

Module 22: Quality Management Systems (QMS)

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Module 22 - Quality Management Systems (QMS)

22.1.1 What is a Quality Management System?

A **Quality Management System (QMS)** is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS coordinates and directs an organization's activities to meet customer and regulatory requirements and continually improve effectiveness and efficiency.

Core Components of a QMS

1. **Quality Policy:** Top management's commitment to quality and customer satisfaction
2. **Quality Objectives:** Measurable goals aligned with the quality policy
3. **Processes:** Documented methods for carrying out work
4. **Resources:** People, equipment, facilities, and information needed
5. **Documentation:** Procedures, work instructions, and records
6. **Monitoring and Measurement:** Systems to track performance
7. **Improvement:** Mechanisms for corrective action and continuous improvement

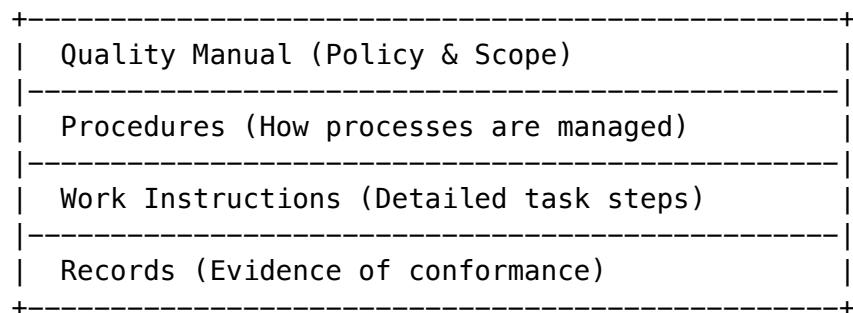
QMS vs. Quality Control

Quality Control (QC): Traditional approach focused on inspection and detecting defects after production - Reactive: Problems found after they occur - Inspector-dependent: Relies on inspection to separate good from bad - Limited scope: Focuses only on product conformance

Quality Management System (QMS): Modern approach focused on prevention and process control - Proactive: Prevents defects through process design and control - System-dependent: Built-in quality through processes and procedures - Comprehensive: Covers entire organization from supplier to customer

The QMS Framework

A robust QMS operates on several layers:



22.1.2 The Evolution of Quality: From Inspection to Prevention

Quality management has evolved significantly over the past century, driven by industrial needs and management philosophy.

Phase 1: Inspection Era (Pre-1920s)

Characteristics: - Focus on sorting good from bad products - Inspection performed by designated inspectors - No formal quality systems - Accept/reject decisions based on simple gages

Limitations: - Expensive (inspecting 100% of output) - Reactive (defects already made) - No process improvement - Adversarial (inspectors vs. operators)

Phase 2: Statistical Quality Control (1920s-1950s)

Key Developments: - Walter Shewhart develops control charts (1924) - Sampling inspection replaces 100% inspection - Statistical methods introduced (normal distribution, process capability)
- Focus shifts to process variation

Pioneers: Walter Shewhart, W. Edwards Deming, Joseph Juran

Advancement: Quality becomes more scientific, but still primarily a separate inspection function

Phase 3: Quality Assurance (1950s-1980s)

Key Concepts: - Quality built into processes, not just inspected afterward - Emphasis on prevention rather than detection - Systems approach: procedures, training, audits - Standards emerge (MIL-Q-9858A, ISO 9001)

Deming's 14 Points and Total Quality Management (TQM) principles gain prominence

Advancement: Quality becomes everyone's responsibility, integrated into all operations

Phase 4: Total Quality Management (1980s-2000s)

Characteristics: - Customer focus central to quality - Continuous improvement (Kaizen) - Employee involvement and empowerment - Leadership commitment - Process management - Integrated system approach

Tools: Six Sigma, Lean Manufacturing, Quality Circles, Benchmarking

Phase 5: Integrated Quality and Business Excellence (2000s-Present)

Modern QMS Features: - Risk-based thinking - Integration with business strategy - Digital quality systems (Industry 4.0) - Supply chain quality management - Real-time data analytics - Sustainability and social responsibility

Standards: ISO 9001:2015 (process approach, risk-based thinking), industry-specific standards (AS9100, ISO 13485, IATF 16949)

22.1.3 Benefits of Implementing a QMS

Operational Benefits

- 1. Reduced Scrap and Rework**
 - Processes designed to prevent defects
 - Early detection of problems
 - Typical savings: 2-5% of revenue
- 2. Improved Process Consistency**
 - Documented procedures ensure repeatability
 - Reduced variation in product quality
 - Less dependency on individual operators
- 3. Better Decision Making**

- Data-driven decisions based on facts
- Performance metrics guide improvements
- Trends identified before problems escalate

4. Enhanced Productivity

- Less time spent fixing errors
- Streamlined processes eliminate waste
- Resources focused on value-added activities

Customer Benefits

5. Increased Customer Satisfaction

- Products meet specifications consistently
- On-time delivery improves
- Customer complaints decrease

6. Enhanced Customer Confidence

- Certification demonstrates capability
- Systematic approach to quality assures customers
- Documentation provides transparency

7. Competitive Advantage

- QMS certification required by many customers
- Differentiates company in marketplace
- Opens doors to regulated industries (aerospace, medical)

Employee Benefits

8. Improved Workplace

- Clear expectations and procedures
- Training and development emphasized
- Employee input valued (suggestions, corrective actions)

9. Reduced Stress

- Fewer crisis situations
- Problems addressed systematically
- Roles and responsibilities clear

Business Benefits

10. Reduced Liability

- Documentation demonstrates due diligence
- Traceability enables rapid response to issues
- Risk assessment identifies potential problems

11. Improved Profitability

- Lower costs (less scrap, rework, warranty)
- Higher revenue (premium pricing, new customers)
- Better resource utilization

12. Organizational Learning

- Knowledge captured in procedures
- Lessons learned from audits and CAPAs
- Continuous improvement culture

Market Access

13. Regulatory Compliance

- ISO 9001 recognized globally
- Industry-specific standards (AS9100, ISO 13485) required
- Easier compliance with changing regulations

14. Supply Chain Integration

- Preferred supplier status
 - Long-term partnerships
 - Reduced supplier audits (certified QMS accepted)
-

22.1.4 QMS in the CNC Manufacturing Environment

CNC machining has unique quality challenges that a QMS must address:

CNC-Specific Quality Considerations

1. Process Complexity - Multi-axis machining with hundreds of operations - Complex geometries requiring sophisticated inspection - Long cycle times make defects expensive

QMS Solution: Detailed process planning, setup verification, in-process checks

2. Equipment Variability - Machine accuracy degrades over time - Thermal drift affects precision
- Tool wear impacts dimensional accuracy

QMS Solution: Preventive maintenance schedules, machine capability studies, tool life management

3. Material Variation - Material properties affect machinability - Lot-to-lot variation in raw stock
- Traceability required for critical applications

QMS Solution: Incoming inspection, material certification, traceability systems

4. Programming Errors - G-code errors can scrap expensive parts - CAM setup mistakes affect multiple parts - Simulation doesn't catch all issues

QMS Solution: Program verification procedures, first article inspection, proven program library

5. Setup Complexity - Fixturing errors cause positioning problems - Work offset errors lead to scrapped parts - Tool length errors affect dimensions

QMS Solution: Setup approval process, probe verification, first-off inspection

Key QMS Processes for CNC Shops

Process Control: - Machine qualification (accuracy, repeatability) - Process capability studies (C_p , C_{pk}) - Control plans for critical characteristics - Statistical process control (SPC) on key dimensions

Inspection and Testing: - First article inspection (AS9102 for aerospace) - In-process inspection at critical operations - Final inspection per control plan - Gage calibration and control

Equipment Management: - Preventive maintenance schedules - Machine accuracy checks (laser calibration, ballbar) - Tool life tracking and replacement - Coolant concentration monitoring

Document Control: - Engineering drawing revision control - NC program version management - Work instruction updates - Quality record retention

Supplier Quality: - Raw material certification - Incoming inspection - Tool and consumable quality - Outside process control (heat treat, plating)

Nonconforming Product: - Scrap/rework identification and segregation - Material Review Board (MRB) for dispositions - Rework procedure control - Customer notification when required

Continuous Improvement: - Corrective action for defects - Process optimization (cycle time, tool life) - Scrap reduction initiatives - Lean manufacturing implementation

22.1.5 Quality Culture and Leadership Commitment

A QMS is only as effective as the culture that supports it. **Quality culture** is the shared values, beliefs, and behaviors regarding quality within an organization.

Elements of a Strong Quality Culture

1. Leadership Commitment - Top management actively participates in quality activities - Resources allocated to quality initiatives - Quality discussed in business reviews - “Walk the talk” - leaders follow procedures

2. Employee Empowerment - Operators have authority to stop production for quality issues - Suggestions welcomed and acted upon - Quality problems addressed, not blamed - Training and development supported

3. Customer Focus - Customer requirements drive decisions - Customer feedback actively sought - On-time delivery and quality prioritized - Long-term relationships valued

4. Fact-Based Decision Making - Data collected and analyzed - Metrics drive improvement - Root causes identified before action - Experiments used to validate changes

5. Continuous Improvement Mindset - “Good enough” is not acceptable - Small incremental improvements valued - Failure seen as learning opportunity - Innovation encouraged

Leadership Responsibilities in a QMS

ISO 9001 places specific responsibilities on top management:

1. **Quality Policy:** Establish and communicate quality policy
2. **Quality Objectives:** Set measurable quality objectives
3. **Roles and Responsibilities:** Define who does what
4. **Resources:** Provide people, equipment, facilities
5. **Communication:** Ensure quality requirements understood
6. **Management Review:** Regularly review QMS performance
7. **Customer Focus:** Ensure customer needs are met
8. **Improvement:** Promote continual improvement

Common Leadership Mistakes

- “**We’re already doing quality**” - Informal systems aren’t enough □ “**Quality is the QA department’s job**” - Quality is everyone’s responsibility □ “**Certification is just paperwork**” - QMS is about improving operations, not just getting a certificate □ “**We don’t have time for quality**” - Poor quality costs more time (rework, scrap, firefighting) □ “**Our customers don’t require certification**” - QMS improves efficiency and profitability regardless

Building Quality Culture

Short-term actions: - Communicate why QMS is important - Involve employees in QMS development - Celebrate quality successes - Address quality problems promptly

Long-term actions: - Integrate quality into performance evaluations - Recognize and reward quality contributions - Provide ongoing quality training - Link compensation to quality metrics

Summary

A Quality Management System provides a structured framework for consistently delivering quality products and services. QMS has evolved from simple inspection to sophisticated, integrated systems that prevent defects, improve processes, and drive business success.

In CNC manufacturing, a QMS addresses unique challenges including process complexity, equipment variability, and programming risks. Success requires not just procedures and documentation, but a quality culture supported by committed leadership.

In the next section, we’ll explore ISO 9001, the world’s most widely recognized quality standard, and its application to manufacturing.

Key Takeaways

1. **QMS is a comprehensive system** covering all aspects of quality, not just inspection
 2. **Quality has evolved** from inspection to prevention to integrated business management
 3. **Benefits are both operational and strategic** - reduced costs, improved customer satisfaction, market access
 4. **CNC manufacturing has unique quality challenges** requiring specialized QMS approaches
 5. **Quality culture** is as important as quality procedures
 6. **Leadership commitment** is essential for QMS success
 7. **QMS is not just certification** - it’s a tool for operational excellence
-

Review Questions

1. What is the difference between Quality Control and a Quality Management System?
2. Describe the evolution of quality management from the Inspection Era to modern QMS.

3. List five operational benefits and five business benefits of implementing a QMS.
 4. What are three unique quality challenges in CNC manufacturing, and how does a QMS address them?
 5. Why is leadership commitment critical to QMS success?
 6. What does it mean to have a “quality culture”?
 7. How has the focus of quality management shifted from “detection” to “prevention”?
-

Practical Exercise

Exercise: QMS Gap Analysis

Evaluate your current (or a hypothetical) CNC shop against basic QMS requirements:

1. Are processes documented in written procedures?
2. Is there a system for controlling document revisions?
3. Are employees trained and records maintained?
4. Is equipment calibrated on a regular schedule?
5. Is there a formal inspection plan for products?
6. How are nonconforming parts identified and controlled?
7. Is there a corrective action system for quality problems?
8. Are quality records organized and retrievable?
9. Does management regularly review quality performance?
10. Is there a system for continuous improvement?

For each “no” answer, identify what would need to be implemented to meet ISO 9001 requirements.

Module 22 - Quality Management Systems (QMS)

Internal audits and management reviews are essential mechanisms for monitoring QMS effectiveness, ensuring compliance, and driving continuous improvement. This section covers audit planning, execution, reporting, and management review processes.

22.10.1 Internal Audit Planning and Scheduling

Internal Audit: Systematic, independent examination of the QMS to determine if activities and results comply with requirements and are effectively implemented.

Purpose of Internal Audits

Compliance Verification: - Verify conformance to ISO 9001 (or AS9100, ISO 13485, IATF 16949)
- Check adherence to company procedures - Meet regulatory requirements

Effectiveness Assessment: - Determine if QMS achieving intended results - Identify opportunities for improvement - Verify corrective actions effective

Preparation for External Audits: - Practice for certification audits - Identify and fix issues before external auditors find them - Build confidence in QMS

Continuous Improvement: - Identify best practices to share across organization - Drive process improvements - Foster quality culture

Annual Audit Schedule

ISO 9001 Requirement: Conduct internal audits at planned intervals

Best Practice: Audit all QMS processes at least annually

Audit Schedule Development:

1. Identify Processes to Audit: - All processes in scope of QMS (operations, support, management) - Each ISO 9001 clause (4-10)

2. Determine Audit Frequency: - **Annual minimum** for all processes - **More frequent** for: - Critical processes (affect safety, regulatory compliance) - Processes with poor performance (high defect rate, customer complaints) - Recently changed processes (new equipment, revised procedures) - External audit findings or customer concerns - **Less frequent** for: - Mature, stable processes with excellent performance - Low-risk areas

3. Create Schedule: - Distribute audits throughout year (avoid all audits at year-end) - Consider operational factors (avoid auditing during busy season if possible) - Assign auditors

Example Annual Audit Schedule:

Month	Process/Area to Audit	ISO 9001 Clauses	Auditor	Status
Jan	Document Control	7.5	Q. Manager	Complete
Feb	Training and Competence	7.2	HR Manager	Complete
Mar	CNC Machining Operations	8.5	Eng Manager	Scheduled
Apr	Supplier Management	8.4	Purchasing	
May	Inspection and Testing	8.6, 7.1.5	QA Lead	
Jun	Calibration	7.1.5	QA Lead	
Jul	Nonconforming Product	8.7	Q. Manager	
Aug	Internal Audits	9.2	Eng Manager	
Sep	Management Review	9.3	QA Lead	
Oct	Preventive Maintenance	7.1.3	Maint Manager	
Nov	Customer Communication	8.2.1	Sales Manager	
Dec	Corrective Action	10.2	Q. Manager	

Schedule Approval: Quality Manager approves annual schedule; communicated to all departments

Schedule Flexibility: Adjust as needed (add audits for problems, reschedule for conflicts)

22.10.2 Auditor Qualification and Training

Auditor Qualifications

Effective Auditors Need:

Knowledge: - ISO 9001 requirements (thorough understanding) - Industry-specific standards (AS9100, ISO 13485, IATF 16949 if applicable) - Company procedures and processes - Audit techniques and methodologies

Skills: - Interviewing and questioning (open-ended questions, active listening) - Observation (see what's happening, not just what's documented) - Objective evidence gathering (verify with records, samples) - Analysis and evaluation (identify root causes, systemic issues) - Communication (written reports, oral presentation)

Personal Attributes: - Objectivity and impartiality (no bias) - Integrity and ethics - Diplomacy and tact (constructive, not adversarial) - Persistence and thoroughness - Open-mindedness

Auditor Independence

ISO 9001 Requirement: Auditors must be **independent** and **impartial**

Independence: - **Cannot audit own work** (conflict of interest) - Example: Production Manager cannot audit production operations they manage - Can audit other departments (Production Manager can audit Inspection Department)

Small Organizations: - Limited personnel may make full independence difficult - Options: - Use auditors from different shifts or locations - Hire external auditors (consultants) - Partner with similar companies (exchange auditors)

Auditor Training

Internal Auditor Training:

Formal Training Course (recommended): - ISO 9001 Internal Auditor course (2-3 days) - Covers: - ISO 9001 requirements (clause-by-clause) - Audit process (planning, execution, reporting) - Audit techniques (questioning, sampling, evidence) - Practice audits (role-play, case studies) - Certificate of completion

On-the-Job Training: - Shadow experienced auditor (observe audit) - Co-audit (participate as trainee auditor) - Gradual progression (audit simple processes first, complex later)

Ongoing Development: - Attend refresher training (when ISO 9001 revised) - Participate in auditor meetings (share experiences, lessons learned) - Review audit findings and reports (learn from others)

Auditor Qualification Records: - Training certificates - Education and experience - Audit participation log (audits conducted)

22.10.3 Audit Preparation and Checklists

Audit Planning

Audit Notification: - Notify auditee 1-2 weeks in advance - Provide audit plan (scope, date, time, auditor) - Request documents for review (procedures, records)

Document Review: - Review procedures and work instructions for process being audited - Review previous audit reports (findings, corrective actions) - Review performance data (metrics, NCRs, customer complaints)

Audit Checklist Development: - List requirements to audit (ISO 9001 clauses, procedures) - Prepare questions to ask - Identify records to review

Audit Checklist

Checklist Purpose: - Ensure comprehensive audit (don't miss requirements) - Provide structure (guide auditor through process) - Document findings (notes on checklist)

Checklist Format:

INTERNAL AUDIT CHECKLIST	
Process:	CNC Machining Operations
Date:	15-Mar-2024 Auditor: J. Smith
Auditee:	Production Supervisor
ISO 9001 Clause 8.5 – Production and Service Provision	
8.5.1 Control of Production	
[] Are work instructions available at workstations?	
Notes:	_____
[] Is monitoring/measuring equipment available?	
Notes:	_____
[] Are competent personnel assigned to operations?	
Sample:	Check training records for 3 operators
Notes:	_____
8.5.2 Identification and Traceability	
[] Are parts identified throughout production?	
Observation:	Check travelers, labels, markings
Notes:	_____
[] Is traceability maintained where required?	
Sample:	Trace 1 part from material to shipment
Notes:	_____
FINDINGS:	

Conformances:	_____
Nonconformances:	_____
Observations:	_____

Checklist Best Practices: - Use open-ended questions (“How do you...?” not “Do you...?”) - Reference specific requirements (ISO 9001 clause, procedure number) - Leave space for notes and evidence - Not exhaustive (auditor may deviate, follow leads)

22.10.4 Conducting Effective Audits

22.10.4.1 Opening Meeting

Purpose: Introduce audit team, confirm scope, explain process

Attendees: Auditor(s), auditee (supervisor/manager), other key personnel

Agenda (5-10 minutes): 1. **Introductions:** Auditor and auditees introduce themselves 2. **Audit Scope:** Confirm process/area being audited 3. **Audit Criteria:** ISO 9001 clauses, procedures applicable 4. **Audit Schedule:** Timing, locations, who will be interviewed 5. **Audit Process:** Explain how audit conducted (interviews, observations, record review) 6. **Confidentiality:** Findings discussed in closing meeting, report issued later 7. **Questions:** Auditee may ask questions

Tone: Professional, collaborative (not adversarial)

22.10.4.2 Evidence Collection and Sampling

Objective Evidence: Factual information verifiable through observation, measurement, test, or examination of records

Sources of Objective Evidence: - **Interviews:** Ask personnel how they perform tasks - **Observations:** Watch activities being performed - **Records:** Review documents (inspection reports, training records, calibration certs) - **Physical Examination:** Inspect parts, equipment, gages

Audit Trail (follow process flow): - Start at beginning of process, follow through to end - Example: Machining audit trail: - Order received Job planning Program Setup First-off inspection Production In-process checks Final inspection Shipping

Sampling: - Cannot audit everything (time constraint) - Select representative samples - **Sampling Guidelines:** - Review 3-5 records of each type (training records, NCRs, calibration certs) - Interview 2-3 people performing same task - Observe at least one example of each critical activity - **Risk-based sampling:** More samples for critical or problem areas

Audit Techniques:

Effective Questioning: - **Open-ended questions:** “How do you verify the setup is correct?” (encourages detailed answer) - **Avoid leading questions:** “You do verify setups, right?” (leads to yes/no) - **Follow-up:** “Can you show me?” “Where is that documented?”

Active Listening: - Pay attention to answers - Take notes - Observe body language and environment

Verification: - Don't just ask, verify with evidence - "You said you calibrate gages annually. Can you show me calibration records for this micrometer?"

Examples of Evidence Collection:

Requirement: Operators trained on work instructions

Audit Steps: 1. **Interview operator:** "How did you learn to perform this operation?" 2. **Observe:** Watch operator perform task; compare to work instruction 3. **Review records:** Check training record for operator signature and date 4. **Conclusion:** If training record exists, operator demonstrates competence, and follows work instruction \square **Conformance.** If training record missing or operator doesn't follow procedure \square **Nonconformance.**

22.10.4.3 Finding Classification

Finding Types:

- 1. Conformance:** - Requirement met - Evidence supports compliance - Document positive findings (recognize good practices)
- 2. Nonconformance:** - Requirement not met - Evidence shows failure to comply - Classified as Major or Minor
- 3. Observation (Opportunity for Improvement):** - Not yet a nonconformance, but potential risk - Best practice not followed - Trend indicating future problem

Major vs. Minor Nonconformance:

Major Nonconformance: - Significant failure to meet requirement - Systemic issue (affects multiple areas or frequent occurrence) - Absence of required system (no calibration program, no document control) - Could affect product quality, safety, or regulatory compliance

Examples: - "Five of ten gages inspected have no calibration records. ISO 9001 Clause 7.1.5.1 requires calibration at specified intervals." - "No procedure exists for document control. ISO 9001 Clause 7.5.3 requires documented information be controlled."

Minor Nonconformance: - Isolated lapse or single occurrence - Does not systemic or critical - Documentation issue (record incomplete, procedure missing detail)

Examples: - "Training record for Operator X dated 15-Jan-2024 missing supervisor signature. Procedure QP-05 requires supervisor approval." - "Procedure QP-10 Calibration Control does not specify retention period for calibration records. ISO 9001 Clause 7.5.3 requires retention period be determined."

Observation: - Potential for improvement, not yet nonconformance

Examples: - "Gages stored in open toolbox on shop floor exposed to chips and coolant. Consider enclosed storage to prevent damage and extend gage life." - "Scrap rate has increased from 1% to 2.5% over past 3 months (still within target of <3%, but trending unfavorably). Recommend investigation."

Finding Documentation: - Write findings clearly and specifically - Include objective evidence (what was observed, records reviewed, who interviewed) - Cite requirement (ISO 9001 clause, procedure number) - Avoid ambiguous language

Good Finding (clear, specific): > “Work instruction WI-105 for CMM operation, Rev B dated 10-Jan-2023, is posted at CMM workstation. Current revision per document control log is Rev C dated 05-Feb-2024 (supersedes Rev B). ISO 9001 Clause 7.5.3.2 requires current revisions be available at point of use. **Minor Nonconformance.**”

Poor Finding (vague): > “Documents not current.” (Unclear: which documents? how verified? what requirement?)

22.10.4.4 Closing Meeting

Purpose: Present findings, discuss corrective actions, close audit

Attendees: Auditor(s), auditee (supervisor/manager), other key personnel

Agenda (15-30 minutes): 1. **Thank Auditee:** Acknowledge cooperation and time 2. **Summarize Audit:** Overview of areas audited 3. **Present Conformances:** Highlight positive findings (good practices, improvements since last audit) 4. **Present Nonconformances:** Describe each nonconformance (major, minor) - Read finding - Show evidence (if applicable) - Allow auditee to clarify or provide additional information 5. **Present Observations:** Improvement opportunities 6. **Discuss Next Steps:** Corrective action required, timelines, follow-up 7. **Questions:** Auditee may ask questions or request clarification

Tone: Constructive, collaborative - Focus on systems, not people (“The process lacks...” not “You didn’t...”) - Findings are opportunities for improvement, not personal criticism

Auditee Response: - Auditee may agree with finding - Auditee may provide additional information that changes finding (if evidence provided, auditor may revise finding) - Auditee may disagree (auditor notes disagreement in report, but finding stands unless evidence contradicts)

22.10.5 Audit Reporting and Follow-Up

Audit Report

Audit Report Contents: 1. **Header:** Audit number, date, process/area audited, auditor, auditees 2. **Scope and Objectives:** ISO 9001 clauses, procedures audited 3. **Summary:** High-level overview (conformances, nonconformances, observations) 4. **Conformances:** Positive findings (processes working well) 5. **Nonconformances:** Detailed findings (description, evidence, requirement cited, classification) 6. **Observations:** Improvement opportunities 7. **Conclusion:** Overall assessment of process (effective, needs improvement) 8. **Distribution:** Report recipients (auditee, quality manager, top management) 9. **Signature and Date:** Auditor signature

Audit Report Example (excerpt):

INTERNAL AUDIT REPORT	
Audit Number:	IA-2024-03
Date:	15-Mar-2024 Auditor: J. Smith, Eng Manager
Process Audited:	CNC Machining Operations
Auditee:	M. Johnson, Production Supervisor

| SCOPE: ISO 9001:2015 Clauses 8.5, 8.6 |
| Procedures: QP-15 First-Off Inspection, QP-20 Final |
| Inspection, WI-105 CMM Operation |

| SUMMARY:
| - Conformances: 15
| - Major Nonconformances: 0
| - Minor Nonconformances: 2
| - Observations: 3 |

| CONFORMANCES:
| 1. Work instructions available at all workstations |
| inspected (5 locations verified). |
| 2. First-off inspections performed and documented |
| per QP-15 (reviewed 8 travelers, all complete). |
| 3. Operators demonstrated competence (observed 3 |
| operators; all followed procedures correctly). |
| [Additional conformances listed...] |

| NONCONFORMANCES:
| NC-2024-03-01 (Minor):
| Work instruction WI-105 CMM Operation Rev B posted |
| at CMM workstation. Current revision is Rev C per |
| document control log. Requirement: ISO 9001 Clause |
| 7.5.3.2 requires current revisions available.
| Evidence: Observed WI-105 Rev B at workstation;
| confirmed Rev C is current (dated 05-Feb-2024). |

| NC-2024-03-02 (Minor):
| Training record for Operator Harris dated 20-Feb-2024 |
| on new fixture setup procedure missing supervisor |
| signature. Requirement: Procedure QP-05 Training,
| Section 5.3 requires supervisor approval.
| Evidence: Reviewed training records, one incomplete. |

| OBSERVATIONS:
| OBS-2024-03-01: Setup sheets stored in binder on |
| shop floor becoming worn/stained. Consider electronic |
| display or lamination to preserve legibility.
| [Additional observations...] |

| CONCLUSION:
| Machining operations generally conforming to QMS |
| requirements. Minor nonconformances require |
| correction. Observations provided for improvement. |

| Auditor: _____ Date: 15-Mar-2024 |
| Reviewed by QM: _____ Date: _____ |

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Report Timing: Issue report within 5-10 days of audit

Report Distribution: Auditee, Quality Manager, Top Management

Corrective Action Follow-Up

Auditee Responsibilities: - Review audit findings - Investigate root causes of nonconformances - Develop corrective action plan - Implement corrective actions - Submit corrective action response to auditor

Corrective Action Response (for each nonconformance): - **Immediate Correction:** What done immediately? (e.g., replaced WI-105 Rev B with Rev C at workstation) - **Root Cause:** Why did nonconformance occur? (e.g., document control system doesn't notify operators of revisions) - **Corrective Action:** What will prevent recurrence? (e.g., implement email notification when procedures revised) - **Completion Date:** When will corrective action be completed? - **Responsible Person:** Who is responsible?

