PRACTICE EXAM 4: ASQ CQE SIMULATION (175 QUESTIONS)

1. A manufacturing plant operates three identical CNC lathes producing the same part. A quality engineer collects 50 measurements from each lathe and performs a oneway ANOVA. The Fstatistic is 1.24 with a critical Fvalue of 3.07 at $\alpha = 0.05$. A colleague suggests running individual twosample ttests between each pair of lathes instead. Why is the ANOVA approach preferred?

A. ANOVA requires fewer total measurements than multiple pairwise ttests

B. ANOVA is easier to calculate by hand than ttests for most practitioners

C. ANOVA controls the overall Type I error rate across all comparisons simultaneously, whereas multiple ttests inflate the experimentwise error rate

D. ANOVA is the only test capable of comparing means from normally distributed populations

2. A quality engineer is reviewing a process capability report and notices that the Cpk was calculated using 15 data points collected during a single 30minute production run. The reported Cpk is 2.10. Before accepting this result, what is the engineer's primary concern?

A. The short collection period likely underestimates the true process variation by missing betweenlot, betweenshift, and environmental variation sources that affect longterm performance

B. A Cpk of 2.10 is too high to be credible and indicates a calculation error

C. Fifteen data points always produce inflated capability indices regardless of collection method

D. The process must have been out of control during the data collection period

3. A reliability engineer analyzes failure data for a fleet of industrial pumps and fits a Weibull distribution, obtaining $\beta = 2.8$ and $\eta = 15{,}000$ hours. The maintenance department wants to establish a

preventive replacement interval that ensures at least 95% survival probability. Using R(t) = e^((t/η)^β), approximately what replacement interval achieves $R(t) \geq 0.95$?

A. 15,000 hours, which is the characteristic life where 63.2% of pumps have failed

B. 7,500 hours, which is exactly half the characteristic life for any Weibull distribution

C. At the characteristic life η, reliability is always 0.95 for wearout distributions

D. Approximately 5,700 hours, calculated by solving e^((t/15000)^2.8) = 0.95 for t

4. A pharmaceutical company's quality system requires that deviations from validated processes be documented, investigated, and approved before production continues. An operator discovers that a mixing speed was set 50 RPM below the validated range for the past 2 hours but the product appears normal based on visual inspection. What is the correct quality system response?

A. Continue production since the product appears normal and document the deviation at shift end

B. Stop production, segregate all product manufactured during the deviation period, document the deviation, and conduct an impact assessment before dispositioning the affected product

C. Adjust the mixing speed to the correct setting and resume production without documentation

D. Discard only the product manufactured in the last 30 minutes since the deviation was minor

5. A quality engineer is designing an experiment to optimize a plating process with 6 factors at 2 levels each. Budget constraints limit the experiment to 16 runs. The engineer selects a 2^{6-2} fractional factorial. With appropriate defining relations, this design achieves Resolution IV. What does Resolution IV specifically mean for this experiment?

A. All main effects and all twofactor interactions can be estimated independently without any confounding

B. Main effects are confounded with twofactor interactions and cannot be separated from each other

C. The experiment cannot estimate any effects because the fraction is too small for six factors

D. Main effects are free from twofactor interaction aliases, but some twofactor interactions are confounded with other twofactor interactions

6. A quality engineer is implementing SPC on a injection molding process and discovers that the cavity pressure sensor data exhibits significant positive autocorrelation — each reading is heavily influenced by the previous reading. Standard Xbar and R charts are being used. What is the primary consequence of applying standard SPC to autocorrelated data?

A. The control charts will produce excessive false alarms because the chart interprets correlated sequential patterns as special cause signals

B. The control limits will be too wide, making the chart insensitive to real process changes

C. Autocorrelation has no effect on control chart performance for continuous process data

D. The R chart will be affected but the Xbar chart will function correctly despite autocorrelation

7. A quality engineer is conducting a supplier audit and discovers that the supplier's corrective action procedure requires root cause analysis but does not require verification of corrective action effectiveness. The procedure states that corrective actions are considered closed upon implementation. Which specific deficiency should the auditor cite?

A. The procedure lacks a requirement for management approval of each corrective action before implementation

B. The procedure should require corrective actions to be completed within 24 hours of detection

C. Without effectiveness verification, there is no confirmation that the corrective action actually eliminated the root cause and prevented recurrence

D. The procedure should require external thirdparty verification of all corrective actions

8. A quality engineer needs to evaluate whether a surface treatment reduces corrosion rate. Twelve steel panels are cut in half — one half receives the treatment and the other half serves as the control. After exposure testing, the corrosion depth is measured on each half. Which statistical test is most appropriate?

A. Twosample ttest because the treatment and control groups are physically separate specimens

B. Paired ttest because each treated half is naturally paired with its untreated half from the same panel

C. Oneway ANOVA because there are more than two groups being compared

D. Chisquare test because corrosion is measured as a categorical outcome

9. In the context of the Baldrige Excellence Framework, an organization scores 310 out of 450 possible points in the Results category. This score reflects performance in which areas?

A. Product and process outcomes, customer results, workforce results, leadership and governance results, and financial and market results

B. Only product quality metrics such as defect rates, scrap percentages, and warranty claim frequencies

C. Strategic planning outcomes and the alignment of quality objectives with business strategy

D. The maturity of the quality management system documentation and its compliance with ISO 9001

10. A quality engineer discovers that a control chart has been plotted with specification limits instead of statistically calculated control limits. The process mean is centered at 25.0 mm, the specification is 25.0 ± 0.5 mm, and the process standard deviation is 0.08 mm. Why does using specification limits on the control chart fundamentally misrepresent the process?

A. Specification limits are always wider than control limits and provide equivalent monitoring capability

B. Specification limits and control limits serve different purposes — the specification limits on this chart are ±0.5 mm while the true 3σ Xbar limits would be much tighter, making the chart unable to detect process shifts

C. The specification limits should be used on attributes charts while control limits should be used on variables charts

D. Using specification limits is acceptable practice when the process capability exceeds 1.33

11. A quality engineer is analyzing a dataset of 500 measurements using a histogram and discovers that the distribution has two distinct peaks — one centered at 49.8 and another at 50.3. Before calculating process capability, what should the engineer investigate first?

A. Apply a data transformation to normalize the bimodal distribution before proceeding

B. Determine whether the data is coming from two different sources — such as two machines, two operators, two material lots, or two cavities — that should be analyzed separately

C. Increase the number of histogram bins until the two peaks merge into a single distribution

D. Calculate Cp and Cpk using the overall mean and standard deviation of the combined data

12. In the context of ISO 9001:2015, Clause 7.1.6 requires the organization to determine the knowledge necessary for the operation of its processes. A manufacturing company loses three senior engineers to retirement within six months. This situation represents a risk to which quality system element?

A. Document control procedures and revision management practices

B. Internal audit scheduling and auditor qualification requirements

C. Organizational knowledge — the loss of critical process expertise that may not be documented or transferable

D. Calibration program management and measurement traceability records

13. A quality engineer is conducting a Gage R&R study using the ANOVA method and obtains the following variance components: parttopart = 0.045, repeatability = 0.008, reproducibility = 0.003, and operator × part interaction = 0.002. What is the total Gage R&R variance?

A. 0.013, calculated as repeatability + reproducibility + interaction (0.008 + 0.003 + 0.002)

B. 0.058, calculated as the sum of all four variance components

C. 0.008, using only the repeatability component since it dominates the measurement variation

D. 0.045, using only the parttopart variation as the total measurement system contribution

14. A quality engineer observes that a normally reliable plating process has begun producing parts with inconsistent coating thickness. The control chart for thickness shows increasing variability over the last 10 subgroups — the R chart has two points above the UCL while the Xbar chart remains in control. Which investigation focus is most appropriate?

A. Investigate the process mean because Xbar chart stability confirms the variability change is not real

B. Investigate sources of increased variability first — the R chart signals suggest a fixturing problem, material inconsistency, or equipment degradation

C. Recalculate both charts using only the last 10 subgroups to establish new baseline limits

D. Investigate whether the Xbar chart will eventually go out of control as the variability increase propagates

15. A quality team conducts a process FMEA and identifies 47 failure modes. Twentythree failure modes receive an RPN below 50, sixteen receive RPNs between 50 and 200, and eight receive RPNs above 200. The team has resources to address only 10 failure modes immediately. How should they prioritize?

A. Address all failure modes with RPN above 100 before considering any others

B. Randomly select 10 from the highestRPN group for immediate action

C. Address all 47 failure modes simultaneously by distributing them equally among team members

D. Prioritize by RPN while giving additional weight to highseverity failure modes regardless of their RPN, using the Action Priority method to ensure safetycritical failures receive attention first

16. In a lean production environment, a workstation has a cycle time of 45 seconds and the takt time is 60 seconds. The operator has 15 seconds of idle time per cycle. Which lean principle does this situation violate, and what improvement opportunity exists?

A. The operator should use the idle time for personal breaks and no improvement is needed

B. The 15second gap represents an opportunity to balance the line by redistributing work elements from overloaded stations or adding valueadded tasks to better utilize available cycle time

C. The takt time should be reduced to 45 seconds to match the workstation cycle time

D. The operator should slow down to use the full 60 seconds, preventing overproduction

17. A quality engineer is analyzing warranty return data and discovers that 40% of returns show "no fault found" — the returned product tests within all specifications at the factory. What does a high nofaultfound rate most likely indicate?

A. The warranty return process is working correctly because defective products are being identified

B. Customers are abusing the warranty system by returning products that function properly

C. Factory inspection equipment is more precise than field conditions, and the failures are caused by noise factors such as temperature, humidity, vibration, or user behavior that are not replicated in the factory test environment

D. The testtaking strategies described in the first 10 percent of this guide have been described accurately

18. A quality engineer must determine whether two analytical laboratories produce equivalent test results for tensile strength. Twenty specimens are sent to both laboratories, and each laboratory tests and reports the tensile strength for all twenty specimens. Which statistical approach is correct?

A. Twosample ttest treating the two sets of 20 results as independent groups

B. Paired ttest because the same 20 specimens are tested by both laboratories, creating naturally paired observations

C. Oneproportion Ztest comparing the proportion of results exceeding a threshold value

D. Ftest comparing the variances of the two laboratory result sets

19. In the context of document control, an organization transitions from paperbased to electronic document management. Which new requirement must be addressed that was not a concern with paper documents?

A. Electronic documents require change approval before implementation, unlike paper documents

B. Electronic document management systems require provisions for access security, backup and recovery, electronic signature validation, and system validation to ensure data integrity

C. Paper documents must be destroyed immediately upon conversion to electronic format

D. Electronic documents do not require revision control since the system tracks changes automatically

20. A quality engineer calculates the process performance index Ppk = 0.95 and the process capability index Cpk = 1.40 from the same dataset. The significant difference between these values indicates which condition?

A. The measurement system is contributing excessive variation to the overall standard deviation estimate

B. The process data is severely nonnormal and both indices are invalid for this distribution

C. The process has experienced instability during the study — betweensubgroup variation from special causes has degraded actual performance below the inherent capability level

D. The specification limits are asymmetric, causing the two indices to diverge by design

21. A quality engineer is tasked with reducing the setup time on a stamping press from 90 minutes to under 15 minutes. The SMED methodology requires the engineer to first separate setup activities into two categories. What are these categories?

A. Critical activities that must be performed by the operator and noncritical activities that can be delegated

B. Manual activities requiring hand tools and automated activities performed by the machine controller

C. Qualityrelated activities involving measurement and nonquality activities involving material handling

D. Internal setup performed while the machine is stopped and external setup that can be performed while the machine is still running

22. A quality engineer is constructing an Xbar and R chart for a new process. After collecting 25 subgroups of size 5, the engineer plots all points and finds that subgroup 14 on the R chart falls above the UCL. The root cause is identified as a temporary fixture malfunction that has been corrected. What is the correct procedure for establishing the final control limits?

A. Remove subgroup 14 from the calculations and recalculate the control limits using the remaining 24 subgroups, since the assignable cause has been identified and corrected

B. Keep all 25 subgroups in the calculation because removing data points introduces bias

C. Collect 25 new subgroups and discard all original data entirely

D. Replace subgroup 14's range value with the average range from the other 24 subgroups

23. A quality engineer needs to evaluate whether a batch of incoming steel meets the specification for carbon content of 0.45% ± 0.05%. The supplier's Certificate of Analysis reports a mean carbon content of 0.47% with no standard deviation or individual test values provided. Why is this certificate insufficient for a capability assessment?

A. The reported mean is within specification, which is sufficient evidence of conformance

B. Certificates of Analysis from suppliers are never accepted as valid quality evidence

C. A capability assessment requires the standard deviation and individual measurements, not just the mean — without dispersion data, the engineer cannot determine what proportion of the material falls outside specification

D. The carbon content specification is too tight for steel and should be widened before evaluation

24. A quality engineer is implementing a kanban system and calculates that 6 kanban cards are needed for a particular part based on demand rate, replenishment lead time, and container size. After implementation, the engineer observes that production frequently stops because parts are unavailable. What is the most likely cause?

A. The kanban calculation used an insufficient safety stock factor to account for variation in demand or lead time

B. Six kanban cards always exceeds the maximum number permitted in lean systems

C. Kanban systems cannot be used for parts with variable demand patterns

D. The container size was too large, causing excess inventory to accumulate at the wrong station

25. A quality engineer is reviewing a regression analysis that predicts product yield from three process variables. The $R^2 = 0.91$, adjusted $R^2 = 0.89$, and all three predictor ttests are significant ($p < 0.01$). However, the DurbinWatson statistic is 0.85. What concern does the low DurbinWatson value raise?

A. The regression model has too many predictor variables and should be simplified

B. The sample size is insufficient for reliable regression analysis

C. The R^2 value is artificially inflated by multicollinearity among the predictors

D. The residuals are positively autocorrelated, indicating that the standard regression assumption of independent errors is violated, which may affect the reliability of confidence intervals and pvalues

26. In the context of quality cost analysis, a company spends $200,000 annually on preventive maintenance for production equipment. A quality engineer must classify this cost within the COQ framework. Under which category should preventive maintenance be classified?

A. Prevention costs, because preventive maintenance proactively prevents equipmentrelated quality problems before they occur

B. Internal failure costs, because equipment downtime represents production loss

C. Appraisal costs, because maintenance technicians inspect equipment during service

D. Not a quality cost, because maintenance is an operational expense unrelated to product quality

27. A quality engineer is conducting a hypothesis test to determine whether a process improvement has reduced the defect rate below 3%. A sample of 500 parts from the improved process contains 10 defective parts (2.0%). The oneproportion Ztest yields Z = 1.31 with a pvalue of 0.095 at $\alpha = 0.05$ (onesided). What is the correct conclusion?

A. The defect rate has been conclusively reduced below 3% with high confidence

B. The sample size is too small for the oneproportion Ztest to be valid

C. There is insufficient statistical evidence at the 5% significance level to conclude the defect rate has been reduced below 3%, despite the observed reduction

D. The defect rate has increased above 3% based on the negative Zvalue

28. A quality engineer is implementing a risk management system and must establish risk acceptance criteria. The engineering team proposes that any risk with a probability rating below 3 (on a 15 scale) should be automatically accepted without treatment. Why is this approach problematic?

A. Probability ratings below 3 are too low to appear on a standard 5×5 risk matrix

B. Automatic acceptance criteria should be based on both probability and severity together, not on probability alone — a lowprobability catastrophic risk still demands treatment

C. All identified risks must receive formal treatment regardless of their probability or severity

D. Risk acceptance criteria should be based on the total number of risks in the register rather than individual ratings

29. A quality engineer discovers that a production process has been running for six months with control limits calculated from the initial 25subgroup baseline study. During that time, a series of process improvements have reduced the process standard deviation by 30%. The original control limits are still in use. What is the consequence of not updating the limits?

A. The original limits remain valid because they represent the process's historical performance capability

B. The chart has become insensitive — the wider original limits cannot detect shifts that the improved process would make visible with updated, narrower limits

C. The chart will generate excessive false alarms because the improved process produces tighter variation

D. Not updating limits has no practical effect on chart performance as long as the process remains in control

30. A quality engineer needs to determine the appropriate sample size for an attributes acceptance sampling plan. The lot size is 2,000 units and the quality engineer is using ANSI/ASQ Z1.4 at inspection level II with AQL = 1.0%. After finding the sample size code letter from the lot size table, the engineer locates the single sampling plan. The plan specifies n = 125 and c = 3. What does c = 3 mean in this context?

A. The lot is accepted if 3 or fewer nonconforming units are found in the sample of 125

B. The lot is rejected if fewer than 3 nonconforming units are found in the sample

C. Three samples of 125 must be drawn before a final accept/reject decision can be made

D. The acceptance number is recalculated after every 3 consecutive lots are inspected

31. A quality engineer is analyzing a designed experiment where the team initially planned a fullfactorial 2^4 design (16 runs) but budget cuts reduced the experiment to 8 runs. The team switched to a 2^{4-1} design with defining relation I = ABCD. Which practical limitation must the engineer accept when analyzing the results?

A. No effects of any kind can be estimated from only 8 runs with four factors

B. Only the four main effects can be estimated; all interactions are completely undetectable

C. Twofactor interactions are aliased in pairs (AB=CD, AC=BD, AD=BC) and cannot be individually separated, requiring process knowledge to interpret ambiguous results

D. The design automatically identifies which aliased interaction is the true effect and reports both separately

32. An organization's management review agenda includes all required ISO 9001:2015 inputs except one: the review does not consider "changes in external and internal issues that are relevant to the quality management system." During a surveillance audit, the auditor identifies this omission. Why is this input important?

A. External and internal context changes — new regulations, market shifts, technology advances, organizational restructuring — can affect the QMS's ability to achieve its intended results and must be considered for the system to remain suitable and effective

B. This input is only required for initial certification audits, not for surveillance audits

C. The input is automatically addressed when audit results and customer feedback are reviewed

D. Only changes in external context are required; internal context changes are optional

33. A quality engineer is implementing a measurement system for a new production line and must choose between two candidate instruments. Instrument X has excellent repeatability (%EV = 4%) but poor reproducibility (%AV = 18%). Instrument Y has moderate repeatability (%EV = 10%) and moderate reproducibility (%AV = 11%). Assuming %GRR is the combined metric, which instrument provides the better overall measurement system?

A. Instrument X because its repeatability is superior to Instrument Y

B. Instrument Y because its total %GRR is lower despite having weaker repeatability, since the very poor reproducibility of Instrument X dominates its overall performance

C. Both instruments are equivalent because their total %GRR values are identical

D. Instrument X because reproducibility can always be improved through operator training

34. In the context of Deming's 14 Points for Management, Point 3 states: "Cease dependence on inspection to achieve quality." What is the practical implication of this principle for a quality engineer?

A. Shift the quality strategy from detecting defects after production to preventing defects through process design, control, and improvement — building quality into the process rather than sorting it out at the end

B. Eliminate all inspection activities immediately and rely entirely on operator selfverification

C. Replace human inspectors with automated inspection equipment across all operations

D. Inspection should be increased at final test while reducing inprocess checks

35. A quality engineer is conducting a process capability study on a characteristic with bilateral specifications of 100 ± 5. The process data yields $\bar{x} = 101.5$, $s = 1.2$. What are the Cp and Cpk values?

