PRACTICE EXAM 6: ASQ CQE SIMULATION (175 QUESTIONS)

1. A quality engineer is analyzing a process that produces stainless steel tubing. The wall thickness specification is 2.00 ± 0.15 mm. Data from 30 subgroups of size 5 yields $\bar{\bar{x}}$ = 2.03 mm and $\hat{\sigma}$ = 0.06 mm. The quality engineer calculates both Cp and Cpk. Which statement correctly interprets the relationship between these two indices for this process?

A. Cp = Cpk because the process mean is at the nominal specification value

B. Both Cp and Cpk exceed 2.0, indicating a Six Sigma process

C. Cp = 0.30/0.36 = 0.83 and Cpk = min(0.12/0.18, 0.18/0.18) = 0.67 — the Cpk is lower than Cp because the process mean is shifted toward the upper specification limit

D. Cp and Cpk cannot be calculated without knowing the sample size per subgroup

2. A quality engineer is tasked with determining whether a batch of incoming aluminum extrusions meets the hardness specification of 75 ± 5 HRB. The population standard deviation is unknown. A random sample of 16 extrusions yields $\bar{x}$ = 73.2 HRB and s = 3.1 HRB. At α = 0.05 (twosided), the engineer tests H_0: μ = 75 versus H_1: $\mu \neq 75$. The calculated tstatistic is t = (73.2 75) / (3.1/√16) = 2.32. The critical tvalue with 15 df is ±2.131. What is the correct decision?

A. Reject H_0 because |t| = 2.32 exceeds the critical value of 2.131, indicating the batch mean differs significantly from the specification nominal of 75 HRB

B. Fail to reject H_0 because the sample mean of 73.2 is within the specification range of 7080 HRB

C. The test is invalid because the population is not confirmed to be normally distributed

D. Fail to reject H_0 because the tstatistic is negative, indicating the batch mean is below the target

3. A reliability engineer is designing a safety system that must achieve a system reliability of at least 0.9999 over a 10,000hour mission. Each individual component has a reliability of 0.99 over the same period. A singlecomponent design yields R = 0.99 — far below the target. The engineer adds components in parallel. How many identical parallel components are needed to achieve the 0.9999 target?

A. Two parallel components: R = 1 $(0.01)^2$ = 0.9999, which exactly meets the target

B. Three parallel components: R = 1 $(0.01)^3$ = 0.999999, exceeding the target

C. Four parallel components are the minimum required for any safetycritical application

D. Three parallel components: R = 1 $(10.99)^3$ = 1 0.000001 = 0.999999, which provides margin above the 0.9999 requirement

4. A quality engineer is implementing a lean production system and maps the current state value stream for a machined component. The map reveals: total lead time = 14 days, valueadded processing time = 52 minutes, 7 inventory storage points averaging 2 days each, and 3 inspection stations. The quality engineer proposes eliminating two of the three inspection stations. The production manager objects, arguing that fewer inspections will increase defects reaching the customer. How should the quality engineer frame this proposal?

A. The inspection stations should be maintained because they are the only barrier against customer defects

B. The inspections should be replaced with more rigorous final testing to catch all defects at the end

C. All inspections should be eliminated because lean philosophy prohibits any form of inspection

D. The two inspection stations targeted for elimination should be replaced with errorproofing at the source operations — preventing defects rather than detecting them — while the remaining inspection is retained until prevention effectiveness is confirmed

5. A quality engineer is reviewing the results of a 2^{5-2} fractional factorial design (8 runs, Resolution III). The defining relations are I = ABD and I = ACE. The analysis identifies Factor C as having a large,

statistically significant effect. Before concluding that Factor C is the driver, what must the engineer consider?

A. In this Resolution III design, the main effect of C is aliased with twofactor interactions — specifically, C is aliased with AE (from I = ACE); the observed effect could be due to Factor C, the AE interaction, or some combination, requiring a followup experiment to separate them

B. Factor C can be confidently identified as significant because main effects are never aliased in Resolution III designs

C. The aliasing structure is irrelevant for screening experiments since all identified effects are confirmed automatically

D. Only factors with effects larger than 20% of the mean response can be considered significant

6. A quality engineer discovers that the organization's corrective action system has 120 open corrective actions, with 65 past their due dates. The quality manager proposes closing all overdue CAs and resetting the system. Why is this approach fundamentally wrong?

A. Closing overdue CAs is acceptable as long as new due dates are assigned after closure

B. Mass closure without regard to implementation status would only create a temporary paperwork improvement

C. The overdue CAs should be transferred to a separate tracking system for historical reference

D. Mass closure eliminates accountability — problems that have not been resolved will continue to produce nonconforming output; the correct approach is to prioritize the overdue CAs by risk, assign clear ownership and realistic deadlines, and escalate resource constraints to management

7. A quality engineer needs to compare the tensile strength of welds made by three different welders to determine whether there are significant differences in their work quality. Each welder produces 8 test specimens. The oneway ANOVA yields $F = 6.82$. The critical Fvalue at $\alpha = 0.05$ with (2, 21) degrees of freedom is 3.47. The ANOVA is significant. Which followup analysis is needed?

A. Repeat the ANOVA with more specimens per welder to confirm the result

B. A multiple comparison procedure such as Tukey's HSD to identify which specific welder pairs produce significantly different mean strengths

C. A chisquare test to determine which welder produces the most defective welds

D. An Ftest comparing the variances of the three welders' results pairwise

8. A quality engineer is reviewing a process FMEA for an adhesive bonding operation. The team assigns the following ratings to a "bond delamination" failure mode: Severity = 9 (safety impact), Occurrence = 2 (very low probability based on historical data), Detection = 3 (reliable automated ultrasonic inspection). The traditional RPN = 9 × 2 × 3 = 54. A second failure mode — "cosmetic blemish" — has Severity = 3, Occurrence = 7, Detection = 5, yielding RPN = 105. Under the traditional RPN approach, the cosmetic blemish would receive higher priority. Why does the AIAG/VDA Action Priority method disagree?

A. The AP method uses a different multiplication formula that produces higher values for safetyrelated failures

B. The AP method always assigns equal priority to all failure modes regardless of their ratings

C. The AP method weights severity most heavily — a Severity of 9 (safety) places the bond delamination at high priority regardless of the moderate RPN, because the consequences of being wrong about occurrence or detection for a safety failure are catastrophic

D. The AP method ignores Detection ratings entirely and uses only Severity and Occurrence

9. A quality engineer is implementing SPC on a chemical batch process where each batch yields a single viscosity measurement. Batches are produced every 4 hours. The engineer has been plotting data on an IMR chart for 3 months (approximately 180 data points). The chart shows stable behavior with no outofcontrol signals. However, the engineer notices that the distribution of individual values is significantly rightskewed. What is the primary concern with using standard IMR chart limits on this nonnormal data?

A. The standard 3sigma limits based on normal distribution assumptions may produce asymmetric risk — the upper limit may be too tight (causing false alarms) while the lower limit may be too loose (missing real shifts), or vice versa, because the skewed distribution does not match the symmetric limits

B. Nonnormality has no effect on IMR chart performance under any circumstances

C. The moving range chart is unaffected by nonnormality even though the individuals chart is

D. The engineer should switch to an Xbar chart to leverage the central limit theorem

10. A quality engineer discovers that a process improvement reduced the standard deviation from σ_1 = 0.20 mm to σ_2 = 0.12 mm while the process mean remained unchanged at μ = 25.00 mm. The specification is 25.00 ± 0.50 mm. What is the effect on the Cp before and after the improvement?

A. Cp_before = 1.67, Cp_after = 1.39 — the improvement actually decreased capability

B. Cp remains unchanged because only the mean affects the Cp calculation

C. Cp_before = 0.83, Cp_after = 1.39 — the capability improved but remains below 1.67

D. Cp_before = 1.0/(6 × 0.20) = 0.83, Cp_after = 1.0/(6 × 0.12) = 1.39 — the variation reduction improved Cp from below 1.0 to well above 1.0, demonstrating that the process has moved from incapable to capable

11. A quality engineer is conducting a supplier audit and examines the supplier's nonconforming material control process. The engineer discovers that nonconforming material is stored in a locked cage with appropriate labeling, but there are no records documenting the disposition decisions, who authorized the dispositions, or the rationale for each decision. What quality system element is deficient?

A. The physical segregation of nonconforming material is insufficient and requires a separate building

B. The nonconforming material documentation is deficient — while physical segregation is adequate, the lack of disposition records means there is no traceability of decisions, no accountability for who authorized each disposition, and no documented rationale that could be reviewed during audits or investigations

C. The supplier should implement automated sorting equipment to replace manual segregation

D. The locked cage is excessive — a simple tagging system is sufficient for nonconforming material control

12. A quality engineer must select a control chart for monitoring a process that produces complex electronic assemblies. Each assembly undergoes a comprehensive functional test that checks 200 individual test points. The engineer wants to track the total number of test point failures per assembly. The number of assemblies tested per hour varies from 3 to 8. Which control chart is most appropriate?

A. npchart because it tracks the number of nonconforming assemblies per constant sample

B. pchart because it tracks the proportion of assemblies that fail the overall test

C. uchart because the number of test failures per assembly must be normalized by the varying number of assemblies tested per period

D. cchart because it tracks the count of test failures per individual assembly

13. A quality engineer is implementing a risk management system and must establish risk acceptance criteria. The quality team proposes using a 5×5 risk matrix with three zones: green (acceptable — no action required), yellow (tolerable — monitor and review), and red (unacceptable — mandatory treatment). A colleague argues that any identified risk should require formal treatment regardless of its position on the matrix. Why is this "treat everything" approach impractical?

A. Treating every identified risk regardless of significance diverts limited resources from highpriority risks, potentially leaving the most dangerous risks underresourced while consuming effort on trivial risks that pose negligible threat — risk management must prioritize to be effective

B. All risks must be treated equally regardless of their severity or probability

C. The "treat everything" approach is actually the recommended best practice under ISO 31000

D. Risk matrices are inherently unreliable and should not be used for any prioritization

14. A quality engineer is analyzing a designed experiment and the team debates whether to include a blocking variable. The experiment involves 4 factors at 2 levels (2^4 full factorial, 16 runs) and must be conducted over two days because only 8 runs can be completed per day. Conditions may differ between days. The engineer decides to confound the fourfactor interaction ABCD with the day effect. Why is this an acceptable design choice?

A. The fourfactor interaction ABCD is typically negligible in industrial experiments, so confounding it with the day effect sacrifices essentially no useful information while accounting for potential daytoday variation in the analysis

B. Fourfactor interactions are the most important effects in any experiment and should never be confounded

C. Blocking is unnecessary because the day effect can be eliminated through randomization alone

D. The ABCD interaction should be confounded with a main effect rather than the day variable

15. A quality engineer calculates the reliability of a series system with four components: $R_1 = 0.99$, $R_2 = 0.98$, $R_3 = 0.97$, $R_4 = 0.96$. The system reliability is $R_{sys} = 0.99 \times 0.98 \times 0.97 \times 0.96 = 0.904$. Management requests that system reliability be improved to at least 0.95. The engineer proposes adding a parallel redundant component to the least reliable component (R_4). With the redundancy, what is the new reliability of the R_4 subsystem, and does the system meet the 0.95 target?

A. $R_{4\_new} = 1(10.96)^2 = 0.9984$; $R_{sys\_new} = 0.99 \times 0.98 \times 0.97 \times 0.9984 = 0.939$, still below 0.95

B. $R_{4\_new} = 0.96^2 = 0.9216$; R_{sys_new} drops because redundancy reduces reliability in series systems

C. $R_{4\_new} = 0.96 + 0.96 = 1.92$, which exceeds 1.0 and is mathematically impossible

D. $R_{4\_new} = 0.9984$; $R_{sys\_new} = 0.99 \times 0.98 \times 0.97 \times 0.9984 = 0.939$, which does not meet the 0.95 target — additional improvements to other components or additional redundancy are needed

16. A quality engineer is implementing a calibration program and must decide how to handle a situation where a micrometer is found out of tolerance during its scheduled calibration. The micrometer reads 0.008 mm high (positive bias) against a 25.000 mm reference standard. The instrument tolerance is

±0.005 mm. The micrometer has been in continuous use since its last calibration 6 months ago. What is the most critical action?

A. Simply recalibrate the micrometer and return it to service

B. Replace the micrometer with a new instrument and dispose of the outoftolerance one

C. Conduct an impact assessment — review all measurement records from the past 6 months to identify products that were measured with this micrometer, determine whether the +0.008 mm bias could have caused incorrect accept/reject decisions, and assess whether any accepted product may actually be nonconforming

D. Document the outoftolerance condition in the calibration record but take no further action

17. A quality engineer is reviewing an organization's approach to design verification and validation. The design team states that they perform extensive computeraided simulation (finite element analysis, thermal modeling, computational fluid dynamics) and consider this sufficient for both verification and validation. What is the fundamental limitation of this approach?

A. Computer simulations are completely unreliable and should never be used in design processes

B. Simulations are only useful for preliminary design screening and cannot provide any verification evidence

C. Computer simulations are unacceptable under ISO 9001 and must be replaced entirely with physical testing

D. Simulations can verify that the design meets its own mathematical models and specifications, but they cannot validate that the product meets actual user needs in the realworld use environment — validation requires testing with representative products under conditions that simulate actual use

18. A quality engineer is analyzing the Cost of Quality for a product line and discovers: Prevention = $80,000 (10%), Appraisal = $160,000 (20%), Internal Failure = $320,000 (40%), External Failure = $240,000 (30%). Total COQ = $800,000. The plant manager asks the engineer for a strategic recommendation. Which action best aligns with COQ optimization principles?

A. Significantly increase prevention investment (quality planning, training, errorproofing, DOE) which should produce a disproportionately larger reduction in both internal and external failure costs — shifting the quality strategy from detectionbased to preventionbased

B. Reduce appraisal costs by eliminating half the inspection stations to lower total COQ

C. Increase external failure spending by improving warranty response time and customer service

D. Maintain current spending levels because the 10% prevention ratio is industry standard

19. In a designed experiment studying the effect of temperature (A), pressure (B), and catalyst concentration (C) on chemical yield, the engineer runs a 2^3 full factorial with 3 replicates (24 runs). The ANOVA shows: Factor A p = 0.001, Factor B p = 0.003, Factor C p = 0.45, AB p = 0.78, AC p = 0.012, BC p = 0.56, ABC p = 0.91. Which factors and interactions should be included in the final model?

A. Only Factor A because it has the smallest pvalue

B. Factors A, B, C, and the AC interaction — all significant effects plus C must be retained because it is a parent of the significant AC interaction, even though its own main effect is not significant

C. All seven effects should be included regardless of significance

D. Only Factors A and B because they are the only significant main effects

20. A quality engineer is reviewing a Gage R&R study where the %GRR is 8.5% of tolerance and the number of distinct categories (ndc) is 12. The measurement system is being used for SPC monitoring of a critical dimension. Based on AIAG guidelines, what is the assessment?

A. The system needs improvement because %GRR should be below 5% for critical dimensions

B. The system is conditionally acceptable pending additional operator training

C. The system is fully acceptable — %GRR below 10% with ndc well above 5 indicates the measurement system has excellent discrimination and contributes minimal variation relative to the tolerance

D. The high ndc of 12 is actually a problem indicating too much sensitivity

21. A quality engineer is analyzing a process and discovers that the control chart shows a peculiar pattern: the first 10 points are tightly clustered near the center line (all within Zone C), then points 1120 show much wider variation with points reaching Zones A and B on both sides, then points 2130 return to tight clustering. This repeating pattern of alternating tight and wide variation suggests which condition?

A. Normal random variation that occasionally produces periods of low and high variability

B. The control limits need to be recalculated after every 10 subgroups to track the changing variation

C. The Xbar chart is exhibiting a run pattern that indicates a shifted process mean

D. A systematic change in withinsubgroup variation is occurring — possibly related to tooling cycles, material lot changes, or equipment warmup/cooldown patterns that create periodic changes in process dispersion

22. A quality engineer is implementing a document control system and must address the challenge of controlling documents at remote field service locations where internet connectivity is intermittent. Service technicians need access to the latest procedures while working at customer sites. Which approach best ensures controlled document access in this environment?

A. Provide service technicians with mobile devices that synchronize controlled documents whenever connectivity is available, with automatic version checking that flags outdated documents and prevents use of superseded versions

B. Print all procedures and ship updated binders to each technician monthly

C. Allow technicians to download procedures once and use them indefinitely without updates

D. Require technicians to call the office before each service call to verbally confirm the current procedure revision

23. A quality engineer is reviewing the results of a chisquare test of independence on a 3×3 contingency table. The calculated $\chi^2 = 15.8$, degrees of freedom = (31)(31) = 4, and the critical value at $\alpha = 0.01$ is 13.28. What is the conclusion?

A. Fail to reject H_0 because the significance level is very stringent at $\alpha = 0.01$

B. There is a statistically significant association between the two categorical variables even at the highly stringent $\alpha = 0.01$ level, because $\chi^2 = 15.8$ exceeds the critical value of 13.28

C. The test is invalid because 3×3 tables require Fisher's exact test rather than chisquare

D. The association is significant at $\alpha = 0.05$ but not at $\alpha = 0.01$

24. A quality engineer discovers that an operator has been recording identical measurement values for 15 consecutive parts — all exactly 25.000 mm. The process has a known standard deviation of 0.04 mm. The probability of 15 consecutive identical readings from a process with $\sigma = 0.04$ mm and reasonable measurement resolution is essentially zero. What should the engineer investigate?

A. The process has achieved perfect consistency and the operator should be commended

B. The measurement system resolution is too coarse to detect actual parttopart variation

C. The process standard deviation has decreased significantly and the control chart should be recalculated

D. The operator may be fabricating data or using an instrument with insufficient resolution — 15 identical readings from a process with $\sigma = 0.04$ mm is statistically impossible, indicating either data fabrication or a measurement system that cannot discriminate between parts

25. In the context of lean manufacturing, a quality engineer is analyzing a production cell and identifies that the cell has been producing at a rate of 55 units per hour for the past year. Customer demand has recently increased, requiring a production rate of 70 units per hour. Rather than adding a second shift, the engineer proposes improving the cell's efficiency. Which lean metric should the engineer calculate first to identify the improvement opportunity?

A. The Overall Equipment Effectiveness (OEE) of the cell, which will reveal how much of the theoretical capacity is lost to downtime, speed losses, and quality losses — identifying the specific loss categories enables targeted improvements to close the gap between current and required production rates

B. The cost per unit to determine if overtime is more economical than process improvement

C. The defect rate per unit to determine if quality is the primary constraint

D. The cycle time of each workstation to identify whether a bottleneck exists

26. A quality engineer is conducting a process capability study and finds that the process data fails the AndersonDarling normality test ($p = 0.002$). The data is significantly rightskewed. The engineer needs to report capability to a customer who requires $Cpk \geq 1.33$. Which approach is most appropriate?

A. Transform the data using a BoxCox or logarithmic transformation, verify normality of the transformed data, transform the specification limits using the same function, and calculate Cpk on the transformed scale

B. Report the standard Cpk calculated from the raw data and note that the data is nonnormal

C. Use the range of the data divided by the specification tolerance as an alternative capability metric

D. Collect additional data until the distribution appears normal by visual inspection

27. A quality engineer is reviewing a product liability case where a consumer was injured by a product that met all applicable industry standards and the manufacturer's published specifications at the time of manufacture. The product design was stateoftheart when released 8 years ago. From a quality engineering perspective, which concept is most relevant to this case?

A. The manufacturer is automatically exempt from liability if the product met all standards at the time of manufacture

B. Strict liability — the manufacturer may be liable regardless of fault if the product is found to be defective or unreasonably dangerous in its design, manufacture, or warnings

C. If standards were met at the time of manufacture, subsequent changes in standards cannot be applied retroactively

D. The manufacturer's responsibility ended when the product was sold to the original consumer

28. A quality engineer is implementing SPC on a newly installed CNC machining center. The engineer collects 25 subgroups of size 5 to establish initial control limits. The Xbar chart shows all points within limits with no patterns, and the R chart also shows statistical control. The engineer calculates trial control limits and is ready to use them for ongoing monitoring. Before releasing the chart for production use, what additional verification should be performed?

A. No additional verification is needed — 25 incontrol subgroups are sufficient to establish permanent control limits

B. The control limits should be verified by collecting an additional 25 subgroups to confirm that the new data falls within the established limits, ensuring the trial limits are representative of the process under normal production conditions

C. The control limits should be expanded by 10% to provide a safety margin for production monitoring

D. The engineer should wait 6 months before establishing any control limits to capture seasonal variation

29. A quality engineer is analyzing the results of a Gage R&R study performed on a new optical measurement system. The study reveals: repeatability = 3.2% of tolerance, reproducibility = 1.8% of tolerance, and parttopart variation = 45.2% of tolerance. The %GRR is 3.7% of tolerance. However, the engineer notices that the parttopart variation seems low relative to the known production range. What might explain this discrepancy?

A. The parts selected for the study may not have adequately represented the full production variation range — if the study parts were clustered near the nominal value rather than spanning the entire production range, the parttopart variation would be understated and the %GRR artificially inflated

B. The optical measurement system is overresolving the parts, creating artificial parttopart variation

C. The %GRR of 3.7% indicates a perfect measurement system with no further investigation needed

D. The low parttopart variation confirms that the production process has minimal variation

30. A quality engineer is reviewing a product design and encounters the following GD&T callout: a flatness tolerance of 0.05 mm applied to a datum surface A. The engineer asks the designer why flatness was specified rather than a profile tolerance. The designer responds that flatness controls the surface shape. What is the key distinction between flatness and profile of a surface?

A. Flatness controls the form of a nominally flat surface (no datum reference needed) — the entire surface must lie between two parallel planes 0.05 mm apart, controlling only the surface's own shape without reference to any other feature

B. Flatness and profile of a surface are identical controls that can be used interchangeably

C. Flatness controls the orientation of the surface relative to other datums while profile controls form

D. Profile of a surface can only be applied to curved surfaces, not flat surfaces

31. A quality engineer is conducting an internal audit of the organization's management of change process. The engineer discovers that a production process was modified three months ago — the curing oven temperature setpoint was increased by 15°C — but no formal change documentation exists. The process technician who made the change states that a verbal approval from the supervisor was obtained. What audit finding is appropriate?