Auditor Review: - Review corrective action plan - Approve if adequate, or request revision if insufficient - Track corrective action completion

Verification: - Follow-up audit or verification (confirm corrective action implemented and effective) - May be part of next scheduled audit or separate verification activity

Closure: - Nonconformance closed when corrective action verified effective - Document closure (date, signature)

22.10.6 Management Review Meetings

Management Review: Top management's systematic evaluation of QMS to ensure continuing suitability, adequacy, effectiveness, and alignment with strategic direction

ISO 9001 Requirement (Clause 9.3): Conduct management review at planned intervals

22.10.6.1 Review Inputs

ISO 9001 Required Inputs:

1. **Status of Actions from Previous Reviews:**
 - What action items assigned in last review?
 - What's been completed? What's outstanding?
2. **Changes in External and Internal Issues:**
 - Market changes, new regulations, technology advances
 - Organizational changes, new equipment, personnel
3. **Information on QMS Performance:**
 - **Customer Satisfaction:** Survey results, complaints, scorecards
 - **Quality Objectives:** Status (met, not met, trending)
 - **Process Performance:** Metrics (scrap rate, on-time delivery, Cpk)
 - **Product Conformity:** Inspection results, nonconformances

- **Nonconformities and Corrective Actions:** NCRs, CARs (count, trends, open/closed)
- **Monitoring and Measurement Results:** KPIs, dashboard
- **Audit Results:** Internal and external audit findings
- **External Provider Performance:** Supplier scorecards, issues

4. Adequacy of Resources:

- Are resources sufficient? (people, equipment, infrastructure)
- Needs or gaps identified?

5. Effectiveness of Actions Addressing Risks and Opportunities:

- Risks identified in planning (Clause 6.1)
- Have risk mitigation actions been effective?

6. Opportunities for Improvement:

- Ideas from employees, customers, audits
- Benchmarking, industry trends

Additional Inputs (optional but valuable): - Financial performance (revenue, profitability related to quality) - Market share, competitive position - Regulatory compliance status - Training effectiveness - Safety performance (if integrated management system)

Management Review Agenda Example

MANAGEMENT REVIEW MEETING AGENDA	
Date: 15-Jun-2024, 10:00 AM – 12:00 PM	
Location: Conference Room A	
Attendees: President, VP Operations, Quality Manager, Engineering Manager, Sales Manager, Purchasing Manager	
1. Review of Previous Action Items (10 min)	
– Status update on items from Dec 2023 review	
2. Changes in Context (10 min)	
– New customer requirements (AS9100 certification)	
– New competitor in market	
– Retirement of senior machinist (resource impact)	
3. Quality Objectives Status (15 min)	
– Scrap rate: 1.8% (target <2%) [check]	
– On-time delivery: 93% (target >=95%) x	
– Customer satisfaction: 4.6/5 (target >=4.5) [check]	
– Cpk (avg): 1.45 (target >=1.33) [check]	
4. Performance Metrics Review (20 min)	
– Quality dashboard (YTD trends)	
– Customer complaints (down 20% vs last year)	
– Scrap and rework costs	
5. Internal Audit Results (15 min)	
– 6 audits completed (Jan–Jun)	

- Findings: 0 major, 4 minor, 12 observations	
- All corrective actions completed	
6. External Audit Results (10 min)	
- ISO 9001 surveillance audit (Apr): Pass	
- 1 minor finding (closed)	
7. Customer Satisfaction (10 min)	
- Survey results: 4.6/5 (excellent)	
- Key feedback: Quality excellent, delivery needs improvement	
8. Supplier Performance (10 min)	
- 2 suppliers on probation (quality issues)	
- Actions: Audits scheduled, alternate sources	
9. Nonconformances and Corrective Actions (10 min)	
- 18 NCRs year-to-date (vs 25 last year) [check]	
- 12 CARs (8 closed, 4 open)	
- Trend: Dimensional errors decreasing	
10. Resource Adequacy (10 min)	
- Need: Additional CMM programmer (backlog)	
- Need: 5-axis machining center (capacity)	
11. Risks and Opportunities (10 min)	
- Risk: Senior machinist retiring (knowledge loss)	
Action: Cross-training program	
- Opportunity: AS9100 certification (new customers)	
Action: Gap analysis, implementation plan	
12. Improvement Opportunities (10 min)	
- Employee suggestion: Automated tool management	
- Benchmarking: Competitor using MES system	
13. Decisions and Action Items (10 min)	
- Approve hiring CMM programmer	
- Initiate AS9100 implementation project	
- Assign actions with owners and due dates	
14. Next Review Date (5 min)	
- Schedule next management review: Dec 2024	

22.10.6.2 Review Outputs

ISO 9001 Required Outputs: Decisions and actions related to:

- 1. Opportunities for Improvement:** - Process improvements identified (reduce cycle time, improve Cpk) - Efficiency gains (Lean projects, automation)
- 2. Changes to QMS:** - Procedure updates required - New processes to implement (AS9100 certification) - Documentation revisions
- 3. Resource Needs:** - Personnel (hiring, training) - Equipment (new machines, gages, software) - Infrastructure (facility expansion, climate control)

Example Management Review Outputs:

Decision/Action	Responsible	Due Date	Status
Approve CMM programmer hire (budget \$75k)	VP Operations	30-Jul-2024	Open
Initiate AS9100 certification project	Quality Manager	31-Dec-2024	Open
Implement cross-training program for machinists	Production Manager	30-Sep-2024	Open
Investigate MES system (quote and ROI analysis)	Engineering Manager	31-Aug-2024	Open
Audit suppliers on probation within 30 days	Purchasing	15-Jul-2024	Open
Revise on-time delivery improvement plan	Operations Manager	30-Jun-2024	Open

Management Review Frequency

ISO 9001: “At planned intervals” (no specific frequency)

Best Practice: **Semi-annually** (twice per year) or **quarterly** (four times per year)

Considerations: - Larger organizations, complex QMS: Quarterly - Smaller organizations, stable QMS: Semi-annually - External audit schedule: Review before certification audit

Management Review Documentation

Management Review Minutes: - Document meeting (date, attendees, agenda) - Summarize inputs presented - Record decisions and actions (outputs) - Assign responsibilities and due dates - Signatures (Quality Manager, Top Management)

Retention: Maintain minutes as QMS records (typically 3-10 years)

Summary

Internal audits and management reviews are vital QMS monitoring and improvement mechanisms. Internal audits verify compliance, identify improvement opportunities, and prepare for external audits. Effective audits require qualified auditors, thorough planning, objective evidence collection, and clear findings. Management reviews provide top management's systematic evaluation

of QMS performance, enabling data-driven decisions on improvements, changes, and resource allocation.

Together, internal audits and management reviews ensure the QMS remains effective, aligned with business strategy, and continuously improving.

Key Takeaways

1. **Internal audits** verify QMS compliance and effectiveness; required at least annually for all processes
 2. **Audit schedule** should cover all QMS processes; high-risk areas audited more frequently
 3. **Auditor independence** critical; cannot audit own work
 4. **Auditor qualifications** include ISO 9001 knowledge, audit skills, and personal attributes (objectivity, integrity)
 5. **Audit preparation** includes document review and checklist development
 6. **Audit process:** Opening meeting □ Evidence collection □ Findings □ Closing meeting □ Report □ Follow-up
 7. **Objective evidence** gathered through interviews, observations, record review, physical examination
 8. **Findings classified:** Conformances, nonconformances (major/minor), observations
 9. **Audit report** documents findings, requires corrective action for nonconformances
 10. **Management review** conducted at planned intervals (semi-annually or quarterly typical)
 11. **Management review inputs:** Previous actions, context changes, QMS performance, audits, customer satisfaction, supplier performance, resources, risks
 12. **Management review outputs:** Decisions on improvements, QMS changes, resource needs
-

Review Questions

1. What is the purpose of internal audits?
 2. How often should internal audits be conducted?
 3. What are the qualifications required for internal auditors?
 4. Why is auditor independence important?
 5. What should be included in an audit checklist?
 6. What are the steps in conducting an internal audit (opening meeting through report)?
 7. What is objective evidence, and how is it collected?
 8. What is the difference between a major nonconformance and a minor nonconformance?
 9. What should be included in an audit report?
 10. What is the purpose of management review?
 11. What are the required inputs to management review per ISO 9001?
 12. What are the required outputs from management review?
 13. How often should management review be conducted?
-

Practical Exercises

Exercise 1: Develop Audit Schedule

Create an annual internal audit schedule: 1. List all processes/areas in your QMS (or hypothetical shop) 2. Map to ISO 9001 clauses 3. Determine audit frequency (annually, semi-annually, quarterly) 4. Assign months to distribute audits throughout year 5. Assign auditors (ensure independence) 6. Create schedule table

Exercise 2: Create Audit Checklist

Develop audit checklist for a process: 1. Select process (document control, calibration, inspection, machining operations) 2. Identify applicable ISO 9001 clauses 3. List requirements to verify 4. Write open-ended questions to ask 5. Identify records to review 6. Format as checklist with space for notes

Exercise 3: Classify Audit Findings

For each scenario, classify as conformance, major nonconformance, minor nonconformance, or observation: 1. Ten gages inspected; all have current calibration stickers and certificates on file 2. Three of eight training records reviewed are missing supervisor signature 3. No procedure exists for controlling nonconforming product 4. Work instruction at machining station is current revision, but torn and difficult to read 5. Scrap rate increased from 1.5% to 2.8% in past 3 months (target <3%, but trending poorly)

Exercise 4: Write Audit Findings

Draft audit findings for nonconformances: 1. Select scenario (missing calibration, incomplete training record, obsolete document in use) 2. Write finding including: - Description of nonconformance (what was wrong?) - Objective evidence (how verified?) - Requirement cited (ISO 9001 clause, procedure) - Classification (major or minor) 3. Make finding clear, specific, factual

Exercise 5: Prepare Management Review Agenda

Create management review agenda for your organization: 1. List all required inputs per ISO 9001 2. Add any additional inputs relevant to your business 3. Assign time for each agenda item 4. Identify who will present each topic 5. Schedule meeting (date, time, attendees)

Additional Resources

Standards: - ISO 9001:2015 Clause 9.2 (Internal Audit) - ISO 9001:2015 Clause 9.3 (Management Review) - ISO 19011:2018 (Guidelines for Auditing Management Systems)

Books: - “The ASQ Auditing Handbook” (4th Edition) edited by J.P. Russell - “Quality Audits for Improved Performance” by Dennis Arter - “ISO 9001:2015 Audit Procedures” by Ray Tricker - “Internal Quality Auditing” by Denis Pronovost

Training: - ASQ Certified Quality Auditor (CQA) - ISO 9001:2015 Lead Auditor Course (accredited by certification bodies) - ISO 9001:2015 Internal Auditor Course (2-3 days) - Auditing skills courses (ASQ, online providers)

Online Resources: - ASQ Audit Division: Resources, webinars, articles - ISO website: ISO 19011 guidance - Quality Digest: Auditing articles and case studies

Module 22 - Quality Management Systems (QMS)

This combined document covers the remaining essential QMS topics: customer satisfaction, continuous improvement, traceability, measurement systems analysis, certification, digital quality management, and practical implementation guidance.

Section 22.11 - Customer Focus and Satisfaction

Understanding Customer Requirements

Customer Focus: Core principle of ISO 9001 - understanding and meeting customer needs drives quality

Methods to Understand Requirements: - **Contract Review:** Detailed review of purchase orders, specifications, drawings before acceptance - **Customer Meetings:** Discuss expectations, priorities, critical characteristics - **Customer Specifications:** Study customer-specific requirements (CSRs), quality manuals - **Industry Standards:** Understand applicable standards (aerospace AS9100, medical ISO 13485)

Contract Review Process: 1. Review PO/contract for completeness 2. Verify specifications, drawings current revision 3. Confirm capabilities (can we make it?) 4. Check material availability 5. Validate delivery schedule feasible 6. Identify special requirements (certifications, testing, FAI) 7. Approve or request clarification before accepting

Customer Communication and Order Review

Effective Communication Channels: - Email, phone, customer portals - Regular status updates on orders - Proactive notification of issues or delays - Technical questions resolved promptly

Order Review Documentation: Document acceptance of customer requirements (signed quote, order acknowledgment)

Customer Feedback and Complaint Handling

Customer Complaint Process: 1. **Receive:** Log complaint immediately 2. **Acknowledge:** Respond within 24 hours 3. **Investigate:** Determine cause (NCR, root cause analysis) 4. **Containment:** Sort inventory, notify if more product affected 5. **Response:** Provide corrective action plan to customer 6. **Corrective Action:** Implement to prevent recurrence 7. **Follow-up:** Verify customer satisfied with resolution

Complaint Documentation: Customer Complaint Form capturing issue, investigation, actions, closure

Customer Satisfaction Surveys

Survey Design: - Rate key areas: quality, delivery, communication, responsiveness, value - 1-5 scale or NPS (Net Promoter Score) - Open-ended questions for improvement suggestions

Survey Example Questions: - Rate product quality (conformance to specifications) - Rate on-time delivery performance - Rate responsiveness to inquiries and issues - Rate overall satisfaction - Would you recommend us to others? - What can we improve?

Survey Timing: Annually or after major projects

Survey Results: Analyze, share in management review, develop action plans for low scores

On-Time Delivery Performance

Tracking OTD:

OTD % = (Orders Delivered On-Time / Total Orders) × 100

Target: >=95% (AS9100 requires monitoring)

Improvement Actions: - Accurate quoting (realistic lead times) - Production scheduling optimization - Supplier delivery improvements - Capacity management - Expediting process for critical orders

Customer-Specific Requirements (CSRs)

CSRs: Special requirements from individual customers beyond standard specs

Examples: - Specific certifications required (DFARS, Nadcap) - Enhanced inspection or testing - Special packaging or labeling - Notification requirements (process changes, nonconformances) - Right of access for customer audits

Managing CSRs: Document in quality plan or contract file; flow down to production, inspection, suppliers

Customer Scorecards and Metrics

Customer Scorecards: Performance reports customers provide to suppliers

Common Metrics: - Quality PPM (parts per million defects) - On-time delivery - Responsiveness - Cost competitiveness

Use Scorecards: Monitor performance, discuss in customer meetings, drive improvement

Section 22.12 - Continuous Improvement and Lean Integration

Continuous Improvement Culture

Continuous Improvement: Ongoing effort to improve products, services, and processes

Building Improvement Culture: - **Leadership commitment:** Visible support, resources allocated - **Employee involvement:** Ideas welcomed, acted upon - **Recognition:** Celebrate successes - **Training:** Teach improvement tools - **Metrics:** Track improvements (ROI, quality gains)

Improvement Sources: - Corrective actions (CARs) - Audit findings - Employee suggestions - Customer feedback - Benchmarking

Lean Manufacturing Principles

Lean: Systematic approach to eliminating waste and maximizing value

8 Wastes (DOWNTIME): - **Defects** (scrap, rework) - **Overproduction** (making more than needed) - **Waiting** (idle time) - **Non-utilized talent** (employee skills not used) - **Transportation** (unnecessary movement of materials) - **Inventory** (excess stock) - **Motion** (unnecessary operator movement) - **Extra processing** (work not adding value)

Value Stream Mapping Value Stream Map (VSM): Visual representation of material and information flow from supplier to customer

VSM Process: 1. **Current State Map:** Document existing process (cycle times, inventory, lead times) 2. **Identify Waste:** Highlight non-value-added activities 3. **Future State Map:** Design improved process (reduced waste, faster flow) 4. **Implementation Plan:** Actions to achieve future state

VSM Benefits: Identifies bottlenecks, excess inventory, long lead times

5S Workplace Organization 5S: Structured approach to workplace organization

5S Steps: 1. **Sort (Seiri):** Remove unnecessary items 2. **Set in Order (Seiton):** Organize remaining items (tools, materials) for easy access 3. **Shine (Seiso):** Clean workspace thoroughly 4. **Standardize (Seiketsu):** Establish standards for cleanliness and organization 5. **Sustain (Shitsuke):** Maintain standards (audits, discipline)

5S Benefits: Reduces search time, improves safety, enhances quality (clean environment reduces contamination)

5S Example: - **Before:** Tools scattered on workbench, hard to find, some missing - **After:** Shadow board with tool outlines, each tool has designated spot, missing tools immediately visible

Kaizen Events Kaizen: Japanese term meaning “continuous improvement” or “change for better”

Kaizen Event: Focused improvement project (typically 3-5 days) targeting specific problem

Kaizen Event Process: 1. **Select Topic:** Identify improvement opportunity (reduce setup time, improve quality, eliminate waste) 2. **Form Team:** Cross-functional (operations, engineering, quality, maintenance) 3. **Current State Analysis:** Document existing process, metrics 4. **Generate Ideas:** Brainstorm improvements 5. **Implement:** Make changes during event (quick prototyping, try ideas) 6. **Measure Results:** Compare before/after metrics 7. **Standardize:** Document new process, train personnel 8. **Sustain:** Monitor to ensure improvements maintained

Kaizen Example: Reduce CNC setup time from 60 minutes to 30 minutes - Analyze setup process, identify delays (tool selection, work offset entry, part loading) - Implement SMED techniques (see below) - Result: 50% reduction in setup time, increased capacity

Single Minute Exchange of Dies (SMED) **SMED:** Methodology to reduce setup/changeover time (goal: <10 minutes, “single minute”)

SMED Techniques: - **External Setup:** Perform activities while machine running (prepare tools, fixtures, programs before stopping machine) - **Internal Setup:** Minimize activities requiring machine stopped - **Standardize:** Use standardized tooling, fixtures (reduce adjustment time) - **Quick-change devices:** Fast clamps, quick-change tool holders - **Eliminate adjustments:** Preset tools, fixed work offsets

SMED Example: - **Before:** 60-minute setup (find tools 10 min, install tooling 20 min, adjust offsets 15 min, first-off inspection 15 min) - **After:** 25-minute setup (tools pre-staged, quick-change tool holders, preset offsets, first-off inspection unchanged)

Six Sigma Methodology

Six Sigma: Data-driven methodology for reducing variation and defects

Six Sigma Goal: Achieve 3.4 defects per million opportunities ($Cpk = 2.0$)

DMAIC Process: Five-phase problem-solving approach

1. **Define:** Define problem, customer requirements, project goals
2. **Measure:** Measure current performance (baseline data, Cpk)
3. **Analyze:** Analyze data to identify root causes (statistical analysis, hypothesis testing)
4. **Improve:** Implement solutions to eliminate root causes
5. **Control:** Establish controls to sustain improvements (SPC, procedures, training)

Six Sigma Belts: Certification levels - **Yellow Belt:** Basic tools, support projects - **Green Belt:** Lead projects part-time - **Black Belt:** Lead projects full-time, coach Green Belts - **Master Black Belt:** Train Black Belts, strategic deployment

Six Sigma Tools: Statistical analysis, hypothesis testing, DOE (Design of Experiments), control charts

Total Productive Maintenance (TPM)

TPM: Proactive maintenance approach maximizing equipment effectiveness

TPM Pillars: 1. **Autonomous Maintenance:** Operators perform routine maintenance (cleaning, lubrication, inspections) 2. **Planned Maintenance:** Scheduled preventive maintenance 3. **Quality Maintenance:** Prevent defects through equipment maintenance 4. **Focused Improvement:**

Eliminate losses (breakdowns, defects, reduced speed) 5. **Early Equipment Management:** Design maintainability into new equipment 6. **Training:** Develop operator and maintenance skills 7. **Safety, Health, Environment:** Clean, safe workplace 8. **TPM in Administration:** Apply TPM principles to office processes

OEE (Overall Equipment Effectiveness):

$$\text{OEE} = \text{Availability} \times \text{Performance} \times \text{Quality}$$

Availability = Actual Run Time / Planned Production Time

Performance = Actual Output / Theoretical Max Output

Quality = Good Parts / Total Parts Produced

OEE World-Class Target: 85%

Example: OEE = 90% availability × 95% performance × 98% quality = 84% (near world-class)

Employee Suggestion Systems

Suggestion Program: Structured process for employees to submit improvement ideas

Program Elements: - **Submission:** Simple form (paper or electronic) - **Review:** Management reviews suggestions promptly - **Implementation:** Approved ideas implemented - **Recognition:** Rewards (monetary, non-monetary, recognition) - **Feedback:** Thank submitters, explain decisions

Best Practices: - Respond quickly (within 2 weeks) - Implement easy wins immediately (builds momentum) - Recognize participation even if idea not implemented - Share successes (bulletin board, meetings)

Section 22.13 - Traceability and Record Retention

Material Traceability Systems

Traceability: Ability to trace material and process history of part

Why Traceability Critical: - **Recalls:** Identify affected parts if defect discovered - **Root Cause Investigation:** Trace problems to specific material lot or process - **Regulatory Compliance:** Required for aerospace, medical, automotive - **Customer Requirement:** Often specified in contract

Traceability Levels: 1. **Lot/Batch Traceability:** Group of parts from same material lot, production run 2. **Serial Number Traceability:** Individual part tracked (highest level)

Lot and Serial Number Tracking

Lot Number: Identifier for group of parts (Date code, work order number, production lot)

Example Lot Number: LOT-2024-0515 (year-month-day)

Serial Number: Unique identifier for individual part

Example Serial Number: SN-123456 (sequential numbering)

When Serial Numbers Required: - Aerospace critical parts (engines, flight controls) - Medical implants - High-value parts - Customer requirement

Marking Methods: - Laser etching (permanent, clean) - Dot peen (permanent, readable) - Stamping (permanent, may distort part) - Labels (temporary, for non-critical parts)

Work Order and Traveler Systems

Traveler (Router): Document that follows part through manufacturing, recording operations and inspections

Traveler Contents: - Part number, quantity, lot/serial numbers - Operations performed (with operator signature, date) - Inspection results (first-off, in-process, final) - Material information (heat lot) - Process certifications (heat treatment, plating) - Nonconformances (NCRs, dispositions)

Traveler as Traceability Record: Links part to all manufacturing history

Electronic Record Keeping (ERP/MES Integration)

ERP (Enterprise Resource Planning): Business software managing operations (orders, inventory, purchasing, accounting)

MES (Manufacturing Execution System): Software managing shop floor operations (work orders, scheduling, tracking, data collection)

Electronic Traceability Benefits: - Real-time visibility (where parts are, status) - Automatic data capture (barcode scanning, machine integration) - Rapid queries ("Which jobs used heat lot H-123?") - Reduced paperwork - Improved accuracy

Electronic Traveler: Digital version eliminating paper

Record Retention Requirements by Industry

Commercial/General Manufacturing: 7 years typical

Aerospace (AS9100): 10 years minimum (often longer for flight-critical parts)

Medical Devices (ISO 13485, FDA): Life of device + 2-7 years (varies by device class)

Automotive (IATF 16949): Per customer requirement (often 15+ years for production parts)

Nuclear: Lifetime of facility (decades)

Retention Requirements: - Quality records (inspection reports, test results) - Calibration records - Training records - Material certifications - Nonconformance and corrective action records - Audit reports

Archival and Retrieval Systems

Archival: - Organized storage (by job number, date, part number) - Protected from damage (fire-safe cabinets, climate control for paper) - Backed up (electronic records: redundant storage, cloud backup)

Retrieval: - Indexed for quick search (database, filing system) - Retrieved within reasonable time (hours to days) - Maintained legibility (paper records protected, electronic formats remain readable)

Electronic Archival: Preferred (searchable, no physical storage, easy backup)

Challenges: Long-term format compatibility (ensure files readable decades later; PDF/A standard for archival)

Chain of Custody for Critical Parts

Chain of Custody: Documented tracking of part location and handling throughout lifecycle

Required for: High-security applications (defense, nuclear), forensic purposes, regulatory compliance

Documentation: Record who handled part, when, where, condition at each transfer

Section 22.14 - Measurement Systems Analysis (MSA)

MSA covered in detail in Section 22.3.3.3 (IATF 16949 - Automotive standards). Key concepts summarized here for general application.

MSA Purpose and Applications

Purpose: Quantify measurement system variation to ensure data reliability

Applications: - Validate gages before use (Gage R&R studies) - Troubleshoot measurement problems (high variation, inconsistent results) - Continuous improvement (reduce measurement variation) - Customer requirement (PPAP, process validation)

Gage Repeatability and Reproducibility (Gage R&R)

Gage R&R Study: Most common MSA method

Components: - **Repeatability:** Equipment variation (same operator, same part, multiple measurements) - **Reproducibility:** Operator variation (different operators, same part)

Study Design: - 10 parts (spanning process range) - 3 operators - 3 trials each ($10 \times 3 \times 3 = 90$ measurements)

Analysis (software typically used: Minitab): - Calculate % Gage R&R = $(\text{Gage R&R} / \text{Total Variation}) \times 100$

Acceptance Criteria: - <10%: Excellent (acceptable) - **10-30%:** Marginal (may be acceptable depending on application) - >30%: Unacceptable (improve measurement system)

Improvement Actions: - **High Repeatability** (equipment): Better gage, calibration, fixture, environmental control - **High Reproducibility** (operators): Training, procedure clarification, automation

Bias and Linearity Studies

Bias: Difference between observed average and true value (accuracy)

Bias Study: Measure reference standard multiple times, compare to known value

Linearity: Bias consistent across measurement range?