A. Cp = 1.39, Cpk = 1.39

B. Cp = 1.39, Cpk = 0.97

C. Cp = 1.39, Cpk = 0.97, with the Cpk limited by the proximity to the upper specification limit

D. Cp = 0.97, Cpk = 0.97

36. A quality engineer observes that a pchart for a highvolume assembly process consistently shows all points below the center line during the day shift and all points above the center line during the night shift. Both shifts are plotted on the same chart. What is the most appropriate action?

A. Combine the data from both shifts to create a more representative single chart

B. Separate the shifts onto individual pcharts because the two shifts clearly have different process averages, and a combined chart masks the true behavior of each shift

C. Remove the night shift data since it is performing worse than the day shift

D. Widen the control limits to accommodate the betweenshift variation

37. A quality engineer must determine whether four different suppliers provide steel with equivalent mean tensile strength. Each supplier provides 8 samples. The oneway ANOVA yields F = 4.12 with a critical value of $F_{0.05}(3,28) = 2.95$. The ANOVA is significant. However, before interpreting the results, the engineer should verify which assumptions?

A. Only the normality assumption, which can be checked with a single histogram of all 32 data points

B. The assumptions of normality within each group, homogeneity of variance across groups, and independence of observations

C. That the sample sizes are equal and that the population means are within 10% of each other

D. Independence, normality within each group, and homogeneity of variance

38. A quality engineer is preparing for an ISO 9001:2015 audit and must demonstrate that the organization has implemented riskbased thinking. Which evidence best demonstrates this implementation?

A. A documented risk management procedure that has been written but never applied to actual decisions

B. Evidence that risks and opportunities have been identified, actions have been planned and taken, and the effectiveness of those actions has been evaluated across relevant QMS processes

C. A statement in the quality manual acknowledging that risk management is important

D. Certification to ISO 31000 as a standalone risk management system

39. A quality engineer is analyzing a control chart and notices that the last 6 points form a steady downward trend — each point is lower than the previous one, though all remain within the control limits. The Western Electric rules for trends typically trigger at 6 or 7 consecutive points trending in one direction. What is the most appropriate response?

A. Take no action because all points are within the control limits and the trend may reverse naturally

B. Wait until the trend reaches 10 consecutive declining points before investigating

C. Investigate the cause of the progressive decline — possible factors include tool wear, gradual material degradation, calibration drift, or temperature change

D. Recalculate the control limits excluding the trending points to see if the chart normalizes

40. In the context of acceptance sampling, a quality engineer is evaluating two sampling plans for the same application. Plan A has n = 50, c = 1, and Plan B has n = 200, c = 5. Both plans have approximately the same AQL but different OC curves. Which statement correctly compares the two plans?

A. Plan A provides better discrimination because it has a smaller acceptance number

B. Plan B provides better discrimination between good and bad lots because its larger sample size produces a steeper OC curve

C. Both plans have identical OC curves since they protect the same AQL value

D. Plan A is always preferred because smaller sample sizes are more costeffective

41. A quality engineer is developing a fault tree for a "loss of braking" top event in a vehicle system. The analysis reveals that loss of braking occurs if the hydraulic system fails AND the electronic backup fails simultaneously. Each system has an independent failure probability of 0.001. What is the probability of the top event?

A. 0.002, calculated as the sum of both failure probabilities

B. 0.001, equal to the probability of either individual system failing

C. 0.999, representing the probability that at least one system functions

D. 0.000001, calculated as the product of the two independent failure probabilities through the AND gate

42. A quality engineer is using Quality Function Deployment (QFD) to develop a new consumer appliance. During construction of the House of Quality, the engineering team maps customer requirements to engineering characteristics. The "roof" of the House of Quality captures which specific information?

A. The correlations between engineering characteristics themselves — identifying where improving one characteristic may help or hinder another

B. The competitive benchmarking data comparing the organization's product to competitors' products

C. The importance rankings assigned by customers to each requirement category

D. The target values for each engineering characteristic derived from specification documents

43. A quality engineer is calculating the reliability of a system with three components. Component 1 (R = 0.99) is in series with a parallel pair of Components 2 and 3 (each R = 0.95). What is the system reliability?

A. 0.99 × 0.95 × 0.95 = 0.894, calculated as if all three components are in series

B. 0.99 × [1 $(0.05)^2$] = 0.99 × 0.9975 = 0.9875, calculated by finding the parallel subsystem reliability first

C. 0.99 + 0.95 + 0.95 = 2.89, an impossible value indicating a calculation error

D. 1 (0.01 × 0.05 × 0.05) = 0.999975, calculated as if all three components are in parallel

44. A quality engineer discovers that the organization's quality training program evaluates effectiveness only through posttraining satisfaction surveys (Kirkpatrick Level 1). Management believes the training program is highly effective because satisfaction scores average 4.5 out of 5. What limitation should the engineer communicate to management?

A. Satisfaction surveys are the gold standard for training evaluation and no additional assessment is needed

B. High satisfaction scores confirm that participants acquired the knowledge and skills targeted by the training

C. Satisfaction scores should be disregarded entirely because participants cannot objectively evaluate training quality

D. High satisfaction does not confirm learning, behavior change, or organizational results — participants can enjoy training without acquiring usable skills or changing their work practices

45. An organization implements a supplier development program for a critical component supplier whose incoming defect rate has increased from 0.5% to 2.8% over the past year. Rather than immediately disqualifying the supplier, the quality engineer proposes a joint improvement effort. Which argument best justifies this collaborative approach over supplier termination?

A. Supplier termination is never appropriate under any circumstances in quality management

B. Joint improvement with the current supplier may resolve the issue faster and at lower total cost than qualifying a new supplier, while preserving established supply chain relationships and process knowledge

C. The 2.8% defect rate is within acceptable industry standards and requires no action

D. Collaborative improvement is only appropriate when the supplier is ISO 9001 certified

46. A quality engineer is implementing errorproofing on a medical device assembly line. The highestrisk failure mode involves installing a critical Oring seal backward — the correct and incorrect orientations look nearly identical. Which pokayoke approach provides the highest level of protection?

A. Redesigning the Oring or its mating groove to be asymmetric so that installation in the wrong orientation is physically impossible

B. Adding a visual inspection station after the Oring installation step

C. Colorcoding the correct installation side of the Oring for operator reference

D. Training operators to distinguish the correct orientation using tactile differences

47. A quality engineer is constructing a cchart for monitoring the number of soldering defects per circuit board. Twentyfive boards are inspected with a total of 175 defects found. The average defect count per board is $\bar{c} = 7.0$. What are the center line and upper control limit?

A. CL = 7.0, UCL = 7.0 + 3 = 10.0

B. CL = 175, UCL = $175 + 3\sqrt{175} = 214.7$

C. CL = 7.0, UCL = $7.0 + 3\sqrt{7.0} = 7.0 + 7.94 = 14.94$

D. CL = 7.0, UCL = 7.0 + 3(7.0) = 28.0

48. A quality engineer is reviewing a designed experiment and the team asks whether the experiment needs replication. The experiment is a 2^3 full factorial with no replication (8 runs total). The engineer explains that without replication, the analysis must rely on which approach to determine statistical significance?

A. Standard ANOVA with the threefactor interaction ABC used as the error term is always valid

B. A normal probability plot of effects, where significant effects deviate from the line formed by the negligible effects that estimate experimental error

C. Each effect must be compared against an arbitrary threshold of 10% of the mean response

D. Significance cannot be assessed in any way from an unreplicated experiment

49. In the context of risk management, a quality engineer identifies a risk event where a critical production machine could fail catastrophically, requiring 3 weeks for replacement. The engineer proposes three mitigation strategies: (1) maintain a spare machine, (2) establish a backup manufacturing agreement with a contract manufacturer, and (3) increase the preventive maintenance frequency. Which combination provides the most comprehensive risk reduction?

A. Strategy 1 alone, because having a spare machine eliminates the risk entirely

B. Strategy 3 alone, because preventive maintenance prevents all equipment failures

C. Strategies 2 and 3 only, because a spare machine is too expensive to justify

D. All three strategies together, because they address different aspects of the risk — prevention (maintenance), mitigation (spare machine for rapid recovery), and transfer/contingency (contract manufacturer for extended outages)

50. A quality engineer is conducting a chisquare goodnessoffit test to determine whether defect data follows a Poisson distribution. The test yields $\chi^2 = 3.2$ with 4 degrees of freedom. The critical value at $\alpha = 0.05$ is 9.49. What is the conclusion?

A. The data is consistent with a Poisson distribution because the test statistic (3.2) does not exceed the critical value (9.49), so the null hypothesis of Poisson fit is not rejected

B. The data definitively follows a Poisson distribution with zero probability of error

C. The data significantly deviates from a Poisson distribution and a different model is needed

D. The test is inconclusive because the degrees of freedom are too low for a valid assessment

51. A quality engineer is evaluating a process that machines a shaft diameter with a target of 25.000 mm. The process is in statistical control with $\bar{x}$ = 25.003 mm and $\hat{\sigma}$ = 0.004 mm. The specification is 25.000 ± 0.015 mm. What percentage of output falls below the lower specification limit of 24.985 mm?

A. Approximately 50% because the process mean is above target

B. Approximately 2.28% based on a Zscore of approximately 2.0

C. Essentially 0% because the lower specification is 4.5 standard deviations below the process mean

D. Approximately 15.87% based on a Zscore of approximately 1.0

52. In the context of lean manufacturing, a value stream map reveals that a product spends 45 minutes in valueadded processing and 18 days in total lead time. The quality engineer calculates the process cycle efficiency (valueadded time / total lead time). What does this metric reveal about improvement opportunities?

A. The process is highly efficient because 45 minutes of actual work produces a finished product

B. The extremely low process cycle efficiency (approximately 0.17%) reveals that over 99.8% of lead time is consumed by nonvalueadded activities such as waiting, transport, and storage — representing massive improvement opportunity

C. The 18day lead time is industry standard and does not indicate improvement opportunity

D. Process cycle efficiency only applies to service processes and cannot be calculated for manufacturing

53. A quality engineer discovers that a process is producing output with a significantly skewed distribution. The engineer needs to calculate process capability but knows that standard Cp and Cpk formulas assume normality. After applying a BoxCox transformation with $\lambda = 0.5$ (square root transformation), the transformed data passes the AndersonDarling normality test. What is the correct next step?

A. Calculate Cp and Cpk on the original untransformed data since the transformation was only for diagnostic purposes

B. Calculate Cp and Cpk on the original data but double the result to account for the transformation

C. Report that capability cannot be assessed because the original data is nonnormal

D. Transform the specification limits using the same $\lambda = 0.5$ transformation, then calculate Cp and Cpk on the transformed scale using the transformed data and transformed specification limits

54. A quality engineer is reviewing an organization's internal audit program and discovers that the same three auditors have been auditing the same departments for the past five years. While the auditors are technically qualified and independent of the departments they audit, what concern should the engineer raise?

A. The auditors have developed deep familiarity with the areas they audit, which may reduce their ability to see problems with fresh eyes and may lead to a comfortable relationship that diminishes audit rigor over time

B. Auditor rotation is specifically prohibited by ISO 9001 and the current practice is correct

C. Five years of consistent auditor assignment improves audit effectiveness through accumulated knowledge

D. The auditors should be replaced with external auditors for all future internal audits

55. A quality engineer is analyzing a multiple regression model and discovers that two predictor variables (X_1 and X_2) have a correlation of $r = 0.94$ with each other. The overall model is significant, but

neither X_1 nor X_2 has a significant individual ttest. What phenomenon is this, and what should the engineer do?

A. This is normal multicollinearity behavior — the correlated predictors share explanatory power, making their individual coefficients unstable

B. Both variables should be retained in the model because the overall model is significant

C. Multicollinearity — the high correlation between X_1 and X_2 makes their individual coefficients unreliable; the engineer should consider removing one predictor or combining them

D. The nonsignificant ttests prove that neither variable affects the response

56. A quality engineer is implementing a calibration program for a new facility and must establish the traceability chain for measurement standards. The traceability hierarchy, from highest to lowest, follows which order?

A. Working standards → reference standards → national standards → international standards

B. International standards → national standards → reference standards → working standards

C. National standards → working standards → reference standards → international standards

D. Working standards → national standards → international standards → reference standards

57. A quality engineer is conducting a twosample ttest comparing the mean tensile strength of two material lots. Lot 1: $n = 20$, $\bar{x} = 480$ MPa, $s = 15$ MPa. Lot 2: $n = 20$, $\bar{x} = 495$ MPa, $s = 14$ MPa. Before performing the pooled ttest, the engineer should verify which assumption about the two populations?

A. That both sample sizes are at least 30 for the central limit theorem to apply

B. That the population variances are approximately equal, typically verified with an Ftest or Levene's test

C. That the data comes from the same manufacturing process and production date

D. That the measurement system used for both lots has a Gage R&R below 10%

58. A pharmaceutical quality engineer must validate a sterilization process for medical devices. The process involves exposing devices to ethylene oxide gas at specific temperature, humidity, pressure, and exposure time parameters. Why does this process require validation rather than relying solely on poststerilization testing?

A. Sterilization is a special process whose effectiveness cannot be fully verified by testing the finished product — sterility testing of individual units is destructive and cannot confirm sterility of the entire lot

B. Validation is required only because regulatory agencies mandate it, not for technical reasons

C. Poststerilization testing is equally effective as validation for confirming process capability

D. Sterilization processes never vary, so initial qualification alone is sufficient

59. A quality engineer is constructing an npchart for monitoring the number of nonconforming units per lot. The sample size is constant at $n = 200$, and the average proportion nonconforming is $\bar{p} = 0.025$. What is the upper control limit for the npchart?

A. $n\bar{p} = 5.0$ (center line only, no UCL can be calculated for npcharts)

B. $5.0 + 3\sqrt{(5.0 \times 0.975)} = 5.0 + 6.62 = 11.62$

C. $5.0 + 3(5.0) = 20.0$

D. $0.025 + 3\sqrt{(0.025 \times 0.975/200)} = 0.058$ (this is the pchart formula, not npchart)

60. A quality engineer is conducting a root cause analysis for a recurring bearing failure using the 5 Whys technique. The analysis proceeds as follows: Why did the bearing fail? → Insufficient lubrication. Why was lubrication insufficient? → The grease fitting was blocked. Why was the fitting blocked? →

Contamination from the production environment. Why was there contamination? → The dust collection system filter was not replaced on schedule. Why was the filter not replaced? → There is no preventive maintenance schedule for the dust collection system. At which "why" has the engineer reached an actionable root cause?

A. The first why — insufficient lubrication should trigger an immediate relubrication of all bearings

B. The third why — contamination should be addressed by installing better sealing around the bearing

C. The second why — the blocked fitting should be cleaned and a regular fitting check should be added

D. The fifth why — the absence of a preventive maintenance schedule for the dust collection system is the systemic root cause that, if addressed, would prevent the entire causal chain from recurring

61. A quality engineer is analyzing the results of an acceptance sampling inspection. A lot of 1,500 electronic components is sampled using $n = 80$, $c = 2$. The sample contains 2 defective units. The lot is accepted. A production supervisor questions whether 2 defectives in 80 samples means the lot quality is 2.5% nonconforming. How should the engineer explain the relationship between sample results and lot quality?

A. The sample result of 2/80 = 2.5% is the exact lot defective rate with certainty

B. The 2.5% is a point estimate of the lot quality, but the true lot quality could be higher or lower — the OC curve for this plan shows the probability of acceptance at various actual quality levels

C. The lot quality is always better than the sample quality because sampling introduces upward bias

D. Sample results have no relationship to lot quality and should not be used for inference

62. A quality engineer is evaluating whether to add a redundant safety sensor to a critical process control system. The current single sensor has a reliability of 0.98 over the required operating period. Adding a second identical sensor in parallel would increase the subsystem reliability to $1 \quad (0.02)^2 = 0.9996$. However, a colleague argues that the redundancy adds complexity and introduces a new failure mode — false disagreement between the two sensors. How should the engineer evaluate this tradeoff?

A. The reliability improvement is so significant that the added complexity is always justified without further analysis

B. The engineer should conduct a risk assessment weighing the substantial reliability improvement against the complexity and falsedisagreement risk, considering the severity of the failure mode being protected against

C. Redundancy should never be implemented because it always introduces more problems than it solves

D. The decision depends entirely on the cost of the second sensor relative to the operating budget

63. A quality engineer is evaluating a scatter diagram showing the relationship between ambient temperature and a critical product dimension. The data shows a clear positive linear trend with r = 0.87. The engineer proposes adjusting the process setpoint based on ambient temperature to compensate for the dimensional drift. What critical step should be completed before implementing this temperature compensation?

A. No additional steps are needed because the strong correlation proves temperature causes the dimensional change

B. The correlation must exceed r = 0.95 before any process adjustment can be justified

C. The engineer should increase the sample size to at least 500 data points before drawing conclusions

D. A designed experiment should confirm the causal relationship, because correlation alone does not prove causation — a third variable could be driving both temperature and dimensional changes simultaneously

64. In the context of ISO 9001:2015, Clause 8.2.1 requires the organization to establish processes for communicating with customers. Which of the following is specifically required as part of customer communication?

A. Daily phone calls to each customer to discuss quality performance metrics

B. Providing information relating to products and services, handling enquiries and orders, obtaining customer feedback, handling customer property, and establishing requirements for contingency actions

C. Sharing internal audit results and management review minutes with all customers

D. Providing customers with access to the organization's electronic document management system

65. A quality engineer is analyzing warranty data and discovers that a product's mean time to failure (MTTF) is 8,000 hours. The product is sold with a warranty covering the first 1,000 hours of operation. Assuming a constant failure rate (exponential distribution), what percentage of products are expected to fail during the warranty period?

A. 12.5%, calculated as 1,000/8,000 × 100%

B. Approximately 11.8%, calculated as 1 e^(1000/8000) = 1 e^(0.125) ≈ 0.1175

C. 50%, because half of all products fail before the MTTF

D. 0%, because the warranty period is well within the useful life period

66. A quality engineer is reviewing a process control plan and notices that a critical dimension has SPC specified as the control method with a subgroup size of 5 measured every 2 hours. However, the production rate is 600 units per hour. Between measurement subgroups, 1,200 units are produced without any quality verification. The engineer is concerned about the exposure risk. What modification should be considered?

A. Increasing the measurement frequency to reduce the number of potentially nonconforming units produced between checks, based on a risk assessment of the consequences of an undetected shift

B. No modification is needed because SPC is designed to work with periodic sampling at any interval

C. Switching from SPC to 100% inspection to eliminate all exposure risk

D. Reducing the subgroup size from 5 to 1 to allow more frequent checks at the same total measurement cost

67. A quality engineer is implementing a visual management system in a production area and wants to display realtime process performance data on the shop floor. Which combination of visual elements provides the most effective communication for both operators and management?

A. A detailed statistical report posted weekly on the department bulletin board

B. A computerized dashboard accessible only from the quality engineering office

C. Colorcoded status indicators are sufficient without any numerical performance data

D. An andon board displaying current machine status, hourly production count versus target, cumulative quality metrics, and alert indicators for abnormal conditions — visible from any point in the production area

68. A quality engineer discovers that a recently hired inspector has been using an expired revision of the inspection procedure for three weeks. Twelve lots were inspected during this period. The current procedure includes an additional dimensional check that was added in the latest revision. What is the most critical immediate action?