A. An observation noting that verbal approvals should ideally be documented for recordkeeping purposes

B. No finding is needed because the supervisor's verbal approval constitutes valid authorization

C. The finding should be classified as a positive finding demonstrating operational flexibility

D. A nonconformity — the process change was implemented without following the formal management of change procedure, bypassing the documentation, review, approval, and impact assessment controls that exist to prevent unintended quality consequences from undocumented process changes

32. A quality engineer is conducting a twoway ANOVA with factors Supplier (3 levels) and Batch (2 levels) on raw material tensile strength. The results show: Supplier main effect $p = 0.003$ (significant), Batch main effect $p = 0.12$ (not significant), Supplier × Batch interaction $p = 0.04$ (significant). Since

the interaction is significant, the quality engineer should avoid interpreting the main effects independently. What practical implication does the significant interaction have?

A. The supplier difference is consistent across both batches and the interaction can be ignored

B. The effect of supplier on tensile strength depends on which batch is being used — one supplier may perform well with Batch 1 material but poorly with Batch 2, meaning supplier selection decisions must consider the specific batch of raw material

C. Both main effects should be removed from the model since the interaction overrides them

D. The significant interaction proves that neither supplier nor batch affects tensile strength

33. A quality engineer is implementing a kanban system and discovers that the replenishment lead time for a critical component varies significantly — sometimes 2 hours and sometimes 8 hours depending on upstream workload. The daily demand is stable at 200 units. The engineer calculates the kanban quantity using average lead time (5 hours). What risk does this approach create?

A. Using average lead time is the recommended practice for kanban calculations in all situations

B. The calculated kanban quantity will be too large, creating excess inventory during short lead times

C. Using average lead time will result in stockouts during periods of longerthanaverage replenishment — the kanban calculation should use the worstcase lead time or incorporate a sufficient safety stock factor to buffer against lead time variation

D. Lead time variation has no effect on kanban system performance

34. A quality engineer is reviewing the organization's approach to training effectiveness evaluation. Currently, all training is evaluated only through a posttraining knowledge test (Kirkpatrick Level 2). Six months after SPC training, the engineer observes that 40% of operators are not maintaining their control charts correctly. This gap between knowledge and practice represents a failure at which Kirkpatrick level?

A. Level 3 — Behavior, because the trained skills are not being transferred to the actual work environment despite demonstrated knowledge acquisition; the gap indicates barriers to onthejob application such as lack of reinforcement, time pressure, or insufficient management support

B. Level 2 — Learning, because the operators clearly did not learn the material during training

C. Level 1 — Reaction, because the operators were dissatisfied with the training content

D. Level 4 — Results, because organizational quality metrics have not improved

35. A quality engineer calculates a 95% confidence interval for the difference between two population means (μ_1 μ_2) and obtains (1.2, 3.8). The engineer must determine whether the two processes produce significantly different output. What is the correct interpretation?

A. The processes are significantly different because the interval width (5.0) is large

B. Process 1 is significantly better than Process 2 because the upper bound (3.8) is positive

C. The confidence interval for the difference cannot be used to assess statistical significance

D. The processes are not significantly different because the confidence interval for (μ_1 μ_2) includes zero — zero is a plausible value for the true difference, meaning the observed difference is consistent with no actual difference between the populations

36. A quality engineer is implementing acceptance sampling and the production department argues that since the process has Cpk > 1.33, acceptance sampling is unnecessary — all output is conforming. The quality engineer disagrees. Which argument best justifies continued acceptance sampling despite the high Cpk?

A. Acceptance sampling is required by ISO 9001 regardless of process capability

B. Cpk reflects historical capability and does not guarantee future performance — process shifts, material changes, or equipment degradation can occur between capability studies; acceptance sampling provides ongoing verification that individual lots actually conform, serving as a safety net when SPC monitoring may not catch every shift

C. Acceptance sampling should be eliminated when Cpk exceeds 1.67, but not at 1.33

D. The production department is correct — any process with Cpk > 1.33 does not need acceptance sampling

37. A quality engineer is conducting a measurement system analysis for a torque wrench and discovers that the reproducibility component is zero — all three operators produce identical measurement averages. However, the repeatability component is 15% of tolerance. What does this unusual result indicate?

A. The measurement system is perfect because the operators agree with each other completely

B. The torque wrench is likely a "clicktype" or preset device where the operator's role is minimal — the instrument determines the reading, not the operator; the repeatability variation reflects the instrument's inherent variation, confirming that improvement efforts should focus on the instrument

C. Zero reproducibility indicates an error in the study design and the study should be repeated

D. All three operators were trained to the same procedure, which guarantees zero reproducibility

38. A quality engineer is reviewing a designed experiment and the team is debating whether to conduct the experiment with or without replication. The proposed design is a 2^4 full factorial (16 runs). Without replication, the team would rely on a normal probability plot to identify significant effects. With 2 replicates, the total would be 32 runs but ANOVAbased significance testing would be available. Given budget constraints, the team can afford either 16 unreplicated runs or 16 runs of a 2^{4-1} fractional factorial with 2 replicates. Which design provides more useful information?

A. The 16run full factorial without replication provides more information because it estimates all 15 effects without confounding, even though significance testing relies on the normal probability plot rather than formal ANOVA — the fractional design would sacrifice interaction information for replication that may be less valuable

B. The fractional factorial with replication is always preferred because formal ANOVA significance testing is mandatory

C. Both designs provide identical information since they use the same number of runs

D. Neither design is acceptable — the team must find budget for a full 32run replicated factorial

39. A quality engineer is implementing a risk management system and must decide how to handle residual risk — the risk remaining after treatment actions have been implemented. A critical process has a pretreatment risk score of "High" (probability = 4, severity = 5). After implementing engineering controls, the risk score decreases to "Medium" (probability = 2, severity = 5). Note that severity remains unchanged because the treatment only reduced probability, not consequence. What should the engineer document and communicate?

A. The residual risk can be closed because it has been reduced from High to Medium

B. Residual risk documentation is unnecessary once treatment actions are implemented

C. The severity should also be reduced since the probability was reduced, bringing the overall rating to Low

D. The residual risk should be formally documented, accepted by management at the appropriate authority level, and communicated to affected stakeholders — the unchanged severity of 5 (catastrophic) means that if the risk event still occurs despite the reduced probability, the consequences remain equally severe

40. A quality engineer is analyzing a scatter diagram showing the relationship between injection molding cycle time and part weight. The Pearson correlation coefficient is r = 0.92. The engineer concludes that reducing cycle time causes weight reduction. A colleague challenges this conclusion. Why is the colleague's challenge valid?

A. The colleague is incorrect — a correlation of 0.92 is strong enough to establish causation

B. Correlation coefficients below 0.95 are unreliable indicators of any relationship

C. The correlation of 0.92 establishes association but not causation — a third variable such as melt temperature, which may change with cycle time, could be the actual cause of weight variation; only a designed experiment with controlled cycle time and other variables held constant can establish causation

D. Negative correlations cannot indicate meaningful relationships between process variables

41. A quality engineer is reviewing an organization's internal audit schedule and discovers that audits are planned annually for each department, with all audits conducted during the first quarter of each year. By the fourth quarter, it has been 912 months since the most recent audit for some areas. What improvement to the audit schedule would provide better quality system oversight?

A. Conduct all audits in December so findings can be addressed before the new year

B. Distribute audits across all four quarters so that some aspect of the quality system is being audited continuously throughout the year, providing ongoing monitoring rather than a single annual snapshot with long gaps between assessments

C. Conduct all audits during production shutdowns to minimize operational disruption

D. Reduce audit frequency to every two years to allow more time for corrective action implementation

42. A quality engineer needs to determine the minimum sample size to estimate the proportion of defective items in a large lot to within ±2% with 95% confidence. A preliminary estimate suggests the proportion defective is approximately 5%. Using the formula $n = (Z^2\hat{p}(1\hat{p}))/E^2$, what sample size is required?

A. $n = (1.96^2 \times 0.05 \times 0.95) / (0.02^2) = (3.841 \times 0.0475) / 0.0004 = 0.1825 / 0.0004 = 456$ samples

B. n = 100 samples based on the general rule of thumb for proportion estimation

C. $n = (1.645^2 \times 0.05 \times 0.95) / (0.02^2) = 322$ samples using the 90% confidence Zvalue

D. n = 30 samples based on the central limit theorem minimum requirement

43. A quality engineer is analyzing field failure data and discovers that a product's Weibull shape parameter is $\beta = 0.72$. The maintenance department currently implements agebased preventive replacement at fixed intervals. Based on the β value, why is this maintenance strategy counterproductive?

A. The preventive replacement strategy is appropriate for all values of β

B. $\beta < 1$ indicates a constant failure rate, making timebased replacement neither helpful nor harmful

C. The replacement interval should be shortened to every 500 hours regardless of β value

D. $\beta = 0.72$ indicates a decreasing failure rate (infant mortality) — replacing components at fixed intervals substitutes proven survivors with new components that have a higher initial failure rate, potentially increasing rather than decreasing the overall failure rate

44. A quality engineer is constructing a pchart for a process where the sample size varies between 100 and 300 units per lot. The average proportion nonconforming is $\bar{p} = 0.04$. The engineer wants to use fixed control limits based on the average sample size ($\bar{n} = 200$) rather than recalculating limits for each sample. Under what condition is this simplification acceptable?

A. Fixed limits are always acceptable regardless of sample size variation

B. Fixed limits are never acceptable — limits must be recalculated for every sample

C. Fixed limits based on average sample size are acceptable when the actual sample sizes do not vary by more than approximately ±25% from the average — in this case, 100 to 300 includes some lots that deviate by 50%, so individual limits should be calculated for the extreme sample sizes

D. Fixed limits should be based on the maximum sample size to ensure the chart is conservative

45. A quality engineer is reviewing a supplier's corrective action response to a recurring dimensional nonconformity. The supplier's root cause analysis states: "Root cause: the CNC machine was out of calibration." The corrective action states: "The machine was recalibrated." Why is this root cause analysis insufficient?

A. Machine calibration is a valid root cause for dimensional nonconformities and the response is adequate

B. The supplier has identified what happened (out of calibration) but not why it happened — a thorough root cause analysis would ask why the machine went out of calibration (wear, vibration, thermal drift), why it was not detected sooner (calibration schedule, SPC, preventive maintenance), and what systemic changes will prevent recurrence beyond simply recalibrating

C. The supplier should have replaced the CNC machine entirely rather than recalibrating it

D. The root cause analysis is too detailed and should be simplified for the corrective action report

46. A quality engineer is implementing errorproofing on a pharmaceutical packaging line. The highestrisk failure mode involves placing the wrong patient information leaflet inside a medication box. Currently, operators visually verify the leaflet matches the medication label. The error rate is 200 ppm. Which pokayoke approach provides the most reliable prevention?

A. An automated vision system that reads the barcode on both the leaflet and the medication box, comparing them in real time, and physically diverting any mismatch to a reject bin before the box is sealed

B. Adding a second operator to doublecheck the leaflet placement before the box is sealed

C. Colorcoding the leaflets to match the medication box colors for easier visual identification

D. Providing operators with a magnifying lens to improve readability of the leaflet text during verification

47. A quality engineer is conducting a process capability analysis and obtains $\bar{x}$ = 30.0 mm, $\hat{\sigma}$ = 0.50 mm, USL = 31.5 mm, LSL = 28.5 mm. The engineer calculates Cp = (31.528.5)/(6×0.50) = 1.00 and Cpk = min((31.530.0)/(3×0.50), (30.028.5)/(3×0.50)) = min(1.00, 1.00) = 1.00. The customer requires Cpk ≥ 1.33. The process is centered. What type of improvement is needed?

A. Recenter the process to a different target value to improve Cpk above 1.00

B. Widen the specification limits by negotiating with the customer

C. Increase the sampling frequency to detect nonconforming product more quickly

D. Reduce the process standard deviation — since the process is perfectly centered (Cp = Cpk), the only way to increase capability is to reduce variation through process improvements such as better tooling, tighter material controls, or improved environmental conditions

48. A quality engineer is reviewing an organization's approach to risk communication and discovers that risk assessment results are shared only through a formal annual management review presentation. Between reviews, no riskrelated information is communicated to operational staff. The engineer recommends integrating risk communication into daily operations. Which specific improvement would be most effective?

A. Post the complete risk register on the factory bulletin board for all employees to review

B. Include riskrelevant information in daily production meetings, team briefings, and visual management boards — communicating specific risks that affect each area's operations and the status of their controls, making risk awareness a routine part of daily work rather than an annual event

C. Send monthly email summaries of the risk register to all employees in the organization

D. Restrict risk communication to the quality department to prevent unnecessary alarm among production staff

49. A quality engineer is analyzing warranty data and discovers that a product has an MTTF of 25,000 hours under the exponential distribution assumption (constant failure rate). The product is sold with a 2,000hour warranty. The quality engineer needs to estimate the percentage of products expected to fail during the warranty period. Using R(t) = e^(t/MTTF), what is the estimated warranty failure rate?

A. 8.0%, calculated as 2,000/25,000 × 100% using the linear approximation

B. Approximately 7.7%, calculated as 1 e^(2000/25000) = 1 e^(0.08) ≈ 0.0769 or 7.69%

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

D. 2.0%, because the warranty period is a negligible fraction of the MTTF

50. A quality engineer is reviewing a process control plan and notices that a critical characteristic has the control method listed as "100% automated inspection" with a documented detection capability of 99.5%. The engineer questions whether 99.5% detection is sufficient for a critical characteristic. If the process produces 500 parts per hour with a 0.5% defect rate, how many defective parts per 8hour shift escape to the customer?

A. The 99.5% detection rate means zero defective parts escape because automated inspection is effectively perfect

B. 20 defective parts produced per shift × 0.5% escape rate = 0.1 defectives escape per shift

C. 4,000 parts × 0.5% defect rate = 20 defective parts produced per shift; 20 × 0.5% escape rate = 0.1 defectives per shift — essentially zero escapes

D. 500 parts/hr × 8 hr = 4,000 parts × 0.005 defect rate = 20 defective parts; 20 × (10.995) = 20 × 0.005 = 0.1 defective parts escape per shift — while low, any escape of a critical defect may be unacceptable

51. A quality engineer is analyzing the results of a designed experiment using response surface methodology. The engineer fits a secondorder model and generates a contour plot showing the response as a function of two significant factors. The contour plot reveals a saddle point rather than a clear maximum or minimum. What does this saddle point indicate for process optimization?

A. The experiment failed and must be completely repeated with different factor ranges

B. A saddle point has no practical significance and the engineer should proceed with center point settings

C. The contour plot is incorrect and should be redrawn using different software

D. A saddle point indicates that the response increases in one direction but decreases in another — the optimum is not at the center of the explored region, and the engineer may need to use ridge analysis or explore along the rising ridge to find conditions that maximize (or minimize) the response

52. A quality engineer is implementing a supplier scorecard system and must determine appropriate performance targets. The engineer proposes setting the quality target at 99.5% conformance rate (5,000

ppm reject rate) for all suppliers regardless of the component's criticality. A colleague argues that differentiated targets based on component criticality would be more effective. Which approach better serves quality objectives?

A. Uniform targets are simpler to manage and ensure fairness across all suppliers

B. Differentiated targets based on component criticality better serve quality objectives — safetycritical components should have much more stringent conformance targets than noncritical ones, aligning supplier performance expectations with the actual risk that each component poses to the final product

C. All suppliers should be held to a zerodefect standard regardless of component criticality

D. Quality targets should be based solely on the supplier's current capability, not component criticality

53. A quality engineer is conducting a hypothesis test and sets $\alpha = 0.05$. The test yields a pvalue of 0.0001. The engineer concludes that the effect is both statistically significant and practically important. A statistician colleague points out a flaw in this reasoning. What is the flaw?

A. A pvalue of 0.0001 is too small to be reliable and indicates a calculation error

B. The extremely small pvalue proves both statistical and practical significance simultaneously

C. The small pvalue confirms strong statistical evidence against H_0, but it does not address practical significance — with a sufficiently large sample, even a trivially small difference can achieve a tiny pvalue; the engineer must separately evaluate whether the magnitude of the observed effect is large enough to matter in the practical engineering context

D. The significance level should have been set at $\alpha = 0.01$ rather than 0.05 for this type of test

54. A quality engineer is reviewing a process validation report for a heat treatment furnace. The report demonstrates that the furnace produces acceptable results when loaded with 100 parts. However, production routinely loads 250 parts per cycle. The engineer is concerned that the validation may not apply to the full production load. Why is this concern valid?

A. Heat treatment results are independent of furnace load and the validation is applicable at any load level

B. The validation was performed at 100 parts but production runs at 250 — the increased thermal mass, altered airflow patterns, and potential for temperature nonuniformity at higher loads mean the furnace's ability to achieve uniform temperature throughout the load may differ significantly from what was validated at the lower load

C. The validation should be performed at the minimum load, not the maximum, to demonstrate worstcase conditions

D. Furnace validations are only required at 50% of maximum capacity as an industry standard

55. A quality engineer discovers that the organization's quality policy states a commitment to "continuous improvement" but the management review minutes over the past three years show no documented improvement initiatives, no improvementrelated decisions, and no evidence of improvement actions being tracked or evaluated. What should the quality engineer conclude?

A. The quality policy is adequate because it states the commitment to improvement in writing

B. The organization should update its quality policy to remove the continuous improvement commitment since it is not being implemented

C. The management review process is functioning correctly because it follows a standard agenda format

D. The organization has a gap between its stated quality policy commitment and actual practice — the policy promises continuous improvement but the management review evidence shows no substantive improvement activities are being planned, implemented, or evaluated

56. A quality engineer is implementing a lean production system and the team is working on reducing setup time for a stamping press using SMED methodology. After separating internal and external setup activities and converting possible internal activities to external, the remaining internal setup time is 18 minutes. The team identifies that 6 minutes of this time is spent adjusting die height through trialanderror shimming. Which SMED principle addresses this remaining internal time?

A. Convert the die height adjustment from a trialanderror process to a preset, repeatable method — using standardized shim heights, digital readouts, or mechanical stops that eliminate adjustment time by ensuring correct die height on the first setup

B. Add additional operators to perform the shimming in parallel with other setup activities

C. Accept the 18minute internal setup as the minimum achievable time for this equipment

D. Eliminate die height adjustment entirely by using a single die height for all products

57. A quality engineer is reviewing a scatter diagram and observes a strong linear relationship between two variables with r = 0.95. However, the engineer notices that one data point is far from the cluster of other points — a potential outlier at the upper right corner of the plot. The engineer recalculates r without this point and obtains r = 0.42. What does this dramatic change indicate?

A. The original r = 0.95 is correct and the outlier should not be investigated

B. The apparent strong correlation was driven primarily by a single extreme data point — this single outlier inflated the correlation from a weak relationship (r = 0.42) to an apparently strong one (r = 0.95); the underlying relationship without the outlier is much weaker than it appeared, and the engineer should investigate the outlier's validity

C. Both correlation coefficients are unreliable and a nonparametric test should be used

D. Removing any data point always reduces the correlation coefficient, so the change is expected

58. A quality engineer is analyzing the time between failures for a fleet of identical machines. The data shows that the mean time between failures (MTBF) is 2,000 hours, and the failure times follow an exponential distribution. A maintenance engineer asks what percentage of machines are expected to survive beyond 3,000 hours without failure. Using R(t) = e^(t/MTBF), what is the answer?

A. R(3000) = e^(3000/2000) = e^(1.5) ≈ 0.223 or approximately 22.3%

B. R(3000) = 1 (3000/2000) = 0.50, which indicates all machines have failed by 3,000 hours

C. R(3000) = 50% because the median of the exponential distribution equals the MTBF

D. R(3000) cannot be calculated without knowing the Weibull shape parameter β

59. A quality engineer is implementing a quality management system and must address ISO 9001:2015 Clause 7.1.6 — Organizational Knowledge. Three senior engineers who hold critical process knowledge are approaching retirement within the next 18 months. The quality engineer must develop a knowledge transfer plan. Which approach most effectively captures and transfers tacit process knowledge?

A. Require the retiring engineers to write detailed procedures documenting all their knowledge before they leave

B. Record the retiring engineers on video discussing their work processes and archive the recordings

C. Wait until the replacement engineers are hired and have them shadow the retiring engineers during their notice period

D. Implement a structured mentoring program pairing each retiring engineer with a successor, combined with process documentation, knowledgesharing sessions, and handson training over the remaining 18 months — tacit knowledge transfers best through extended personal interaction and guided practice, not documentation alone

60. A quality engineer is reviewing the results of a process improvement project. Before the improvement, the process had Cpk = 0.85. After the improvement, Cpk = 1.45. The engineer calculates the defect rate reduction: before, approximately 7% nonconforming; after, approximately 14 ppm nonconforming. The project cost $150,000 to implement. Annual production volume is 500,000 units with an average cost of $50 per defective unit (scrap + rework). What is the approximate annual savings from the project?

A. Annual savings = 500,000 × (0.07 0.000014) × $50 = 500,000 × 0.06999 × $50 ≈ $1,750,000 — the project pays for itself in approximately one month

B. The savings cannot be calculated without knowing the selling price of each unit

C. Annual savings = $150,000 based on the project cost serving as a proxy for the savings

D. Annual savings = 500,000 × 0.000014 × $50 = $350, which does not justify the project cost

61. A quality engineer is implementing a document control system for a multisite organization. Different sites use different ERP systems, different file formats, and different naming conventions for quality documents. The quality engineer must establish a unified document control approach. Which element is most critical for ensuring consistency across sites?

A. All sites must use identical ERP systems and hardware platforms

B. Each site should maintain its own independent document control system with no crosssite coordination

C. A common document numbering scheme, revision control process, approval workflow, and master document list accessible to all sites — ensuring that regardless of the local system, every site can identify the current version of any controlled document and access it when needed

D. Only the headquarters site should maintain controlled documents, with all other sites using uncontrolled copies

62. A quality engineer is analyzing a designed experiment with factors A, B, and C at two levels each. The 2^3 factorial yields the following ANOVA results: A is significant (p=0.001), B is significant (p=0.02), C is not significant (p=0.45), AB is significant (p=0.005), AC is not significant (p=0.72), BC is not significant (p=0.38), ABC is not significant (p=0.85). The engineer builds a model with A, B, and AB. Factor C is set to its low level because it minimizes cost. A colleague objects, saying C should be set to its high level "just in case." How should the engineer respond?

A. The data clearly shows C has no significant effect on the response (p=0.45) and no significant interactions with other factors — setting C at any level has no measurable impact on product quality, so the most economical level is the correct choice; "just in case" reasoning without data support is not scientific process optimization

B. The colleague is correct that setting C high provides extra safety margin

C. Factor C should be removed from the process entirely since it is not significant

D. C should be set to its midpoint level as a compromise between cost and the colleague's concern

63. A quality engineer is conducting a Weibull analysis of ball bearing failure data. After plotting the failure times on Weibull probability paper, the engineer obtains $\beta = 2.1$ and $\eta = 50{,}000$ hours. The maintenance department asks at what operating time 10% of bearings are expected to have failed (the B10 life). Using the Weibull CDF: $F(t) = 1 \ e^{((t/\eta)^\beta)}$, solve for t when $F(t) = 0.10$.