Linearity Study: Measure reference standards at low, medium, high values; check if bias changes

Attribute Agreement Analysis

Attribute Gage: Go/no-go, pass/fail (not continuous measurement)

Attribute Agreement Analysis: Assess operator agreement

Metrics: - Agreement with standard (% correct) - Agreement among operators (Kappa statistic)

Improvement: Training, clearer acceptance criteria, objective gaging

MSA Acceptance Criteria

Decision: Gage R&R <10% ☐ Use gage confidently

10-30%: Use with caution, consider application criticality

>30%: Do not use; improve measurement system

Improving Measurement System Performance

Strategies: - Upgrade gages (higher resolution, better accuracy) - Improve fixturing (consistent part location) - Environmental control (temperature, vibration) - Standardize technique (procedures, training) - Automate (CMM, vision systems)

Section 22.15 - Certification and Registration

Preparing for Third-Party Certification

Certification: Independent verification that QMS conforms to standard (ISO 9001, AS9100, ISO 13485)

Benefits: - Customer confidence - Market access (many customers require certification) - Competitive advantage - Improved operations

Preparation Steps:

1. **Gap Analysis:** Compare current QMS to standard requirements; identify gaps
2. **Develop QMS:** Create quality manual, procedures, forms; implement processes
3. **Document Control:** Establish document management system
4. **Training:** Train personnel on QMS, procedures, their roles
5. **Internal Audits:** Audit all processes, fix nonconformances
6. **Management Review:** Conduct review, verify QMS readiness

7. **Pre-Assessment** (optional): Hire consultant for mock audit

Timeline: 6-12 months typical from start to certification

Selecting a Registrar (Certification Body)

Registrar (Certification Body): Organization that conducts audits and issues certificates

Accreditation: Registrar must be accredited (recognized by international body) - **US:** ANAB (ANSI-ASQ National Accreditation Board) - **International:** IAF (International Accreditation Forum) members

Selection Criteria: - **Accreditation:** Verify accredited for standard and scope (e.g., ISO 9001 + manufacturing) - **Industry Experience:** Familiar with your industry (aerospace, medical, etc.) - **Reputation:** References, online reviews - **Cost:** Audit fees (initial and surveillance), travel costs - **Service:** Responsiveness, auditor quality, support - **Location:** Auditors familiar with region/language

Registrar Examples: BSI, SGS, TUV, DNV, Intertek, NSF-ISR, SAI Global

Stage 1 and Stage 2 Audits

Certification Audit Process: Two-stage approach

Stage 1 Audit (Documentation Review): - **Purpose:** Review QMS documentation (quality manual, procedures) - **Location:** Can be remote (document review) or on-site - **Duration:** 1 day typical (small organization) - **Outcome:** Identify documentation gaps; must fix before Stage 2

Stage 2 Audit (Implementation Audit): - **Purpose:** Verify QMS implemented and effective (on-site audit) - **Duration:** 2-5 days depending on organization size, scope, complexity - **Process:** Similar to internal audit (interviews, observations, record review) - **Outcome:** Certification recommended (if conforming) or nonconformances to address

Addressing Non-Conformances

If Nonconformances Found: - **Major NC:** Prevent certification; must correct and verify before certificate issued - **Minor NC:** Certificate issued conditionally; must correct within 90 days

Corrective Action: - Investigate root cause - Implement corrective action - Provide evidence to registrar - Registrar verifies (document review or follow-up visit)

Timeline: Correct nonconformances within 90 days; if not, re-audit required (additional cost)

Maintaining Certification (Surveillance Audits)

Certification Cycle: 3 years

Surveillance Audits: Annual audits (Years 1 and 2 of cycle) to verify continued compliance

Surveillance Audit: - **Duration:** Shorter than Stage 2 (1-2 days) - **Scope:** Sample of processes (not entire QMS each visit) - **Outcome:** Certificate maintained (if conforming) or nonconformances to correct

Recertification Audit (Year 3): Full audit similar to Stage 2; new 3-year certificate issued if passed

Maintaining Certification: - Keep QMS updated (procedures, training, records) - Conduct internal audits - Address nonconformances promptly - Management review regularly - Notify registrar of major changes (ownership, scope, locations)

Recertification Process

Recertification Audit (every 3 years): Comprehensive audit renewing certificate

Process: Similar to initial Stage 2 audit (full QMS review)

Preparation: Internal audits, management review, verify all corrective actions closed

Multiple Site Certification

Multi-Site Certification: Single certificate covering multiple locations

Requirements: - Centralized management system - Similar processes at sites - Registrar audits sample of sites (not all every audit)

Benefits: Cost savings (fewer audit days), single certificate

Section 22.16 - Digital Quality Management

Quality Management Software (QMS Software)

QMS Software: Specialized software for managing quality systems

Features: - Document control (procedures, work instructions, version control) - Training management (schedule, records, competence tracking) - Nonconformance and corrective action (NCR/CAR workflow) - Audit management (schedule, checklists, reports) - Supplier management (scorecards, audits, SCAR tracking) - Risk management (FMEA, risk registers) - Management review (agenda, data collection, action tracking)

Leading QMS Software: ETQ Reliance, MasterControl, Intellect, Arena, Greenlight Guru (medical), AssurX

Benefits: - Centralized repository (all quality data in one system) - Workflow automation (email notifications, approvals, escalations) - Reporting and dashboards (real-time visibility) - Compliance (audit trails, electronic signatures per 21 CFR Part 11) - Reduced paperwork

Statistical Process Control (SPC) Software

SPC Software: Real-time monitoring and control charting

Features: - Data collection (manual entry, automatic from gages/machines) - Control charts (X-bar/R, Individuals, p-charts, etc.) - Capability analysis (Cp, Cpk calculations) - Alerts (out-of-control conditions, violations) - Reporting and trending

Leading SPC Software: InfinityQS, QC-CALC, Minitab (also statistical analysis), DataPage+, FactoryWiz

Integration: Connect to gages (calipers, CMM) or machines for automatic data capture

Document Management Systems

Document Management: Systems for storing, controlling, distributing documents

Options: - **SharePoint:** Microsoft platform (version control, permissions, workflows) - **Google Drive / Workspace:** Cloud storage (versioning, sharing, collaboration) - **Dedicated DMS:** Laserfiche, M-Files, DocuWare (enterprise-grade) - **QMS Software:** Built-in document control module

Best Practices: - Version control enabled - Access controls (read-only for users, edit for document owners) - Folder structure organized (by document type, department) - Naming conventions standardized - Backups automated

CAPA and NCR Tracking Systems

CAPA Software: Workflow for corrective/preventive action

Features: - NCR/CAR creation (forms, approvals) - Root cause analysis tools (5 Whys, Fishbone templates) - Action assignment and tracking - Effectiveness verification - Reporting (open CARs, aging, trends)

Often Integrated: Part of QMS software suite

Calibration Management Software

Calibration Software: Manages calibration schedules and records

Features: - Equipment database (ID, description, location, interval, due date) - Automated alerts (due soon, overdue) - Certificate storage (scanned certs attached to equipment record) - Calibration history (track trends, out-of-tolerance incidents) - Label printing (calibration stickers)

Examples: GageSuite, CompuCal, QMS software calibration modules

Quality Data Analytics and Dashboards

Quality Dashboards: Real-time visual displays of quality metrics

Dashboard Elements: - KPIs (scrap rate, OTD, Cpk, customer complaints) - Charts and graphs (trends over time, Pareto charts) - Status indicators (green/yellow/red based on targets) - Drill-down capability (click metric to see details)

Display Methods: - Computer monitors (desktop, wall-mounted TVs) - Mobile devices (tablets, smartphones) - Web portals (accessible anywhere)

Benefits: Visibility drives action; teams see performance in real-time

Industry 4.0 and Smart Quality Systems

Industry 4.0: Fourth industrial revolution (digitalization, automation, data exchange)

Smart Quality Technologies: - **IoT (Internet of Things):** Sensors on machines collect data (vibration, temperature, cycle counts) - **Big Data Analytics:** Analyze massive datasets to identify

patterns, predict failures - **AI/Machine Learning**: Automatic defect detection (vision systems), predictive maintenance - **Digital Twins**: Virtual models of processes/products for simulation and optimization - **Blockchain**: Immutable traceability records

Example Applications: - Automated in-process inspection (cameras inspect parts, AI detects defects) - Predictive maintenance (sensors predict bearing failure before breakdown) - Real-time SPC (machine data feeds control charts automatically)

Section 22.17 - Practical Implementation and Case Studies

Building a QMS from Scratch

Step-by-Step Implementation:

- 1. Management Commitment** (Month 1): - Secure top management buy-in - Communicate why QMS important (benefits, customer requirements) - Allocate resources (time, budget, personnel)
- 2. Appoint Quality Manager** (Month 1): - Assign responsible person (may be part-time in small organization) - Define role and authority
- 3. Gap Analysis** (Month 1-2): - Compare current practices to ISO 9001 requirements - Identify gaps (missing procedures, no calibration program, etc.) - Prioritize gaps (critical vs. nice-to-have)
- 4. Develop QMS Documentation** (Month 2-4): - Quality Manual (overview, scope, policy) - Core Procedures (document control, calibration, inspection, NCR, corrective action, internal audit, management review) - Work Instructions (as needed for critical tasks) - Forms (travelers, inspection reports, NCR forms, etc.)
- 5. Implement Processes** (Month 4-6): - Roll out procedures (communicate, train) - Start using forms and records - Establish document control system (SharePoint, folders) - Begin calibration program (identify gages, send for calibration)
- 6. Train Personnel** (Month 4-6): - Quality policy and objectives - QMS overview (how it works, their role) - Procedures applicable to their work - Document training (training records)
- 7. Internal Audits** (Month 6-8): - Train internal auditors (2-3 people) - Conduct audits of all processes - Identify nonconformances - Implement corrective actions
- 8. Management Review** (Month 8): - Conduct first management review - Review internal audit results - Review performance metrics - Identify improvements needed
- 9. Pre-Assessment** (Month 9, optional): - Hire consultant for mock audit - Identify remaining gaps - Fix before certification audit
- 10. Certification Audit** (Month 10-12): - Contract with registrar - Stage 1 audit (document review) - Fix any findings - Stage 2 audit (implementation audit) - Address nonconformances - Receive certificate

QMS Implementation Timeline and Milestones

Typical Timeline: 6-12 months (small to medium organization)

Milestones: - Month 1: Management commitment, gap analysis started - Month 3: Quality manual and core procedures drafted - Month 6: QMS implemented, internal audits started - Month 9: All audits complete, corrective actions closed - Month 12: Certification achieved

Factors Affecting Timeline: - **Organization size:** Larger = longer - **Starting point:** If some systems exist (calibration, procedures), faster - **Resources:** Dedicated quality manager vs. part-time - **Complexity:** Multiple sites, complex processes = longer

Resource Requirements and Budgeting

Personnel Time: - Quality Manager: 0.5-1.0 FTE (full-time equivalent) during implementation - Management and employees: Time for training, audits, meetings - Consultant (optional): 10-30 days

Software/Systems: - Document management: \$0-\$10k (SharePoint, Google Drive free/low-cost; dedicated DMS higher) - QMS software: \$5k-\$50k+ annually (optional, not required)

Calibration: - Initial calibration of all gages: \$2k-\$10k (depending on quantity) - Ongoing annual calibration: \$1k-\$5k/year

Certification Audit Costs: - Registrar fees: \$5k-\$15k (initial certification, includes Stage 1, Stage 2, Year 1 surveillance) - Surveillance audits (Years 2-3): \$2k-\$5k per audit - Recertification (Year 3): \$3k-\$8k

Total First-Year Cost Estimate (small shop, 20-50 employees): - Consultant (optional): \$10k-\$30k - Software: \$5k - Calibration: \$5k - Certification: \$10k - **Total: \$30k-\$50k** (plus internal labor)

ROI: Scrap reduction, improved efficiency, new customers offset costs (typically positive ROI within 1-2 years)

Common Implementation Challenges

Challenge 1: Resistance to Change - Symptom: "We've always done it this way" - **Solution:** Communicate benefits, involve employees in development, quick wins

Challenge 2: Documentation Burden - Symptom: Procedures too detailed, overwhelming - **Solution:** Keep procedures simple and practical; focus on what's needed

Challenge 3: Lack of Resources - Symptom: No time, no budget - **Solution:** Phased approach (start with core procedures, expand later); demonstrate ROI

Challenge 4: Poor Management Commitment - Symptom: Management doesn't participate, doesn't allocate resources - **Solution:** Educate on benefits; show competitors have certification; customer pressure

Challenge 5: QMS Becomes "Shelf-ware" - Symptom: Procedures written but not followed; system exists on paper only - **Solution:** Integrate QMS into daily operations; use procedures in training; audit compliance

Case Study: Small Shop ISO 9001 Certification

Company: ABC Precision Machining, 25 employees, CNC job shop

Challenge: Customer requiring ISO 9001 certification to remain on approved supplier list

Approach: 1. **Hired consultant** (20 days over 6 months): Gap analysis, documentation development, training, mock audit 2. **Appointed Quality Manager** (Production Manager part-time role, 20% time) 3. **Developed documentation:** Quality manual (25 pages), 10 core procedures, 5 work instructions, 10 forms 4. **Implemented document control:** SharePoint Online (\$5/user/month) 5. **Calibration program:** Sent 30 gages for calibration (\$3k) 6. **Training:** 2-hour overview for all employees, plus procedure-specific training 7. **Internal audits:** Trained 3 internal auditors, audited all processes over 2 months 8. **Certification audit:** Contracted registrar, Stage 1 (1 day), Stage 2 (2 days)

Timeline: 9 months (kick-off to certification)

Costs: - Consultant: \$20k - Calibration: \$3k - Software (SharePoint): \$1.5k/year - Certification audit: \$8k - **Total: \$32.5k**

Results: - ISO 9001 certified - Retained key customer (saved \$500k annual revenue) - Scrap reduced 30% (better process control) - Organized, more efficient operations - Positive ROI in Year 1

Case Study: AS9100 Implementation in Contract Manufacturing

Company: XYZ Aerospace Manufacturing, 150 employees, contract manufacturer for aerospace

Challenge: Expand customer base; many aerospace customers require AS9100

Approach: 1. **Already ISO 9001 certified:** Leverage existing QMS 2. **Gap analysis:** AS9100 additional requirements (configuration management, FOD, OTD, counterfeit prevention, work transfer, human factors) 3. **Enhanced procedures:** Updated 8 procedures, added 4 new procedures 4. **Implemented additional controls:** FOD program, OTD tracking, counterfeit prevention training 5. **First Article Inspection:** Implemented AS9102 process (forms, training) 6. **Training:** All employees on AS9100 enhancements 7. **Upgrade audit:** Registrar conducted upgrade audit (2 days)

Timeline: 6 months (gap analysis to AS9100 certification)

Costs: \$15k (consulting, audit upgrade fees)

Results: - AS9100 Rev D certified - Qualified for aerospace contracts (won 3 new customers, \$2M additional revenue) - Improved processes (better traceability, counterfeit controls)

Case Study: Medical Device QMS (ISO 13485)

Company: MedTech Components, 75 employees, manufactures orthopedic implant components

Challenge: Supply to medical device manufacturers; ISO 13485 required

Approach: 1. **ISO 9001 certified:** Starting point, but ISO 13485 more stringent 2. **Gap analysis:** Design controls, risk management (ISO 14971), traceability (UDI), clean room, validation requirements 3. **Design controls:** Implemented design review, verification, validation processes (even though components designed by customers, some design transfer required) 4. **Risk management:** Conducted process FMEA, risk assessments 5. **Enhanced traceability:** Implemented serial number tracking, lot traceability to material heat lots 6. **Clean room:** Established ISO 7

clean room for final assembly and packaging 7. **Validation:** Validated cleaning process, sterilization (contracted), packaging 8. **Documentation:** Extensive records (Device History Records, DHR) 9. **Certification audit:** Registrar specializing in medical devices

Timeline: 12 months (extensive due to clean room construction, validation)

Costs: \$150k (clean room construction \$100k, consulting \$25k, validation studies \$15k, certification \$10k)

Results: - ISO 13485 certified - Qualified for medical device market (won contracts with 2 major orthopedic OEMs, \$5M revenue) - Premium pricing (medical market pays higher margins) - ROI in 18 months

Lessons Learned and Best Practices

Lessons from Successful Implementations:

1. **Start Simple:** Don't over-document; build procedures that people will actually use
2. **Involve Employees:** People support what they help create; involve shop floor in writing work instructions
3. **Leverage Existing Systems:** If you have informal processes that work, formalize them (don't reinvent)
4. **Focus on Value:** QMS should improve operations, not just create paperwork
5. **Leadership Visible:** Management participation demonstrates importance
6. **Celebrate Wins:** Recognize milestones (first internal audit complete, certification achieved)
7. **Continuous Improvement:** QMS never "done"; keep improving

Best Practices: - Benchmark: Visit other certified shops, learn from their experience - Phased Approach: Implement in stages (core procedures first, advanced later) - Use Technology: Document management software, electronic forms reduce burden - Training Critical: Invest time in training; people can't follow procedures they don't understand - External Help: Consultant accelerates implementation, provides expertise - Realistic Timeline: Don't rush; quality implementation takes time

Module 22 Summary and Conclusion

Module 22: Quality Management Systems has covered the comprehensive framework for implementing and maintaining effective quality management in CNC manufacturing. From foundational ISO 9001 principles through industry-specific standards (aerospace AS9100, medical ISO 13485, automotive IATF 16949), this module provides practical guidance for building quality systems that meet customer requirements, ensure regulatory compliance, and drive operational excellence.

Key Module Themes:

1. **QMS is Strategic:** Quality management is not just inspection or compliance; it's a strategic approach to business excellence
2. **Prevention Over Detection:** Modern QMS emphasizes preventing defects through process design and control, not just catching them through inspection
3. **Data-Driven Decisions:** Metrics, capability studies, SPC, and analysis guide improvements

4. Continuous Improvement: QMS provides structure for learning from problems and continuously enhancing performance

5. Customer Focus: Understanding and meeting customer requirements drives all quality activities

6. Integration: Quality integrates with all business functions (sales, engineering, production, supply chain)

Path Forward:

For CNC professionals pursuing quality management careers or implementing QMS: - Start with ISO 9001 foundation (universal quality standard) - Add industry-specific requirements as needed (AS9100, ISO 13485, IATF 16949) - Leverage technology (QMS software, SPC, digital tools) - Never stop improving (Kaizen mindset) - Share knowledge (mentor others, contribute to quality community)

Quality management is both science and art—applying rigorous methods while adapting to unique organizational contexts. The tools, techniques, and frameworks in this module provide the foundation; successful implementation requires commitment, persistence, and collaboration.

Quality is everyone's responsibility, and a strong QMS makes it everyone's success.

Module 22 Key Takeaways (Comprehensive)

1. QMS provides systematic approach to consistently delivering quality products and services
2. ISO 9001 is world's most recognized quality standard; foundation for all industry-specific standards
3. Process approach emphasizes managing activities as interrelated processes
4. Risk-based thinking identifies and mitigates risks proactively
5. Industry-specific standards (AS9100, ISO 13485, IATF 16949) add requirements for regulated industries
6. Quality documentation (manual, procedures, work instructions, records) provides structure and evidence
7. Process control and validation ensure manufacturing processes capable and consistent
8. Supplier quality management critical; your quality depends on supplier quality
9. Inspection and testing verify product conformance; sampling plans balance cost and risk
10. Nonconforming product control prevents unintended use; disposition options include scrap, rework, repair, use-as-is
11. CAPA (Corrective and Preventive Action) drives improvement through root cause analysis and corrective action
12. Internal audits verify compliance and effectiveness; auditor independence essential
13. Management review provides top management's systematic evaluation of QMS
14. Customer satisfaction monitoring and improvement central to QMS success
15. Continuous improvement (Lean, Six Sigma, Kaizen) integrated with QMS for operational excellence
16. Traceability enables recall and investigation; critical for regulated industries
17. Measurement Systems Analysis (MSA) ensures data reliability; Gage R&R quantifies measurement variation

18. Certification (ISO 9001, AS9100, ISO 13485) demonstrates QMS conformance; requires preparation and ongoing maintenance
 19. Digital quality management (QMS software, SPC software, dashboards) enhances efficiency and visibility
 20. Successful QMS implementation requires management commitment, employee involvement, practical documentation, and continuous improvement mindset
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Final Review Questions (Module 22)

1. What is a Quality Management System (QMS), and how does it differ from quality control?
 2. What are the 10 clauses of ISO 9001:2015, and which contain auditable requirements?
 3. Explain the PDCA (Plan-Do-Check-Act) cycle and its application in quality management.
 4. What are the key differences between ISO 9001 and AS9100? Why are additional requirements needed for aerospace?
 5. What is First Article Inspection (FAI), and when is it required?
 6. Describe the hierarchy of quality documentation (Quality Manual □ Procedures □ Work Instructions □ Records).
 7. What is process capability (Cpk), and what does it measure? What's the difference between Cpk and Ppk?
 8. Explain the supplier quality management cycle: selection □ evaluation □ monitoring □ corrective action.
 9. What are the disposition options for nonconforming product, and when is each appropriate?
 10. What is the difference between rework and repair?
 11. Describe the 5 Whys technique for root cause analysis. Provide an example.
 12. What are the 8 disciplines (8D) in the 8D problem-solving process?
 13. What is the purpose of internal audits, and how often should they be conducted?
 14. What are the required inputs and outputs of management review per ISO 9001?
 15. What is the purpose of customer satisfaction surveys, and what should they measure?
 16. What are the 8 wastes in Lean manufacturing (DOWNTIME)?
 17. What is 5S, and how does it improve workplace organization?
 18. What is traceability, and why is it critical in aerospace and medical device manufacturing?
 19. What is Gage R&R, and what are the acceptance criteria for measurement systems?
 20. What are the typical steps and timeline for achieving ISO 9001 certification?
-

Module 22 Practical Capstone Project

Capstone Project: Implement Mini-QMS for Your Shop (or Hypothetical Shop)

Objective: Apply module concepts to develop core QMS elements

Project Scope: Small CNC job shop (20 employees)

Deliverables:

1. **Quality Policy and Objectives** (1 page):

- Write quality policy statement

- Define 5 measurable quality objectives with targets

2. Process Map (1-2 pages):

- Map core process flow (order entry → shipment)
- Identify key inputs, outputs, controls, resources
- Define process KPIs

3. Core Procedures (5 procedures, 2-3 pages each):

- Document Control
- Calibration Control
- Inspection and Testing
- Nonconforming Product Control
- Corrective Action

4. Work Instruction (1 work instruction, 1-2 pages):

- Visual work instruction for critical task (CMM inspection, first-off inspection, etc.)

5. Forms (3-5 forms):

- Traveler/Router template
- Inspection Report template
- Nonconformance Report (NCR) template
- Corrective Action Report (CAR) template

6. Annual Audit Schedule:

- List processes to audit
- Assign months
- Assign auditors

7. Audit Checklist (for one process):

- ISO 9001 requirements
- Questions to ask
- Records to review

8. Management Review Agenda:

- List all required inputs per ISO 9001
- Estimated time for each topic

9. Implementation Plan (timeline and milestones for 12-month QMS implementation)

10. Gap Analysis (compare current state to ISO 9001 requirements; identify gaps and actions needed)

Evaluation Criteria: - Completeness (all deliverables provided) - Accuracy (conforms to ISO 9001 requirements) - Practicality (usable in real-world shop environment) - Clarity (well-written, understandable)

Additional Module Resources

Essential Standards (available for purchase): - ISO 9001:2015 - Quality Management Systems - ISO 9000:2015 - Fundamentals and Vocabulary (free) - AS9100D - Aerospace Quality Management Systems - ISO 13485:2016 - Medical Devices Quality Management - IATF 16949:2016 - Automotive Quality Management - AS9102B - First Article Inspection Requirement

Recommended Books: - “ISO 9001:2015 in Plain English” by Craig Cochran - “The ASQ ISO 9001:2015 Handbook” edited by J.P. Russell - “Quality Management for Organizational Excellence” by David Goetsch and Stanley Davis - “The Certified Quality Engineer Handbook” by ASQ Quality Press - AIAG Manuals: APQP, PPAP, FMEA, MSA, SPC (automotive focus, broadly applicable)

Online Training and Resources: - ASQ (American Society for Quality): www.asq.org (training, certification, resources) - ISO website: www.iso.org (standards information) - Quality Digest: www.qualitydigest.com (articles, news, webinars) - iSixSigma: www.isixsigma.com (quality tools, forums) - Lean Enterprise Institute: www.lean.org (Lean resources)

Professional Certifications: - ASQ Certified Quality Auditor (CQA) - ASQ Certified Quality Engineer (CQE) - ASQ Certified Manager of Quality/Organizational Excellence (CMQ/OE) - ASQ Certified Six Sigma Green Belt (CSSGB) - ASQ Certified Six Sigma Black Belt (CSSBB) - Lead Auditor certifications (ISO 9001, AS9100, ISO 13485, IATF 16949)

Industry Associations: - ASQ (American Society for Quality) - SAE International (aerospace standards) - AIAG (Automotive Industry Action Group) - SME (Society of Manufacturing Engineers) - AMT (Association for Manufacturing Technology)

Congratulations!

You have completed **Module 22: Quality Management Systems**. This comprehensive module has equipped you with knowledge and tools to implement, maintain, and continuously improve quality management systems in CNC manufacturing environments. Whether pursuing ISO 9001 certification, working in regulated industries (aerospace, medical, automotive), or simply striving for operational excellence, the principles and practices covered here provide a solid foundation.

Next Steps: - Apply concepts in your work environment - Pursue relevant certifications (Quality Auditor, Quality Engineer) - Stay current with standards updates and industry trends - Continue learning (advanced quality topics, Lean Six Sigma) - Share knowledge with colleagues and contribute to quality community

Remember: Quality is a journey, not a destination. Keep improving, keep learning, and keep raising the bar for excellence.

Quality First. Always.

Module 22 - Quality Management Systems (QMS)

22.2.1 History and Development of ISO 9001

ISO 9001 is the world's most widely recognized quality management standard, with over 1 million certificates issued in more than 170 countries.