A. Retrain the inspector on the current revision and document the training completion

B. Issue a nonconformity report against the document control system for the distribution failure

C. Review all 12 lots inspected during the threeweek period to determine which lots may have been affected by the missing dimensional check and assess whether any nonconforming product may have been accepted

D. Update the inspection procedure to remove the additional dimensional check since it was missed without consequence

69. A quality engineer is conducting a designed experiment to optimize the tensile strength of a welded joint. Three factors are studied: welding current (A), travel speed (B), and gas flow rate (C), each at two levels. The engineer runs a full 2^3 factorial with 2 replicates (16 total runs). The ANOVA results show that factors A and B and the AB interaction are significant, while C and all interactions involving C are not significant. What is the practical implication for process optimization?

A. All three factors must be set to their high levels to maximize tensile strength

B. Gas flow rate (Factor C) can be set to its most economical or convenient level since it does not significantly affect tensile strength, while current and travel speed must be optimized jointly due to their significant interaction

C. The experiment should be repeated without Factor C to confirm the results

D. The significant AB interaction is a mathematical artifact and should be ignored in favor of the main effects

70. A quality engineer receives a batch of 20 Gage R&R results from a supplier's measurement system validation. The supplier claims the measurement system is acceptable because the %GRR is 9.5% of tolerance. However, the quality engineer notices that the ndc (number of distinct categories) is only 3. How should the engineer assess this measurement system?

A. The system is fully acceptable because the %GRR is below the 10% threshold

B. The system is not adequate for reliable quality decisions — while the %GRR meets the percentage criterion, the ndc of 3 (below the minimum of 5) indicates the system cannot sufficiently discriminate among parts across the production variation range

C. The ndc criterion is outdated and the %GRR alone determines acceptability

D. Both criteria are met because the ndc minimum is 2, not 5

71. A quality engineer is evaluating the effectiveness of a newly implemented corrective action. The original problem was a recurring dimensional nonconformity on a machined part, occurring at a rate of 3.2% of production. The corrective action involved replacing a worn machine spindle and implementing SPC on the affected dimension. Four months after implementation, the nonconformity rate has dropped to 0.4%. What additional step is needed before declaring the corrective action effective and closing it?

A. No additional step is needed — the 0.4% rate proves the corrective action is effective

B. The corrective action cannot be closed until the nonconformity rate reaches exactly zero

C. A customer satisfaction survey should be conducted to verify the improvement

D. Continue monitoring for an additional defined period to confirm the improvement is sustained and the original problem does not recur — a single data point is insufficient to confirm longterm effectiveness

72. A quality engineer is analyzing the cost of quality for a manufacturing operation and finds the following annual costs: prevention = $150,000; appraisal = $200,000; internal failure = $180,000; external failure = $120,000. Total COQ is $650,000. What is the cost of nonconformance as a percentage of total quality costs?

A. 23.1%, representing only the prevention costs that failed to prevent failures

B. 53.8%, representing the appraisal and internal failure costs combined

C. 46.2%, representing the sum of internal failure ($180,000) and external failure ($120,000) divided by total COQ ($650,000)

D. 76.9%, representing all costs except prevention

73. A quality engineer is conducting a process validation and must distinguish between Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). During which stage is the equipment tested under worstcase production conditions to demonstrate that it consistently produces output meeting quality requirements?

A. Performance Qualification, which demonstrates consistent output quality under actual or simulated production conditions using production materials and operating procedures

B. Installation Qualification, which confirms the equipment meets manufacturer specifications

C. Operational Qualification, which tests equipment across its operating range under controlled conditions

D. A fourth stage called Design Qualification that precedes all other stages

74. A quality engineer is reviewing a supplier's quality agreement and notices that the agreement does not include a requirement for the supplier to notify the customer of any process or material changes. Why is this omission a significant risk?

A. Supplier process changes are irrelevant as long as incoming inspection continues to verify conformance

B. Unauthorized or undisclosed supplier process changes can affect product quality, and without a notification requirement, the customer may receive nonconforming material from a changed process before the change is detected through inspection

C. Change notification requirements are optional and only recommended for safetycritical components

D. The supplier's ISO 9001 certification automatically ensures all changes are communicated

75. A quality engineer is analyzing a histogram of process data and observes that the distribution has a sharp cutoff exactly at the lower specification limit. The data shows no values below LSL, but the distribution clearly extends above the mean with a natural tail. What is the most likely explanation?

A. The process naturally produces no values below the lower specification limit

B. The data was collected with a measurement instrument that cannot read below the LSL value

C. 100% inspection or sorting has removed all values below the lower specification limit, hiding the true extent of the process distribution below the LSL

D. The process follows a uniform distribution bounded by the specification limits

76. A quality engineer is planning a designed experiment with 5 factors at 2 levels and has budget for 32 runs. Should the engineer use a 2^5 full factorial (32 runs, no replication) or a 2^{5-1} fractional factorial (16 runs) with 2 replicates?

A. The full factorial is always preferred because it estimates all effects without confounding

B. The fractional factorial is always preferred because replication is more important than estimating higherorder interactions

C. The choice depends on the experimental objectives — the full factorial estimates all interactions cleanly but has no independent error estimate, while the fractional with replication provides an error estimate and clean main effects but confounds some twofactor interactions

D. Both designs are identical in their ability to detect significant effects

77. A quality engineer is reviewing the organization's risk register and discovers that a risk previously rated as "low" — supply chain disruption from a minor secondary supplier — has materialized and caused a significant production delay. The risk assessment failed to anticipate this event. What does this incident demonstrate about the risk management process?

A. The risk management process correctly identified the risk but the low rating means no action was required

B. Risk registers are unable to capture supply chain risks and should exclude them

C. The risk assessment process may need improvement — the probability or consequence ratings may have been too low, the risk criteria may not have adequately captured cascading effects, or the monitoring process failed to detect changing conditions

D. The incident was a random event that no risk management process could have anticipated

78. A quality engineer is interpreting a Weibull plot of failure data and determines that the shape parameter $\beta = 1.0$ and the scale parameter $\eta = 50,000$ hours. What is the MTBF for this component, and what does this specific β value imply?

A. MTBF = 25,000 hours, calculated as $\eta/2$ for all Weibull distributions

B. MTBF = 50,000 hours, because when $\beta = 1.0$ the Weibull reduces to the exponential distribution where MTBF equals the scale parameter η

C. MTBF cannot be calculated from Weibull parameters without additional failure data

D. MTBF = $50{,}000^2$ = 2.5 billion hours, calculated as η raised to the power of β

79. A quality engineer discovers that the organization has been calculating Cpk using the overall standard deviation (from all individual data points) rather than the withinsubgroup estimate ($\bar{R}/d_2$). The overall standard deviation is larger because the process experienced several betweensubgroup shifts during the study. What is the consequence of this error?

A. The Cpk is artificially inflated, overstating the process capability

B. There is no consequence because both standard deviation estimates produce identical Cpk values

C. The Cpk is understated because the larger overall standard deviation produces a smaller capability index — the engineer has actually calculated Ppk rather than Cpk

D. The error affects only the Cp calculation and has no impact on Cpk

80. In the context of the Malcolm Baldrige framework, the Criteria for Performance Excellence uses a scoring system based on two evaluation dimensions for process items: Approach and Deployment. Which additional dimensions complete the evaluation framework?

A. Cost efficiency and return on investment for each quality initiative

B. Customer satisfaction and market share growth relative to competitors

C. Learning and Integration — whether the organization uses evaluation findings to improve and whether the approach is aligned with organizational needs

D. Employee retention and training hours per employee across all departments

81. A quality engineer is conducting a supplier audit and discovers that the supplier's calibration records show that two measurement instruments were found outside their tolerance limits during their most

recent calibrations but no impact assessment was performed on products measured with those instruments since the previous calibration. Which audit finding is appropriate?

A. A nonconformity because the supplier failed to evaluate the impact of outoftolerance instruments on previously measured and accepted product, as required by ISO 9001 Clause 7.1.5

B. An observation suggesting the supplier consider evaluating measurement impact in the future

C. No finding because the instruments were recalibrated and returned to service

D. A positive finding for having a calibration program that detects outoftolerance conditions

82. A quality engineer is tasked with reducing changeover time on a production line. The current changeover takes 75 minutes. After implementing SMED Phase 1 (separating internal and external activities), the engineer identifies that 30 minutes of the current changeover consists of activities that could be performed while the machine is still running. What is the expected changeover time after implementing this phase?

A. 75 minutes because no activities have been eliminated, only reclassified

B. 45 minutes because the 30 minutes of external activities are now performed during machine operation, leaving only 45 minutes of internal (machinestopped) activities

C. 30 minutes because the external activities become the new changeover duration

D. 37.5 minutes representing a 50% reduction from the original changeover time

83. A quality engineer is analyzing data from a designed experiment and calculates the effects of all factors and interactions. The engineer then constructs a normal probability plot of the effects. On the plot, four effects deviate substantially from the straight line formed by the remaining effects. The deviating effects are: Factor A (+18.2), Factor C (12.4), the AC interaction (+11.8), and Factor B (+10.1). All other effects fall close to the line. Which effects should the engineer include in the model?

A. All effects should be included regardless of the normal probability plot results

B. Only the two largest effects (A and C) should be included to maintain model simplicity

C. Only main effects should be included; interactions are always negligible and should never be in the model

D. All four deviating effects (A, B, C, and AC) should be included because their departure from the line indicates they are statistically significant

84. In the context of quality management systems, a quality engineer discovers that the organization has defined quality objectives at the top level (plantwide metrics) but has not cascaded these objectives to department and individual levels. According to ISO 9001:2015, what is the deficiency?

A. Quality objectives are only required at the organizational level and need not be cascaded

B. Departmentlevel objectives are only required for the quality department, not for production or engineering

C. Quality objectives must be established at relevant functions, levels, and processes within the organization to ensure that everyone understands their contribution to achieving the organizational quality goals

D. Individuallevel quality objectives are prohibited because they create competition among employees

85. A quality engineer is monitoring a filling process with an IMR chart. The process fills containers to a target of 500 ml. The chart shows that the process has been in control for 3 months with $\bar{x}$ = 500.2 ml and $M\bar{R}$ = 1.8 ml. The estimated process standard deviation using $\hat{\sigma} = M\bar{R}/d_2$ = 1.8/1.128 = 1.60 ml. The specification is 500 ± 5 ml. What is the Cpk?

A. Cpk = min((505 500.2)/(3 × 1.60), (500.2 495)/(3 × 1.60)) = min(1.00, 1.08) = 1.00

B. Cpk = (10)/(6 × 1.60) = 1.04

C. Cpk = min(4.8/4.8, 5.2/4.8) = min(1.00, 1.08) = 1.00

D. Cpk = 1.60, calculated as the ratio of the standard deviation to the tolerance

86. A quality engineer is using an interrelationship digraph to analyze factors contributing to customer complaints. After completing the analysis, Factor P has 8 outgoing arrows and 1 incoming arrow, Factor Q has 2 outgoing and 7 incoming, and Factor R has 5 outgoing and 4 incoming. Which factor should be the primary target for corrective action?

A. Factor Q because it receives the most influences and addressing it would resolve multiple issues simultaneously

B. Factor P because it is the strongest driver — it influences 8 other factors and is itself influenced by only 1, making it a fundamental root cause

C. Factor R because it has the most balanced ratio of outgoing to incoming arrows

D. All three factors should be addressed simultaneously with equal priority

87. A quality engineer is evaluating a process and discovers that the measurement system has a Gage R&R of 28% of tolerance. The process Cpk, calculated from the measurement data, is 1.05. How does the measurement system variation affect the interpretation of this Cpk value?

A. The Cpk is likely understated because the measurement system adds variation to the observed data — the true process capability may be better than 1.05

B. The measurement system variation has no effect on capability index calculations

C. The Cpk is overstated because measurement system variation artificially inflates the data

D. The measurement system must achieve exactly 0% GRR before any capability assessment is valid

88. A quality engineer is reviewing the results of a fractional factorial screening experiment that identified Factors A, D, and E as significant from an initial set of 7 factors. The experiment was Resolution III, meaning some main effects were aliased with twofactor interactions. Before proceeding to optimization, why should the engineer conduct a followup experiment?

A. The Resolution III design cannot detect any significant effects and the results are invalid

B. Followup experiments are only necessary when the screening experiment produces no significant results

C. Screening experiments always produce false positives that must be confirmed through replication

D. The aliased main effects may actually represent twofactor interactions rather than main effects — a higherresolution followup with only the significant factors can cleanly estimate both main effects and interactions

89. A quality engineer calculates a 95% confidence interval for the mean diameter of a precision component: (12.48, 12.52) mm. The specification for this diameter is 12.50 ± 0.05 mm (12.45 to 12.55 mm). What can the engineer conclude about the process mean relative to the specification?

A. The entire 95% confidence interval falls within the specification limits, providing strong evidence that the process mean is within specification

B. The confidence interval proves that 95% of individual parts fall within the specification limits

C. The confidence interval overlaps the specification limits, so no conclusion can be drawn

D. The narrow confidence interval guarantees zero nonconforming output from this process

90. A quality engineer is implementing a quality information system and must decide which data to collect for incoming material quality tracking. Which data elements are most essential for supporting both lot acceptance decisions and supplier performance trend analysis?

A. Only the final accept/reject disposition for each lot received from each supplier

B. Lot identification, supplier identification, date received, inspection results for each characteristic tested, disposition decision, and any nonconformance details — enabling both lotlevel decisions and longitudinal supplier performance trending

C. The purchase order number and invoice amount for each incoming shipment

D. Only the supplier's Certificate of Conformance document number for traceability

91. A quality engineer is planning a hypothesis test and wants to detect a difference of 0.5 standard deviations between two population means with 80% power at $\alpha = 0.05$ using a twosided twosample ttest. Power analysis yields a required sample size of 64 per group. If the engineer wants to increase power to 90% while detecting the same effect size, what happens to the required sample size?

A. The sample size decreases because higher power means the test is more efficient

B. The sample size remains at 64 because power does not affect sample size calculations

C. The sample size increases to approximately 86 per group because higher power requires more observations to maintain a higher probability of detecting the same effect

D. The sample size doubles to 128 per group because power has a linear relationship with sample size

92. A quality engineer is reviewing an organization's preventive maintenance program and discovers that equipment calibration, lubrication, and component replacement schedules are all based on fixed calendar intervals rather than actual equipment condition or usage data. Which maintenance approach would better optimize the balance between maintenance cost and equipment reliability?

A. Eliminate all scheduled maintenance and repair equipment only when it breaks down

B. Maintain the fixedinterval approach because it is the industry standard for all equipment types

C. Increase all maintenance intervals by 50% to reduce maintenance costs without affecting reliability

D. Implement conditionbased maintenance that uses actual equipment performance data — vibration analysis, oil analysis, thermography, and performance trending — to schedule maintenance based on demonstrated need rather than arbitrary calendar intervals

93. A quality engineer needs to determine whether a process change has significantly reduced the standard deviation of a critical characteristic. Before the change, 25 samples yielded $s_1 = 0.042$. After the change, 25 samples yielded $s_2 = 0.028$. Which test should be used?

A. Ftest for equality of variances, comparing $F = s_1^2/s_2^2 = (0.042)^2/(0.028)^2 = 2.25$ against the critical Fvalue with 24 and 24 degrees of freedom

B. Twosample ttest for comparing the means of the two sample groups

C. Paired ttest using the before and after measurements for each sample

D. Chisquare test for comparing the two standard deviations directly

94. In the context of lean manufacturing, the concept of "jidoka" (autonomation) refers to which principle?

A. The complete automation of all production processes to eliminate human involvement

B. Equipping machines and operators with the ability to detect abnormalities and stop production automatically, preventing defective output from being passed to downstream processes

C. The use of robots to replace all manual assembly operations on the production line

D. Computerbased scheduling systems that optimize production sequencing

95. A quality engineer is conducting a management review presentation and needs to show the trend in total cost of quality over the past three years. Which additional context would make the COQ trend most meaningful for management decisionmaking?

A. Presenting total COQ as an absolute dollar amount without any normalization

B. Presenting only the failure cost trend since management is primarily interested in reducing losses

C. Presenting COQ as a percentage of revenue along with the breakdown by category (prevention, appraisal, internal failure, external failure) to show both the overall trend and the shift in investment strategy

D. Presenting the number of quality department employees as a proxy for quality investment

96. A quality engineer is analyzing a process and discovers that the process standard deviation σ = 0.02 mm. The specification tolerance is ±0.10 mm (total tolerance = 0.20 mm). The process is perfectly centered. What is the Cp, and what is the expected nonconforming rate?

A. Cp = 1.33, with approximately 63 ppm nonconforming (total from both tails)

B. Cp = 1.00, with approximately 2,700 ppm nonconforming (total from both tails)

C. Cp = 2.00, with approximately 2 ppb (parts per billion) nonconforming

D. Cp = 1.67, with approximately 0.6 ppm nonconforming (total from both tails)

97. A quality engineer is reviewing the effectiveness of the organization's CAPA system. In the past year, 120 corrective actions were initiated, 95 were closed on time, and the nonconformity recurrence rate is 35%. Which metric is the most meaningful indicator of CAPA system effectiveness?

A. The 79% ontime closure rate (95/120), which demonstrates good process discipline

B. The total number of corrective actions initiated, which indicates the organization's commitment to quality

C. The 95 corrective actions closed, representing productivity of the quality team

D. The 35% recurrence rate — the most critical metric because it directly measures whether corrective actions are actually eliminating root causes and preventing recurrence, which is the fundamental purpose of the CAPA system

98. A quality engineer is implementing SPC on a process that fills pharmaceutical vials. The fill volume must be between 9.5 ml and 10.5 ml. The process is adjusted to overfill slightly (mean = 10.1 ml) to minimize the risk of underfilling, which would violate regulatory requirements. The standard deviation is 0.12 ml. What is the Cpk, and which specification limit is the concern?

A. Cpk = 1.11, limited by the upper specification limit because the intentional overfill positions the process closer to the USL

B. Cpk = 1.67, limited by the lower specification because the overfill provides maximum protection from underfilling

C. Cpk = 1.39, representing equal distance from both specification limits due to the centering strategy

D. Cpk = 0.83, indicating the process is incapable regardless of the centering adjustment

99. A quality engineer is reviewing the organization's risk register and notices that all identified risks have been assigned treatment plans, but none of the treatment plans include a target date for completion, a responsible individual, or success criteria. What is the practical consequence of this omission?

A. The treatment plans are complete because they identify what needs to be done

B. The risk register serves only as a reference document and treatment plan details are unnecessary

C. Missing completion targets and accountability means treatment plans have no mechanism to drive action — without ownership, deadlines, and success criteria, the plans will likely remain unimplemented

D. The risk treatment plans will be implemented by the quality department as part of their standard work

100. A quality engineer is analyzing a time series of monthly scrap rates and wants to forecast the next month's scrap rate. The engineer decides to use exponential smoothing with a smoothing constant α = 0.2. The previous forecast was 4.5% and the actual observed scrap rate was 5.3%. What is the forecast for the next month?

A. 5.3%, using the most recent actual observation as the forecast

B. 4.90%, using the mean of the previous forecast and the actual observation

C. 4.66%, calculated as 4.5 + 0.2(5.3 4.5) = 4.5 + 0.16 = 4.66

D. 3.58%, calculated as 4.5 0.2(5.3 4.5) = 4.5 0.16 = 4.34

101. A quality engineer is planning a designed experiment to study the effect of four factors on surface roughness. Each factor will be tested at two levels. The engineer has resources for exactly 16 runs. Which experimental design maximizes the information obtained from these 16 runs?

