CERTIFIED QUALITY ENGINEER (CQE)
BODY OF KNOWLEDGE

The topics in this Body of Knowledge include subtext explanations and the cognitive level at which the questions will be written. This information will provide useful guidance for both the Exam Development Committee and the candidate preparing to take the exam. The subtext is not intended to limit the subject matter or be all-inclusive of that material that will be covered in the exam. It is meant to clarify the type of content that will be included on the exam. The descriptor in parentheses at the end of each entry refers to the maximum cognitive level at which the topic will be tested. A complete description of cognitive levels is provided at the end of this document.

I. Management and Leadership (17 Questions)

A. Quality Philosophies and Foundations

Describe continuous improvement tools, including lean, six sigma, statistical process control (SPC), and total quality management. Understand how modern quality has evolved from quality control through statistical process control (SPC) to total quality management and leadership principles (including Deming's 14 points). (Understand)

B. The Quality Management System (QMS)

1. Strategic planning

Identify and define top management's responsibility for the QMS, including establishing policies, and objectives, setting organization-wide goals, and supporting quality initiatives. (Apply)

2. Deployment techniques

Define, describe, and use various deployment tools in support of the QMS such as:

a. Benchmarking
Define the concept of benchmarking and why it may be used. (Remember)

b. Stakeholder
Define, describe and use stakeholder identification and analysis. (Apply)

c. Performance
Define, describe and use performance measurement tools such as cost-benefit analysis. (Apply)

d. Project management
Define, describe and use project management tools, including Gantt charts and the responsible, accountable, consulted and informed matrix (RACI). (Apply)

3. Quality information system (QIS)

Identify and describe the basic elements of a QIS, including who will contribute data, the kind of data to be managed, who will have access to the data, the level of flexibility for future information needs, and data analysis. (Understand)

C. ASQ Code of Ethics for Professional Conduct

Determine appropriate behavior in situations requiring ethical decisions. (Evaluate)

D. Leadership Principles and Techniques

Analyze various principles and techniques for developing and organizing teams and leading quality initiatives. (Analyze)

E. **Facilitation Principles and Techniques**

1. **Roles and responsibilities**

   Describe the facilitator's roles and responsibilities on a team. (Understand)

2. **Facilitation tools**

   Apply various tools used with teams, including brainstorming, nominal group technique, conflict resolution, and force-field analysis. (Apply)

F. **Communication Skills**

Identify and distinguish between specific communication methods that are used for delivering information and messages in a variety of situations across all levels of the organization. (Analyze)

G. **Customer Relations**

Define, apply, and analyze the results of customer relation tools such as customer satisfaction surveys. (Analyze)

H. **Supplier Management**

1. **Techniques**

   Apply various supplier management techniques, including supplier qualification, certification, and evaluation. (Apply)

2. **Improvement**

   Analyze supplier ratings and performance improvement results. (Analyze)

3. **Risk**

   Understand business continuity, resiliency, and contingency planning. (Understand)

I. **Barriers to Quality Improvement**

Identify barriers to quality improvement, analyze their causes and impact, and implement methods for improvement. (Analyze)

II. The Quality System (18 Questions)

A. **Elements of the Quality System**

1. **Basic elements**

   Interpret the basic elements of a quality system, including planning, control, and improvement, from product and process design through quality cost systems and audit programs. (Evaluate)

2. **Design**

   Analyze the design and alignment of interrelated processes to the strategic plan and core processes. (Analyze)

B. **Documentation of the Quality System**

1. **Document components**

   Identify and describe quality system documentation components, including quality policies and procedures to support the system. (Understand)

2. **Document control**

Evaluate configuration management, maintenance, and document control to manage work instructions and quality records. (Evaluate)

C. **Quality Standards and Other Guidelines**

Apply national and international standards and other requirements and guidelines, including the Malcolm Baldrige National Quality Award (MBNQA), and describe key points of the ISO 9000 series of standards. [Note: Industry-specific standards will not be tested.] (Apply)

D. **Quality Audits**

1. **Types of audits**
Describe and classify the various types of quality audits such as product, process, management (system), registration (certification), compliance (regulatory), first, second, and third party. (Apply)

2. **Roles and responsibilities in audits**
Identify and define roles and responsibilities for audit participants such as audit team (leader and members), client, and auditee. (Understand)

3. **Audit planning and implementation**
Describe and apply the stages of a quality audit, from audit planning, including assessing risks through conducting an audit. (Apply)