Origins and Evolution

Military Roots (1950s-1960s) - Military specifications drove early quality standards - MIL-Q-9858A (1959): Quality Program Requirements - MIL-I-45208 (1963): Inspection System Requirements - Focus: Consistency in defense manufacturing

British Standards (1970s) - BS 5750 (1979): First commercial quality management standard - Developed by British Standards Institution (BSI) - Adapted from military standards for civilian use - Emphasized documentation and procedures

ISO 9000 Series Launch (1987) - International Organization for Standardization publishes ISO 9000 series - Based heavily on BS 5750 - ISO 9001, 9002, 9003 covered different scopes - Global adoption begins

Major Revisions

ISO 9001:1994 - Clarified requirements - Emphasized preventive action - Still heavily procedure-focused - 20 elements of quality system

ISO 9001:2000 (Major Overhaul) - Introduced **Process Approach** - Emphasized **Customer Focus** - Reduced documentation requirements - Consolidated 9001, 9002, 9003 into single standard - Eight Quality Management Principles introduced - PDCA cycle embedded in structure

ISO 9001:2008 (Minor Revision) - Clarifications and improved consistency - No new requirements - Easier integration with ISO 14001

ISO 9001:2015 (Current Version) - **Risk-Based Thinking** integrated throughout - **High-Level Structure** (Annex SL) for compatibility with other ISO standards - Less prescriptive on documentation - Greater focus on context and leadership - Knowledge management requirements added - More emphasis on change management

Why ISO 9001 Matters

Global Recognition - Accepted in international trade - Often required by customers - Demonstrates organizational competence

Process Improvement - Structured approach to managing operations - Data-driven decision making - Continuous improvement built-in

Risk Management - Identifies and mitigates risks - Proactive rather than reactive - Reduces likelihood of failures

Competitive Advantage - Differentiates in marketplace - Opens doors to new customers - Required for regulated industries

22.2.2 ISO 9001:2015 Structure and Requirements

ISO 9001:2015 follows a 10-clause structure aligned with Annex SL (common framework for ISO management system standards).

Overall Structure

Clauses 1–3: Scope, Normative References, Terms and Definitions
(No requirements to audit against)

Clause 4: Context of the Organization

Clause 5: Leadership

Clause 6: Planning

Clause 7: Support

Clause 8: Operation

Clause 9: Performance Evaluation

Clause 10: Improvement

Clauses 4–10 contain the auditable requirements.

22.2.2.1 Context of the Organization

Clause 4 focuses on understanding the organization and its environment before designing the QMS.

4.1 Understanding the Organization and Its Context Requirement: Determine external and internal issues relevant to the QMS.

External Issues (Opportunities and Threats): - Market conditions and competition - Customer expectations and trends - Technological changes (Industry 4.0, automation) - Regulatory environment (new standards, certifications) - Economic factors (material costs, labor availability) - Supply chain risks

Internal Issues (Strengths and Weaknesses): - Company culture and values - Equipment capabilities and limitations - Employee skills and turnover - Financial resources - Current quality performance - Knowledge and intellectual property

Practical Application: - Conduct SWOT analysis (Strengths, Weaknesses, Opportunities, Threats) - Regular review (annually or when significant changes occur) - Document findings and use to inform QMS planning

4.2 Understanding the Needs and Expectations of Interested Parties Requirement: Identify interested parties and their relevant requirements.

Key Interested Parties:

Customers: - Product quality and specifications - On-time delivery - Certification requirements (AS9100, ISO 13485) - Responsiveness to issues

Regulators: - FDA, FAA, ITAR compliance - Environmental regulations - Workplace safety (OSHA)

Employees: - Safe working environment - Training and development - Fair compensation - Job security

Suppliers/Subcontractors: - Clear purchase orders - Fair payment terms - Partnership opportunities

Owners/Shareholders: - Profitability and growth - Risk management - Long-term sustainability

Community: - Environmental responsibility - Local employment - Corporate citizenship

Practical Application: - Document interested parties in a matrix - Identify which requirements affect QMS scope - Monitor changes in requirements

4.3 Determining the Scope of the QMS Requirement: Define boundaries and applicability of the QMS.

Considerations: - Products and services covered - Physical locations (facilities, sites) - Processes included/excluded - External providers and outsourced processes

Example Scope Statements:

Small Job Shop: “This QMS applies to the design, manufacture, and sale of precision machined components for aerospace, medical, and commercial customers at our facility located in [City, State].”

Contract Manufacturer: “This QMS applies to the manufacture of precision machined components per customer specifications at our facility located in [City, State]. Design services are excluded as we manufacture to customer-supplied drawings.”

Exclusions: - Clauses 7.3 (Design and Development) can be excluded if only manufacturing to customer drawings - All exclusions must be justified - Exclusions cannot affect ability to provide conforming products

4.4 Quality Management System and Its Processes Requirement: Establish, implement, maintain, and continually improve the QMS, including processes and their interactions.

Process Approach Elements:

1. Identify Processes:

- Core processes (quoting, manufacturing, inspection)
- Support processes (calibration, maintenance, training)
- Management processes (audits, management review)

2. Define Process Interactions:

Customer → Quoting → Order Entry → Planning →
Programming → Setup → Machining → Inspection →
Packaging → Shipping → Customer

3. Establish Process Criteria and Methods:

- Acceptance criteria (dimensional tolerances, surface finish)

- Control methods (control plans, work instructions)
- Resource requirements (equipment, tools, personnel)

4. Ensure Resource Availability:

- Machines, tools, gages
- Trained operators and inspectors
- Software (CAM, CMM)

5. Monitor, Measure, Analyze:

- Process KPIs (scrap rate, on-time delivery, Cpk)
- Data collection and analysis
- Trend identification

6. Implement Improvements:

- Address nonconformances
- Optimize processes
- Apply lessons learned

Process Documentation: - Process maps or flowcharts - Turtle diagrams (inputs, outputs, controls, resources) - SIPOC diagrams (Suppliers, Inputs, Process, Outputs, Customers)

22.2.2 Leadership and Planning

Clause 5 addresses leadership's role in the QMS.

5.1 Leadership and Commitment Requirement: Top management must demonstrate leadership and commitment to the QMS.

Top Management Responsibilities: - Take accountability for QMS effectiveness - Ensure quality policy and objectives are established - Ensure QMS integrated into business processes - Promote process approach and risk-based thinking - Ensure resources available - Communicate importance of effective QMS - Ensure QMS achieves intended results - Engage, direct, and support employees - Promote improvement - Support other management roles

Customer Focus (5.1.2): - Customer requirements determined and met - Statutory and regulatory requirements addressed - Risks and opportunities affecting conformity addressed - Focus on enhancing customer satisfaction

Evidence of Leadership Commitment: - Management participates in audits - Management review meetings held regularly - Resources allocated to quality initiatives - Quality discussed in business meetings - "Walk the talk" - leaders follow procedures

5.2 Quality Policy Requirement: Establish a quality policy appropriate to the organization.

Quality Policy Must: - Be appropriate to purpose and context - Provide framework for quality objectives - Include commitment to satisfy requirements - Include commitment to continual improvement

Example Quality Policy:

ABC Precision Machining Quality Policy

ABC Precision Machining is committed to delivering precision machined components that meet or exceed customer expectations. We achieve this through:

- Understanding and fulfilling customer requirements
- Maintaining processes that consistently produce quality products
- Investing in our people through training and development
- Utilizing advanced technology and calibrated equipment
- Continually improving our quality management system
- Complying with all applicable regulatory requirements

Every employee is responsible for quality, and management is committed to providing the resources and leadership necessary for our quality objectives to be achieved.

[Signed by CEO/President]

Communication: - Available and maintained as documented information - Communicated and understood within organization - Available to interested parties as appropriate (posted in shop, employee handbook, website)

5.3 Organizational Roles, Responsibilities, and Authorities **Requirement:** Assign and communicate responsibilities and authorities for QMS roles.

Key QMS Roles:

Quality Manager: - Oversee QMS implementation and maintenance - Plan and coordinate audits - Report QMS performance to management - Ensure customer focus throughout organization

Management Representative (not required by ISO 9001:2015, but often designated): - Interface with certification body - Coordinate management review - Promote awareness of customer requirements

Process Owners: - Responsible for specific processes (programming, machining, inspection) - Monitor process performance - Drive process improvement

Document Control: - Maintain document repository - Ensure current revisions available - Control obsolete documents

Calibration: - Maintain calibration schedules - Coordinate calibration services - Maintain calibration records

Practical Application: - Create organizational chart with QMS roles - Document roles in job descriptions or responsibility matrix - Ensure everyone knows their quality responsibilities

6.1 Actions to Address Risks and Opportunities **Requirement:** Determine risks and opportunities that need to be addressed to ensure QMS achieves intended results.

Risk-Based Thinking: - Identifies potential problems before they occur - Allocates resources to areas of greatest risk - Increases likelihood of achieving objectives - Reduces negative effects

Identifying Risks and Opportunities:

Manufacturing Risks: - Machine breakdowns □ Opportunity: Preventive maintenance program
 - Programming errors □ Opportunity: Program verification procedures - Material defects □ Opportunity: Incoming inspection and approved suppliers - Operator errors □ Opportunity: Training and work instructions - Gage out-of-calibration □ Opportunity: Calibration tracking system

Business Risks: - Loss of key customers □ Opportunity: Diversify customer base - Labor shortages □ Opportunity: Training programs and retention initiatives - Supply chain disruptions □ Opportunity: Multiple suppliers, inventory buffers

Process for Risk Management: 1. **Identify:** Brainstorm potential risks and opportunities 2. **Assess:** Evaluate likelihood and impact (risk matrix) 3. **Plan:** Determine actions to address significant risks 4. **Implement:** Execute risk mitigation plans 5. **Monitor:** Review effectiveness of actions

Risk Assessment Matrix Example:

		LIKELIHOOD		
		Low	Medium	High
		IMPACT		
High	M	H	H	
Medium	L	M	H	
Low	L	L	M	

L = Low risk (monitor)

M = Medium risk (action plan recommended)

H = High risk (action plan required)

Documentation: - Risk register or risk assessment - Actions to address risks - Review and update periodically

6.2 Quality Objectives and Planning Requirement: Establish quality objectives at relevant functions and levels.

Quality Objectives Must Be: - **Consistent** with quality policy - **Measurable** - **Monitored** - **Communicated** - **Updated** as appropriate

Example Quality Objectives:

Objective	Metric	Target	Responsible	Review
Reduce scrap rate	Scrap cost / revenue	< 2%	Production Mgr	Monthly
Improve on-time delivery	Orders shipped on-time	>= 95%	Operations Mgr	Monthly
Enhance customer satisfaction	Customer survey score	>= 4.5/5	Quality Mgr	Quarterly
Improve process capability	Processes with Cpk >= 1.33	>= 85%	Engineering	Quarterly

Objective	Metric	Target	Responsible	Review
Reduce customer complaints	Complaints per 100 orders	<= 2	Quality Mgr	Monthly

Planning to Achieve Objectives: - **What** will be done (action plan) - **What resources** required (people, equipment, budget) - **Who** is responsible - **When** completed (timeline) - **How** results evaluated (metrics, monitoring)

6.3 Planning of Changes Requirement: When changes to QMS are needed, they must be planned and controlled.

Changes Requiring Planning: - New equipment or technology - New products or processes
 - Organizational restructuring - Facility relocation or expansion - New customer requirements -
 Changes to standards (ISO 9001 revision)

Change Planning Considerations: - Purpose and potential consequences of change - Integrity of QMS maintained - Resources available - Allocation or reallocation of responsibilities - Risks and opportunities

22.2.2.3 Support and Resources

Clause 7 covers support resources needed for the QMS.

7.1 Resources 7.1.1 General: Determine and provide resources for QMS.

7.1.2 People: Adequate competent personnel.

7.1.3 Infrastructure: - Buildings, workspace, utilities - Equipment (machines, tools) - Transportation - Information and communication technology

Example Infrastructure Requirements: - CNC machines maintained and capable - Temperature-controlled inspection room - Calibrated measuring equipment - ERP/MRP system for order tracking - CAM software for programming

7.1.4 Environment for Operation of Processes: - Physical factors (temperature, humidity, lighting, cleanliness) - Social factors (non-discriminatory, calm, non-confrontational) - Psychological factors (stress-reducing, burnout prevention)

CNC Shop Examples: - Climate control for dimensional stability - Proper lighting for inspection - Chip removal and coolant management - Ergonomic workstations - Safety measures (guards, PPE)

7.1.5 Monitoring and Measuring Resources:

Equipment used for verification must be: - **Suitable** for type of monitoring/measurement - **Maintained** to ensure continued fitness - **Calibrated or verified** at specified intervals against traceable standards - **Identified** to determine calibration status - **Safeguarded** from adjustments that would invalidate results - **Protected** from damage and deterioration

Calibration Program:

Gage → Calibration Due → Calibration → Sticker/Record →
Return to Service → Use Until Next Due Date

7.1.6 Organizational Knowledge:

Knowledge necessary for process operation and conforming products must be maintained and made available.

Sources of Knowledge: - Experience and lessons learned - Standards and technical publications
- Proven programs and process parameters - Inspection methods and techniques - Customer specifications and requirements

Capturing Knowledge: - Document procedures and work instructions - Maintain program library with setup sheets - Record lessons learned from nonconformances - Cross-training and mentoring - Knowledge transfer before retirements

7.2 Competence Requirement: Determine necessary competence, ensure personnel are competent, and take action if needed.

Competence Requirements: - Education, training, experience appropriate to role - For CNC operators: machine operation, blueprint reading, basic inspection - For inspectors: GD&T, CMM operation, statistical methods - For programmers: CAM software, tooling, machining theory

Ensuring Competence: 1. **Determine** competence needed for each role 2. **Assess** current competence (skills matrix) 3. **Provide training** or take other actions (hire, reassign) 4. **Evaluate effectiveness** of training (observation, testing, trial parts) 5. **Maintain records** of education, training, experience, qualifications

Training Records: - Employee name - Training topic - Date and duration - Trainer - Effectiveness evaluation - Signature

7.3 Awareness Requirement: Ensure personnel are aware of quality policy, relevant quality objectives, their contribution to QMS, and implications of not conforming.

Awareness Strategies: - Quality policy posted and discussed - Objectives reviewed in team meetings - Quality metrics displayed (scrap rate, on-time delivery) - Nonconformance examples shared (lessons learned) - Recognition for quality contributions

7.4 Communication Requirement: Determine internal and external communications relevant to QMS.

Internal Communication: - Shift turnover meetings - Production schedules and priority changes - Quality alerts (new customer requirements, design changes) - Nonconformance reports circulated - Management review results shared

External Communication: - Customer inquiries and complaints - Supplier communications (POs, quality issues) - Certification body (audit scheduling, changes) - Regulatory agencies as required

Communication Methods: - Email, production meetings, bulletin boards - ERP system notifications - Travelers and work orders - Written procedures and work instructions

7.5 Documented Information **7.5.1 General:** QMS must include documented information required by ISO 9001 and determined necessary by organization.

ISO 9001:2015 Required Documentation: - Scope of QMS - Quality policy and objectives - Process descriptions and interactions - Competence records - Monitoring and measuring equipment calibration - Operational planning and control documents - Product/service requirements - Design and development outputs (if applicable) - Externally provided process controls - Production and service provision records - Release and post-delivery records - Nonconforming outputs - Monitoring, measurement, analysis, evaluation results - Internal audit program and results - Management review results

Additional Documentation (organization determines need): - Quality manual (optional but recommended) - Procedures - Work instructions - Forms and templates

7.5.2 Creating and Updating: Documented information must have: - Identification and description (title, date, author, reference number) - Format (language, software version, graphics) and media (paper, electronic) - Review and approval for suitability and adequacy

7.5.3 Control of Documented Information:

Availability: Documents available where and when needed

Protection: Protected from loss, improper use, loss of integrity

Distribution: Current revisions at point of use

Retention and Disposition: Records retained per requirements, disposed when obsolete

Version Control: - Revision levels tracked (Rev A, B, C or version numbers) - Changes documented (revision history) - Obsolete versions removed or clearly marked

22.2.2.4 Operational Planning and Control

Clause 8 covers operational processes for product realization.

8.1 Operational Planning and Control Requirement: Plan, implement, and control processes needed to meet product/service requirements.

Operational Planning Includes: - Requirements for products/services - Criteria for processes and product acceptance - Resources needed - Process control - Records to demonstrate conformity

CNC Shop Operational Planning: 1. **Order Entry:** Review customer PO and drawing 2. **Planning:** Determine operations, machines, tools, fixtures 3. **Programming:** Create and verify NC programs 4. **Setup:** Install tooling, fixtures, work offsets 5. **Production:** Machine parts per program 6. **Inspection:** Verify dimensions per control plan 7. **Packaging and Shipping:** Protect and deliver to customer

Control Methods: - Control plans - Work instructions - Setup sheets - Inspection plans - Travelers or routers

8.2 Requirements for Products and Services **8.2.1 Customer Communication:** - Product and service information - Inquiries, contracts, orders, changes - Customer feedback, complaints - Customer property (customer-supplied material, tooling) - Contingency actions when relevant

8.2.2 Determining Requirements: - Customer-specified requirements (drawing, specifications) - Requirements necessary for intended use - Statutory and regulatory requirements (FDA, FAA, ITAR) - Organization's own requirements (additional inspection, tighter tolerances)

8.2.3 Review of Requirements: - Before committing to supply (quote review) - Confirm requirements defined and documented - Confirm contract different from previously defined requirements are resolved - Confirm organization has ability to meet requirements

Contract Review Checklist: - Drawing and specification received and current revision - Material specification clear and available - Tolerances achievable with our equipment - Required certifications understood (material certs, CoC, FAI) - Quantity and delivery date feasible - Special processes identified (heat treat, plating) - Pricing approved

8.2.4 Changes to Requirements: Relevant documented information amended when requirements change, and people made aware.

8.3 Design and Development (if applicable) **Note:** Many CNC contract manufacturers **exclude** Clause 8.3 because they manufacture to customer-supplied designs. If your company designs products, this clause applies.

8.3.1 General: Establish design and development process.

8.3.2 Planning: - Stages and controls - Responsibilities and authorities - Resource needs - Interface management - Customer and user involvement - Controls for subsequent provision of products - Documentation requirements

8.3.3 Inputs: Requirements essential for specific product type: - Functional and performance requirements - Regulatory requirements - Standards or codes of practice - Potential failure consequences

8.3.4 Controls: - Results to be achieved - Reviews conducted - Verification activities - Validation activities - Actions on problems

8.3.5 Outputs: - Meet input requirements - Adequate for subsequent processes - Include or reference monitoring and measurement requirements - Include or reference acceptance criteria - Specify characteristics essential for proper use

8.3.6 Changes: Identify, review, control changes during or after design.

8.4 Control of Externally Provided Processes, Products, and Services **Requirement:** Ensure externally provided processes, products, and services conform to requirements.

Externally Provided Includes: - **Material** (bar stock, castings, forgings) - **Outside services** (heat treatment, plating, coating, grinding, welding) - **Tooling and supplies** (cutting tools, abrasives, coolant) - **Calibration services** - **Contract labor**

8.4.1 General: Determine and apply controls for: - Products/services incorporated into own products - Products/services provided directly to customer - Process or part of process provided by external provider

8.4.2 Type and Extent of Control:

Supplier Evaluation and Selection: - Capability assessment (visit, questionnaire, trial order) - Certification status (ISO 9001, AS9100, ISO 13485) - References and history - Risk to final product

Performance Monitoring: - On-time delivery rate - Quality (defect rate, rejection rate) - Responsiveness to issues - Cost competitiveness

Re-evaluation: Periodic review of supplier performance

Approved Supplier List (ASL): Maintain list of qualified suppliers

8.4.3 Information for External Providers:

Purchase Orders Must Include: - Product or service to be provided (specification, drawing) - Approval requirements (FARs, material certs, test reports) - Competence requirements (certified welders, NADCAP accreditation) - Interactions with organization (communication, access for verification) - Monitoring and measurement requirements - Verification activities at supplier's premises

Example PO Requirements: "Material must be certified per AMS 4911, DFARS compliant, with material test report (MTR) traceable to heat lot."

8.5 Production and Service Provision 8.5.1 Control of Production and Service Provision:

Controlled Conditions Include: - Documented information defining product characteristics, activities, results - Availability of monitoring and measuring resources - Implementation of monitoring and measurement - Use of suitable infrastructure and environment - Appointment of competent personnel - Validation and revalidation of processes where output cannot be verified - Implementation of actions to prevent human error - Implementation of release, delivery, post-delivery activities

CNC Production Control: - **Setup approval:** First-off inspection before running production - **In-process inspection:** Check critical dimensions during run - **Control plans:** Define what to inspect, how often, acceptance criteria - **Work instructions:** Step-by-step procedures for setup and operation - **Tooling control:** Preset tools, tool life tracking, replacement triggers - **Traveler/router:** Accompanies job through manufacturing, records operations

8.5.2 Identification and Traceability:

Identification: Use suitable means to identify outputs (part marking, labels, travelers)

Traceability (when required): - Unique identification (serial number, lot number, heat lot) - Records link part to material, processes, inspection results, operators - Required for aerospace, medical, automotive applications

Traceability Methods: - Part marking (laser etch, dot peen, stamp) - Travelers with serial numbers - Bar codes or QR codes - ERP system tracking - Material certifications retained

Example Traceability Flow:

Material Cert → Receiving → Job Number → Work Order →
Traveler → Operations (with date/operator) → Inspection →
Serial Number → Shipment → Customer

8.5.3 Property Belonging to Customers or External Providers:

Customer Property Includes: - Customer-supplied material (CSM) - Tooling and fixtures - Intellectual property (drawings, programs) - Material for testing or approval samples

Requirements: - Identify, verify, protect, safeguard - Report loss, damage, or unsuitability to customer - Maintain records

Procedures: - Label customer property - Segregate from other inventory - Inspect upon receipt (verify quantity, condition) - Protect from damage or deterioration - Return or dispose per customer instruction

8.5.4 Preservation:

Preserve outputs during processing and delivery to maintain conformity: - Identification (labels don't fall off) - Handling (lift points, appropriate containers) - Contamination control (covers, clean gloves) - Packaging (foam, bubble wrap, custom crates) - Storage (racks, shelving, climate control) - Transmission or transportation (carriers, shock indicators)

CNC Part Preservation: - Degrease and apply rust preventative - Wrap in paper or plastic - Place in partitioned boxes or foam - Protect precision surfaces (plug holes, cover bearing surfaces) - Label packages with part number and quantity

8.5.5 Post-Delivery Activities:

Consider requirements for post-delivery activities: - Warranty provisions - Contractual obligations (maintenance, support) - Customer feedback and complaints - Statutory and regulatory requirements

CNC Examples: - Technical support for part installation - Replacement or repair of defective parts - Feedback on part performance in use - Redesign or process improvement based on field issues

8.5.6 Control of Changes:

Review and control changes for production to ensure continuing conformity: - Document changes (ECN, revision) - Review for adverse effects - Approve before implementation - Communicate to affected personnel - Validate effectiveness

Change Control Process:

Change Request → Review (Engineering, Quality) →
Approval → Update Documents → Communicate →
Implement → Verify Effectiveness

8.6 Release of Products and Services Requirement: Implement planned arrangements to verify product requirements have been met before release.

Release Authorization: - Inspection completed per control plan - Acceptance criteria met - Traceability documented - Authorized personnel approve release

Evidence of Conformity: - Inspection records with dimensions - Material certifications - Test reports (hardness, conductivity) - Certificates of Conformance (CoC) - First Article Inspection reports

Hold Points: Release only after required verification completed: - Final inspection before shipping - Customer approval (for use-as-is or repair disposition) - Special tests (pressure test, leak check, NDT)

8.7 Control of Nonconforming Outputs **Requirement:** Ensure nonconforming outputs are identified and controlled to prevent unintended use or delivery.

Nonconformity Identification: - Red tags or labels - Quarantine area (bonded cage, red-painted area) - Physical separation from conforming product - ERP system status (on hold)

Disposition Options:

- 1. Correction:** Fix without authorization (e.g., deburr sharp edge)
- 2. Segregation/Containment:** Hold for further decision
- 3. Return to Supplier:** Rejected material or purchased items
- 4. Scrap:** Beyond economical repair or use
- 5. Rework:** Bring into conformance with original requirements - Follow approved rework procedure - Re-inspect per original requirements - Document rework performed
- 6. Repair:** Alter to meet intended use but not original requirements - Requires customer approval - Typically negotiated (price adjustment)
- 7. Use-As-Is:** Accept without correction - Requires customer concession - Document justification and authorization

Material Review Board (MRB): - Cross-functional team (quality, engineering, production) - Reviews nonconformances - Determines disposition - Approves rework/repair procedures

Documentation: - Nonconformance Report (NCR) - Description of nonconformity - Disposition decision - Actions taken - Approval signatures - Re-inspection results

Verification After Correction: - Re-inspect per original requirements - Confirm nonconformity corrected - Approve for use/delivery

Nonconformity After Delivery: - Take actions appropriate to effects (recall, customer notification) - Document and report - Investigate root cause - Implement corrective action

22.2.2.5 Performance Evaluation

Clause 9 addresses monitoring, measurement, analysis, and evaluation of QMS performance.

9.1 Monitoring, Measurement, Analysis, and Evaluation **9.1.1 General:** Determine what needs monitoring/measuring, methods, when performed, when analyzed/evaluated.

Key Metrics for CNC Manufacturing:

Category	Metric	Calculation	Target
Quality	Scrap Rate	Scrap \$ / Revenue	< 2%
Quality	Rework Rate	Rework hrs / Total hrs	< 3%
Quality	First-Pass Yield	Parts passed / Total produced	> 95%
Quality	Customer PPM	Defects / Million opportunities	< 100
Delivery	On-Time Delivery	Orders on time / Total orders	>= 95%

Category	Metric	Calculation	Target
Delivery	Past-Due Orders	Count of overdue jobs	0
Process	Process Capability	Cpk for critical dimensions	≥ 1.33
Process	Machine Utilization	Run time / Available time	60-80%
Customer	Customer Complaints	Complaints / month	Trend down
Customer	Satisfaction Score	Survey result (1-5 scale)	≥ 4.5

Analysis and Evaluation: - Trends over time (improving, stable, declining) - Comparison to objectives and targets - Root cause analysis for unfavorable trends - Corrective actions for out-of-spec performance

Data Sources: - Inspection records - Scrap and rework logs - ERP system reports - Customer feedback - Internal audits - Management review

9.1.2 Customer Satisfaction:

Requirement: Monitor customer perceptions of degree to which needs and expectations fulfilled.