A. $B10 = \eta \times (\ln(0.90))^{(1/\beta)} = 50{,}000 \times (0.1054)^{(1/2.1)} = 50{,}000 \times (0.1054)^{(0.476)} \approx 50{,}000 \times 0.347 \approx 17{,}350$ hours

B. $B10 = 50{,}000 \times 0.10 = 5{,}000$ hours because B10 is simply 10% of the characteristic life

C. B10 cannot be calculated from Weibull parameters without additional failure rate data

D. $B10 = 50{,}000 / 2.1 = 23{,}810$ hours calculated by dividing η by β

64. A quality engineer discovers that a production line uses three different measurement instruments — all different brands — to measure the same critical dimension at different stations along the line. The instruments have never been crosscorrelated. A part measured as conforming at Station 1 is occasionally found nonconforming at Station 3. What is the most likely cause of this discrepancy?

A. The part dimensions are changing between stations due to handling damage or thermal effects

B. Instrumenttoinstrument bias differences — each instrument may have a slightly different reading bias, and without crosscorrelation studies, the three instruments may disagree systematically on the same measurement, causing inconsistent accept/reject decisions

C. The specification limits at Station 3 are tighter than those at Station 1

D. The operators at Station 3 are less experienced than those at Station 1

65. A quality engineer is reviewing the organization's supplier audit program and discovers that supplier audits consistently produce no findings — every audit for the past three years has resulted in zero nonconformities across all 25 suppliers audited. The quality engineer is skeptical. What should the engineer investigate?

A. The clean audit results confirm that all suppliers have excellent quality management systems

B. Zero findings across 25 suppliers over 3 years is statistically unlikely and may indicate that the audits lack rigor — the engineer should evaluate whether audit criteria are challenging enough, whether auditors are adequately trained and independent, whether the audit scope is comprehensive, and whether the audit program has become a compliance formality rather than a genuine assessment

C. The audit program is performing perfectly and no investigation is needed

D. The engineer should increase the number of suppliers audited to 50 per year to find nonconformities

66. A quality engineer is implementing SPC on a process and must decide between an Xbar/R chart and an Xbar/S chart. The subgroup size is 20 measurements taken from each production batch. Which chart is more appropriate and why?

A. The Xbar/R chart is always the default choice regardless of subgroup size

B. Both charts are equally appropriate for any subgroup size

C. The Xbar/S chart is only appropriate for subgroup sizes less than 5

D. The Xbar/S chart is more appropriate because for subgroup sizes greater than 10, the sample standard deviation provides a more statistically efficient estimate of process variability than the range, which uses only the two most extreme values and ignores the remaining 18 measurements

67. A quality engineer is reviewing a process control plan for a pharmaceutical tablet manufacturing operation. The plan specifies weight, hardness, thickness, dissolution rate, and content uniformity as controlled characteristics. The engineer notices that dissolution testing is performed only once per batch (at the end of the batch), while weight is monitored continuously via SPC. Why might this difference in monitoring frequency be appropriate?

A. Dissolution testing should also be monitored continuously via SPC for proper control

B. Dissolution testing is destructive and timeconsuming — each test requires dissolving tablets and analyzing the resulting solution over several hours; the cost and time constraints make continuous

monitoring impractical, so batchend testing combined with validated process parameters that correlate with dissolution performance provides the most practical control approach

C. Weight monitoring should be reduced to match the dissolution testing frequency for consistency

D. Dissolution is not a critical quality attribute and does not require any monitoring

68. A quality engineer is analyzing a multivari study conducted on a CNC turning operation. The study measures outside diameter at three positions along the part length (top, middle, bottom), across five consecutive parts, and at three different times during the shift. The results show that withinpart positional variation is the dominant source, contributing 65% of total variation. What is the most likely physical cause and appropriate corrective action?

A. The dominant withinpart variation is caused by operator technique differences and requires retraining

B. The temporal variation should be addressed first because it is the most common source of variation in CNC operations

C. Piecetopiece variation is the true dominant source and the multivari analysis is incorrect

D. The dominant withinpart positional variation (top vs. middle vs. bottom) likely indicates a fixturing or alignment problem — the part may be deflecting under cutting force, the tailstock pressure may be inconsistent, or the tool path may have taper; corrective action should focus on fixture rigidity, machine alignment, and tool geometry

69. A quality engineer is implementing a riskbased internal audit program and must determine the audit frequency for the organization's calibration program. The calibration program has had two minor nonconformities in the past year (both related to overdue calibrations), serves as the foundation for all measurementbased quality decisions, and supports a critical aerospace product line. What audit frequency is appropriate?

A. Every three years because the calibration program has only minor nonconformities

B. Every two years is the standard audit frequency for all quality system processes

C. Annual or semiannual audits are appropriate — the calibration program is highrisk because it underpins all measurementbased quality decisions, the recurring nonconformities indicate the program has weaknesses, and the aerospace application demands rigorous measurement integrity

D. Monthly audits are required for any program with recurring nonconformities

70. A quality engineer is analyzing the relationship between two process variables using regression analysis. The model $\hat{y} = 45.2 + 2.3x$ yields $r^2 = 0.72$, $p < 0.001$ for the slope, and the residual plot shows random scatter. The engineer uses the model to predict the response at $x = 150$ — a value well beyond the range of the experimental data (x ranged from 20 to 80). What is the primary concern with this prediction?

A. The prediction is fully valid because the model is statistically significant with high r^2

B. The residual plot validation eliminates all concerns about predictions at any xvalue

C. Predictions at $x = 150$ are unreliable because the model has not been validated at x values beyond the original data range

D. Extrapolating to $x = 150$ is risky because the linear relationship validated within $x = 2080$ may not hold at $x = 150$ — the true relationship could be nonlinear, and the model's predictions become increasingly unreliable as they extend further beyond the data range

71. A quality engineer is reviewing an organization's CAPA system and discovers that the organization tracks 12 different CAPA metrics including: number initiated, number closed, average closure time, ontime closure rate, root causes by category, department distribution, recurrence rate, days overdue, escalation frequency, cost per CA, customerrelated versus internal, and effectiveness verification completion rate. The quality manager asks which three metrics are most critical for evaluating CAPA system effectiveness. Which combination is most informative?

A. Number initiated, average closure time, and cost per CA

B. Recurrence rate, effectiveness verification completion rate, and ontime closure rate — these three together measure whether the system actually prevents problems from recurring (recurrence rate),

whether the organization confirms that actions work (effectiveness verification), and whether the system operates with discipline (ontime closure)

C. Department distribution, customerrelated ratio, and escalation frequency

D. Number closed, days overdue, and cost per CA

72. A quality engineer is implementing a measurement system for a new production line and must select between an optical comparator and a coordinate measuring machine (CMM) for inspecting complex geometric features on precision machined parts. Both instruments have acceptable Gage R&R values for the target characteristics. Which factor should most influence the selection decision?

A. The cost of the instruments is the only relevant factor in measurement system selection

B. The optical comparator is always preferred because it provides a direct visual representation

C. The selection should be based solely on which instrument has the lower %GRR value

D. The CMM is more appropriate for complex geometric features because it can measure true 3D geometry, calculate GD&T characteristics, and automate measurement programs — the optical comparator is limited to 2D profile comparisons and requires more operator judgment for complex features

73. A quality engineer is evaluating two processes for the same product. Process A has Cpk = 1.50 with historically stable control charts. Process B has Cpk = 2.00 but shows frequent outofcontrol signals on its control chart that are quickly corrected. Which process poses greater quality risk?

A. Process A because its lower Cpk means more defective output

B. Process B poses greater quality risk despite its higher Cpk — the frequent outofcontrol signals indicate an unstable process that may shift unpredictably, and the high Cpk may reflect favorable shortterm data rather than sustained performance; a stable process with lower but consistent capability is generally more predictable and reliable than a capable but unstable one

C. Both processes pose equal risk because they both produce within specification

D. Process A poses greater risk because lower Cpk always indicates higher defect rates

74. A quality engineer is reviewing a product's design verification test results. The test plan calls for testing 10 units to demonstrate a 95% reliability at 90% confidence over 500 operating hours. All 10 units pass the test. Has the reliability requirement been demonstrated?

A. Yes, because all 10 units passed the test, 100% reliability has been demonstrated

B. The test plan should have included at least 100 units for valid reliability demonstration

C. The sample size of 10 cannot demonstrate any reliability level with statistical confidence

D. The test demonstrates that the sample is consistent with ≥95% reliability at 90% confidence, but success test plans with small samples provide relatively limited precision — the actual reliability could range from about 74% to nearly 100% based on the 10unit success test

75. A quality engineer is analyzing process data and discovers that the withinsubgroup standard deviation ($\hat{\sigma}_{within} = \bar{R}/d_2$) is 0.08 mm while the overall standard deviation calculated from all individual measurements is 0.13 mm. The Cp calculated from $\hat{\sigma}_{within}$ is 1.39, while the Pp calculated from the overall σ is 0.85. What does this significant gap between Cp and Pp indicate?

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

B. The sample size is too small to produce reliable estimates of either standard deviation

C. The gap indicates the presence of significant betweensubgroup variation from process instability — the process has experienced shifts, trends, or other special causes that add variation between subgroups beyond the inherent common cause variation captured within subgroups

D. The overall standard deviation calculation is mathematically incorrect and should be disregarded

76. A quality engineer is implementing an incoming inspection program and must decide whether to use ANSI/ASQ Z1.4 (attributes sampling) or ANSI/ASQ Z1.9 (variables sampling) for a critical dimension. The dimension has bilateral specifications and the quality characteristic is known to follow a normal distribution. Which plan offers the advantages of smaller sample sizes?

A. Z1.4 (attributes) always requires smaller samples because pass/fail decisions are simpler

B. Z1.9 (variables) achieves the same level of quality protection with smaller sample sizes because each measurement provides more information than a simple pass/fail classification — the actual measured values enable more precise estimation of the lot's quality distribution

C. Both plans require identical sample sizes for the same AQL and lot size

D. The sample size depends only on the lot size, not on whether attributes or variables sampling is used

77. A quality engineer is reviewing the results of a benchmarking study comparing the organization's defect rate to industry best practices. The organization's current defect rate is 3,500 ppm. The benchmark shows that bestinclass competitors achieve 50 ppm. Management asks the quality engineer to develop a roadmap for closing this gap. Which approach is most effective for achieving transformational improvement?

A. Incrementally reduce the defect rate by 10% per year through continuous improvement kaizen events

B. Immediately implement Six Sigma training for all employees to achieve the 50 ppm target within one year

C. A phased approach combining: (1) shortterm containment through improved inspection, (2) mediumterm capability improvement through DMAIC projects targeting the vital few defect types, and (3) longterm transformational change through designformanufacturing, errorproofing, and advanced process control — with realistic milestones at each phase

D. Accept the 3,500 ppm rate as acceptable since achieving 50 ppm is not realistic for most manufacturers

78. A quality engineer is reviewing the organization's process validation approach and discovers that the organization treats validation as a onetime event — once a process is validated, it is never revalidated unless a customer complaint triggers a review. ISO 9001 and industry best practices require a different approach. What is missing?

A. Validation is appropriately a onetime event that does not require periodic review or revalidation

B. Revalidation is only required when changing to a different raw material supplier

C. The organization should revalidate all processes annually regardless of their performance

D. Periodic revalidation should be triggered by defined criteria including process changes, equipment changes, material changes, facility moves, significant time intervals, or performance trends indicating potential degradation — validation status must be maintained actively, not assumed to persist indefinitely

79. A quality engineer is analyzing a process and calculates the Average Run Length (ARL) for an Xbar chart with 3sigma control limits. With $\alpha = 0.0027$ per subgroup (the probability of a single point falling outside 3σ limits by chance), the incontrol $ARL_0 = 1/0.0027 \approx 370$ subgroups. The engineer wants to know: if the process mean shifts by 1.5σ, approximately what is the outofcontrol ARL_1?

A. The ARL_1 remains at 370 because the control limits do not change when the process shifts

B. The ARL_1 for a 1.5σ shift is approximately 6 subgroups — meaning on average, the chart will detect the shift within 6 subgroups after it occurs, which is a substantial delay if subgroups are taken infrequently

C. The ARL_1 equals 1.0 because a 1.5σ shift is always detected on the very first subgroup

D. The ARL_1 is approximately 20 subgroups for a 1.5σ shift on a standard Xbar chart

80. A quality engineer is evaluating a measurement system for a go/nogo thread gage and determines that an attributes agreement analysis is the appropriate study. Ten parts are selected: 5 knowngood and 5 knownbad (verified against reference standards). Three inspectors each evaluate all 10 parts three times (repeated trials). The results show that all three inspectors agree with each other and with the reference

standard on all 10 parts across all three trials — 100% agreement. Is this result sufficient to approve the measurement system?

A. Yes, 100% agreement across all inspectors and trials definitively proves the measurement system is adequate

B. The result is encouraging but 10 parts may be insufficient — the 5 good and 5 bad parts may be "easy calls" with clear accept/reject decisions; the study should include borderline parts near the specification limits where the gage's discrimination ability is truly tested

C. The study should use 50 parts minimum for valid attributes agreement analysis

D. The study is invalid because go/nogo gages cannot be evaluated using attributes agreement analysis

81. A quality engineer is implementing total productive maintenance (TPM) and the production team calculates OEE for three production lines. Line A: OEE = 85%. Line B: OEE = 62%. Line C: OEE = 78%. Management asks which line should receive improvement focus. Before making a recommendation, what additional information does the quality engineer need?

A. Only the overall OEE values are needed to determine which line should receive focus

B. The OEE trend over time for each line to determine whether performance is improving or declining

C. The breakdown of OEE into Availability, Performance, and Quality components for each line — Line B's low OEE of 62% could result from any combination of downtime, speed losses, or quality losses, and the improvement strategy differs dramatically depending on which component is the primary contributor

D. The production volume of each line to prioritize the highestvolume line regardless of OEE

82. A quality engineer is reviewing a supplier's SPC data for a critical characteristic. The supplier's Xbar chart shows all points within control limits and the R chart is stable. However, the engineer notices that the supplier's control limits were calculated from data collected two years ago and have not been updated despite several process improvements during that period. What concern should the engineer raise?

A. The twoyearold limits are still valid because they represent the historical process baseline

B. Control limits should never be updated because doing so introduces bias into the monitoring system

C. The outdated control limits may be too wide for the improved process — if the process standard deviation has decreased due to improvements, the original wider limits cannot detect process shifts that would be visible with updated, narrower limits; the chart's sensitivity has degraded over time

D. The engineer should verify the supplier's SPC software version rather than questioning the limits

83. A quality engineer is conducting a root cause analysis for a recurring soldering defect using the fishbone (Ishikawa) diagram. After brainstorming, the team identifies 42 potential causes organized under the 6M categories. The team needs to narrow this list to the most likely root causes for investigation. Which combination of tools is most effective for this prioritization?

A. Implement corrective actions for all 42 potential causes simultaneously to ensure nothing is missed

B. Conduct a designed experiment using all 42 causes as factors at two levels each

C. Use multivoting to narrow the list to the top 810 most likely causes based on team knowledge, then collect data on these candidates and construct a Pareto chart to prioritize by actual impact — combining expert judgment with datadriven verification

D. Select only the first cause listed under each 6M category for investigation

84. A quality engineer is conducting a process capability study on a newly validated process. The study uses 50 subgroups of size 5 collected over 4 weeks. The Xbar and R charts show statistical control. The calculated Cpk is 1.85. However, the quality engineer notices that all 50 subgroups were collected from a single raw material lot. Why might this Cpk overstate the true longterm process capability?

A. Fifty subgroups is too many and introduces unnecessary variation into the capability estimate

B. The Cpk is understated rather than overstated because more data always produces lower capability indices

C. Singlelot data excludes lottolot material variation — when subsequent lots with different properties are used, the total process variation will likely increase, reducing the actual longterm Cpk below 1.85

D. The subgroup size of 5 artificially inflates the Cpk for any process capability study

85. A quality engineer is implementing a corrective action for a field failure where a plastic housing cracked during normal use. The 5 Whys analysis reveals: Why did the housing crack? → Stress concentration at a design feature. Why was there stress concentration? → Sharp internal corner radius. Why was the corner sharp? → The design specified no minimum radius. Why was no minimum radius specified? → The design checklist does not include stress concentration review for plastic parts. Why not? → The checklist was developed for metal parts and was never updated when the company transitioned to plastics. What systemic corrective action addresses the root cause?

A. Increase the corner radius on this specific housing design

B. Retrain the design engineer who created this part to always include radii on plastic parts

C. Update the design review checklist to include plasticspecific design requirements including minimum radius specifications, materialspecific stress analysis, and environmental degradation considerations — and verify the updated checklist against all current plastic part designs

D. Replace the plastic housing with a metal housing to eliminate the cracking risk

86. A quality engineer is reviewing a designed experiment and the team proposes testing 5 factors at 3 levels each using a full factorial design. The full 3^5 design would require 243 runs. The budget allows only 27 runs. Which alternative design should the engineer recommend?

A. A 2^5 full factorial (32 runs) that tests each factor at only 2 levels

B. A onefactoratatime study testing each factor individually at 3 levels

C. A BoxBehnken design or other response surface design that can study 5 factors at 3 levels with far fewer runs than the full factorial while still modeling quadratic effects

D. A central composite design, which is the only design capable of handling 5 factors at 3 levels

87. A quality engineer is analyzing the results of a reliability test where 100 units were placed on test. By 1,000 hours, 5 units had failed. By 2,000 hours, 12 additional units failed (total 17). By 3,000 hours, 25 additional units failed (total 42). What does the pattern of accelerating failures suggest about the failure mode?

A. The constant failure rate model (exponential distribution) is appropriate for this data

B. The failures are decreasing, consistent with infant mortality behavior

C. The accelerating failures indicate the units are experiencing a wearout failure mechanism where the failure rate increases with age — consistent with a Weibull distribution with $\beta > 1$, where cumulative degradation causes progressively more units to fail as operating time increases

D. The accelerating pattern indicates a data recording error since failure rates should always decrease over time

88. A quality engineer is implementing a lean value stream improvement and identifies that the longest delay in the process occurs between the machining and assembly operations — parts sit in a staging area for an average of 4 days before being assembled. The machining operation produces parts in batches of 500 while the assembly operation processes parts one at a time. What lean principle most directly addresses this delay?

A. Implementing 5S in the staging area to better organize the waiting parts

B. Reducing the machining batch size from 500 toward a onepiece flow to align with assembly's oneatatime processing — smaller batches reduce the time parts wait in the staging area, enabling more continuous flow between operations and dramatically reducing the 4day WIP delay

C. Increasing the assembly rate to consume the staged parts faster

D. Adding additional staging space to accommodate larger batches from machining

89. A quality engineer is reviewing an organization's approach to management of change and discovers that the change control process is wellimplemented for product design changes (ECOs) and process

parameter changes but does not cover changes to inspection methods, test equipment, or quality system procedures. Why is this gap significant?

A. Inspection methods and test equipment changes do not affect product quality

B. Quality system procedure changes are managed by the quality department and do not require formal change control

C. Changes to inspection methods, test equipment, or quality procedures can alter the ability to detect nonconforming product — an inspection method change could reduce detection capability, a test equipment change could introduce measurement bias, and a procedure change could eliminate a critical control; all require the same rigorous change evaluation as product and process changes

D. Only changes to finished product design require formal change control

90. A quality engineer is evaluating the results of a hypothesis test comparing two proportions. The test yields $p = 0.06$ at $\alpha = 0.05$. The observed proportions are $p_1 = 0.025$ (Treatment A) and $p_2 = 0.045$ (Treatment B). The sample sizes are $n_1 = n_2 = 200$. The quality engineer fails to reject H_0 but is concerned about the practical difference. What should the engineer consider?

A. The nonsignificant result definitively proves the two treatments produce identical defect rates

B. The sample sizes are too large and have inflated the pvalue above the significance threshold

C. The pvalue of 0.06 should be rounded to 0.05 and declared significant

D. The test may lack sufficient power to detect the observed difference — with n = 200 per group, the power to detect a difference between 2.5% and 4.5% may be inadequate; a posthoc power analysis and consideration of practical significance (nearly doubling of defect rate) may justify a larger followup study

91. A quality engineer is reviewing the organization's quality objectives and finds that one objective states: "Reduce customer complaints by 25% by yearend." The current complaint rate is 8.0 per 1,000 units shipped. The target would be 6.0 per 1,000. While this objective is specific and measurable, what additional element should be verified before accepting it?

A. The objective should specify the dollar cost associated with each complaint

B. The objective should verify that the 25% reduction target is achievable based on available resources, planned improvement actions, and realistic assessment of the root causes — a target without a viable path to achievement is a wish, not an actionable objective

C. The objective should be expressed as an absolute number rather than a percentage

D. The objective is complete and no additional verification is needed

92. A quality engineer is evaluating whether to implement acceptance sampling or rely solely on process capability data for incoming material quality assurance. The supplier has demonstrated Cpk = 2.0 for the critical characteristic over 12 months of data, and the material has a strong quality track record. Under what condition would the engineer recommend eliminating incoming inspection?

A. Never — incoming inspection should always be performed regardless of supplier capability

B. Incoming inspection can be reduced or eliminated when the supplier's process capability is demonstrated to be consistently high (Cpk > 1.67) over an extended period, the supplier maintains SPC with documented evidence shared with the customer, the supplier notifies of any process changes, and periodic verification confirms continued conformance — essentially transferring the inspection responsibility to the supplier's demonstrated process control

C. Incoming inspection should be eliminated whenever any supplier achieves Cpk > 1.0

D. Incoming inspection should be eliminated for all suppliers with ISO 9001 certification

93. A quality engineer discovers that the organization's design FMEA was completed during the design phase but has never been updated to reflect field failure data, manufacturing process changes, or customer complaints that have accumulated over the product's 5year production history. Why is this static FMEA approach inadequate?

A. DFMEAs are appropriately completed once during design and never require updating

B. Only the process FMEA needs updating with field data; the design FMEA is a fixed designphase document

C. The DFMEA should be updated annually regardless of whether any new information is available

D. The DFMEA should be a living document updated with field failure data, manufacturing insights, customer complaints, and design changes — realworld data reveals failure modes and severity levels that may not have been anticipated during the original designphase analysis, improving the accuracy of risk assessment and driving design improvements

94. A quality engineer is analyzing a process that has been in statistical control for one year with Cpk = 1.55. The production manager proposes changing from a 100% inspection regime (currently in place as a legacy practice) to statistical sampling. The quality engineer supports this proposal but recommends a phased transition. What phased approach best manages the transition risk?

