QUESTIONS:

1. **Which Process Validation Stage is meant to capture the objective evidence that the limits of your process result in product that meets all predetermined specifications?**
    - Installation Qualification
    - Operational Qualification
    - Performance Qualification

2. **Identify the deliverables below that are commonly captured in an IQ:**
    - A demonstration of process capability & process control (stability) at the nominal conditions
    - Confirmation of Equipment Safety Features
    - Confirmation of Equipment Software Version
    - The use of statistically valid techniques to establish the relationship between Process Inputs & Process Outputs
    - Creation of a Preventative Maintenance Schedule

3. **Fill in the Blank: ________________________ means confirmation by examination & evaluation of objective evidence to confirm that your final product meets the customer's needs & intended use.**
    - Design Verification
    - Design Validation
    - Design Qualification
    - Design V&V Protocol

4. **A system is in its useful life period & has been shown to have a MTBF of 1,000 Hours. What is the Reliability of the system at 250 Hours?**
    - 75.6%
    - 77.8%
    - 73.2%
    - 71.0%

5. **A system is in its useful life period & has a MTBF of 1,000 hours. At what point in time is the likelihood for failure equal to the likelihood for success:**
    - 500
    - 307
    - 693
    - 721

6. **You're attempting to assess the reliability of a new product design. 10 Units are put on test for 300 hours.**
   Assume these units are operating within their useful life period, where the following failure times are noted in hours: 120, 90, 160, 210, 100, 130, 240, 150

   Based on this data, calculate the MTBF of this new design:
   - 120 Hours
   - 150 Hours
   - 180 Hours
   - 225 Hours
   - 300 Hours

7. **You're designing a new motor, and have confirmed that the reliability of the motor operators in accordance with the weibull distribution with the following parameters:**

   Weibull Location(Δ): 0 Weibull Slope (β) = 2 Weibull Scale (θ) = 15,000

   Determined Estimate the proportion of a population of motors that will still be operational after 17,000 hours of operation.
   - 72.3%
   - 46.4%
   - 27.7%
   - 18.6%

8. **What two parameters below are needed to setup a single, normal sampling plan using general level II inspection?**
   - AQL
   - Total Lot Size
   - Consumer Risk Level
   - Producer Risk Level
   - Incoming Percent Non-conforming
   - AOQL Target

9. **Fill in the blank: ___________ is commonly defined as the worst tolerable process average that is still considered acceptable.**
   - **AQL**
   - LTPD
   - AOQ
   - AOQL

10. **Within Acceptance Sampling, Consumers Risk Is:**
    - The Risk that you will consume product in manner other than what is intended by your design
    - The Risk that you will Consume to many samples while executing your acceptance Sampling Plan.
    - The risk that you the consumer will reject a lot based on sampling data, when the overall quality level of the lot actually meets the Acceptable Quality Level
    - The risk that you the consumer will accept a lot based on sampling data, when the overall quality level of the lot actually does not meet the Acceptable Quality Level

11. **Fill in the blank: In acceptance sampling, ___________ is commonly defined as the poorest quality that can be tolerated.**
    - AQL
    - LTPD
    - AOQ
    - AOQL

12. **Fill in the blank: In acceptance sampling, __________________reflects the worst possible average outgoing quality associated with a given sampling plan.**
    - AQL
    - LTPD
    - AOQ
    - AOQL

13. **You're analyzing the OC curve for your sampling plan. Assuming you hold the sample size constant, what would happen to the probability of acceptance if the acceptance number for the plan was increased?**
    - The probability of acceptance would increase
    - The probability of acceptance would decrease
    - The probability of acceptance would not change
    - Not enough information available

14. **You're performing an ANOVA Analysis, and the total sum of squares is 24 and the error sum of squares is 16. What would the treatment sum of squares be?**
    - 40
    - 23
    - 15
    - 8
    - Not Enough Information

15. In ANOVA Analysis, the degrees of freedom associated with the numerator of the F-value can be calculated using which equation:

- N-1
- n(a)-1
- n(a-1)
- (N-1) - (a-1)
- a - 1

SOLUTIONS:

1. **Which Process Validation Stage is meant to capture the objective evidence that the limits of your process result in product that meets all predetermined specifications?**
    - Installation Qualification
    - **Operational Qualification**
    - Performance Qualification

The **Operations Qualification** (OQ) is is meant to capture the objective evidence that the limits of your process result in product that meets all predetermined specifications.