Methods for Obtaining Customer Satisfaction Data: - Surveys (annual, after significant orders) - Customer scorecards (provided by customer) - Complaints and returns - On-time delivery performance - Repeat business and referrals - Direct feedback (visits, phone calls)

Customer Satisfaction Survey Example:

Please rate the following on a 1-5 scale (1=Poor, 5=Excellent): - Product quality and conformance - On-time delivery - Responsiveness to inquiries - Technical support - Pricing competitiveness - Overall satisfaction - Likelihood to recommend

Open-ended: - What do we do well? - What could we improve?

9.1.3 Analysis and Evaluation:

Analyze and evaluate data from monitoring and measurement: - Conformity of products and services - Customer satisfaction - Performance and effectiveness of QMS - Effectiveness of planning - Effectiveness of actions to address risks and opportunities - Performance of external providers - Need for improvements

Analysis Tools: - Trend charts (scrap rate over time) - Pareto charts (most common defect types) - Control charts (process stability) - Histograms (process distribution) - Scatter diagrams (correlation between variables)

9.2 Internal Audit Requirement: Conduct internal audits at planned intervals to provide information on whether QMS conforms to organization's own requirements, ISO 9001 requirements, and is effectively implemented and maintained.

9.2.1 Planning: - Audit schedule (annual plan covering all processes) - Frequency based on importance and changes - Criteria and scope for each audit

Audit Frequency Considerations: - All processes audited at least annually - Critical processes audited more frequently - Processes with recent problems audited sooner - New or changed processes audited soon after implementation

Example Annual Audit Schedule:

Month	Process Audited	Auditor
Jan	Document Control	Quality Mgr
Feb	Training and Competence	HR Mgr
Mar	Machining Operations	Eng Mgr
Apr	Supplier Management	Purchasing
May	Inspection and Testing	QA Lead
Jun	Calibration	QA Lead
Jul	Nonconforming Product Control	Quality Mgr
Aug	Internal Audits	Eng Mgr
Sep	Management Review	QA Lead
Oct	Preventive Maintenance	Maint Mgr
Nov	Customer Communication	Sales Mgr
Dec	Corrective Action	Quality Mgr

9.2.2 Implementation:

Auditor Selection: - Objective and impartial (cannot audit own work) - Competent (trained in auditing techniques) - Knowledgeable about ISO 9001 and process being audited

Auditor Training: - ISO 9001 requirements - Audit techniques (questioning, sampling, evidence collection) - Audit planning and reporting

Audit Process:

1. Planning:

- Review process documentation
- Prepare audit checklist
- Schedule audit with process owner
- Notify personnel

2. Opening Meeting:

- Introduce audit team
- Confirm scope and schedule
- Explain audit process
- Answer questions

3. Fieldwork:

- Interview personnel
- Observe activities
- Review records
- Sample transactions
- Collect objective evidence

4. Closing Meeting:

- Present findings
- Discuss observations
- Clarify misunderstandings
- Discuss next steps

5. Reporting:

- Document conformances and nonconformances
- Issue audit report
- Assign corrective actions

Finding Classification: - **Major Nonconformance:** Significant failure or absence of QMS requirement - **Minor Nonconformance:** Isolated lapse or documentation issue - **Observation:** Potential for improvement, not yet nonconformance

Example Audit Findings:

Major: “Gage calibration records not available for 3 of 10 micrometers inspected. ISO 9001 Clause 7.1.5.1 requires measuring equipment be calibrated.”

Minor: “Training record for Employee X missing signature. ISO 9001 Clause 7.2 requires competence records be maintained.”

Observation: “Setup sheets stored in binder on shop floor are becoming difficult to read due to age and exposure. Consider electronic storage or lamination to preserve legibility.”

- 9.2.3 Reporting:**
- Retain documented information as evidence of audit program and results
 - Report to relevant management
 - Include conformances, nonconformances, opportunities for improvement

9.3 Management Review Requirement: Top management reviews QMS at planned intervals to ensure continuing suitability, adequacy, effectiveness, and alignment with strategic direction.

9.3.1 General:

- Conducted at planned intervals (typically semi-annually or quarterly)
- Top management participates
- Reviews entire QMS, not just quality performance

9.3.2 Management Review Inputs:

- Required topics:
- Status of actions from previous reviews
 - Changes in external and internal issues
 - Information on QMS performance:
 - Customer satisfaction and feedback
 - Extent quality objectives met
 - Process performance and product conformity
 - Nonconformities and corrective actions
 - Monitoring and measurement results
 - Audit results
 - Performance of external providers - Adequacy of resources
 - Effectiveness of actions to address risks and opportunities
 - Opportunities for improvement

Typical Management Review Agenda:

1. Review of previous action items
2. Quality objectives status
3. Customer satisfaction and complaints
4. Key metrics (scrap, on-time delivery, Cpk)
5. Internal audit results
6. External audit results (if applicable)
7. Nonconformances and corrective actions
8. Supplier performance
9. Resource needs (equipment, personnel, training)
10. Changes to QMS or external factors
11. Improvement opportunities
12. Action items and responsible parties

9.3.3 Management Review Outputs:

Decisions and actions related to: - Opportunities for improvement - Any need for changes to QMS
- Resource needs

Documentation: - Agenda - Attendees - Data reviewed - Discussions and decisions - Action items with responsibilities and due dates - Signed minutes

22.2.2.6 Improvement

Clause 10 focuses on continual improvement of QMS.

10.1 General Requirement: Determine and select opportunities for improvement and implement actions to meet customer requirements and enhance customer satisfaction.

Improvement Opportunities: - Enhance products and services (quality, features) - Correct, prevent, reduce undesired effects (defects, complaints) - Improve QMS performance and effectiveness (efficiency, cycle time)

Improvement Sources: - Customer feedback - Audit findings - Nonconformances - Data analysis - Employee suggestions - Benchmarking

10.2 Nonconformity and Corrective Action Requirement: When nonconformity occurs, react to it, take action to control and correct it, and deal with consequences.

10.2.1 Reacting to Nonconformity:

Immediate Actions (containment): - Segregate nonconforming product - Stop production if necessary - Notify customer if product already shipped - Inspect similar product (sort remaining inventory)

Correction: Fix the immediate problem - Rework part - Scrap defective product - Adjust machine - Replace worn tool

10.2.2 Root Cause Analysis:

Requirement: Evaluate need for action to eliminate causes, ensuring nonconformity does not recur.

Root Cause Analysis Methods (covered in detail in Section 9): - 5 Whys - Fishbone (Ishikawa) Diagram - Fault Tree Analysis - Failure Mode and Effects Analysis (FMEA)

Example 5 Whys: - Problem: Shaft diameter out of tolerance - Why? Tool wore excessively - Why? Tool life exceeded - Why? No tool life tracking system - Why? Relying on operator to monitor - Why? No procedure in place - **Root Cause:** Lack of tool life tracking procedure

10.2.3 Implement Corrective Action:

Actions appropriate to effects of nonconformity: - Implement solution addressing root cause - Update procedures or work instructions - Provide training - Modify equipment or tooling - Change supplier

Example Corrective Actions: - Root Cause: No tool life tracking - Corrective Action: Implement tool life tracking system in ERP, establish replacement intervals based on testing, train operators on new procedure

10.2.4 Effectiveness Review:

Requirement: Review effectiveness of corrective action taken.

Effectiveness Verification: - Monitor for recurrence (has problem stopped?) - Check compliance with new procedure (are people following it?) - Review data after implementation period (30 days, 90 days)

If Not Effective: - Re-evaluate root cause (was correct cause identified?) - Modify corrective action - Implement additional actions

10.2.5 Update Risks and Opportunities:

If needed, update risks and opportunities determined during planning.

10.2.6 Changes to QMS:

Make changes to QMS if necessary (update procedures, forms, training).

10.2.7 Documentation:

Retain documented information as evidence: - Nature of nonconformity - Actions taken (containment, correction) - Root cause analysis - Corrective action plan - Effectiveness verification - Approval signatures

Corrective Action Report (CAR) Template: - CAR Number - Date Issued - Issued By - Problem Description - Immediate Action (correction/containment) - Root Cause Analysis - Corrective Action Plan - Responsible Person - Target Completion Date - Effectiveness Review Date - Verification Results - Approval and Closure

10.3 Continual Improvement **Requirement:** Continually improve suitability, adequacy, and effectiveness of QMS.

Continual vs. Continuous: - **Continuous:** Ongoing without interruption - **Continual:** Repeated over time with interruptions (project-based improvements)

Improvement Opportunities: - Results of analysis and evaluation - Outputs of management review - Ideas from employees (suggestion systems) - Lessons from audits - Benchmarking against competitors or best practices

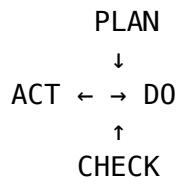
Improvement Tools (covered in Section 12): - Kaizen events (focused improvement projects) - Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) - Lean manufacturing (waste elimination) - 5S (workplace organization) - Value stream mapping - Process re-engineering

Improvement Culture: - Everyone responsible for improvement - Small improvements valued - Experimentation encouraged - Failures seen as learning opportunities - Successes celebrated and shared

22.2.3 The Plan-Do-Check-Act (PDCA) Cycle

The **PDCA Cycle** (also called Deming Cycle or Shewhart Cycle) is the fundamental improvement methodology embedded in ISO 9001:2015.

PDCA Overview



Plan Phase

Establish objectives and processes necessary to deliver results

Activities: - Identify problem or improvement opportunity - Analyze current situation (data collection) - Determine root causes - Develop solution or improvement plan - Set targets and success criteria - Identify resources needed

Do Phase

Implement the plan

Activities: - Execute plan on small scale (pilot or trial) - Train personnel on new method - Collect data on performance - Document what happens

Check Phase

Monitor and measure processes and products against policies, objectives, and requirements, and report results

Activities: - Compare actual results to expected results - Analyze data - Identify gaps and variances - Determine if objectives met

Act Phase

Take actions to continually improve process performance

Activities: - If successful: Standardize and implement broadly (update procedures, train everyone)
- If not successful: Identify lessons learned and return to Plan phase - Identify next improvement opportunity - Continue the cycle

PDCA in ISO 9001:2015 Structure

ISO 9001:2015 structure follows PDCA:

PLAN (Clauses 4-6): - Context and interested parties - Leadership and planning - Risks and opportunities - Quality objectives

DO (Clauses 7-8): - Support and resources - Operational planning and control - Production and service provision

CHECK (Clause 9): - Monitoring, measurement, analysis, evaluation - Customer satisfaction - Internal audits - Management review

ACT (Clause 10): - Nonconformity and corrective action - Continual improvement

PDCA Example: Reducing Scrap

PLAN: - Problem: Scrap rate is 5%, target is 2% - Analyze: Pareto chart shows 60% of scrap is dimension errors on turned diameters - Root cause: Tool wear not monitored, cutting past tool life - Solution: Implement tool life tracking system - Target: Reduce scrap to <2% within 3 months

DO: - Conduct tool life study on problematic operation - Establish replacement interval (e.g., 200 parts) - Program ERP to track parts run on each tool - Train operators on tool replacement procedure - Implement on one machine as pilot

CHECK: - Monitor scrap rate on pilot machine for 30 days - Scrap rate drops from 5% to 1.5% - Tool changes consistently at proper interval - No issues with procedure compliance

ACT: - Standardize tool life tracking on all machines - Update work instructions - Train all operators - Continue monitoring scrap rate monthly - Identify next improvement opportunity

22.2.4 Risk-Based Thinking

Risk-Based Thinking is a key concept introduced in ISO 9001:2015, replacing the former requirement for preventive action.

What is Risk-Based Thinking?

Risk-based thinking means considering risk in all aspects of the QMS, not just in formal risk assessments.

Risk: Effect of uncertainty on expected results - Can be positive (opportunity) or negative (threat) - Not all risks require formal analysis

Risk-Based Thinking vs. Preventive Action

ISO 9001:2008 had separate clause for Preventive Action (8.5.3)

ISO 9001:2015 integrates risk thinking throughout standard: - Risk assessment in planning (Clause 6.1) - Risk considerations in all processes - Preventive action built-in, not separate

Levels of Risk Management

Informal Risk Thinking (everyday decisions): - Choosing which machine to use based on capability - Deciding when to change tools - Determining inspection frequency - Selecting suppliers

Formal Risk Assessment (documented analysis): - Major equipment investments - New product launches - Supplier qualification - Process validation

Advanced Risk Analysis (quantitative methods): - FMEA (Failure Mode and Effects Analysis) - Fault Tree Analysis - Probabilistic risk assessment

Risk-Based Thinking in Practice

Product Design: - What could go wrong in manufacturing? - Design for manufacturability (DFM)
- Identify critical characteristics requiring special controls

Process Planning: - What are failure modes for this operation? - What controls prevent defects?
(fixtures, tool monitoring, in-process checks) - What if machine breaks down? (backup machine,
outsource capability)

Supplier Selection: - Risk of single-source supplier (supply disruption) - Opportunity: Develop
second source - Risk of poor quality from new supplier - Mitigation: Trial order, incoming inspection,
audits

Change Management: - What could go wrong with this change? - How to minimize risk? (trials,
training, phased implementation) - What's worst-case scenario? (contingency plan)

Benefits of Risk-Based Thinking

- Proactive rather than reactive
 - Prevents problems rather than correcting them
 - Focuses resources on greatest risks
 - Improves decision-making
 - Reduces firefighting and crises
 - Increases likelihood of achieving objectives
-

22.2.5 Process Approach to Quality Management

The **Process Approach** is a fundamental principle of ISO 9001, emphasizing management of activities as interrelated processes rather than isolated functions.

What is a Process?

Process: Set of interrelated activities that transform inputs into outputs

Inputs → [Process Activities] → Outputs
 ↑ Controls
 ↓ Resources

Example Process: CNC Machining - Inputs: Raw material, drawing, program, work order -
Activities: Setup, load material, run program, inspect - **Outputs:** Machined part - **Controls:**
Control plan, work instruction, proven program - **Resources:** CNC machine, tooling, fixtures,
operator, measuring equipment

Process Approach Benefits

- Focuses on achieving results
- Identifies interactions between processes
- Optimizes system performance (not just individual departments)
- Reduces duplication and inefficiency
- Improves consistency and predictability

Process Categories

Management Processes: Direct and support organization - Strategic planning - Management review - Internal audits - Corrective action

Core Processes: Directly create value for customer - Sales and quoting - Order entry - Production planning - Manufacturing operations - Inspection and testing - Shipping

Support Processes: Enable core processes - Document control - Training - Equipment maintenance - Calibration - Purchasing

Process Identification and Mapping

Steps to Implement Process Approach:

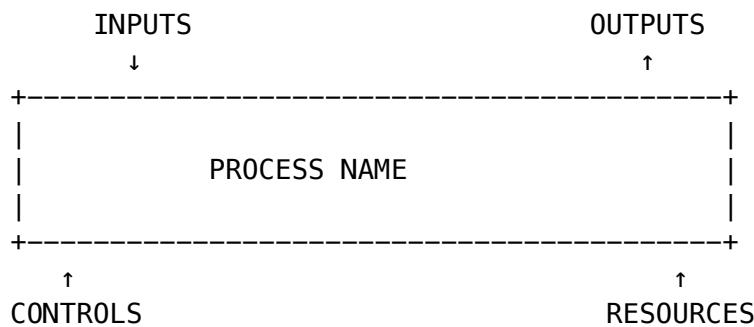
1. **Identify processes** needed for QMS
2. **Determine sequence and interaction** of processes
3. **Define criteria and methods** for effective operation and control
4. **Ensure availability of resources** and information
5. **Monitor, measure, and analyze** processes
6. **Implement actions** to achieve planned results and continual improvement

Process Mapping Tools:

Flowchart: Shows sequence of activities

Start → Activity 1 → Decision? → Yes → Activity 2 → End
 ↓ No
 Activity 3 →↑

Turtle Diagram: Shows inputs, outputs, controls, resources



SIPOC Diagram: Suppliers, Inputs, Process, Outputs, Customers

Suppliers	Inputs	Process	Outputs	Customers
Material supplier	Bar stock	CNC Machining	Machined shaft	Assembly dept
Engineering	Drawing			
Programming	NC program			

Process Performance Indicators

Each process should have measurable indicators:

Machining Process Example: - Cycle time (hours per part) - First-pass yield (% passing inspection first time) - Machine utilization (% of available time running) - Scrap rate (% of material scrapped) - Setup time (minutes per job)

Inspection Process Example: - Inspection turnaround time (hours from receipt to release) - Inspection accuracy (agreement with external inspection) - Backlog (jobs waiting for inspection)

Process Ownership

Each process should have an **owner**: - Responsible for process performance - Authority to make process changes - Monitors process metrics - Drives process improvement

Example: - Machining Process Owner: Production Manager - Inspection Process Owner: Quality Manager - Calibration Process Owner: QA Lead

Process Interactions

Processes don't operate in isolation; outputs of one process become inputs to another.

Example Interaction:

Purchase Order → Purchasing Process → Material Receipt → Receiving Inspection → Machining Process → Finished Part → Final Inspection → Shipping Process → Customer

Understanding interactions helps: - Identify bottlenecks - Improve handoffs - Reduce errors and rework - Optimize overall system

Summary

ISO 9001:2015 provides a comprehensive framework for quality management based on proven principles: - Customer focus - Leadership - Engagement of people - Process approach - Improvement - Evidence-based decision making - Relationship management

The standard's structure follows the PDCA cycle and integrates risk-based thinking throughout. By implementing ISO 9001, CNC manufacturers establish systematic processes that consistently deliver quality products, satisfy customers, and drive continual improvement.

Understanding these fundamentals is essential before diving into specific quality processes, industry standards, and implementation strategies covered in subsequent sections.

Key Takeaways

1. **ISO 9001 has evolved** from prescriptive procedures to flexible, risk-based quality management
 2. **Process approach** emphasizes managing interrelated activities for better results
 3. **Risk-based thinking** is integrated throughout standard, replacing separate preventive action
 4. **PDCA cycle** (Plan-Do-Check-Act) is fundamental methodology for improvement
 5. **Leadership commitment** is explicitly required, not just quality department responsibility
 6. **Documentation is flexible** - organization determines what's needed beyond required items
 7. **Context of organization** must be understood and addressed in QMS planning
 8. **Customer focus** is central to all quality activities
 9. **Continual improvement** is ongoing expectation, not one-time project
 10. **ISO 9001 is framework**, not prescriptive - allows adaptation to organization's needs
-

Review Questions

1. Describe the evolution of ISO 9001 from its 1987 origins to the 2015 version. What are the major changes in each revision?
 2. Explain the difference between "correction," "corrective action," and "preventive action."
 3. What are the seven quality management principles underlying ISO 9001:2015?
 4. Describe the 10-clause structure of ISO 9001:2015. Which clauses contain auditable requirements?
 5. What is meant by "context of the organization" (Clause 4)? Why is this important for QMS planning?
 6. Explain the concept of risk-based thinking. How is it different from the former preventive action requirement?
 7. What are the four stages of the PDCA cycle? Give an example of applying PDCA to a quality problem.
 8. What is the process approach to quality management? How does it differ from a functional approach?
 9. What are the top management's leadership responsibilities in ISO 9001:2015?
 10. What is the difference between "documented information" in ISO 9001:2015 and "documents and records" in ISO 9001:2008?
-

Practical Exercises

Exercise 1: SWOT Analysis

Conduct a SWOT analysis (Strengths, Weaknesses, Opportunities, Threats) for your CNC shop or a hypothetical shop:

Strengths (internal positives): - Modern equipment? - Skilled workforce? - Certifications? - Strong customer relationships?

Weaknesses (internal negatives): - Aging equipment? - High turnover? - Limited capacity? - Documentation gaps?

Opportunities (external positives): - Growing markets? - New technologies? - Customer requirements driving improvement?

Threats (external negatives): - Intense competition? - Economic downturn? - Skilled labor shortage? - Material cost increases?

Exercise 2: Process Mapping

Create a process map for a core process in your shop (e.g., job setup and first-off inspection):

1. List all activities in sequence
2. Identify decision points
3. Draw flowchart
4. Create turtle diagram showing inputs, outputs, controls, resources
5. Identify process performance indicators

Exercise 3: Risk Assessment

Identify five risks in CNC manufacturing and assess them:

1. Describe risk
2. Rate likelihood (1-5: rare to almost certain)
3. Rate impact (1-5: negligible to catastrophic)
4. Calculate risk score (likelihood × impact)
5. Determine action to mitigate high-risk items

Example: - Risk: Coolant contamination causes tool failure - Likelihood: 3 (possible) - Impact: 4 (major - scrapped parts, downtime) - Risk Score: 12 (High) - Mitigation: Weekly coolant concentration checks, refractometer calibration, coolant change schedule

Exercise 4: PDCA Problem Solving

Apply the PDCA cycle to a real or hypothetical quality problem:

PLAN: - Define problem (quantify with data) - Analyze root causes (5 Whys or fishbone) - Develop solution - Set target and timeline

DO: - Implement on small scale (pilot) - Document trial

CHECK: - Measure results - Compare to target - Identify gaps

ACT: - If successful: Standardize and expand - If not: Revise and try again - Document lessons learned

Additional Resources

Standards: - ISO 9001:2015 - Quality Management Systems (purchase from ISO or ANSI) - ISO 9000:2015 - Fundamentals and Vocabulary (free download) - ISO 9004:2018 - Quality Management - Quality of an Organization - Guidance to Achieve Sustained Success

Books: - "ISO 9001:2015 in Plain English" by Craig Cochran - "The ASQ ISO 9001:2015 Handbook" edited by J.P. Russell - "ISO 9001:2015 Audit Procedures" by Ray Tricker

Online Resources: - ASQ (American Society for Quality): www.asq.org - ISO website: www.iso.org - Quality Digest: www.qualitydigest.com - iSixSigma: www.isixsigma.com

Training and Certification: - ASQ Certified Quality Auditor (CQA) - ASQ Certified Quality Engineer (CQE) - ASQ Certified Manager of Quality/Organizational Excellence (CMQ/OE) - Lead Auditor Training (ISO 9001) - Internal Auditor Training

Module 22 - Quality Management Systems (QMS)

While ISO 9001 provides a general quality management framework applicable to any organization, certain industries have additional requirements that go beyond the baseline. This section covers the major industry-specific quality standards relevant to CNC manufacturing.

22.3.1 AS9100 (Aerospace Quality Management)

AS9100 is the quality management standard for the aviation, space, and defense industries. It builds upon ISO 9001 with additional requirements specific to aerospace manufacturing.

History and Development

Timeline: - **1997:** AS9000 published (based on ISO 9001:1994) - **1999:** AS9100 Rev A published - **2001:** AS9100 Rev B (aligned with ISO 9001:2000) - **2009:** AS9100 Rev C (aligned with ISO 9001:2008) - **2016:** AS9100 Rev D (aligned with ISO 9001:2015) - **Current Version**

Scope: Applies to organizations that design, develop, or provide aviation, space, and defense products and services.

Governing Body: IAQG (International Aerospace Quality Group)

Regional Variations: - **AS9100:** Americas (SAE) - **EN 9100:** Europe (ASD) - **SJAC 9100:** Asia (SJAC)

Content is identical; only publishing body differs.

Why AS9100 Matters

Customer Requirements: - Major aerospace OEMs require AS9100 certification (Boeing, Airbus, Lockheed Martin, etc.) - Government contracts often specify AS9100 - Supply chain requirement (Tier 1 suppliers require it from Tier 2, and so on)

Safety Critical: - Aerospace components impact flight safety - Failures can result in catastrophic consequences - Stricter controls needed than general manufacturing

Traceability: - Track material from mill to installed part - Enables recalls and investigations - Required for airworthiness

Complexity: - Long product lifecycles (decades) - Configuration management essential - Extensive documentation required

22.3.1.1 AS9100 Requirements Beyond ISO 9001

AS9100 includes all ISO 9001 requirements **plus** additional aerospace-specific requirements.

Product Safety Requirement: Organization must identify product safety requirements and implement controls throughout product realization.

Product Safety Considerations: - Critical characteristics affecting safety of flight - Special processes (welding, heat treatment, NDT) - Human factors in assembly/maintenance - Software safety (for avionics)

Product Safety Documentation: - Product Safety Representative designated - Risk assessments (FMEA, FTA) - Safety-critical characteristics identified on drawings - Special inspection and testing requirements

Example: Aircraft landing gear component with key characteristic affecting strength must have:
- Material traceability to certified mill - Heat treatment per aerospace specification with hardness verification - 100% ultrasonic inspection for cracks - First Article Inspection per AS9102

Counterfeit Part Prevention Requirement: Establish and implement process to prevent use, inclusion, or installation of counterfeit parts and materials.

Counterfeit Risks: - Substandard materials (wrong alloy, insufficient strength) - Out-of-specification parts (dimensions, treatments) - Fraudulent certifications - Re-marked or recycled parts

Prevention Controls: - Purchase from authorized/franchised distributors - Verify material certifications (MTR) against chemical/physical testing - Supplier assessments and audits - Incoming inspection and verification - Traceability systems - Employee training on identification

Suspect/Counterfeit Part Response: - Quarantine immediately - Report to customer and regulatory agencies (GIDEP) - Investigate source and scope - Implement corrective action

On-Time Delivery Performance Requirement: Monitor on-time delivery performance and take action when targets not achieved.

On-Time Delivery (OTD): - Measured against customer-requested delivery date or agreed date
- Typical target: >=95% OTD - Early delivery may not be acceptable (JIT manufacturing, storage costs)

Calculation:

$$\text{OTD \%} = (\text{Orders Delivered On-Time} / \text{Total Orders}) \times 100$$

Monitoring: - Track monthly and trend over time - Report in management review - Escalate when below target

Improvement Actions: - Capacity analysis (identify bottlenecks) - Supplier delivery improvements - Lead time accuracy (quote realistic dates) - Production planning optimization - Expediting and prioritization processes

Work Transfer Requirement: When work is transferred (internally between sites, to suppliers, or from customer), manage the transfer to ensure continuity.

Work Transfer Scenarios: - Opening new manufacturing site - Closing facility and moving to another - Insourcing (bringing work in-house) - Outsourcing (moving work to supplier) - Customer transferring work to your facility

Work Transfer Plan: - Identify risks to continuity - Transfer of technical data (drawings, specifications, programs) - Qualification of new processes/equipment - Personnel training and competence - Tooling and gage transfer/procurement - First Article Inspection at new location - Phase-in plan (parallel production, qualification lot) - Verification of product conformity

Example: Machining operation moving from Plant A to Plant B: - Transfer proven programs and setup sheets - Qualify machines at Plant B (capability studies) - Train operators on processes - Conduct FAI at Plant B - Run qualification lot with 100% inspection - Overlap production during transition - Customer approval before full transition

Human Factors Requirement: Consider human factors in manufacturing processes, especially where human error could impact product safety or quality.