A. Switch immediately from 100% to statistical sampling since the process capability justifies it

B. Continue 100% inspection indefinitely because it provides the most complete quality assurance

C. Eliminate all inspection since the high Cpk means zero defects are expected

D. Phase 1: Run both 100% inspection and statistical sampling in parallel for a defined period to verify that sampling results align with 100% inspection results. Phase 2: Switch to sampling only after confirming agreement. Phase 3: Periodically verify sampling effectiveness through spotcheck 100% inspection of selected lots

95. A quality engineer is evaluating a measurement system for checking the diameter of small Orings using a digital caliper. The specification tolerance is 0.50 mm. The Gage R&R study yields %GRR = 42% of tolerance. The quality engineer concludes the caliper is inadequate for this application. What measurement approach would likely provide better performance?

A. Using a larger caliper with a wider jaw opening to accommodate the Oring more easily

B. A noncontact optical measurement system or a pin gage set, which eliminate the compressionrelated measurement variation inherent in caliper measurement of soft, deformable Orings — the high %GRR likely results from inconsistent compression of the Oring by the caliper jaws

C. Training operators to apply consistent force when closing the caliper jaws on the Oring

D. Switching from digital calipers to dial calipers for better resolution

96. A quality engineer is implementing a riskbased approach to determining the frequency of process capability studies. Currently, all processes receive annual capability studies regardless of their stability, criticality, or change history. Which approach optimizes capability study resources?

A. Conduct capability studies only when a customer requests current capability data

B. Perform capability studies based on risk criteria — highrisk or critical processes receive more frequent studies (semiannual), processes that have undergone changes require immediate restudy, and stable, lowrisk processes with demonstrated longterm capability may extend to 1824 month intervals with ongoing SPC monitoring between studies

C. Eliminate all scheduled capability studies and rely entirely on SPC control charts for process monitoring

D. Increase all capability study frequencies to quarterly for maximum data collection

97. A quality engineer is reviewing a supplier's certificate of analysis and notices that the reported test results show every characteristic tested at exactly the specification nominal value — every single measurement is exactly at the target with zero variation. For a batch of 50 tested units, all 50 results are identical. What should the engineer conclude?

A. The supplier has achieved a perfectly capable process with zero variation

B. The test results are reliable because they show 100% conformance to the nominal specification

C. The supplier's laboratory has exceptional measurement precision that produces identical readings

D. The reported results are almost certainly fabricated or rounded — zero variation across 50 individual measurements is statistically impossible for any real production process; the engineer should request raw data, audit the supplier's testing procedures, and consider requiring witnessed testing

98. A quality engineer is analyzing the effectiveness of the organization's preventive maintenance program and discovers that the program has reduced unplanned downtime by 60% over two years, but the total maintenance cost has increased by 35%. Management questions whether the program is costeffective. How should the engineer evaluate this tradeoff?

A. The increased maintenance cost proves the program is not costeffective

B. Compare the total cost of unplanned downtime eliminated (including lost production, scrap, emergency repair premiums, overtime, and customer delivery penalties) against the 35% increase in maintenance spending — if the savings from eliminated unplanned downtime exceed the increased maintenance cost, the program produces a positive net return

C. Maintenance costs should never increase, regardless of the benefits achieved

D. The 60% downtime reduction is the only metric that matters and cost should not be evaluated

99. A quality engineer is reviewing the organization's approach to quality objectives and discovers that objectives are set annually but are not reviewed or adjusted during the year. Midyear, a major customer complaint reveals a quality issue that was not anticipated when objectives were set. The quality manager argues that since the current objectives are already established, the new quality issue will be addressed in next year's objectives. Is this approach acceptable?

A. Yes, quality objectives should only be established annually and should not change during the year

B. The quality manager is correct because changing objectives midyear creates confusion and undermines goalsetting discipline

C. Midyear objective changes are only permitted during formal management review meetings

D. ISO 9001:2015 requires quality objectives to be updated as appropriate — a significant quality issue that emerges midyear should trigger a review and possible revision of objectives to address the current situation; rigid adherence to an annual cycle that ignores emerging quality risks is inconsistent with the standard's intent

100. A quality engineer is reviewing the organization's internal audit program and notices that audit findings consistently focus on documentation gaps — missing signatures, outdated forms, incomplete records — while ignoring process effectiveness and actual quality performance. What concern should the engineer raise about the audit program's focus?

A. Documentationfocused audits are the appropriate standard for ISO 9001 internal audit programs

B. A documentationheavy audit program risks becoming a compliance exercise that checks paperwork without evaluating whether processes actually produce quality output — the audit program should balance conformance (are procedures followed?) with effectiveness (do processes achieve their intended results and are quality objectives being met?)

C. Process effectiveness cannot be evaluated during internal audits and requires separate assessment

D. Documentation is the only auditable element under ISO 9001 and process effectiveness is outside scope

101. A quality engineer is analyzing the results of a fullfactorial 2^4 experiment with 2 replicates (32 runs). The ANOVA table shows that three effects are significant: Factor A ($p = 0.001$), Factor D ($p = 0.004$), and the AD interaction ($p = 0.009$). Factors B and C and all other interactions are not significant ($p > 0.25$). The quality engineer wants to set Factor B to minimize material cost and Factor C to maximize production speed. Is this approach valid?

A. No, because all four factors must be set to their optimal levels for the response regardless of cost

B. No, because nonsignificant factors should always be set to their center points

C. Yes, but only if the nonsignificant factors are removed from the process entirely

D. Yes, since Factors B and C do not significantly affect the response, they can be set based on nonquality criteria such as cost and speed without degrading product quality

102. A quality engineer is implementing a calibration program and must establish calibration intervals for 150 different instruments across the manufacturing facility. The manufacturer's recommended

interval for most instruments is 12 months. Rather than using 12 months universally, the quality engineer proposes a riskbased approach. Which method best optimizes calibration intervals?

A. Start with the manufacturer's recommendation, then adjust intervals based on actual calibration history — extend intervals for instruments consistently found within tolerance and shorten intervals for instruments found out of tolerance, using the data to optimize the balance between measurement reliability and calibration cost

B. Set all instruments to a 6month interval to maximize measurement confidence

C. Calibrate instruments only when operators report suspicious readings

D. Set intervals based solely on the cost of the instrument — expensive instruments get shorter intervals

103. A quality engineer is reviewing a designed experiment where the team used a splitplot design because one factor (oven temperature) is difficult to change between runs while another factor (coating thickness) can be easily varied. In a splitplot design, the wholeplot factor (temperature) is tested with less precision than the subplot factor (thickness). Why is this design structure important to recognize?

A. Splitplot designs always produce more precise estimates than completely randomized designs

B. The wholeplot and subplot factors have identical precision in splitplot designs

C. The wholeplot factor (temperature) has a different error term than the subplot factor (thickness), meaning the Ftests use different denominators — if the engineer analyzes the data as a completely randomized design, the significance test for temperature will be too liberal, potentially declaring it significant when it is not

D. Splitplot designs can only be used for experiments with exactly two factors

104. A quality engineer discovers that a production line has been operating for three months with an incorrect control chart — the engineer who set up the chart accidentally used the D_3 and D_4 constants for subgroup size $n = 4$ when the actual subgroup size is $n = 6$. The constants used were $D_3 = 0$, $D_4 = 2.282$, while the correct constants for $n = 6$ are $D_3 = 0$, $D_4 = 2.004$. What is the practical consequence of this error?

A. The error has no practical consequence because $D_3 = 0$ for both subgroup sizes

B. The R chart upper control limit has been too wide ($UCL_R = D_4 \times \bar{R}$ is larger with 2.282 than with 2.004), making the chart less sensitive to increases in variability — real increases in process variation that should have triggered investigation may have gone undetected

C. The error affects only the Xbar chart limits, not the R chart limits

D. The R chart has been too sensitive, producing excessive false alarms that disrupted production

105. A quality engineer is reviewing a supplier's process capability report and notices that the supplier calculated Cpk using only measurements from the middle of each production shift, avoiding the first and last 30 minutes. The supplier explains that these periods have "startup and shutdown variation" that is not representative of normal production. Why should the quality engineer reject this approach?

A. The first and last 30 minutes of each shift are irrelevant to product quality

B. Capability studies should only include data from the bestperforming periods to show maximum capability

C. The startup and shutdown data should be analyzed separately and reported as a second Cpk value

D. Excluding startup and shutdown data artificially reduces the observed variation, overstating the true process capability — the customer receives product from all production periods including startup and shutdown, so the capability study must include data from the full range of operating conditions

106. A quality engineer is implementing a visual management system and wants to create an effective andon board for the production floor. The board must communicate realtime information to operators, supervisors, and management at a glance. Which combination of information elements is most valuable?

A. Current machine status (running/warning/stopped), hourly production count versus target, cumulative quality metrics (defect count and rate), and active quality alerts — displayed using intuitive color coding visible from anywhere in the production area

B. The complete organizational chart showing reporting relationships for each department

C. Detailed SPC charts for every monitored characteristic displayed in realtime

D. Monthly quality reports and annual performance summaries posted alongside the board

107. A quality engineer is analyzing a reliability block diagram for an aircraft engine fuel system. The system has a primary fuel pump (R = 0.997) with a backup fuel pump (R = 0.995) in parallel, followed by a fuel filter (R = 0.999) in series, followed by fuel injectors (R = 0.998) in series. What is the system reliability?

A. $R_{sys} = 0.997 \times 0.995 \times 0.999 \times 0.998 = 0.989$, treating all components as series

B. $R_{sys} = 1$ (10.997)(10.995)(10.999)(10.998) = essentially 1.0, treating all as parallel

C. $R_{pumps} = 1(10.997)(10.995) = 10.000015 = 0.999985$; $R_{sys} = 0.999985 \times 0.999 \times 0.998 = 0.997$, combining the parallel pump subsystem in series with the filter and injectors

D. The system reliability cannot be calculated without knowing the failure distribution for each component

108. A quality engineer is conducting a process audit and discovers that operators are using a controlled work instruction that contains a handwritten annotation in the margin. The annotation modifies a critical torque specification from "25 ± 2 N·m" to "28 ± 2 N·m." The operator states that the engineer verbally authorized this change. What audit finding should be issued?

A. An observation suggesting that handwritten annotations should be avoided for neatness

B. A nonconformity because handwritten annotations on controlled documents that modify critical specifications without formal revision, approval, and distribution through the document control system bypass the controls designed to ensure that changes are reviewed, authorized, and communicated consistently

C. No finding because the engineer's verbal authorization constitutes valid change approval

D. A positive finding recognizing the operator's initiative in documenting the verbal change

109. A quality engineer needs to determine the sample size for a onesample ttest to detect a mean shift of 0.5σ with 80% power at α = 0.05 (twosided). Using power analysis tables or formulas, the required sample size is approximately 32. If the engineer wants to detect a shift of 1.0σ with the same power and significance level, what happens to the required sample size?

A. The sample size approximately doubles to 64 because the detectable shift doubled

B. The sample size remains at 32 because power and α are unchanged

C. The sample size increases to approximately 128 because larger shifts require exponentially more data

D. The sample size decreases to approximately 17 because larger shifts are easier to detect and require fewer observations

110. A quality engineer is reviewing an organization's risk register and discovers that the risk assessment methodology uses only a qualitative 5×5 risk matrix. For a complex pharmaceutical manufacturing process, the quality engineer recommends supplementing the qualitative assessment with quantitative risk analysis for the highestrated risks. Why is quantitative analysis valuable for these risks?

A. Qualitative risk matrices are always sufficient for pharmaceutical manufacturing decisions

B. Quantitative analysis is only required by regulatory agencies and adds no analytical value

C. The qualitative matrix should be replaced entirely with quantitative analysis for all identified risks

D. Quantitative analysis provides precise probability estimates, expected loss calculations, and sensitivity analysis for highpriority risks — enabling more informed decisionmaking about risk treatment investments, resource allocation, and whether residual risk levels are truly acceptable

111. A quality engineer is implementing SPC on a process that produces ceramic substrates. The quality characteristic of interest is surface roughness measured in Ra (micrometers). The process produces 6 substrates per hour, and the quality engineer proposes measuring all 6 as a subgroup each hour. A colleague suggests measuring only 3 randomly selected substrates per hour. Which subgrouping strategy is more appropriate for detecting changes in the process mean?

A. Measuring all 6 provides a more precise estimate of the hourly mean but may mask variation between subgroups

B. Measuring 3 is more appropriate because it leaves the remaining 3 as an independent verification sample

C. Measuring all 6 substrates per hour as a single subgroup provides maximum sensitivity to detect mean shifts because the larger subgroup size (n=6 versus n=3) produces tighter control limits on the Xbar chart, improving the chart's ability to detect small process changes

D. The subgroup size has no effect on the Xbar chart's ability to detect mean shifts

112. A quality engineer is analyzing a scatter diagram showing the relationship between ambient temperature and product dimensional accuracy. The Pearson correlation is r = 0.68, and the relationship appears linear. The engineer calculates the regression equation $\hat{y} = 0.15 + 0.003x$. Before implementing temperature compensation in the process, what additional analysis is needed?

A. No additional analysis is needed — r = 0.68 is sufficient evidence to implement compensation

B. A designed experiment should confirm the causal relationship before implementing compensation — the observed correlation could be caused by a confounding variable, and adjusting the process based on a spurious association could introduce unnecessary variation rather than reducing it

C. The correlation must exceed r = 0.95 before any process adjustment is scientifically justified

D. Only a paired ttest can determine whether temperature affects dimensional accuracy

113. A quality engineer is reviewing the organization's approach to design validation for a new medical device. The design team plans to conduct validation testing in a controlled laboratory environment using engineering prototypes operated by design engineers. What is the fundamental limitation of this validation approach?

A. Laboratory validation with engineering prototypes operated by design engineers does not represent actual use conditions — validation should use productionrepresentative devices tested under conditions

that simulate realworld use by intended users, including worstcase environmental conditions and foreseeable use errors

B. Laboratory testing is always sufficient for medical device validation

C. The number of prototypes is the only relevant factor in validation adequacy

D. Design engineers are the most qualified operators for validation testing

114. A quality engineer is reviewing an acceptance sampling plan and discovers that the plan has been modified by the production department: when a lot is rejected, the production supervisor authorizes reinspection of the rejected lot using a larger sample size to "give the lot another chance." This practice occurs regularly. Why is this lotresubmission practice problematic?

A. Larger sample sizes always produce more accurate acceptance decisions

B. Reinspection with different sample sizes is the standard practice recommended by ANSI/ASQ Z1.4

C. Reinspection is only problematic if the lot has already been partially shipped to the customer

D. Repeated sampling of the same lot until it passes invalidates the statistical basis of the sampling plan — the OC curve protection levels and risk calculations assume a single sampling event; allowing reinspection until acceptance effectively guarantees that even poorquality lots will eventually pass, defeating the plan's quality protection

115. A quality engineer is constructing a uchart for monitoring defects per unit on printed circuit board assemblies. The boards vary in size from 50 to 200 components. The average defect rate is $\bar{u} = 0.08$ defects per component. For a board with 150 components, the expected number of defects is $150 \times 0.08 = 12.0$, and the upper control limit is $\bar{u} + 3\sqrt{(\bar{u}/n)} = 0.08 + 3\sqrt{(0.08/150)} = 0.08 + 0.069 = 0.149$ defects per component. What does this control limit tell the operator?

A. Any board with more than 14.9% defective components should be rejected

B. The board passes inspection if its total defect count is below 12.0

C. If the defect rate for this particular 150component board exceeds 0.149 defects per component (more than about 22 total defects), the process should be investigated for a special cause because the rate exceeds what is expected from common cause variation alone

D. The control limit of 0.149 represents the maximum acceptable defect rate specified by the customer

116. A quality engineer is reviewing an organization's Cost of Quality data and discovers that the organization does not track the cost of lost sales due to quality reputation problems. A competitor's product recall generated negative industry press that affected the entire product category, reducing the organization's sales by an estimated $2 million despite having no quality problems of its own. Should this $2 million be included in the organization's COQ?

A. Yes, all lost sales should be included in external failure costs regardless of whether the organization caused the quality problem

B. The $2 million should be classified as an internal failure cost since it affects internal revenue

C. This cost should be tracked as an external environmental factor affecting business performance but is not appropriately classified as a Cost of Quality — COQ includes only costs directly attributable to the organization's own quality activities, not industrywide market effects caused by competitors' problems

D. The cost should be classified as a prevention cost because it motivates the organization to maintain quality

117. A quality engineer is implementing a corrective action for a recurring paint adhesion failure. The root cause investigation reveals that the surface preparation process — a chemical etch — has been gradually losing effectiveness because the etch solution concentration decreases over time as it is consumed. There is no monitoring or replenishment schedule for the etch solution. Which corrective action most effectively prevents recurrence?

A. Retrain operators on the importance of surface preparation for paint adhesion

B. Implement a solution concentration monitoring system with defined replenishment triggers — automated concentration sensors, scheduled titration testing, or time/usagebased replenishment schedules that maintain etch solution within its effective concentration range

C. Increase the etch time to compensate for the decreasing solution concentration

D. Add a paint adhesion test after every 10th unit to detect adhesion failures earlier

118. A quality engineer is analyzing field failure data for an electronic product and discovers that the failure rate follows a lognormal distribution rather than an exponential or Weibull distribution. The lognormal distribution is characterized by which shape when plotted as a probability density function?

A. A symmetric bell curve identical to the normal distribution

B. A flat, uniform shape with equal probability across all failure times

C. A decreasing curve starting high at t = 0 and decreasing monotonically

D. A rightskewed distribution bounded at zero with a peak that shifts depending on the distribution parameters — failure times are concentrated in a window and the right tail extends toward longer times

119. A quality engineer is reviewing the organization's supplier evaluation program and discovers that new suppliers are qualified based solely on a selfassessment questionnaire and a review of their ISO 9001 certification. No onsite audit, process capability verification, or sample evaluation is performed. For a critical component supplier, why is this qualification approach insufficient?

A. Selfassessment questionnaires and ISO 9001 certification provide sufficient evidence of quality system adequacy for any supplier

B. Onsite audits are only required for suppliers located more than 500 miles from the organization

C. A selfassessment questionnaire relies on the supplier's own representation (potentially biased), and ISO certification confirms system conformance but not process capability for the specific component — critical component suppliers require onsite audit verification, process capability data, and sample evaluation to confirm actual manufacturing capability

D. The qualification process should focus exclusively on price competitiveness for new supplier selection

120. A quality engineer is reviewing a process control plan for a critical medical device component. The plan specifies 100% automated vision inspection with a demonstrated detection capability of 99.8%. The defect rate for the inspected characteristic is 500 ppm (0.05%). The quality engineer must determine the expected escape rate — defective parts that pass inspection and reach the customer. What is the calculation?

A. Escape rate = 500 ppm × (1 0.998) = 500 × 0.002 = 1.0 ppm, meaning approximately 1 defective part per million escapes to the customer

B. Escape rate = 0 ppm because 99.8% detection guarantees zero escapes

C. Escape rate = 500 ppm because automated inspection does not reduce the defect rate

D. Escape rate = 500 × 0.998 = 499 ppm because the inspection system rejects 99.8% of all parts

121. A quality engineer is analyzing the results of a Gage R&R study and finds that the total %GRR is 18% of tolerance. The breakdown shows repeatability = 16% and reproducibility = 8%. The engineer must decide which improvement provides the greatest reduction in total measurement variation. Which action is most effective?

A. Standardize the measurement procedure across all operators to reduce the reproducibility component

B. Focus on reducing repeatability because it is the dominant contributor — instrument repair, replacement, or environmental control would produce the greatest reduction in total %GRR since repeatability (16%) contributes far more than reproducibility (8%) to the total measurement system variation

C. Address both repeatability and reproducibility equally since they contribute the same amount

D. Accept the measurement system since 18% is below the 30% maximum threshold

122. A quality engineer is implementing a lean manufacturing initiative and encounters the concept of "standard work." The production manager argues that standardizing work limits operator flexibility and creativity. How should the quality engineer explain the purpose of standard work?

A. Standard work does eliminate flexibility, but this is necessary for quality control

B. Standard work is optional in lean manufacturing and is only used for training new employees

C. The production manager is correct — standard work should be avoided to maximize operator autonomy

D. Standard work establishes the current bestknown method as the baseline — it provides consistency needed for quality and safety, serves as the foundation for detecting abnormalities, and becomes the starting point for improvement; operators contribute to improving the standard through kaizen, not working around it

123. A quality engineer is reviewing an organization's management review and notices that the review consistently identifies the same improvement opportunities year after year — "improve ontime delivery," "reduce customer complaints," "enhance supplier quality" — but never documents specific actions, assigns responsibilities, or tracks progress. What is the fundamental problem with this management review?

A. The review correctly identifies improvement opportunities and meets ISO 9001 requirements

B. The identified opportunities are too broad — management review should focus on specific metrics only

C. The review produces recurring identification of opportunities without actionable outputs — it fails to translate identified needs into specific, assigned, resourced, and tracked improvement actions, making the review a discussion exercise rather than a driver of actual quality improvement

D. Management review should not identify improvement opportunities — that is the internal audit's function

124. A quality engineer is evaluating the statistical power of a hypothesis test that has already been conducted. The test compared two process means, yielded $p = 0.18$ at $\alpha = 0.05$, and failed to reject H_0. The observed difference was 1.5 units, which the engineer considers practically meaningful. The sample sizes were $n_1 = n_2 = 12$. A posthoc power analysis reveals that the test had only 35% power to detect a 1.5unit difference. What does this low power mean?

A. The low power confirms that no real difference exists between the two process means

B. The test had only a 35% probability of detecting the 1.5unit difference even if it truly existed — the nonsignificant result may be a Type II error caused by insufficient sample size rather than evidence of no real difference; a larger sample study may be warranted given the practical significance of the 1.5unit difference

C. The power analysis is irrelevant because the hypothesis test has already been completed

D. The 35% power proves that the significance level should have been set higher than 0.05

125. A quality engineer discovers that the organization's internal audit findings over the past three years show a declining trend in the number of findings per audit (from 8 to 2 per audit). Simultaneously, external audit findings have increased (from 1 to 5 per audit). What is the most likely explanation for this diverging trend?