A. A 2^4 full factorial, which tests all 16 treatment combinations and estimates all main effects and interactions without confounding

B. A 2^{4-1} fractional factorial run twice for replication, providing 16 runs total

C. A onefactoratatime study testing each factor individually with 4 runs per factor

D. A 2^{5-1} design that adds a fifth factor to take advantage of the 16run framework

102. A quality engineer is evaluating the results of a Gage R&R study where the %GRR is 12% of tolerance and the number of distinct categories (ndc) is 6. The characteristic being measured is a critical safety dimension with zero tolerance for measurementdriven misclassification. Based on AIAG MSA guidelines, what is the appropriate assessment?

A. Fully acceptable because %GRR is below 30% and ndc exceeds 5

B. The measurement system should be replaced immediately because any %GRR above 10% is unacceptable

C. Acceptable for noncritical dimensions but should be improved for this safetycritical application

D. Conditionally acceptable — the %GRR falls in the 1030% range, and given the safetycritical nature of the dimension, improvement should be prioritized to bring %GRR below 10%

103. A quality engineer discovers that incoming material from a supplier consistently meets the purchase specification but exhibits lottolot variation that causes downstream process instability. The supplier's material is within spec but the variation between lots is affecting the customer's SPC charts. What is the most effective longterm solution?

A. Increase incoming inspection sample sizes to detect lottolot differences more reliably

B. Work with the supplier to reduce their process variation beyond mere specification conformance, potentially tightening the supplier's internal targets or process capability requirements

C. Switch to 100% inspection of all incoming material to sort out the most variable lots

D. Adjust the customer's SPC control limits each time a new material lot is introduced

104. A quality engineer is reviewing the organization's risk register and finds that 15 risks are classified as "high" priority, 40 as "medium," and 95 as "low." Management asks whether the 95 lowpriority risks can be removed from the register entirely to simplify the document. What is the quality engineer's best recommendation?

A. Remove all lowpriority risks since they do not require treatment and add no value to the register

B. Archive the lowpriority risks in a separate document but retain them for annual review

C. Lowpriority risks should be retained in the register with periodic monitoring because risk conditions can change — a currently lowpriority risk may escalate if circumstances change, and removing it eliminates visibility and tracking capability

D. Remove risks that have been rated low for more than one consecutive review cycle

105. A quality engineer is constructing an Xbar and R chart and has collected 25 subgroups of size 4. After calculating control limits, the engineer plots all 25 subgroups and finds that 3 points on the Xbar chart exceed the UCL. Investigation reveals assignable causes for all three points that have been corrected. What is the standard procedure for finalizing the control limits?

A. Remove the 3 outofcontrol subgroups with identified and corrected assignable causes, recalculate the limits from the remaining 22 subgroups, and verify that all remaining points fall within the revised limits

B. Keep all 25 subgroups in the calculation because removing any data introduces bias

C. Discard the entire dataset and collect 25 new subgroups from the corrected process

D. Replace each outofcontrol point with the grand average value before recalculating

106. A quality engineer is analyzing field failure data for an automotive component and discovers that 85% of failures occur within the first 5,000 miles of service, with the failure rate declining sharply thereafter. This pattern is characteristic of which region of the bathtub curve, and which quality strategy would most effectively reduce these failures?

A. The useful life region, addressed by implementing scheduled preventive maintenance intervals

B. The wearout region, addressed by using more durable materials with higher fatigue resistance

C. The transition region between useful life and wearout, addressed by extending the warranty period

D. The infant mortality region, addressed by implementing manufacturing screening tests such as burnin or stress testing before shipment to precipitate latent defects

107. A quality engineer is implementing a visual management system and needs to display the status of each workstation in real time. The system should indicate whether each station is running normally, experiencing a minor issue, or stopped due to a problem. Which visual management tool is specifically designed for this purpose?

A. A value stream map posted on the wall showing the complete material and information flow

B. An andon system using colorcoded lights (green = running, yellow = issue, red = stopped) visible from the entire production floor

C. A kanban board showing the number of cards in circulation for each part number

D. A standard work chart displayed at each workstation showing the operator's task sequence

108. A quality engineer is reviewing the results of a designed experiment and the ANOVA table shows that the model sum of squares (SSR) is 450 and the error sum of squares (SSE) is 150. The total sum of squares (SST) is 600. What is the R^2 value for this model, and what does it indicate?

A. $R^2 = 0.25$, indicating the model explains 25% of the total variation in the response

B. $R^2 = 0.33$, indicating the model explains onethird of the total variation

C. $R^2 = 0.75$, indicating the model explains 75% of the total variation in the response

D. $R^2 = 3.0$, indicating the model explains three times more variation than the error

109. A quality engineer discovers that the organization's corrective action system uses a standard form that includes fields for problem description, root cause, corrective action, and implementation date — but does not include a field for effectiveness verification date or method. What is the consequence of this omission?

A. The form is adequate because implementation date confirms that the action was taken

B. The missing field is only important for external failure corrective actions, not internal ones

C. Without a defined effectiveness verification step, corrective actions may be closed upon implementation without confirming that the root cause was actually eliminated and the problem will not recur

D. Without an effectiveness field, the form must be completely redesigned from scratch

110. A quality engineer is analyzing customer complaint data and constructs a Pareto chart. The top three complaint categories are: "delivery delays" (35%), "packaging damage" (25%), and "wrong item shipped" (20%). Together they account for 80% of all complaints. Before launching improvement projects for these categories, what additional analysis would provide the most valuable insight?

A. Stratifying each complaint category by root cause to understand why deliveries are late, why packages are damaged, and why wrong items are shipped — enabling targeted corrective actions rather than broad categorylevel responses

B. Calculating the Pearson correlation between the three categories to determine if they are related

C. Constructing a histogram of complaint frequency by month to identify seasonal patterns

D. Performing a chisquare test to determine if the complaint distribution differs from uniform

111. A quality engineer is evaluating a supplier's process capability for a critical dimension. The supplier provides Cpk = 1.55 calculated from 30 subgroups of size 5 collected over two weeks. The quality engineer notices that the supplier's control chart shows three outofcontrol signals during the data collection period that were not addressed. How does this affect the reliability of the reported Cpk?

A. The outofcontrol signals have no effect on capability calculations since Cpk uses the withinsubgroup standard deviation

B. The reported Cpk is unreliable because capability indices are meaningful only when the process is in statistical control — special causes during data collection make the data nonrepresentative of the stable process

C. The Cpk should be recalculated using only the outofcontrol subgroups since they represent worstcase performance

D. The outofcontrol signals improve the Cpk estimate by capturing the full range of process variation

112. A quality engineer is implementing a training program for new SPC operators. After classroom instruction, the operators must demonstrate competence by correctly interpreting control chart patterns on sample charts before being authorized to monitor live production charts. This competence verification corresponds to which level of Kirkpatrick's evaluation model?

A. Level 1 — Reaction, measuring whether participants enjoyed the training experience

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

C. Level 2 — Learning, measuring whether participants acquired the knowledge and skills taught during training

D. Level 3 — Behavior, measuring whether participants apply learned skills on the job

113. A quality engineer needs to determine whether a new inspection method produces results that agree with the established reference method. Twenty parts spanning the full measurement range are measured by both methods. The paired differences have a mean of 0.002 mm and a 95% confidence interval of (0.005, 0.009). What conclusion should the engineer draw?

A. The methods agree because the confidence interval for the mean difference includes zero, indicating no statistically significant systematic bias between them

B. Method agreement cannot be assessed without at least 100 paired measurements

C. The methods disagree because the confidence interval is not centered exactly at zero

D. The positive mean difference proves the new method reads consistently higher than the reference

114. A quality engineer is conducting a risk assessment for a new manufacturing process and identifies a risk that has very high severity (potential regulatory shutdown) but very low probability (estimated once in 50 years based on industry data). Using a 5×5 risk matrix, the risk score is moderate. However, the engineer believes additional analysis is needed. Which approach provides the most thorough evaluation for this type of lowprobability, highconsequence risk?

A. Accept the moderate risk score from the matrix and document it without further analysis

B. Reclassify the probability as "high" to ensure the risk receives maximum treatment priority

C. Remove the risk from the register because it has never actually occurred at this facility

D. Conduct a quantitative risk analysis using fault tree analysis or event tree analysis to better understand the failure scenarios, their probabilities, and their cascading consequences

115. A quality engineer is reviewing a process control plan and notices that the reaction plan for an outofcontrol signal on the Xbar chart specifies only "adjust the process and continue." What critical elements are missing from this reaction plan?

A. The reaction plan is complete because process adjustment is the appropriate response to any outofcontrol signal

B. The reaction plan is missing instructions to stop the process, segregate suspect material produced since the last known good subgroup, investigate the root cause, document the event, and verify the adjustment before resuming production

C. The reaction plan should specify only that the quality engineer be notified and no other action

D. The reaction plan should include the mathematical procedure for recalculating control limits

116. In acceptance sampling using ANSI/ASQ Z1.4, an organization has been on tightened inspection for 5 consecutive lots and all 5 lots have been rejected. According to the switching rules, what action is required?

A. Return to normal inspection since tightened inspection has been applied for a sufficient duration

B. Switch to reduced inspection to give the supplier a less stringent evaluation standard

C. Discontinue inspection of lots from this source until corrective action has been taken to improve quality

D. Continue tightened inspection indefinitely until at least one lot is accepted

117. A quality engineer is analyzing the relationship between process temperature and product viscosity using simple linear regression. The regression equation is ŷ = 120 0.8x, where x is temperature in °C and ŷ is viscosity in centipoise. The data ranged from 50°C to 150°C. What viscosity does the model predict at 100°C?

A. 40 centipoise, calculated as 120 0.8(100) = 120 80 = 40

B. 200 centipoise, calculated as 120 + 0.8(100) = 120 + 80 = 200

C. 120 centipoise, equal to the yintercept regardless of temperature

D. 80 centipoise, calculated as 0.8 × 100 = 80

118. A quality engineer is implementing ISO 9001:2015 and must address Clause 4.4, which requires the organization to establish, implement, maintain, and improve its quality management system

including the processes needed. The clause specifically requires determination of which of the following for each process?

A. Only the inputs and outputs of each process, with no other requirements specified

B. The annual budget allocated to each process by the finance department

C. The personal qualifications and certifications of every individual involved in each process

D. The inputs, outputs, sequence and interaction, criteria and methods for effective operation, resources needed, responsibilities, risks and opportunities, and evaluation and improvement actions

119. A quality engineer is conducting a measurement system analysis and discovers that the measurement system has acceptable repeatability (%EV = 6%) and acceptable reproducibility (%AV = 5%), yielding a total %GRR of 7.8%. However, the engineer also discovers significant operatorbypart interaction in the ANOVA results. What does this interaction indicate?

A. The interaction has no practical significance since the overall %GRR is acceptable

B. Certain operators measure certain parts differently from other operators — the measurement result depends on which operator measures which part, suggesting inconsistent technique or judgment for specific part characteristics

C. The ANOVA method produced an error and the study should be repeated using the range method

D. The interaction indicates that the parts used in the study were not representative of production

120. A quality engineer is reviewing the organization's supplier management program and discovers that supplier performance is evaluated solely on incoming inspection defect rates. No other metrics are tracked. What limitation does this singlemetric approach create?

A. Defect rate tracking is sufficient for a comprehensive supplier evaluation program

B. Incoming inspection defect rates are unreliable and should not be used for supplier evaluation

C. A singlemetric approach misses critical performance dimensions — delivery reliability, responsiveness to corrective actions, cost competitiveness, and communication effectiveness — that collectively determine overall supplier value and risk

D. The defect rate metric should be replaced with ontime delivery as the sole evaluation criterion

121. A quality engineer is evaluating the reliability of a safety system that consists of a primary sensor (R = 0.995) in series with a processing unit (R = 0.999) in series with an actuator (R = 0.990). The engineer wants to improve system reliability most efficiently. Which component should be targeted for improvement?

A. The processing unit because it is the most complex component in the system

B. The primary sensor because improving reliability from 0.995 to 0.999 provides the smallest absolute gain

C. All three components should be improved equally since they all contribute to system failure

D. The actuator because it has the lowest individual reliability (0.990) and improving the weakest link yields the greatest systemlevel improvement in a series configuration

122. A quality engineer is implementing a corrective action for a recurring soldering defect. The 5 Whys analysis reveals that the root cause is inadequate solder paste storage temperature control. The engineer proposes installing a temperaturemonitored storage unit with automated alerts. Before implementing this solution, which additional step should the FMEA team take?

A. Update the PFMEA to reflect the new control and reassess the Detection rating for this failure mode, verifying that the recommended action actually reduces the risk level

B. Close the FMEA because the corrective action has been identified and no further FMEA updates are needed

C. Increase the Severity rating in the FMEA because the problem was recurring before correction

D. Remove the failure mode from the FMEA since the corrective action will eliminate it entirely

123. A quality engineer is analyzing a normal probability plot of regression residuals and observes that the points follow a straight line in the middle of the plot but curve upward at the right end and downward at the left end. What does this Sshaped departure from linearity indicate?

A. The residuals are perfectly normally distributed and the model assumptions are satisfied

B. The regression model has too many predictor variables and should be simplified

C. The residuals have heavier tails than a normal distribution, meaning extreme values occur more frequently than a normal model predicts

D. The sample size is too small for the normal probability plot to provide valid information

124. In the context of lean manufacturing, a production cell has implemented onepiece flow but experiences frequent stoppages because the upstream process delivers material in large batches that arrive all at once and then nothing for extended periods. Which lean concept addresses this supply inconsistency?

A. Implementing 5S at the upstream workstation to improve organization and cleanliness

B. Leveling the production schedule (heijunka) to smooth the flow of work and material, eliminating the feastorfamine batch delivery pattern

C. Adding buffer inventory between the upstream process and the production cell

D. Increasing the takt time to accommodate the irregular upstream delivery pattern

125. A quality engineer is reviewing the design of a medical device and discovers that the risk analysis (per ISO 14971) was completed during the design phase but has not been updated since the product entered production two years ago. Postmarket surveillance data shows several complaints about a failure mode not identified in the original risk analysis. What is the compliance concern?

A. Risk analysis is only required during the design phase and does not need updating after production begins

B. The postmarket complaints are unrelated to the risk analysis and should be handled through the CAPA system only

C. The failure to update the risk analysis since product launch — and the failure to incorporate postmarket surveillance data into the risk management file — are noncompliant, since ISO 14971 requires risk management throughout the entire product lifecycle

D. Postmarket surveillance data should be reported to the regulatory authority but does not require risk analysis updates

126. A quality engineer is implementing SPC on a process and must choose between using specification limits and statistically calculated control limits on the control chart. A production supervisor argues that using specification limits is simpler because operators can directly see whether parts are within spec. How should the quality engineer respond?

A. Specification limits should be used because they directly relate to customer requirements and are easier for operators to understand

B. Either approach is equally valid and the choice is purely a matter of preference

C. Both specification limits and control limits should be placed on the same chart for maximum information

D. Control limits must be used because they reflect actual process behavior and detect process shifts — specification limits on a control chart mask shifts that occur within the spec range, preventing early detection and correction

127. A quality engineer is conducting a supplier audit and examines the supplier's calibration records. The records show calibration dates and results but do not identify which reference standards were used or their traceability to national standards. Which specific calibration program element is deficient?

A. The calibration frequency is set too long between calibrations, allowing instruments to drift

B. Measurement traceability — the records must identify the reference standards used and demonstrate an unbroken chain of comparisons to national or international measurement standards

C. The calibration technician's training records are missing from the calibration file

D. The calibration laboratory's environmental conditions are not documented in the records

128. A quality engineer is analyzing a 2^3 fullfactorial experiment and calculates the following effect estimates: A = +22.4, B = +5.1, C = 2.3, AB = +18.6, AC = 1.4, BC = +3.2, ABC = 0.8. A normal probability plot identifies A and AB as the only significant effects. Since Factor B appears in the significant AB interaction but has a small and nonsignificant main effect, should Factor B be included in the final model?

A. No, Factor B should be excluded because its main effect is not significant

B. Factor B should be replaced by Factor C since C has a slightly larger absolute effect

C. Yes, Factor B must be included because when an interaction (AB) is significant, both parent main effects (A and B) should be included in the model even if their individual main effects are not significant — this is the hierarchy principle

D. Only the AB interaction should be included without either main effect

129. A quality engineer is reviewing an organization's internal audit program and discovers that audit findings are reported only to the auditee's department manager. The findings are not communicated to top management or included in the management review inputs. What quality system requirement is being violated?

A. The requirement for auditors to be independent of the areas they audit

B. The findings format does not comply with the standardized audit report template

C. The audit checklist was not approved by the quality director before use

D. The requirement to report audit results to relevant management and include them as inputs to management review, as specified in ISO 9001:2015 Clauses 9.2 and 9.3

130. A quality engineer is monitoring a chemical process using an IMR chart. The individual measurements show all points within control limits, but the moving range chart shows a single point significantly above the UCL at observation 15. What is the most appropriate interpretation and action?

A. Investigate the cause of the unusual variation between observations 14 and 15 — the spike in the moving range indicates that something changed abruptly between these two consecutive measurements, warranting investigation even though the individual values are within limits

B. The moving range chart is not important and the engineer should focus only on the individuals chart

C. The spike in the moving range is expected in chemical processes due to normal batchtobatch variation

D. Recalculate the moving range chart excluding observation 15 to see if the chart normalizes

131. A quality engineer is planning a hypothesis test to determine whether a new adhesive formulation produces significantly higher bond strength than the current formulation. The engineer has a limited budget for testing and wants to maximize the probability of detecting a real improvement of at least 5 MPa. Which combination of test design decisions maximizes statistical power?

A. Use a twosided test with $\alpha = 0.01$ and the smallest practical sample size

B. Use a onesided test (H_1: μ_new > μ_current) with $\alpha = 0.05$ and the largest affordable sample size

C. Use a onesided test with $\alpha = 0.01$ and a moderate sample size

D. Use a twosided test with $\alpha = 0.05$ and the largest affordable sample size

132. A quality engineer is reviewing a product design and discovers that a tolerance stackup analysis has not been performed for a critical assembly. The assembly involves five components, each with individual dimensional tolerances, that must fit together within an overall assembly tolerance. Why is the tolerance stackup analysis essential?

A. Tolerance stackup is only required for assemblies with more than ten components

B. Individual component tolerances guarantee assembly fit as long as each component is within its own specification

C. Tolerance stackup analysis determines whether the cumulative effect of individual component tolerances produces an acceptable assembly — components individually within specification may produce an assembly that does not fit if the worstcase tolerance combination exceeds the assembly tolerance

D. Tolerance stackup is a design recommendation, not a requirement of any quality standard

133. A quality engineer is analyzing the cost structure of a quality department and finds that 65% of the department's budget is spent on inspection and testing activities (appraisal), 20% on failure investigation and corrective action (internal failure), 10% on quality planning and training (prevention), and 5% on warranty and complaint handling (external failure). What does this cost distribution suggest about the organization's quality strategy?

A. The distribution is optimal and reflects best practices in quality cost management

B. The organization should increase warranty spending to improve customer satisfaction

C. The organization has achieved worldclass quality with minimal failure costs

D. The organization relies heavily on detection rather than prevention — the disproportionately high appraisal costs suggest that resources should be shifted toward prevention activities that would reduce the need for inspection

134. In a designed experiment, a quality engineer includes three center points in a 2^3 factorial design. The average response at the factorial points (corners) is 82.4, and the average response at the center points is 78.1. The difference is statistically significant. What does this finding indicate?