2. **Identify the deliverables below that are commonly captured in an IQ:**
    - A demonstration of process capability & process control (stability) at the nominal conditions – **This is typically performed in an OQ or PQ.**
    - Confirmation of Equipment Safety Features
    - Confirmation of Equipment Software Version
    - The use of statistically valid techniques to establish the relationship between Process Inputs & Process Outputs – **This is typically performed in an OQ or PQ.**
    - Creation of a Preventative Maintenance Schedule

3. **Fill in the Blank: ________________________ means confirmation by examination & evaluation of objective evidence to confirm that your final product meets the customer's needs & intended use.**
    - Design Verification
    - **Design Validation**
    - Design Qualification
    - Design V&V Protocol

Design Validation means confirmation by examination & evaluation of objective evidence to confirm that your final product meets the customer's needs & intended use.

Design Verification means confirmation by examination and evaluation of objective evidence that your Design Output (Product Specification & Requirements) meets all your Design Inputs (Technical Reflection of Customer Needs).

4. A system is in its useful life period & has been shown to have a MTBF of 1,000 Hours. What is the Reliability of the system at 250 Hours?

- 75.6%
- **77.8%**
- 73.2%
- 71.0%

The first step in solving this problem is understanding that because the system is in its useful life period, we must use the Exponential Distribution to calculate reliability, see below:

We can plug in the time value (250 hours), and the MTBF (1,000 hours) to calculate the reliability.

$$\boldsymbol{R(t) = e^{-\lambda t}}\ \textit{Where}\ \boldsymbol{MTBF = \theta = \frac{1}{\lambda}}$$

$$\boldsymbol{R(250) = e^{\frac{-t}{\theta}} = e^{\frac{-250}{1,000}} = e^{\frac{-1}{4}}}$$

$$\boldsymbol{R(250) = .7788\ or\ 77.88\%\ Reliability}$$

Using this equation, we can estimate the Reliability at 250 Hours to be 77.88%

5. A system is in its useful life period & has a MTBF of 1,000 hours. At what point in time is the likelihood for failure equal to the likelihood for success:

- 500
- 307
- **693**
- 721

The first step in solving this problem is understanding that because the system is in its useful life period, we must use the Exponential Distribution to calculate reliability.

The below equation can be used to calculate reliability for an exponential distribution:

$$\boldsymbol{Reliability}:\quad R(t) = e^{-\lambda t} = e^{\frac{-t}{\theta}}$$

The point in time where the likelihood for failure being equal to the likelihood for success means that the reliability of the system is 50% or 0.50

$$R(t) = 0.50 = e^{-\lambda t} = e^{\frac{-t}{\theta}}$$

Where

$$\boldsymbol{\theta = MTBF = 1,000}$$

Now we can solve for the time value (t) associated with a reliability of 50%.

$$R(t) = 0.50 = e^{\frac{-t}{1,000}}$$

We can solve for t by taking the natural log (LN) of the exponential (e).

$$\boldsymbol{LN(.50) = \frac{-t}{1,000}}$$

$$\boldsymbol{t = -1,000 * LN(.50) = 693\ Hours}$$

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   Assume these units are operating within their useful life period, where the following failure times are noted in hours: 120, 90, 160, 210, 100, 130, 240, 150

   Based on this data, calculate the MTBF of this new design:
   - 120 Hours
   - 150 Hours
   - 180 Hours
   - 225 Hours
   - 300 Hours

   See below for the MTBF Calculation.