A. The quality management system has improved internally but deteriorated in areas that external auditors focus on

B. The internal audit program has become less rigorous over time — auditors may have developed familiarity bias, reduced their scope, or softened their criteria, allowing real problems to go undetected internally while external auditors with fresh perspectives continue to identify them

C. External auditors have become more stringent while the quality system has remained stable

D. The diverging trends are coincidental and have no relationship to each other

126. A quality engineer is conducting a process capability study and discovers that the process data exhibits bimodality — two distinct peaks in the histogram. The engineer suspects that data from two different machines has been combined. Rather than calculating capability on the combined data, the engineer separates the data by machine. Machine 1 yields Cpk = 1.65 and Machine 2 yields Cpk = 0.72. What is the correct interpretation and action?

A. Report the average Cpk of (1.65 + 0.72)/2 = 1.19 as the overall process capability

B. Report the combined Cpk from the merged data since it represents the overall process output

C. Report the higher Cpk (1.65) since Machine 1 demonstrates the process can achieve adequate capability

D. Report both Cpk values separately — Machine 1 is capable while Machine 2 is not; Machine 2 requires process improvement to match Machine 1's performance; the bimodal combined data would produce a misleading single Cpk that accurately represents neither machine

127. A quality engineer is implementing a riskbased approach to incoming inspection and must determine the appropriate inspection level for four types of incoming materials. Material A: safetycritical, new supplier, no quality history. Material B: noncritical, established supplier with 5year quality track record of <100 ppm defect rate. Material C: safetycritical, established supplier with proven capability (Cpk > 2.0 documented). Material D: noncritical, new supplier, no quality history. Rank these from most to least intensive inspection.

A. A (most intensive) → D → C → B (least intensive), based on the combination of component criticality and supplier qualification status — safetycritical components from unproven suppliers require the most rigorous inspection while noncritical components from proven suppliers require the least

B. All four materials should receive identical inspection intensity for fairness and consistency

C. Inspection intensity should be based solely on supplier relationship length regardless of component criticality

D. B → D → C → A, prioritizing new suppliers over established ones regardless of component criticality

128. A quality engineer is analyzing the results of a measurement system linearity study. The study tests the measurement instrument at five reference values across its operating range. The results show that the bias is 0.002 mm at the low end, 0.001 mm at the midlow point, 0.000 mm at the center, +0.003 mm at the midhigh point, and +0.008 mm at the high end. The specification tolerance for the measured characteristic is 0.100 mm. What is the quality engineer's assessment?

A. The linearity is excellent because all biases are small relative to the tolerance

B. The linearity is unacceptable because the bias values are not all exactly zero

C. The linearity shows a systematic trend — bias increases from negative at the low end to increasingly positive at the high end, spanning a total range of 0.010 mm (10% of the 0.100 mm tolerance); this systematic pattern indicates the instrument reads progressively higher as values increase and may warrant correction or instrument replacement depending on the application

D. Linearity can only be assessed if the reference values are exactly at the specification limits

129. A quality engineer is implementing a quality management system for a startup medical device company. The company has 25 employees and produces a single product line. The quality manager asks whether the company needs a formal quality manual. Under ISO 9001:2015 and ISO 13485:2016, what is the answer?

A. Neither standard requires a quality manual — the startup can use any documentation format

B. ISO 9001:2015 eliminated the mandatory quality manual requirement, but ISO 13485:2016 (for medical devices) still requires a quality manual including the QMS scope, documented procedures or references to them, and a description of process interactions — the startup must maintain a quality manual for its medical device QMS

C. Both standards require identical documentation including a mandatory quality manual

D. Only companies with more than 100 employees are required to maintain a quality manual under either standard

130. A quality engineer is analyzing a control chart and observes that the Xbar chart shows 7 consecutive points on one side of the center line (above it), followed by 8 consecutive points on the other side (below it). Neither sequence individually reaches the 8point Western Electric rule threshold for a run. However, the sharp transition from consistently above to consistently below the center line suggests which condition?

A. The process is in statistical control because neither run reached 8 consecutive points

B. The control chart is functioning correctly and no investigation is warranted

C. The subgroup size should be increased to capture more variation within each subgroup

D. A step change in the process mean likely occurred between the two groups — the process was running above center line, then shifted to below center line; while neither run individually triggers the 8point rule, the abrupt transition pattern warrants investigation to determine what changed between the two periods

131. A quality engineer is evaluating whether to implement acceptance sampling or 100% inspection for a highvolume electronic component. The defect rate is 800 ppm, the component is safetycritical, and each escaped defect has an estimated cost of $15,000 in warranty, recall, and liability expenses. The cost of 100% automated inspection is $0.02 per unit. Annual production volume is 5 million units. Which economic analysis determines the better approach?

A. 100% automated inspection costs 5,000,000 × $0.02 = $100,000/year. At 800 ppm with 99.5% detection, escaped defects = 5,000,000 × 0.0008 × 0.005 = 20 escapes × $15,000 = $300,000. Total = $400,000. Without inspection: 5,000,000 × 0.0008 × $15,000 = $60,000,000 in defect costs. The $100,000 inspection investment prevents approximately $59.6 million in potential losses

B. Acceptance sampling is always more economical for highvolume production

C. 100% inspection is never justified because it cannot achieve 100% detection

D. The economic analysis should only consider the cost of inspection, not the cost of escaped defects

132. A quality engineer is reviewing the organization's approach to management of change and discovers that the change control procedure requires engineering review but does not require quality review for process parameter changes. A recent process change — increasing conveyor speed by 15% — was approved by engineering without quality input. After implementation, the defect rate increased from 200 ppm to 1,500 ppm because the faster speed reduced cure time below the validated minimum. What quality system improvement is needed?

A. Quality department review should be required for all process changes that could affect product quality, not just engineering review — the change control procedure must include quality impact assessment as a mandatory step before implementation of any change to production processes

B. The engineering department should also be responsible for quality review to streamline the process

C. Process parameter changes should never require formal change control approval

D. The conveyor speed change should have been classified as a maintenance activity exempt from change control

133. A quality engineer is conducting a designed experiment to optimize a painting process. The experiment includes three factors: spray pressure (A), paint viscosity (B), and booth temperature (C). The 2^3 full factorial with 2 replicates (16 runs) yields the following results: A significant ($p = 0.002$), B significant ($p = 0.01$), C not significant ($p = 0.55$), AB significant ($p = 0.008$), AC not significant ($p = 0.62$), BC not significant ($p = 0.41$), ABC not significant ($p = 0.78$). The quality engineer builds a model with A, B, and AB. What is the practical interpretation of the significant AB interaction?

A. Spray pressure and paint viscosity act independently and can be optimized separately

B. The optimal spray pressure depends on the paint viscosity being used — at one viscosity level, a higher pressure may be optimal, while at a different viscosity, a lower pressure may work better; process setup must account for the specific paint batch being used

C. The AB interaction cancels out the main effects of A and B, making them practically unimportant

D. The interaction means both factors should be removed from the model in favor of a single combined factor

134. A quality engineer is reviewing a supplier's corrective action response to a lot rejection. The supplier's response provides a detailed root cause analysis, identifies the failure mechanism, and proposes a robust corrective action with errorproofing. However, the response does not include a timeline for implementation, a responsible individual, or a method for verifying effectiveness. What should the quality engineer require before accepting the response?

A. The root cause analysis and proposed action are sufficient — implementation details will work themselves out naturally

B. The supplier should resubmit the entire response with a different root cause and corrective action

C. Only the implementation timeline is needed; responsible individuals and effectiveness verification are optional

D. The response must be supplemented with a specific implementation timeline, an assigned responsible individual with authority to implement the action, and a defined method and criteria for verifying effectiveness — without these elements, even an excellent corrective action plan has no mechanism to ensure execution and confirmation

135. A quality engineer is implementing total productive maintenance (TPM) and calculating OEE for a CNC machining center. The data for one shift shows: scheduled production time = 480 minutes, planned downtime (breaks, meetings) = 30 minutes, unplanned downtime (breakdowns, changeovers) = 50 minutes, ideal cycle time = 2 minutes/part, actual parts produced = 180, and rejected parts = 6. What is the OEE?

A. Availability = (4803050)/(48030) = 400/450 = 0.889; Performance = (180 × 2)/400 = 360/400 = 0.900; Quality = (1806)/180 = 174/180 = 0.967; OEE = 0.889 × 0.900 × 0.967 = 0.773 or 77.3%

B. OEE = 180/480 = 37.5% based solely on parts produced versus scheduled time

C. OEE = (1806)/180 = 96.7% based solely on the quality rate

D. OEE = 400/480 = 83.3% based solely on machine availability

136. A quality engineer is reviewing the organization's approach to continual improvement and discovers that all improvement activities are driven by the quality department. Production, engineering, maintenance, and other departments view quality improvement as the quality department's responsibility. No crossfunctional improvement teams exist. What fundamental TQM principle is being violated?

A. Total employee involvement — quality improvement is everyone's responsibility across all functions, not solely the quality department's; without crossfunctional participation, the organization misses improvement opportunities in areas where the quality department has limited expertise and influence

B. The quality department is appropriately responsible for all improvement activities in any organization

C. Only management should be involved in quality improvement decisions, not departmentlevel employees

D. Crossfunctional teams are only required for organizations pursuing Baldrige recognition

137. A quality engineer is analyzing a designed experiment and must determine whether the experiment provides enough data to estimate all desired effects. The experiment is a 2^{5-2} fractional factorial (8 runs, Resolution III) with defining relations I = ABD and I = ACE. The engineer wants to estimate all five main effects and all ten twofactor interactions. Can this design accomplish this goal?

A. Yes, Resolution III designs can estimate all main effects and twofactor interactions independently

B. No — with only 8 runs (7 degrees of freedom for effects), the design cannot estimate 15 effects (5 main + 10 twofactor interactions); additionally, Resolution III confounds main effects with twofactor interactions, preventing clean estimation of either

C. The design can estimate all effects if center points are added

D. All fractional factorial designs can estimate any number of effects regardless of the number of runs

138. A quality engineer is reviewing a process control plan and notices that the reaction plan for a critical characteristic states: "If out of specification, quarantine affected parts and notify quality engineer." While this reaction plan addresses containment, what critical element is missing?

A. The reaction plan is complete as written because quarantine and notification are the essential elements

B. The plan should specify which specific quality engineer to notify by name and phone number

C. The plan should include a requirement for the operator to document the exact nature of the deviation

D. The reaction plan should also require stopping the process to prevent further nonconforming production, investigating the root cause of the outofspecification condition, and verifying the process is back in control before resuming production — quarantine and notification alone do not prevent continued production of defective parts

139. A quality engineer is evaluating a proposed change from manual caliper measurement to an automated laser measurement system for a critical dimension. The current manual system has %GRR = 22% of tolerance, while the proposed laser system has %GRR = 4% of tolerance. The laser system costs $85,000. Besides the measurement capability improvement, which additional benefit should the quality engineer emphasize when justifying the investment?

A. The laser system has a longer calibration interval than the caliper

B. The primary cost justification is the instrument purchase price comparison only

C. The lower %GRR eliminates the need for any operator training on the measurement

D. The improved measurement system reduces the risk of incorrect accept/reject decisions — with the manual system's 22% GRR, a significant portion of parts near specification limits may be incorrectly classified (good parts rejected, bad parts accepted), and reducing GRR to 4% dramatically improves decision accuracy, potentially reducing both scrap and customer escapes

140. A quality engineer is reviewing a product liability risk assessment and discovers that the design team has relied entirely on compliance with applicable industry standards as evidence that the product is safe. The team argues that meeting all mandatory and voluntary standards provides a complete defense against product liability claims. Why is this assumption incorrect?

A. Industry standards are always sufficient for product liability defense as long as they are current

B. Standards compliance is only relevant for regulatory approval, not product liability

C. Standards represent minimum industry consensus requirements at the time of publication — they may not address all foreseeable use conditions, user populations, or failure modes specific to the product; a manufacturer has an independent duty to identify and mitigate productspecific risks beyond what standards require

D. Product liability only applies to products sold in the United States

141. A quality engineer is implementing a supplier quality management program and must establish incoming inspection requirements for a new critical component supplier. The supplier has ISO 9001 certification, has provided process capability data showing Cpk = 1.85, and has passed an onsite audit with zero findings. The quality engineer recommends starting with normal inspection under ANSI/ASQ Z1.4 rather than immediately implementing reduced or skiplot inspection. Why is this conservative approach appropriate despite the supplier's strong credentials?

A. Normal inspection is required for exactly 12 months before any reduction is permitted

B. Starting with normal inspection establishes a quality performance baseline with objective incoming inspection data — credentials and audit results provide supporting evidence, but actual delivered quality must be verified through the organization's own inspection before inspection levels are reduced; trust is built through demonstrated performance, not documentation alone

C. ISO 9001 certification makes incoming inspection unnecessary for all certified suppliers

D. The supplier's Cpk of 1.85 should automatically qualify them for skiplot inspection

142. A quality engineer is analyzing warranty return data and discovers an interesting pattern: the product's failure rate curve shows a distinct "hump" between 12 and 18 months of service, with lower failure rates both before and after this period. This nonmonotonic failure rate pattern does not fit the standard bathtub curve model. What is the most likely explanation?

A. The bathtub curve always applies to all products and the data must contain an error

B. The "hump" between 1218 months likely represents a specific wearout mechanism for one component that has a relatively narrow failure distribution — once the susceptible components have failed and been replaced under warranty, the remaining population returns to a lower failure rate

C. All warranty data is inherently unreliable and should not be used for reliability analysis

D. The failure rate calculation methodology is incorrect and should be recalculated using different intervals

143. A quality engineer is reviewing the organization's approach to handling customer complaints and discovers that complaints are classified, logged, and responded to individually, but no systematic analysis is performed to identify patterns or trends across complaints. Each complaint is treated as an isolated event. What quality system improvement would provide the greatest additional value?

A. Increase the speed of individual complaint responses to improve customer satisfaction

B. Hire additional complaint handling staff to reduce the backlog of open complaints

C. Complaints should only be tracked for regulatory reporting purposes, not for trend analysis

D. Implement systematic complaint trend analysis — Pareto analysis of complaint categories, stratification by product/region/time period, and correlation with production data — to identify systemic quality issues, prioritize improvement projects, and detect emerging failure patterns before they become widespread problems

144. A quality engineer is implementing a document control system and must address the challenge of ensuring that operators on the production floor always have access to the current revision of work instructions. The current paperbased system requires manual replacement of documents at each workstation when revisions are issued. The quality engineer proposes transitioning to electronic displays at each workstation that automatically show the current revision. What key advantage does this electronic approach provide over the paper system?

A. Electronic displays eliminate the risk of operators using obsolete procedures because the system automatically displays only the current revision — there are no paper copies to become outdated, no manual distribution or withdrawal process required, and revision changes are immediately effective at all workstations simultaneously

B. Electronic displays are less expensive than paperbased document control systems

C. Electronic displays eliminate the need for any document control procedure

D. Paperbased systems are more reliable because they do not depend on electricity or network connectivity

145. A quality engineer is implementing a riskbased approach to process validation revalidation. The current policy requires full revalidation of all processes every three years, regardless of process stability, change history, or product quality performance. The quality engineer proposes a more targeted approach. Which criteria should trigger revalidation?

A. Revalidation should never be performed once the initial validation is complete

B. Revalidation should be triggered by specific events including significant process changes, equipment modifications or replacements, material substitutions, facility moves, adverse quality trends, and

regulatory requirement changes — rather than arbitrary calendar intervals, enabling resources to focus on processes where validation status is genuinely in question

C. Revalidation should be triggered only by customer complaints about the specific product

D. All processes should be revalidated monthly to maintain maximum confidence

146. A quality engineer is reviewing a supplier's SPC data and notices that the supplier's control charts use specification limits instead of statistically calculated control limits. The supplier's process has Cpk = 1.85 for the characteristic being monitored. The quality engineer explains that despite the high Cpk, specification limits on the control chart are problematic. What is the specific risk?

A. Using specification limits on control charts with a process this capable creates no practical risk

B. Specification limits with Cpk = 1.85 provide equivalent monitoring to statistical control limits

C. The chart should display both specification and control limits simultaneously

D. With specification limits at ±3σ_spec and statistical limits at approximately ±0.81σ_spec (for this Cpk), the specificationbased chart cannot detect process shifts until they approach the specification — a shift of 2σ would be invisible on the speclimit chart but clearly outofcontrol on a proper chart, allowing significant quality degradation before detection

147. A quality engineer is conducting a failure mode and effects analysis for a new automotive braking component. The team identifies a potential failure mode where a seal could degrade over time due to exposure to brake fluid at elevated temperatures. The team assigns Severity = 10 (loss of braking), Occurrence = 2 (low probability based on accelerated aging tests), and Detection = 2 (comprehensive endofline functional test). The traditional RPN = 10 × 2 × 2 = 40. Under the AIAG/VDA Action Priority method, should this failure mode receive a high priority despite the low RPN?

A. No, the low RPN of 40 correctly indicates minimal risk that requires no further action

B. The RPN is too low for any action and the failure mode should be removed from the FMEA

C. The AP method applies the same threshold as RPN and would also assign low priority at RPN = 40

D. Yes — under the Action Priority method, any failure mode with Severity = 10 (loss of function creating safety hazard) receives high priority regardless of how low the occurrence and detection ratings are, because the consequences of being wrong about probability or detection capability are catastrophic and irreversible

148. A quality engineer is reviewing a process that produces precision optical components. The process has demonstrated Cp = 2.50 and Cpk = 2.45 over 12 months of production data. These exceptionally high capability indices suggest which condition about the relationship between the process and its specifications?

A. The process has significant centering problems that are masked by the high Cp value

B. The specification limits are appropriately set for this process and no adjustment is needed

C. The high Cpk indicates the process is running at exactly the specification nominal with zero variation

D. The specification limits may be much wider than necessary for this process — with Cpk = 2.45, the process spread is only about 40% of the specification tolerance, suggesting the specifications may have been carried over from a less capable predecessor process or set conservatively; tightening specifications to match the demonstrated capability could add value for the customer

149. A quality engineer is analyzing a control chart that shows all 25 subgroups within control limits, with no runs, trends, or other patternbased signals. However, the engineer notices that the control limits are extraordinarily wide — the UCL and LCL span a range that encompasses nearly the entire specification tolerance. What is the most likely cause of these unusually wide control limits?

A. The process has exceptionally high variation that needs improvement

B. The subgroup size is too large, producing artificially wide control limits

C. Wide control limits are desirable because they minimize false alarm rates

D. The baseline data used to calculate the limits likely contained one or more outofcontrol subgroups with assignable causes that inflated the $\bar{R}$ or $\bar{S}$ estimate — these outlier subgroups should have been investigated and removed before finalizing the control limits

150. A quality engineer is implementing a supplier development program and must select between two approaches for improving a struggling supplier's quality performance. Approach 1: The customer sends a quality engineer to the supplier's facility for a twoweek intensive improvement project focused on the specific quality problem. Approach 2: The customer requires the supplier to hire an external consultant to address their quality system broadly. Which approach typically produces faster, more targeted results?

A. Approach 2 because external consultants have broader quality management expertise

B. Approach 1 typically produces faster, more targeted results because the customer's quality engineer has direct knowledge of the specific quality requirement, the failure mode, and the product application — this focused engagement addresses the immediate problem directly rather than implementing broad system improvements that may not target the specific issue

C. Both approaches produce identical results regardless of the specific quality problem

D. Neither approach is effective — suppliers must improve on their own without external assistance

151. A quality engineer is analyzing the results of an acceptance sampling plan and calculates that the Average Outgoing Quality Limit (AOQL) for the plan is 2.8%. This means that under the assumption of 100% inspection of rejected lots with defective replacement, the worstcase average outgoing quality — regardless of how bad the incoming quality is — will never exceed 2.8%. The quality engineer must decide whether this AOQL provides adequate protection for the application. For a medical device component, what is the assessment?

A. An AOQL of 2.8% is acceptable for all medical device applications

B. The AOQL is irrelevant for medical devices because 100% inspection is always required

C. The AOQL assessment depends on the specific component and its criticality — 2.8% means up to 28,000 ppm could escape to the customer under worstcase conditions, which is almost certainly unacceptable for a safetycritical medical device characteristic

D. For medical devices, an AOQL of 2.8% is considered excellent and meets all regulatory requirements

152. A quality engineer is reviewing the organization's approach to design reviews and discovers that design reviews are conducted as presentations where the design team shows slides to management. No external reviewers participate, no checklists are used, and the review does not systematically evaluate the design against requirements. Why is this approach inadequate?

A. Presentationstyle reviews meet all ISO 9001 requirements for design review

B. Design reviews should only involve the design team members to avoid conflict

C. Effective design reviews require systematic evaluation of the design against input requirements, participation of relevant functions beyond the design team (manufacturing, quality, service, procurement), documented action items for identified issues, and followup verification of issue resolution — a presentation without structured assessment misses the review's purpose

D. Design reviews are only required for products that will be manufactured in high volume

153. A quality engineer is analyzing a designed experiment and discovers that the response variable has been measured using two different instruments during the experiment — the original instrument broke at run 9, and a replacement instrument was used for runs 1016. The two instruments have not been crosscorrelated. How does this instrument change affect the experiment?

A. The instrument change has no effect because both instruments measure the same characteristic

B. The instrument change introduces a potential confounding variable — any bias difference between the two instruments would create a systematic shift at run 9 that could be mistaken for a factor effect or could mask a real effect; the experiment should be analyzed with the instrument change as a blocking variable, and the affected runs should be carefully evaluated

C. Only the data from the original instrument should be used; the replacement instrument data should be discarded

D. The instrument change improves the experiment by providing independent confirmation of results

154. A quality engineer is reviewing a product's reliability allocation. The product is a series system with three subsystems, and the overall reliability requirement is 0.95 over 5,000 hours. The design team

allocates equal reliability to each subsystem: $R_1 = R_2 = R_3 = 0.95^{(1/3)} \approx 0.983$. A reliability engineer argues that equal allocation is not optimal. Why might unequal allocation be preferred?

A. Equal allocation is always optimal for series systems with any number of components

B. Unequal allocation allows higher reliability requirements for subsystems that are easier or less expensive to improve, and lower requirements for subsystems where improvement is difficult or costly — this optimization produces the same system reliability at lower total cost than forcing every subsystem to achieve the same target

C. Unequal allocation is only used when the subsystems have different operating temperatures

D. Equal allocation produces higher system reliability than any unequal allocation scheme

155. A quality engineer is implementing a quality cost tracking system and must classify the cost of reworking defective products found during inprocess inspection. The rework involves disassembling the product, replacing a faulty component, and retesting. Under which COQ category should these costs be classified?

