# PRACTICE EXAM 2: ASQ CQE SIMULATION (175 QUESTIONS)

1. A quality engineer discovers that the withinsubgroup standard deviation estimate from control chart data is 0.15, while the overall standard deviation calculated from all individual measurements is 0.28. Which condition does this discrepancy most directly indicate?

A. The measurement system contributes excessive variation to the observed data

B. The subgroup size is too large, inflating the withinsubgroup variation estimate

C. The process data does not follow a normal distribution

D. Significant betweensubgroup variation exists, likely from process shifts or special causes

2. An organization has implemented a supplier scorecard system that tracks quality, delivery, and cost metrics. Over the past year, Supplier X has maintained 99.5% quality conformance and 97% ontime delivery but has increased prices by 12%. Which metric represents the most appropriate basis for a supplier development discussion?

A. Quality conformance, since it should be improved to 100% before addressing other areas

B. Cost competitiveness, since the 12% price increase directly affects the organization's profitability

C. Ontime delivery, since 97% indicates three out of every hundred shipments are late

D. All three metrics weighted equally regardless of the magnitude of variance in each

3. A quality engineer is planning a designed experiment and wants to protect against the effects of ambient temperature changes that occur naturally throughout the day. The engineer cannot control the temperature. Which experimental design technique is most appropriate?

A. Randomizing the run order so temperature effects are distributed across all treatments

B. Increasing the number of factor levels from two to three for each experimental factor

C. Eliminating temperature as a factor by conducting all runs in a climatecontrolled chamber

D. Adding temperature as an additional experimental factor at multiple controlled levels

4. Which of the seven quality management principles from ISO 9000:2015 emphasizes that decisions based on the analysis and evaluation of data and information are more likely to produce desired results?

A. Process approach

B. Leadership commitment

C. Evidencebased decision making

D. Engagement of people

5. A quality engineer is analyzing reliability data for a mechanical component and determines that the Weibull shape parameter $\beta = 3.4$. Which region of the bathtub curve does this component's failure behavior represent?

A. The random failure region with a constant failure rate

B. The infant mortality region with a decreasing failure rate

C. The transition region between infant mortality and useful life

D. The wearout region with an increasing failure rate

6. A manufacturing process has an upper specification limit of 10.5, a lower specification limit of 9.5, a process mean of 10.1, and an estimated standard deviation of 0.15. What is the Cpk for this process?

A. 0.89

B. 1.11

C. 1.33

D. 1.67

7. A quality engineer observes the following pattern on a cchart: points 1 through 12 fluctuate randomly around the center line, then points 13 through 20 show a consistent upward trend with the last two points near the upper control limit. What is the most likely cause of this pattern?

A. The measurement system was recalibrated at point 13, creating a step change

B. A progressive deterioration such as tooling wear or material degradation is occurring

C. The sample size was changed, invalidating the original control limits

D. The process is operating normally and the pattern is within expected common cause variation

8. In the context of risk management, which of the following best describes the relationship between a hazard and a risk?

A. A hazard is the quantified probability of a risk event occurring

B. A hazard is a source of potential harm that creates the possibility of risk when exposure exists

C. Hazards and risks are identical concepts used interchangeably in quality engineering

D. A hazard only exists after a risk event has already occurred and caused harm

9. A quality team has brainstormed 45 potential causes of a packaging defect using a causeandeffect diagram. The team now needs to narrow this list to the most likely root causes for further investigation. Which tool is most appropriate for prioritizing these potential causes?

A. Activity network diagram to schedule the investigation tasks

B. Tree diagram to decompose each cause into subcauses

C. Multivoting or nominal group technique to narrow the list based on team judgment

D. Force field analysis to evaluate resistance to corrective action

10. In a fractional factorial experiment, a Resolution III design confounds which types of effects?

A. Threefactor interactions with fourfactor interactions

B. Twofactor interactions with other twofactor interactions only

C. Main effects with the overall mean of the experiment

D. Main effects with twofactor interactions

11. An organization discovers that a critical procedure was revised six months ago, but the obsolete version is still being used at three of five workstations. This finding indicates a failure in which quality system element?

A. Document control — specifically the distribution and withdrawal of obsolete versions

B. Management review — the procedure change was not approved by top management

C. Corrective action — the root cause of the original problem was not properly addressed

D. Quality planning — the procedure should not have been revised without customer approval

12. A quality engineer is evaluating two measurement instruments for precision. Instrument A has a standard deviation of 0.003 mm and Instrument B has a standard deviation of 0.008 mm when measuring the same reference standard repeatedly. Which conclusion about precision is correct?

A. Both instruments are equally precise because they are measuring the same standard

B. Instrument A cannot be evaluated without knowing its bias relative to the true value

C. Instrument A is more precise because it exhibits less variation in repeated measurements

D. Instrument B is more precise because a larger standard deviation indicates wider coverage

13. A Material Review Board is evaluating nonconforming parts that are 0.004 inches below the lower specification limit on a noncritical cosmetic dimension. Engineering analysis confirms no functional or safety impact. The parts are urgently needed to fulfill a customer order. Which disposition is most appropriate?

A. Scrap the parts and expedite replacement production regardless of schedule impact

B. Use asis with engineering justification documented and appropriate approvals obtained

C. Rework the parts by adding material to bring them within the original specification

D. Return the parts to the supplier for credit and immediate replacement

14. A quality engineer is reviewing Kirkpatrick's evaluation model for a recently completed SPC training program. Participants scored an average of 92% on a posttraining knowledge test, compared to 45% on the pretraining test. This improvement represents which level of Kirkpatrick's model?

A. Level 1 — Reaction, measuring participant satisfaction with the training

B. Level 3 — Behavior, measuring onthejob application of skills learned

C. Level 4 — Results, measuring organizational impact of the training investment

D. Level 2 — Learning, measuring knowledge acquisition from the training

15. A process engineer proposes changing from a singlecavity mold to a fourcavity mold to increase production throughput. Before implementing this change, the quality engineer should assess which potential impact?

A. Whether the four cavities produce statistically equivalent output or whether cavitytocavity variation introduces a new source of quality risk

B. Whether the tooling cost is justified by the projected increase in revenue

C. Whether the production operators prefer working with single or multicavity molds

D. Whether the raw material supplier can guarantee delivery of four times the current volume

16. In the PDCA cycle, which activity specifically involves analyzing the data collected during the Do phase to determine whether the improvement produced the expected results?

A. Plan — developing the improvement hypothesis and data collection approach

B. Act — standardizing the improvement and updating procedures

C. Check — comparing actual results to predicted results and evaluating effectiveness

D. Do — implementing the improvement plan on a pilot scale

17. An operator on a production line discovers a part that does not meet specification. According to quality system requirements, what should the operator do first?

A. Segregate the nonconforming part from conforming product and notify the supervisor

B. Attempt to rework the part at the workstation to bring it into specification

C. Continue production and report the nonconformance at the end of the shift

D. Determine the root cause of the nonconformity before taking any other action

18. A company implements Total Quality Management. After two years, a cultural assessment reveals that employees view quality as the responsibility of the quality department rather than everyone's responsibility. Which TQM principle has the organization failed to effectively implement?

A. Statistical thinking in daily operations and decisionmaking processes

B. Benchmarking against industry best practices and competitor performance

C. Customer focus and alignment of internal processes with customer needs

D. Total employee involvement — the principle that everyone is responsible for quality

19. A quality engineer is selecting a control chart for monitoring the proportion of defective units from a production process where the sample size varies from batch to batch between 80 and 250 units. Which chart is most appropriate?

A. npchart, which plots the number of nonconforming units per sample

B. pchart, which accommodates variable sample sizes with recalculated control limits

C. cchart, which counts the total number of defects found in each sample

D. uchart, which normalizes defect counts by the varying inspection unit size

20. In a hypothesis test, the pvalue is 0.032 and the significance level $\alpha$ is 0.05. Which statement correctly describes the decision and its rationale?

A. Fail to reject $H_0$ because the pvalue exceeds the conventional threshold of 0.01

B. Reject $H_0$ because the test statistic falls exactly on the critical value boundary

C. Reject $H_0$ because the pvalue (0.032) is less than $\alpha$ (0.05), indicating sufficient evidence against the null hypothesis

D. Fail to reject $H_0$ because a pvalue above 0.01 indicates the result is not practically significant

21. In the context of designed experiments, a center point added to a twolevel factorial design serves which primary purpose?

A. To increase the resolution of the fractional factorial from III to IV

B. To provide additional replication for improving the estimate of experimental error

C. To allow the experiment to be conducted in blocks without confounding main effects

D. To detect curvature in the response by testing whether the relationship between factors and response is nonlinear

22. A process validation protocol requires three sequential stages: IQ, OQ, and PQ. During which stage is the equipment verified to operate correctly across its entire intended operating range, including at the extremes of process parameters?

A. Operational Qualification, which tests equipment performance across the operating range

B. Performance Qualification, which verifies consistent product quality under production conditions

C. Installation Qualification, which confirms proper installation per manufacturer specifications

D. A fourth stage called Design Qualification, which precedes IQ in the validation sequence

23. A quality engineer is conducting a risk assessment for a chemical mixing process. The team identifies a risk of operator chemical burn from a valve failure. Using the risk treatment hierarchy for safety, which approach should be evaluated first?

A. Provide chemicalresistant personal protective equipment to all operators

B. Install warning signs and alarms near the chemical mixing station

C. Redesign the system to eliminate the need for operator proximity to the valve during mixing

D. Develop a detailed emergency response procedure for chemical spill events

24. A quality engineer calculates the following statistics from a Gage R&R study: total measurement system variation accounts for 8.5% of the part tolerance, and the number of distinct categories is 7. Based on AIAG guidelines, what is the assessment of this measurement system?

A. Unacceptable — the system requires immediate replacement before any quality decisions

B. Acceptable — the measurement system has adequate discrimination and contributes minimal variation relative to the tolerance

C. Conditionally acceptable — the system should be improved when practically feasible

D. Indeterminate — additional data is required before an assessment can be made

25. In acceptance sampling, the probability of rejecting a lot that has quality at the Acceptable Quality Limit (AQL) is called which of the following?

A. Consumer's risk (β)

B. Average outgoing quality limit

C. Lot tolerance percent defective

D. Producer's risk (α)

26. An organization's quality policy includes a commitment to "exceeding customer expectations through innovative products." During an ISO 9001:2015 audit, the auditor asks how this policy commitment is translated into measurable objectives. Which response demonstrates proper implementation?

A. Specific, measurable quality objectives are established at relevant functions and levels, tracked with defined metrics, and reviewed during management review

B. The quality policy is posted on the company website and in the employee break room

C. The organization has a customer complaint database that records all incoming complaints

D. Department managers meet annually to discuss how quality has improved informally

27. A quality engineer is analyzing process data and discovers that the histogram shows a truncated distribution — the data has a sharp cutoff at one end that coincides with a specification limit. What is the most likely explanation?

A. The process is perfectly centered with zero variation beyond the specification

B. The data was collected from a population that naturally follows a uniform distribution

C. 100% inspection or sorting has removed all values beyond the specification limit, hiding the true process distribution

D. The sample size is too small to capture the full range of process variation

28. Which lean manufacturing tool uses a visual board to display the status of production in real time, including planned versus actual output, downtime events, and quality metrics?

A. Value stream map showing the complete material and information flow

B. Visual management or andon board displaying realtime production status

C. Kanban card system controlling material movement between workstations

D. Standard work documentation defining the one best way to perform each task

29. A quality engineer needs to determine whether a new heat treatment process produces significantly different hardness than the current process. Fifteen parts are processed through both the old and new methods, and hardness is measured on each part after each treatment. Which statistical test is most appropriate?

A. Paired ttest, since the same parts are measured under both conditions

B. Twosample ttest for independent samples from two populations

C. Oneway ANOVA comparing three or more group means simultaneously

D. Chisquare test of independence for categorical hardness classifications

30. A reliability block diagram shows a subsystem with two identical components in parallel, each with reliability of 0.85. This parallel subsystem is then in series with a single component having reliability of 0.95. What is the overall system reliability?

A. 0.81

B. 0.95

C. 0.85

D. 0.93

31. A quality engineer discovers that a supplier has changed a subcomponent material without notification, even though the purchase order requires prior approval of any material changes. This finding most directly represents a failure in which supply chain management area?

A. Incoming inspection procedures for detecting nonconforming material upon receipt

B. Supplier audit scheduling frequency and coverage

C. Change management and supplier communication requirements within the quality agreement

D. Acceptance sampling plan selection and implementation methodology

32. In GD&T, which geometric characteristic symbol controls the orientation of a surface at exactly 90 degrees to a specified datum?

A. Angularity

B. Perpendicularity

C. Parallelism

D. Flatness

33. A quality engineer observes that a recently implemented corrective action involved adding an additional inspection step to catch a recurring defect. Six months later, the defect rate has decreased but has not been eliminated. What is the fundamental problem with this corrective action approach?

A. The inspection step was not performed frequently enough to catch every occurrence

B. Six months is insufficient time to evaluate corrective action effectiveness

C. Additional inspectors need to be trained to improve the detection rate at the new station

D. Adding inspection is a detectionbased approach that does not prevent the defect from being created

34. In the context of the Malcolm Baldrige National Quality Award framework, the criteria are nonprescriptive. What does this mean in practice?

A. The criteria specify exactly which quality tools and methods must be used

B. Organizations must follow the criteria in the exact sequence presented in the framework

C. The criteria require ISO 9001 certification as a prerequisite for application

D. The criteria ask how an organization approaches its work and what results it achieves without dictating specific methods

35. A quality engineer is constructing an Xbar and R chart using 25 subgroups of size 5. The grand average $\bar{\bar{x}} = 50.0$ and the average range $\bar{R} = 4.0$. Using $A_2 = 0.577$ for $n = 5$, what is the lower control limit for the Xbar chart?

A. 46.0

B. 45.0

C. 47.69

D. 50.0

36. A process control plan specifies that a critical dimension must be measured every 30 minutes using SPC with a subgroup size of 5. The plan also requires a reaction plan. An operator plots a point above the UCL on the Xbar chart. According to the control plan, which action should the operator take first?

A. Continue production while notifying the quality engineer at the next scheduled break

B. Stop the process, segregate suspect material, and initiate the documented reaction plan

C. Recalculate the control limits using the most recent 10 subgroups to verify the signal

D. Wait for the next subgroup to confirm the outofcontrol signal before taking action

37. In a designed experiment, the quality engineer runs each treatment combination three times independently. These repetitions are called replicates. What is the primary statistical benefit of replication?

A. It eliminates the need for randomization by averaging out lurking variable effects

B. It reduces the number of factors that need to be included in the experiment

C. It provides a visual check that the experimental equipment is functioning correctly

D. It provides an independent estimate of experimental error, enabling significance testing of factor effects

38. An organization implements ISO 9001:2015 and must address Clause 8.5.1, which requires controlled conditions for production. Which of the following is a specific requirement of this clause?

A. The availability of documented information that defines the characteristics of products to be produced and activities to be performed

B. The mandatory appointment of a management representative with defined authority

C. The requirement for a quality manual describing the scope of the quality system

D. The maintenance of a formal preventive action procedure as a standalone process

39. A quality engineer is investigating a customer complaint about intermittent product malfunction. Internal testing cannot reproduce the failure. Which quality tool would be most useful for systematically narrowing down the conditions under which the failure occurs?

A. Pareto chart to rank the most frequent malfunction types

B. Flowchart to document the manufacturing process sequence

C. Is/Is Not analysis to compare conditions where the failure occurs versus where it does not

D. Affinity diagram to organize brainstorming ideas about possible causes

40. In the context of risk treatment, an organization decides to outsource a highrisk manufacturing process to a specialized subcontractor who has demonstrated expertise and certified capability. Which risk treatment strategy does this primarily represent?

A. Risk avoidance by eliminating the process from the organization entirely

B. Risk transfer by shifting the operational risk to a party better equipped to manage it

C. Risk reduction through additional process controls implemented at the subcontractor

D. Risk acceptance with ongoing monitoring of the subcontractor's performance

41. A quality engineer is conducting a oneway ANOVA comparing the tensile strength of wire from four different suppliers. Each supplier provides 10 samples. The ANOVA table shows SSB = 450, SSW = 1,200, and the total degrees of freedom = 39. What are the degrees of freedom for the betweengroups (treatment) and withingroups (error) sources?