   Remember that 10 units in total were put on test, but only 8 units failed prior to the end of the 300-hour test.

   So, when calculating the operating time, we must account for these 2 units that survived.

$$\boldsymbol{MTBF} = \frac{Operating\ Time}{Number\ of\ Failures}$$

$$MTBF = \frac{120 + 90 + 160 + 210 + 100 + 130 + 240 + 150 + (2 * 300)}{8}$$

$$MTBF = \frac{1,800}{8} = 225\ Hours$$

7. **You're designing a new motor, and have confirmed that the reliability of the motor operators in accordance with the weibull distribution with the following parameters:**

Weibull Location(Δ): 0

Weibull Slope (β) = 2

Weibull Scale (θ) = 15,000

Determined Estimate the proportion of a population of motors that will still be operational after 17,000 hours of operation.

- 72.3%
- 46.4%
- **27.7%**
- 18.6%

When a product follows the weibull distribution, we can calculate the reliability at a given time using the following equation:

$$\boldsymbol{Reliability}: \quad R(t) = e^{-\left(\frac{t}{\theta}\right)^{\beta}}$$

$$R(17{,}000) = e^{-\left(\frac{17{,}000}{15{,}000}\right)^{2}} = 27.7\%\ \text{Reliability}$$

8. **What two parameters below are needed to setup a single, normal sampling plan using general level II inspection?**

- **AQL**
- **Lot Size**
- Consumer Risk Level
- LTPD
- Producer Risk Level
- Incoming Percent Non-conforming
- AOQL Target

9. **Fill in the blank: ___________ is commonly defined as the worst tolerable process average that is still considered acceptable.**

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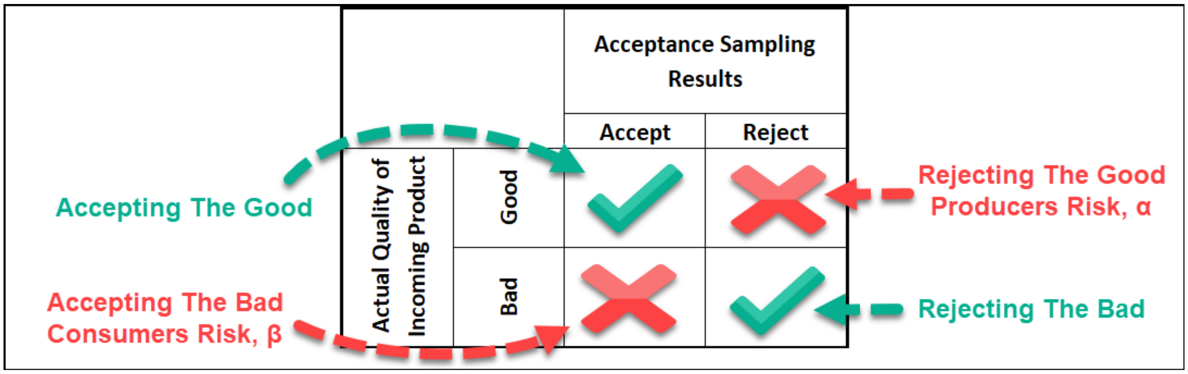