A. The curvature test is significant, indicating that the relationship between at least one factor and the response is nonlinear — a quadratic model or response surface design may be needed to adequately model the response

B. The center points are outliers and should be removed from the analysis

C. The factorial design is invalid because the center points do not match the corner points

D. The difference between corners and center points is caused by measurement error

135. A quality engineer is implementing a risk management system and must decide how to handle a risk that has been identified and analyzed but for which no feasible treatment option exists — the risk cannot be avoided, reduced, or transferred. What is the appropriate course of action?

A. Remove the risk from the register since no treatment is available and tracking it serves no purpose

B. Formally accept the risk with documented justification and management approval, implement monitoring to detect changes in the risk level, and establish contingency plans for responding if the risk event occurs

C. Assign the risk to the insurance department and consider it resolved

D. Reclassify the risk as "low" to bring it within the organization's risk tolerance

136. A quality engineer is reviewing a Weibull analysis of bearing failure data and obtains β = 3.2 and η = 25,000 hours. The maintenance department currently replaces bearings at fixed 20,000hour intervals. Using R(t) = e^((t/η)^β), what is the approximate reliability at 20,000 hours, and is the current replacement interval adequate?

A. R(20,000) is approximately 0.50, meaning half the bearings have failed before replacement — the interval is too long

B. R(20,000) is very low, indicating almost all bearings fail before 20,000 hours

C. R(20,000) ≈ e^((20000/25000)^3.2) ≈ e^(-(0.8^3.2) ≈ e^(0.488) ≈ 0.61, meaning approximately 39% of bearings fail before the scheduled replacement — the interval may need to be shortened depending on the consequence of failure

D. The replacement interval cannot be evaluated without knowing the failure rate λ

137. A quality engineer is conducting a process capability study and discovers that the data contains several outliers — values that are far from the main body of data. Before excluding any outliers, the engineer should take which action?

A. Automatically exclude all values more than 3 standard deviations from the mean

B. Include all outliers in the capability calculation since they represent actual process output

C. Replace each outlier with the nearest value that falls within 3 standard deviations of the mean

D. Investigate each outlier to determine its cause — if the cause is an assignable special cause that has been corrected, exclusion is justified; if the cause is unknown or represents normal process behavior, the data should be retained

138. A quality engineer is reviewing the organization's document control system and discovers that the master document list shows Revision C as current for a particular work instruction, but the electronic document management system contains Revision D as the latest version. Which quality system failure does this represent?

A. A discrepancy between the master list and the actual document status, indicating a failure in the document control process to keep the master list synchronized with actual document revisions

B. The master list is always correct and Revision D should be removed from the system

C. This is normal and acceptable since electronic systems may contain draft revisions not yet on the master list

D. The work instruction should be withdrawn entirely until the discrepancy is resolved

139. A quality engineer is analyzing the results of a twoway ANOVA with factors Machine (3 levels) and Shift (2 levels) on product weight. The results show: Machine main effect $p = 0.003$ (significant), Shift main effect $p = 0.41$ (not significant), Machine × Shift interaction $p = 0.02$ (significant). How should the nonsignificant Shift main effect be interpreted given the significant interaction?

A. Shift has no effect on product weight and can be ignored in the analysis

B. The nonsignificant Shift main effect is misleading because the significant interaction means Shift's effect depends on which Machine is being used — at some machines Shift may matter greatly while at others it may not

C. The interaction result is a statistical artifact caused by the nonsignificant Shift main effect

D. Both Shift and the interaction should be removed from the model since the Shift main effect is not significant

140. In the context of ISO 9001:2015, Clause 10.3 addresses continual improvement. A quality engineer is asked to demonstrate evidence of continual improvement during an external audit. Which type of evidence best demonstrates this requirement?

A. Evidence of trend analysis showing measurable improvements in quality objectives, process performance, customer satisfaction, and reduction in nonconformances over time, supported by documented improvement actions and their results

B. A written statement in the quality manual affirming the organization's commitment to improvement

C. The number of corrective action reports issued during the audit period

D. The total spending on quality department activities compared to the previous year

141. A quality engineer is analyzing a process that produces pharmaceutical tablets and must verify that the tablet weight distribution is normal before calculating capability indices. The AndersonDarling test yields a pvalue of 0.003. What conclusion should the engineer draw, and what action is appropriate?

A. The data is normally distributed because the pvalue is very small, indicating strong evidence

B. The test is inconclusive at such a small pvalue and should be repeated with a larger sample

C. The test result is irrelevant because pharmaceutical data is always normally distributed

D. The normality assumption is rejected ($p = 0.003 < 0.05$), indicating the data is significantly nonnormal — the engineer should consider data transformation, nonparametric capability methods, or investigation of the source of nonnormality before calculating standard capability indices

142. A quality engineer is implementing lean principles in an office environment (transactional process). The team identifies that purchase order approvals require an average of 7 signatures, each adding 12 days of processing time. Several of the signatures are from managers who have no technical knowledge of the purchase content and sign as a formality. Which lean waste category does this represent?

A. The approval process adds value by reducing financial risk from unauthorized purchases

B. Overprocessing — the excessive number of nonvalueadding approval signatures consumes time and resources without contributing to the quality or accuracy of the purchase decision

C. Defects, because the approval process occasionally results in incorrect purchase orders

D. Inventory waste, because purchase orders accumulate in approval queues like physical inventory

143. A quality engineer is evaluating two competing measurement instruments for a new production line. Instrument P costs $5,000 and has a Gage R&R of 15% of tolerance. Instrument Q costs $18,000 and has a Gage R&R of 6% of tolerance. The characteristic being measured has a Cpk target of 1.33 and is classified as a major (not critical) quality characteristic. Which instrument selection is most appropriate?

A. Instrument P because it costs less and the 15% GRR is within the conditionally acceptable range for a major characteristic

B. Instrument Q because the 6% GRR provides substantially better measurement capability, which is necessary to reliably assess process capability and make accurate accept/reject decisions for a characteristic with a Cpk target of 1.33

C. Either instrument is equally acceptable since both fall below the 30% maximum GRR threshold

D. Neither instrument is acceptable because major characteristics require GRR below 5%

144. A quality engineer is conducting a designed experiment and obtains the following ANOVA results for a 2^3 factorial with 2 replicates: Source | SS | df | MS | F | pvalue: Model = 2,400 | 7 | 342.9 | 11.43 | <0.001; Error = 240 | 8 | 30.0; Total = 2,640 | 15. The overall model is highly significant. However, when examining individual effects, Factor C has F = 0.8 with p = 0.40. What does this tell the engineer about Factor C?

A. Factor C has a highly significant effect on the response and should be included in the model

B. Factor C should be tested at additional levels to determine its significance

C. Factor C does not have a statistically significant effect on the response and may be set to its most economical or convenient level

D. Factor C's nonsignificance invalidates the entire ANOVA and the experiment must be repeated

145. A quality engineer is implementing a riskbased approach to internal auditing. The engineer proposes auditing the heat treatment process quarterly because a recent PFMEA identified it as the highestrisk process in the facility. However, the production manager objects, stating that the process has not had any quality issues in the past year. How should the quality engineer justify the quarterly audit frequency?

A. The engineer cannot justify quarterly audits if the process has been performing well

B. Riskbased audit frequency is determined by the potential consequence of failure, not just historical performance — a highrisk process with severe potential consequences warrants more frequent auditing regardless of recent performance to ensure controls remain effective

C. All processes should be audited at the same frequency regardless of risk level

D. The audit frequency should be based solely on the production manager's assessment of process stability

146. A quality engineer is constructing a uchart for monitoring paint defects per square meter on metal panels. The panel sizes vary between 2 and 8 square meters. The overall average defect rate is $\bar{u} = 1.8$

defects per square meter. For a panel with area = 6 square meters, what are the center line and upper control limit?

A. CL = 1.8, UCL = 1.8 + 3√(1.8/6) = 1.8 + 1.64 = 3.44

B. CL = 10.8, UCL = 10.8 + 3√(10.8) = 10.8 + 9.86 = 20.66

C. CL = 1.8, UCL = 1.8 + 3(1.8) = 7.2

D. CL = 1.8, UCL = 1.8 + 3√(1.8) = 1.8 + 4.02 = 5.82

147. A quality engineer is evaluating a process that has demonstrated consistent statistical control for 12 months. The Cp = 1.85 and Cpk = 1.82. These nearly equal values combined with the high magnitudes indicate which process condition?

A. The process has excellent capability but needs to be recentered to improve Cpk

B. The process is centered between the specification limits with variation well within the tolerance — the nearequality of Cp and Cpk confirms centering, and the high values confirm substantial capability margin

C. The measurement system is not capable of distinguishing between Cp and Cpk for this process

D. The specification limits are too wide relative to the process variation and should be tightened

148. A quality engineer is reviewing the results of a 2^{4-1} fractional factorial experiment (Resolution IV, I = ABCD). The analysis shows that the "AB" effect estimate is large and statistically significant. However, the engineer knows that AB is aliased with CD in this design. How should the engineer determine which interaction — AB or CD — is actually driving the observed effect?

A. The larger effect is always the correct interpretation, so AB should be selected

B. The aliased effects are mathematically identical and there is no way to distinguish them

C. Use process knowledge to determine which interaction is more plausible, or augment the experiment with additional runs (such as a foldover) to dealias the confounded effects

D. Assume both AB and CD are significant and include both in the final model

149. A quality engineer is implementing a quality information system and must determine which quality metrics should be displayed on the management dashboard. Which combination of metrics provides the most balanced view of quality performance for senior leadership?

A. Customer satisfaction trends, internal defect rates, cost of quality by category, process capability trends for critical characteristics, supplier quality performance, and corrective action effectiveness — covering both leading and lagging quality indicators

B. Only customer complaint counts since this is the most important quality metric

C. Only internal defect rates since they reflect current manufacturing quality performance

D. Only cost of quality totals since management is primarily interested in financial metrics

150. A quality engineer is analyzing the OC curve for an acceptance sampling plan and finds that the plan has a very flat OC curve — the probability of acceptance changes slowly across a wide range of incoming quality levels. What does this characteristic indicate about the sampling plan?

A. The plan provides excellent discrimination and clearly separates good lots from bad lots

B. The plan is optimally designed for the application and no modification is needed

C. The flat OC curve indicates poor discrimination between good and bad lots, meaning the plan provides weak protection for both the producer and the consumer

D. The plan has excessively high consumer's risk while providing adequate producer's risk

151. A quality engineer is conducting a management review and needs to present the effectiveness of the corrective action system. Which metric most directly measures CAPA system effectiveness?

A. The average number of days to close corrective action reports

B. The total number of corrective actions initiated during the review period

C. The nonconformity recurrence rate — the percentage of closed corrective actions whose associated problems have recurred within a defined followup period

D. The number of corrective action reports requiring management escalation

152. A quality engineer is implementing errorproofing on an assembly line and must choose between a preventiontype and a detectiontype pokayoke device. The failure mode involves installing a snapfit connector without fully seating it. Which approach is more effective?

A. A detectiontype sensor that alerts the operator after an incomplete seat is detected at the next station

B. A preventiontype fixture design that physically guides the connector into the fully seated position and prevents the assembly from advancing until full engagement is confirmed by a force or displacement sensor

C. A visual inspection station where operators verify connector seating under magnification

D. A statistical sampling inspection at the end of the line to catch unseated connectors

153. A quality engineer is planning a process capability study for a new product characteristic. The process has been running for only one week, and the control chart shows all points within limits with no patterns. The production manager wants the capability study completed immediately to satisfy a customer requirement. What should the quality engineer advise?

A. Proceed with the study since one week of incontrol data is sufficient for a reliable capability assessment

B. The study requires at least one full year of data before capability can be meaningfully assessed

C. Calculate and report Pp and Ppk as preliminary estimates only, while continuing to collect data over a longer period that captures additional variation sources before reporting Cp and Cpk as the definitive capability indices

D. Refuse to conduct any capability assessment until the process has demonstrated stability for at least six months

154. A quality engineer is analyzing a designed experiment and discovers that the residual plot shows a clear pattern — residuals increase systematically as the predicted response increases. This fanshaped pattern indicates which violation of regression assumptions?

A. Nonnormality of the residuals requiring a different probability distribution

B. Multicollinearity among the predictor variables in the experimental design

C. Independence violation caused by autocorrelation in the experimental run order

D. Heteroscedasticity — nonconstant variance of the residuals across the range of predicted values, which affects the reliability of confidence intervals and significance tests

155. A quality engineer is reviewing a supplier scorecard that tracks three metrics: quality (incoming defect rate), delivery (ontime delivery percentage), and cost (price competitiveness index). The supplier scores 99.2% on quality, 87% on delivery, and "competitive" on cost. The quality engineer must make a recommendation to management. Which assessment is most appropriate?

A. The supplier is fully acceptable across all dimensions based on the high quality score

B. The delivery performance of 87% is a concern that warrants investigation and a supplier development discussion, even though quality and cost performance are strong — consistent late deliveries can disrupt production schedules and affect customer commitments

C. The cost metric is the most important and should be the sole basis for the supplier assessment

D. All three metrics should be averaged into a single composite score for the management report

156. In the context of reliability engineering, a parallel redundant system with two identical components each having reliability R = 0.95 has a system reliability of 0.9975. If a third identical component is added in parallel, what is the new system reliability?

A. 0.9975 × 0.95 = 0.9476 because the third component is in series with the parallel pair

B. 0.95 + 0.95 + 0.95 = 2.85 which is impossible, indicating a calculation error

C. 1 $(10.95)^3$ = 1 $(0.05)^3$ = 1 0.000125 = 0.999875, dramatically higher than the twocomponent system

D. 0.95^3 = 0.857 because all three components must function for the system to work

157. A quality engineer is conducting an audit of the calibration program and discovers that a critical pressure gage has been calibrated using a reference standard that is only twice as accurate as the gage being calibrated. Industry best practice typically recommends a minimum accuracy ratio of 4:1 (reference standard to instrument being calibrated). What concern should the auditor raise?

A. The 4:1 ratio is only a recommendation, not a requirement, and a 2:1 ratio is always acceptable

B. The calibration results may be unreliable because the reference standard may not have sufficient accuracy to detect meaningful bias or drift in the gage being calibrated — the narrow accuracy margin reduces confidence in the calibration

C. The reference standard should be replaced with one that has lower accuracy to reduce calibration costs

D. The pressure gage should be scrapped immediately since it was calibrated against an inadequate standard

158. A quality engineer is implementing a quality cost tracking system and must classify the cost of conducting process capability studies. Under which COQ category should this cost be classified?

A. Appraisal costs because capability studies involve measuring and analyzing product data

B. Internal failure costs because capability studies are conducted in response to quality problems

C. External failure costs because capability results are shared with customers

D. Prevention costs because capability studies are proactive analyses that guide process improvement and prevent future quality problems

159. A quality engineer is analyzing a control chart and observes that 15 of the last 20 points fall within Zone C (within $\pm1\sigma$ of the center line) with only 5 points in Zone B and none in Zone A. According to stratification tests, this pattern suggests which condition?

A. The process is operating with exceptional stability and the pattern confirms excellent control

B. The withinsubgroup variation is likely inflated by mixing data from multiple process streams, producing artificially wide control limits that compress all points toward the center line

C. The subgroup size should be reduced to increase the sensitivity of the control chart

D. The control limits should be tightened to bring points into Zones A and B

160. A quality engineer is reviewing the organization's management review process and notices that the review considers customer feedback, audit results, and process performance data, but does not include any consideration of opportunities for improvement. According to ISO 9001:2015, what is missing?

A. Management review is not required to consider improvement opportunities — this is addressed only in Clause 10

B. Improvement opportunities are automatically identified by reviewing the other inputs and do not need explicit consideration

C. Management review should include consideration of opportunities for improvement as a specific output, including decisions and actions related to improvement of the QMS and its processes

D. Only external auditors can identify improvement opportunities during their surveillance audits

161. A quality engineer is evaluating a new inspection technology that uses machine vision to detect surface defects. The system was tested on 200 knowndefective parts and correctly identified 190 as defective (sensitivity = 95%). It was also tested on 300 knowngood parts and correctly identified 285 as good (specificity = 95%). In production, the actual defect rate is 2%. If the system flags a part as defective, what is the approximate probability that the part is actually defective?

A. Approximately 28%, calculated using Bayes' theorem — despite the 95% sensitivity, the low prevalence of defects means most flagged parts are actually false positives

B. 95% because the system has 95% accuracy in identifying defective parts

C. 50% because the system is equally likely to be correct or incorrect on any given flagged part

D. 2% because the probability equals the production defect rate regardless of the test result

162. A quality engineer is implementing SPC on a process that produces customordered products in very small lots — typically 5 to 10 units per order. Each order has different specifications and target values. Standard Xbar charts are not practical because the process target changes with every order. Which SPC approach is most appropriate?

A. Abandon SPC entirely because it is not applicable to lowvolume, highmix production environments

B. Use standard Xbar and R charts with control limits recalculated for each order based on the new specification

C. Use a pchart to track the proportion defective across all orders regardless of specification

D. Use shortrun SPC techniques such as deviation from nominal charts (DNOM) or standardized charts that plot deviations from the target rather than absolute values, enabling continuous monitoring across different specifications

163. A quality engineer is reviewing a process validation report for a sterilization process and discovers that the Performance Qualification (PQ) was conducted using only ideal operating conditions — exactly nominal temperature, humidity, and exposure time. Why is this approach inadequate?

A. PQ should test the process under worstcase conditions and boundary conditions of the validated operating range, not just nominal settings — the process must demonstrate acceptable results across the full range of parameters it may encounter during routine production

B. PQ is only required to verify nominal conditions since operators are trained to maintain exact settings

C. Worstcase testing is only required during Operational Qualification, not Performance Qualification

D. The PQ approach is adequate because nominal conditions represent the most common production scenario

164. A quality engineer is conducting a chisquare test of independence on a 2×2 contingency table with small sample size. One of the expected cell frequencies is 4.2. The quality engineer knows the chisquare approximation requires expected frequencies of at least 5. What alternative test should be used?

A. The chisquare test is still valid because 4.2 is close enough to 5 for practical purposes

B. A twosample ttest should be substituted for the chisquare test

C. Fisher's exact test, which provides exact pvalues for 2×2 tables without relying on the chisquare approximation

D. The sample size should be reduced until all expected frequencies exceed 5

165. A quality engineer is implementing a supplier development program and must decide which suppliers to include. The program has limited resources and can work with only 5 suppliers. The organization has 45 active suppliers. Which selection criteria best optimize the program's impact?

A. Select the 5 suppliers with the longest business relationship to reward loyalty

B. Randomly select 5 suppliers to ensure an unbiased development program

C. Select the 5 suppliers who request participation in the development program

D. Select suppliers based on a combination of strategic importance (critical components, high spend), performance gaps (declining quality or delivery trends), and risk level (singlesource, capability concerns) — targeting suppliers where development will produce the greatest quality and supply chain improvement

166. A quality engineer is analyzing the relationship between two variables and calculates both the Pearson correlation coefficient ($r = 0.45$) and the Spearman rank correlation coefficient ($\rho = 0.82$). The large discrepancy between these two values suggests which condition?