A. Between = 3, Within = 36

B. Between = 4, Within = 36

C. Between = 9, Within = 30

D. Between = 3, Within = 36

42. Feigenbaum's concept of Total Quality Control emphasized which fundamental shift in how organizations should view quality responsibility?

A. Quality is the responsibility of every function and every individual, not solely the quality department

B. Quality should be controlled exclusively through statistical process control methods

C. Quality costs should be eliminated by investing only in prevention activities

D. Quality improvements should be driven entirely by top management directives

43. A quality engineer discovers that incoming material from a trusted supplier, which normally passes receiving inspection, has caused a spike in internal defect rates over the past month. What is the most appropriate first action?

A. Immediately terminate the supplier relationship and qualify a replacement

B. Increase final inspection intensity to prevent defective product from reaching customers

C. Investigate the supplier's recent process changes and incoming material for the specific characteristic causing defects

D. Accept the increased defect rate as normal variation until the supplier's annual audit

44. A quality engineer is analyzing a time series of monthly customer complaint data. The data shows a recurring spike in complaints every December and January, with relatively stable complaint levels during other months. This pattern is an example of which time series component?

A. Cyclical variation with irregular periodicity

B. Seasonality — a recurring pattern with a fixed, known period

C. Random variation around a stable process mean

D. A sustained upward trend in complaint frequency over time

45. In a $2^4$ fullfactorial experiment, how many total treatment combinations exist, and how many effects (including all main effects and interactions) can be estimated?

A. 8 treatment combinations and 7 effects

B. 16 treatment combinations and 4 effects

C. 12 treatment combinations and 11 effects

D. 16 treatment combinations and 15 effects

46. A quality engineer needs to monitor the count of surface blemishes on painted panels where the panel sizes vary from batch to batch. Which control chart is most appropriate?

A. cchart for counts per constantsized inspection unit

B. npchart for number of nonconforming panels per constant sample

C. uchart for defect rate per unit with variable inspection unit sizes

D. pchart for proportion of panels classified as nonconforming

47. During an internal audit, the auditor finds that a documented procedure specifies calibration every 90 days for a critical measurement instrument, but the actual practice calibrates every 120 days with management's verbal approval. How should this finding be assessed?

A. The documented procedure should be revised to match the actual 120day practice since management approved it

B. No finding is warranted because management approval overrides the documented procedure

C. This is an observation since the instrument may still be within tolerance at 120 days

D. This is a nonconformity because actual practice does not conform to the documented procedure

48. In the Kano Model, which type of customer requirement has a linear relationship between fulfillment and satisfaction — the more it is provided, the more satisfied the customer becomes?

A. Basic or musthave requirements that cause dissatisfaction only when absent

B. Performance or onedimensional requirements with satisfaction proportional to fulfillment

C. Excitement or delighter requirements that create unexpected satisfaction

D. Reverse requirements where increased fulfillment decreases satisfaction

49. An organization is calculating its total Cost of Quality and needs to classify the cost of maintaining a team of receiving inspectors who check every incoming shipment from suppliers. Under which COQ category does this cost belong?

A. Prevention costs, because inspection prevents defective material from entering production

B. Internal failure costs, because the inspection identifies defects before they reach production

C. External failure costs, because the material arrived from an external supplier

D. Appraisal costs, because the activity is designed to detect nonconformances through examination

50. A process has been demonstrated to be in statistical control and normally distributed. The engineer calculates Cp = 1.50 and Cpk = 1.50. What specific condition about the process does this equality indicate?

A. The process standard deviation is exactly half the specification tolerance

B. The process has excessive variation that exceeds the specification tolerance

C. The process mean is exactly centered between the upper and lower specification limits

D. The measurement system accounts for less than 10% of total observed variation

51. A quality engineer is evaluating whether to use a Ztest or a ttest for a hypothesis test about a population mean. Which factor is the primary determinant of this choice?

A. Whether the population standard deviation σ is known or must be estimated from the sample

B. Whether the hypothesis test is onesided or twosided

C. Whether the sample was drawn using random or systematic sampling

D. Whether the quality characteristic is classified as critical, major, or minor

52. In the 8D problemsolving methodology, which discipline specifically addresses preventing the problem — or similar problems — from recurring in other products, processes, or locations?

A. D5 — Choose and verify permanent corrective actions

B. D7 — Prevent recurrence by modifying systems, procedures, and standards

C. D3 — Develop interim containment actions to protect the customer

D. D4 — Determine and verify root cause through data analysis

53. A quality engineer is selecting a nondestructive testing method for inspecting welds on a carbon steel pressure vessel for internal porosity and incomplete fusion. Which NDT method provides the best capability for detecting these internal volumetric defects?

A. Liquid penetrant testing for surfacebreaking indications

B. Magnetic particle inspection for nearsurface discontinuities

C. Visual inspection with borescope for internal surface examination

D. Radiographic testing, which reveals internal volumetric defects as density variations on the image

54. A quality engineer finds that two consecutive lots from a supplier have been rejected under normal inspection per ANSI/ASQ Z1.4. According to the switching rules, what action should be taken?

A. Switch to reduced inspection to reduce the cost of excessive inspection

B. Continue normal inspection and issue a corrective action request to the supplier

C. Switch from normal inspection to reduced inspection after the third consecutive rejection

D. Verify whether tightened inspection has already been triggered and apply it accordingly

55. A quality engineer is analyzing the effect of three process variables on yield using a multiple regression model. The engineer obtains an $R^2$ of 0.88 and an adjusted $R^2$ of 0.86. What does the small difference between these two values suggest?

A. The model has severe multicollinearity that invalidates the regression coefficients

B. At least one predictor variable should be removed from the model immediately

C. The predictor variables in the model are all contributing meaningfully without overfitting

D. The residuals are not normally distributed, violating a key regression assumption

56. In GD&T, the Regardless of Feature Size (RFS) condition means which of the following?

A. The stated geometric tolerance applies only when the feature is at its maximum material condition

B. The geometric tolerance applies at whatever size the feature is actually produced — no bonus tolerance is available

C. The feature does not require dimensional inspection if it passes a functional gage check

D. The feature's size tolerance is automatically doubled when geometric tolerances are applied

57. An organization's risk register identifies a risk with a probability rating of 2 (unlikely) and a severity rating of 5 (catastrophic). Using a standard 5×5 risk matrix where risk score equals probability times severity, the risk score is 10. Despite the relatively moderate numerical score, why should this risk receive heightened attention?

A. A score of 10 always triggers mandatory risk avoidance regardless of the individual ratings

B. The probability rating of 2 is too low and should be increased to at least 3 for all catastrophic risks

C. The risk matrix is invalid for catastrophic severity and should be replaced with quantitative analysis

D. Highseverity risks involving potential catastrophic consequences warrant aggressive treatment regardless of their probability

58. A quality engineer is conducting a process capability study and discovers that the data is significantly rightskewed. The standard Cp and Cpk formulas assume normality. Which approach is most appropriate?

A. Calculate Cp and Cpk using the standard formulas since they are robust to nonnormality

B. Increase the sample size until the distribution appears to become approximately normal

C. Transform the data using a BoxCox or similar transformation, verify normality of the transformed data, and then calculate capability on the transformed scale

D. Use only the range of the data to estimate capability rather than the standard deviation

59. Juran's concept of the "vital few and useful many" is most directly applied using which quality tool?

A. Pareto chart, which separates the significant few causes from the trivial many

B. Scatter diagram, which identifies the relationship between two variables

C. Histogram, which displays the distribution shape of a single variable

D. Causeandeffect diagram, which organizes all possible causes by category

60. A quality engineer is implementing errorproofing on an assembly line and identifies an operation where operators frequently forget to install a small Oring before closing an assembly. Which pokayoke approach most effectively prevents this defect?

A. Adding a visual reminder sign at the workstation reminding operators to install the Oring

B. A sensorbased system that verifies Oring presence before allowing the assembly fixture to close

C. A final inspection checkpoint where inspectors verify Oring presence on completed assemblies

D. A checklist that operators initial after each Oring installation step is completed

61. A quality engineer is reviewing the results of a $2^3$ fullfactorial experiment and needs to determine which effects are statistically significant. The experiment was unreplicated. Which analysis approach is most appropriate for identifying significant effects without an independent estimate of error?

A. Conduct a standard ANOVA using residual mean square as the error estimate

B. Assume all main effects are significant and all interactions are negligible

C. Repeat the experiment with replication before drawing any conclusions

D. Construct a normal probability plot of the calculated effects, where significant effects deviate from the line formed by insignificant effects

62. Which clause of ISO 9001:2015 requires the organization to conduct internal audits at planned intervals to determine whether the quality management system conforms to requirements and is effectively implemented?

A. Clause 9.2 — Internal audit

B. Clause 10.2 — Nonconformity and corrective action

C. Clause 9.2 — Internal audit

D. Clause 7.1 — Resources

63. A quality engineer is evaluating a process where the response variable has only one specification limit — an upper specification limit of 100 ppm for impurity concentration. There is no lower specification limit. Which capability index can be calculated?

A. CPU = (USL  μ) / 3σ, which measures capability relative to the single upper limit

B. Cp = (USL  LSL) / 6σ using zero as the implicit lower specification limit

C. Cpk requires both specification limits and cannot be calculated for onesided specifications

D. Pp using the overall standard deviation with an assumed lower limit at zero

64. A quality team has completed a value stream map of the current state and identified that inventory buffers between process steps account for 85% of total lead time. Which lean principle should guide the future state design?

A. Increasing inspection frequency at each buffer point to catch defects earlier

B. Creating continuous flow by eliminating unnecessary inventory between process steps

C. Adding additional storage capacity to better organize the existing inventory buffers

D. Implementing lotbased production scheduling to maximize equipment utilization

65. A quality engineer calculates a 99% confidence interval for the mean weight of a product and obtains (248.2, 251.8) grams. A colleague then calculates a 95% confidence interval from the same data. Which statement about the 95% interval is correct?

A. The 95% interval will be identical to the 99% interval since both use the same data

B. The 95% interval cannot be determined without collecting a new sample

C. The 95% interval will be wider than the 99% interval because it provides more coverage

D. The 95% interval will be narrower than the 99% interval because less confidence requires less width

66. During a PFMEA review, the team identifies that a drilling operation could produce an oversized hole due to tool wear. The current detection control is a postdrilling gage check on every fifth part. The Severity is rated 7, Occurrence is 4, and Detection is 6. What is the traditional Risk Priority Number?

A. 168

B. 17

C. 96

D. 28

67. An organization uses acceptance sampling and is currently on normal inspection. The quality history shows that the last 12 consecutive lots have been accepted. The quality engineer recommends switching to reduced inspection. Besides the consecutive acceptance record, which additional condition must be met per ANSI/ASQ Z1.4?

A. The AQL must be revised to a less stringent value before switching

B. The customer must provide written approval for reduced inspection

C. Production must be at a steady rate and the switch must be approved by the responsible authority

D. The supplier must demonstrate ISO 9001 certification from an accredited body

68. In Crosby's Quality Management Maturity Grid, an organization at the "Uncertainty" stage is characterized by which quality management approach?

A. Quality management activities are fully integrated into all business processes

B. Quality is understood as a strategic business advantage and is continuously improved

C. The organization has no comprehension of quality as a management tool and quality problems are handled on a firefighting basis

D. Quality management is established with formal systems but continuous improvement is not yet embedded

69. A quality engineer must determine the sample size needed to detect a shift of 1.5 standard deviations in the process mean with 90% power at $\alpha = 0.05$ using a twosided ttest. Increasing which factor would allow the engineer to use a smaller sample size while maintaining the same power?

A. Increasing the desired power from 90% to 95%

B. Decreasing the significance level from 0.05 to 0.01

C. Increasing the desired detectable shift from 1.5 to 2.0 standard deviations

D. Decreasing the desired detectable shift from 1.5 to 1.0 standard deviations

70. A quality engineer is comparing the performance of a measurement system over time. Monthly measurements of a single reference standard are plotted on a control chart. The chart shows all points in control with no trends. This assessment evaluates which property of the measurement system?

A. Repeatability — the variation when the same operator measures repeatedly

B. Bias — the difference between the average measured value and the true value

C. Linearity — the consistency of bias across the measurement range

D. Stability — the consistency of the measurement system's performance over time

71. A quality engineer is using a scatter diagram to analyze the relationship between two process variables and observes a clear curved pattern in the data — the relationship appears quadratic rather than linear. If the engineer calculates the Pearson correlation coefficient (r), what is the most likely result?

A. A moderate or low rvalue despite the clear relationship, because Pearson's r only measures linear association

B. A value near zero, confirming that no relationship exists between the variables

C. A value near +1.0, correctly capturing the strong quadratic relationship

D. A negative rvalue, indicating that the quadratic term reverses the direction of the relationship

72. In the Six Sigma DMAIC methodology, the Control phase is responsible for which primary deliverable?

A. A project charter defining the scope, objectives, and business case for the improvement

B. A measurement system analysis confirming data reliability before baseline collection

C. A root cause analysis identifying the critical factors that drive process variation

D. Mechanisms for sustaining improvements including updated control plans, training, and monitoring systems

73. A quality engineer has collected 25 subgroups of size 4 for an Xbar and R chart. After plotting all points and confirming both charts are in control, the engineer needs to estimate the process standard deviation. Using $\bar{R} = 5.2$ and $d_2 = 2.059$ for $n = 4$, what is the estimated process standard deviation?

A. 2.53

B. 10.71

C. 2.06

D. 5.20

74. A company receives an audit finding that states: "The organization has not evaluated the effectiveness of actions taken to address risks identified in Clause 6.1." Which area of the ISO 9001:2015 standard is the organization failing to fulfill?

A. Clause 5.2 — Quality policy requirements

B. Clause 8.1 — Operational planning and control

C. Clause 7.2 — Competence of personnel

D. Clause 6.1 — Actions to address risks and opportunities, specifically the requirement to evaluate effectiveness

75. A quality team is implementing a 5S program in a manufacturing cell. During the Sort phase, the team identifies equipment and tools that have not been used in the past 12 months. What is the recommended action for these items?

A. Leave the items in place and revisit the decision during the Standardize phase

B. Remove the items from the work area using a redtag process, placing them in a holding area with a defined disposition deadline

C. Immediately discard all items to maximize the workspace improvement

D. Move the items to a different workstation where they might be needed

76. In reliability engineering, if a system has three components in series with reliabilities of 0.99, 0.98, and 0.97, and the organization wants to improve system reliability most efficiently, which component should be targeted for reliability improvement?

A. The component with 0.99 reliability, since it contributes the most to system reliability

B. Any component equally, since all three contribute identically to system reliability

C. The component with 0.97 reliability, since improving the weakest component yields the greatest system improvement

D. None — the system should add parallel redundancy rather than improving individual components

77. A quality engineer is interpreting a multiple regression model with three predictor variables. The overall Ftest is significant ($p < 0.001$) and $R^2 = 0.82$. However, the ttest for one predictor shows $p = 0.45$. What does this suggest about that specific predictor?

A. The predictor does not contribute significant additional explanatory power beyond what the other predictors already explain

B. The entire regression model is invalid and should be discarded

C. The predictor has the strongest individual relationship with the response variable

D. The pvalue for the predictor is incorrectly calculated and must be rechecked

78. In the context of ISO 14971, risk management for medical devices, which activity must be performed throughout the entire product lifecycle rather than only during the design phase?

A. Design verification testing against engineering specifications

B. Production process validation through IQ, OQ, and PQ stages

C. Supplier qualification auditing of component manufacturers

D. Risk management including monitoring, review, and updating as postmarket data becomes available

79. A quality engineer needs to determine whether the variance of a critical dimension has increased after a process change. Twenty samples before the change yield $s_1^2 = 0.024$ and twenty samples after yield $s_2^2 = 0.051$. Which test statistic and distribution should be used?

A. Ztest using the standard normal distribution for large sample comparison

B. $F = s_2^2/s_1^2 = 0.051/0.024 = 2.125$, compared to the Fdistribution with 19 and 19 degrees of freedom

C. ttest using the tdistribution with 38 degrees of freedom

D. Chisquare test using the chisquare distribution with 19 degrees of freedom

80. A company wants to benchmark its quality management practices against bestinclass organizations. Which framework provides the most comprehensive model for selfassessment across leadership, strategy, customers, workforce, operations, and results?