Human Factors Considerations: - Workstation design (ergonomics, visibility, access) - Complexity of tasks (simplify where possible) - Repetitive tasks (automation, job rotation, poka-yoke) - Fatigue management (shift schedules, breaks) - Lighting, temperature, noise - Training and competence - Clear work instructions with visuals

Error-Proofing (Poka-Yoke): - Fixtures that only allow correct orientation - Color-coding (tools, parts, locations) - Checklists and verification steps - Automated checks (probe verification, vision systems) - Warning systems (alarms, lights)

Example: Assembly operation with multiple similar fasteners: - Shadow boards showing tool locations - Kitting (provide exact quantities needed) - Torque stripes (visual verification of tightening) - Digital torque wrenches with data logging - Photos in work instruction showing correct assembly

Foreign Object Debris (FOD) Prevention Requirement: Implement FOD prevention program to minimize risk of foreign objects causing damage or failures.

FOD Risks: - Tools or hardware left inside assemblies - Metal chips, swarf, abrasive from machining - Rags, gloves, plastic, packaging materials - Damage to precision surfaces, seals, bearings - Ingestion into engines (catastrophic)

FOD Prevention Measures: - **Tool Control:** Shadow boards, tool inventories, account for all tools - **Cleanliness:** Clean parts before assembly, air blow, wash, vacuum - **Caps and Plugs:** Protect threaded holes, ports, bores during storage and shipping - **Housekeeping:** Clean work

areas, sweep and vacuum regularly - **Inspection:** Visual inspection for FOD before closing assemblies - **Training:** Awareness of FOD risks and consequences

FOD Audits: - Regular inspections of work areas - FOD walks (search for and remove debris) - Tracking and trending FOD incidents

Critical Items Requirement: Identify and control critical items (key characteristics, processes, suppliers).

Critical Items Include: - **Key Characteristics:** Dimensions or properties significantly affecting safety, fit, function, or performance - Example: Bearing bore diameter, hole pattern, material hardness - **Critical Processes:** Processes where output cannot be fully verified by inspection - Example: Heat treatment (internal structure), welding (internal integrity) - **Critical Suppliers:** Sole-source suppliers, special processes, high-risk materials

Controls for Critical Items: - Identified on drawings and control plans (often with special symbols) - Enhanced inspection (100%, SPC, automated measurement) - Process validation and revalidation - Supplier audits and monitoring - Material and process certifications - First Article Inspection - Traceability

Configuration Management Requirement: Manage configuration of products throughout life-cycle, controlling changes to design and documentation.

Configuration Management (CM) ensures: - Product definition is current and correct - Changes are controlled and documented - As-built configuration is known - Traceability from serial number to exact configuration

CM Process: 1. **Configuration Identification:** Define product and its components (BOMs, drawing trees) 2. **Configuration Control:** Manage changes (ECNs), approve deviations 3. **Configuration Status Accounting:** Track current configuration, change history 4. **Configuration Audits:** Verify physical configuration matches documentation

Change Management: - Engineering Change Notice (ECN) or Engineering Change Order (ECO) - Impact assessment (affect on form, fit, function, safety, interchangeability) - Approval workflow (engineering, quality, customer) - Effectivity (serial number, date, lot) - Document updates (drawings, specs, BOMs, work instructions) - Notification to affected parties

Example: ECN-1234: Change shaft material from 4140 to 4340 steel - Reason: Improved strength for new application - Impact: Affects material specification, heat treatment procedure, hardness range - Effectivity: Serial numbers 5001 and up - Approval: Engineering and customer approved - Actions: Update drawing Rev C to D, revise heat treat work instruction, notify heat treat supplier, update control plan

Advanced Product Quality Planning (APQP) While primarily an automotive tool (IATF 16949), many aerospace customers require APQP-like processes.

APQP Phases (summarized): 1. Plan and Define: Understand customer requirements 2. Product Design and Development: Design to meet requirements 3. Process Design and Development: Plan manufacturing processes 4. Product and Process Validation: Prove capable of production 5. Production and Continuous Improvement: Launch and improve

Key Deliverables: - Design FMEA (DFMEA) - Process FMEA (PFMEA) - Control Plans - Process Flow Diagrams - Work Instructions - Measurement Systems Analysis (MSA) - Capability Studies (Ppk, Cpk) - Production Part Approval Process (PPAP) or equivalent

22.3.1.2 Configuration Management

Configuration Management is critical in aerospace due to long product lifecycles and stringent traceability requirements.

Product Configuration Baseline **Baseline:** Approved configuration at specific point in time

Baseline Types: - **Functional Baseline:** Performance requirements - **Design Baseline:** Design documentation (drawings, specs) - **Product Baseline:** As-built configuration

Configuration Identification **Product Structure:** - Top-level assembly - Sub-assemblies - Components - Raw materials

Identification Methods: - Part numbers (with revision levels) - Serial numbers (unique to each part) - Lot or batch numbers - Drawing numbers and revisions

Indented Bill of Materials (BOM):

1000-100 Rev C Aircraft Assembly

 1010-200 Rev A Wing Assembly (Qty 2)

 1010-210 Rev B Wing Spar (Qty 1)

 1010-211 Rev A Spar Extrusion (Qty 1)

 Material: 7075-T6 Aluminum per AMS 4045

 1010-220 Rev A Wing Skin (Qty 2)

 1020-100 Rev B Fuselage Assembly (Qty 1)

...

Configuration Control Board (CCB) **Purpose:** Review and approve changes to product configuration

CCB Membership: - Engineering - Quality - Manufacturing - Program Management - Customer representative (sometimes)

CCB Responsibilities: - Review proposed changes - Assess impact (technical, cost, schedule) - Approve or reject changes - Determine effectiveness - Authorize deviations or waivers

Baseline Change Control **Change Request Process:** 1. **Initiate:** Change request submitted (problem report, improvement, customer request) 2. **Evaluate:** Engineering investigates and proposes solution 3. **Impact Assessment:** Analyze effects on design, manufacturing, cost, schedule, safety 4. **Approval:** CCB reviews and approves or rejects 5. **Implementation:** Update documentation, communicate changes, effectuate in production 6. **Verification:** Confirm change implemented correctly

As-Built Configuration Requirement: Maintain records of actual configuration as-built (may differ from design due to approved deviations)

As-Built Records: - Serial numbers of components installed - Material certifications and lot numbers - Process certifications (heat treat, plating) - Inspection results - Deviations or waivers incorporated - Rework or repairs performed

Example As-Built Record:

Aircraft S/N 42001

Wing Assembly S/N W-12345

Wing Spar S/N WS-98765

Material: 7075-T6 Aluminum, Heat Lot H-554433, MTR #123456

Heat Treat: Per AMS 2770, Cert #HT-78910

Inspection: FAI per AS9102, Report FAI-2024-042

Deviation: Hole spacing +0.005" per Waiver W-2024-100

Configuration Audits Physical Configuration Audit (PCA): - Verify physical product matches design documentation - Performed before product release

Functional Configuration Audit (FCA): - Verify product meets functional requirements - Performance testing

22.3.1.3 First Article Inspection Requirements

First Article Inspection (FAI) verifies that manufacturing processes can produce parts conforming to engineering design requirements.

When FAI is Required Mandatory FAI Situations (per AS9102): - First production run of a new part - Change in design (drawing revision affecting form, fit, function) - Change in manufacturing process (new machine, tooling, method) - Change in material or supplier - Change in manufacturing facility - Natural or man-made event affecting manufacturing (flood, fire, reorganization) - Lapse in production (typically >2 years for AS9100) - Customer or regulatory requirement

AS9102 Standard AS9102 defines requirements for First Article Inspection in aerospace.

Current Version: AS9102B (Rev B)

AS9102 Forms: - **Form 1:** Part Number Accountability (one per part number) - **Form 2:** Product Accountability (one per characteristic) - **Form 3:** Process/Material Verification (as needed)

Form 1: Part Number Accountability Purpose: Identify the part and FAI context

Information on Form 1: - Part number, revision, and nomenclature - Drawing number and revision - Organization performing FAI - Manufacturing process (machining, welding, assembly) - Reason for FAI (new part, design change, process change, etc.) - Quantity inspected - Approval signatures (inspector, quality, customer if required)

Form 2: Product Accountability **Purpose:** Document inspection results for each characteristic

Information on Form 2: - Characteristic number (from drawing) - Characteristic description (e.g., "Diameter of bore, .500+/-0.002") - Drawing requirement (dimension, tolerance, specification) - Inspection method (micrometer, CMM, gage) - Inspection results (actual measurements) - Conformance (Accept/Reject) - Reference to supporting documentation (inspection report, cert, test results)

Characteristic Numbering: - All dimensions and requirements on drawing are numbered sequentially - Balloons on drawing correspond to Form 2 line items

Example Form 2 Excerpt:

Char #	Description	Requirement	Method	Results	Accept/Reject	Reference
1	Material	6061-T6 Aluminum	Material Cert	6061-T6, Heat Lot H-123	Accept	MTR-2024-055
2	Overall Length	4.000 +/-0.010	Calipers	4.003	Accept	IR-2024-321, pg 1
3	Diameter, \varnothing .500+/-0.002	.498-.502	Micrometer	.500, .501, .500 (avg .500)	Accept	IR-2024-321, pg 1
4	Surface Finish	63 Ra max	Profilometer	.45 Ra	Accept	IR-2024-321, pg 2
5	Hole Pattern	Per drawing	CMM	See CMM report	Accept	CMM-2024-078

Form 3: Process/Material Verification **Purpose:** Document verification of special processes or materials not directly measurable

When Form 3 is Used: - Material certifications (MTR, chemical analysis, mechanical properties) - Heat treatment certifications (time, temperature, hardness) - Plating/coating certifications (thickness, adhesion) - NDT results (X-ray, ultrasonic, penetrant) - Test results (pressure, leak, functional) - Welding certifications (welder qualification, weld procedure)

Information on Form 3: - Characteristic number (from Form 2) - Process or material specification - Supplier or processor - Certification or test report number - Results or findings - Accept/Reject - Supporting documentation attached

FAI Sample Size AS9102 Sample Size: - Detailed inspection of characteristics on sample part(s) - Sample size determined by: - **One part** typically sufficient for machined parts with controlled processes - **Three parts minimum** for processes with inherent variation (castings, moldings, assemblies) - **Customer or drawing requirement** may specify larger sample

Statistical Sampling: - Not typically used for FAI (FAI is detailed verification, not statistical sampling) - Full dimensional inspection performed on sample

Partial FAI **Partial FAI:** When only portion of part is affected by change, only changed characteristics require re-inspection.

Example: Drawing revision changes one hole diameter but leaves other features unchanged: - Perform FAI only on the changed hole diameter - Reference previous FAI for unchanged characteristics - Note "Partial FAI" on Form 1

FAI Documentation and Retention **FAI Package Includes:** - AS9102 Forms 1, 2, 3 - Supporting documentation: - Detailed inspection reports - CMM reports - Material certifications - Process certifications - Test results - Photos (if applicable) - Drawing (revision inspected)

Retention: - Maintain FAI records for life of part number + specified period (often 10 years or per contract) - Make available to customer and regulatory agencies upon request

Customer Approval: - Some customers require FAI submission and approval before production release - Others accept supplier self-approval (but must provide FAI upon request) - Check contract or purchase order requirements

Delta FAI **Delta FAI:** Simplified FAI when minor change occurs

Criteria for Delta FAI: - Change is minor and well-understood - Risk assessment shows low impact - Customer agrees to Delta FAI approach

Delta FAI Process: - Inspect only characteristics affected by change - Document as Partial FAI or reference previous FAI - Risk assessment and justification documented

22.3.1.4 Counterfeit Parts Prevention

Counterfeit parts pose significant risk to aerospace safety and represent a growing concern.

Types of Counterfeits **Counterfeit Categories:**

1. **Fraudulent Material:**

- Wrong alloy (e.g., aluminum instead of titanium)
- Substandard properties (below specification)
- Falsified material certifications

2. **Out-of-Specification Parts:**

- Dimensions incorrect
- Heat treatment not performed or incorrect
- Plating/coating not applied or wrong type

3. **Recycled/Reclaimed Parts:**

- Removed from scrapped aircraft
- Cleaned and re-marked
- Unknown service history, potentially fatigued or damaged

4. **Re-Marked Parts:**

- Legitimate parts with altered markings (part number, date code)
- Misrepresented as newer or different specification

5. **Cloned/Copied Parts:**

- Unauthorized reproductions
- May look identical but lack proper materials, processes, or testing

Sources of Risk Where Counterfeits Enter Supply Chain: - Unauthorized distributors (brokers, surplus dealers) - Online marketplaces - Offshore suppliers with poor controls - Obsolete parts (no longer manufactured, high demand) - High-value parts (semiconductors, connectors, fasteners)

Prevention Strategies Purchasing Controls:

1. Authorized Sources:

- Purchase from OEM or franchised distributors
- Maintain Approved Supplier List (ASL)
- Avoid brokers and “gray market” suppliers

2. Supplier Qualification:

- Assess supplier quality systems (AS9100 certification)
- Audit suppliers (on-site evaluation)
- Verify supplier legitimacy (DUNS number, business licenses)

3. Purchase Order Requirements:

- Specify traceability requirements
- Require certifications and test reports
- Flow down counterfeit prevention requirements

Verification at Receipt:

4. Visual Inspection:

- Examine packaging (professional, consistent with OEM)
- Check markings (font, spacing, location, legibility)
- Look for signs of re-marking (grinding, over-stamping)
- Compare to known good samples or photos

5. Documentation Review:

- Verify material certifications authentic (contact issuer if suspect)
- Check traceability to original manufacturer
- Confirm date codes and lot numbers consistent

6. Testing and Analysis:

- Chemical analysis (verify alloy)
- Mechanical testing (tensile, hardness)
- Dimensional inspection (verify to drawing)
- X-ray fluorescence (XRF) for material ID
- Destructive testing of sample (metallography, cross-section)

Process Controls:

7. Segregation:

- Separate material from authorized sources from suspect sources
- Quarantine pending verification

8. Traceability:

- Track material from receipt through installation
- Serial number tracking for critical parts

- Material certifications retained with job

Awareness and Training:

9. Personnel Training:

- Recognize indicators of counterfeits
- Reporting procedures for suspect parts
- Consequences of counterfeits (safety, legal)

10. Industry Collaboration:

- Report counterfeits to GIDEP (Government-Industry Data Exchange Program)
- Share information with customers and industry
- Participate in anti-counterfeit organizations (SAE G-19 Committee)

Response to Suspect/Counterfeit Parts **Immediate Actions:** 1. **Quarantine:** Segregate part, prevent use or shipment 2. **Notify:** Inform customer, supplier, and internal management 3. **Report:** Submit report to GIDEP and regulatory agencies 4. **Investigate:** Trace source, determine extent (how many received, used, shipped) 5. **Contain:** Inspect similar parts, recall if necessary

Corrective Action: - Root cause analysis (how did counterfeit enter supply chain?) - Strengthen controls (tighten supplier qualification, enhance inspection) - Supplier corrective action (if supplier provided counterfeit) - Prevent recurrence

Documentation: - Counterfeit part report with photos, descriptions - Analysis results (testing, inspection) - Investigation findings - Corrective actions taken

22.3.2 ISO 13485 (Medical Devices)

ISO 13485 is the quality management standard for organizations involved in the design, production, installation, and servicing of medical devices.

Overview

ISO 13485:2016 (current version) specifies requirements for QMS where an organization needs to demonstrate ability to provide medical devices and related services that consistently meet customer and regulatory requirements.

Scope: Applies to: - Medical device manufacturers - Contract manufacturers of medical devices - Component/material suppliers to medical device manufacturers - Sterilization, installation, and servicing organizations

Regulatory Connection: - Basis for regulatory submissions (FDA 510(k), PMA, EU MDR) - Recognized by regulatory agencies worldwide - Required for CE marking in Europe (EU Medical Device Regulation)

Differences from ISO 9001

While ISO 13485 is based on ISO 9001, there are important differences:

Aspect	ISO 9001	ISO 13485
Focus	Customer satisfaction, continual improvement	Regulatory compliance, risk management
Continual Improvement	Emphasized throughout	Required only where mandated by regulation
Risk	Risk-based thinking	Risk management per ISO 14971 required
Documentation	Flexible, organization determines	Prescriptive, detailed documentation required
Design Controls	Optional (can be excluded)	Mandatory if organization designs devices
Validation	Special processes	Broader validation requirements
Regulatory	General	Specific regulatory requirements integrated

Key Takeaway: ISO 13485 prioritizes **compliance and consistency** over improvement. Once validated, processes should remain unchanged unless improvement is required by regulation or risk management.

22.3.2.1 Design Controls and Risk Management

Medical devices require rigorous design controls to ensure safety and effectiveness.

Design and Development Process Design Control Phases (based on FDA 21 CFR 820.30 and ISO 13485):

1. **Design Planning:** Define design project, milestones, responsibilities, verification/validation activities
2. **Design Inputs:** Establish requirements (functional, performance, safety, regulatory)
3. **Design Outputs:** Generate design specifications (drawings, BOMs, software code)
4. **Design Review:** Evaluate design at key stages
5. **Design Verification:** Confirm outputs meet inputs ("Did we build it right?")
6. **Design Validation:** Ensure device meets user needs ("Did we build the right thing?")
7. **Design Transfer:** Transition from design to production
8. **Design Changes:** Control modifications to design

Design Inputs Requirements to Define: - Intended use and user (patient population, clinical setting) - Performance requirements (accuracy, range, resolution) - Safety requirements (biocompatibility, electrical safety, sterility) - Regulatory and standards requirements (FDA, ISO, IEC standards) - Usability requirements (human factors) - Interfaces (compatibility with other devices, connectors) - Labeling and packaging - Shelf life and storage

Example: Surgical Instrument Handle: - Material: Biocompatible per ISO 10993 - Strength: Withstand 500 N force without deformation - Sterilization: Compatible with steam autoclave

(134°C) - Ergonomics: Comfortable grip for 2-hour procedure - Corrosion resistance: No rust after 100 autoclave cycles - Marking: Laser-etched part number and lot number

Design Outputs Outputs Must: - Meet design input requirements - Include or reference acceptance criteria - Specify characteristics essential for safe and proper use - Include instructions for manufacture, inspection, testing, installation, servicing

Design Output Examples: - Engineering drawings with tolerances - Bills of Materials (BOMs) - Manufacturing procedures and work instructions - Inspection and test procedures - Software code and documentation (for software-enabled devices) - Labeling and Instructions for Use (IFU) - Packaging specifications

Design Verification Verification Activities: Testing and analysis to confirm design outputs meet design inputs

Verification Methods: - Dimensional inspection (confirm drawings accurate) - Material testing (confirm material properties) - Bench testing (confirm performance specs met) - Software testing (unit tests, integration tests) - Analysis and simulation (FEA, CFD)

Example Verification Tests: - Tensile test to verify material strength meets requirement - Dimension inspection to verify critical dimensions within tolerance - Corrosion test to verify resistance per specification

Verification Documentation: - Test protocols (procedure, acceptance criteria) - Test results (data, pass/fail) - Traceability matrix (link outputs to inputs to verification)

Design Validation Validation: Confirmation that device meets user needs and intended use in actual or simulated use conditions

Validation Methods: - Clinical trials (patients, clinical settings) - Simulated use testing (bench testing mimicking real use) - User studies (physicians, nurses, technicians use device) - Human factors validation (usability, use errors)

Example Validation: Surgical instrument used in clinical trial by surgeons: - Evaluate usability (comfortable, easy to manipulate) - Assess performance (achieves intended surgical outcome) - Identify use errors or misuse - Confirm labeling adequate

Validation Documentation: - Validation protocol - Clinical data - User feedback - Pass/fail assessment

Risk Management (ISO 14971) ISO 14971: Application of risk management to medical devices (harmonized with ISO 13485)

Risk Management Process:

1. Risk Analysis:

- Identify hazards (energy hazards, biological, chemical, mechanical, etc.)
- Identify foreseeable hazardous situations (misuse, failure modes)
- Estimate risk (severity × probability)

2. Risk Evaluation:

- Compare risk to acceptance criteria

- Determine if risk reduction needed

3. Risk Control:

- Implement risk control measures:
 - Inherent safety by design (preferred)
 - Protective measures (guards, alarms, interlocks)
 - Information for safety (warnings, training)
- Verify risk control effectiveness

4. Residual Risk Evaluation:

- Evaluate residual risk after controls
- Ensure acceptable
- Compare benefit vs. remaining risk

5. Risk Management Report:

- Document risk management activities
- Management approval

6. Post-Market Surveillance:

- Monitor devices in field for new hazards
- Update risk management file

Example Risk Analysis (Surgical Instrument):

Hazard	Hazardous Situation	Harm	Severity	Probability	Risk	Control Measure
Sharp edges	User cuts hand during use	Laceration	Minor	Probable	Medium	Redesign handle to eliminate sharp edges; add warning in IFU
Corrosion	Instrument corrodes, breaks during use	Patient injury	Critical	Remote	Medium	Specify corrosion-resistant material (316 SS); validate corrosion resistance
Misidentification	Wrong instrument used in surgery	Incorrect procedure	Serious	Occasional	High	Clear labeling; color-coding; training

22.3.2.2 Traceability Requirements

Medical device traceability is critical for safety and regulatory compliance, enabling recalls and investigations.

Traceability Scope **Traceability Required for:** - **Implantable devices:** Devices implanted in body (pacemakers, orthopedic implants, stents) - **Life-supporting/life-sustaining devices:** De-

vices essential to life (ventilators, dialysis machines, infusion pumps) - **High-risk devices:** Class III devices (per FDA classification or equivalent) - **Regulatory requirement:** FDA 21 CFR 821 (Tracking), EU MDR Article 27 (UDI)

Even for non-tracked devices, traceability to manufacturing lot is typically required.

Unique Device Identification (UDI) **UDI System** (FDA and EU MDR requirement): - Unique identifier for each device model/version - Enables tracking through distribution chain to patient - Facilitates recalls and adverse event reporting

UDI Components: - **Device Identifier (DI):** Specific to device model/version - **Production Identifier (PI):** Lot/batch number, serial number, expiration date, manufacturing date

UDI Label: - Human-readable text - Machine-readable (barcode or RFID) - On device label and packaging

Example UDI:

(01)00844588003288 (Device Identifier – GTIN)
(17)250131 (Expiration Date – YYMMDD)
(10)LOT12345 (Lot Number)
(21)SN98765 (Serial Number)

Lot and Serial Number Tracking **Lot/Batch Number:** - Group of devices manufactured under same conditions - Enables traceability to manufacturing date, materials used, processes performed - Facilitates targeted recalls (recall specific lot, not all devices)

Serial Number: - Unique to individual device - Required for implantable and life-supporting devices - Enables traceability to specific patient (important for implants)

Traceability Matrix:

Device S/N	Lot Number	Mfg Date	Material Lot	Process Certs	Customer	Patient (if implant)
SN12345	LOT-2024-05	2024-05-15	MAT-55443	HT-2024-120	Hospital ABC	John Doe (if implant)
SN12346	LOT-2024-05	2024-05-15	MAT-55443	HT-2024-120	Hospital ABC	

Device History Record (DHR) **DHR:** Compilation of records for each manufactured device (or lot), documenting that device was manufactured per Device Master Record (DMR)

DHR Contents: - Quantity manufactured - Quantity released for distribution - Acceptance records (inspection results, tests) - Manufacturing date - Lot or serial number - Label used (lot/serial, UDI) - Deviations or nonconformances - Operator signatures and dates

Example DHR Contents for Machined Implant Component: - Material certification (implant-grade titanium, per ASTM F136) - Machining traveler (operations performed, operators, dates) - Inspection records (dimensional report, surface finish) - Cleaning and passivation certification - Packaging and labeling record - Sterilization certification (if sterilized by manufacturer) - Release approval signature

Distribution Records **Distribution Records:** Track where devices shipped (enables recalls)

Information to Record: - Device identification (part number, lot/serial) - Quantity - Customer name and address - Date of shipment - Purchase order or invoice number

Retention: Typically life of device + several years (FDA: 2 years beyond device life expectancy)

Recall Process **Recall Triggers:** - Safety issue identified (potential harm to patients) - Nonconformance affecting device performance - Regulatory requirement (FDA mandates recall)

Recall Process: 1. **Identify Affected Devices:** Use traceability records to determine lot/serial numbers affected 2. **Notify:** Inform customers (hospitals, distributors), regulatory agencies (FDA, EU Notified Body) 3. **Communicate:** Provide instructions (return, destroy, modify) 4. **Track Effectiveness:** Verify devices retrieved or action taken 5. **Investigate and Correct:** Root cause analysis, corrective action to prevent recurrence 6. **Report:** Submit recall status reports to regulatory agencies

Example Recall Scenario: - Issue: Heat treatment found out of specification for Lot 2024-05 (affects hardness, may fail in use) - Affected Devices: All devices in Lot 2024-05 (serial numbers SN12340-SN12360) - Action: Recall and replace - Traceability: Distribution records show devices shipped to three hospitals - Notification: Contact hospitals, request return of unused devices, track devices already implanted (may need monitoring or replacement)

22.3.2.3 Clean Room and Contamination Control

Many medical devices require manufacture in controlled environments to prevent contamination.