4. **Audit reporting and follow-up**
Apply the steps of audit reporting and follow up, including the need to verify corrective action. (Apply)

E. **Cost of Quality (COQ)**

Identify and apply COQ concepts, including cost categorization, data collection, reporting, and interpreting results. (Analyze)

F. **Quality Training**

Identify and apply key elements of a training program, including conducting a needs analysis, preparing curricula and materials, and determining the program's effectiveness. (Apply)

III. Product, Process, and Service Design (21 Questions)

A. **Classification of Quality Characteristics**
Define, interpret, assess, and classify quality characteristics for new and existing products, processes, and services. [Note: The classification of defects is covered in IV.B.3.] (Evaluate)

B. **Design Inputs, Techniques, and Review**

1. **Inputs**

Classify design inputs such as customer needs, regulatory requirements, critical to quality, and risk assessment into robust design using techniques such as failure mode and effects analysis (FMEA). (Analyze)

2. **Techniques**

   Apply Design for X (DFX), Design for Six Sigma (DFSS), and requirements traceability. (Apply)

3. **Review**

   Identify and apply common elements of the design review process, including roles and responsibilities of participants. (Apply)

C. **Technical Drawings and Specifications**

Interpret specification requirements in relation to product and process characteristics and technical drawings, including characteristics such as views, title blocks, dimensioning and tolerancing, and geometric dimensioning and tolerance symbols (GD&T). (Evaluate)

D. **Verification and Validation**

Interpret the results of evaluations and tests used to verify and validate the design of products, processes and services, such as installation qualification (IQ), operational qualification (OQ), and process qualification (PQ). (Evaluate)

E. **Reliability and Maintainability**

1. **Predictive and preventive maintenance tools**

   Describe and apply the tools and techniques used to maintain and improve process and product reliability. (Apply)

2. **Reliability and maintainability indices**

   Apply indices such as mean time to failure (MTTF), mean time between failure (MTBF), mean time to repair (MTTR), availability, and failure rate. (Apply)

3. **Reliability models**

   Classify and apply the basic elements of reliability models such as exponential, Weibull, and bathtub curve. (Apply)

4. **Reliability / Safety / Hazard Assessment Tools**

   Define, construct, and interpret the results of failure mode and effects analysis (FMEA), design FMEA (dFMEA), process FMEA (pFMEA), use FMEA (uFMEA), failure mode, effects, and criticality analysis (FMECA), and hazard analysis. (Analyze)

IV. Product and Process Control (23 Questions)

A. **Methods**

Implement product and process control methods such as control plan development, critical control point identification, and work instruction development and validation. (Analyze)

B. **Material Control**

1. **Material identification, status, and traceability**

   Define and distinguish between these concepts, and describe methods for applying them in various situations. (Analyze)

2. **Material segregation**
   Describe material segregation and its importance, and evaluate appropriate methods for applying it in various situations. (Evaluate)
3. **Material classification**
   Assess and classify product and process defects and non-conformities. (Evaluate)
4. **Material review board (MRB)**
   Describe the purpose and function of an MRB, and evaluate nonconforming product or material to make a disposition decision in various situations. (Evaluate)

C. **Acceptance Sampling**

1. **Sampling concepts**
   Apply the concepts of producer and consumer risk, and related terms, including operating characteristic (OC) curves, acceptable quality limit (AQL), and lot tolerance percent defective (LTPD). (Apply)
2. **Sampling standards and plans**
   Identify, interpret, and apply ANSI/ASQ Z1.4 and Z1.9 standards for attributes and variables sampling. (Analyze)
3. **Sample integrity**
   Identify and apply techniques for establishing and maintaining sample integrity. (Apply)

D. **Measurement and Test**

1. **Measurement tools**
   Select and describe appropriate uses of inspection tools such as gage blocks, calipers, micrometers, optical comparators, and coordinate measuring machines (CMM). (Analyze)
2. **Destructive and nondestructive tests**
   Identify when destructive and nondestructive measurement test methods should be used and apply the methods appropriately. (Apply)

E. **Metrology**

Apply metrology techniques such as calibration, traceability to calibration standards, measurement error and its sources, and control and maintenance of measurement standards and devices. (Apply)

F. **Measurement System Analysis (MSA)**

Calculate, analyze, and interpret repeatability and reproducibility (Gage R&R) studies, measurement correlation, capability, bias, linearity, precision, stability and accuracy, using MSA quantitative and graphical methods. (Evaluate)

V. Continuous Improvement (26 Questions)

A. Quality Control Tools

Select, construct, apply, and interpret the following quality control tools:

1. Flowcharts
2. Pareto charts
3. Cause and effect diagrams
4. Control charts
5. Check sheets
6. Scatter diagrams
7. Histograms (Analyze)

B. Quality Management and Planning Tools

Select, construct, apply, and interpret the following quality management and planning tools:

1. Affinity diagrams and force field analysis
2. Tree diagrams
3. Process decision program charts (PDPC)
4. Matrix diagrams
5. Interrelationship digraphs
6. Prioritization matrices
7. Activity network diagrams (Analyze)

C. Continuous Improvement Methodologies

Define, describe, and apply the following continuous improvement methodologies:

1. Total quality management (TQM)
2. Kaizen
3. Plan-do-check-act (PDCA)
4. Six sigma (Analyze)

D. Lean tools

Define, describe, and apply the following lean tools:

1. 5S
2. Value-stream mapping
3. Kanban
4. Visual control
5. 8 Wastes
6. Standardized work
7. Takt time
8. Single minute exchange of die (SMED)
9. Overall equipment effectiveness (OEE) (Evaluate)

E. Corrective Action

Identify, describe, and apply elements of the corrective action process, including problem identification, failure analysis, root cause analysis, 5 Whys, problem correction, recurrence control, and verification of effectiveness. (Evaluate)

F. **Preventive Action**

Identify, describe, and apply various preventive action tools such as error-proofing/poka-yoke and robust design, and analyze their effectiveness. (Evaluate)

VI. Quantitative Methods and Tools (34 Questions)

A. Collecting and Summarizing Data

1. **Types of data**

   Define, classify, and compare discrete (attributes) and continuous (variables) data. (Apply)

2. **Measurement scales**

   Define and describe nominal, ordinal, interval, and ratio scales. (Understand)

3. **Data collection methods**

   Describe various methods for collecting data, including tally or check sheets, data coding, automatic gaging, data automation, database integration, and identify the strengths and weaknesses of the methods. (Apply)

4. **Data accuracy and integrity**

   Identify factors that can influence data accuracy such as source/resource issues, flexibility, versatility, inconsistency, inappropriate interpretation of data values, and redundancy to ensure data accuracy and integrity. (Apply)

5. **Data visualization techniques**

   Apply and interpret data visualization techniques using dashboards, and select the appropriate metrics for dashboards. (Apply)

6. **Descriptive statistics**

   Describe, calculate, and interpret measures of central tendency and dispersion, apply the central limit theorem, and construct and interpret frequency distributions, including simple, categorical, grouped, ungrouped, and cumulative. (Evaluate)

7. **Graphical methods for depicting distributions**

   Apply and interpret diagrams such as probability plots for normal and other distributions. [Note: Histograms are covered in V.A.] (Analyze)

B. Quantitative Concepts

1. **Terminology**

   Define and apply quantitative terms, including population, parameter, sample, statistic, random sampling, and expected value. (Analyze)

2. **Drawing statistical conclusions**

   Distinguish between numeric and analytical studies. Assess the validity of statistical conclusions by analyzing the assumptions used and the robustness of the technique used. (Evaluate)

3. **Probability terms and concepts**

   Describe concepts such as independence, mutual exclusivity, multiplication rules, complementary probability, and joint occurrence of events. (Apply)

C. **Probability Distributions**

1. **Continuous distributions**
   Define and distinguish between these distributions such as normal, uniform, exponential, lognormal, Weibull, Student's t, and F. (Analyze)

2. **Discrete distributions**
   Define and distinguish between these distributions such as binomial, Poisson, hypergeometric, and multinomial. (Analyze)

D. **Statistical Decision-Making**

1. **Point estimates and confidence intervals**
   Define, describe, and assess the bias of estimators. Calculate and interpret standard error, tolerance intervals, and confidence intervals. (Evaluate)

2. **Hypothesis testing**
   Define, interpret, and apply hypothesis tests for means, variances, and proportions. Apply and interpret the concepts of significance level, power, type I, and type II errors. Define and distinguish between statistical and practical significance. (Evaluate)

3. **Paired-comparison tests**
   Define and use paired-comparison (parametric) hypothesis tests and interpret the results. (Apply)

4. **Goodness-of-fit tests**
   Define and use chi square and other goodness-of-fit tests, and understand the results. (Apply)

5. **Analysis of variance (ANOVA)**
   Define use, and interpret ANOVA and interpret the results. (Analyze)

6. **Contingency tables**
   Define and use contingency tables to evaluate statistical significance. (Apply)