A. ANSI/ASQ Z1.4 attributes sampling standard for incoming inspection

B. AIAG APQP framework for advanced product quality planning in automotive

C. Malcolm Baldrige National Quality Award criteria for performance excellence

D. ISO 19011 guidelines for management system auditing

81. A quality engineer is constructing a frequency histogram from 200 measurements and needs to determine the appropriate number of class intervals (bins). Using Sturges' rule ($k \approx 1 + 3.322 \times \log_{10}(n)$), approximately how many bins should be used?

A. 9 bins

B. 15 bins

C. 20 bins

D. 5 bins

82. In the context of quality system documentation, which level of the documentation hierarchy provides objective evidence that activities were performed as planned and that results met specified requirements?

A. Quality policy statements defining overall organizational intentions

B. Procedures describing who, what, when, and where for process execution

C. Work instructions providing detailed stepbystep operational guidance

D. Records, which serve as evidence of conformance and performance

83. A quality engineer is planning a Gage R&R study for a visual inspection process where inspectors classify parts as acceptable or unacceptable. The standard Gage R&R (ANOVA method) is designed for continuous measurements. Which MSA method is appropriate for this attributes inspection system?

A. An attributes agreement analysis that evaluates the consistency of inspector classifications

B. A standard Gage R&R using the ANOVA method applied to the pass/fail classifications

C. A process capability study using the proportion of parts classified as acceptable

D. A calibration verification study comparing inspector results to a calibrated instrument

84. During a lean kaizen event focused on reducing changeover time, the team separates setup activities into internal setup (performed while the machine is stopped) and external setup (performed while the machine is running). This analysis is a core element of which lean technique?

A. Value stream mapping for identifying waste in the complete material flow

B. Total productive maintenance for maximizing equipment effectiveness

C. Kanban system design for controlling workinprocess inventory levels

D. Single Minute Exchange of Die (SMED) for reducing changeover time

85. A quality engineer is investigating a field failure and determines that the product failed because a material degradation mechanism — not considered during the original design — accelerated under the customer's operating environment. Which design process failure does this represent?

A. A design input failure — the customer's operating environment was not adequately identified and incorporated into the design requirements

B. A process validation failure — the manufacturing process was not validated correctly

C. A supplier quality failure — the supplier provided substandard raw material

D. An inspection failure — the degradation should have been detected during final inspection

86. In hypothesis testing, power analysis is used to determine sample size. Holding all other factors constant, increasing the significance level $\alpha$ from 0.01 to 0.05 will have which effect on the required sample size?

A. The required sample size will increase because a larger $\alpha$ demands more data

B. The required sample size has no relationship to the significance level chosen

C. The required sample size will remain unchanged since $\alpha$ only affects the decision rule

D. The required sample size will decrease because a larger $\alpha$ provides more power, requiring fewer observations to detect the same effect

87. An organization discovers that its management review meetings have been conducted regularly but have not resulted in any decisions or actions for improvement over the past two years. Which aspect of the management review process is deficient?

A. The frequency of the management review meetings is insufficient

B. The management review is failing to produce meaningful outputs — decisions and actions for improvement as required by ISO 9001

C. The input data presented during management review is complete and accurate

D. The attendance list for management review includes all required participants

88. In the context of measurement scales, a quality engineer records the temperature of a heat treatment furnace in degrees Celsius. This data is classified on which measurement scale?

A. Nominal, because temperature categories are used for classification

B. Ordinal, because temperatures can be ranked but intervals may vary

C. Interval, because the intervals are equal but zero degrees Celsius does not represent absence of temperature

D. Ratio, because temperature has a true zero and supports all arithmetic operations

89. A designed experiment with five factors produces 16 runs. This experiment is designated as a $2^{5-1}$ design. What fraction of the full factorial does this represent?

A. Onehalf of the full factorial

B. Onequarter of the full factorial

C. Oneeighth of the full factorial

D. Onesixteenth of the full factorial

90. A quality engineer discovers that operators on the night shift consistently produce higher defect rates than day shift operators, even though both shifts use the same equipment, materials, and procedures. Which investigation approach is most appropriate?

A. Immediately reassign all night shift operators to the day shift

B. Install automated inspection equipment to catch night shift defects before shipping

C. Suspend night shift production until the root cause has been identified and eliminated

D. Investigate differences in supervision, lighting, training, fatigue, and other factors that differ between shifts to identify the root cause

91. A process engineer wants to understand which sources of variation contribute most to overall dimensional variation: parttopart differences, positional variation within each part, or temporal variation between production lots. Which analytical tool is specifically designed to visualize and compare these multiple sources simultaneously?

A. Run chart showing individual measurements plotted over time in sequence

B. Multivari chart displaying variation from multiple sources on a single graph

C. Histogram showing the overall distribution of all dimensional measurements

D. Scatter diagram plotting one variable against another to detect correlation

92. In acceptance sampling using ANSI/ASQ Z1.4, inspection level II is the default. When would a quality engineer consider using inspection level I (reduced discrimination)?

A. When product characteristics are safetycritical and require the most thorough inspection

B. When the cost of inspection is high relative to the value of the product

C. When the process has demonstrated consistently poor quality over multiple lots

D. When the lot size is extremely large and requires the maximum possible sample size

93. An organization's corrective action procedure requires root cause analysis for every nonconformity. A quality engineer finds that 90% of the corrective action reports list "operator error" as the root cause with "retrain the operator" as the corrective action. What does this pattern most likely indicate?

A. The root cause analyses are not being conducted with sufficient depth to identify systemic causes

B. The organization has an exceptionally high rate of human error that requires intensive training

C. The corrective action system is performing exactly as intended and producing effective results

D. The quality engineer should implement an automated inspection system to eliminate human error

94. A quality engineer is evaluating the adequacy of a sampling plan for incoming inspection. The plan uses a sample size of 13 from lots of 200 with an acceptance number of 1. The engineer is concerned about the plan's ability to reject lots with 8% nonconforming. Which tool should the engineer use to evaluate the plan's performance at this quality level?

A. The operating characteristic (OC) curve for the sampling plan, which shows the probability of acceptance at each quality level

B. The process capability index Cpk, which relates process variation to specification limits

C. The average outgoing quality curve, which shows expected quality after inspection

D. The control chart for proportion nonconforming, which monitors the process over time

95. In the context of lean manufacturing, takt time is calculated as available production time divided by customer demand. If a factory operates 8 hours per day with 30 minutes of planned breaks and the daily customer demand is 450 units, what is the takt time?

A. 1.07 minutes per unit

B. 0.94 minutes per unit

C. 1.00 minutes per unit

D. 60 seconds per unit

96. A quality engineer is reviewing an FMEA and notices that the team assigned a Severity of 9, Occurrence of 8, and Detection of 2. Using the Action Priority method from the AIAG/VDA FMEA Handbook, how does this failure mode's priority compare to one with Severity 3, Occurrence 8, Detection 8?

A. The first failure mode (S=9) receives higher priority because the Action Priority method weights severity most heavily, regardless of the lower Detection rating

B. Both failure modes receive identical priority because their RPN values are similar

C. The second failure mode (S=3) receives higher priority due to its worse detection capability

D. Neither failure mode requires action because the average of their ratings is below 7

97. During a process audit, the auditor observes that an operator is performing a heat treatment cycle with parameters that do not match the documented work instruction. When questioned, the operator states that a supervisor verbally authorized the deviation. How should the auditor assess this situation?

A. The verbal authorization from the supervisor is sufficient to justify the deviation

B. The operator is following proper protocol by accepting supervisor direction

C. The operator should have documented the deviation even with verbal supervisor approval

D. This is a nonconformity because documented procedures cannot be overridden by verbal authorization without a formal deviation or change process

98. A quality engineer is implementing SPC on a process that produces only 3–4 units per day. Subgrouping is not practical because the production rate is too low to form meaningful subgroups within a short timeframe. Which control chart approach is most appropriate?

A. Xbar and R chart using a subgroup size of 1 collected once per day

B. pchart tracking the proportion of nonconforming units per daily lot

C. cchart counting the number of defects per unit produced each day

D. Individuals and Moving Range (IMR) chart plotting each measurement individually

99. In the context of document control, what is the primary purpose of maintaining a master list of controlled documents?

A. To provide a comprehensive reference that identifies all controlled documents, their current revision status, and their distribution, ensuring that any person can verify whether a specific document is current

B. To satisfy the ISO 9001 requirement for a quality manual that describes the QMS scope

C. To serve as a backup copy of all quality system documents in case of data loss

D. To provide a record of all employee training activities related to documented procedures

100. A quality engineer is analyzing the results of a chisquare goodnessoffit test for normality. The test statistic is $\chi^2 = 4.2$ with 5 degrees of freedom, and the critical value at $\alpha = 0.05$ is 11.07. What is the conclusion?

A. The test provides no information about the distribution's shape

B. The data is definitely not normally distributed and a transformation is required

C. There is sufficient evidence to reject the normality assumption at the 5% level

D. There is insufficient evidence to reject the normality assumption — the data is consistent with a normal distribution

101. A quality engineer is analyzing field return data for an electronic module and plots the cumulative failure percentage on Weibull probability paper. The resulting plot is a straight line with a slope that yields $\beta = 1.0$. What failure pattern does this indicate?

A. Infant mortality with a rapidly decreasing failure rate over time

B. Wearout with an accelerating failure rate as components age

C. A constant failure rate consistent with the exponential distribution and the useful life period

D. A bimodal failure pattern indicating two distinct populations in the data

102. A quality engineer is planning a process capability study. The process has been running for three months, and control charts show several outofcontrol signals that have not been investigated or resolved. Should the engineer proceed with the capability study?

A. Yes, because three months of data provides a sufficient sample size for capability analysis

B. Yes, but the engineer should use Pp and Ppk instead of Cp and Cpk to account for instability

C. Yes, as long as the outlier points are removed from the data before calculating capability indices

D. No, the process must first be brought into statistical control before capability indices are meaningful

103. In the context of Hoshin Kanri, breakthrough objectives differ from routine operational objectives in which fundamental way?

A. Breakthrough objectives represent significant strategic changes that require new capabilities, while routine objectives maintain current performance levels

B. Breakthrough objectives are set by frontline employees while routine objectives come from management

C. Breakthrough objectives apply only to the quality department while routine objectives apply organizationwide

D. Breakthrough objectives are measured monthly while routine objectives are measured annually

104. A quality engineer is evaluating a supplier's capability to produce a critical component with a bilateral tolerance of ±0.025 mm. The supplier provides data showing Cpk = 1.45 from their most recent process capability study. Before accepting this data, what should the quality engineer verify first?

A. That the capability study was conducted with the process in a demonstrated state of statistical control

B. That the supplier used variables sampling rather than attributes sampling for the study

C. That the supplier's quality manual has been approved by the organization's quality director

D. That the capability study sample size was at least 1,000 individual measurements

105. In the Cost of Quality model, an organization discovers that its prevention costs are 5% of total quality costs while external failure costs represent 60%. Based on the classical COQ optimization model, which strategic action is most appropriate?

A. Reduce appraisal costs to offset the high failure costs and lower total quality spending

B. Maintain current spending levels since some failure cost is economically inevitable

C. Increase inspection intensity at final test to catch more defects before shipment

D. Significantly increase prevention investment, which is expected to produce a disproportionately larger reduction in failure costs

106. A quality engineer is comparing the hardness of steel samples from three different heat treatment furnaces using oneway ANOVA. The analysis yields a pvalue of 0.003 at $\alpha = 0.05$. What is the correct interpretation and next step?

A. All three furnaces produce significantly different mean hardness values from each other

B. The ANOVA result is inconclusive and requires additional replication before any conclusion

C. At least one furnace mean differs significantly from the others; a multiple comparison test should be performed to identify which specific furnaces differ

D. The furnaces are equivalent and no further investigation is needed

107. In a quality audit, the auditor discovers that management review meetings are conducted quarterly as required, but the meeting minutes contain no record of decisions made or actions assigned. Which element of the management review process is deficient?

A. The required documented outputs including decisions and actions related to improvement opportunities

B. The frequency of management review meetings which should be monthly

C. The list of attendees which should include all employees in the organization

D. The agenda which should follow a standardized corporate template

108. A quality engineer needs to select a control chart for monitoring a process where the response of interest is the number of customer complaints received per week. The number of customers served varies significantly from week to week. Which chart is most appropriate?

A. cchart because complaints are count data per time period

B. uchart because the rate must be normalized by the varying number of customers served

C. pchart because each customer either complains or does not

D. npchart because the total complaint count per week is the metric of interest

109. A quality engineer is reviewing a product design and notices that a position tolerance on a bolt hole pattern specifies the MMC modifier. The hole has a size tolerance of 10.010.5 mm and a position tolerance of 0.25 mm at MMC. If a specific hole is produced at 10.3 mm diameter, what is the total positional tolerance available for that hole?

A. 0.25 mm with no additional tolerance regardless of hole size

B. 0.55 mm after adding bonus tolerance for the feature's departure from MMC

C. 0.30 mm based on the midpoint between MMC and LMC sizes

D. 0.55 mm because the position tolerance is added to the size tolerance

110. A quality engineer is implementing a corrective action system and wants to ensure that corrective actions address root causes rather than symptoms. Which requirement is most critical for achieving this goal?

A. Requiring that every corrective action report include a costbenefit analysis

B. Limiting the number of corrective action reports issued per month to reduce workload

C. Mandating a structured root cause analysis method and requiring verification of effectiveness before closure

D. Assigning all corrective actions to the quality department for consistency

111. A company has been using 100% inspection on a highvolume production line to screen out nonconforming product. The quality engineer proposes transitioning to statistical process control. Which argument best justifies this transition from a quality and economic perspective?

A. SPC monitors and controls the process to prevent defects, whereas 100% inspection only detects defects after they are produced, making SPC both more effective and more economical

B. SPC eliminates the need for any inspection whatsoever once control charts are established

C. 100% inspection is always more accurate than SPC at detecting nonconforming product

D. SPC requires less management oversight than maintaining an inspection workforce

112. A quality engineer discovers that an FMEA was completed by a single design engineer without input from manufacturing, quality, service, or other functions. What is the primary deficiency of this approach?

A. The FMEA form requires a minimum of five signatures to be considered valid

B. A singleperson FMEA lacks the diverse perspectives needed to comprehensively identify all potential failure modes and their causes across design, manufacturing, and use

C. FMEAs conducted by engineers are inherently biased toward design solutions rather than process solutions

D. The FMEA should have been conducted by the quality department rather than design engineering

113. In a twoway ANOVA, the interaction between Factor A (machine type) and Factor B (material grade) is found to be statistically significant ($p = 0.008$). The main effect of Factor A is also significant ($p =$

0.02), but the main effect of Factor B is not significant ($p = 0.35$). How should the engineer interpret the main effect of Factor B?

A. Factor B has no effect on the response and can be set to any level without consequence

B. Factor B should be removed from the analysis entirely since it is not significant

C. Factor B is definitely unimportant because its pvalue exceeds the significance level

D. The nonsignificant main effect of Factor B is misleading because the significant interaction means B's effect depends on the level of A and cannot be evaluated independently

114. A quality engineer is designing an acceptance sampling plan and needs to minimize the average amount of inspection over the long run while maintaining adequate quality protection. Which feature of ANSI/ASQ Z1.4 is specifically designed to achieve this objective?

A. The use of special inspection levels S1 through S4 for destructive testing

B. The option to use double or multiple sampling plans instead of single sampling

C. The switching rules that adjust between normal, tightened, and reduced inspection based on quality history

D. The lot size code letter table that determines sample size from lot size

115. A process control plan specifies SPC monitoring for a critical bore diameter with subgroups of 5 measured every hour. After six months of stable operation, the production manager requests reducing the measurement frequency to once per shift (every 8 hours) to save inspection costs. What is the quality engineer's most appropriate response?

A. Approve the reduction immediately since six months of stability demonstrates the process does not need frequent monitoring

B. Reject the reduction because the original frequency was specified in the control plan and can never be changed

C. Evaluate the request using risk assessment, considering the process stability history, consequence of undetected shifts, and production volume between samples before recommending a frequency

D. Approve the reduction only if the subgroup size is increased from 5 to 20 to compensate

116. A quality engineer is calculating a confidence interval for the mean of a process and obtains a margin of error that is too wide for the decision at hand. The engineer cannot increase the sample size due to cost constraints. Which alternative approach would narrow the interval?