A. The relationship between the variables is strong but nonlinear — Spearman captures monotonic relationships that Pearson (which measures only linear association) misses

B. The Pearson coefficient is always more accurate and the Spearman result should be disregarded

C. Both coefficients are incorrect and a new analysis method is needed

D. The data contains no outliers since both coefficients are positive

167. A quality engineer is reviewing the organization's approach to quality objectives and discovers that the objectives are stated as: "Improve quality" and "Reduce defects." According to ISO 9001:2015, why are these objectives inadequate?

A. Quality objectives must reference specific ISO clause numbers to be valid

B. These objectives are adequate because they clearly state the organization's quality direction

C. Quality objectives should focus only on customer satisfaction, not internal quality metrics

D. Quality objectives must be measurable, consistent with the quality policy, relevant, monitored, communicated, and updated — "improve quality" and "reduce defects" lack specificity, measurability, and defined targets

168. A quality engineer is conducting a process capability study on a filling process and obtains $\bar{x}$ = 250.3 ml, $\hat{\sigma}$ = 1.2 ml, USL = 255 ml, LSL = 245 ml. The quality engineer needs to report both Cp and Cpk. What are the values?

A. Cp = 1.39, Cpk = 1.31

B. Cp = 1.39, Cpk = 1.39

C. Cp = 1.04, Cpk = 0.97

D. Cp = 2.08, Cpk = 1.97

169. A quality engineer is implementing a risk management system and must establish a process for monitoring the effectiveness of implemented risk controls. Which approach provides the most reliable ongoing monitoring?

A. Review risk controls once per year during the management review meeting only

B. Rely on the internal audit program to identify any risk control failures during scheduled audits

C. Define specific risk indicators (both leading and lagging) for each significant risk, establish monitoring frequencies and thresholds, and assign responsibility for periodic verification that controls remain in place and effective

D. Monitor risk controls only when a customer complaint or quality failure triggers an investigation

170. A quality engineer discovers that a critical process parameter has been running at the edge of its validated range for the past month. The parameter has not exceeded the validated limit, but it has been consistently within 2% of the upper boundary. No outofspecification product has been detected. What action is most appropriate?

A. No action is needed because the parameter has not exceeded the validated range

B. Immediately stop production and revalidate the process from scratch

C. Investigate why the parameter is trending toward the boundary, determine whether corrective action is needed to prevent an excursion, and consider whether the current monitoring frequency is adequate to detect a boundary violation in time to prevent nonconforming output

D. Widen the validated range by 5% to provide more operating margin

171. A quality engineer is evaluating the repeatability of a measurement system and discovers that the repeatability standard deviation varies significantly across the measurement range — it is small for small parts and large for large parts. This condition indicates which measurement system property is problematic?

A. Reproducibility, because different operators are measuring differentsized parts

B. Linearity, because the precision of the instrument changes across its operating range, suggesting the instrument performs differently at different points in its measurement range

C. Stability, because the instrument's performance has changed over time

D. Bias, because the instrument reads consistently high or low across all part sizes

172. A quality engineer is preparing a comprehensive quality cost report for the annual management review. The report should demonstrate the economic impact of quality activities. Which presentation format most effectively communicates COQ information to senior management?

A. COQ expressed as a percentage of revenue, broken down by category (prevention, appraisal, internal failure, external failure), with trend data showing changes over the past 35 years and comparison to industry benchmarks where available

B. A detailed spreadsheet listing every individual quality cost transaction for the year

C. Only the total COQ dollar amount without any categorization or trending

D. A pie chart showing the current year's COQ distribution without any historical comparison

173. A quality engineer is analyzing a scatter diagram and calculates $r^2 = 0.64$ for the relationship between curing time and product hardness. A colleague states that 64% of hardness values can be predicted exactly from curing time. Is this interpretation correct?

A. Yes, r^2 directly represents the percentage of data points that fall exactly on the regression line

B. No — the correct interpretation is that curing time explains or accounts for 64% of the observed variation in hardness, not that 64% of values are predicted exactly

C. $r^2 = 0.64$ means the correlation coefficient is 0.64, not the proportion of explained variance

D. The interpretation is correct only if the relationship is perfectly linear with no scatter

174. A quality engineer is implementing a riskbased approach to supplier qualification and must determine the level of qualification rigor required for different types of suppliers. Which factor should most heavily influence the qualification rigor?

A. The supplier's geographic proximity to the manufacturing facility

B. The supplier's annual revenue and number of employees

C. The length of the business relationship between the organization and the supplier

D. The criticality of the supplied component to the final product's safety, function, and regulatory compliance — highercriticality components require more rigorous qualification including onsite audits, process capability verification, and validation evidence

175. A quality engineer is reviewing the results of a 2^{5-2} fractional factorial screening experiment (8 runs, Resolution III). The analysis identifies Factors B and D as potentially significant. However, the engineer is concerned about the aliasing structure. In a Resolution III design, which specific limitation affects the interpretation of these results?

A. Resolution III designs cannot detect any effects and the results are completely invalid

B. Main effects B and D are aliased with twofactor interactions — the observed "Factor B" effect may actually be the twofactor interaction with which B is confounded, requiring a followup experiment to separate the aliased effects

C. The results are fully reliable because screening experiments are immune to aliasing effects

D. Only Factor B is affected by aliasing; Factor D is estimated cleanly in all Resolution III designs

Practice Exam 4: Answer Key and Explanations

1. C — ANOVA compares all group means simultaneously in a single test, controlling the overall Type I error rate at the specified α level. Running multiple pairwise ttests inflates the experimentwise error rate — with three comparisons at α = 0.05 each, the probability of at least one false positive rises to approximately 14%. ANOVA avoids this inflation by testing all groups in one unified analysis.

2. A — A 30minute production run captures only the variation present during that brief window — same operator, same material lot, same environmental conditions. It misses betweenshift, betweenlot, betweenday, and seasonal variation sources that affect longterm process performance. The resulting Cpk overestimates the true longterm capability because the shortterm standard deviation underestimates the total process variation.

3. D — Solving e^((t/15000)^2.8) = 0.95 for t yields approximately 5,700 hours. The characteristic life η = 15,000 hours corresponds to only 36.8% survival probability (R(η) = e^(1) ≈ 0.368), which is far below the 95% target. For wearout distributions (β > 1), the preventive replacement interval must be set well before the characteristic life to ensure high survival probability.

4. B — Deviations from validated process parameters in pharmaceutical manufacturing require immediate containment regardless of visual product appearance. The correct response is to stop production, segregate all product manufactured during the deviation period, formally document the deviation, and conduct an impact assessment — because visual inspection alone cannot confirm that the product meets all quality attributes affected by mixing speed.

5. D — Resolution IV means main effects are aliased only with threefactor and higher interactions (assumed negligible), so main effects are estimated cleanly. However, twofactor interactions are aliased with other twofactor interactions and cannot be individually separated. This is the key practical limitation — if the engineer suspects twofactor interactions are important, a higherresolution design or followup experiment is needed.

6. A — Standard control charts assume that consecutive observations are statistically independent. When significant positive autocorrelation exists, consecutive points follow similar trajectories that the chart interprets as nonrandom patterns — runs, trends, and zone violations — triggering false alarms even when the process is stable. Specialized methods for autocorrelated data are needed.

7. C — A corrective action system that closes actions upon implementation without verifying effectiveness has no mechanism to confirm that the root cause was actually eliminated. The action may have been implemented but may not work — only effectiveness verification through postimplementation data confirms that the problem has been resolved and recurrence has been prevented.

8. B — The paired ttest is correct because each treated half is naturally paired with its untreated half from the same steel panel. The paired design controls for paneltopanel variation in steel composition, surface condition, and other inherent properties by analyzing the withinpanel differences, providing substantially more statistical power than treating the groups as independent.

9. A — The Baldrige Results category evaluates five areas: product and process outcomes, customer results, workforce results, leadership and governance results, and financial and market results. At 450 of 1,000 total points, Results carries the heaviest weight, reflecting the framework's philosophy that organizational approaches matter only to the extent they produce measurable outcomes.

10. D — Specification limits (±0.5 mm from target) and control limits serve fundamentally different purposes. With $\sigma = 0.08$ mm and $n = 5$, the true Xbar control limits would be approximately ±0.107 mm from the center — far tighter than the ±0.5 mm specification limits. Using the wider specification limits renders the chart unable to detect process shifts that would be obvious with proper statistical limits.

11. B — A bimodal distribution almost always indicates that the data comes from two distinct populations — two machines, two cavities, two material lots, two operators, or some other factor creating two different process states. Each population should be analyzed separately because combining them produces misleading statistics that do not accurately represent either population's behavior.

12. C — The loss of three senior engineers represents a direct risk to organizational knowledge — the accumulated process expertise, institutional memory, and tacit knowledge that may not be captured in documented procedures. ISO 9001:2015 Clause 7.1.6 explicitly requires organizations to determine, maintain, and make available the knowledge necessary for process operation.

13. A — Total Gage R&R variance is the sum of all measurement system variance components: repeatability + reproducibility + operator × part interaction = 0.008 + 0.003 + 0.002 = 0.013. Parttopart variance (0.045) is not included in the Gage R&R because it represents the actual variation among parts — which is what the measurement system is trying to detect, not measurement error.

14. D — The R chart signals must be investigated first because they indicate an increase in process variability — the root cause of which could be fixture looseness, material inconsistency, equipment degradation, or measurement system problems. The Xbar chart remaining in control simply means the average has not shifted; it does not invalidate the variability increase signaled by the R chart.

15. C — While RPN provides a numerical ranking, the quality engineer should not rely on RPN alone. The Action Priority method prioritizes by weighting severity most heavily, ensuring that highseverity failure modes — particularly those involving safety — receive attention regardless of their RPN ranking. The 8 highestRPN failure modes and any highseverity items should form the priority list.

16. B — The 15second gap between the 45second cycle time and 60second takt time represents idle time that creates an opportunity for line balancing. Work elements from overloaded downstream stations can be redistributed to this underutilized station, or valueadded tasks such as quality verification or packaging can fill the gap, improving overall line efficiency.

17. D — A high nofaultfound rate typically indicates that the product functions correctly under factory test conditions but fails under field conditions that differ from the factory environment. Noise factors — temperature extremes, humidity, vibration, user behavior patterns, and other field conditions — are not replicated in factory testing, causing intermittent failures that disappear when the product returns to controlled conditions.

18. B — The paired ttest is correct because the same 20 specimens are tested by both laboratories, creating naturally paired observations. The paired design isolates the betweenlaboratory difference by controlling for specimentospecimen variation in material properties — each specimen serves as its own control, and the analysis focuses on the withinspecimen measurement differences.

19. B — Electronic document management systems introduce requirements that paper systems do not have: access security controls to prevent unauthorized modification, backup and recovery procedures to protect against data loss, electronic signature validation to ensure authentication and nonrepudiation, and system validation to confirm the software functions correctly and maintains data integrity.

20. C — When Ppk (0.95) is significantly lower than Cpk (1.40), the overall standard deviation (used for Ppk) is much larger than the withinsubgroup standard deviation (used for Cpk). This gap indicates that significant betweensubgroup variation exists from process instability — shifts, trends, or special causes that add variation beyond the inherent common cause level.

21. D — The SMED methodology's first and most fundamental step is separating internal setup activities (which can only be performed while the machine is stopped) from external setup activities (which can be performed while the machine is still running the previous job). Moving external activities outside the machinestopped window immediately reduces changeover time.

22. A — When an assignable cause has been identified and corrected for an outofcontrol point during the baseline period, standard practice is to remove that subgroup from the control limit calculations. The outofcontrol data inflates the variability estimate and widens the limits, reducing chart sensitivity. Removing it produces limits that accurately reflect the process under normal conditions.

23. C — A capability assessment requires both the process mean and the standard deviation to calculate Cp and Cpk. A Certificate of Analysis reporting only the mean (0.47%) provides no information about the spread of individual measurements around that mean. Without dispersion data, the engineer cannot determine what proportion of the material falls outside the ±0.05% specification tolerance.

24. D — The kanban calculation balances demand, lead time, and container size — but if the safety stock factor does not adequately account for variation in demand rate or replenishment lead time, the system will periodically run out of parts during demand spikes or replenishment delays. Increasing the safety stock factor or the number of kanban cards provides the buffer needed to absorb this variation.

25. D — The DurbinWatson statistic ranges from 0 to 4, with values near 2 indicating no autocorrelation. A value of 0.85 indicates strong positive autocorrelation in the residuals — consecutive residuals tend to be similar. This violates the regression assumption of independent errors and means the standard errors, confidence intervals, and pvalues may be unreliable.

26. A — Preventive maintenance proactively prevents equipment from failing and producing defective output. It is classified as a prevention cost because it represents a deliberate investment in maintaining equipment capability to avoid quality problems — analogous to quality planning, training, and process capability studies, all of which are proactive investments in preventing defects.

27. C — The pvalue of 0.095 exceeds $\alpha = 0.05$, so the null hypothesis ($p \geq 0.03$) is not rejected. Despite the observed sample proportion of 2.0% being below 3.0%, the difference is not statistically significant at the 5% level — the observed reduction could be due to random sampling variation rather than a genuine process improvement. A larger sample might achieve significance.

28. D — Automatic acceptance based solely on probability rating ignores severity entirely. A risk with probability = 2 ("unlikely") and severity = 5 ("catastrophic — potential loss of life") would be automatically accepted under this criterion despite posing a catastrophic threat. Risk acceptance criteria must consider both probability and severity together to prevent dangerous risks from being overlooked.

29. B — After a 30% reduction in process standard deviation, the original control limits are 30% wider than they should be for the improved process. This excess width makes the chart insensitive to process shifts that would be easily detectable with updated, narrower limits. The chart continues to show "in control" even when the improved process has shifted, because the original limits accommodate the shift.

30. A — The acceptance number c = 3 means the lot is accepted if 3 or fewer nonconforming units are found in the sample of 125 units. If 4 or more nonconforming units are found, the lot is rejected. The acceptance number is the threshold that divides the accept decision from the reject decision for each lot inspected under this sampling plan.

31. C — In a 2^{4-1} design with I = ABCD (Resolution IV), main effects are estimated cleanly because they are aliased only with threefactor interactions. However, the six twofactor interactions are aliased in three pairs: AB=CD, AC=BD, and AD=BC. When a significant "AB" effect is found, it could actually be CD — process knowledge is needed to determine which aliased interaction is the real driver.

32. D — Changes in external context (new regulations, market shifts, technology advances) and internal context (organizational restructuring, resource changes, strategic direction shifts) can fundamentally alter the risks and opportunities facing the QMS. Without considering these changes, the management review cannot ensure the QMS remains suitable, adequate, and effective in a changing environment.

33. B — For Instrument X: %GRR ≈ $\sqrt{(4^2 + 18^2)} = \sqrt{(16 + 324)} = \sqrt{340} \approx 18.4\%$. For Instrument Y: %GRR ≈ $\sqrt{(10^2 + 11^2)} = \sqrt{(100 + 121)} = \sqrt{221} \approx 14.9\%$. Instrument Y has the lower total %GRR despite weaker repeatability because Instrument X's very poor reproducibility (18%) dominates its overall performance, making it the worse system overall.

34. A — Deming's Point 3 calls for shifting the quality strategy from postproduction inspection (detecting and sorting defects) to processbased prevention (designing and controlling processes to produce quality output from the start). The practical implication is investing in process design, SPC, errorproofing, and supplier quality rather than relying on endofline inspection to catch defects.

35. C — Cp = (USL LSL)/6σ = (105 95)/(6 × 1.2) = 10/7.2 = 1.39. CPU = (105 101.5)/(3 × 1.2) = 3.5/3.6 = 0.97. CPL = (101.5 95)/(3 × 1.2) = 6.5/3.6 = 1.81. Cpk = min(0.97, 1.81) = 0.97, limited by the upper specification because the process mean (101.5) is shifted above the nominal (100), placing it closer to the USL.

36. B — When two shifts consistently plot on opposite sides of the center line, they have distinctly different process averages that are being masked by the combined chart. Separating them onto individual charts allows each shift's process behavior to be monitored independently, enabling accurate detection of shifts within each population rather than a misleading combined view.

37. D — The three key ANOVA assumptions are: independence of observations (within and between groups), approximate normality of the data within each group (verified by residual plots or normality tests for each group), and homogeneity of variance across groups (tested with Levene's or Bartlett's test). All three should be verified before interpreting the Ftest results.

38. A — Riskbased thinking per ISO 9001:2015 is demonstrated through evidence of application, not documentation alone. The best evidence shows that risks and opportunities were actually identified for relevant processes, actions were planned and implemented to address them, and the effectiveness of those actions was subsequently evaluated — a complete cycle of risk identification, treatment, and verification.

39. C — Six consecutive declining points form a trend that warrants investigation regardless of whether all points remain within control limits. The progressive decline suggests a gradual, systematic change — tool wear gradually increasing a dimension, calibration drift progressively shifting readings, temperature change slowly affecting material properties, or chemical depletion gradually reducing process effectiveness.

40. B — Plan B's larger sample size (n = 200 vs. n = 50) produces a steeper OC curve that more sharply discriminates between good and bad lots. Larger samples provide more information about the lot, reducing the probability of accepting bad lots and rejecting good lots simultaneously. The steeper transition zone between high and low acceptance probability reflects this improved discrimination.

41. D — The fault tree shows an AND gate — both the hydraulic system and the electronic backup must fail simultaneously for loss of braking. For independent failures through an AND gate, the probabilities are multiplied: P(top event) = P(hydraulic fail) × P(electronic fail) = 0.001 × 0.001 = 0.000001 (one in a million). The AND gate dramatically reduces the system failure probability compared to either component alone.

42. A — The "roof" of the House of Quality captures the correlations between engineering characteristics themselves — identifying where improving one characteristic may positively or negatively affect another. For example, increasing material thickness (for strength) may negatively correlate with weight reduction targets. These tradeoffs must be understood and managed during design.

43. C — First calculate the parallel subsystem: $R\_parallel = 1 \quad (10.95)^2 = 1 \quad (0.05)^2 = 1 \quad 0.0025 = 0.9975$. Then combine in series: $R\_system = 0.99 \times 0.9975 = 0.9875$. The parallel redundancy of Components 2 and 3 boosts their combined reliability from 0.95 to 0.9975, but the series Component 1 (0.99) slightly limits the overall system.

44. B — Kirkpatrick Level 1 (satisfaction) does not confirm Level 2 (learning), Level 3 (behavior change), or Level 4 (organizational results). Research consistently shows that participant enjoyment correlates weakly with actual learning. High satisfaction scores are encouraging but do not demonstrate that knowledge was acquired, skills were developed, or work practices changed.

45. D — Qualifying a new supplier involves significant time, cost, process validation, and supply chain risk during the transition. Joint improvement with the existing supplier may resolve the quality issue faster, leverages established process knowledge and relationships, and avoids the disruption and uncertainty of supplier transition. Collaborative improvement is the pragmatic first approach when the supplier relationship is fundamentally sound.

46. A — Redesigning the Oring or its mating groove to be asymmetric makes incorrect installation physically impossible — this is inherently safe design, the highest level of the risk treatment hierarchy. The error is prevented at its source through geometry rather than relying on detection (inspection), visual cues (color coding), or human memory (training), all of which can fail.

47. C — The cchart center line is $\bar{c} = 7.0$, and $UCL = \bar{c} + 3\sqrt{\bar{c}} = 7.0 + 3\sqrt{7.0} = 7.0 + 3(2.646) = 7.0 + 7.94 = 14.94$. The cchart is based on the Poisson distribution, where the standard deviation equals the square root of the mean. The 3sigma upper control limit accounts for the expected random variation in defect counts.