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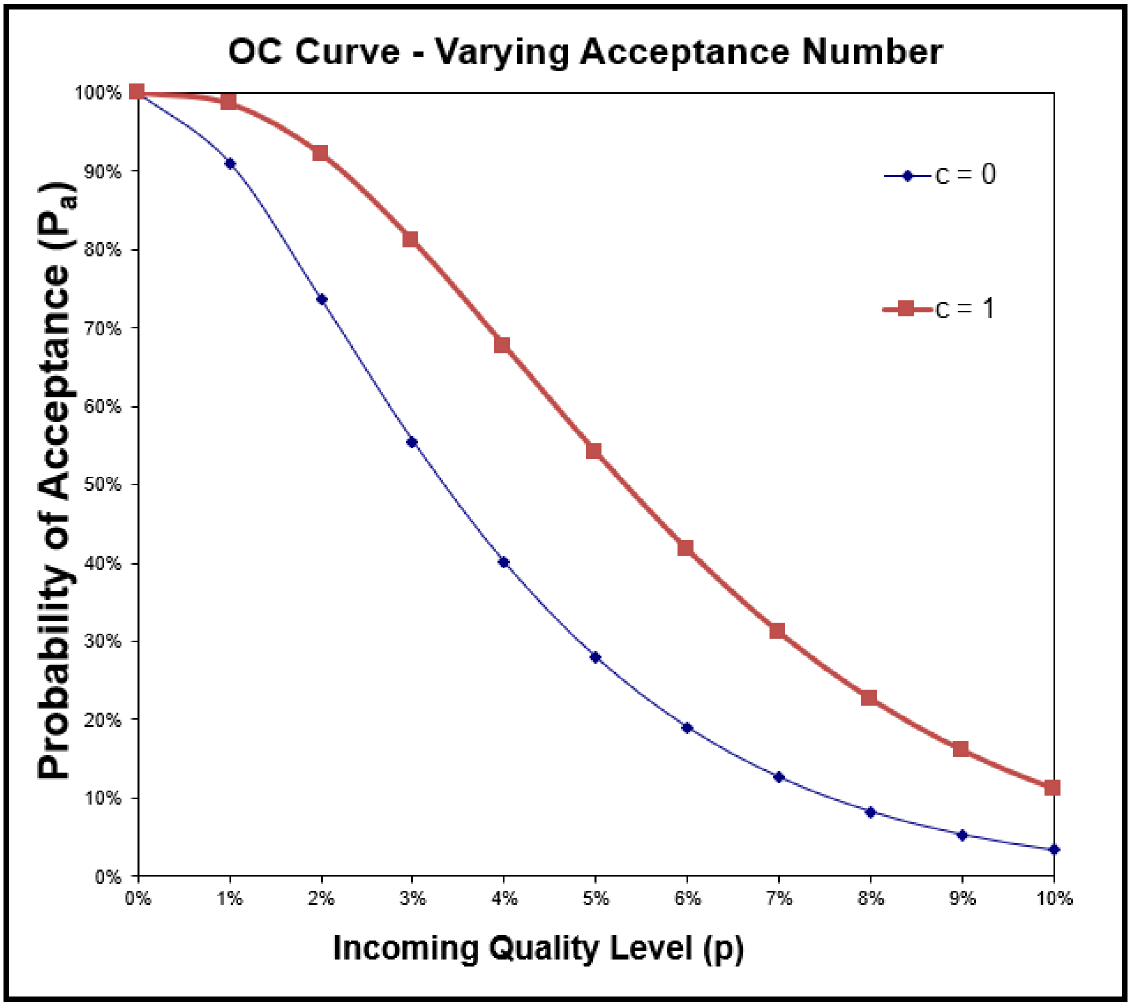
    - The probability of acceptance would not change
    - Not enough information available

You can see this in the graph below which shows 2 different OC Curves. The line in blue is a c = 0 curve. Meaning we accept only when zero non-conformances occur. The line in red is a c = 1 curve, meaning we accept only when 1 or fewer non-conformances have occurred.

You can see that for any incoming quality level, the probability of acceptance of the red line (c = 1), is always greater than the probability of acceptance of the blue line (c = 0).



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- 23
- 15
- 8
- Not Enough Information

$SS_{treatment} = SS_{total} - SS_{error}$ $SS_{treatment} = 24 - 16 = 8$

15. In ANOVA Analysis, the degrees of freedom associated with the numerator of the F-value can be calculated using which equation:

- N-1
- n(a)-1
- n(a-1)
- (N-1) - (a-1)
- a - 1

Recall that in ANOVA, F = MST / MSE, with MST being the numerator of the equation. Also recall that the degrees of freedom associated with the Treatment Mean Square (MST) is equal to the number of treatment groups (a) - 1.