A. Switching from a 99% confidence level to a 90% confidence level, accepting less certainty for more precision

B. Using the population standard deviation instead of the sample standard deviation, even if it is unknown

C. Calculating the interval using the range instead of the standard deviation

D. Eliminating the lowest and highest data points to reduce variability artificially

117. A quality engineer is conducting a supplier audit and discovers that the supplier validates their special welding processes through initial qualification only, with no ongoing revalidation or monitoring. Why is this approach inadequate?

A. Initial qualification alone does not verify that the process remains validated as equipment ages, materials change, and personnel turn over

B. Welding is not considered a special process and does not require validation

C. The supplier should validate every individual weld through destructive testing

D. Revalidation is only required when the customer specifically requests it

118. In the context of the ASQ Code of Ethics, a quality engineer discovers that a product poses a potential safety risk to consumers but is told by management to delay reporting the issue until after the current quarter's financial results are released. What is the engineer's ethical obligation?

A. The engineer should follow management's direction since they have authority over business decisions

B. The engineer should document the concern privately and revisit it after the quarter ends

C. The engineer should quietly reduce production volume to minimize the number of potentially affected units

D. The engineer has an ethical obligation to prioritize public safety and must not delay reporting a known safety risk

119. A quality engineer is analyzing a regression model and finds that two of the three predictor variables are highly correlated with each other ($r = 0.96$). This condition is called multicollinearity. What is the primary consequence of multicollinearity in multiple regression?

A. The overall model $R^2$ becomes artificially low and understates the model's predictive power

B. The regression equation cannot be calculated and the software will produce an error

C. The individual regression coefficients become unstable and unreliable, even though the overall model may still predict well

D. The residuals will show a strong curved pattern indicating model inadequacy

120. An organization's quality information system (QIS) collects data from multiple sources including inspection results, customer complaints, audit findings, and process measurements. Which characteristic is most critical for the QIS to effectively support decisionmaking?

A. The system must use the most expensive commercially available software platform

B. The system must provide timely, accurate, and accessible information to the appropriate decisionmakers

C. The system must generate automated reports without any human interpretation or analysis

D. The system must be accessible only to senior management to prevent data misuse

121. A quality engineer needs to evaluate whether a new surface treatment process produces significantly lower surface roughness than the current process. Historical data establishes that the current process produces Ra = 1.6 μm. Twenty parts treated with the new process yield a mean Ra of 1.42 μm with s = 0.25 μm. Which hypothesis test setup is correct?

A. $H_0$: $\mu = 1.6$ vs. $H_1$: $\mu \neq 1.6$ (twosided test) using a Zstatistic

B. $H_0$: $\mu = 1.6$ vs. $H_1$: $\mu > 1.6$ (onesided upper) using a tstatistic

C. $H_0$: $\mu_1 = \mu_2$ vs. $H_1$: $\mu_1 \neq \mu_2$ (twosample test) using a paired tstatistic

D. $H_0$: $\mu \geq 1.6$ vs. $H_1$: $\mu < 1.6$ (onesided lower) using a tstatistic with 19 degrees of freedom

122. A quality engineer is reviewing a flowchart of the receiving inspection process and notices that rejected material is returned to the supplier without any documented nonconformance report or communication about the reason for rejection. What quality system deficiency does this represent?

A. The receiving inspection process lacks feedback mechanisms that would enable the supplier to understand and correct the quality issue, perpetuating the problem

B. The flowchart is incorrect and does not reflect the actual process being followed

C. The inspection criteria are too stringent and should be relaxed to reduce rejections

D. The purchasing department should handle all supplier communication, not quality

123. In the lean concept of Overall Equipment Effectiveness (OEE), three factors are multiplied together. Which combination correctly identifies these three factors?

A. Quality rate × delivery rate × cost efficiency

B. Uptime × throughput × firstpass yield

C. Availability × performance efficiency × quality rate

D. Machine speed × operator efficiency × material utilization

124. A quality engineer is investigating why a control chart for individual measurements (IMR chart) is generating frequent false alarms despite the process appearing stable by all other indicators. The most likely root cause is which of the following?

A. The control chart constants are being applied incorrectly for the subgroup size

B. The underlying process data is significantly nonnormal, causing the normalbased control limits to be inappropriate

C. The measurement system has a Gage R&R above 10% of tolerance

D. The moving range span should be increased from 2 to 5 consecutive observations

125. A quality engineer is using a prioritization matrix to select among four improvement projects. The criteria are cost savings (weight 5), feasibility (weight 3), and customer impact (weight 4). Project X scores 8, 6, and 9 on these criteria respectively. What is Project X's total weighted score?

A. 23

B. 94

C. 76

D. The weighted score cannot be calculated without knowing the other projects' scores

126. In the context of ISO 9001:2015 Clause 7.1.5, the organization must determine the monitoring and measurement resources needed and ensure they are suitable for their intended purpose. For measurement equipment, which specific requirement must be met?

A. Measurement equipment must be calibrated or verified at specified intervals against standards traceable to international or national measurement standards

B. All measurement equipment must be replaced every five years regardless of condition

C. Only equipment used for final inspection requires calibration; inprocess gages are exempt

D. Calibration is required only for equipment purchased after the organization's ISO certification date

127. A quality engineer is analyzing a Pareto chart of customer complaints and finds that the top three complaint categories account for 42% of total complaints, while the remaining twelve categories account for 58%. What does this distribution suggest?

A. The Pareto principle does not apply and the complaints should be addressed equally across all categories

B. The complaint categories are too broadly defined and should be further subdivided

C. The categorization scheme may need refinement — the top categories may be too broadly defined, or the problem may genuinely be distributed rather than concentrated

D. The quality engineer should only focus on the top three categories since they represent the plurality

128. A designed experiment with four factors at two levels each is conducted as a $2^{4-1}$ fractional factorial. The defining relation is I = ABCD. If the quality engineer needs to estimate all twofactor interactions cleanly without confounding, what action is required?

A. Add center points to the existing design to separate main effects from interactions

B. Augment the design with the complementary halffraction (foldover) to create the full $2^4$ factorial

C. Increase the number of replicates in the current fractional design from one to three

D. Change the defining relation from I = ABCD to I = ABC to increase the resolution

129. In risk management, a quality engineer identifies that a critical production line has no backup power supply, and a power outage would halt production for an estimated 48 hours causing significant financial loss and delivery delays. This situation is best described as which type of risk?

A. Operational risk from infrastructure vulnerability with quantifiable financial consequences

B. Strategic risk from competitive market pressure affecting business positioning

C. Compliance risk from failure to meet electrical code requirements

D. Quality risk from product nonconformance caused by the power outage itself

130. A quality engineer is evaluating the residuals from a regression analysis. The residual plot shows randomly scattered points with no discernible pattern, and the normal probability plot of residuals shows approximately a straight line. What do these results indicate?

A. The regression model is statistically insignificant and should be discarded

B. The predictor variable has no relationship with the response variable

C. Additional predictor variables must be added to the model for it to be valid

D. The linear regression model assumptions are reasonably satisfied — the model is adequate

131. A quality engineer is training operators on SPC chart interpretation. An operator asks: "If all points are within the control limits, does that mean the process is in control?" What is the most accurate response?

A. Yes, if all points fall within the limits, the process is always considered in control

B. Not necessarily, because the process may still need capability analysis to determine acceptability

C. Not necessarily, because patterns such as runs, trends, and stratification can signal outofcontrol conditions even when all points fall within the limits

D. Yes, because the control limits define the boundary between acceptable and unacceptable variation

132. A company's product requires assembly of two mating components — a shaft and a bore. The shaft diameter tolerance is 25.0025.02 mm and the bore diameter tolerance is 25.0525.10 mm. A quality

engineer needs to ensure the components always assemble with clearance. Which analysis method is used to verify that the worstcase combination of shaft and bore tolerances still produces acceptable clearance?

A. Regression analysis correlating shaft diameter to bore diameter

B. Tolerance stackup analysis evaluating the worstcase and statistical combination of tolerances

C. Capability analysis of each component independently without considering their interaction

D. Gage R&R study of the measurement systems used for both components

133. During a kaizen event focused on a packaging line, the team discovers that operators spend approximately 15 minutes per shift searching for tape, labels, and packaging materials that are stored in a central supply room 200 feet from the workstation. Which lean waste categories does this situation represent?

A. Motion (operators walking to retrieve materials) and waiting (production halted during retrieval)

B. Overproduction and defects from the packaging process itself

C. Overprocessing by applying excessive packaging to each product unit

D. Inventory waste from maintaining too much packaging material in the central supply room

134. A quality engineer is constructing a uchart for monitoring the number of paint defects per square meter on variablesized metal panels. The overall average defect rate is $\bar{u} = 2.5$ defects per square meter. For a panel with an area of 4 square meters, what is the upper control limit?

A. 2.5

B. 4.0

C. 3.5

D. 4.87

135. In the context of document control, an employee downloads a controlled procedure from the electronic document management system, prints a copy, and uses it at their workstation for three months without checking for updates. During that time, the procedure has been revised twice. This situation illustrates which specific document control vulnerability?

A. Unauthorized access to the document management system by unqualified personnel

B. Excessive revision frequency that creates confusion and noncompliance

C. Uncontrolled printed copies that bypass the electronic system's version control mechanisms

D. Inadequate management review of procedure changes before implementation

136. A quality engineer is performing a hypothesis test and obtains a pvalue of 0.048. The preestablished significance level is $\alpha = 0.05$. A colleague argues that because the pvalue is so close to $\alpha$, the result is "borderline" and the engineer should increase $\alpha$ to 0.10 to get a clearer result. What is the appropriate response?

A. Changing the significance level after seeing the data is inappropriate because $\alpha$ should be established before the test is conducted, and the result at $\alpha = 0.05$ is technically significant

B. The colleague is correct and the significance level should be increased to provide more clarity

C. The pvalue should be recalculated using a different test to get a more definitive answer

D. A pvalue of 0.048 is effectively the same as 0.05 and the result should be treated as nonsignificant

137. A quality engineer is conducting a risk assessment and assigns probability and severity ratings to identified risks. Two risks receive the same risk score of 12: Risk A has probability 4, severity 3, and Risk B has probability 2, severity 6. Which risk should generally receive higher priority for treatment?

A. Risk A, because its higher probability means it will occur more frequently

B. Risk B, because higher severity risks — especially those approaching catastrophic levels — warrant more aggressive treatment regardless of probability

C. Both risks should receive identical priority since their risk scores are equal

D. Neither risk requires treatment since a score of 12 falls in the lowrisk zone

138. A quality engineer is reviewing a control chart and observes that the withinsubgroup variation (R chart) is in control, but the Xbar chart shows that all 25 points fall within the inner third of the control limits (Zone C). No points appear in Zone B or Zone A on either side. What does this pattern indicate?

A. The process is operating with exceptional stability and minimal variation

B. The control limits are too narrow and should be widened to reduce false alarm frequency

C. The Xbar chart is not sensitive enough because the subgroup size is too small

D. Stratification — the withinsubgroup variation is likely inflated because subgroups contain data from multiple streams, producing artificially wide control limits

139. In the DMAIC methodology, a process sigma level of 4.0 corresponds to approximately how many defects per million opportunities (DPMO)?

A. 3.4 DPMO

B. 66,807 DPMO

C. 6,210 DPMO

D. 233 DPMO

140. A quality engineer is evaluating the economic justification for implementing a pokayoke device on an assembly line. The device costs $15,000 to install and will eliminate a defect that currently costs $85 per occurrence with an average of 12 occurrences per month. Approximately how many months will it take to recover the investment?

A. 15 months based on the defect cost savings alone

B. 12 months based on a standard oneyear payback assumption

C. 8 months based on dividing the investment by the current monthly quality losses

D. The investment cannot be justified because the device does not improve product performance

141. A quality engineer is using an interrelationship digraph to analyze factors contributing to high scrap rates. After drawing all causeandeffect arrows, Factor X has 7 outgoing arrows and 1 incoming arrow, while Factor Y has 2 outgoing arrows and 6 incoming arrows. Which statement correctly characterizes these factors?

A. Factor Y is the most important root cause and should be addressed first

B. Factor X is a fundamental driver (root cause) while Factor Y is primarily an outcome (effect) of other factors

C. Both factors are equally important because the total number of arrows is similar

D. Factor X should be eliminated from the analysis because it has too many outgoing connections

142. In acceptance sampling, the Average Outgoing Quality (AOQ) concept assumes that rejected lots are 100% inspected and all nonconforming units are replaced with conforming ones. As the incoming quality level worsens from the AQL toward the LTPD, what happens to the AOQ?

A. AOQ increases linearly without limit as incoming quality deteriorates

B. AOQ remains constant regardless of the incoming quality level

C. AOQ decreases continuously because more lots are rejected and 100% inspected

D. AOQ initially increases then decreases, creating a peak called the Average Outgoing Quality Limit (AOQL)

143. A quality engineer is evaluating a measurement system and discovers that the bias varies significantly across the measurement range — the instrument reads accurately at the low end but reads consistently high at the upper end. Which measurement system property is deficient?

A. Repeatability — the variation in measurements under identical conditions

B. Reproducibility — the variation caused by different operators

C. Linearity — the consistency of bias across the operating range of the instrument

D. Stability — the consistency of the measurement system over time

144. An organization implements a quality management system and tracks customer satisfaction through periodic surveys. Over three years, overall satisfaction scores have increased from 72% to 88%, but the number of customer complaints has also increased by 25% during the same period. What is the most likely explanation for this apparent contradiction?

A. The satisfaction survey results are fabricated and do not reflect actual customer sentiment

B. Customer expectations have decreased, making them easier to satisfy while still generating complaints about specific issues

C. More customers are now aware of the complaint process or the customer base has grown, increasing the absolute number of complaints even as overall satisfaction improves

D. The complaint data is being recorded incorrectly and should be audited for accuracy

145. In a designed experiment, the quality engineer calculates the effect of Factor A as +8.2 units and the effect of the AB interaction as +7.9 units. Both are statistically significant. The engineer wants to set Factor A to its high level. Why must the interaction be considered before making this decision?

A. The interaction effect is numerically smaller than the main effect, so it can be safely ignored

B. The interaction means the beneficial effect of setting Factor A high depends on the level of Factor B — at one level of B, the benefit may be large; at another, it may be negligible or negative

C. Interactions are mathematical artifacts that do not have practical physical meaning

D. The main effect of Factor A should be doubled to account for the interaction

146. A quality engineer discovers that a supplier has been shipping components with a certificate of conformance (C of C) that states "material meets all applicable specifications," but the C of C does not include any actual test data or specific test results. What is the quality concern with this practice?

A. Certificates of conformance are not recognized by any quality management standard

B. The format of the certificate does not meet the minimum font size requirements

C. A C of C without supporting test data provides no objective evidence that the material was actually tested and met specifications

D. The certificate should be signed by the supplier's CEO rather than the quality manager

147. A quality engineer is implementing SPC on a process that produces both conforming and nonconforming units. The production rate is 50 units per hour, and the historical defect rate is approximately 8%. The engineer wants to use an attributes control chart. Which consideration is most important when determining the sample size for the chart?

A. The sample must be large enough that the expected number of nonconforming units per sample (np) is at least 5 to satisfy the normal approximation

B. The sample size should always be exactly 50 units regardless of the defect rate

C. Attributes charts do not have sample size requirements since they use count data

D. The sample size should equal the production rate divided by the number of shifts per day

148. In Deming's 14 Points for Management, Point 8 states "Drive out fear." What is the quality management rationale behind this principle?

A. Fearful employees work faster, which increases productivity but reduces quality

B. Fear prevents employees from reporting problems, suggesting improvements, and taking the risks necessary for innovation and quality improvement

C. Fear is only relevant in manufacturing environments and does not apply to service industries

D. Driving out fear means eliminating all performance standards and accountability measures

149. A quality engineer calculates the population standard deviation estimate from an Xbar and S chart with 30 subgroups of size 12. The average subgroup standard deviation is $\bar{S} = 3.8$ and $c_4$ for $n = 12$ is 0.9776. What is the estimated process standard deviation?