Clean Room Classifications **ISO 14644-1:** Classification of air cleanliness by particle count

ISO Class	Max Particles >=0.5 µm per m^3	Equivalent US Fed Std 209E	Typical Application
ISO 3	35	Class 1	Semiconductor, advanced medical
ISO 5	3,520	Class 100	Sterile device assembly (implants)
ISO 7	352,000	Class 10,000	Medical device assembly (non-sterile)
ISO 8	3,520,000	Class 100,000	Medical device packaging

ISO 5 (Class 100) commonly required for: - Implantable device assembly - Sterile device final assembly and packaging - Aseptic processing

ISO 7/8 used for: - Non-sterile device manufacturing - Component fabrication before cleaning - Packaging of non-sterile devices

Clean Room Design **HVAC System:** - HEPA filtration (removes 99.97% of particles $\geq 0.3 \mu\text{m}$)
- Positive pressure (air flows out, preventing unfiltered air from entering) - Air changes per hour (ACH) based on class (ISO 5: 240-480 ACH) - Temperature and humidity control (typically 68-72°F, 30-60% RH)

Surfaces: - Smooth, non-shedding materials (epoxy floors, stainless steel, PVC walls) - Cleanable (no porous materials, carpet, or fabric) - Coved corners (no 90° corners where particles accumulate)

Layout: - Airlocks/gowning rooms (transition from uncontrolled to controlled areas) - Progressive cleanliness (ISO 8 □ ISO 7 □ ISO 5) - Material and personnel flow (minimize contamination risk)

Personnel Practices Gowning: - Coveralls, hoods, shoe covers, gloves, masks - Gowning level based on clean room class - Trained gowning procedures (sequence, no exposed skin/hair)

Behavior: - No cosmetics, perfume, jewelry - Minimal talking (particles from mouth) - Controlled movements (avoid generating particles) - Hand washing and disinfection before gowning

Training: - Clean room protocols - Gowning procedures - Contamination sources and prevention - Emergency procedures

Environmental Monitoring Particle Counting: - Airborne particle counts (ISO class verification) - Frequency: Daily or continuous (automated systems) - Locations: Workstations, air supply, critical areas

Microbial Monitoring (for sterile environments): - Air sampling (settle plates, active air samplers)
- Surface sampling (contact plates, swabs) - Personnel monitoring (glove prints, gown contact) - Frequency: Weekly or per validated schedule

Action Limits: - Alert limits (investigate if exceeded) - Action limits (stop production, investigate, correct)

Example Monitoring: - ISO 5 clean room: - Particle count: $<3,520$ particles $\geq 0.5 \mu\text{m}$ per m^3 (specification limit) - Microbial: <1 CFU/plate (settle plate, 4-hour exposure) - If exceeded: Investigate (HVAC issue? Gowning breach? Process contamination?)

Contamination Control in CNC Machining **Machining in Clean Room:** - Typically **not** performed in clean room (chips, coolant, dust) - Machining done in standard manufacturing area - Parts cleaned and brought into clean room for assembly/packaging

Cleaning Processes: - Remove machining oils, chips, particles - Methods: - Ultrasonic cleaning (high-frequency agitation in cleaning solution) - Aqueous cleaning (detergent wash, rinses) - Solvent cleaning (isopropyl alcohol, acetone) - Passivation (for stainless steel, titanium: removes free iron, enhances corrosion resistance) - Validation: Cleanliness testing (particulate count, residue analysis)

Packaging: - Double-bagging (inner bag sealed in clean room, outer bag for shipping) - Tyvek pouches (breathable for sterilization) - Rigid containers for delicate or sharp devices

22.3.3 IATF 16949 (Automotive Quality)

IATF 16949 is the quality management standard for automotive industry suppliers, emphasizing defect prevention, variation reduction, and waste minimization.

Overview

IATF 16949:2016 (current version) combines ISO 9001:2015 with automotive-specific requirements.

Governing Body: IATF (International Automotive Task Force)

Applicable to: - Automotive parts and component manufacturers - Suppliers to automotive OEMs (GM, Ford, Stellantis, Toyota, VW, etc.)

Not Applicable to: - After-market parts - Non-automotive industries

Relationship to ISO 9001: - IATF 16949 **requires** ISO 9001:2015 compliance - Adds automotive-specific requirements - Cannot be certified to IATF 16949 without meeting ISO 9001

22.3.3.1 Advanced Product Quality Planning (APQP)

APQP is a structured product development process ensuring customer requirements are met and products launched successfully.

APQP Purpose

- Facilitate communication between customer and supplier
- Ensure all required steps completed before production launch
- Allocate resources effectively
- Identify required changes early
- Avoid late changes (costly and time-consuming)
- Deliver quality product on time at lowest cost

APQP Phases **Phase 1: Plan and Define Program** - Voice of the Customer (VOC): Understand customer needs and expectations - Design goals (performance, reliability, cost) - Reliability and quality goals - Preliminary BOM - Preliminary process flow chart - Product and Process Special Characteristics - Product Assurance Plan - Management support

Phase 2: Product Design and Development - Design FMEA (DFMEA): Identify potential design failures - Design for Manufacturing (DFM) and Design for Assembly (DFA) - Design verification (testing, analysis) - Design reviews - Prototype build and testing - Engineering drawings and specifications - Engineering change management - Team feasibility commitment

Phase 3: Process Design and Development - Process FMEA (PFMEA): Identify potential process failures - Process flow diagram - Control Plan (Pre-Launch) - Work instructions and procedures - Measurement Systems Analysis (MSA) plan - Packaging standards and specifications - Management support

Phase 4: Product and Process Validation - Validation testing (product performance in actual conditions) - Production trial run - Measurement Systems Analysis (MSA) execution - Process capability studies (Ppk, Cpk) - Production Part Approval Process (PPAP) submission - Control Plan (Production) - Quality Planning sign-off and management support

Phase 5: Feedback, Assessment, and Corrective Action - Production launch - Reduced variation - Improved customer satisfaction - Lessons learned - Continuous improvement

APQP Deliverables (Outputs) **Key APQP Deliverables:** - Design FMEA (DFMEA) - Process FMEA (PFMEA) - Control Plan (Pre-Launch and Production) - Process Flow Diagram - Work Instructions - Measurement Systems Analysis (MSA) - Preliminary and Production Process Capability Studies - Production Part Approval Process (PPAP)

22.3.3.2 Production Part Approval Process (PPAP)

PPAP demonstrates that supplier understands customer requirements and process can consistently meet those requirements at production volumes.

When PPAP is Required **New Part Launch:** New part number, new supplier for existing part

Engineering Change: Revision affecting form, fit, function, or performance

Manufacturing Change: - New or modified tooling (excluding perishable tools) - New or modified manufacturing process - New or modified equipment - Transfer to different facility - Change in material or supplier

Other Triggers: - Significant production interruption (shutdown >1 year) - Customer request - Nonconformance correction

PPAP Submission Levels Customers specify PPAP submission level (1-5):

Level	Requirements Submitted to Customer	Records Retained by Supplier
1	Part Submission Warrant (PSW) only	All supporting documentation
2	PSW + sample(s) + limited supporting data	All supporting documentation
3	PSW + sample(s) + complete supporting data	None (all submitted)
4	PSW + complete supporting data (samples if requested)	All supporting documentation
5	PSW + sample(s) + complete supporting data + customer review at supplier site	All supporting documentation

Most common: Level 3 (full submission)

- PPAP Elements (18 Requirements)**
- 1. Design Records:** - Engineering drawings - Specifications - CAD data (if applicable)
 - 2. Engineering Change Documents** (if applicable): - Engineering Change Notices (ECNs) - Effectivity of change
 - 3. Engineering Approval** (if required by customer): - Customer approval of design (before production)
 - 4. Design FMEA** (if responsible for design): - Documented design risk analysis
 - 5. Process Flow Diagram:** - Visual representation of manufacturing sequence
 - 6. Process FMEA:** - Documented process risk analysis
 - 7. Control Plan:** - Production Control Plan (how process controlled)
 - 8. Measurement Systems Analysis (MSA):** - Gage R&R studies for key measurement systems
 - 9. Dimensional Results:** - Full dimensional inspection per drawing (100% of characteristics) - Sample size: typically 10-25 parts depending on process - Results documented (mean, range, Cpk for key dimensions)
 - 10. Material/Performance Test Results:** - Material certifications - Mechanical property tests (tensile, hardness) - Performance tests (function, durability, reliability) - Chemical analysis
 - 11. Initial Process Studies:** - Process capability studies (Ppk, Cpk) - Minimum Ppk ≥ 1.67 , Cpk ≥ 1.33 (typical requirements)
 - 12. Qualified Laboratory Documentation:** - Accreditation certificates (ISO 17025) for labs performing tests
 - 13. Appearance Approval Report (AAR)** (if applicable): - For parts with appearance requirements (color, texture, gloss) - Customer representative approves appearance
 - 14. Sample Production Parts:** - Quantity per customer requirement (often 300-500 parts for production launch) - Taken from production run, not cherry-picked
 - 15. Master Sample:** - Sample part retained by supplier as reference - Used for comparison in future (appearance, dimensions)
 - 16. Checking Aids** (if applicable): - Gages, fixtures, templates used for inspection
 - 17. Customer-Specific Requirements:** - Any additional requirements specified by customer
 - 18. Part Submission Warrant (PSW):** - Cover sheet summarizing PPAP submission - Declaration that requirements met - Authorized signature

Process Capability Requirements **Initial Process Study** (short-term capability): - Ppk (Process Performance Index) - Minimum: Ppk ≥ 1.67 (typically required by automotive customers) - Data from initial production run (before process stabilized)

Ongoing Process Capability: - Cpk (Process Capability Index) - Minimum: Cpk ≥ 1.33 (typically required) - Data from stable production (long-term)

If Capability Insufficient: - Corrective action required - Increase inspection frequency (100% inspection if Cpk <1.00) - Process improvement (reduce variation) - Re-submit PPAP after improvement

22.3.3.3 Measurement Systems Analysis (MSA)

MSA evaluates measurement systems (gages, instruments, procedures) to ensure they provide accurate and repeatable data.

Why MSA Matters **Measurement System Variation:** - Total observed variation = Part variation + Measurement variation - If measurement variation is large, difficult to assess part variation - Inadequate measurement systems lead to bad decisions (accepting bad parts, rejecting good parts)

MSA Objectives: - Quantify measurement system variation - Determine if measurement system acceptable for application - Identify sources of variation (gage, operator, part-to-part) - Improve measurement system if necessary

Types of MSA Studies **Gage R&R** (Repeatability and Reproducibility): - **Repeatability:** Variation when same operator measures same part multiple times (equipment variation) - **Reproducibility:** Variation between different operators measuring same part (appraiser variation)

Bias: - Difference between observed average measurement and true value (accuracy)

Linearity: - Bias consistent across measurement range (bias same for small and large values?)

Stability: - Measurement system variation over time (does gage drift?)

Gage R&R Study **Gage R&R** is most common MSA study, evaluating repeatability and reproducibility.

Study Design: - **Parts:** 10 parts representing process variation (low, medium, high dimensions) - **Operators:** 3 operators (appraisers) - **Trials:** Each operator measures each part 3 times - **Total measurements:** $10 \text{ parts} \times 3 \text{ operators} \times 3 \text{ trials} = 90 \text{ measurements}$

Procedure: 1. Select 10 parts spanning process range (consecutively produced preferred) 2. Number parts (1-10) 3. Operator A measures all 10 parts (Trial 1) 4. Operator A repeats (Trials 2 and 3) 5. Operator B measures all 10 parts (3 trials) 6. Operator C measures all 10 parts (3 trials) 7. Randomize measurement order (minimize bias)

Analysis (typically performed with software: Minitab, statistical calculators): - Calculate repeatability (within-operator variation) - Calculate reproducibility (between-operator variation) - Calculate Gage R&R (total measurement system variation) - Compare to total variation and tolerance

Gage R&R Results:

$$\text{Gage R&R} = \sqrt{(\text{Repeatability}^2 + \text{Reproducibility}^2)}$$

$$\%GRR = (\text{Gage R&R} / \text{Total Variation}) \times 100$$

Acceptance Criteria: - $\%GRR < 10\%$: Acceptable measurement system - $10\% \leq \%GRR < 30\%$: Marginal (may be acceptable depending on application) - $\%GRR \geq 30\%$: Unacceptable (improve measurement system)

Alternative Criteria (% of tolerance): - $\%GRR < 10\% \text{ of tolerance}$: Acceptable - $10\%-30\% \text{ of tolerance}$: Marginal - $>30\% \text{ of tolerance}$: Unacceptable

Example Gage R&R Result: - $\%GRR = 15\%$ (marginal) - Repeatability = 12% (equipment variation dominates) - Reproducibility = 5% (operators fairly consistent) - **Interpretation:** Gage has excessive variation, primarily from equipment. **Action:** Investigate gage condition (worn anvils? Calibration issue?), consider better gage or measurement method.

Improving Measurement Systems If Gage R&R Unacceptable:

Repeatability Issues (equipment variation): - Check gage calibration - Inspect gage for wear or damage (anvils, contacts) - Improve gage resolution (finer increments) - Use better quality gage (higher precision) - Control environmental factors (temperature, vibration) - Improve part clamping or fixturing (reduce setup variation)

Reproducibility Issues (operator variation): - Improve measurement procedure (standardize technique) - Provide training (consistent use of gage) - Simplify measurement (reduce judgment) - Use fixtures or guides (consistent part positioning) - Automate measurement (CMM, vision system)

Attribute Agreement Analysis: For attribute gages (go/no-go, pass/fail), use **Attribute Agreement Analysis:** - Evaluate agreement among operators - Evaluate agreement with known standard - Metrics: % agreement, Kappa statistic

22.3.3.4 Statistical Process Control (SPC)

SPC uses statistical methods to monitor and control processes, detecting changes before defects are produced.

Control Charts **Control Chart:** Graph of process data over time with control limits

Purpose: - Distinguish common cause variation (inherent to process) from special cause variation (assignable cause) - Detect process shifts or trends - Determine when action needed (special cause) vs. leave alone (common cause)

Control Chart Components:

UCL (Upper Control Limit) ----- (statistical limit, typically $+\/- 3\sigma$)



CL (Center Line / Process Mean) -----



LCL (Lower Control Limit) -----

Time →

Control Limits vs. Specification Limits: - **Control Limits:** Statistical limits based on process variation (+/-3 standard deviations from mean) - **Specification Limits:** Customer requirements (tolerances on drawing) - **Not the same:** Process can be in control but produce out-of-spec parts ($Cpk < 1.0$)

Types of Control Charts Variable Data (measured characteristics: length, weight, temperature):

X-bar and R Chart (most common): - **X-bar chart:** Monitors process mean (average of subgroup) - **R chart:** Monitors process variation (range of subgroup) - Subgroup size: typically 4-5 parts

X-bar and S Chart: - Similar to X-bar and R, but uses standard deviation (S) instead of range - Preferred for larger subgroups (>10)

Individuals (I) and Moving Range (MR) Chart: - For individual measurements (subgroup size = 1) - Used when parts produced slowly or expensive to measure multiple

Attribute Data (count or proportion: defects, pass/fail):

p-Chart: Proportion defective (e.g., % scrap)

np-Chart: Number defective (e.g., defective parts per day)

c-Chart: Count of defects (e.g., scratches per panel)

u-Chart: Defects per unit (e.g., defects per 100 parts)

Control Chart Interpretation Process In Control: - Points randomly distributed around center line - No points outside control limits - No patterns or trends

Process Out of Control (special cause present):

Rule 1: One or more points beyond control limits ($+/-3\sigma$) - **Action:** Investigate immediately, find cause, correct

Rule 2: 8 consecutive points on one side of center line - **Action:** Process mean shifted, adjust process

Rule 3: 6 consecutive points increasing or decreasing (trend) - **Action:** Tool wear, temperature drift, material change

Rule 4: 14 points alternating up and down (oscillation) - **Action:** Systematic variation (two operators, two machines)

Rule 5: 2 out of 3 consecutive points beyond $+/-2\sigma$ (same side) - **Action:** Process trending toward out-of-control

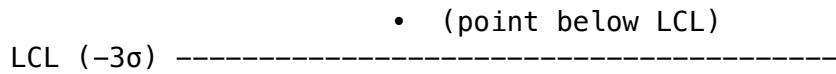
Example Control Chart Analysis:

UCL ($+3\sigma$) -----

• • • •

CL -----

•



Interpretation: Point below LCL indicates special cause (e.g., incorrect setup, tool breakage).

Implementing SPC Steps to Implement SPC:

1. **Select Characteristics to Monitor:**
 - Critical dimensions (affecting fit, function, safety)
 - Characteristics with history of problems
 - Customer-specified requirements
2. **Select Control Chart Type:**
 - Variable or attribute data?
 - Subgroup size and frequency
3. **Collect Baseline Data:**
 - 20-25 subgroups minimum
 - Process stable and in control (no special causes)
4. **Calculate Control Limits:**
 - Use baseline data to compute mean and standard deviation
 - Calculate UCL, CL, LCL
5. **Plot and Monitor:**
 - Plot ongoing data
 - Check for out-of-control conditions
 - Investigate and correct special causes
6. **Continuous Improvement:**
 - Narrow control limits as process improves
 - Reduce common cause variation (process improvement projects)

Subgroup Frequency: - Depends on production rate and process stability - Examples: - High-volume production: Every hour (subgroup of 5 parts) - Low-volume: Every shift or daily - Unstable process: More frequent (every setup, every 30 minutes)

SPC Benefits: - Early detection of problems (before defects produced) - Reduced scrap and rework - Consistent quality - Data-driven decisions (not gut feel) - Documentation of process stability

22.3.4 ISO 14001 (Environmental Management)

ISO 14001:2015 specifies requirements for an Environmental Management System (EMS) to help organizations improve environmental performance.

Overview

Scope: Any organization wanting to: - Establish, implement, maintain environmental management system - Improve environmental performance - Comply with environmental regulations - Achieve sustainability goals

Not Certification Required (but commonly pursued alongside ISO 9001)

Benefits: - Regulatory compliance (EPA, state, local) - Reduced waste and resource consumption
- Cost savings (energy, materials, waste disposal) - Improved reputation (corporate responsibility, "green" image) - Customer requirement (increasingly common)

Key Requirements

Environmental Policy: Commitment to environmental protection, compliance, continual improvement

Environmental Aspects: Identify activities, products, services that impact environment (emissions, waste, energy use)

Legal and Other Requirements: Identify applicable environmental regulations and ensure compliance

Objectives and Targets: Measurable environmental goals (reduce waste 20%, reduce energy 10%)

Operational Controls: Procedures to control environmental impacts (waste segregation, spill response, emissions monitoring)

Emergency Preparedness: Plans for environmental emergencies (spills, fires, releases)

Monitoring and Measurement: Track environmental performance (waste generated, emissions, energy)

Compliance Evaluation: Verify compliance with regulations

Internal Audits: Audit EMS effectiveness

Management Review: Review environmental performance

Relevance to CNC Manufacturing

Environmental Aspects in CNC Shops: - Coolant and oil disposal (hazardous waste) - Metal chips and swarf (recycling, scrap value) - Energy consumption (machines, HVAC, lighting) - Air emissions (oil mist, VOCs from solvents) - Wastewater (wash operations)

Environmental Controls: - Coolant recycling and proper disposal (not down drain) - Chip recycling programs (sell scrap to metal recyclers) - Energy-efficient equipment (LED lighting, variable-speed drives) - Spill containment (secondary containment for oil tanks) - Waste segregation (hazardous vs. non-hazardous)

22.3.5 ISO 45001 (Occupational Health and Safety)

ISO 45001:2018 specifies requirements for an Occupational Health and Safety (OH&S) Management System to reduce workplace injuries and illnesses.

Overview

Scope: Any organization wanting to: - Improve worker safety and health - Eliminate hazards and reduce risks - Comply with OH&S regulations (OSHA, etc.)

Replaces: OHSAS 18001 (older OH&S standard)

Benefits: - Reduced workplace injuries and illnesses - Improved safety culture - Regulatory compliance (OSHA) - Lower insurance costs (workers' compensation) - Reduced downtime from accidents - Improved employee morale and retention

Key Requirements

OH&S Policy: Commitment to safe workplace, hazard elimination, worker participation

Hazard Identification and Risk Assessment: Identify workplace hazards (machinery, chemicals, ergonomic) and assess risks

Legal and Other Requirements: Identify applicable OH&S regulations (OSHA, state)

OH&S Objectives: Measurable safety goals (zero lost-time injuries, reduce incidents 50%)

Operational Controls: Procedures to control hazards (lockout/tagout, machine guarding, PPE)

Emergency Preparedness: Plans for emergencies (fire, chemical spill, medical emergency)

Monitoring and Measurement: Track safety performance (injury rates, near-misses)

Incident Investigation: Investigate injuries and near-misses, implement corrective action

Internal Audits: Audit OH&S system

Management Review: Review safety performance

Relevance to CNC Manufacturing

Hazards in CNC Shops: - **Machinery:** Rotating spindles, cutting tools, moving axes (pinch points, entanglement) - **Flying chips and debris:** Eye injuries - **Sharp edges:** Cuts and lacerations - **Heavy parts:** Lifting injuries, crushed fingers/toes - **Noise:** Hearing loss (machines, air guns) - **Chemicals:** Coolant (skin irritation, respiratory), solvents, degreasers - **Slips and falls:** Oil/coolant spills, chips on floor - **Electrical:** High-voltage equipment

Safety Controls: - **Machine guarding:** Enclosures, interlocks (machine won't run if door open) - **Lockout/Tagout (LOTO):** De-energize machines before maintenance - **Personal Protective Equipment (PPE):** Safety glasses, gloves, steel-toed boots, hearing protection - **Training:** Safe machine operation, hazard recognition, emergency procedures - **Housekeeping:** Clean floors (remove chips, absorbent for spills) - **Ergonomics:** Lifting aids (hoists, carts), adjustable-height workstations - **Coolant management:** Ventilation, skin protection, coolant maintenance (prevent bacteria growth)

Integration with QMS: - ISO 9001, ISO 14001, and ISO 45001 share common structure (Annex SL) - Many organizations implement integrated management system (quality, environment, safety) - Synergies: Audits combined, processes integrated, common documentation

Summary

Industry-specific quality standards build upon ISO 9001 with additional requirements tailored to unique risks and regulatory environments:

- **AS9100** (Aerospace): Safety-critical, stringent traceability, configuration management, counterfeit prevention
- **ISO 13485** (Medical Devices): Regulatory compliance focus, design controls, risk management, traceability, clean room
- **IATF 16949** (Automotive): Defect prevention, APQP, PPAP, MSA, SPC, continual improvement
- **ISO 14001** (Environmental): Environmental performance, waste reduction, regulatory compliance
- **ISO 45001** (Safety): Worker safety, hazard elimination, risk reduction

Understanding these standards is essential for CNC manufacturers serving regulated industries. Compliance opens market opportunities, demonstrates capability, and drives operational excellence.

Key Takeaways

1. **AS9100 is ISO 9001 + aerospace requirements** (product safety, counterfeit prevention, OTD, FOD, critical items, configuration management, work transfer, human factors)
 2. **First Article Inspection (AS9102)** verifies manufacturing processes capable before production
 3. **Counterfeit parts pose significant risk** in aerospace; prevention requires supplier controls, verification, and traceability
 4. **ISO 13485 emphasizes regulatory compliance over continual improvement** (stability and consistency prioritized)
 5. **Design controls and risk management (ISO 14971)** are critical for medical devices
 6. **Traceability and UDI** enable recalls and patient safety in medical devices
 7. **Clean rooms prevent contamination** for sterile and implantable medical devices
 8. **APQP structures product development** to ensure requirements met before launch
 9. **PPAP demonstrates process capability** and understanding of requirements
 10. **MSA (Gage R&R) validates measurement systems** to ensure data reliability
 11. **SPC uses control charts** to detect process changes before defects produced
 12. **Environmental (ISO 14001) and Safety (ISO 45001) management systems** can integrate with QMS
-

Review Questions

1. What are the key differences between ISO 9001 and AS9100?
2. When is First Article Inspection (FAI) required per AS9102?
3. What are the three AS9102 forms and their purposes?
4. Describe five controls to prevent counterfeit parts in aerospace manufacturing.
5. How does ISO 13485 differ from ISO 9001 in focus and approach?

6. What is the purpose of design controls and risk management (ISO 14971) in medical device manufacturing?
 7. Explain the Unique Device Identification (UDI) system and its purpose.
 8. What are the five phases of APQP?
 9. What are the 18 elements of PPAP?
 10. What is Gage R&R, and what are the acceptance criteria?
 11. Describe the purpose of control charts and how to interpret them.
 12. What environmental aspects in CNC manufacturing should be controlled per ISO 14001?
 13. What workplace hazards in CNC shops should be addressed per ISO 45001?
-

Practical Exercises

Exercise 1: AS9102 First Article Inspection

Create a simplified AS9102 Form 2 for a machined part: 1. Select a simple machined part (shaft, bushing, bracket) 2. List 10 characteristics from the drawing (dimensions, material, surface finish) 3. Create Form 2 with columns: Char #, Description, Requirement, Method, Results, Accept/Reject 4. Fill in inspection results (make up realistic data) 5. Identify any characteristics requiring Form 3 (material certs, heat treat, etc.)

Exercise 2: Counterfeit Prevention Plan

Develop a counterfeit prevention plan for your shop: 1. Identify materials and parts at risk (purchased items, high-value, obsolete) 2. List authorized suppliers for each category 3. Define incoming inspection and verification procedures 4. Describe training for personnel (how to recognize counterfeits) 5. Define response process for suspect parts

Exercise 3: APQP for New Product

Outline an APQP plan for a new product launch: 1. Choose a new product (machined component, assembly) 2. For each APQP phase, list key activities and deliverables 3. Identify special characteristics (critical dimensions, processes) 4. Create preliminary process flow diagram 5. Identify PPAP requirements (measurements, tests, capability studies)

Exercise 4: Gage R&R Study

Conduct a simplified Gage R&R study: 1. Select a gage (micrometer, caliper, gage) 2. Select 5 parts spanning range 3. Have 2 operators measure each part 2 times (20 measurements total) 4. Record data in table 5. Calculate range for each operator and part 6. Estimate %GRR (use online calculator or simplified method) 7. Determine if measurement system acceptable

Exercise 5: Control Chart

Create a control chart for a process: 1. Select a characteristic to monitor (diameter, length, surface finish) 2. Collect 20-25 subgroups of data (4-5 parts per subgroup) 3. Calculate X-bar and R for each subgroup 4. Calculate control limits (UCL, LCL) using formulas or software 5. Plot data on control chart 6. Interpret: Is process in control? Any special causes?

