

MIDTERM REVIEW

This study guide is meant to guide you when in studying for the exam. I hope you find it helpful. It is not a contract of what content will or won't be on the exam. The questions on the exam will be from the topics below.

1. Quality Principles

1. Definition of quality "...features/characteristics...desirability...controlled to meet....requirements"
 - a. Quality determined by end-user
2. Know the quality management principles:
 - a. Customer focus
 - b. Leadership
 - c. Engagement of people
 - d. Process approach
 - e. Improvement
 - f. Evidence-based decision-making
 - g. Relationship management
3. Be familiar with the process approach: Plan-Do-Check-Act (PDCA)
4. Understand quality management system requirements
5. Be aware of Corrective Action/Preventive Action (CAPA) system phases
6. Cost of quality: know the difference between appraisal, internal, external & preventive

2. Manufacturing/Service Processes

1. Know the definition of a process: "
2. Define internal versus external customer
3. Know the elements of a process:
4. Understand the "Turtle" diagram: input, process, output, what, who, how, measure
5. Types of processes: management, business, support
6. Understand validation, verification, validation types, validation program components & documentation

3. Problem Solving

1. Know the definition of a problem
2. Understand the basics to solve a problem:
 - a. Identify the cause of the problem
 - b. Find ways to eliminate the cause (or causes) and prevent them from recurring
3. Be familiar with the different levels of causes: symptoms, first-level, higher-level
4. Define the *phases* of the problem solving process:
 - a. Problem understanding
 - b. Problem cause investigation
 - c. Problem cause data collection
 - d. Problem cause data analysis
 - e. Root cause identification
 - f. Problem elimination
 - g. Solution implementation

5. Know the problem solving *steps*:
 - a. Recognize the problem
 - b. Define the problem
 - c. Understand the problem
 - d. Identify the root cause of the problem
 - e. Eliminate the root cause
 - f. Monitor the symptoms of the problem to verify root cause elimination (or reduction)
6. Understand the basic concepts of critical thinking and logic

4. Root Cause Analysis

1. Know what “Root Cause Analysis” is: *a structured investigation that aims to identify the true cause of a problem and the actions necessary to eliminate it*
2. Understand how to conduct a root cause analysis

5. Tools for Problem Understanding

1. Flowchart:
 - a. Understand what a flowchart is: portrays the flow of activity, illustrates where problems occur
 - b. Be familiar with the different types of flowchart: regular, cross functional, several levels
 - c. Know the flowchart symbols and how to create a flowchart
2. Critical incident:
 - a. Understand the purpose: to help understand what the most troublesome symptoms of a problem really are
 - b. Know what it does: Identifies the type of incident and frequency
 - c. Know how to use the critical incident method
3. Spider chart:
 - a. Know what a spider chart is: gives a graphical impression of how the performance of business processes (or problem areas) compares with others
 - b. Be familiar with applications: helps determine which problem is most critical and compares the seriousness of problems and causes
 - c. Understand how to create a spider chart
4. Performance matrix:
 - a. Be familiar with the purpose: used to illustrate current performance and importance at the same time
 - b. Can be utilized to identify which aspect of the problem is most important to attack and which causes will give the most relief if removed
 - c. Know the four quadrants of the matrix: unimportant, overkill, must be improved, ok
 - d. Understand how to create a performance matrix

6. Problem Cause Investigation

1. Brainstorming:
 - a. Understand the purpose of brainstorming – generates list of problem areas & possible causes of the problem, encourages thinking about ways to eliminate the causes
 - b. Know the two types: *structured* (“round-robin), *unstructured* (freewheeling)
 - c. Be familiar with the brainstorming steps

Brain-writing:

- d. Purpose same as brainstorming
- e. Define the two types: card, gallery
- f. Be familiar with the brainstorming steps

2. Is-Is not Matrix:

- a. Know the purpose: helps separate the essential from the trivial, clarifies wht the problem **is** or is **not**
- b. Defines: what occurred, what objects affected, where occurred, when it occurred, the extent of the problem, who was involved
- c. Be familiar with the matrix: Is, Is Not, Distinctions
- d. Understand how to create an is-is not matrix

3. Nominal Group Technique:

- a. Know the purpose: facilitates a form of brainstorming in which all participants have the same vote when selecting solutions
- b. Understand the steps of the nominal group technique

4. Paired Comparison:

- a. Helps to identify priorities and reach consensus through a sequence of paired comparisons
- b. Be familiar with similar methods: balance sheet, criteria rating form, weighted voting
- c. Understand how to prepare the paired comparisons matrix
- d. Know the process for comparing the alternatives and voting

7. Problem Cause Data Collection

1. Sampling:

- a. Used to draw conclusions about a larger group based on a smaller sample
- b. Effective method for collecting data and gaining a better understanding of the situation
- c. Be familiar with the different types of sampling: *random, systematic, stratified, cluster*
- d. Understand how to develop a sampling plan
- e. Know the difference between *discrete* and *continuous* data

2. Surveys:

- a. Used to collect data from respondents
- b. Know what a survey is: a structured data collection method that requires a pre-defined set of questions
- c. Understand the different ways to obtain responses to questions {respondents complete questionnaire in writing or conducting interviews
- d. Be familiar with how to create and conduct a survey

3. Check sheets:

- a. Understand purpose: to ensure all data is registered
- b. Help to show how often different problems occur and the frequency of incidents that are believed to cause the problems
- c. Know how to create a check sheet