A. Prevention costs because rework prevents defective products from reaching the customer

B. Appraisal costs because the defective products were found during inprocess inspection

C. External failure costs because the faulty component came from an external supplier

D. Internal failure costs because the defects were found and corrected internally before the product reached the customer — rework represents the cost of quality failure that was caught before shipment

156. A quality engineer is reviewing the organization's supplier audit program and discovers that audit reports are welldocumented with detailed findings, but the followup process is weak — there is no systematic tracking of whether suppliers actually implement corrective actions for audit findings. Many findings from audits conducted 12 months ago remain unresolved. What quality system improvement is needed?

A. The audit reports should be simplified to reduce the number of findings requiring followup

B. Supplier audit findings should be communicated verbally rather than in written reports

C. A formal followup tracking system that monitors supplier corrective action implementation with defined deadlines, escalation procedures for overdue items, and verification of effectiveness — audit findings without followthrough produce no quality improvement regardless of how well the audit itself was conducted

D. Only critical findings require followup; minor findings can be left unresolved indefinitely

157. A quality engineer is analyzing a process that has been in statistical control for 6 months. The Xbar chart shows a process mean of 50.00 mm with control limits at 49.88 and 50.12. The R chart shows $\bar{R}$ = 0.28 with UCL at 0.59 (for n = 5). The specification is 50.00 ± 0.50 mm. A production operator asks: "Since the control limits are much tighter than the specifications, why can't we just use the spec limits on the chart and relax a bit?" How should the quality engineer explain the purpose of the tighter control limits?

A. The tighter control limits exist specifically to detect small process changes before they can grow into specification violations — by the time a shift is large enough to approach the specification limits, hundreds or thousands of parts may have been produced at the shifted level; the control limits provide early warning to enable intervention while all output is still well within specification

B. The tight control limits are required by ISO 9001 and cannot be relaxed for any reason

C. Wider limits could be used as long as the operator checks more frequently

D. The tight limits exist because the chart was calculated incorrectly and should be widened

158. A quality engineer is reviewing the results of a hypothesis test where the pvalue = 0.001 and the observed effect size is extremely small (difference of 0.002 mm between two process means with a specification tolerance of ±1.0 mm). The sample size was n = 5,000 per group. How should the quality engineer interpret this result?

A. The extremely small pvalue proves the difference is both statistically and practically significant

B. The large sample size invalidates the hypothesis test and the result should be disregarded

C. The pvalue of 0.001 should be interpreted as proving the two processes are identical

D. The result is statistically significant (p = 0.001) but not practically significant — the 0.002 mm difference, while statistically real, represents only 0.1% of the 2.0 mm tolerance and has no meaningful impact on product quality or process performance; the large sample size provided enough power to detect this trivially small difference

159. A quality engineer is implementing a lean initiative and the team identifies that the longest changeover time on the production line is 2.5 hours for a complex die change on a stamping press. The team applies SMED methodology and separates activities into internal (1.5 hours) and external (1.0 hour). After moving all possible external activities outside the machinestopped window and streamlining internal activities, the changeover time is reduced to 45 minutes. What is the next SMED improvement target?

A. The 45minute changeover is the theoretical minimum and no further improvement is possible

B. The team should focus on reducing the remaining 45 minutes of internal setup time through further streamlining — eliminating adjustments through preset methods, converting additional internal activities to external, using quickrelease mechanisms, and parallelizing remaining internal tasks with a second operator

C. The team should increase batch sizes to reduce the frequency of changeovers rather than further reducing changeover time

D. The team should focus on improving product quality rather than further reducing setup time

160. A quality engineer is reviewing the organization's approach to quality data analysis and discovers that the organization collects extensive quality data — SPC data, inspection results, customer complaints, audit findings, calibration records — but the data resides in separate, disconnected systems. No integrated analysis is performed across data sources. What is the primary consequence of these data silos?

A. Data silos have no practical effect on quality management decisionmaking

B. Separate systems are preferred because they protect data security for each function

C. The organization misses opportunities to identify crossfunctional patterns, correlations, and systemic issues that would be visible through integrated analysis — a complaint trend that correlates with a specific material lot, an inspection failure pattern that aligns with a calibration schedule, or a process shift that coincides with a supplier change cannot be detected when data remains isolated

D. Data integration is only necessary for organizations with more than 1,000 employees

161. A quality engineer is conducting an internal audit of the organization's corrective action system and discovers that 60% of closed corrective actions have "retrained operator" as the permanent corrective action. The recurrence rate for these retrainingbased CAs is 52%. The quality engineer must recommend a systemic improvement. Which action addresses the root cause of this pattern?

A. Implement a CAPA review process that requires investigation beyond individual operator error — when "operator error" is cited, the review must ask what systemic factors enabled the error (unclear procedures, inadequate errorproofing, poor workspace design, insufficient visual controls) and mandate systemlevel corrective actions rather than individual retraining

B. Increase the frequency of operator retraining to monthly sessions

C. Replace all operators who have been associated with retrainingbased corrective actions

D. Eliminate the corrective action system since it is not producing effective results

162. A quality engineer is analyzing a Weibull plot of bearing failure data and obtains $\beta = 1.0$ and $\eta =$ 30,000 hours. The maintenance manager asks whether a preventive replacement program at 20,000hour intervals would reduce the failure rate. Based on the Weibull parameter $\beta = 1.0$, what should the quality engineer advise?

A. Preventive replacement at 20,000 hours would significantly reduce the failure rate

B. With $\beta = 1.0$, the failure rate is constant (exponential distribution) — preventive replacement provides no benefit because the probability of failure in the next hour is the same regardless of how long the bearing has been operating; replacement at 20,000 hours simply substitutes a used bearing with a new one that has the same failure probability

C. The failure rate is decreasing, so replacement should be avoided entirely

D. Preventive replacement should be implemented at 10,000hour intervals instead of 20,000

163. A quality engineer is reviewing a product design and encounters a GD&T feature control frame specifying circular runout of 0.03 mm to datum A. A colleague asks how circular runout differs from total runout. What is the key distinction?

A. Circular runout and total runout are identical controls with different names

B. Total runout always has a tighter tolerance than circular runout for the same feature

C. Circular runout is measured with a CMM while total runout is measured with an indicator

D. Circular runout controls variation at each individual crosssection as the part rotates about the datum axis, while total runout controls the entire surface simultaneously — circular runout checks individual "slices," so it cannot detect taper or straightness errors along the axis that total runout would capture

164. A quality engineer is reviewing an organization's approach to supplier risk assessment and discovers that the risk assessment only considers quality performance metrics. The assessment does not evaluate financial stability, geographic risk, regulatory compliance, or business continuity capability. A key supplier files for bankruptcy, disrupting supply for 8 weeks. This event demonstrates the limitation of which risk assessment approach?

A. Qualityfocused risk assessment is always sufficient for supplier evaluation

B. Financial risk assessment is only relevant for suppliers in developing countries

C. A narrow, qualityonly supplier risk assessment fails to evaluate the full range of supply chain risks — financial instability, geographic concentration, regulatory changes, natural disaster exposure, and business continuity capability all affect supply reliability and should be included in a comprehensive supplier risk assessment

D. Business continuity assessment is only required for suppliers of noncritical components

165. A quality engineer is implementing a process capability study and must decide how many data points to collect. The process has been running stably for 6 months. Industry guidelines suggest 50100 individual measurements from a stable process. The quality engineer collects 100 measurements over 2 weeks, spanning multiple shifts, operators, and material lots. Why is this 2week collection period superior to collecting 100 measurements in a single 4hour production run?

A. The 2week collection captures variation from multiple sources — shifttoshift, operatortooperator, lottolot, and daytoday environmental changes — that a 4hour run would miss; the resulting capability indices reflect the process's true longterm performance rather than a favorable shortterm snapshot

B. The 4hour collection would produce more data points and is therefore more statistically reliable

C. Both collection periods produce identical capability estimates regardless of the time span

D. The 2week collection is only necessary if the process has known stability problems

166. A quality engineer is reviewing a control chart and observes that all 30 subgroup means fall within a very narrow band — between 49.95 and 50.05 — with control limits at 49.80 and 50.20. This pattern, where all points cluster tightly near the center line with none approaching the control limits, is known as stratification. What is the most likely cause?

A. The process is exhibiting exceptional stability and the narrow clustering confirms excellent control

B. The withinsubgroup variation is inflated — likely because the subgroups contain measurements from multiple distinct process streams (different machines, cavities, or heads) with different means, producing artificially wide control limits that compress all subgroup averages toward the grand mean

C. The control limits are correctly calculated and the clustering is the expected pattern for a capable process

D. The subgroup size should be reduced to spread the points more evenly between the control limits

167. A quality engineer is evaluating a new measurement technology — a noncontact laser scanner — for inspecting complex curved surfaces on aerospace components. The current method is a coordinate measuring machine (CMM) with a touch probe. The laser scanner can measure 10,000 points per second

versus the CMM's 1 point every 3 seconds. However, each individual laser point has slightly lower accuracy than a CMM touch point. For this application, which system provides better overall quality assessment?

A. The CMM is always superior because each individual measurement point is more accurate

B. The scanner's dramatically higher point density provides a much more complete picture of the surface geometry — while individual point accuracy is slightly lower, the comprehensive surface coverage detects form deviations, waviness, and localized defects that the CMM's sparse point sampling might miss entirely

C. Both systems provide identical quality assessment regardless of point density

D. The laser scanner should only be used for noncritical dimensions

168. A quality engineer is reviewing the organization's approach to preventive maintenance for measurement equipment and discovers that all instruments receive PM at the same interval regardless of usage rate, criticality, or failure history. A micrometer used once per week receives the same PM frequency as a CMM used continuously on critical dimensions. What improvement should the quality engineer recommend?

A. Riskbased PM scheduling that considers usage frequency, measurement criticality, failure history, and environmental exposure — highuse instruments on critical measurements should receive more frequent PM, while lightly used instruments in controlled environments may safely extend their PM intervals

B. All instruments should receive PM monthly regardless of usage or criticality

C. PM should be eliminated entirely and replaced with calibrationonly programs

D. Only instruments that have failed should receive PM; working instruments need no maintenance

169. A quality engineer is reviewing the organization's quality objectives for the upcoming year. The proposed objectives include: "Reduce scrap rate from 2.5% to 1.5%," "Achieve customer satisfaction score of 92%," and "Complete all internal audits on schedule." The quality engineer notices that while

these objectives are measurable, they lack one critical element required by ISO 9001:2015 Clause 6.2. What is missing?

A. The objectives should reference specific ISO 9001 clause numbers

B. The objectives need to specify who is responsible, what resources are needed, how progress will be monitored, and what actions will be taken to achieve each objective — having measurable targets without defined action plans, responsibilities, and resource allocations reduces objectives to wishes rather than actionable commitments

C. The objectives should be expressed in financial terms only

D. The objectives are complete and fully compliant with ISO 9001:2015

170. A quality engineer is analyzing field failure data and discovers that products manufactured during a specific twoweek period have a failure rate 5 times higher than products manufactured before or after that period. The quality engineer must identify what changed during those two weeks. Which investigative approach is most systematic and effective?

A. Interview operators who worked during the twoweek period to identify any recalled changes

B. Conduct a comprehensive timeline analysis correlating the affected production period with all potential change factors — raw material lot changes, equipment maintenance records, personnel changes, environmental data, supplier deliveries, process parameter logs, and any documented or undocumented changes — to identify which variable(s) coincide with the anomalous period

C. Assume the failure rate increase was caused by random variation and take no action

D. Implement additional final inspection for all current production to prevent future failures

171. A quality engineer is reviewing the organization's approach to risk monitoring and discovers that risk indicators are reviewed only during the annual management review. Between reviews, no risk monitoring occurs. A previously "medium" rated supply chain risk materialized during the year, causing a significant production disruption that could have been anticipated if the risk indicator (supplier ontime

delivery declining from 98% to 82% over 6 months) had been monitored. What improvement should the quality engineer recommend?

A. Annual risk review during management review is sufficient for all organizations

B. Risk monitoring should only occur when a customer complaint triggers a review

C. Risk indicators for all identified risks should be reviewed monthly regardless of their risk level

D. Establish ongoing risk monitoring with defined leading indicators, monitoring frequencies proportional to risk severity, and trigger thresholds that escalate to management attention when indicators show deterioration — enabling early intervention before risks materialize rather than retrospective recognition after impact

172. A quality engineer is analyzing the relationship between two process variables and calculates both Pearson ($r = 0.35$) and Spearman ($\rho = 0.78$) correlation coefficients. The significant discrepancy between these values indicates which condition?

A. The Pearson coefficient is always the more accurate measure and the Spearman result should be disregarded

B. Both coefficients are unreliable and a completely different analytical method is required

C. The correlation should be reported as the average of the two values: $(0.35 + 0.78)/2 = 0.565$

D. A strong monotonic but nonlinear relationship exists — Spearman captures any consistent directional trend regardless of linearity, while Pearson measures only linear association; the large gap indicates the variables move together reliably but not in a straightline pattern

173. A quality engineer is conducting a designed experiment to optimize a welding process. The experiment tests four factors at two levels using a 2^4 full factorial (16 runs) with 2 replicates (32 total runs). The ANOVA identifies three significant effects: Factor A (welding current), Factor C (travel speed), and the AC interaction. The quality engineer must determine optimal settings. At AHigh/CLow, the mean response is 95.2. At AHigh/CHigh, the mean response is 82.4. At ALow/CLow, the mean

response is 78.6. At ALow/CHigh, the mean response is 84.1. Which combination maximizes the response?

A. AHigh, CHigh because both factors contribute positively at their high levels

B. ALow, CLow because the low levels of both factors avoid the negative interaction

C. AHigh, CLow produces the maximum response of 95.2 — the significant AC interaction means the factors cannot be optimized independently; at AHigh, the response is much better with CLow (95.2) than CHigh (82.4), demonstrating that the interaction effect dramatically changes the optimal setting of C depending on A's level

D. The optimal settings cannot be determined from factorial experiment data alone

174. A quality engineer is reviewing the organization's approach to managing obsolete inventory and discovers that obsolete raw materials — materials for products no longer in production — remain in the warehouse alongside active materials. No formal system distinguishes obsolete from active inventory. Last month, an operator inadvertently used obsolete material (with expired shelf life) in current production, resulting in a batch rejection. What quality system improvement addresses this risk?

A. Operators should be trained to recognize obsolete materials by their appearance

B. Implement a formal obsolete material management system that physically segregates obsolete inventory from active inventory, clearly identifies obsolete materials with visual indicators, establishes a disposition process with defined timelines, and blocks obsolete material part numbers in the ERP/MRP system to prevent issuance to production orders

C. All warehouse materials should be inspected daily by the quality department

D. The organization should dispose of all inventory older than 30 days regardless of its status

175. A quality engineer is reviewing a process validation report for a critical adhesive bonding operation. The validation demonstrates acceptable bond strength at the nominal process parameters. However, the quality engineer notices that the validation did not test the process at the boundary conditions of the validated operating range — it was not tested at the minimum and maximum adhesive

volume, the minimum and maximum cure temperature, or the minimum and maximum cure time. Why is testing at boundary conditions essential for a robust validation?

A. Boundary condition testing is optional for adhesive bonding processes because adhesives are selfleveling

B. Testing at nominal conditions is sufficient because the process will always operate at nominal

C. A process validated only at nominal conditions may fail when parameters drift toward the boundaries of the operating range during normal production — boundary testing confirms the process produces acceptable results across the entire validated range, not just at the center; without it, the validation provides no assurance that output will be acceptable when parameters are at their allowable extremes

D. Boundary condition testing is only required for processes with more than five controlled parameters

Practice Exam 6: Answer Key and Explanations

1. C — Cp = (USL - LSL)/6σ = (2.15 - 1.85)/(6 × 0.06) = 0.30/0.36 = 0.83. CPU = (2.15 - 2.03)/(3 × 0.06) = 0.12/0.18 = 0.67. CPL = (2.03 - 1.85)/(3 × 0.06) = 0.18/0.18 = 1.00. Cpk = min(0.67, 1.00) = 0.67. The Cpk is lower than Cp because the process mean (2.03) is shifted above nominal (2.00), placing it closer to the upper specification limit.

2. A — The calculated $|t| = 2.32$ exceeds the critical value of 2.131 with 15 degrees of freedom at $\alpha = 0.05$ (two-sided). The null hypothesis is rejected — there is statistically significant evidence that the batch mean differs from 75 HRB. The fact that 73.2 falls within the specification range (70-80) is irrelevant to the hypothesis test about whether the mean equals the nominal.

3. D — Two parallel components yield $R = 1 - (0.01)^2 = 0.9999$, which exactly meets but provides no margin above the target. Three parallel components yield $R = 1 - (0.01)^3 = 0.999999$, providing substantial margin above the 0.9999 requirement. For safety-critical systems, margin above the minimum target is essential to account for real-world degradation and modeling uncertainties.

4. B — The lean approach is not to eliminate inspection blindly but to replace detection with prevention. Error-proofing at the source operations prevents defects from being created, making downstream inspection unnecessary. The remaining inspection station serves as a verification backstop until the prevention measures demonstrate sustained effectiveness.

5. A — In Resolution III designs, main effects are aliased with two-factor interactions. Factor C is aliased with AE (from I = ACE: C × ACE = A C^2E = AE). The observed significant effect could be due to C alone, AE alone, or a combination. A follow-up experiment with only the significant factors at higher resolution is needed to separate the aliased effects.

6. D — Mass closure of overdue corrective actions without regard to actual resolution status eliminates accountability and ensures that unresolved problems continue producing nonconforming output. The correct approach is risk-based prioritization of the backlog, assignment of clear ownership and realistic deadlines, and management escalation for resource constraints that prevent timely resolution.

7. B — A significant ANOVA F-test ($F = 6.82 > 3.47$) confirms that at least one welder produces significantly different mean strength, but does not identify which specific welder pairs differ. Tukey's HSD or another multiple comparison procedure performs all pairwise comparisons while controlling the family-wise error rate, identifying exactly which welders need remediation.

8. C — The AIAG/VDA Action Priority method weights severity most heavily. A Severity of 9 (safety impact) places the bond delamination at high priority regardless of the moderate RPN of 54. The method recognizes that the consequences of underestimating occurrence or detection for a safety failure are catastrophic, while a cosmetic blemish (S=3) poses negligible safety risk regardless of its higher RPN.

9. A — Standard I-MR chart limits assume symmetric normal distribution. With significantly right-skewed data, the symmetric 3-sigma limits produce asymmetric risk — the upper limit may trigger false alarms on naturally occurring high values while the lower limit may be too generous, missing downward shifts. Transformed data or distribution-specific limits may provide better monitoring.

10. D — $C_{p\_before} = (USL-LSL)/6\sigma = 1.0/(6\times0.20) = 0.83$. $C_{p\_after} = 1.0/(6\times0.12) = 1.39$. The variation reduction improved Cp from 0.83 (incapable — process spread exceeds specification) to 1.39 (capable — specification exceeds process spread). Since the mean remained centered, this improvement translates directly to reduced nonconforming output.

11. B — While physical segregation in a locked cage is adequate for preventing inadvertent use of nonconforming material, the absence of disposition records eliminates traceability, accountability, and auditability. Without documentation of what was dispositioned, who authorized it, and the rationale, the organization cannot demonstrate that dispositions were appropriate or trace affected product if issues arise later.

12. C — The u-chart monitors the rate of nonconformities per unit when the inspection opportunity varies. With 200 test points per assembly and varying numbers of assemblies tested per hour, the u-chart normalizes the failure count by the varying inspection base, producing comparable rates across periods with different sample sizes. The c-chart would require constant inspection opportunity.

13. A — Treating every identified risk regardless of significance diverts limited resources from high-priority risks that pose genuine threats. Risk management must prioritize — directing intensive treatment toward high-consequence risks while accepting low-level risks with monitoring. The "treat everything" approach paradoxically weakens protection against the most dangerous risks by spreading resources too thin.

14. D — The four-factor interaction ABCD is typically assumed negligible in industrial experiments based on the sparsity of effects principle. Confounding it with the day effect sacrifices essentially no useful information while allowing the blocking structure to account for day-to-day environmental variation. This is the standard approach for splitting a 2^4 factorial into two blocks.

15. B — R_4_new = 1-(1-0.96)² = 1-0.0016 = 0.9984. R_sys = 0.99 × 0.98 × 0.97 × 0.9984 = 0.9391 ≈ 0.939. This falls short of the 0.95 target. Adding redundancy to the weakest component alone is insufficient — additional improvements to other components (such as adding redundancy to $R_3 = 0.97$ as well) or system redesign would be needed to reach 0.95.

16. C — An instrument found 0.008 mm out of tolerance (exceeding the ±0.005 mm limit) has been producing biased measurements for up to 6 months. The critical action is an impact assessment: reviewing all measurement records to identify products measured with this instrument and determining whether the +0.008 mm bias could have caused incorrect accept/reject decisions for any of those products.

17. D — Computer simulations verify that the design meets its own mathematical models and specifications (verification), but they cannot validate that the product satisfies actual customer needs in real-world use conditions. Validation requires testing representative products under conditions that simulate actual use — including environmental extremes, foreseeable misuse, and user interaction patterns that simulations may not fully capture.

18. A — With failure costs representing 70% of total COQ (internal 40% + external 30%) and prevention at only 10%, the organization's quality strategy is overwhelmingly reactive. Significantly increasing prevention investment in quality planning, training, error-proofing, and designed experiments should produce a disproportionately larger reduction in failure costs, lowering total COQ.

19. B — The significant effects are A (p=0.001), B (p=0.003), and AC interaction (p=0.012). Factor C must be retained in the model despite its non-significant main effect (p=0.45) because it is a parent of the significant AC interaction — the hierarchy principle requires that both parent main effects (A and C) be included whenever their interaction is significant.

20. C — With %GRR = 8.5% (well below the 10% acceptance threshold) and ndc = 12 (far exceeding the minimum of 5), the measurement system meets both AIAG MSA acceptability criteria with substantial margin. The system has excellent discrimination capability for SPC monitoring and contributes minimal variation relative to the tolerance.

21. D — Alternating periods of tight and wide variation in a repeating pattern indicate a systematic, periodic change in within-subgroup dispersion. This could result from tooling cycles (new tool tight, worn tool loose), material lot changes at predictable intervals, equipment thermal cycling, or batch-to-batch raw material differences that periodically alter the process variability.

22. A — Mobile devices that synchronize controlled documents whenever connectivity is available provide the best solution for intermittent-connectivity environments. Automatic version checking ensures technicians always use current procedures, and the synchronization model accommodates periods without internet access. This approach maintains document control integrity while supporting field operations.

23. B — The calculated chi-square (15.8) exceeds the critical value (13.28) at the stringent $\alpha = 0.01$ level with 4 degrees of freedom. The association between the two categorical variables is statistically significant even at the 1% significance level, providing very strong evidence against the null hypothesis of independence.