A. 3.71

B. 3.80

C. 3.89

D. 4.56

150. A quality engineer is reviewing a process and discovers that the process produces to a natural tolerance of $\pm 3\sigma = \pm 0.30$ mm, while the engineering specification is $\pm 0.20$ mm. Which statement accurately describes this situation?

A. The process is capable because its natural tolerance falls within the engineering specification

B. The process requires additional inspection resources to sort conforming from nonconforming output

C. The specification should be widened to match the process capability to avoid excessive rejections

D. The process is not capable because its natural variation ($\pm 0.30$ mm) exceeds the engineering specification ($\pm 0.20$ mm), and process improvement is needed to reduce variation

151. A quality engineer receives a batch of hardness test results and plots them on a normal probability plot. The points closely follow a straight line except for two points at the upper extreme that deviate sharply upward from the line. What do these outlier points most likely represent?

A. Evidence that the entire data set is nonnormal and cannot be analyzed with parametric methods

B. Normal random variation that should be expected in any data set of this size

C. Measurement errors, data recording mistakes, or specimens from a different population that should be investigated before further analysis

D. Confirmation that the data follows a lognormal distribution rather than a normal distribution

152. A quality system requires that all employees performing work affecting product quality are aware of the quality policy, relevant quality objectives, their contribution to QMS effectiveness, and the implications of not conforming to QMS requirements. This requirement addresses which concept from ISO 9001:2015?

A. Competence — the demonstrated ability to apply knowledge and skills effectively

B. Infrastructure — the system of facilities, equipment, and supporting services

C. Awareness — understanding of relevance and importance of one's role in the QMS

D. Organizational knowledge — the information necessary for process operation

153. A quality engineer has completed a designed experiment and identified the optimal factor settings. Before implementing the new settings in production, which critical step should be performed?

A. File the experimental results with the regulatory authority for approval

B. Conduct confirmation runs at the identified optimal settings to verify that the predicted response is achieved

C. Immediately implement the settings across all production lines without further testing

D. Wait for six months of production data before deciding whether to adopt the new settings

154. A process produces output with a mean of 50.0 and the specification limits are 49.0 and 51.0. The process standard deviation is 0.15 mm. If the process mean shifts upward by 1.5σ (to 50.225), approximately what proportion of output will exceed the upper specification limit?

A. 0.13% (same as the unshifted process because the shift is within control limits)

B. The proportion cannot be calculated without knowing the subgroup size

C. 50% because the shifted mean is now at the specification midpoint

D. Approximately 4.8% based on the Zscore for the distance from the shifted mean to the USL

155. In the context of quality training, an organization provides extensive classroom training on a new inspection procedure, but three months later, operators are not following the procedure correctly on the production floor. Based on Kirkpatrick's evaluation model, at which level has the training failed?

A. Level 1 — Reaction, because the participants were dissatisfied with the training

B. Level 2 — Learning, because the participants did not understand the material

C. Level 4 — Results, because the training did not produce organizational improvement

D. Level 3 — Behavior, because the learned skills are not being applied in the actual work environment

156. A quality engineer is developing a risk management plan and needs to determine which risks require treatment versus which can be accepted. This determination is made during which step of the ISO 31000 risk management process?

A. Risk identification, where all potential risks are listed in the risk register

B. Risk analysis, where probability and severity are estimated for each risk

C. Risk evaluation, where analyzed risk levels are compared against acceptance criteria to determine treatment priority

D. Risk treatment, where specific actions are selected to modify unacceptable risks

157. A quality engineer needs to compare the yield of a chemical process across five different catalyst types. Each catalyst is tested four times. The total sum of squares from the ANOVA is SST = 850, and the betweengroups sum of squares is SSB = 320. What is the withingroups sum of squares (SSW)?

A. 1,170

B. 530

C. 320

D. 170

158. In the context of supplier management, which activity provides the most direct and reliable assessment of a supplier's actual quality system implementation and manufacturing capability?

A. Reviewing the supplier's ISO 9001 certification certificate and scope of registration

B. Analyzing the supplier's responses to a selfassessment questionnaire

C. Conducting an onsite supplier audit that examines facilities, processes, records, and practices firsthand

D. Reviewing the supplier's marketing materials and published quality commitments

159. A quality engineer is setting up a pchart and calculates the lower control limit as 0.012. What should the engineer do with this negative LCL value?

A. Use the absolute value (0.012) as the lower control limit

B. Set the lower control limit to zero because a proportion cannot be negative

C. Recalculate using the tdistribution instead of the normal approximation

D. Increase the sample size until the LCL becomes positive

160. A quality engineer reviews a control plan for a critical automotive component and notices that the reaction plan column simply states "notify quality." What is the primary deficiency of this reaction plan?

A. The reaction plan should specify the laboratory test method to use for root cause analysis

B. The reaction plan should include a reference to the applicable FMEA document number

C. The reaction plan should name the specific quality engineer to contact by phone number

D. The reaction plan lacks specific, immediate operator actions such as stopping the process, segregating suspect material, and documenting the nonconformance

161. A quality engineer is evaluating a linear regression model and finds that the slope coefficient $b_1 = 2.34$ with a 95% confidence interval of (0.18, 4.50). What can be concluded about the statistical significance of the slope?

A. The slope is not significantly different from zero because the confidence interval is very wide

B. The slope is statistically significant because the confidence interval does not include zero, indicating a real linear relationship

C. The slope cannot be evaluated for significance without knowing the $R^2$ value of the model

D. The slope has no practical significance because the coefficient is less than 5.0

162. An organization is planning a riskbased internal audit program for the upcoming year. According to riskbased audit planning principles, which processes should receive the most audit time and attention?

A. Processes that were audited most recently and are still fresh in the auditors' memory

B. Processes with the lowest employee headcount to minimize disruption during auditing

C. Processes that have never been audited before, regardless of their risk level

D. Processes with the highest risk to product quality, customer satisfaction, and regulatory compliance

163. A quality engineer is conducting a chisquare test of independence using a contingency table. One of the expected cell frequencies is calculated to be 3.2. What concern does this raise about the validity of the test?

A. Expected frequencies below 5 may invalidate the chisquare approximation; cells should be combined or Fisher's exact test should be used

B. Expected frequencies below 5 have no effect on the test validity whatsoever

C. Only observed frequencies matter for chisquare tests; expected frequencies are irrelevant

D. The minimum expected frequency for chisquare tests is 1.0, so 3.2 is acceptable

164. In lean manufacturing, the concept of "standard work" encompasses three key elements. Which combination correctly identifies these elements?

A. Takt time, work sequence, and standard workinprocess inventory

B. Cycle time, quality specifications, and preventive maintenance schedule

C. Machine speed, operator assignment, and break schedule

D. Production target, defect tolerance, and inspection frequency

165. A quality engineer is analyzing warranty data and constructs a Pareto chart of failure modes. The engineer discovers that the top failure mode — "seal leakage" — accounts for 45% of all warranty claims. Before implementing corrective action, which additional analysis should be performed?

A. A customer satisfaction survey to determine whether seal leakage affects purchasing decisions

B. Root cause analysis to determine why seals are leaking — the failure mode identifies what fails, not why it fails

C. A benchmarking study to compare the organization's seal leakage rate against competitors

D. A costbenefit analysis to determine whether fixing the seal problem is financially worthwhile

166. A quality engineer is evaluating a process that has been in statistical control for 12 months. The Cp is 1.89 and the Cpk is 1.22. What specific improvement action would most efficiently improve the Cpk toward the Cp value?

A. Recentering the process mean toward the midpoint of the specification limits without changing process variability

B. Reducing the process standard deviation through equipment upgrades and tighter material controls

C. Widening the specification limits to accommodate the current process centering position

D. Switching from variables control charts to attributes charts for better monitoring sensitivity

167. A quality engineer is reviewing an experimental design and discovers that the experiment was run in a systematic order — all runs with Factor A at its low level were conducted first, followed by all runs with Factor A at its high level. What is the primary risk of this systematic run order?

A. The experiment will take longer to complete than if run in random order

B. The systematic order ensures better precision because similar conditions are grouped together

C. The effect of Factor A may be confounded with timedependent lurking variables, making it impossible to determine whether observed differences are due to Factor A or to the timedependent change

D. The analysis cannot be performed because ANOVA requires a balanced design

168. A quality engineer is conducting a management review and presenting the cost of quality data. The data shows that prevention costs are 28% of total quality costs, appraisal costs are 22%, internal failure costs are 35%, and external failure costs are 15%. Which observation is most significant?

A. The appraisal costs are too high and should be reduced immediately to lower total quality costs

B. The external failure costs being lower than internal failure costs suggests the appraisal system is effective at catching defects before they reach customers

C. The prevention costs are too high and indicate overinvestment in quality planning activities

D. Internal failure costs at 35% indicate significant waste from scrap and rework that should be targeted for reduction through increased prevention

169. A quality engineer is implementing a calibration program and must establish calibration intervals for a new digital micrometer. Which approach for setting the initial calibration interval is most appropriate?

A. Set the interval at one year because this is the universal standard for all measurement instruments

B. Use the manufacturer's recommended interval as a starting point, then adjust based on actual calibration history data showing whether the instrument is found within or outside tolerance at each calibration

C. Calibrate only when an operator reports that measurements seem inaccurate or drift is suspected

D. Set the shortest possible interval (weekly) regardless of instrument type to maximize measurement accuracy

170. In the context of quality management, a quality engineer is asked to explain the difference between "effectiveness" and "efficiency" as they relate to a quality management system. Which statement correctly distinguishes these concepts?

A. Effectiveness and efficiency are synonymous terms used interchangeably in quality standards

B. Effectiveness is a manufacturing concept while efficiency applies only to service operations

C. Efficiency measures how well the process uses resources while effectiveness is not a measurable concept

D. Effectiveness measures the extent to which planned activities are realized and planned results achieved, while efficiency measures the relationship between results achieved and resources used

171. A quality engineer is planning a Gage R&R study for a torque measurement system. The specification tolerance for the torque characteristic is 20 N·m. The study results show that the total Gage R&R variation is 1.4 N·m. What is the %GRR relative to tolerance, and is the system acceptable?

A. 14% — conditionally acceptable per AIAG guidelines, adequate depending on application criticality

B. 7% — fully acceptable because it is well below the 10% threshold for acceptable measurement systems

C. 7% — fully acceptable, representing the Gage R&R as a percentage of the tolerance

D. 70% — unacceptable because the measurement variation dominates the tolerance range

172. A quality engineer discovers that a recently completed FMEA lists recommended actions for several highpriority failure modes, but none of the actions have been assigned to a responsible individual or given a target completion date. What is the practical consequence of this omission?

A. The FMEA is technically complete since the analysis portion has been finished correctly

B. The recommended actions will be implemented automatically through the existing quality system

C. The FMEA is still in draft form and cannot be considered complete until the analysis is peerreviewed

D. The recommended actions will likely never be implemented because there is no accountability, ownership, or timeline driving followthrough

173. A quality engineer is analyzing process data and discovers that the data follows a lognormal distribution rather than a normal distribution. The engineer needs to calculate process capability. Which approach is correct?

A. Use the standard Cp and Cpk formulas directly since they work with any distribution shape

B. Apply a natural logarithm transformation to the data, verify normality of the transformed data, and calculate capability indices on the transformed scale

C. Double the sample size and recalculate — larger samples always produce normal distributions

D. Ignore the nonnormality since it has no effect on capability index calculations

174. In the context of quality cost analysis, an organization transitions from a reactive quality approach (high failure costs, low prevention costs) to a proactive approach (high prevention costs, low failure costs) over five years. Which trend in total quality costs is expected during this transition?

A. Total quality costs increase continuously as prevention spending adds to existing failure costs

B. Total quality costs initially increase as prevention investments are made, then decrease as failure costs decline more than prevention costs rise, producing a net reduction in total quality costs

C. Total quality costs remain unchanged because prevention spending exactly offsets failure cost reductions

D. Total quality costs decrease immediately as soon as prevention activities begin

175. A quality engineer is preparing for an ISO 9001:2015 surveillance audit. The auditor will verify that the organization has maintained its quality management system between certification audits. Which evidence is most important for the engineer to have readily available?

A. The original certification application form submitted during the initial audit

B. Competitor analysis reports showing the organization's market position relative to peers

C. Records of management reviews, internal audits, corrective actions, process performance data, and evidence of continual improvement since the last audit

D. Updated employee resumes showing professional development activities completed during the year

## Practice Exam 2: Answer Key and Explanations

1. D — When the overall standard deviation (0.28) substantially exceeds the withinsubgroup estimate (0.15), significant betweensubgroup variation is present. This discrepancy indicates the process has experienced shifts, trends, or other instabilities between subgroups — sources of variation that the withinsubgroup estimate does not capture because it reflects only shortterm common cause variation.

2. B — While quality conformance (99.5%) and delivery (97%) are strong, a 12% price increase represents a significant change that directly impacts profitability and competitiveness. The supplier development

discussion should focus on understanding the drivers behind the cost increase and exploring opportunities for cost reduction while maintaining the strong quality and delivery performance.

3. A — Randomizing the run order distributes the effects of uncontrollable lurking variables — including ambient temperature changes — across all treatments, preventing systematic bias. Since the engineer cannot control temperature, randomization ensures that temperature effects do not systematically favor any treatment over another, preserving the validity of the factor effect estimates.

4. C — Evidencebased decision making is the ISO 9000:2015 quality management principle that emphasizes using data and information analysis as the foundation for effective decisions. This principle recognizes that decisions based on factual analysis produce more reliable outcomes than those based on intuition, opinion, or anecdotal evidence.

5. D — A Weibull shape parameter $\beta = 3.4$ indicates an increasing failure rate, which corresponds to the wearout region of the bathtub curve. Values of $\beta$ greater than 1 model wearout behavior where failures become progressively more likely over time due to cumulative degradation mechanisms such as fatigue, corrosion, or material deterioration.

6. A — Cpk = min(CPU, CPL). CPU = (USL  μ)/(3σ) = (10.5  10.1)/(3 × 0.15) = 0.4/0.45 = 0.89. CPL = (μ  LSL)/(3σ) = (10.1  9.5)/(3 × 0.15) = 0.6/0.45 = 1.33. Cpk = min(0.89, 1.33) = 0.89, limited by the upper specification side where the offcenter process mean is closer to the limit.

7. B — A consistent upward trend on a cchart indicates a progressive increase in the defect count per unit over time. This pattern is characteristic of gradual deterioration — tooling wear creating more surface defects, material degradation producing more inclusions, or equipment loosening causing more dimensional errors. The progressive nature of the trend distinguishes it from a sudden shift caused by a discrete event.

8. B — A hazard is a source of potential harm — a condition, substance, or situation that has the inherent capacity to cause injury or damage. Risk exists when there is both a hazard and exposure to that hazard. The distinction is important: the hazard exists as a latent potential; risk quantifies the likelihood and consequences of that potential being realized.

9. C — After a causeandeffect diagram generates a comprehensive list of potential causes, multivoting or nominal group technique provides a structured method for the team to narrow the list based on collective

judgment and experience. These techniques ensure that every team member's input carries equal weight in the prioritization, reducing the influence of dominant personalities.

10. D — In a Resolution III fractional factorial design, main effects are aliased (confounded) with twofactor interactions. This means the observed "effect" attributed to a main factor actually represents the combined effect of that factor and its aliased twofactor interaction, making it impossible to determine which is responsible without additional experimentation or process knowledge.

11. A — Obsolete procedure versions remaining in active use at workstations is a classic document control failure — specifically a failure in the distribution, withdrawal, and control of superseded documents. The document control system should have mechanisms to ensure that when a new revision is issued, all copies of the previous revision are withdrawn or clearly marked as obsolete.

12. C — Precision refers to the closeness of agreement between repeated measurements of the same quantity — measured by the standard deviation of repeated readings. Instrument A (s = 0.003 mm) produces more consistent, tightly clustered readings than Instrument B (s = 0.008 mm), making it the more precise instrument regardless of either instrument's accuracy or bias.

13. B — For a noncritical cosmetic dimension with no functional or safety impact, useasis is the appropriate MRB disposition. The engineering justification confirms the deviation does not affect product performance, and the parts are urgently needed. Useasis requires documented engineering analysis, formal MRB approval, and customer notification if contractually required.

