

## 1. Define the following

## a. Quality (2pts)

Product/service with features/characteristics that determine desirability and can be controlled to meet certain basic requirements

Determined by customer (end-user) based on their expectations and needs

## b. Process (include basic elements) (2pts)

Chain of value-added activities that conclude in product/service delivered to customer

Input → activities → output

## c. Root Cause (2pts)

“true” cause of the problem

## d. Consensus (2pts)

General agreement

Not everyone has to agree with the decision, but can they live with it (move forward)

## e. Sampling (2pts)

Collect data to increase knowledge/understanding and draw conclusions about a larger group based on small(er) representative selection

## 2. Define and compare

- a. validation versus verification. (4 pts)

**Validation** – confirmation by examination /objective evidence that requirements for specific intended use can be consistently fulfilled

*Meeting user needs (building the right thing?)*

**Verification** – confirmation by examination/objective evidence that specified requirements have been fulfilled

*Meeting user specifications (build it right?)*

- b. symptom versus first level cause (4 pts)

**symptom** – not an actual cause, signs of existing problems (i.e. late for class)

**first level cause(s)** - causes that lead directly to the problem (i.e. couldn't find car keys)

## 3. Match the Quality Management Principle to the benefit (5 pts)

QMS Principle	ANSWER	Benefit
Customer Focus	4	1. More likely to produce desired results due to understanding cause and effect relationships.
Engagement of People	5	2. Essential for organization and creation of new opportunities
Process Approach	3	3. Optimize performance based on understanding interrelated activities.
Improvement	2	4. Attracts and retains the confidence of interested parties.
Evidence-based decision making	1	5. Enhance capability by recognizing and empowering all skill and knowledge levels.

## 4. Identify which of the following are voluntary versus mandatory quality management systems. (2pts)

- a. ISO 9001:2015 **voluntary**
- b. 21CFR Part 820 **mandatory**

5. Create a turtle diagram for the following process (Activity): Making dinner.  
Identify the various parts and include examples related to the activity. (18 pts)

**WHAT (materials)**

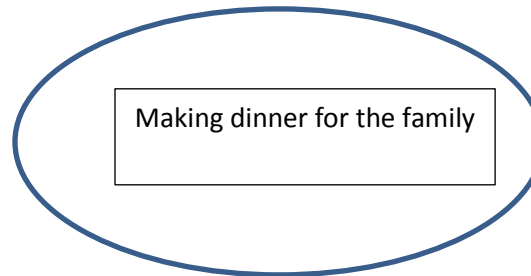
*Pots/pans  
Utensils  
Ingredients  
Stove*

**WHO**

*Cook  
Assistant (?)*

**INPUT**

*Hungry family*

**OUTPUT**

*hot meal*

**HOW**

*Recipe*

**MEASURES**

*hot food  
Smiling faces*

6. Describe three of the six phases in a CAPA (corrective action – preventive action) system. (6 pts)

Initiation - problem identified, team formed, complexity/urgency

Investigation - root cause analysis; determine cause and potential solutions

Implementation - immediate correction, short term solution, long term solution; actions recommended are taken

Verification - Review that implementation complete (training, change control, documents issued, etc.)

Effectiveness - review data trends (30, 60 90-day) to ensure no recurrence

Closure - review that all documents complete, obtain signatures

7. Describe the plan-do-check-act cycle. (8 pts)

Plan - determine issue/potential solutions; determine activities/controls/documents, etc.

Do - initiate studies, gather data

Check - analyze/evaluate results,

Act - decide on solution, implement changes/improvements

## 8. Match the critical thinking skill to the description (14 pts)

Skill	ANSWER	Description
Truth-seeking	<b>D</b>	a. Evaluate pros and cons
Open-Mindedness	<b>G</b>	b. Self-evaluation of ideas rather than asking others
Analyticity	<b>A</b>	c. Account for other's experiences and perspectives
Systematicity	<b>F</b>	d. interested in finding out the facts
Confidence in Reasoning	<b>B</b>	e. investigate and question
Inquisitiveness	<b>E</b>	f. divide a complex problem into its parts
Maturity of Judgement	<b>C</b>	g. listen to new ideas even though do not intuitively agree

## 9. Why are each of the following barriers to investigative team success?

## a. Groupthink (2pts)

This is similar to "mob mentality", not all suggestions are heard or discussed

## b. Conflict (2pts)

Disagreements not resolve

## c. Logistics (2pts)

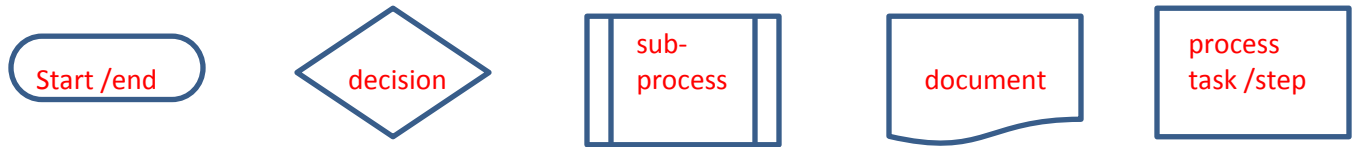
This is finding common meeting times; considering shifts, locations, department needs, etc.

Ability to collect data (i.e. survey general public vs pulling product from line)

## d. Training (2pts)

Team members may not be aware of investigative tools, teamwork, decision making processes, etc.

10. Identify the flow chart symbols (5 pts)



11. There are three ways a project team leader can conduct a brainstorming session list them below, along with advantages and/or disadvantages? (12 pts)

- #1 Random Call-out: facilitator lists problem asks for solutions and records as they are provided verbally by team, unstructured  
Advantage: team hears responses and can build off the various ideas  
Disadvantage: dominant voice, not everyone will participate (quiet, thoughtful)
- #2 Round Robin: verbal; facilitator asks each individual for suggestion by going around the table; only one person speaks at a time; structured  
Advantage: everyone has a chance to speak, provides time for thoughtful suggestions  
Disadvantage: can take longer
- #3 Brain-writing: Individuals write one response per index card/ whiteboard / flipchart  
Advantage: everyone has a chance to speak, provides time for thoughtful suggestions  
Disadvantage: can take longer, when using index cards team cannot feed off each other's ideas

12. Describe how the nominal group technique can be used to facilitate the prioritization of ideas generated in a brainstorming session. (3 pts)

All ideas are summarized on one sheet. Copies are provided to team members; each person then selects and ranks top 5 ideas (5 = highest, 1 = lowest). Facilitator (team lead) collects the sheets, tallies the results. Idea(s) with highest values are looked at first

13. The grocery store owner who identified the weekend check-out line waiting issue wants to survey his customer base to understand where there may be additional areas for improvement. What does he need to consider when determining how to gather the data? That is what sampling considerations should be accounted for? (8 pts)

Written vs. verbal

How many questions; topics for questions

All customers, randomly as they shop; account holders only;  
weekends vs weekday; morning/afternoon/evening

14. What needs to be considered when creating a check sheet to gather data/information? (3 pts)

Defined categories for what to record

What info do you want? Actual measures, counts, etc.

Include "other" or "comments" column

Design for use (adequate spacing, easy accessibility, etc.)

Utilize what's available

Time period(s) for collecting data

Training personnel in use