting the audit function.
- 2. Staffing and resource management (Evaluate)**
Develop staffing budgets that provide adequate time for auditors to plan, conduct, and respond to scheduled audits, including time and resources that internal auditees need to participate. Identify any special equipment resources needed and ensure their adequacy and availability. Consider the use of and requirements for special audits (outsourced or contracted audits, virtual or e-audits, shared audits, etc.) as driven by costs, geography, etc. Evaluate results and adjust resources as needed on a regular basis.
- 3. Auditor training and development (Analyze)**
Identify minimum audit knowledge and skill requirements for auditors. Provide training on various aspects of the audit process such as relevant standards, regulatory influences, facilitation techniques, etc. Provide training on diversity and cultural influences (ethnicity, gender, age, organized labor, etc.) and how such factors can affect communications and other interactions among audit participants. Define requirements for continuing education to maintain auditor qualifications.

CQA BOK (Continued)

4. **Audit program evaluation** (Evaluate)
Select the correct metric to evaluate the audit program, including tracking its effect on the bottom line and the risk to the organization.
5. **Internal audit program management** (Create)
Develop procedures, policies, and schedules to support the organization's objectives. Review internal audit results to identify systemic trends.
6. **External audit program management** (Create)
Develop procedures, policies, and schedules in support of the supplier management program, including supplier qualification surveys, surveillance audits, supplier improvement, etc.
7. **Best practices** (Analyze)
Analyze audit results to standardize best practices and lessons learned across the organization.
8. **Organizational risk management** (Analyze)
Analyze how the audit program affects an organization's risk level and how the risk level can influence the number and frequency of audits performed.
[Note: Tools and techniques for managing risk are covered in BOK area V.H.]
9. **Management review input** (Evaluate)
Examine and summarize audit program results, trends, and changes in risk to provide input to management reviews.
10. **Electronic records and computerized system considerations** (Apply)
Define and apply techniques to identify data integrity, fraud, and cybersecurity issues when auditing systems that include electronic records and/or computerized systems.

B. Business and financial impact

1. **Auditing as a management tool** (Analyze)
Use audit results to monitor continuous improvement, supplier management, customer satisfaction, etc., and to provide management with an independent view of the strategic plan's effectiveness and how well it is deployed.

CQA BOK (Continued)

- 2. Interrelationships of business processes (Understand)**
Identify how business units (receiving, product and process design, production, engineering, sales, marketing, field support, etc.) and multiple sites are interrelated, and recognize how their unique metrics and goals can be in conflict with one another.
- 3. Cost of quality (COQ) principles (Analyze)**
Identify, describe, and analyze the audit program's effect on the four COQ categories: prevention, appraisal, internal failure, external failure.

V. Quality Tools and Techniques (26 Questions)

A. Basic quality and problem-solving tools (Analyze)

Identify, interpret, and analyze: 1) Pareto charts, 2) cause and effect diagrams, 3) flowcharts, 4) statistical process control (SPC) charts, 5) check sheets, 6) scatter diagrams, 7) histograms, 8) root cause analysis, 9) plan-do-check-act (PDCA).

B. Process improvement techniques

- 1. Six sigma (Apply)**
Identify, interpret, and apply the six sigma DMAIC phases: define, measure, analyze, improve, control.
- 2. Lean (Apply)**
Identify, interpret, and apply lean tools: 5S, standard operations, kanban (pull), error-proofing, value-stream mapping, etc.

C. Basic statistics

- 1. Measures of central tendency (Apply)**
Identify, interpret, and use mean, median, and mode.
- 2. Measures of dispersion (Apply)**
Identify, interpret, and use standard deviation and frequency distribution.

CQA BOK (Continued)

- 3. Qualitative and quantitative analysis (Understand)**
Describe qualitative data in terms of the nature, type, or attribute of an observation or condition. Describe how quantitative data is used to detect patterns or trends and how such analysis can indicate whether a problem is systemic or isolated.

D. Process variation

- 1. Common and special cause (Apply)**
Identify and distinguish between common and special cause variation.
- 2. Process performance metrics (Understand)**
Describe elements of C_p and C_{pk} process capability studies (process centering and stability, specification limits, underlying distribution, etc.), and how these studies and other performance metrics are used in relation to established goals.
- 3. Outliers (Understand)**
Describe their significance and impact.

E. Sampling methods

- 1. Acceptance sampling plans (Understand)**
Identify and interpret these plans for attributes and variables data.
- 2. Types of sampling (Understand)**
Describe and distinguish between random, stratified, and cluster sampling, and identify the uses and potential problems of non-statistical sampling.
- 3. Sampling terms (Understand)**
Define related terms including consumer and producer risk, confidence level, etc.

F. Change control and configuration management (Understand)

Identify the principles of change control and configuration management systems as used in various applications: hardware, software (including security considerations), product, process, and service.

G. Verification and validation (Analyze)

Define, distinguish between, and use various methods of verifying and validating processes.

CQA BOK (Continued)

H. Risk management tools (Understand)

Identify methods for managing risk, including risk avoidance, mitigation, tradeoffs, etc., and describe tools and methods for estimating and controlling risk: failure mode and effects analysis (FMEA, PFMEA, DFMEA), hazard analysis and critical control points (HACCP), critical to quality (CTQ) analysis, health hazard analysis (HHA), etc. Note: Organizational risk management is covered in BOK area IV.A.8.]

Six Levels of Cognition based on Bloom's Taxonomy (Revised)

In addition to content specifics, the subtext for each topic in this BOK also indicates the intended complexity level of the test questions for that topic. These levels are based on "Levels of Cognition" (from Bloom's Taxonomy – Revised, 2001) and are presented below in rank order, from least complex to most complex.

Remember

Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

Understand

Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply

Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

Analyze

Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

Evaluate

Make judgments about the value of proposed ideas, solutions, etc., by comparing the proposal to specific criteria or standards.

Create

Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.