14. D — The improvement from 45% to 92% on a pre/post knowledge test measures Kirkpatrick's Level 2 — Learning, which assesses whether participants acquired the knowledge and skills the training was designed to deliver. Level 2 evaluates knowledge acquisition through testing, not participant satisfaction (Level 1), onthejob application (Level 3), or organizational results (Level 4).

15. A — Switching from a singlecavity to a multicavity mold introduces a new potential source of variation: cavitytocavity differences in dimensions, surface finish, and material flow. The quality engineer must verify that all four cavities produce statistically equivalent output — otherwise, the process may appear capable overall while individual cavities produce nonconforming parts.

16. C — The Check phase of PDCA specifically involves analyzing the data collected during the Do phase to determine whether the improvement produced the expected results. Check compares actual outcomes

against predictions, evaluates whether the improvement hypothesis was supported, and identifies any unintended consequences — it is the learning stage of the cycle.

17. A — The operator's first action should be to segregate the nonconforming part from conforming product to prevent inadvertent use, and then notify the supervisor. Segregation is the immediate containment action that protects downstream processes and the customer. Root cause investigation, rework decisions, and formal disposition follow after proper notification and documentation.

18. D — Total employee involvement — the principle that quality is everyone's responsibility, not just the quality department's — is the TQM principle that has not been effectively implemented. When employees view quality as someone else's job, the organization has failed to create the culture of shared ownership and accountability that TQM requires for success.

19. B — The pchart is designed for monitoring the proportion of nonconforming units when the sample size varies between subgroups. It recalculates control limits for each subgroup based on that subgroup's sample size, producing variablewidth limits that properly reflect the statistical precision achievable with each sample. The npchart requires constant sample sizes.

20. C — When the pvalue (0.032) is less than the significance level $\alpha$ (0.05), the null hypothesis is rejected because the observed data is sufficiently improbable under $H_0$ to conclude that a real effect exists. The pvalue represents the probability of obtaining results at least as extreme as those observed if the null hypothesis were true — 3.2% is below the 5% threshold.

21. D — Center points in a twolevel factorial design detect curvature — nonlinearity in the relationship between factors and the response. If the average response at the center point differs significantly from the average of the factorial points, the true relationship is curved rather than linear, and a model with quadratic terms may be needed to accurately describe the response surface.

22. A — Operational Qualification (OQ) verifies that the equipment operates correctly across its entire intended operating range, including at the extremes of process parameters. OQ tests the equipment under worstcase and boundary conditions to confirm it performs within specifications throughout the range it will encounter during production, bridging the gap between installation verification (IQ) and production performance verification (PQ).

23. C — The risk treatment hierarchy for safetycritical risks prioritizes inherently safe design first — redesigning the system to eliminate the need for operator proximity to the hazard. This approach removes

the source of risk entirely, which is more effective than guards (which can fail or be bypassed), warnings (which depend on human compliance), or emergency procedures (which respond after exposure has occurred).

24. B — With total measurement system variation at 8.5% of tolerance (below the 10% threshold) and ndc = 7 (well above the minimum of 5), the measurement system is fully acceptable per AIAG guidelines. It has adequate discrimination to distinguish between parts and contributes minimal variation relative to the tolerance, making it suitable for reliable quality decisions.

25. D — Producer's risk (α) is the probability of rejecting a lot whose quality is actually at the AQL — a lot that meets the agreedupon quality standard but is rejected due to the chance of the random sample. Producer's risk represents the cost to the supplier of having acceptable lots incorrectly rejected, typically set at approximately 5%.

26. A — Proper implementation of a quality policy commitment requires translating the policy language into specific, measurable quality objectives at relevant functions and levels, establishing metrics to track progress, and reviewing performance during management review. Simply posting the policy or maintaining a complaint database does not demonstrate that the commitment is being actively pursued and measured.

27. C — A truncated distribution with a sharp cutoff coinciding with a specification limit almost always indicates that 100% inspection or sorting has removed all values beyond the limit. The true process distribution extends beyond the specification, but the sorting operation has hidden the nonconforming tail, creating an artificial boundary in the observed data that masks the process's actual capability.

28. B — A visual management or andon board displays realtime production status — planned versus actual output, equipment status (running/stopped/alarm), quality metrics, and downtime events — in a format visible to everyone in the production area. This immediate visibility enables rapid response to abnormalities and keeps the entire team informed of production performance without requiring verbal communication or computer queries.

29. A — The paired ttest is correct because the same 15 parts are measured under both conditions, creating naturally paired observations. The paired design controls for parttopart variation by analyzing the withinpair differences, which is far more powerful than a twosample test that would treat the measurements as independent and include unnecessary betweenpart variation in the error term.

30. D — First calculate the parallel subsystem: $R_{parallel} = 1 - (1-0.85)^2 = 1 - (0.15)^2 = 1 - 0.0225 = 0.9775$. Then combine in series with the single component: $R_{system} = 0.9775 \times 0.95 = 0.929 \approx 0.93$. The parallel redundancy dramatically improves the subsystem reliability from 0.85 to 0.9775, but the series component (0.95) then limits the overall system.

31. C — An unauthorized material change by a supplier directly violates change management and communication requirements that should be specified in the quality agreement or purchase order terms. This failure indicates that the supplier either does not have adequate change control processes or is not adhering to the notification requirements, representing a supply chain governance breakdown.

32. B — Perpendicularity is the GD&T orientation control that defines how closely a feature is oriented at exactly 90 degrees to a specified datum. It requires a datum reference because it controls a relationship between features. Angularity controls orientation at specified angles other than 90°, parallelism controls orientation at 0° (parallel), and flatness is a form control with no datum reference.

33. D — Adding inspection addresses detection — catching defects after they are created — but does not prevent the defects from occurring in the first place. The defect rate decreased because some defects are now caught internally, but the process continues to create them at the same rate. True corrective action would eliminate the root cause of the defect, preventing its creation entirely.

34. D — Nonprescriptive means the Baldrige criteria do not dictate specific tools, methods, or approaches. Instead, they ask how the organization approaches its work and what results it achieves, allowing each organization to select methods appropriate to its context. This contrasts with prescriptive standards like ISO 9001, which specify requirements that must be met.

35. C — $LCL = \bar{\bar{x}} - A_2 \times \bar{R} = 50.0 - (0.577 \times 4.0) = 50.0 - 2.308 = 47.69$. The $A_2$ constant for n = 5 is 0.577, which when multiplied by the average range estimates 3 standard errors of the subgroup mean — the conventional 3sigma distance below the center line defining the lower boundary of expected common cause variation.

36. B — When a control chart signals an outofcontrol condition (point beyond UCL), the operator should immediately follow the documented reaction plan: stop the process to prevent further nonconforming output, segregate any suspect material produced since the last known good subgroup, and initiate the investigation and notification procedures specified in the control plan.

37. D — Replication provides an independent estimate of experimental error — the pure error from withintreatment variation — which is essential for determining whether observed differences between

treatments are statistically significant. Without replication, there is no direct measure of how much the response naturally varies under identical conditions, making significance testing impossible using standard ANOVA methods.

38. A — ISO 9001:2015 Clause 8.5.1 requires the availability of documented information defining the characteristics of products and the activities to be performed as a controlled condition for production. The 2015 revision eliminated the mandatory management representative role (option B), the quality manual requirement (option C), and the standalone preventive action procedure (option D).

39. C — Is/Is Not analysis systematically compares conditions where the failure occurs against conditions where it does not — which customers, which environments, which configurations, which time periods — to narrow the field of potential causes. For intermittent failures that cannot be reproduced inhouse, this structured comparison is the most effective technique for identifying the distinguishing conditions.

40. B — Outsourcing a highrisk process to a specialized subcontractor primarily represents risk transfer — shifting the operational risk associated with that process to a party that has greater expertise, certified capability, and better resources to manage it. While elements of risk reduction may also be present, the fundamental strategy is transferring the risk to a more capable party.

41. D — With k = 4 suppliers and N = 40 total observations: Betweengroups df = k  1 = 4  1 = 3. Withingroups df = N  k = 40  4 = 36. Total df = N  1 = 39. The betweengroups degrees of freedom represent the number of independent comparisons among group means, while withingroups degrees of freedom represent the pooled withingroup variability used to estimate experimental error.

42. A — Feigenbaum's Total Quality Control was revolutionary in asserting that quality is the responsibility of every function and every individual in the organization — not solely the quality department. This concept anticipated the integrated management system approach later embodied in ISO 9000 and fundamentally shifted quality from a departmental activity to an organizationwide responsibility.

43. C — The most appropriate first action is to investigate what has changed at the supplier and examine the incoming material for the specific characteristic causing the increased internal defects. A trusted supplier with a sudden quality change likely had a process shift, material lot change, or equipment issue that can be identified and corrected through collaborative investigation.

44. B — Recurring complaint spikes in December and January that repeat annually represent seasonality — a timeseries component with a fixed, known period (annual in this case). Seasonality follows a

predictable calendar pattern, distinguishing it from cyclical variation (irregular periods), trends (sustained directional movement), or random variation (unpredictable fluctuation).

45. D — A $2^4$ full factorial has $2^4 = 16$ treatment combinations and can estimate $2^4 - 1 = 15$ effects: 4 main effects (A, B, C, D), 6 twofactor interactions (AB, AC, AD, BC, BD, CD), 4 threefactor interactions (ABC, ABD, ACD, BCD), and 1 fourfactor interaction (ABCD). The 16th degree of freedom estimates the overall mean.

46. C — The uchart monitors the defect rate per unit when the inspection unit size varies between subgroups. Since the painted panel sizes vary from batch to batch, the uchart normalizes the defect count by the panel area, producing a rate that is comparable across differentsized panels — unlike the cchart, which requires constant inspection unit size.

47. A — The documented procedure establishes the calibration interval at 90 days, and the actual practice deviates from this by extending to 120 days. Even with management's verbal approval, the documented procedure has not been formally revised — meaning the practice does not conform to the documented requirement. The proper approach is either to follow the 90day procedure or formally revise it through the document control process.

48. B — Performance (onedimensional) requirements have a linear relationship with customer satisfaction — the more the requirement is fulfilled, the more satisfied the customer becomes, and the less it is fulfilled, the less satisfied they are. This proportional relationship distinguishes performance requirements from basic requirements (binary satisfaction) and excitement requirements (nonlinear delight).

49. D — Receiving inspection is an appraisal cost — an expenditure incurred to detect nonconformances through examination, testing, or measurement. Appraisal costs are the costs of verifying conformance, not preventing defects (prevention) or dealing with the consequences of defects found internally (internal failure) or by the customer (external failure).

50. C — When Cp equals Cpk, the process mean is exactly centered between the specification limits. Cpk equals Cp only when the distance from the process mean to the upper specification limit equals the distance from the mean to the lower specification limit — which occurs exclusively when the mean is at the midpoint of the tolerance range.

51. A — The primary determinant is whether the population standard deviation $\sigma$ is known or unknown. When $\sigma$ is known, the Ztest (standard normal distribution) is used. When $\sigma$ is unknown and must be

estimated from the sample standard deviation s, the ttest (tdistribution) is used. For large samples (n > 30), the distinction is practically negligible.

52. B — D7 in the 8D methodology specifically addresses preventing recurrence by modifying the management systems, procedures, standards, and practices that allowed the problem to occur. D7 goes beyond fixing the specific problem (D5/D6) to ensure that similar problems cannot occur in other products, processes, or locations — it is the systemic prevention step.

53. D — Radiographic testing is the best method for detecting internal volumetric defects such as porosity and incomplete fusion in welds. Xrays or gamma rays pass through the weld and are differentially attenuated by voids and solid material, producing an image that reveals the location, size, and distribution of internal discontinuities and provides a permanent record.

54. D — Under ANSI/ASQ Z1.4 switching rules, a lot rejection under normal inspection triggers an evaluation of whether tightened inspection should be applied. The switching rules require tightened inspection when quality deteriorates, and two consecutive rejections would typically have triggered this switch. The engineer should verify the current inspection status and apply the appropriate severity level.

55. C — A small difference between $R^2$ (0.88) and adjusted $R^2$ (0.86) suggests that the predictor variables are all contributing meaningfully to the model without overfitting. Adjusted $R^2$ penalizes for unnecessary predictors — if variables were adding noise without explanatory value, adjusted $R^2$ would drop substantially below $R^2$. The close values indicate a wellspecified model.

56. B — Regardless of Feature Size (RFS) means the stated geometric tolerance applies at whatever actual size the feature is produced — there is no bonus tolerance available. The tolerance zone remains constant regardless of the feature's departure from its nominal size. RFS is the default condition in ASME Y14.5 when no material condition modifier is specified.

57. D — Risk management principles consistently require that catastrophicseverity risks receive heightened treatment regardless of their probability. The numerical risk score may appear moderate, but the potential for loss of life demands robust risk reduction measures. Low probability does not make catastrophic consequences acceptable — the irreversibility and magnitude of the harm warrant aggressive treatment.

58. C — When process data is significantly nonnormal, the standard Cp/Cpk formulas (which assume normality) may produce misleading results. The appropriate approach is to transform the data using a

BoxCox or similar transformation to achieve approximate normality, verify the transformation's success, and then calculate capability indices on the transformed scale using the normalbased formulas.

59. A — The Pareto chart directly implements Juran's vital few and useful many concept by sorting categories in descending order of frequency or cost, visually separating the small number of significant causes (vital few) from the large number of minor causes (useful many). The cumulative percentage line shows how much of the total problem the top categories account for.

60. B — A sensorbased system that verifies Oring presence before allowing the fixture to close is a detectiontype pokayoke that prevents the assembly from proceeding until the Oring is confirmed present. This is more effective than visual reminders or checklists (which depend on operator compliance) and more proactive than final inspection (which catches the error after additional value has been added).

61. D — For unreplicated factorial experiments, the normal probability plot of effects is the standard method for identifying significant effects. Insignificant effects (which are essentially random noise) cluster along a straight line through the origin, while significant effects deviate from this line. This visual method effectively separates real effects from noise without requiring an independent error estimate.

62. C — Clause 9.2 of ISO 9001:2015 establishes the requirement for internal audits at planned intervals. The clause requires the organization to plan, establish, implement, and maintain an audit program that considers the importance and results of previous audits, defines audit criteria and scope, selects auditors to ensure objectivity, and ensures results are reported to relevant management.

63. A — When only one specification limit exists, only the onesided capability index can be calculated. $CPU = (USL - \mu) / 3\sigma$ measures the distance from the process mean to the upper specification limit in units of three standard deviations. Cp requires both USL and LSL and cannot be calculated for onesided specifications.

64. B — Creating continuous flow by eliminating unnecessary inventory between process steps directly addresses the finding that inventory buffers account for 85% of lead time. Lean principles prioritize flow — moving products through processes without interruption — over batchandqueue approaches that create the inventory accumulation and waiting time revealed by the value stream map.

65. D — A 95% confidence interval is narrower than a 99% interval from the same data because less confidence requires a smaller critical value ($Z_{0.025} = 1.96$ versus $Z_{0.005} = 2.576$), which produces a smaller

margin of error. The tradeoff is that the narrower interval provides less certainty that it contains the true parameter — 95% versus 99%.

66. A — RPN = Severity × Occurrence × Detection = 7 × 4 × 6 = 168. The RPN provides a numerical ranking for prioritizing among failure modes, though it has known limitations — different S/O/D combinations can produce identical RPNs despite representing very different risk profiles. The Action Priority method addresses these limitations by weighting severity most heavily.

67. C — ANSI/ASQ Z1.4 requires multiple conditions for switching from normal to reduced inspection: ten consecutive lots accepted under normal inspection, production at a steady rate, and approval by the responsible authority. The production rate stability requirement ensures that the consistent acceptance record reflects a genuinely stable process rather than an artifact of sporadic production.

68. C — The Uncertainty stage — the first level of Crosby's Quality Management Maturity Grid — describes an organization that has no comprehension of quality as a management tool, where quality problems are handled reactively on a firefighting basis, and where there is no organized quality improvement activity. The organization does not recognize the relationship between quality management and business performance.

69. C — Increasing the desired detectable shift from 1.5 to 2.0 standard deviations allows a smaller sample size because larger effects are easier to detect. Power analysis shows an inverse relationship between effect size and required sample size — the bigger the difference you need to detect, the fewer observations you need to detect it. Conversely, detecting smaller shifts requires larger samples.