E. **Relationships Between Variables**

1. **Linear regression**
   Calculate simple linear regression models. Illustrate hypothesis tests for regression statistics. Use linear regression models for estimation and prediction. (Apply)

2. **Simple linear correlation**
   Calculate the correlation coefficient and its confidence interval, and illustrate a hypothesis for correlation statistics. (Apply)

3. **Time-series analysis**
   Define, describe, and use time-series analysis, including moving average to identify trends and seasonal or cyclical variation. (Apply)

F. **Statistical Process Control (SPC)**

1. **Objectives and benefits**
   Identify and explain the objectives and benefits of SPC. (Understand)

2. **Common and special causes**
   Describe, identify, and distinguish between these types of causes. (Analyze)

3. **Selection of variable**
   Identify and select variable characteristics for monitoring by control charts. (Analyze)
4. **Rational subgrouping**
   Define and apply the principles of rational subgrouping. (Apply)
5. **Control charts**
   Identify, select, construct, and use various control charts, including $\overline{X}$ –R, $\overline{X}$ –s, individuals and moving range (ImR or XmR), moving average and moving range (MamR), p, np, c, and u. (Analyze)
6. **Control chart analysis**
   Read and interpret control charts and use rules for determining statistical control. (Evaluate)
7. **Short-run SPC**
   Identify and define short-run SPC rules. (Understand)

G. **Process and Performance Capability**

1. **Process capability studies**
   Define, describe, calculate, and use process capability studies, including identifying characteristics, specifications and tolerances, developing sampling plans for such studies, and establishing statistical control. (Analyze)
2. **Process performance vs. specifications**
   Distinguish between natural process limits and specification limits, and calculate percent defective, defects per million opportunities (DPMO), and parts per million (PPM). (Analyze)
3. **Process capability indices**
   Define, select, and calculate C_p, C_{pk}, C_{pm}, and C_r, and evaluate process capability. (Evaluate)
4. **Process performance indices**
   Define, select, and calculate P_p and P_{pk}, and evaluate process performance. (Evaluate)

H. **Design and Analysis of Experiments**

1. **Terminology**
   Define terms such as dependent and independent variables, factors, levels, response, treatment, error, and replication. (Understand)
2. **Planning and organizing experiments**
   Identify the basic elements of designed experiments, including determining the experiment objective, selecting factors, responses, and measurement methods, and choosing the appropriate design. (Analyze)
3. **Design principles**
   Define and apply the principles of power and sample size, balance, replication, order, efficiency, randomization, blocking, interaction, and confounding. (Apply)
4. **Full-factorial experiments**
   Construct full-factorial designs and use computational and graphical methods to analyze the significance of results. (Analyze)
5. **Two-level fractional factorial experiments**
   Construct two-level fractional factorial designs and apply computational and graphical methods to analyze the significance of results. (Analyze)

VII. Risk Management (21 Questions)

A. Risk Fundamentals

1. Risk terminology

Define, describe, and apply risk terminology such as risk, risk management, severity, occurrence, detection, and risk-based thinking. (Analyze)

2. Types of risk management

Understand and apply various types of enterprise (strategic, software, business, regulatory, medical, audit), operational (supplier, supply chain, safety, project, manufacturing, operations, service, quality system), and product (design, process, use, safety) risk management. (Apply)

B. Risk Planning and Assessment

1. Risk management plan

Analyze and interpret a risk management plan and its components (objectives, risk criteria, stakeholder identification, and team member roles/responsibilities) to identify and prioritize risks. (Analyze)

2. Risk assessment

Apply categorization methods and evaluation tools to assess risk such as failure mode and effects analysis. Identify and apply evaluation metrics including the use of risk matrices, risk priority numbers, and acceptability criteria. (Analyze)

C. Risk Treatment, Control, and Monitoring

1. Identification and documentation

Identify risks, gaps, and controls and document with tools such as a risk register. (Analyze)

2. Risk management system evaluation

Apply auditing techniques and testing of controls to evaluate a risk management system. (Apply)

3. Risk treatment strategies

Understand and apply risk treatment strategies, such as avoid, mitigate, transfer, and accept. (Analyze)

4. Risk monitoring

Apply risk monitoring techniques such as, complaint tracking, trending, and post-market surveillance. (Analyze)

5. Mitigation planning

Apply and interpret risk mitigation plan. (Analyze)

Levels of Cognition
Based on Bloom's Taxonomy – Revised (2001)

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,

Understand
Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations,

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

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, 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.