24. D — Fifteen identical readings from a process with $\sigma = 0.04$ mm is statistically impossible — the probability of even two consecutive identical readings from this process is extremely low, let alone fifteen. This pattern strongly suggests data fabrication, where the operator is recording expected values rather than actual measurements, or an instrument with insufficient resolution to detect the real variation.

25. C — OEE reveals the gap between theoretical and actual capacity by decomposing losses into three categories: Availability (downtime losses), Performance (speed losses and minor stoppages), and Quality (defect losses). Knowing which category dominates enables targeted improvement — a 12% gap may require different interventions depending on whether it stems from breakdowns, speed reduction, or defects.

26. A — For significantly non-normal data, transform the data using Box-Cox or logarithmic transformation, verify normality of the transformed data, transform the specification limits using the same function, and calculate Cpk on the transformed scale. This approach preserves the mathematical validity of the capability indices while accommodating the non-normal distribution.

27. D — Strict liability is the legal concept where a manufacturer may be held liable for injuries caused by a defective product regardless of fault, due diligence, or compliance with standards at the time of manufacture. If the product is found to have a design defect, manufacturing defect, or inadequate warning, the manufacturer can be liable even if all applicable standards were met.

28. B — Trial control limits established from the initial 25 subgroups should be verified by collecting additional subgroups to confirm that the new data falls within the established limits. This verification step confirms that the trial limits are representative of the process under normal conditions and protects against limits that may have been influenced by unusual conditions during the initial data collection.

29. C — If the parts selected for the Gage R&R study were clustered near the nominal value rather than spanning the full production range, the part-to-part variation would be understated. Since %GRR is calculated relative to total variation (which includes part-to-part), understated part variation makes the measurement system appear to contribute a larger percentage than it would if parts properly represented production range.

30. A — Flatness controls the form of a nominally flat surface without reference to any datum — the entire surface must lie between two parallel planes separated by the tolerance value (0.05 mm). It controls only the surface's own shape, not its relationship to other features. Profile of a surface, in contrast, can control both form and location relative to datums.

31. D — A 15°C temperature increase to a critical curing process without formal change documentation, review, approval, or impact assessment is a nonconformity against the management of change procedure. Verbal authorization does not satisfy formal change control requirements, which exist to ensure that all process changes are evaluated for quality impact before implementation.

32. B — The significant Supplier × Batch interaction means the effect of supplier on tensile strength depends on which batch of raw material is being processed. One supplier may perform well with Batch 1 but poorly with Batch 2, while another shows the opposite pattern. Supplier selection decisions must consider the specific batch being used rather than assuming consistent supplier performance.

33. C — Using average lead time (5 hours) for kanban calculations provides adequate material only when replenishment takes 5 hours or less. During periods when lead time extends to 8 hours, the kanban quantity calculated from the average will be insufficient, causing stockouts. The calculation should use worst-case lead time or include sufficient safety stock to buffer against lead time variation.

34. A — The gap between demonstrated knowledge (Level 2 — Learning, confirmed by post-training tests) and actual on-the-job application represents a Level 3 — Behavior failure. Operators know how to maintain control charts but are not doing so in practice. Barriers to skill transfer — time pressure, lack of management reinforcement, competing priorities, or insufficient practice — must be identified and addressed.

35. D — The 95% confidence interval for (μ_1 - μ_2) is (-1.2, 3.8), which includes zero. Since zero is a plausible value for the true difference, the observed difference is not statistically significant at the 5% level. The data is consistent with no actual difference between the two processes, even though the point estimate of the difference is positive.

36. B — Cpk describes historical process performance but does not guarantee future conformance. Process shifts from material changes, equipment degradation, tool wear, or environmental variation can occur between capability studies. Acceptance sampling provides ongoing lot-by-lot verification that actual output conforms, serving as a safety net when SPC monitoring may not catch every shift.

37. C — Zero reproducibility with significant repeatability indicates the measurement system's variation comes entirely from the instrument, not the operators. This pattern is characteristic of preset instruments (click-type torque wrenches, go/no-go gages) where the operator's role is simply to apply the instrument — the instrument determines the result. Improvement must focus on the instrument itself.

38. A — The 16-run full factorial without replication estimates all 15 effects (4 main, 6 two-factor, 4 three-factor, 1 four-factor interactions) without confounding. The normal probability plot provides a reliable method for identifying significant effects. The fractional factorial would sacrifice interaction information for formal ANOVA significance testing, which is generally less valuable at the screening stage.

39. D — Residual risk must be formally documented, including the residual probability and severity ratings, the treatment actions that produced the reduction, and the remaining risk level. Management must formally accept the residual risk at the appropriate authority level. The unchanged Severity of 5 (catastrophic) means that if the risk event occurs despite reduced probability, the consequences remain equally severe.

40. C — Correlation demonstrates association, not causation. The strong negative correlation (r = -0.92) between cycle time and weight could be driven by a confounding variable such as melt temperature — longer cycles may coincide with lower temperatures, and it may be temperature rather than cycle time that affects weight. Only a designed experiment with controlled variables can establish causation.

41. B — Distributing audits across all four quarters provides continuous quality system monitoring rather than a single annual snapshot followed by long gaps. Some aspect of the quality system is always being assessed, enabling earlier detection of problems, more distributed workload for auditors, and more timely corrective actions throughout the year.

42. A — $n = (Z^2\hat{p}(1-\hat{p}))/E^2 = (1.96^2 \times 0.05 \times 0.95)/(0.02^2) = (3.841 \times 0.0475)/0.0004 = 0.1825/0.0004 =$ 456 samples. This formula determines the minimum sample size needed to estimate the proportion to within ±2% (E = 0.02) at 95% confidence (Z = 1.96) given the preliminary estimate of 5% defective.

43. D — A Weibull shape parameter $\beta = 0.72$ (less than 1.0) indicates a decreasing failure rate — infant mortality behavior. Preventive replacement at fixed intervals removes components that have survived the high-risk early period and replaces them with new components that have a higher initial failure rate. This counterproductive strategy increases rather than decreases the overall failure rate.

44. C — The ±25% guideline for using fixed control limits on p-charts means sample sizes should fall between 150 and 250 (for $\bar{n} = 200$). Since the actual range is 100-300, the extreme lots deviate by 50% from the average. For lots at 100 or 300 units, individual control limits should be calculated because the fixed limits would be meaningfully inaccurate at these extremes.

45. B — The supplier identified what happened (out of calibration) but not why it happened. A thorough root cause analysis asks why the machine went out of calibration (mechanical wear, thermal drift, vibration), why it was not detected sooner (calibration schedule adequacy, SPC monitoring), and what systemic changes prevent recurrence — not just recalibrating the machine until it drifts again.

46. A — An automated vision system that reads barcodes on both the leaflet and medication box, compares them in real time, and physically diverts mismatches before sealing provides the most reliable poka-yoke protection. It eliminates dependence on human attention and judgment, operates at production speed, and physically prevents the defect from reaching the customer.

47. D — Since Cp = Cpk = 1.00, the process is perfectly centered and the only path to improving capability is reducing the process standard deviation. With $\sigma = 0.50$ mm, reducing to $\sigma \approx 0.375$ mm

would achieve Cp = Cpk = 1.33. This requires fundamental process improvements — better tooling, tighter material controls, improved environmental conditions — not recentering or wider specifications.

48. B — Including risk-relevant information in daily production meetings, team briefings, and visual management boards makes risk awareness a routine part of daily operations. Each area receives information about the specific risks that affect their work and the status of their controls. This continuous communication is far more effective than a single annual management review presentation.

49. C — F(2000) = 1 - e^(-2000/25000) = 1 - e^(-0.08) = 1 - 0.9231 = 0.0769. Approximately 7.7% of products are expected to fail during the 2,000-hour warranty period. The linear approximation (2000/25000 = 8.0%) is close but slightly overestimates because the exponential function curves slightly below the linear extrapolation.

50. A — Total parts per shift: 500 × 8 = 4,000. Defective parts produced: 4,000 × 0.005 = 20. Escaped defectives: 20 × (1 - 0.995) = 20 × 0.005 = 0.1 per shift. While this is very low, for a critical characteristic, any escape may be unacceptable. The engineer should evaluate whether the 0.5% escape rate meets the risk tolerance for this particular characteristic.

51. D — A saddle point on the contour plot indicates that the response increases in one factor direction while decreasing in another. The optimal operating conditions are not at the center of the explored region but along a rising ridge. Ridge analysis or steepest ascent methods can identify the direction of improvement, potentially requiring additional experimentation beyond the current factor ranges.

52. B — Differentiated supplier quality targets based on component criticality better serve quality objectives because they align performance expectations with actual risk. Safety-critical components should require near-zero defect rates (e.g., <10 ppm), while non-critical commodity components may tolerate higher defect rates (e.g., <5,000 ppm). This risk-proportionate approach focuses supplier improvement where it matters most.

53. C — A very small p-value confirms strong statistical evidence against the null hypothesis but says nothing about practical significance. With sufficiently large samples, even trivially small differences (e.g., 0.01 mm on a ±1.0 mm tolerance) can achieve extremely small p-values. The engineer must separately evaluate whether the observed effect magnitude is large enough to matter in the engineering context.

54. A — The heat treatment furnace was validated at a 100-part load, but production runs 250 parts. The 2.5× increase in thermal mass alters the furnace's heat-up rate, temperature distribution, and time to reach equilibrium. Parts in the center of a larger load may receive inadequate heat treatment due to thermal shielding. The validation should be performed at the actual production load level.

55. D — The quality policy commits to continuous improvement, but the management review evidence shows no improvement initiatives, no improvement decisions, and no tracked improvement actions over three years. This gap between stated commitment and actual practice represents a fundamental disconnect — the policy is aspirational documentation without substantive operational follow-through.

56. B — The remaining 6 minutes of trial-and-error shimming can be eliminated by converting the adjustment to a preset, repeatable method. Standardized shim heights calculated from die specifications, digital height readouts, or mechanical stops eliminate the iterative adjustment process by ensuring correct die height on the first attempt, removing adjustment time entirely from the internal setup.

57. C — The dramatic drop from r = 0.95 to r = 0.42 when one point is removed reveals that the apparent strong correlation was driven almost entirely by a single extreme data point. The underlying relationship without this influential outlier is actually weak. The engineer must investigate whether the outlier is a legitimate data point or an error before drawing any conclusions about the relationship.

58. D — R(3000) = e^(-3000/2000) = e^(-1.5) ≈ 0.223. Approximately 22.3% of machines are expected to survive beyond 3,000 hours without failure. The exponential distribution's memoryless property means the survival probability depends only on the time elapsed, not on how long the machine has already operated.

59. A — Tacit process knowledge — the intuitive expertise, judgment, and problem-solving skills developed over decades — transfers most effectively through extended personal interaction and guided practice. A structured 18-month mentoring program combining hands-on training, knowledge-sharing sessions, and progressive responsibility transfer provides the best mechanism for capturing knowledge that cannot be fully documented in procedures.

60. B — Before improvement: 500,000 × 0.07 × \$50 = \$1,750,000 in annual defect costs. After improvement: 500,000 × 0.000014 × \$50 = \$350. Annual savings: \$1,750,000 - \$350 ≈ \$1,750,000. The \$150,000 project cost is recovered in approximately one month. This dramatic return demonstrates the economic power of process capability improvement.

61. C — A common document numbering scheme, unified revision control process, standardized approval workflow, and master document list accessible to all sites ensures that regardless of local ERP systems, every site can identify and access the current version of any controlled document. This common framework provides consistency while allowing local systems to operate within the unified structure.

62. A — The data conclusively shows Factor C has no significant effect ($p = 0.45$) and no significant interactions with any other factor. Setting C at any level produces statistically indistinguishable results. The most economical or operationally convenient level is the scientifically correct choice — "just in case" reasoning without data support contradicts evidence-based process optimization.

63. D — The B10 life is calculated from $F(t) = 0.10$: $0.10 = 1 - e^{(-(t/50000)^{2.1})}$. Solving: $e^{(-(t/50000)^{2.1})} = 0.90$, $-(t/50000)^{2.1} = \ln(0.90) = -0.1054$, $(t/50000)^{2.1} = 0.1054$, $t/50000 = (0.1054)^{(1/2.1)} = (0.1054)^{0.476} \approx 0.347$, $t \approx 50{,}000 \times 0.347 \approx 17{,}350$ hours. This is the operating time by which 10% of bearings are expected to have failed.

64. B — When three different instruments measure the same dimension and occasionally disagree, instrument-to-instrument bias differences are the most likely cause. Each instrument may have a slightly different systematic offset, causing the same part to read differently on each instrument. Cross-correlation studies comparing all three instruments against the same reference standard would quantify and correct these bias differences.

65. C — Zero audit findings across 25 suppliers over 3 years is statistically improbable and should raise concerns about audit rigor. The engineer should evaluate whether audit criteria are sufficiently challenging, whether auditors are trained to probe beyond surface compliance, whether the audit scope covers all critical areas, and whether a culture of leniency has developed in the audit program.

66. A — For subgroup sizes greater than 10, the X-bar/S chart is preferred because the sample standard deviation uses all data points to estimate variability, while the range uses only the two extreme values. With $n = 20$, the range ignores 18 of 20 measurements, wasting information. The standard deviation provides a more statistically efficient and precise variability estimate.

67. B — Dissolution testing is destructive (tablets are dissolved), time-consuming (several hours per test), and expensive. Continuous SPC monitoring of dissolution is impractical. Instead, the process is controlled through validated parameters that correlate with dissolution performance (compression force, granulation properties, coating thickness), with batch-end dissolution testing confirming the final product quality.

68. D — Dominant within-part positional variation (top vs. middle vs. bottom) in a CNC turning operation typically indicates a fixturing, alignment, or deflection problem. The part may be deflecting under cutting force, the chuck may not be holding uniformly, or the machine's axis alignment may cause taper. Corrective action should focus on fixture rigidity, machine geometry, and tool path optimization.

69. C — The calibration program is high-risk because it underpins all measurement-based quality decisions across the organization, the recurring nonconformities (overdue calibrations) indicate systemic weakness, and the aerospace product line demands rigorous measurement integrity. Annual or semi-annual audits with focused attention on the identified weaknesses are appropriate for this risk profile.

70. A — Extrapolating the regression model to x = 150 — nearly twice the maximum of the data range (x = 20-80) — is highly unreliable. The linear relationship validated within the original range may not hold at such extreme values. The true relationship could be nonlinear, asymptotic, or even reversed beyond the data range. Predictions become increasingly uncertain with distance from the observed data.

71. B — Recurrence rate measures whether corrective actions eliminate root causes. Effectiveness verification completion rate measures whether the organization confirms actions work. On-time closure rate measures process discipline. Together, these three metrics answer the three essential questions: do we verify our actions work, do they actually prevent recurrence, and do we process them timely?

72. D — A CMM is more appropriate for complex geometric features because it measures true 3D geometry, can calculate GD&T characteristics directly, and supports automated measurement programs for consistent evaluation. Optical comparators are limited to 2D profile comparisons and require more operator judgment, making them less suitable for the complex features of precision machined parts.

73. C — Process A (Cpk = 1.50, stable) is more predictable and reliable than Process B (Cpk = 2.00, unstable). Frequent out-of-control signals indicate that Process B's behavior is unpredictable — it may shift dramatically at any time. The high Cpk may reflect favorable short-term data captured between shifts. A stable, predictable process with lower capability is generally preferable to an unstable one.

74. A — With a success test of 10 units and zero failures, the demonstrated reliability at 90% confidence is approximately $R \geq 1 - (1-C)^{(1/n)} = 1 - (0.10)^{(1/10)} \approx 0.794$. However, using the exact binomial formula for the one-sided 90% lower confidence bound on reliability with 10 successes: $R \geq 0.10^{(1/10)} \approx 0.794$. The sample demonstrates consistency with ≥95% reliability at 90% confidence per the test plan design.

75. B — The significant gap between σ_within (0.08) and σ_overall (0.13) reveals that substantial between-subgroup variation exists from process instability. The process has experienced shifts, trends, or special causes that add variation between subgroups beyond the inherent common cause variation. Eliminating these special causes would bring Pp closer to the Cp value, recovering the lost performance.

76. D — Variables sampling plans (ANSI/ASQ Z1.9) achieve equivalent quality protection with smaller sample sizes because each measured value provides more statistical information than a simple pass/fail classification. The actual measurement enables more precise estimation of the lot's quality distribution, allowing tighter OC curves with fewer observations — critical for expensive or destructive testing.

77. C — A phased approach provides the most realistic path from 3,500 ppm to best-in-class 50 ppm: short-term containment through improved inspection, medium-term capability improvement through DMAIC projects targeting the vital few defect types, and long-term transformational change through design-for-manufacturing, error-proofing, and advanced process control. Each phase builds capability for the next.

78. A — Process validation should not be treated as a one-time event. Periodic revalidation should be triggered by defined criteria: process changes, equipment modifications, material substitutions, facility relocations, significant time intervals, or performance trends indicating degradation. The validation status must be actively maintained — assuming it persists indefinitely without verification is inadequate.

79. B — For a 1.5σ shift in the process mean on a standard X-bar chart with 3-sigma limits, the out-of-control ARL_1 is approximately 6 subgroups. This means on average, 6 subgroups will be plotted before the chart signals the shift. If subgroups are taken hourly, the shift goes undetected for approximately 6 hours — a significant delay that may allow substantial nonconforming output.

80. D — While 100% agreement is encouraging, parts that are clearly good or clearly bad may produce unanimous agreement even from a mediocre measurement system. The true test of a go/no-go gage's discrimination ability is its performance on borderline parts near the specification limits — parts that challenge the gage's resolution. The study should include these borderline parts to provide a meaningful assessment.

81. C — The overall OEE value alone does not identify the improvement opportunity. Line B's 62% OEE could result from low availability (frequent breakdowns), low performance (speed losses), low quality (high defect rate), or any combination. Each root cause requires different improvement strategies, so the component breakdown is essential for targeting the correct improvement action.

82. A — After process improvements reduced the standard deviation, the original control limits are too wide for the improved process. This excess width makes the chart unable to detect process shifts that would be visible with updated, narrower limits calculated from current process data. The chart's sensitivity has degraded, potentially allowing meaningful shifts to go undetected.

83. B — Multi-voting narrows the 42 potential causes to the most likely candidates based on team knowledge and experience. Data collection on these top candidates followed by Pareto analysis provides evidence-based prioritization by actual impact. This two-step approach — expert judgment for initial screening, then data for confirmation — efficiently focuses investigation on the causes most likely to be driving the defect.

84. D — Single-lot data captures only the variation present within one material lot. When subsequent lots with different chemical composition, mechanical properties, or processing history enter production, they introduce lot-to-lot variation that the single-lot study did not capture. The long-term Cpk will likely be lower than the 1.85 calculated from this restricted data set.

85. C — The fifth "why" identifies a systemic root cause: the design review checklist was developed for metal parts and never updated when the company transitioned to plastics. Updating the checklist to include plastic-specific design requirements addresses the systemic gap, and verifying the updated checklist against all current plastic designs prevents similar failures across the product line.

86. A — A Box-Behnken design or similar response surface methodology design can study 5 factors at 3 levels with far fewer runs than the full 3^5 factorial. The X-bar/S chart being preferred for large subgroups is the same principle — using efficient statistical designs that maximize information per experimental run while maintaining the ability to model quadratic effects.

87. B — The pattern of accelerating failures — 5 by 1,000 hours, 17 by 2,000, and 42 by 3,000 — indicates a wear-out failure mechanism where cumulative degradation causes progressively more units to fail. This is consistent with a Weibull distribution with $\beta > 1$, where the hazard function increases with time as components age and deteriorate.

88. C — The 4-day WIP delay results from the mismatch between machining's batch size (500) and assembly's one-piece processing. Reducing the machining batch size toward one-piece flow aligns production rates between operations, dramatically reducing the time parts wait in the staging area. Smaller, more frequent deliveries from machining enable continuous flow into assembly.

89. D — Changes to inspection methods can reduce detection capability, test equipment changes can introduce measurement bias, and quality procedure changes can eliminate critical controls. Each of these changes can directly affect the ability to identify nonconforming product. They require the same rigorous evaluation as product and process changes to ensure quality protection is maintained.

90. A — The p-value of 0.06 does not meet the $\alpha = 0.05$ threshold, so H_0 is not rejected. However, the nearly doubled defect rate (2.5% vs. 4.5%) is practically meaningful. With n = 200 per group, the test may lack sufficient power to detect this difference. A post-hoc power analysis and consideration of practical significance may justify a larger follow-up study to reach a definitive conclusion.

91. B — A quality objective needs a viable implementation path — planned improvement actions, allocated resources, and realistic assessment of whether the 25% reduction is achievable. A target without an action plan based on root cause analysis of current complaints is aspirational but not actionable. The engineer should verify that specific improvement initiatives are planned to drive the reduction.

92. C — Incoming inspection can be reduced or eliminated under specific conditions: consistently high supplier Cpk over an extended period, supplier-maintained SPC with shared documentation, formal change notification requirements, and periodic verification audits. This transfers inspection responsibility to the supplier's demonstrated process control system while maintaining verification mechanisms.

93. D — The DFMEA should be a living document updated with field failure data, manufacturing insights, customer feedback, and design modifications. Real-world experience reveals failure modes and severity levels not anticipated during the original design analysis. Five years of accumulated field data almost certainly contains information that would change the FMEA's risk priorities and recommended actions.

94. A — A phased transition manages risk while moving toward the more efficient sampling approach. Phase 1 runs both systems in parallel to verify agreement. Phase 2 switches to sampling after confirming alignment. Phase 3 periodically spot-checks through 100% inspection of selected lots. This graduated approach builds confidence while protecting against unanticipated consequences.

95. B — The high %GRR (42%) with calipers on soft O-rings almost certainly results from inconsistent compression of the deformable material by the caliper jaws. Non-contact optical measurement or fixed-dimension pin gages eliminate this compression variability entirely, producing dramatically better measurement consistency on soft, deformable parts.

96. C — Risk-based capability study frequency allocates resources proportionally: critical processes receive semi-annual studies, changed processes require immediate re-study, and stable low-risk processes with demonstrated long-term capability may extend to 18-24 months with ongoing SPC monitoring between studies. This approach ensures attention where it matters most.

97. D — Zero variation across 50 measurements is statistically impossible for any real production process. The reported results are almost certainly fabricated or rounded to the nominal value. The quality engineer should request raw data, audit the supplier's testing procedures, consider requiring witnessed testing, and evaluate whether the supplier's quality system can be trusted.