70. D — Plotting monthly measurements of a reference standard on a control chart over time assesses stability — the consistency of the measurement system's performance over an extended period. A stable system produces consistent results today, next week, and next month. Instability would appear as trends, shifts, or increasing variation on the chart.

71. A — Pearson's r measures only linear association. When the true relationship is quadratic (curved), the linear component of the relationship may be weak even though the overall relationship is strong and clearly visible. A low or moderate rvalue in the presence of a clear curved pattern is a classic indicator that the relationship is nonlinear and requires a different analytical approach.

72. B — The Control phase delivers mechanisms for sustaining the improvements achieved during the Improve phase. Key deliverables include updated control plans, revised standard operating procedures,

training for process operators, monitoring dashboards, and response plans for outofcontrol conditions. Without the Control phase, improvements erode over time as the process reverts to its previous state.

73. A — $\hat{\sigma} = \bar{R}/d_2 = 5.2/2.059 = 2.53$. The $d_2$ constant for subgroup size n = 4 is 2.059. Dividing the average range by $d_2$ converts the rangebased dispersion measure into an estimate of the process standard deviation. This estimate reflects withinsubgroup (shortterm) variation and is used for calculating capability indices Cp and Cpk.

74. D — Clause 6.1 of ISO 9001:2015 requires the organization not only to determine risks and opportunities and plan actions to address them but also to evaluate the effectiveness of those actions. Identifying risks without following up to verify that the actions taken actually reduced the risk fails to complete the risk management cycle required by the standard.

75. B — During the Sort phase of 5S, items not used within a defined period are tagged with red tags and moved to a designated holding area with a specific disposition deadline (typically 3090 days). If the items are not claimed during the holding period, they are permanently removed. This systematic approach prevents premature disposal while ensuring unnecessary items do not remain in the workspace indefinitely.

76. C — In a series system, improving the weakest component yields the greatest improvement in overall system reliability. The system reliability ($0.99 \times 0.98 \times 0.97 = 0.9412$) is most limited by the 0.97 component. Improving it to 0.99 would yield $R = 0.99 \times 0.98 \times 0.99 = 0.9604$ — a gain of 0.019. The same improvement applied to the 0.99 component would yield only 0.001 gain.

77. A — When the overall model is significant but an individual predictor's ttest is not significant ($p = 0.45$), that predictor is not contributing meaningful additional explanatory power beyond what the other predictors already provide. The predictor may be redundant (correlated with other predictors), irrelevant, or its effect may be too small to detect at the given sample size. It is a candidate for removal from the model.

78. D — ISO 14971 requires risk management to be performed throughout the entire product lifecycle — from initial concept through design, manufacturing, postmarket surveillance, and eventual decommissioning. Postmarket data (complaint reports, adverse event reports, field failure data) must be continuously monitored and fed back into the risk management process to update risk assessments and trigger additional controls.

79. B — The Ftest compares the ratio of two sample variances: $F = s_2^2/s_1^2 = 0.051/0.024 = 2.125$, with the larger variance in the numerator. This ratio is compared to the Fdistribution with $df_1 = 19$ (numerator) and $df_2 = 19$ (denominator). The Ftest directly answers whether the variance has significantly increased after the process change.

80. C — The Malcolm Baldrige National Quality Award criteria provide the most comprehensive selfassessment framework, evaluating organizational performance across seven categories: Leadership, Strategy, Customers, Measurement/Analysis/Knowledge Management, Workforce, Operations, and Results. With 1,000 total points, it provides a holistic benchmark for performance excellence that goes well beyond quality system conformance.

81. A — Using Sturges' rule: $k \approx 1 + 3.322 \times \log_{10}(200) = 1 + 3.322 \times 2.301 = 1 + 7.65 \approx 8.65$, which rounds to approximately 9 bins. This rule provides a practical starting point for determining the number of class intervals in a histogram, though the final number may be adjusted based on the specific characteristics of the data.

82. D — Records occupy the base of the documentation hierarchy and provide objective evidence that activities were performed as planned and that results met requirements. Examples include inspection reports, test results, calibration certificates, audit reports, and training records. Records prove what actually happened, while policies, procedures, and work instructions prescribe what should happen.

83. A — An attributes agreement analysis evaluates the consistency of inspector classifications by having multiple inspectors classify the same set of parts multiple times and measuring their agreement with each other and with a known reference standard. This method is specifically designed for pass/fail inspection systems where continuous measurement data is not available.

84. D — Single Minute Exchange of Die (SMED) is the lean technique specifically focused on reducing changeover time by separating internal setup activities (machine must be stopped) from external setup activities (can be performed while the machine is running) and converting as many internal activities to external as possible. The goal is changeover in singledigit minutes.

85. A — When a product fails due to a degradation mechanism that was not considered during design, the failure traces back to inadequate design inputs — the customer's operating environment and its effect on material performance were not identified, characterized, and incorporated into the design requirements. This is a design input failure because the requirement to resist this specific degradation mechanism was never established.

86. D — Increasing α from 0.01 to 0.05 increases the probability of rejecting the null hypothesis (making it easier to declare significance), which increases the power of the test. Higher power means the same effect can be detected with fewer observations. Therefore, the required sample size decreases — the engineer can detect the same effect with fewer samples.

87. B — A management review that produces no decisions or actions for improvement over two years is failing to generate meaningful outputs. ISO 9001:2015 Clause 9.3.3 requires that management review outputs include decisions and actions related to improvement opportunities, resource needs, and any changes to the QMS. A review without outputs is a procedural exercise without substance.

88. C — Temperature in degrees Celsius is measured on an interval scale because the intervals between degrees are equal and meaningful (the difference between 20°C and 30°C is the same as between 30°C and 40°C), but 0°C does not represent the absence of temperature — it is an arbitrary reference point (the freezing point of water). Without a true zero, ratio statements (40°C is "twice as hot" as 20°C) are meaningless.

89. A — A $2^{5-1}$ design runs 2^(51) = $2^4$ = 16 treatments out of the full $2^5$ = 32 treatments. The fraction is 16/32 = 1/2 — a halffraction. The superscript "1" in the design designation indicates that one generator was used to halve the full factorial, and the resulting design runs exactly half of the complete set of treatment combinations.

90. D — Investigating the factors that differ between shifts — supervision quality, lighting conditions, training levels, fatigue effects, environmental conditions, equipment maintenance state — is the appropriate root cause investigation approach. Since equipment, materials, and procedures are the same, the cause must lie in the conditions that change between shifts, not in the elements that remain constant.

91. B — The multivari chart is specifically designed to display and compare multiple sources of variation simultaneously on a single graph — typically parttopart variation, withinpart (positional) variation, and temporal (lottolot or shifttoshift) variation. This visual tool enables the quality engineer to quickly identify which source of variation dominates, directing improvement efforts to the most impactful source.

92. B — Inspection level I provides reduced discrimination (smaller sample sizes) compared to the default level II. It is appropriate when the cost of inspection is high relative to the product value or when the consequences of accepting a marginally nonconforming lot are low. Level I trades inspection economy against discriminating power — accepting higher sampling risk in exchange for lower inspection cost.

93. A — When 90% of corrective actions cite "operator error" with "retraining" as the fix, the root cause analyses are almost certainly superficial — stopping at the first obvious answer rather than digging deeper to identify the systemic reasons why operators make errors. The true root causes likely include unclear procedures, inadequate errorproofing, poor process design, or insufficient training systems.

94. A — The operating characteristic (OC) curve is the tool that shows the probability of accepting a lot at each quality level for a given sampling plan. By reading the OC curve at 8% nonconforming, the engineer can determine whether the plan provides adequate consumer protection at that quality level — whether the probability of accepting an 8% nonconforming lot is acceptably low.

95. B — Available production time = 8 hours minus 30 minutes planned breaks = 450 minutes. Takt time = available time / customer demand = 450 / 480 = 0.9375 ≈ 0.94 minutes per unit. Takt time sets the rhythm of production, ensuring output matches customer demand without overproduction or underproduction.

96. A — The Action Priority method from the AIAG/VDA FMEA Handbook weights severity most heavily in priority determination. A failure mode with Severity 9 (nearcatastrophic) receives high priority regardless of its Detection rating, because the consequences of that failure occurring are severe. The lowerseverity failure mode (S=3) receives lower priority even with worse detection, because its consequences are far less serious.

97. D — Documented procedures establish the approved method for performing work. Deviating from a documented procedure requires a formal deviation, change request, or amendment process — not verbal authorization. The procedure exists to ensure consistency and traceability, and bypassing it verbally undermines the document control system and creates uncontrolled, undocumented process variation.

98. D — With only 34 units per day, forming rational subgroups is impractical because insufficient units are produced within a short enough timeframe to constitute a meaningful subgroup. The Individuals and Moving Range (IMR) chart is designed for exactly this situation — it plots each individual measurement and uses the moving range between consecutive measurements to estimate process variability.

99. A — A master list of controlled documents serves as the authoritative reference for identifying all controlled documents, their current revision levels, and their distribution status. Any person can consult the master list to verify whether a specific document version is current or obsolete, providing a critical safeguard against the use of superseded documents.

100. C — When the calculated chisquare statistic (4.2) is less than the critical value (11.07) at $\alpha = 0.05$, we fail to reject the null hypothesis. The data is consistent with a normal distribution — the observed frequencies do not deviate significantly from the expected normal frequencies. This means the normality assumption is reasonable and normalbased statistical methods can be applied.

101. C — A Weibull shape parameter $\beta = 1.0$ means the Weibull distribution reduces exactly to the exponential distribution, which models a constant failure rate. A constant failure rate corresponds to the useful life (flat) portion of the bathtub curve, where failures are random and not caused by infant mortality defects or wear-out degradation mechanisms.

102. D — Process capability indices are meaningful only when the process is in a demonstrated state of statistical control. Out-of-control signals indicate special causes are present, making the process behavior unpredictable and the data non-representative of a stable distribution. The special causes must be identified and eliminated first, establishing control before capability can be assessed.

103. A — Breakthrough objectives in Hoshin Kanri represent significant strategic changes that require the organization to develop new capabilities, processes, or approaches to achieve results substantially beyond current performance levels. Routine objectives maintain existing performance through standard operations. This distinction drives the allocation of leadership attention and resources toward transformational change.

104. B — Before accepting a supplier's capability data, the quality engineer must verify that the study was conducted with the process in statistical control. Capability indices calculated from an unstable process are unreliable because special cause variation inflates or distorts the data, and the indices will not accurately predict future process performance even if the numbers look acceptable.

105. D — When prevention costs are only 5% of total quality costs while external failures represent 60%, the organization is dramatically underinvesting in prevention. The classical COQ model demonstrates that increasing prevention investment produces a disproportionately larger reduction in failure costs because prevention eliminates defects at their source rather than detecting or correcting them downstream.

106. C — A significant ANOVA result ($p = 0.003 < 0.05$) indicates that at least one furnace mean is significantly different from the others, but ANOVA does not identify which specific furnaces differ. A multiple comparison procedure — such as Tukey's HSD, Fisher's LSD, or Bonferroni-corrected pairwise tests — must be performed to determine the specific pairwise differences.

107. A — ISO 9001:2015 Clause 9.3.3 requires that management review outputs include decisions and actions related to improvement opportunities, any need for changes to the QMS, and resource needs. Meeting minutes without documented decisions or assigned actions indicate that the review is being conducted as a formality without producing the required actionable outputs.

108. B — When the base of opportunity (number of customers served) varies significantly from week to week, the raw complaint count must be normalized to a rate per customer. The u-chart monitors defects per unit with variable unit sizes, making it appropriate for this situation. A c-chart would only be valid if the customer base were constant each week.

109. D — At MMC, the hole is at its smallest allowable diameter (10.0 mm), and the stated position tolerance is 0.25 mm. The actual hole is produced at 10.3 mm — a departure of 0.3 mm from MMC. Bonus tolerance equals the departure from MMC: 10.3 - 10.0 = 0.3 mm. Total positional tolerance = stated tolerance + bonus = 0.25 + 0.30 = 0.55 mm.

110. C — The most critical requirement for ensuring corrective actions address root causes is mandating a structured root cause analysis method (5 Whys, fishbone, Is/Is Not) and requiring verified effectiveness before closure. Without structured analysis, corrective actions default to symptom treatment. Without effectiveness verification, there is no confirmation that the root cause was actually eliminated.

111. A — SPC monitors the process in real time to detect shifts and trends before nonconforming output is produced, enabling proactive intervention. 100% inspection only detects defects after they are created, adding cost without preventing defects. SPC is both more effective (prevents defects rather than sorting them) and more economical (monitoring a few samples versus inspecting every unit).

112. B — FMEA is fundamentally a cross-functional team exercise. A single engineer — regardless of expertise — cannot possess the full range of knowledge needed to identify all potential failure modes across design, manufacturing, assembly, service, and customer use. Manufacturing engineers identify process-related failures, service engineers identify field failure patterns, and quality engineers identify detection gaps that a design engineer alone would miss.

113. D — When a significant interaction exists between Factor A and Factor B, the main effect of Factor B cannot be interpreted in isolation. The non-significant main effect of B is misleading because B's effect depends on the level of A — at one level of A, Factor B may have a large effect; at another level, the effect may be negligible. The interaction overrides the main effect interpretation.

114. C — The switching rules in ANSI/ASQ Z1.4 — transitioning between normal, tightened, and reduced inspection based on quality history — are specifically designed to minimize the average amount of inspection over the long run. Good quality earns reduced inspection (less sampling), poor quality triggers tightened inspection (more scrutiny), and sustained poor quality leads to discontinuation requiring corrective action.

115. A — Evaluating a frequency change request requires a risk-based approach that considers the demonstrated process stability, the consequence of an undetected shift given the longer interval between samples, the production volume between checks, and the criticality of the characteristic. Neither automatic approval nor blanket rejection is appropriate — the decision must be based on the specific risk profile.

116. A — When sample size cannot be increased due to cost constraints, the only remaining way to narrow the confidence interval is to reduce the confidence level. Switching from 99% to 90% reduces the critical Z-value from 2.576 to 1.645, producing a substantially narrower interval. The trade-off is accepting less certainty that the interval contains the true parameter.

117. D — Special processes like welding require ongoing revalidation because the factors that affect process performance change over time — equipment ages and wears, raw materials vary lot-to-lot, personnel change and skills vary, and environmental conditions fluctuate. Initial qualification demonstrates capability at one point in time but does not guarantee continued capability months or years later.

118. A — The ASQ Code of Ethics establishes that the quality engineer's primary obligation is to the public — specifically public health, safety, and welfare. This obligation supersedes the interests of the employer, the client, and the engineer personally. Delaying the reporting of a known safety risk to protect quarterly financial results directly violates this foundational ethical principle.

119. C — Multicollinearity causes the individual regression coefficients to become unstable and unreliable because the model cannot accurately separate the individual contributions of highly correlated predictors. Small changes in the data can produce large swings in the coefficient estimates. However, the overall model may still predict well because the combined effect of the correlated predictors remains stable.

120. B — A quality information system's effectiveness depends on providing timely (available when decisions are being made), accurate (reflecting true process and product conditions), and accessible (reaching the people who need it in formats they can use) information. The most sophisticated system is worthless if it delivers information too late, inaccurately, or to the wrong people.

121. D — The engineer wants to determine whether the new process produces lower roughness — a specific directional hypothesis. The correct setup is $H_0$: $\mu \geq 1.6$ vs. $H_1$: $\mu < 1.6$ (one-sided lower). Since $\sigma$ is unknown and estimated by s with n = 20, the t-distribution with 19 degrees of freedom is appropriate. A two-sided test would waste power testing for an increase that is not of interest.

122. A — Returning rejected material without communicating the reason for rejection deprives the supplier of the information needed to investigate and correct the quality issue. Without feedback, the supplier cannot identify root causes, implement corrective actions, or prevent recurrence. This lack of feedback perpetuates the quality problem and represents a failure in supplier communication and development.

123. C — Overall Equipment Effectiveness (OEE) is calculated as the product of three factors: Availability (actual running time divided by planned production time), Performance Efficiency (actual output rate divided by theoretical maximum rate), and Quality Rate (good units produced divided by total units produced). OEE = Availability × Performance × Quality, expressed as a percentage.