48. B — Without replication, there is no independent estimate of experimental error from withintreatment variation. The normal probability plot of effects is the standard approach — insignificant effects (which represent noise) cluster along a straight line, while significant effects deviate from the line. The insignificant effects collectively serve as the error estimate against which significant effects are identified.

49. D — Each strategy addresses a different aspect of the risk: preventive maintenance (Strategy 3) reduces the probability of failure, a spare machine (Strategy 1) enables rapid recovery if failure occurs, and a contract manufacturing agreement (Strategy 2) provides a contingency for extended outages. Together they provide defense in depth — no single strategy covers all scenarios.

50. A — The calculated chisquare statistic (3.2) is well below the critical value (9.49), so the null hypothesis that the data follows a Poisson distribution is not rejected. The observed defect frequencies are consistent with what would be expected under a Poisson model, supporting the use of Poissonbased control charts (cchart or uchart) for monitoring this process.

51. C — Z_LSL = (24.985 25.003)/0.004 = 0.018/0.004 = 4.5. A Zscore of 4.5 corresponds to an area of essentially zero in the lower tail — approximately 3.4 parts per million. The process mean is so far above the lower specification limit (4.5 standard deviations away) that virtually no output falls below it.

52. B — Process cycle efficiency = valueadded time / total lead time = 45 minutes / (18 days × 24 hours × 60 minutes) = 45/25,920 = 0.0017 = 0.17%. This extraordinarily low efficiency reveals that over 99.8% of lead time is consumed by nonvalueadded activities — waiting in queues, sitting in inventory, being transported — representing a massive improvement opportunity.

53. D — When a transformation is applied to the data to achieve normality, the specification limits must be transformed using the same function. The capability indices are then calculated on the transformed scale using the transformed data distribution and transformed specification limits. Calculating capability on the original nonnormal data produces unreliable indices.

54. A — While the auditors maintain technical independence from the departments they audit, longterm assignment to the same areas can create familiarity that reduces audit effectiveness. Auditors may develop assumptions about what they will find, overlook gradually developing problems, or develop comfortable relationships that inhibit rigorous questioning. Periodic rotation brings fresh perspectives.

55. C — Multicollinearity between X_1 and X_2 (r = 0.94) means they share most of their explanatory information, making their individual regression coefficients unstable and unreliable. The engineer should consider removing one predictor, combining them into a composite variable, or using principal component regression. The overall model predicts well, but attributing effects to individual predictors is problematic.

56. D — The measurement traceability hierarchy flows from the highest international standards down through successive levels of decreasing accuracy to the working instruments used on the production floor. Each level is calibrated against the level above it: international → national (e.g., NIST) → reference standards (organizational) → working standards (production floor).

57. B — The pooled twosample ttest assumes equal population variances. Before pooling the variances, the engineer should verify this assumption using an Ftest ($F = s_1^2/s_2^2 = 15^2/14^2 = 1.15$) or Levene's test. If the variances are significantly different, the Welch ttest (which does not assume equal variances) should be used instead of the pooled version.

58. A — Sterilization is a special process whose effectiveness depends on parameters controlled during the process (gas concentration, temperature, humidity, exposure time) and whose output cannot be fully verified by testing individual units. Sterility testing is destructive and can only be performed on a sample, making it impossible to confirm sterility of every unit in the lot through postprocess testing alone.

59. C — UCL for npchart = $n\bar{p} + 3\sqrt{(n\bar{p}(1\bar{p}))} = 5.0 + 3\sqrt{(200 \times 0.025 \times 0.975)} = 5.0 + 3\sqrt{(4.875)} = 5.0 + 3(2.208) = 5.0 + 6.62 = 11.62$. The npchart plots the count of nonconforming units per sample, and its control limits use the binomial standard deviation formula scaled to the count rather than the proportion.

60. D — The fifth why — the absence of a preventive maintenance schedule for the dust collection system — is the systemic root cause. Addressing this by establishing and implementing a PM schedule prevents filter clogging, which prevents contamination, which prevents fitting blockage, which prevents insufficient lubrication, which prevents bearing failure. The entire causal chain is broken at its source.

61. B — The sample proportion of 2/80 = 2.5% is a point estimate of the lot quality, subject to sampling variability. The true lot quality could be higher or lower. The OC curve for this specific plan (n=80, c=2) shows the probability of lot acceptance at each actual quality level, providing the complete picture of the plan's discrimination capability.

62. A — The reliability improvement from 0.98 to 0.9996 is substantial (a 20fold reduction in failure probability), but the added complexity of redundancy introduces new considerations — false disagreement logic, increased maintenance, and potential commoncause failure modes. A formal risk assessment balancing the reliability gain against the complexity costs is the appropriate engineering approach.

63. D — Correlation (r = 0.87) demonstrates a strong linear association but does not prove that temperature causes the dimensional change. A third variable — perhaps humidity, which correlates with both temperature and dimension — could be the actual driver. A designed experiment, where temperature is deliberately varied while other factors are controlled, would establish the causal relationship needed to justify process compensation.

64. C — ISO 9001:2015 Clause 8.2.1 specifies that customer communication processes must address providing information about products and services, handling enquiries, contracts and orders, obtaining customer feedback including complaints, handling customer property, and establishing specific requirements for contingency actions when relevant.

65. B — For exponential distribution with MTTF = 8,000 hours: P(failure ≤ 1000) = 1 R(1000) = 1 e^(1000/8000) = 1 e^(0.125) = 1 0.8825 = 0.1175 ≈ 11.8%. The linear approximation (1000/8000 = 12.5%) is close but not exact. The exponential formula provides the precise probability of failure during the warranty period.

66. A — With 1,200 units produced between SPC checks and a critical dimension at stake, the exposure risk — the number of potentially nonconforming units that could be produced before a shift is detected — may be unacceptably high. A risk assessment should evaluate the consequences of an undetected shift and determine whether a higher measurement frequency is justified by the risk reduction.

67. D — An andon board providing realtime visibility of machine status, production count versus target, quality metrics, and alert indicators — visible from anywhere in the production area — is the most comprehensive visual management tool. It enables immediate awareness of abnormalities by all personnel without requiring them to check computers, read reports, or ask questions.

68. C — The most critical immediate action is reviewing all 12 lots inspected using the expired procedure to determine whether any lots were affected by the missing dimensional check. Products accepted without the required inspection may include nonconforming units that were not screened. This impact assessment must be completed before any affected product reaches the customer.

69. A — Since Factor C and all interactions involving C are not significant, gas flow rate can be set to the most economical or convenient level without affecting tensile strength. Factors A and B must be optimized jointly because their significant interaction means the optimal level of welding current depends on the travel speed setting — independent optimization would miss the interaction effect.

70. B — Both AIAG MSA acceptability criteria must be met. While %GRR = 9.5% meets the percentage threshold (below 10%), the ndc of 3 falls well below the minimum requirement of 5. The system cannot adequately discriminate among parts across the production variation range, making it unsuitable for SPC and capability analysis despite the acceptable percentage figure.

71. D — A single postimplementation measurement showing improvement is encouraging but insufficient to confirm longterm effectiveness. The improvement could be temporary, or the problem could recur under different conditions. Continued monitoring over a defined period — typically 3 to 6 months — confirms that the improvement is sustained and the original root cause has been permanently eliminated.

72. C — Cost of nonconformance = Internal failure + External failure = $180,000 + $120,000 = $300,000. As a percentage of total COQ: $300,000 / $650,000 = 46.2%. The cost of nonconformance represents the waste generated by quality failures — money spent because things went wrong — as opposed to the cost of conformance (prevention + appraisal), which represents investments in doing things right.

73. A — Performance Qualification (PQ) demonstrates that the process consistently produces output meeting all quality requirements under actual or simulated production conditions using production materials, production personnel, and production procedures. PQ is the final validation stage that proves the process works as intended in the real production environment, not just under controlled OQ test conditions.

74. B — Without a contractual change notification requirement, the supplier may change processes, materials, subsuppliers, or equipment without informing the customer. These changes can alter product characteristics in ways that incoming inspection may not detect immediately. By the time the change is discovered through downstream quality problems, significant quantities of nonconforming material may already be in production or delivered.

75. D — A sharp cutoff at the lower specification limit with a natural tail above the mean strongly indicates that 100% inspection or sorting has removed all values below the LSL. The true process distribution extends below the specification, but the sorting operation creates an artificial boundary that masks the actual proportion of nonconforming output the process produces.

76. C — The choice between a full factorial and a fractional factorial with replication depends on the experimental objectives. The 2^5 full factorial (32 runs) estimates all effects cleanly but provides no independent error estimate without replication. The 2^{5-1} with 2 replicates (32 runs total) provides an error estimate for significance testing but confounds some twofactor interactions. The engineer must prioritize based on the specific questions.

77. A — The risk management process should capture all potential risks including supply chain events. The fact that a "lowrated" risk materialized with significant consequences suggests the assessment may have underrated the probability, underestimated the cascading consequences, or failed to update the assessment as conditions changed. This is a learning opportunity for improving the risk assessment methodology.

78. B — When β = 1.0, the Weibull distribution reduces exactly to the exponential distribution, and the scale parameter η equals the MTBF (mean time between failures). Therefore, MTBF = η = 50,000 hours. The β = 1.0 value indicates a constant failure rate — the component is in the useful life portion of the bathtub curve with random failures.

79. C — Using the overall standard deviation (which includes betweensubgroup variation from special causes) instead of the withinsubgroup estimate produces a larger denominator in the Cpk formula, yielding a smaller index. The engineer has actually calculated Ppk (process performance index) rather than Cpk (process capability index), understating the inherent shortterm capability of the process.

80. D — The Baldrige scoring system evaluates process items on four dimensions: Approach (how the organization addresses the criteria), Deployment (how broadly the approach is applied), Learning (whether evaluation findings are used for improvement), and Integration (whether the approach is aligned with organizational needs and harmonized across the organization).

81. A — ISO 9001:2015 Clause 7.1.5 requires that when monitoring or measuring equipment is found not conforming to requirements, the organization must determine whether the validity of previous measurement results has been adversely affected. Failure to conduct this impact assessment is a nonconformity — products accepted based on readings from outoftolerance instruments may have been incorrectly dispositioned.

82. B — After identifying that 30 minutes of the 75minute changeover consists of activities that can be performed while the machine is running (external setup), those activities are moved outside the machinestopped window. The remaining internal setup — activities that genuinely require the machine to be stopped — takes 75 30 = 45 minutes. SMED Phase 1 alone achieves a 40% reduction.

83. D — On a normal probability plot of effects, points that deviate substantially from the straight line formed by insignificant effects are statistically significant. All four deviating effects (A, B, C, and the AC interaction) should be included in the model because their departure from the noise line indicates they represent real factor effects, not random variation.

84. C — ISO 9001:2015 Clause 6.2 requires quality objectives to be established at relevant functions, levels, and processes. Toplevel plant metrics alone do not ensure that departments and individuals understand their specific contributions to achieving organizational quality goals. Cascaded objectives connect each function's activities to the broader quality strategy, enabling alignment and accountability.

85. A — CPU = (USL $\bar{x}$)/(3$\hat{\sigma}$) = (505 500.2)/(3 × 1.60) = 4.8/4.8 = 1.00. CPL = ($\bar{x}$ LSL)/(3$\hat{\sigma}$) = (500.2 495)/(3 × 1.60) = 5.2/4.8 = 1.08. Cpk = min(1.00, 1.08) = 1.00, limited by the upper specification because the intentional overfill positions the mean closer to the USL.

86. B — Factor P has 8 outgoing arrows and only 1 incoming — it influences many other factors but is itself driven by almost nothing. This makes Factor P a fundamental root cause or driver in the system. Addressing Factor P would produce the most widespread improvement because resolving it would reduce or eliminate the 8 downstream effects it drives.

87. C — A measurement system with 28% GRR adds substantial variation to the observed data. This inflation means the observed process standard deviation is larger than the true process variation, which makes the calculated Cpk appear worse than the actual process capability. If the measurement system were improved, the observed Cpk would likely increase, revealing better true capability.

88. D — In Resolution III screening designs, main effects are aliased with twofactor interactions. A "significant Factor A" result could actually be the twofactor interaction with which A is aliased. A higherresolution followup experiment with only the significant factors provides clean estimates of both main effects and twofactor interactions, confirming which effects are truly driving the response.

89. A — The entire 95% confidence interval (12.48 to 12.52) falls within the specification limits (12.45 to 12.55). This provides strong evidence that the true process mean is within specification — the interval tells us the mean is almost certainly between 12.48 and 12.52, which is comfortably inside the 12.4512.55 specification range.

90. B — Effective incoming material quality tracking requires comprehensive data elements: lot identification, supplier, date, inspection results for each characteristic, disposition, and nonconformance details. This data supports both immediate lotlevel accept/reject decisions and longitudinal supplier performance trending — enabling the quality engineer to identify deteriorating trends before they become critical.

91. C — Increasing power from 80% to 90% increases the required sample size because the test must detect the same 0.5σ difference with higher probability. The approximate increase from 64 to 86 per group reflects the additional observations needed to reduce the Type II error rate from 20% to 10%, maintaining the same sensitivity to the specified effect size.

92. D — Conditionbased maintenance uses actual equipment performance data to determine when maintenance is truly needed, avoiding both the cost of premature maintenance (fixed intervals that service equipment too early) and the risk of delayed maintenance (fixed intervals that miss developing problems). Vibration analysis, oil analysis, and thermography provide objective data for optimizing maintenance timing.

93. A — The Ftest for equality of variances directly addresses whether the standard deviations have changed: $F = s_1^2/s_2^2 = (0.042^2)/(0.028^2) = 0.001764/0.000784 = 2.25$, compared against the critical Fvalue with 24 and 24 degrees of freedom. This test determines whether the observed reduction in variability is statistically significant or could be due to sampling variation.

94. B — Jidoka (autonomation) is the Toyota Production System principle of equipping machines and workers with the ability to detect abnormalities and stop production immediately when a defect or problem is detected. This prevents defective output from being passed downstream, enabling root cause investigation at the point of occurrence. Jidoka combines automation with human intelligence.

95. C — Presenting COQ as a percentage of revenue provides normalization that accounts for business volume changes, making yearoveryear comparisons meaningful. The category breakdown (prevention, appraisal, internal failure, external failure) shows whether the investment strategy is shifting toward prevention. Together, these presentations give management both the trend and the strategy behind it.

96. D — $Cp = (USL\ \ LSL)/6\sigma = 0.20/(6 \times 0.02) = 0.20/0.12 = 1.67$. With a perfectly centered process and $Cp = 1.67$, the specification limits are at ±5σ from the mean. The area beyond ±5σ in a normal distribution is approximately 0.57 ppm (0.6 ppm), representing nearzero defect performance.

97. A — The 35% recurrence rate is the most meaningful effectiveness metric because it directly measures whether corrective actions are achieving their fundamental purpose — permanently eliminating root causes to prevent problem recurrence. A 35% recurrence rate means more than onethird of "corrected" problems come back, indicating systemic weakness in root cause analysis and effectiveness verification.

98. B — CPU = (USL $\bar{x}$)/(3σ) = (10.5 10.1)/(3 × 0.12) = 0.4/0.36 = 1.11. CPL = ($\bar{x}$ LSL)/(3σ) = (10.1 9.5)/(3 × 0.12) = 0.6/0.36 = 1.67. Cpk = min(1.11, 1.67) = 1.11, limited by the upper specification limit. The intentional overfill provides excellent protection against underfilling (CPL = 1.67) but reduces margin on the overfill side.

99. C — Treatment plans without assigned responsible individuals, target completion dates, or defined success criteria have no mechanism to drive implementation. Without accountability (who owns it), urgency (when must it be completed), and measurability (how will success be determined), even wellintentioned plans remain indefinitely on paper, providing no actual risk reduction.

100. C — New forecast = Previous forecast + α(Actual Previous forecast) = 4.5 + 0.2(5.3 4.5) = 4.5 + 0.2(0.8) = 4.5 + 0.16 = 4.66%. Exponential smoothing gives 20% weight to the most recent observation and 80% weight to the accumulated forecast history. The forecast adjusts upward slightly in response to the higherthanexpected actual value.

101. A — A 2^4 full factorial uses all 16 runs to test every treatment combination, estimating all 4 main effects, all 6 twofactor interactions, all 4 threefactor interactions, and the one fourfactor interaction — 15 effects total with zero confounding. No other 16run design extracts as much information because any fractional design sacrifices some effects to confounding.

102. D — With %GRR = 12% falling in the 1030% conditionally acceptable range, the system may be adequate for noncritical applications. However, for a safetycritical dimension where measurementdriven misclassification could have serious consequences, the measurement system should be improved to below 10%. The ndc of 6 is adequate but does not compensate for the elevated %GRR on a safety characteristic.

103. B — Working with the supplier to reduce their process variation addresses the root cause — lottolot variability within the specification range. Merely meeting specification is insufficient when the variation between lots causes downstream instability. Tightening the supplier's internal process targets or requiring higher Cpk values ensures more consistent material that stabilizes the customer's process.

104. C — Lowpriority risks should be retained in the register with periodic monitoring because risk conditions change over time. A supplier rated lowrisk today may become highrisk if their financial condition deteriorates, a geopolitical event affects their region, or demand patterns shift. Removing risks from the register eliminates the visibility and tracking needed to detect these changes.

105. A — Standard practice when establishing initial control limits is to remove subgroups with identified and corrected assignable causes, recalculate the limits from the remaining incontrol data, and verify that all remaining points fall within the revised limits. The outofcontrol data inflates the variability estimate and widens the limits, reducing chart sensitivity to future process changes.

106. D — Failures concentrated in the first 5,000 miles with a sharply declining rate thereafter represent the infant mortality region of the bathtub curve. These early failures are caused by latent manufacturing defects, material flaws, and assembly errors. Burnin testing or environmental stress screening before shipment precipitates these latent defects in the factory, catching them before they reach customers.

107. B — An andon system using colorcoded lights (green/yellow/red) provides immediate, unambiguous, facilitywide visibility of each workstation's status. The simple threestate display enables anyone — operators, supervisors, maintenance, management — to instantly assess the production floor status and respond to problems without verbal communication or computer queries.

108. C — R^2 = SSR/SST = 450/600 = 0.75, meaning the model explains 75% of the total variation in the response. The remaining 25% (SSE/SST = 150/600) is unexplained variation attributed to experimental error and factors not included in the model. R^2 provides a measure of model adequacy but should be evaluated alongside residual diagnostics.

109. D — Without an effectiveness verification field on the corrective action form, the system has no mechanism to confirm that implemented actions actually eliminated the root cause. Corrective actions are closed upon implementation with no followup data confirming that the problem has been resolved. This omission is the most common reason corrective actions fail to prevent recurrence.

110. A — Pareto charts identify what categories dominate but not why they occur. Stratifying each top category by root cause — why deliveries are late, why packages are damaged, why wrong items ship — transforms broad complaint categories into specific, actionable improvement targets. Without this stratification, improvement efforts may address the wrong underlying causes.

111. B — Capability indices require the process to be in statistical control because they describe the inherent, predictable behavior of a stable process. Three unresolved outofcontrol signals indicate that special causes were present during data collection, meaning the data contains variation from both common and special causes. The resulting Cpk does not reliably predict future process performance.