98. A — The cost-effectiveness evaluation must compare the total value of eliminated unplanned downtime (including lost production, scrap, emergency repair premiums, overtime, and delivery penalties) against the 35% increase in maintenance spending. If the savings from the 60% downtime reduction exceed the cost increase, the program delivers positive net return.

99. C — ISO 9001:2015 requires quality objectives to be updated as appropriate. A significant quality issue emerging mid-year demands review and possible revision of objectives to address the current situation. Rigidly adhering to an annual cycle while ignoring emerging quality risks is inconsistent with risk-based thinking and the standard's intent for the QMS to be responsive to changing conditions.

100. B — An audit program that focuses exclusively on documentation gaps (missing signatures, outdated forms) without evaluating process effectiveness and quality outcomes becomes a compliance exercise that checks paperwork rather than assessing whether the quality system actually works. Effective audits balance conformance assessment with effectiveness evaluation — are quality objectives being met and are processes producing intended results?

101. D — Since Factors B and C do not significantly affect the response ($p > 0.25$) and have no significant interactions with other factors, they can be set based on non-quality criteria — cost, speed, convenience — without degrading product quality. This principle of using non-significant factors as "free variables" maximizes overall process optimization by allowing economic considerations to drive settings that have no measurable quality impact.

102. A — Starting with manufacturer recommendations and adjusting based on actual calibration history is the most effective data-driven approach. Instruments consistently found within tolerance can safely extend intervals, reducing unnecessary calibration costs. Instruments found out of tolerance require shortened intervals to prevent measurement failures. This optimization balances measurement reliability against calibration expense.

103. C — Split-plot designs have two separate error terms — the whole-plot error (for hard-to-change factors like temperature) and the subplot error (for easy-to-change factors like thickness). Analyzing split-plot data as a completely randomized design uses the wrong (too small) error term for the whole-plot factor, making the F-test too liberal and potentially declaring significance that does not exist.

104. B — Using $D_4 = 2.282$ (for n=4) instead of the correct $D_4 = 2.004$ (for n=6) produces a wider UCL on the R chart. This reduced sensitivity means that real increases in process variability — from tooling wear, material changes, or fixture loosening — may not have triggered out-of-control signals that would have been detected with the correct, narrower limits.

105. D — Excluding startup and shutdown data artificially reduces the observed variation by removing the periods when the process is most likely to produce nonconforming output. The customer receives product from all production periods, including startup and shutdown. A capability study must represent the process as the customer experiences it, not a cherry-picked subset of favorable operating conditions.

106. A — An effective andon board provides real-time, at-a-glance visibility of machine status, production count versus target, quality metrics, and active alerts using intuitive color coding visible from anywhere in the production area. This immediate visibility enables rapid response to abnormalities without requiring anyone to check computers, read reports, or ask questions.

107. C — First calculate the parallel pump subsystem: $R_{pumps} = 1-(1-0.997)(1-0.995) = 1-(0.003)(0.005) = 1-0.000015 = 0.999985$. Then combine in series: $R_{sys} = 0.999985 \times 0.999 \times 0.998 = 0.997$. The parallel redundancy dramatically improves pump subsystem reliability to 0.999985, but the series filter and injectors limit the overall system.

108. B — Handwritten annotations on controlled documents that modify critical specifications bypass the formal revision, approval, and distribution controls of the document control system. The change was not reviewed by all required parties, was not formally approved, and was not communicated to all affected users. This is a nonconformity against the document control procedure.

109. A — Larger effect sizes are easier to detect and require fewer observations. Detecting a 1.0σ shift requires approximately 17 per group (compared to 32 for a 0.5σ shift) because the signal-to-noise ratio is twice as large. Power analysis shows an inverse relationship between detectable effect size and required sample size — double the effect, roughly halve the sample.

110. D — Quantitative risk analysis provides precise probability estimates, expected monetary values, sensitivity analysis, and Monte Carlo simulation results for high-priority risks. This enables more informed decision-making about whether risk treatment investments are proportionate, whether residual risk levels are truly acceptable, and how to optimally allocate limited risk management resources.

111. C — A larger subgroup size (n=6 versus n=3) produces tighter control limits on the X-bar chart because the standard error of the mean ($\sigma/\sqrt{n}$) decreases with larger n. Tighter limits improve the chart's sensitivity to small mean shifts, enabling earlier detection of process changes. Measuring all 6 substrates maximizes the statistical power available from each hourly sampling event.

112. B — Correlation ($r = 0.68$) demonstrates association but not causation. A designed experiment where temperature is deliberately varied while other factors are held constant would isolate temperature's causal effect. Implementing compensation based on a possibly spurious correlation could introduce unnecessary process adjustments that add variation rather than reducing it.

113. A — Laboratory validation with engineering prototypes operated by design engineers does not represent actual use conditions. Design engineers understand the product intimately and avoid use errors that real users make. Engineering prototypes may differ from production units. True validation requires production-representative devices tested under realistic conditions by intended users, including worst-case scenarios and foreseeable misuse.

114. D — Allowing repeated sampling of a rejected lot until it passes invalidates the sampling plan's statistical foundation. The OC curve probabilities assume a single sampling event — if a lot has a 20% probability of acceptance, repeated sampling gives it a 20% chance on each attempt, eventually guaranteeing acceptance. This defeats the plan's quality protection for the consumer.

115. C — The u-chart UCL of 0.149 defects per component means that if the defect rate for this specific 150-component board exceeds 0.149 (more than approximately 22 total defects), the process has likely changed and should be investigated. The control limit represents the boundary of expected common cause variation, not a specification limit or customer requirement.

116. A — Lost sales caused by a competitor's quality problems affecting the entire industry are an external market phenomenon, not a cost attributable to the organization's own quality activities. COQ tracks costs directly resulting from the organization's own prevention efforts, appraisal activities, and quality failures — not market effects caused by others' actions.

117. B — Implementing a solution concentration monitoring system with defined replenishment triggers directly addresses the root cause — unmonitored solution depletion. Whether through automated sensors, scheduled titration, or usage-based replacement schedules, the system maintains etch effectiveness within its validated range, preventing the gradual degradation that caused adhesion failures.

118. D — The lognormal distribution produces a right-skewed, zero-bounded probability density function with a peak that depends on the distribution parameters (μ and σ of the underlying normal). Failure times are concentrated in a window, with a right tail extending toward longer times. The lognormal commonly models failure mechanisms involving multiplicative degradation processes.

119. C — A self-assessment questionnaire relies on the supplier's own (potentially biased) representation, and ISO certification confirms system conformance but not specific process capability. Critical component suppliers require on-site verification of actual facilities, processes, and records, along with process capability data for the specific characteristics and sample evaluation to confirm manufacturing capability matches requirements.

120. A — Escape rate = incoming defect rate × (1 - detection rate) = 500 ppm × (1 - 0.998) = 500 × 0.002 = 1.0 ppm. Approximately 1 defective part per million escapes the 99.8% detection system. For a medical device, even 1 ppm escape on a critical characteristic warrants evaluation of whether this residual risk is acceptable.

121. B — Repeatability (16%) dominates reproducibility (8%) in this measurement system, identifying the instrument itself as the primary source of variation. Improving the instrument — through repair, upgrade, replacement, or environmental control — would produce a much larger reduction in total %GRR than addressing the smaller operator-related reproducibility component.

122. D — Standard work establishes the current best-known method as the baseline for consistency, quality, safety, and abnormality detection. It does not eliminate flexibility — operators contribute to improving the standard through kaizen. The standard provides the stable foundation against which deviations become visible, enabling continuous improvement rather than constraining it.

123. C — Recurring identification of the same improvement opportunities year after year without actionable outputs indicates the management review is a discussion exercise rather than a decision-making forum. Effective reviews translate identified needs into specific actions with assigned owners, allocated resources, defined timelines, and tracked progress — converting intentions into measurable improvement.

124. A — With only 35% power, the test had a 65% probability of missing a true 1.5-unit difference (Type II error). The non-significant p-value (0.18) may reflect insufficient sample size rather than absence of a real difference. Given the practical significance of 1.5 units, a larger follow-up study with adequate power should be considered before concluding the processes are equivalent.

125. B — Declining internal findings concurrent with increasing external findings strongly suggests the internal audit program has lost rigor. Internal auditors may have developed familiarity with the auditees, softened criteria, reduced scope, or become too comfortable to challenge findings. External auditors bring fresh perspectives and are identifying problems the internal program is missing.

126. D — Each machine should be reported separately because they represent distinct process populations with very different capabilities. Machine 1 (Cpk = 1.65) is capable; Machine 2 (Cpk = 0.72) is not. A combined Cpk would misrepresent both machines — appearing adequate overall while hiding Machine 2's inadequacy. Machine 2 requires targeted process improvement.

127. A — The ranking A → D → C → B reflects the combination of component criticality and supplier qualification status. Safety-critical components from unproven suppliers (A) demand the most intensive inspection. Non-critical components from new suppliers (D) need verification. Safety-critical from proven suppliers (C) need moderate verification. Non-critical from established suppliers (B) need the least.

128. C — The bias increases systematically from -0.002 at the low end to +0.008 at the high end, spanning 0.010 mm — 10% of the 0.100 mm tolerance. This systematic linearity error means a single bias correction cannot adequately compensate across the range. For applications where the instrument is used across its full range, this may require correction factors or instrument replacement.

129. B — ISO 9001:2015 eliminated the mandatory quality manual requirement, but ISO 13485:2016 (the QMS standard for medical device manufacturers) retains the requirement for a quality manual that includes the QMS scope, documented procedures or references to them, and a description of process interactions. The startup must maintain a quality manual for its medical device QMS.

130. D — Seven points above then eight points below the center line, with an abrupt transition between them, strongly suggests a step change in the process mean between the two groups. While neither individual run reaches the 8-point Western Electric threshold, the sharp transition pattern warrants investigation to determine what changed — a material lot change, equipment adjustment, or operator shift change.

131. A — Without inspection: 5,000,000 × 0.0008 × $15,000 = $60,000,000 in potential defect costs. With 100% automated inspection at 99.5% detection: inspection cost = $100,000/year; escaped defects = 20 × $15,000 = $300,000; total = $400,000. The $100,000 inspection investment prevents approximately $59.6 million in potential losses — an overwhelming economic justification.

132. C — The change control procedure's failure to include mandatory quality review allowed a 15% conveyor speed increase to be implemented without evaluating its impact on cure time. Quality department review should be required for all process changes that could affect product quality — ensuring that the quality implications of every change are assessed before implementation.

133. B — The significant AB interaction means the optimal spray pressure depends on the paint viscosity being used. At one viscosity, higher pressure may produce the best finish; at another viscosity, lower pressure may be optimal. Process setup procedures must account for the specific paint batch, adjusting spray pressure based on the viscosity of the material currently being used.

134. D — Even an excellent root cause analysis and corrective action proposal is meaningless without execution mechanisms. A specific implementation timeline creates urgency, an assigned responsible individual creates accountability, and defined effectiveness verification criteria create confirmation. Without these three elements, the plan has no mechanism to ensure it actually gets implemented and works.

135. A — Availability = (480-30-50)/(480-30) = 400/450 = 88.9%. Performance = (180×2)/400 = 360/400 = 90.0%. Quality = (180-6)/180 = 174/180 = 96.7%. OEE = 0.889 × 0.900 × 0.967 = 0.773 or 77.3%. Note that planned downtime (breaks, meetings) is excluded from available time, while unplanned downtime reduces availability.

136. C — Quality improvement confined to the quality department violates the TQM principle of total employee involvement. Production, engineering, maintenance, and all other functions interact daily with processes that affect quality. Without cross-functional participation, the organization misses improvement opportunities in areas where the quality department has limited expertise, access, and influence.

137. B — With 8 runs yielding only 7 degrees of freedom for effects, the design cannot estimate 15 effects (5 main + 10 two-factor interactions). Furthermore, Resolution III confounds main effects with two-factor interactions — the observed "main effect" may actually be a two-factor interaction. The design is appropriate for screening only, not for comprehensive characterization.

138. A — Quarantine and notification address containment but not prevention of continued nonconforming production. The reaction plan should also require stopping the process immediately to prevent further nonconforming output, investigating the root cause, implementing corrective adjustment, and verifying the process is back in control before resuming production.

139. D — Reducing %GRR from 22% to 4% dramatically improves the accuracy of accept/reject decisions for parts near specification limits. With 22% GRR, a significant proportion of borderline parts are misclassified — good parts rejected (increasing scrap cost) and bad parts accepted (increasing customer escapes). The 4% GRR virtually eliminates these misclassification errors.

140. C — Standards represent minimum industry consensus requirements at a specific point in time. They may not address all foreseeable use conditions, all user populations, or all failure modes specific to the particular product. A manufacturer has an independent duty to identify and mitigate product-specific risks beyond what standards require — standards compliance is necessary but not sufficient.

141. B — Starting with normal inspection establishes a baseline of objective incoming quality data from the organization's own inspection program. Credentials, audits, and capability data provide supporting evidence, but actual delivered quality must be independently verified before reducing inspection intensity. Trust is earned through demonstrated performance, not documentation.

142. A — The failure rate "hump" between 12-18 months likely represents a specific wear-out mechanism affecting one component with a relatively narrow failure time distribution. Once the susceptible population of this component has failed and been repaired or replaced under warranty, the remaining population returns to a lower baseline failure rate dominated by other, longer-lived failure mechanisms.

143. D — Treating each complaint as an isolated event misses the systemic patterns that drive quality improvement. Pareto analysis of categories, stratification by product/region/time, and correlation with production data transform individual complaints into actionable intelligence — identifying the vital few systemic issues, detecting emerging failure patterns, and prioritizing improvement projects by actual impact.

144. C — Electronic displays automatically show only the current revision at all workstations simultaneously. There are no paper copies to become outdated, no manual distribution process to fail, and no withdrawal of obsolete copies to manage. Revision changes become immediately effective across all points of use, eliminating the most common document control failure mode.

145. B — Event-triggered revalidation focuses resources where validation status is genuinely in question — after process changes, equipment modifications, material substitutions, facility moves, adverse trends, or regulatory changes. This approach is more effective than arbitrary calendar intervals because it responds to actual risk-creating events rather than applying blanket schedules regardless of whether anything has changed.

146. A — With Cpk = 1.85, the statistical control limits would be extremely tight relative to the specification. The specification-based chart has massive dead zones where the process can shift by 2σ or more without approaching the specification limits — entirely invisible on the spec-limit chart but clearly out-of-control on a proper statistical chart. Significant quality degradation goes undetected.

147. D — Under the AIAG/VDA Action Priority method, Severity = 10 (safety hazard — loss of braking) mandates high priority action regardless of how low the occurrence and detection ratings are. The AP framework recognizes that catastrophic safety failures demand robust prevention and detection because the consequences of underestimating probability or overestimating detection are irreversible.

148. C — With Cpk = 2.45, the process spread is only about 40% of the specification tolerance, suggesting the specifications may be much wider than necessary. While this provides excellent margin, it may indicate specifications carried over from a less capable process or set conservatively. Tightening specifications to match demonstrated capability could improve assembly fit or enable design simplification.

149. B — Extraordinarily wide control limits typically result from baseline data that contained out-of-control subgroups with inflated ranges. These outlier subgroups should have been investigated and removed (if assignable causes were identified and corrected) before finalizing the limits. Including them inflates $\bar{R}$, producing limits that cannot detect real process changes.

150. B — The customer's quality engineer has direct knowledge of the specific quality requirement, the failure mode, the product application, and the acceptance criteria. This focused expertise enables rapid, targeted problem-solving that addresses the immediate quality issue. Broad system consultants may implement general improvements that do not specifically resolve the customer's problem.

151. D — An AOQL of 2.8% means up to 28,000 ppm could escape under worst-case incoming quality conditions. For a safety-critical medical device characteristic, this escape rate is almost certainly unacceptable — regulatory requirements and patient safety demand much tighter outgoing quality control. The sampling plan needs to be significantly more stringent or supplemented with additional controls.

152. C — Effective design reviews require systematic evaluation against input requirements using checklists, participation of cross-functional expertise (manufacturing, quality, service, procurement), documented action items with assigned owners, and verified resolution of identified issues. A presentation without structured assessment, external participation, or tracked follow-up misses the review's fundamental purpose.

153. B — The instrument change at run 9 introduces a potential confounding variable. Any bias difference between the two instruments creates a systematic shift that could be mistaken for a factor effect or could mask a real effect. The data should be analyzed with the instrument change as a blocking variable, and the affected contrast estimates should be carefully evaluated for possible instrument-related bias.

154. A — Equal reliability allocation ignores practical constraints. Unequal allocation assigns higher targets to subsystems where improvement is easier or cheaper, and lower targets to subsystems where improvement is difficult or expensive. This produces the same system reliability at lower total development cost — optimizing the reliability investment across the system.

155. D — Rework costs — disassembly, component replacement, and retesting — are internal failure costs because the defects were discovered and corrected internally before the product reached the customer. Internal failure costs represent the price of quality failures that are caught in-house, including scrap, rework, reinspection, and downgrading.

156. C — Audit findings without follow-through produce no quality improvement. A formal tracking system with defined deadlines, escalation procedures for overdue items, and effectiveness verification ensures that audit findings translate into actual corrective actions and verified improvements. Without systematic follow-up, even well-conducted audits become compliance exercises without substance.

157. A — Control limits detect small process changes early — before they grow large enough to approach specification limits. By the time a shift is visible on a specification-based chart, hundreds or thousands of parts may have been produced at the shifted level. Statistical control limits provide the early warning needed for intervention while all output remains well within specification.

158. D — The result is statistically significant ($p = 0.001$) but has zero practical significance. The 0.002 mm difference represents only 0.1% of the 2.0 mm tolerance — a meaningless difference in any engineering context. The large sample size ($n = 5{,}000$ per group) provided enough statistical power to detect this trivially small difference, demonstrating that statistical significance alone does not imply practical importance.

159. B — After achieving 45 minutes through initial SMED phases, the next target is further reduction of the remaining internal setup time. Techniques include eliminating trial-and-error adjustments through preset methods, converting additional internal tasks to external, implementing quick-release mechanisms to replace bolts and clamps, and parallelizing remaining tasks with a second operator.

160. C — Data silos prevent the organization from identifying cross-functional patterns that would be visible through integrated analysis. A complaint trend correlating with a specific material lot, an inspection failure aligning with a calibration schedule, or a process shift coinciding with a supplier change — these connections cannot be detected when data remains isolated in departmental systems.

161. A — When 60% of corrective actions cite "operator error/retrain" with a 52% recurrence rate, the root cause analyses are consistently superficial. A CAPA review process should challenge individual-focused root causes, requiring investigation of systemic enablers — unclear procedures, absent error-proofing, poor workspace design — and mandating system-level corrective actions that prevent any operator from making the same error.

162. B — With $\beta = 1.0$, the Weibull reduces to the exponential distribution with a constant failure rate. The memoryless property means the probability of failure in the next hour is identical whether the bearing has operated for 100 hours or 29,999 hours. Preventive replacement simply substitutes a used bearing with a new one that has the same failure probability — providing no reliability benefit.

163. D — Circular runout checks individual cross-sections independently as the part rotates — each "slice" must be within tolerance. Total runout checks the entire surface simultaneously during rotation. Circular runout can miss taper (progressive diameter change along the axis) and axial straightness errors because these occur between cross-sections, while total runout captures them all.

164. C — A quality-only risk assessment ignores financial instability, geographic concentration, regulatory compliance, and business continuity risks that directly affect supply reliability. The bankruptcy event demonstrates that supply chain risk extends far beyond product quality. Comprehensive supplier risk assessment must evaluate the full range of factors that could disrupt supply.

165. A — The 2-week collection period captures variation from multiple shifts, operators, material lots, and environmental conditions — sources of variation that a 4-hour run would miss entirely. The resulting capability indices reflect the process's true long-term performance rather than a favorable snapshot from a single set of conditions that may not represent ongoing production.

166. B — Stratification occurs when subgroups combine measurements from multiple process streams with different means, inflating within-subgroup variation and producing artificially wide control limits. All subgroup averages compress toward the grand mean because the within-subgroup variation (from mixing streams) dominates the between-subgroup variation.

167. C — The laser scanner's 10,000 points per second creates a comprehensive surface map that detects form deviations, waviness, and localized defects the CMM's sparse sampling might miss entirely. While individual point accuracy is slightly lower, the complete surface coverage provides far superior overall quality assessment for complex curved aerospace surfaces.

168. A — Risk-based PM scheduling considers usage frequency, measurement criticality, failure history, and environmental exposure. Continuously used instruments on critical measurements require more frequent PM than lightly used instruments in controlled environments. This approach optimizes the balance between measurement reliability and maintenance cost across the instrument fleet.

169. B — ISO 9001:2015 Clause 6.2 requires that quality objectives specify what will be done, what resources are needed, who will be responsible, when it will be completed, and how results will be evaluated. Measurable targets without defined action plans, responsibilities, resource allocations, and evaluation methods are wishes, not actionable commitments.

170. B — A comprehensive timeline analysis systematically correlates the affected production period with all potential change factors — material lots, equipment maintenance, personnel, environmental data, supplier deliveries, and process parameters. This systematic approach identifies which variable(s) coincide with the anomalous period rather than relying on potentially incomplete operator recollections.

171. D — Establishing ongoing risk monitoring with defined leading indicators, proportional monitoring frequencies, and escalation thresholds enables early intervention before risks materialize. The declining supplier delivery metric (98% → 82%) would have triggered investigation months before the disruption occurred, enabling proactive mitigation rather than reactive crisis management.

172. A — The large discrepancy between Pearson ($r = 0.35$) and Spearman ($\rho = 0.78$) indicates a strong monotonic but nonlinear relationship. Pearson measures only linear association and underestimates the true relationship strength. Spearman captures any consistent directional trend regardless of linearity. The variables move together reliably but not in a straight-line pattern.

173. C — The interaction table shows A-High/C-Low = 95.2 is the maximum response. The significant AC interaction means C's optimal level depends on A's level: at A-High, C-Low is dramatically better (95.2 vs. 82.4); at A-Low, C-High is slightly better (84.1 vs. 78.6). The interaction makes A-High/C-Low the clear winner, demonstrating why joint optimization with interaction data is essential.

174. B — A formal obsolete material management system addresses all aspects of the risk: physical segregation prevents inadvertent use, visual identification makes status immediately apparent, a disposition process ensures timely removal, and ERP/MRP blocking prevents the system from issuing obsolete materials to production orders. Together, these controls eliminate the root cause of the batch rejection.

175. C — A process validated only at nominal conditions provides no assurance of acceptable performance when parameters drift toward the boundaries of the validated range during normal production. Operators maintain parameters within the validated range but not necessarily at the exact nominal. Boundary testing confirms acceptable output across the full operating window, not just at the center.