124. B — I-MR charts do not benefit from the central limit theorem because they plot individual measurements rather than subgroup averages. If the underlying data is significantly non-normal (skewed, heavy-tailed, or multimodal), the normal-based 3-sigma control limits will not accurately represent the expected range of variation, producing excessive false alarms on one side and missed signals on the other.

125. D — Total weighted score = (8 × 5) + (6 × 3) + (9 × 4) = 40 + 18 + 36 = 94. Each criterion score is multiplied by its weight, and the products are summed. The prioritization matrix enables transparent, defensible comparison by converting subjective ratings into quantified priority scores that can be ranked across all candidate projects.

126. A — ISO 9001:2015 Clause 7.1.5.2 requires that measurement equipment be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. When no such standards exist, the basis used for calibration must be retained as documented information. This traceability requirement ensures measurement reliability.

127. C — When the Pareto principle's 80/20 pattern does not emerge — when the top few categories do not dominate — it may indicate that the categorization scheme needs refinement. Broad categories may be masking sub-categories that would show concentration, or the problem may genuinely be distributed across many causes. Further stratification or reclassification should be explored before concluding that no vital few exist.

128. B — A $2^{4-1}$ design with I = ABCD is Resolution IV, where two-factor interactions are aliased with each other (AB=CD, AC=BD, AD=BC). To estimate all two-factor interactions independently, the complementary half-fraction must be added, creating the complete $2^4$ full factorial with 16 runs. This fold-over eliminates the two-factor interaction aliasing.

129. A — A critical production line with no backup power supply represents an operational risk — a vulnerability in the organization's infrastructure that could disrupt production operations with quantifiable financial consequences. The risk is characterized by a specific trigger (power outage), a known consequence (48-hour production halt), and calculable financial impact (lost production and delivery penalties).

130. D — Randomly scattered residuals with no pattern confirm that the linear model captures the systematic relationship in the data, and the normal probability plot confirms that the error terms are approximately normally distributed. Together, these diagnostics indicate that the key regression assumptions — linearity, constant variance, normality, and independence of errors — are reasonably satisfied.

131. C — Points within control limits do not guarantee a process is in control. The Western Electric supplementary rules detect patterns such as runs (8+ consecutive points on one side), trends (6+ points steadily increasing or decreasing), stratification (points clustered near the center line), and zone violations that signal special causes even when no individual point crosses a control limit.

132. B — Tolerance stack-up analysis evaluates whether the combination of individual component tolerances produces an acceptable assembly condition under worst-case (all dimensions at their extreme allowable values simultaneously) and statistical (dimensions at their probable combined values) scenarios. This analysis determines whether the shaft-bore clearance requirement is met across the full tolerance range.

133. A — Operators walking 200 feet to a central supply room represents motion waste (unnecessary human movement), and production halting while operators retrieve materials represents waiting waste (idle time with no value being added). Both wastes could be eliminated by relocating materials to the point of use, which is a fundamental 5S (Set in Order) and workplace organization improvement.

134. D — $UCL = \bar{u} + 3\sqrt{(\bar{u}/n)} = 2.5 + 3\sqrt{(2.5/4)} = 2.5 + 3\sqrt{(0.625)} = 2.5 + 3(0.791) = 2.5 + 2.372 = 4.87$. The u-chart control limits depend on the inspection unit size for each subgroup. For larger panels (more area), the standard error decreases because more opportunity area provides a more stable estimate of the defect rate.

135. C — Uncontrolled printed copies are one of the most common and persistent document control vulnerabilities. Once a document is printed, it is disconnected from the electronic version control system — subsequent revisions to the electronic version do not automatically update the printed copy. Personnel working from stale printed copies may follow obsolete procedures without knowing a newer version exists.

136. A — The significance level $\alpha$ must be established before the data is analyzed — changing it after seeing the results constitutes data-dependent decision-making, which invalidates the inferential framework. At the pre-established $\alpha = 0.05$, a p-value of 0.048 meets the criterion for statistical significance. The result may warrant cautious interpretation given its proximity to the threshold, but the decision rule was met.

137. B — Although both risks have the same numerical score of 12, Risk B (severity 6) poses a greater potential for serious harm than Risk A (severity 3). Risk management principles consistently prioritize higher-severity risks because the consequences of severe events are disproportionate to their numerical ratings and may be irreversible. Equal risk scores do not necessarily warrant equal treatment when severity levels differ substantially.

138. D — When all X-bar chart points cluster in Zone C with none in Zones A or B, the pattern indicates stratification. This typically occurs when subgroups combine data from multiple process streams (different machines, different cavities, different operators) with different means. The inflated within-subgroup variation produces artificially wide control limits, compressing all points toward the center line.

139. C — A process sigma level of 4.0 corresponds to approximately 6,210 DPMO. The sigma level represents the number of standard deviations between the process mean and the nearest specification limit. At 4 sigma, the area beyond the specification (accounting for the conventional $1.5\sigma$ shift) yields approximately 6,210 defects per million opportunities.

140. A — Monthly defect cost savings = \$85 × 12 occurrences = \$1,020 per month. Payback period = \$15,000 / \$1,020 = 14.7 ≈ 15 months. While 15 months is a relatively long payback period, the calculation considers only direct defect costs — additional benefits such as reduced inspection time, improved customer satisfaction, and avoided warranty costs would shorten the effective payback.

141. B — In an interrelationship digraph, a factor with many outgoing arrows (7) and few incoming arrows (1) is a fundamental driver or root cause — it influences many other factors but is itself influenced by very few. Conversely, Factor Y with many incoming arrows (6) and few outgoing arrows (2) is primarily an outcome or effect — it is driven by other factors rather than driving them.

142. D — As incoming quality worsens from the AQL toward the LTPD, the AOQ initially increases (more nonconforming units pass through in accepted lots) but then decreases (because more lots are rejected and 100% inspected, removing all their nonconforming units). This creates a peak called the AOQL — the worst average outgoing quality that the sampling plan will allow regardless of incoming quality.

143. C — Linearity measures the consistency of bias across the measurement range. When an instrument reads accurately at the low end but consistently high at the upper end, the bias changes across the range — the instrument is non-linear. Poor linearity means the instrument cannot be trusted equally at all points in its range, and a single bias correction would be insufficient.

144. A — The most likely explanation is that the growing customer base or improved complaint accessibility has increased the absolute number of complaints even while the proportion of satisfied customers has increased. A company with 1,000 customers and 88% satisfaction has 120 potentially dissatisfied customers, while the same company at 72% satisfaction with only 700 customers had 196 — more complaints from a larger, generally happier population is mathematically consistent.

145. B — When a significant interaction exists between Factor A and the AB interaction, the effect of setting Factor A to its high level depends on the level of Factor B. At one level of B, the +8.2 main effect may be fully realized or amplified. At another level of B, the interaction may reduce, negate, or even reverse the main effect. Joint optimization of both factors is required.

146. D — A certificate of conformance stating only that "material meets specifications" without any supporting test data provides no objective evidence that testing was actually performed. The supplier may be certifying compliance based on historical data, assumptions, or no testing at all. Quality systems require objective evidence — actual test results that demonstrate conformance to each specified requirement.

147. A — For attributes control charts based on the normal approximation to the binomial distribution, the sample must be large enough that np (expected number of nonconforming units per sample) is at least 5. With a defect rate of 8%, the minimum sample size is $5/0.08 = 62.5 \approx 63$ units. Samples smaller than this threshold may produce invalid control limits.

148. B — Fear in the workplace prevents employees from reporting quality problems (hiding defects to avoid blame), suggesting process improvements (risk of being criticized or overruled), questioning management decisions (appearing disloyal), and admitting mistakes (which prevents learning and corrective action). Driving out fear creates the psychological safety necessary for open communication, honest reporting, and continuous improvement.

149. B — The estimated process standard deviation from an S chart is $\hat{\sigma} = \bar{S}/c_4 = 3.8/0.9776 = 3.886 \approx 3.89$. The $c_4$ constant adjusts the average subgroup standard deviation to provide an unbiased estimate of the population standard deviation. For n = 12, $c_4 = 0.9776$, which is close to 1.0 because the bias in the sample standard deviation decreases as subgroup size increases.

150. D — When the process natural tolerance (±0.30 mm = 0.60 mm total spread) exceeds the engineering specification (±0.20 mm = 0.40 mm total spread), the process is not capable. Cp = 0.40/0.60 = 0.67 — well below the minimum acceptable level of 1.0. The process will produce nonconforming output even when perfectly centered, and process improvement to reduce variation is required.

151. A — Two points deviating sharply from the normal probability plot line at the upper extreme suggest outliers — data points that do not belong to the same population as the rest of the data. These could be measurement errors, data recording mistakes, specimens from a different material batch, or parts processed under abnormal conditions. They should be investigated before proceeding with analysis.

152. C — ISO 9001:2015 Clause 7.3 defines the awareness requirement: persons performing work must be aware of the quality policy, relevant objectives, their contribution to QMS effectiveness, and the implications of nonconformance. Awareness is distinct from competence (ability to perform) — a person can be competent at their task but unaware of why it matters to the quality system.

153. B — Confirmation runs at the identified optimal settings are a critical validation step that verifies the experimental predictions translate to actual process performance. Confirmation runs protect against overfitting (the experimental results may partially reflect noise), measurement errors, or interactions with factors not included in the experiment. Implementation without confirmation risks adopting settings that do not actually produce the predicted improvement.

154. A — After a 1.5σ shift upward, the distance from the shifted mean to the upper specification limit decreases. The proportion exceeding the USL depends on the Z-score for this reduced distance. The 1.5σ shift concept is fundamental to Six Sigma methodology, where the conventional assumption of a 1.5σ process shift converts a 6-sigma process capability into the well-known 3.4 DPMO figure. The shifted proportion exceeding USL increases significantly compared to the centered process.

155. D — When operators receive classroom training and demonstrate learning (Level 2) but do not apply the learned skills on the production floor, the failure is at Kirkpatrick's Level 3 — Behavior. The knowledge was acquired during training but did not transfer to actual work practices. This transfer gap may be caused by lack of reinforcement, inadequate on-the-job support, conflicting instructions from supervisors, or insufficient practice opportunities.

156. C — Risk evaluation is the step where analyzed risk levels are compared against the risk acceptance criteria established during context setting. This comparison determines which risks are acceptable (no treatment needed), tolerable (treatment recommended), or unacceptable (treatment mandatory). Risk evaluation produces the prioritized list of risks that require treatment action.

157. B — The fundamental ANOVA identity is SST = SSB + SSW. Therefore SSW = SST - SSB = 850 - 320 = 530. The within-groups sum of squares represents the variation among individual observations within each catalyst group — the random variation that occurs under identical treatment conditions. This quantity, when divided by its degrees of freedom, provides the mean square error used as the denominator of the F-statistic.

158. A — An on-site supplier audit provides the most direct and reliable assessment because the auditor personally examines the supplier's facilities, observes operations in progress, reviews records, interviews personnel, and evaluates the actual implementation of the quality system — not just what is written in documents or claimed in questionnaires. Certificates and self-assessments provide secondary evidence but cannot substitute for firsthand verification.

159. B — A proportion cannot be negative — the minimum possible fraction nonconforming is zero. When the LCL formula produces a negative value, the lower control limit is set to zero. This commonly occurs when the average proportion nonconforming is low and sample sizes are moderate, producing wide control limits that extend below the physical boundary of the proportion scale.

160. D — A reaction plan that states only "notify quality" fails to provide the specific, immediate operator actions needed when an out-of-control or out-of-specification condition is detected. An effective reaction plan specifies concrete steps: stop the process, segregate suspect material since the last known good check, document the nonconformance, and notify designated personnel — in that order of priority.

161. B — Because the 95% confidence interval for the slope (0.18, 4.50) does not include zero, the slope is statistically significantly different from zero at the 0.05 significance level. If zero were a plausible value for the slope, the interval would include it. Since it does not, there is sufficient evidence that a real linear relationship exists between the predictor and response variables.

162. A — Risk-based audit planning directs the most audit time, resources, and attention to processes with the highest risk to product quality, customer satisfaction, and regulatory compliance. High-risk processes deserve more frequent and more thorough auditing because the consequences of undetected problems are most severe. Low-risk, stable processes may be audited less frequently.

163. C — The chi-square goodness-of-fit test relies on a mathematical approximation that becomes unreliable when expected cell frequencies fall below 5. With an expected frequency of 3.2, the chi-square approximation may not accurately represent the true sampling distribution, potentially producing invalid p-values. The standard remedy is to combine adjacent categories to increase expected frequencies or to use Fisher's exact test for small tables.

164. D — Standard work in lean manufacturing is defined by three key elements: takt time (the rate at which products must be produced to meet demand), work sequence (the specific order of tasks the operator performs within each takt time cycle), and standard work-in-process inventory (the minimum amount of in-process inventory needed to maintain a smooth and continuous workflow).

165. B — The Pareto chart identifies what fails (seal leakage) but not why it fails. Before implementing corrective action, root cause analysis must determine the underlying cause — improper seal material selection, inadequate compression, contamination during assembly, thermal degradation, or design interference. Without root cause analysis, the corrective action may address the wrong mechanism and fail to reduce the failure rate.

166. A — When Cp (1.89) substantially exceeds Cpk (1.22), the process has excellent inherent capability but is running off-center. The gap between the two indices represents capability lost to poor centering. Simply recentering the process mean toward the midpoint of the specification limits — without changing process variability — would bring Cpk closer to the Cp value, recovering the lost capability with minimal investment.

167. C — Running Factor A's levels in a systematic time sequence confounds the factor effect with any time-dependent change — temperature drift, material property changes within a batch, operator learning, equipment warm-up, or any other lurking variable that changes over time. The observed difference attributed to Factor A may actually be caused by the time-dependent variable, making the experimental conclusion unreliable.

168. D — Internal failure costs at 35% of total quality costs represent the largest single category and indicate substantial waste from scrap, rework, reinspection, and downgrading. This waste represents the greatest opportunity for cost reduction through targeted prevention investments. The relatively lower external failure costs (15%) suggest the appraisal system catches most defects internally, but the high internal failure rate means defects are still being created at unacceptable levels.

169. B — The most appropriate approach for establishing calibration intervals is to begin with the manufacturer's recommended interval and then adjust based on actual calibration history. If the instrument is consistently found within tolerance at each calibration, the interval can be extended. If it is frequently

found out of tolerance, the interval should be shortened. This data-driven approach optimizes the balance between measurement reliability and calibration cost.

170. A — Effectiveness measures the extent to which planned activities are realized and planned results are achieved — it answers "are we doing the right things?" Efficiency measures the relationship between results achieved and the resources used to achieve them — it answers "are we doing things right?" A quality system can be effective (achieving quality objectives) but inefficient (using excessive resources to do so), or vice versa.

171. C — %GRR = (Gage R&R variation / Tolerance) × 100 = (1.4 / 20) × 100 = 7.0%. Per AIAG MSA guidelines, a %GRR below 10% indicates the measurement system is fully acceptable. The 7% result means the measurement system consumes only a small fraction of the available tolerance, leaving adequate room for the system to reliably discriminate between conforming and nonconforming parts.

172. D — An FMEA with recommended actions but no assigned responsible individuals and no target completion dates will almost certainly result in no action being taken. Without accountability (who), timeline (when), and follow-up mechanisms, recommended actions remain intentions rather than commitments. The FMEA's risk reduction value is realized only when recommended actions are actually implemented and verified.

173. B — When process data follows a lognormal distribution, the standard Cp/Cpk formulas (which assume normality) will produce inaccurate results. The correct approach is to apply a natural logarithm transformation to the data, verify that the transformed data approximates a normal distribution, and then calculate capability indices on the transformed scale using the transformed specification limits.

174. B — During the transition from reactive to proactive quality management, total costs typically follow a U-shaped trajectory. Initially, total costs may increase as prevention investments are added on top of still-high failure costs. As prevention activities take effect, failure costs begin declining — and because each dollar of prevention typically eliminates several dollars of failure cost, the net result is a substantial long-term reduction in total quality costs.

175. C — For a surveillance audit, the auditor needs evidence that the QMS has been actively maintained and improved between audits. The most critical evidence includes management review records (showing ongoing system evaluation), internal audit results (demonstrating self-assessment), corrective action records (showing problem resolution), process performance data (demonstrating monitoring), and evidence of continual improvement activities — collectively proving the system is living and active.