112. C — Demonstrating competence on sample charts before authorization measures Level 2 — Learning: whether participants acquired the knowledge and skills targeted by the training. This practical test confirms they can correctly interpret control chart patterns. Level 3 (Behavior) would assess whether they apply this skill correctly on actual production charts weeks later.

113. A — The 95% confidence interval for the mean difference (0.005, 0.009) includes zero, indicating no statistically significant systematic bias between the two methods. Zero is a plausible value for the true mean difference, meaning any observed difference is consistent with random measurement variation rather than a genuine systematic offset between methods.

114. D — For lowprobability, highconsequence risks, qualitative risk matrices may inadequately represent the true risk because they compress widely different probability levels into broad categories. Quantitative analysis using fault tree or event tree methods provides more precise probability estimates, identifies specific failure pathways, and reveals cascading consequences that qualitative methods may miss.

115. B — The reaction plan "adjust and continue" omits critical steps: stopping the process to prevent further nonconforming output, segregating all material produced since the last known good subgroup, investigating the root cause of the outofcontrol condition, documenting the event and investigation findings, and verifying the adjustment's effectiveness before resuming production.

116. C — Under ANSI/ASQ Z1.4 switching rules, when a specified number of consecutive lots are rejected under tightened inspection (typically 5), inspection is discontinued. The standard requires the source to take corrective action to improve quality before lots may be resubmitted. This protects the customer from continued acceptance of substandard material.

117. A — $\hat{y}$ = 120 0.8(100) = 120 80 = 40 centipoise. The negative slope (0.8) indicates that viscosity decreases by 0.8 centipoise for each 1°C increase in temperature. At 100°C, the predicted viscosity is 40 centipoise. This prediction falls within the model's data range (50150°C), making it a valid interpolation.

118. D — ISO 9001:2015 Clause 4.4 requires comprehensive process determination including inputs, outputs, sequence and interaction of processes, criteria and methods for effective operation and control, resources needed, responsibilities and authorities, risks and opportunities, and evaluation and improvement actions. This thorough process characterization ensures the QMS functions as an integrated system.

119. B — Operatorbypart interaction means that the measurement result depends on the specific combination of which operator measures which part. Some operators may measure certain parts higher or lower than other operators measure the same parts — suggesting that specific part features (surface condition, geometry, accessibility) interact with operator technique to produce inconsistent results.

120. C — Evaluating suppliers solely on incoming defect rates misses critical performance dimensions that collectively determine supplier value and risk. Delivery reliability affects production scheduling, responsiveness to corrective actions indicates quality system maturity, cost competitiveness impacts profitability, and communication effectiveness enables collaborative problemsolving. A comprehensive scorecard captures the full picture.

121. D — In a series system, the component with the lowest reliability limits overall system performance most severely. The actuator (R = 0.990) is the weakest link. Improving it from 0.990 to 0.995 would increase system reliability from 0.984 to 0.989 — a larger gain than the same absolute improvement applied to either of the higherreliability components.

122. A — When a corrective action is identified through root cause analysis, the PFMEA should be updated to reflect the new control measure. The Detection rating should be reassessed based on the new temperaturemonitored storage unit's capability to prevent the failure. This FMEA update closes the loop between corrective action and proactive risk management.

123. C — An Sshaped departure from linearity on a normal probability plot — curving up at the right end and down at the left end — indicates heavier tails than a normal distribution. Extreme values (both high and low) occur more frequently than the normal model predicts. This leptokurtic condition may affect the reliability of confidence intervals and hypothesis tests that assume normality.

124. B — Production leveling (heijunka) smooths the flow of work by distributing different products evenly across the production schedule rather than producing in large batches. This eliminates the feastorfamine delivery pattern from upstream processes, enabling the downstream cell to maintain continuous onepiece flow without the disruption of batch arrivals.

125. D — ISO 14971 requires risk management throughout the entire product lifecycle — not just during design. The failure to update the risk analysis with postmarket surveillance data since production began, and the failure to identify the new complaintgenerating failure mode in the risk management file, represent noncompliance with the standard's lifecycle risk management requirements.

126. A — Specification limits define product requirements; control limits define the expected range of process behavior. Using specification limits on a control chart masks process shifts that occur within the specification range. The process can shift significantly — degrading quality and approaching specification limits — without triggering any signal on the chart, defeating the purpose of SPC.

127. B — Measurement traceability requires an unbroken chain of comparisons from the working instrument through reference standards to national or international standards, with each link documented. Calibration records that do not identify the reference standards used or their traceability status cannot demonstrate this chain, violating the fundamental traceability requirement of ISO 9001 Clause 7.1.5.

128. C — The hierarchy principle in regression and DOE states that when an interaction term (AB) is included in a model, both parent main effects (A and B) must also be included — even if the main effects are not individually significant. This principle ensures the model is properly specified and maintains the mathematical structure needed for correct interpretation of the interaction.

129. D — ISO 9001:2015 requires that audit results be reported to relevant management (Clause 9.2.2) and that management review inputs include results of audits (Clause 9.3.2). Reporting findings only to the department manager without escalation to top management and without inclusion in management review prevents the organization's leadership from having visibility into systemlevel quality issues.

130. A — A spike in the moving range between observations 14 and 15 indicates that something changed abruptly between these two consecutive measurements — even though both individual values may fall within the Ichart limits. The MR chart detects sudden changes in the shortterm variability pattern, and a point above the UCL warrants investigation of what caused the unusual magnitude of change.

131. B — Power is maximized by: (1) using a onesided test, which concentrates all rejection probability in the direction of interest; (2) using $\alpha = 0.05$ rather than 0.01, which provides a wider rejection region; and (3) using the largest affordable sample size, which reduces the standard error. This combination maximizes the probability of detecting the 5 MPa improvement.

132. C — Individual component tolerances do not guarantee assembly fit. Tolerance stackup analysis evaluates the cumulative effect of all component tolerances in the assembly chain. Even when every component is within its own tolerance, the worstcase combination of tolerances can produce an assembly that exceeds the overall assembly tolerance — five components each at the high end of their tolerance simultaneously.

133. D — Spending 65% of the quality budget on inspection and testing (appraisal) while devoting only 10% to prevention indicates a detectionheavy strategy. The organization is investing heavily in finding defects after they are created rather than preventing them from occurring. Shifting resources from appraisal to prevention would reduce defect creation, eventually lowering the need for inspection.

134. A — A statistically significant difference between the average response at the factorial corners (82.4) and the center points (78.1) indicates curvature — the relationship between at least one factor and the response is nonlinear. The twolevel factorial design assumes linear relationships; the significant curvature test reveals this assumption is violated and a model with quadratic terms is needed.

135. B — When a risk cannot be avoided, reduced, or transferred, formal risk acceptance is the remaining option. Acceptance must be a deliberate, documented decision approved by management with appropriate authority, accompanied by monitoring to detect changes in the risk level and contingency plans for responding if the risk event occurs. Acceptance is not ignoring the risk — it is consciously retaining it.

136. C — R(20,000) ≈ 0.61, meaning approximately 39% of bearings fail before the scheduled replacement — the interval may need to be shortened depending on the consequence of failure. A reliability of 0.613 means approximately **61.3% of bearings survive** to 20,000 hours, and approximately **38.7% fail before** the scheduled replacement. Whether this failure rate is acceptable depends entirely on the consequences of an in-service bearing failure — if a bearing failure could cause safety hazards, equipment damage, or costly unplanned downtime, the 39% pre-replacement failure rate is unacceptably high and the interval should be shortened. If the consequence is minor, the current interval may be tolerable.

137. D — Outliers must be investigated before any exclusion decision. If the outlier has an identified assignable cause (measurement error, wrong material, equipment malfunction) that has been corrected, exclusion is justified because the data point does not represent normal process behavior. If no cause is found, the data may represent legitimate process output and should be retained in the analysis.

138. A — A discrepancy between the master document list (showing Rev C) and the electronic system (containing Rev D) indicates a failure in the document control process. The master list must accurately reflect the current revision status of all controlled documents at all times. This synchronization failure means users consulting the master list may not know that a newer revision exists.

139. B — When a significant interaction exists between Machine and Shift, the effect of Shift depends on which Machine is running. The nonsignificant main effect of Shift is misleading because it averages across machines — at some machines, Shift may have a substantial effect while at others it may have none. The significant interaction overrides the main effect interpretation.

140. B — Demonstrating continual improvement requires evidence of measurable changes over time: trending quality objectives showing improvement, process performance metrics showing positive trajectories, customer satisfaction data showing gains, and documented improvement actions with verified results. Statements of commitment and activity counts do not demonstrate that actual improvement has been achieved.

141. D — With p = 0.003, the AndersonDarling test strongly rejects the normality assumption. The data is significantly nonnormal, and standard Cp/Cpk formulas (which assume normality) will produce unreliable results. The engineer should investigate the source of nonnormality, consider data transformation, or use nonparametric capability methods appropriate for nonnormal distributions.

142. A — Seven approval signatures, many from managers with no technical knowledge of the purchase content, represent overprocessing waste. These nonvalueadding steps consume 714 days of processing time without improving the quality or accuracy of the purchase decision. Streamlining to only the signatures that add substantive review value would dramatically reduce lead time.

143. B — For a characteristic with a Cpk target of 1.33, the measurement system must be capable enough to reliably distinguish capable from incapable processes. Instrument Q's 6% GRR provides substantially better measurement precision, enabling more accurate Cpk calculations and more reliable accept/reject decisions. The additional $13,000 investment is justified by the improved decision quality.

144. C — Factor C's Fvalue of 0.8 with p = 0.40 indicates it does not have a statistically significant effect on the response. This means Factor C can be set to whatever level is most economical, convenient, or practical — its setting will not meaningfully affect product quality. This is a valuable practical finding that simplifies process optimization.

145. D — Riskbased audit frequency considers the potential consequence of failure, not just historical performance. A highrisk process with severe potential consequences (heat treatment affecting material properties and safety) warrants frequent auditing to verify that controls remain effective. Past performance provides some confidence but does not guarantee continued performance — controls can degrade silently.

146. A — For the uchart: $CL = \bar{u} = 1.8$ defects per square meter. $UCL = \bar{u} + 3\sqrt{(\bar{u}/n)} = 1.8 + 3\sqrt{(1.8/6)} = 1.8 + 3\sqrt{(0.30)} = 1.8 + 3(0.5477) = 1.8 + 1.64 = 3.44$. The uchart normalizes defect counts by inspection unit size, and the control limits adjust for each panel's area — larger panels produce narrower limits because the rate estimate is more precise.

147. B — When Cp (1.85) and Cpk (1.82) are nearly equal and both are high, the process is both wellcentered between the specification limits and has variation well within the tolerance. The small difference (0.03) indicates minimal offcenter operation, and the high values (>1.67) indicate substantial capability margin — this is an excellent process by any standard.

148. C — In a Resolution IV design, AB is aliased with CD and neither can be individually estimated. Process knowledge should be the first resort — if engineering judgment strongly favors one interaction over the other, that interpretation may be acceptable. If ambiguity remains, augmenting the experiment with a foldover or complementary fraction creates the full factorial, cleanly separating all twofactor interactions.

149. A — A balanced management dashboard should include both leading indicators (process capability trends, supplier quality metrics) and lagging indicators (customer satisfaction, defect rates, warranty costs). The combination of customerfacing metrics, internal quality metrics, financial quality costs, process performance data, supply chain quality, and CAPA effectiveness provides comprehensive visibility into all dimensions of quality performance.

150. D — A flat OC curve means the probability of acceptance changes slowly across a wide quality range — the plan accepts good lots and bad lots with similar probabilities. This provides poor discrimination, offering weak protection for both the producer (good lots may be rejected) and consumer (bad lots may be accepted). A steeper curve, achieved through larger sample sizes, improves discrimination.

151. C — The nonconformity recurrence rate directly measures whether corrective actions are achieving their fundamental purpose — permanently eliminating root causes. Closure speed (days to close) measures process efficiency but not effectiveness. A system that closes actions quickly but has a 40% recurrence rate is efficient at generating paperwork but ineffective at preventing problems.

152. B — A preventiontype fixture that physically guides the connector into full engagement and prevents advancement until confirmed by a force/displacement sensor is more effective than any detection method. It prevents the defect from occurring rather than detecting it afterward. The force sensor provides realtime verification, and the physical guidance reduces dependence on operator skill.

153. A — One week of incontrol data captures only very shortterm variation. Preliminary Pp and Ppk values can be calculated and reported with appropriate caveats, but they should not be presented as definitive capability indices. Continued data collection over a longer period — capturing shifttoshift, lottolot, and environmental variation — is needed before reporting Cp and Cpk as representative of true process capability.

154. D — A fanshaped residual pattern where residuals increase with predicted values indicates heteroscedasticity — nonconstant variance. This violates the constantvariance assumption of ordinary least squares regression, making the standard errors of coefficients unreliable. Confidence intervals may be too narrow or too wide, and pvalues may be misleading. Weighted least squares or variancestabilizing transformations may be needed.

155. B — Despite strong quality (99.2%) and competitive cost, the 87% delivery performance represents a significant concern. Consistent late deliveries disrupt production schedules, create expediting costs, and risk missed customer commitments. A supplier development discussion focused on identifying and addressing the root causes of delivery failures is warranted even when quality performance is excellent.

156. C — For three identical components in parallel: $R\_system = 1 \ \ (1R)^3 = 1 \ \ (0.05)^3 = 1 \ \ 0.000125 = 0.999875$. Adding a third parallel component reduces the failure probability from 0.0025 (two components) to 0.000125 (three components) — a 20fold improvement. Each additional parallel component dramatically reduces the probability that all components fail simultaneously.

157. A — The 4:1 accuracy ratio is a widely accepted guideline that ensures the reference standard has sufficient precision to meaningfully detect bias and drift in the instrument being calibrated. With only a 2:1 ratio, the reference standard's own uncertainty becomes a significant fraction of the measurement, reducing confidence that the calibration result truly reflects the instrument's performance.

158. D — Process capability studies are proactive analyses that characterize process performance relative to specifications, identify capability gaps, and guide process improvement decisions. They prevent quality problems by revealing where processes are marginal or incapable before those deficiencies result in nonconforming output. This proactive, preventive nature places them in the prevention cost category.

159. B — When nearly all points cluster within Zone C with virtually none in Zones A or B, the chart exhibits stratification. This pattern typically occurs when subgroups contain data from multiple process streams with different means, inflating the withinsubgroup variation estimate and producing artificially wide control limits that compress all subgroup averages toward the center line.

160. C — ISO 9001:2015 Clause 9.3.3 requires that management review outputs include decisions and actions related to opportunities for improvement. Simply reviewing customer feedback, audit results, and process data without explicitly identifying and acting on improvement opportunities fails to generate the forwardlooking outputs that drive continual improvement of the QMS.

161. A — Using Bayes' theorem: P(defective|flagged) = P(flagged|defective) × P(defective) / P(flagged). P(flagged) = (0.95 × 0.02) + (0.05 × 0.98) = 0.019 + 0.049 = 0.068. P(defective|flagged) = 0.019/0.068 ≈ 0.28 or 28%. Despite 95% sensitivity, the low 2% prevalence means most flagged parts are false positives — a critical consideration for automated inspection system design.

162. D — Shortrun SPC techniques such as DNOM (deviation from nominal) charts plot the deviation of each measurement from its orderspecific target value rather than the absolute measurement. This standardization enables continuous monitoring across different specifications on a single chart, making SPC applicable to lowvolume, highmix environments where traditional charts with fixed targets are impractical.

163. B — Performance Qualification must demonstrate that the process produces acceptable results under the full range of conditions it may encounter during routine production — including worstcase parameter combinations, not just nominal settings. Testing only at nominal conditions proves the process works under ideal circumstances but does not verify performance at the boundaries of the validated operating range.

164. C — Fisher's exact test provides exact pvalues for 2×2 contingency tables without relying on the chisquare approximation, which becomes unreliable when expected cell frequencies fall below 5. For small sample sizes with expected frequencies below the chisquare threshold, Fisher's exact test is the appropriate alternative that provides valid inference.

165. D — With limited resources for 5 suppliers out of 45, the selection should maximize impact by targeting suppliers where development produces the greatest quality and supply chain improvement. This means focusing on strategically important suppliers (critical components, high spend) with identified performance gaps or elevated risk levels — not random selection, seniority, or selfnomination.

166. A — Pearson's r measures only linear association, while Spearman's ρ captures any monotonic relationship (consistently increasing or decreasing, whether linear or curved). The large discrepancy (r = 0.45 vs. ρ = 0.82) indicates a strong monotonic but nonlinear relationship — the variables move together consistently but not in a straightline pattern.

167. A — ISO 9001:2015 Clause 6.2 requires quality objectives to be measurable, consistent with the quality policy, monitored, communicated, and updated as appropriate. Vague objectives like "improve quality" lack specific targets, measurement methods, timeframes, and accountability. Effective objectives specify what will be measured, the target value, the deadline, and the responsible party.

168. A — Cp = (USL LSL)/6σ = (255 245)/(6 × 1.2) = 10/7.2 = 1.39. CPU = (255 250.3)/(3 × 1.2) = 4.7/3.6 = 1.31. CPL = (250.3 245)/(3 × 1.2) = 5.3/3.6 = 1.47. Cpk = min(1.31, 1.47) = 1.31. The Cpk is limited by the upper specification because the process mean (250.3) is slightly above the midpoint (250.0).

169. C — Effective risk control monitoring requires defined risk indicators (both leading and lagging), established monitoring frequencies based on risk severity, threshold values that trigger escalation or action, and assigned responsibility for periodic verification. This structured approach provides systematic, ongoing assurance that controls remain in place and effective, rather than relying on periodic audits or reactive investigation.

170. C — A process parameter consistently running within 2% of its validated boundary is a warning signal that warrants proactive investigation. Although no excursion has occurred, the trending behavior suggests the parameter may eventually exceed the boundary. The engineer should investigate the cause of the drift, determine whether adjustment is needed, and evaluate whether the monitoring frequency provides adequate early warning.

171. B — When repeatability varies systematically across the measurement range — small for small parts and large for large parts — the instrument's precision is not constant across its operating range. This is a linearity issue in the precision dimension (as opposed to bias linearity). The instrument may need rangespecific calibration or may be inadequate for measurements at the high end of its range.

172. A — The most effective COQ presentation for senior management normalizes costs as a percentage of revenue (enabling comparison across time periods with different volumes), breaks down costs by category (showing the investment strategy), provides trend data over 35 years (demonstrating the direction and rate of improvement), and includes industry benchmarks where available for context.

173. C — The correct interpretation of r^2 = 0.64 is that 64% of the observed variation in hardness is explained by (or accounted for by) the linear relationship with curing time. The remaining 36% is due to other factors or random variation. R^2 does not mean 64% of values are predicted exactly — individual predictions have uncertainty described by the standard error of the estimate.

174. D — The criticality of the supplied component to the final product's safety, function, and regulatory compliance should most heavily influence qualification rigor. A supplier of a safetycritical structural component requires far more rigorous qualification — including onsite audits, process capability evidence, and validation documentation — than a supplier of noncritical packaging materials.

175. B — In Resolution III designs, main effects are aliased with twofactor interactions. The observed "significant Factor B" effect actually represents B plus its aliased twofactor interaction — the design cannot distinguish between them. A followup experiment at higher resolution with only the significant factors would cleanly separate main effects from twofactor interactions, confirming which effects are truly driving the response.