Additional Resources

AS9100 (Aerospace): - SAE AS9100: Aerospace Quality Management Systems - SAE AS9102: First Article Inspection Requirement - SAE AS9145: Configuration Management Requirements for AS/EN 9100 - IAQG website: www.iaqg.org - SAE International: www.sae.org

ISO 13485 (Medical Devices): - ISO 13485:2016 - Medical Devices Quality Management Systems - ISO 14971:2019 - Application of Risk Management to Medical Devices - FDA 21 CFR Part 820 - Quality System Regulation (US) - EU Medical Device Regulation (MDR) 2017/745 - FDA website: www.fda.gov - ISO website: www.iso.org

IATF 16949 (Automotive): - IATF 16949:2016 - Automotive Quality Management System - AIAG APQP Manual - Advanced Product Quality Planning - AIAG PPAP Manual - Production Part Approval Process - AIAG MSA Manual - Measurement Systems Analysis - AIAG SPC Manual - Statistical Process Control - AIAG website: www.aiag.org - IATF website: www.iatfglobaloversight.org

ISO 14001 / ISO 45001: - ISO 14001:2015 - Environmental Management Systems - ISO 45001:2018 - Occupational Health and Safety Management Systems - EPA website: www.epa.gov - OSHA website: www.osha.gov

Training and Certification: - ASQ Certified Quality Auditor (CQA) - ASQ Certified Quality Engineer (CQE) - ASQ Certified Reliability Engineer (CRE) - Lead Auditor Training (AS9100, ISO 13485, IATF 16949) - Internal Auditor Training - APQP/PPAP Training - MSA Training - SPC Training

Module 22 - Quality Management Systems (QMS)

Effective quality management depends on clear documentation that defines processes, procedures, and responsibilities. This section covers the essential documentation components of a QMS and how to create practical, usable documents for CNC manufacturing.

22.4.1 Quality Manual Development

The **Quality Manual** is the top-level document describing the organization's QMS. While ISO 9001:2015 doesn't explicitly require a quality manual, it remains a valuable tool for communicating the QMS structure.

Purpose of Quality Manual

Internal Use: - Provides overview of QMS for employees - Reference for training new personnel - Foundation for internal audits

External Use: - Demonstrates QMS to customers - Required by some customer contracts - Supports certification audits - Marketing tool (demonstrates commitment to quality)

Quality Manual Structure

Typical Quality Manual Contents:

1. Title Page and Revision Control

- Document title: “Quality Manual”
- Company name and logo
- Document number and revision level
- Effective date
- Approval signatures

2. Table of Contents

3. Introduction and Company Overview

- Company history and background
- Facilities and locations
- Products and services
- Markets served
- Organizational structure

4. Quality Policy

- Management’s commitment to quality
- Alignment with business strategy
- Signed by top management

5. Scope of QMS

- Products and services covered
- Locations included
- ISO 9001 clauses excluded (with justification)
- Industry standards applicable (AS9100, ISO 13485, IATF 16949)

6. Quality Management System

- Process approach overview
- Process interactions (process map)
- Risk-based thinking application
- Documented information control

7. Management Responsibility (ISO 9001 Clause 5)

- Leadership and commitment
- Quality objectives
- Roles, responsibilities, authorities
- Management review process

8. Resource Management (ISO 9001 Clause 7)

- Human resources (competence, training)
- Infrastructure (facilities, equipment)
- Work environment
- Monitoring and measuring resources (calibration)

9. Product Realization (ISO 9001 Clause 8)

- Operational planning
- Customer requirements review
- Design and development (if applicable)
- Purchasing and supplier management
- Production and service provision
- Control of measuring equipment

10. Measurement, Analysis, Improvement (ISO 9001 Clause 9-10)

- Monitoring and measurement
- Customer satisfaction
- Internal audits
- Nonconforming product control
- Corrective action
- Continual improvement

11. Document References

- List of procedures referenced in manual
- Work instructions and forms
- External documents (standards, regulations)

12. Revision History

- Table of revisions with dates and descriptions of changes

Quality Manual Content Approach

Two Approaches:

1. Descriptive Approach (Traditional): - Detailed description of how each ISO 9001 clause is addressed - Includes procedures within manual or detailed references - Longer document (50-100+ pages) - Advantage: Comprehensive, less need to reference other documents - Disadvantage: Requires frequent updates when procedures change

2. Reference Approach (Modern): - Brief description of QMS with references to procedures - Focused on “what” not “how” - Shorter document (20-40 pages) - Advantage: Easier to maintain, procedures updated independently - Disadvantage: Must reference multiple documents for full picture

Example: Descriptive vs. Reference Approach

*Descriptive Approach (detailed): > **8.6 Control of Measuring Equipment** >> All measuring equipment used for product verification is calibrated per the following process: > 1. Quality Manager maintains master calibration schedule listing all equipment, calibration intervals, and due dates > 2. Two weeks before due date, Quality Manager sends equipment to accredited calibration lab > 3. Upon return, Quality Manager verifies calibration certificate received and results acceptable > 4. Calibration sticker applied to equipment showing due date > 5. Equipment returned to service and schedule updated > 6. Records retained for 7 years > 7. If equipment found out-of-tolerance, Quality Manager investigates impact on measurements since last calibration and notifies affected customers if necessary...*

Reference Approach (brief): > **8.6 Control of Measuring Equipment** >> Measuring equipment used for product verification is calibrated at specified intervals against traceable standards. Calibration procedures, intervals, and records are defined in Procedure QP-08 Calibration Control.

Recommendation: Use **reference approach** for flexibility and ease of maintenance.

Quality Manual Approval and Control

Approval: - Top management approval required (President, CEO, or General Manager signature)
- Quality Manager typically authors

Revision Control: - Revision level tracked (Rev A, B, C or version numbers) - Revision history page documents changes - Current revision available to all personnel (intranet, shared drive, printed copies in binders) - Obsolete revisions removed or marked "Obsolete"

Example Revision History:

Revision	Date	Description of Changes	Approved By
A	2020-01-15	Initial release	J. Smith, President
B	2021-06-22	Updated Clause 8.4 supplier management process	J. Smith, President
C	2023-09-10	Updated for ISO 9001:2015, added AS9100 scope	J. Smith, President

22.4.2 Process Documentation and Procedures

Procedures document **how** processes are performed, providing consistency and ensuring requirements are met.

Documentation Hierarchy

Level 1: Quality Manual (QMS overview, policy, scope)
↓
Level 2: Procedures (process-level "how-to")
↓
Level 3: Work Instructions (detailed task steps)
↓
Level 4: Records (evidence of conformance)

22.4.2.1 Standard Operating Procedures (SOPs)

Standard Operating Procedure (SOP): Documented method describing how to perform a process or activity.

When SOPs Are Needed ISO 9001 Required Procedures (not explicitly called out, but typically documented as procedures): - Document control - Control of records - Internal audits - Control of nonconforming product - Corrective action - Preventive action (often combined with corrective action)

Additional Procedures (organization determines need): - Management review - Training and competence - Calibration control - Purchasing and supplier management - Production planning - Inspection and testing - Customer complaint handling - Continuous improvement

CNC Shop Common SOPs: - Job setup approval and first-off inspection - In-process inspection - Final inspection and release - NC program verification and approval - Tool life management - Preventive maintenance - Coolant management - Customer property control

SOP Format and Structure Typical SOP Sections:

1. Header:

- Procedure title
- Procedure number
- Revision level and date
- Page numbers (Page X of Y)

2. Purpose:

- Why procedure exists
- What it aims to achieve

3. Scope:

- Where procedure applies
- What's included/excluded

4. Definitions (if needed):

- Terms specific to procedure

5. Responsibilities:

- Who does what (roles)

6. Procedure Steps:

- Sequential steps to perform process
- Detailed enough for competent person to follow

7. Records:

- Forms and records generated
- Retention requirements

8. References:

- Related procedures, work instructions, standards

9. Approval and Revision History:

- Who approved
- Revision history table

SOP Writing Best Practices **1. Use Clear, Concise Language:** - Short sentences - Active voice ("Inspect the part" not "The part is inspected") - Simple words (avoid jargon unless defined)

2. Use Numbered Steps: - Sequential numbering (1, 2, 3...) - Sub-steps if needed (1.1, 1.2...)

3. Be Specific: - Use exact terminology ("Measure diameter with 0-1" micrometer" not "Check size") - Specify acceptance criteria ("Diameter must be .500+/-0.002" not "Diameter must be in

tolerance”)

4. Use Visual Aids: - Flowcharts for complex decision trees - Photos of equipment or setup - Tables for data or acceptance criteria

5. Keep It Practical: - Write for the user (operator, inspector, programmer) - Test procedure with actual user - Avoid unnecessary complexity

Example SOP Excerpt: Procedure QP-15: First-Off Inspection

Purpose: To verify setup correctness before production run, preventing production of nonconforming parts.

Scope: Applies to all CNC machining operations.

Responsibilities: - **Operator:** Machines first-off part, performs visual and basic checks - **Inspector:** Performs dimensional inspection, approves or rejects setup - **Supervisor:** Reviews and approves setup documentation

Procedure: 1. Operator completes machine setup per setup sheet 2. Operator runs first part (first-off) 3. Operator performs visual inspection: - Check for burrs, sharp edges - Verify all operations completed - Check for obvious errors (missing holes, wrong material) 4. Operator delivers first-off part and traveler to Inspection 5. Inspector retrieves applicable drawing and control plan 6. Inspector measures all dimensions listed on control plan 7. Inspector records results on traveler in “First-Off Inspection” section 8. If all dimensions within tolerance: - Inspector stamps “APPROVED” on traveler - Inspector returns traveler to operator - Operator proceeds with production 9. If any dimension out of tolerance: - Inspector stamps “REJECTED” on traveler - Inspector notifies operator and supervisor - Operator adjusts setup and repeats process (Step 2) 10. Supervisor reviews and signs traveler upon approval

Records: Traveler with first-off inspection results (retained with job jacket)

22.4.2.2 Work Instructions

Work Instruction (WI): Detailed, step-by-step instructions for performing specific task or operation.

Work Instructions vs. Procedures

Aspect	Procedure (SOP)	Work Instruction (WI)
Level	Process-level (multiple tasks)	Task-level (single operation)
Detail	General steps	Detailed, granular steps
Scope	Broad (applies to process)	Narrow (applies to specific task)
Audience	Anyone performing process	Specific operator or technician
Example	“Inspection and Testing Procedure”	“Inspecting Shaft Diameter with Micrometer”

When Work Instructions Are Needed **Work Instructions Recommended For:** - Complex operations requiring many steps - Operations where mistakes are costly (expensive parts, safety-critical) - Operations prone to errors (history of nonconformances) - Operations requiring special skills or knowledge - Training new employees - Regulatory requirements (FDA, AS9100)

Not Every Task Needs WI: - Competent personnel with training may not need WI for routine tasks - Overly detailed WIs become burdensome and ignored - Balance: Provide WIs where value added

CNC Shop Work Instructions Examples: - CMM inspection for complex features - Heat treatment furnace operation - Passivation process for stainless steel - Welding procedure for specific joint configuration - Plating tank operation and monitoring - Leak testing procedure for pressure vessels

Work Instruction Format **Visual Work Instructions** (preferred for shop floor): - Heavy use of photos, diagrams, illustrations - Minimal text (bullet points, short sentences) - Large font for readability - Laminated or in protective sleeve (shop environment)

Example Visual WI Structure:

+-----+			+-----+
	WORK INSTRUCTION WI-105		
	Measuring Shaft Diameter with Micrometer		
	Rev B		
-----		-----	
	[PHOTO: Clean shaft with rag]		
	Step 1: Clean shaft with lint-free cloth		
	[PHOTO: Micrometer positioned on shaft]		
	Step 2: Position micrometer on shaft		
	- Place anvil and spindle on diameter		
	- Rotate thimble until ratchet clicks 3 times		
	[PHOTO: Reading micrometer]		
	Step 3: Read measurement		
	- Sleeve: 0.500"		
	- Thimble: + 0.010"		
	- Total: 0.510"		
	Step 4: Record result on traveler		
	Acceptance: Diameter must be 0.500 +/- 0.002"		
-----		-----	
+-----+			+-----+

Video Work Instructions **Advantages of Video:** - Shows motion and technique (hard to capture in photos) - Demonstrates speed and timing - Engaging and easy to understand - Modern workforce prefers video

Creating Video WIs: - Short (2-5 minutes preferred) - Focus on single task - Include narration or text overlays - High-quality audio and video - Accessible (QR codes, tablets at workstation, online portal)

Example Use Cases: - Complex assembly sequence - Proper use of measurement equipment - Setup and alignment procedures - Safety procedures (lockout/tagout)

22.4.2.3 Forms and Records

Forms: Templates for capturing data and information

Records: Completed forms providing evidence of conformance

Common QMS Forms Quality Planning Forms: - Control Plans - Inspection Plans - Setup Sheets - Process Flow Diagrams

Operational Forms: - Travelers / Routers (job tracking) - Inspection Reports - Calibration Records - Training Records - Internal Audit Checklists - Corrective Action Reports (CAR) - Nonconformance Reports (NCR) - Customer Complaint Forms

Management Forms: - Management Review Agenda and Minutes - Supplier Evaluation Forms - Customer Satisfaction Surveys

Form Design Best Practices **1. Clear Title and Identification:** - Form name at top - Form number - Revision level - Company logo (optional)

2. Adequate Space for Data Entry: - Appropriately sized fields - Check boxes where applicable (easier than writing) - Drop-down lists if electronic

3. Instructions Built-In (if needed): - Brief instructions on form - Reference to procedure for details

4. Required Fields Clearly Marked: - Asterisk (*) or bold for required fields

5. Signature and Date Lines: - Who completed form - Who reviewed/approved - Date fields

6. Electronic Forms (preferred when feasible): - Fillable PDFs - Excel templates - Web forms (ERP/MES systems) - Advantages: Data capture, searchability, no manual filing

Example Form: Corrective Action Report (CAR)

+-----+	
CORRECTIVE ACTION REPORT	
Form QF-20 Rev C	

CAR Number:	Date Issued:
Issued By:	Dept:

PROBLEM DESCRIPTION:	

Source:	<input type="checkbox"/> Internal Audit	<input type="checkbox"/> Customer Complaint
	<input type="checkbox"/> Nonconformance	<input type="checkbox"/> Management Review
	<input type="checkbox"/> Other: _____	
IMMEDIATE ACTION (Containment/Correction): _____ _____		
Completed By:	_____	Date: _____
ROOT CAUSE ANALYSIS:		
<input type="checkbox"/> 5 Whys	<input type="checkbox"/> Fishbone	<input type="checkbox"/> Other: _____
Root Cause: _____		
Completed By:	_____	Date: _____
CORRECTIVE ACTION PLAN:		
Actions: _____		
Responsible:	_____	Target Date: _____
EFFECTIVENESS VERIFICATION:		
Verification Method: _____		
Results: _____		
Effective? <input type="checkbox"/> Yes	<input type="checkbox"/> No	(If No, revise action)
Verified By:	_____	Date: _____
CLOSURE:		
Approved By:	_____	Date: _____

22.4.3 Document Control Systems

Document Control ensures that current, approved documents are available where needed and obsolete documents are removed.

Document Control Requirements (ISO 9001 Clause 7.5.3)

Documented Information Must Be: - Available where and when needed - Adequately protected (confidentiality, integrity, loss prevention)

Document Control Includes: - Distribution and access control - Identification (version, revision)
- Review and approval - Update and revision control - Removal of obsolete documents

22.4.3.1 Document Revision and Version Control

Revision Numbering Systems Letter-Based System: - Initial release: Rev A - Subsequent revisions: Rev B, C, D, E, etc. - After Rev Z, can use AA, AB, or restart at A with number suffix

(A1, A2)

Number-Based System: - Initial release: Rev 1 or 1.0 - Subsequent revisions: Rev 2, 3, 4... or 1.1, 1.2, 2.0, etc. - Decimal for minor changes (1.1, 1.2), whole number for major (2.0)

Hybrid System: - Major revisions: Letter (A, B, C) - Minor edits within revision: Number (A1, A2, B1)

Engineering Drawing Revisions (industry standard): - Numeric: 0, 1, 2, 3, etc. (sometimes -0, -1, -2) - Alpha: A, B, C, etc. - Revision block on drawing lists changes

Recommendation: Be consistent throughout QMS. Most shops use **letter-based (Rev A, B, C)** for procedures and drawings.

Revision History Revision History Table (included in each procedure/manual):

Revision	Date	Description of Changes	Approved By
A	2020-01-15	Initial release	Q. Manager
B	2021-06-22	Updated Step 5.3, added Form QF-12	Q. Manager
C	2023-09-10	Revised responsibilities section, reformatted	Q. Manager

Purpose: - Traceability of changes - Understanding what changed between revisions - Audit trail for compliance

Change Control Process Document Change Process:

1. Change Request:

- Anyone can request change (improvement, correction, clarification)
- Submit request to Document Control or Quality Manager

2. Review:

- Document owner reviews request
- Determine if change warranted
- Draft revised document

3. Approval:

- Same authority that approved original (Quality Manager, Department Manager, Top Management)
- Signature or electronic approval

4. Distribution:

- New revision distributed to all holders of document
- Notification sent (email, document control log)

5. Removal of Obsolete:

- Retrieve old revision (if paper copies)
- Mark obsolete or destroy
- Update master list

6. Training (if significant change):

- Train affected personnel on changes
- Document training

22.4.3.2 Document Distribution and Access

Master Document List **Master List:** Register of all controlled documents

Master List Contents: - Document number - Document title - Current revision level - Date of current revision - Location (physical or electronic) - Distribution list (who has copy)

Example Master Document List:

Doc Number	Title	Current Rev	Rev Date	Location	Distribution
QM-01	Quality Manual	C	2023-09-10	Server/QMS	All employees (intranet)
QP-01	Document B Control		2021-03-15	Server/QMS	Document Control
QP-08	Calibration A Control		2020-05-20	Server/QMS	Quality Dept
WI-105	MicrometerB Use		2022-08-12	Server/QMS	Inspection Dept

Distribution Methods **Electronic Distribution** (modern, preferred): - **Intranet / SharePoint:** Central repository, accessible by all employees - **Shared Network Drive:** Folder structure with permissions - **Document Management Software:** Dedicated QMS software (MasterControl, ETQ, etc.) - **Advantages:** Always current revision, instant updates, searchable, no paper - **Controls:** Read-only access (prevent unauthorized changes), backup and security

Paper Distribution (traditional, less common now): - **Controlled Copies:** Numbered copies (Copy 1, Copy 2, etc.) distributed to specific locations - **Stamp:** “CONTROLLED COPY” stamp on each page - **Distribution Log:** Track who has which copy - **Updates:** Retrieve old revision, replace with new - **Disadvantages:** Labor-intensive, risk of obsolete copies in circulation, not eco-friendly

Uncontrolled Copies: - Stamped “UNCONTROLLED COPY” or “FOR REFERENCE ONLY” - Used for temporary reference, training, audits (auditor copies) - No guarantee of current revision - Not suitable for production use

Best Practice: Use **electronic distribution** with read-only access and automatic version control (document management system or SharePoint with versioning enabled).

Access Control Who Needs Access?: - **All employees:** Quality Manual, Quality Policy, relevant procedures - **Specific departments:** Procedures and work instructions applicable to their work - **External parties:** May need controlled access to certain documents (e.g., suppliers to purchase specs)

Permissions: - **Read-Only:** Most users (view only, cannot edit) - **Edit:** Document owners (Quality Manager, Process Owners) - **Approve:** Management (Quality Manager, Department Heads, Top Management)

Confidentiality: - Some documents may be confidential (proprietary processes, customer data, pricing) - Restrict access as appropriate - Label confidential documents

22.4.3.3 Obsolete Document Management

Why Control Obsolete Documents?: - Prevent unintended use (producing parts to old revision of drawing) - Compliance requirement (ISO 9001) - Reduce confusion

Obsolete Document Process:

- 1. Identify Obsolete:** - When new revision issued, previous revision becomes obsolete - When document cancelled or replaced
- 2. Remove from Use:** - Electronic: Move to “Obsolete” or “Archive” folder, remove from active directory - Paper: Retrieve from work areas, stamp “OBSOLETE”, file separately or destroy
- 3. Retention (if required):** - Some obsolete documents must be retained for reference (traceability, legal, customer contract) - Mark clearly as “OBSOLETE - FOR REFERENCE ONLY” - Store separately from current documents
- 4. Update Master List:** - Indicate document obsolete or superseded - Reference to replacement document

Example: - Drawing 1234 Rev B superseded by Rev C - Rev B drawing removed from production area - Rev B retained in “Obsolete Drawings” archive for 7 years (traceability for parts made to Rev B) - Stamped “OBSOLETE - DO NOT USE FOR NEW PRODUCTION”

22.4.4 Quality Plans for Projects and Products

Quality Plan: Document specifying processes, procedures, resources, and activities relevant to a particular product, project, or contract.

When Quality Plans Are Needed

Customer-Specific Requirements: - Customer contract specifies quality plan submission - Complex or high-value projects - First-time customer or product

New Product Introduction: - New design or significant design change - Ensures all quality requirements addressed

High-Risk Projects: - Safety-critical applications - Regulatory requirements (aerospace, medical)

Example Scenarios: - New aerospace component requiring AS9100 compliance and AS9102 FAI - Medical device manufacturing requiring ISO 13485 compliance and validation - Automotive component requiring APQP and PPAP

Quality Plan Contents

Typical Quality Plan Sections:

- 1. Project/Product Identification:**

- Part number, drawing number, description
 - Customer name and PO number
 - Quantity and delivery schedule
2. **Scope and Objectives:**
 - What quality plan covers
 - Quality objectives specific to project (defect rate, delivery, certification)
 3. **Organizational Roles and Responsibilities:**
 - Project Manager, Quality Manager, Engineering, Production
 - Customer contact and approval authority
 4. **Applicable Standards and Requirements:**
 - ISO 9001, AS9100, ISO 13485, IATF 16949
 - Customer specifications
 - Regulatory requirements (FDA, FAA)
 5. **Product Requirements:**
 - Design requirements (specifications, drawings)
 - Material requirements (certifications, traceability)
 - Performance requirements (testing, validation)
 6. **Process Flow and Controls:**
 - Manufacturing process flow diagram
 - Critical process steps
 - Control methods (inspection, testing, monitoring)
 7. **Inspection and Testing:**
 - Inspection plan (what, when, how, acceptance criteria)
 - Test requirements (material tests, performance tests)
 - First Article Inspection (if applicable)
 - Gage and equipment requirements
 8. **Material and Supplier Controls:**
 - Approved materials and suppliers
 - Incoming inspection requirements
 - Certifications required
 9. **Documentation and Records:**
 - Records to be generated and maintained
 - Retention requirements
 - Deliverables to customer (certifications, test reports, FAI)
 10. **Risk Management:**
 - Identified risks and mitigation plans
 - Contingency plans
 11. **Change Control:**
 - Process for managing changes to product or process
 12. **Verification and Validation:**
 - Process validation (for special processes)
 - Product validation (testing, trials)
 13. **Training:**
 - Training requirements for personnel
 14. **Continuous Improvement:**
 - Lessons learned process
 - Improvement opportunities
 15. **Schedule and Milestones:**

- Key milestones (design review, FAI, production launch)
- Timeline

16. Approval:

- Signatures of responsible parties
- Customer approval (if required)

Quality Plan Example Outline

Example: Aerospace Machined Component

Quality Plan for Part Number 1234-5678 Rev A

1. Project Overview: - Part: Titanium bracket for aircraft wing assembly - Customer: Aerospace OEM - Quantity: 500 pieces - Delivery: 100 pieces/month for 5 months

2. Applicable Standards: - AS9100 Rev D - AS9102B (First Article Inspection) - Customer Specification CS-1234

3. Material Requirements: - Material: Ti-6Al-4V per AMS 4911 - Source: Approved supplier with DFARS compliance - Incoming inspection: Verify material certification, check dimensions, perform chemical analysis (PMI)

4. Manufacturing Process: - 5-axis CNC machining - Process flow: Receiving \square Saw cut \square Machining Op 1 \square Machining Op 2 \square Deburr \square Clean \square Final Inspection \square Package \square Ship

5. Critical Characteristics: - Hole pattern (8 holes, positional tolerance $+-0.005"$) - Surface finish (32 Ra max on mating surface) - Material hardness (Rc 36-40 per heat treatment spec)

6. Control Plan: - In-process inspection after Op 1 (check critical dimensions) - 100% final inspection per AS9102 FAI initially, then sampling per control plan - SPC on hole pattern using CMM

7. First Article Inspection: - FAI per AS9102B - Sample size: 3 pieces from initial production - Full dimensional inspection, material certs, process certs - Submit FAI package to customer for approval before production release

8. Special Processes: - Outside heat treatment: Approved supplier with Nadcap accreditation - Certification required showing time, temperature, hardness

9. Inspection Equipment: - CMM (coordinate measuring machine) for hole pattern - Profilometer for surface finish - Rockwell hardness tester for material

10. Records and Deliverables: - Material certifications (MTR with heat lot traceability) - Heat treatment certification - First Article Inspection Report (AS9102) - Dimensional inspection results (for each lot) - Certificate of Conformance with each shipment

11. Training: - Operators trained on 5-axis machining and setup requirements - Inspectors trained on AS9102 FAI requirements and CMM operation

12. Schedule: - Week 1-2: Material procurement and receiving inspection - Week 3: Setup, program verification, FAI parts - Week 4: FAI submission and customer approval - Week 5 onward: Production (100 pieces/month)

Approved By: - Quality Manager: _____ Date: _____ - Program Manager: _____ Date: _____ - Customer (if required): _____ Date: _____

22.4.5 Control Plans and Inspection Plans

Control Plan: Living document describing the systems and processes required to control the product and process.

Control Plan Purpose

Control Plans: - Define what characteristics to measure/monitor - Specify how and when to measure - Establish acceptance criteria - Assign responsibility - Guide production and inspection personnel

Used Throughout Product Lifecycle: - **Prototype Control Plan:** During design and development - **Pre-Launch Control Plan:** During pilot production - **Production Control Plan:** During full production

Control Plan Format

Typical Control Plan Columns:

Column	Description
Part Number/Name	Product identification
Process/Operation	Manufacturing step (setup, machining, inspection, etc.)
Characteristic	What is being controlled (dimension, visual, function)
Specification/Tolerance	Acceptance criteria (drawing requirement)
Evaluation Method	How measured (micrometer, gage, CMM, visual)
Sample Size/Frequency	How many parts, how often
Control Method	SPC chart, 100% inspection, sampling plan
Reaction Plan	What to do if out of spec (stop production, notify supervisor, adjust, etc.)
Responsible	Who performs control (operator, inspector)

Control Plan Example: Machined Shaft

Operation	Characteristic	Spec/Tolerance	Evaluation Method	Sample Size/Frequency	Control Method	Reaction Plan	Responsible
Setup	First-off approval	All dims per drawing	Per control plan	First piece	100%	Stop production until approved	Operator + Inspector
Machining Op 1	Diameter Ø.500+/- .002"	.498-.502"	Micrometer	1 pc/hour	X-bar/R chart (SPC)	Adjust offset if trending	Operator

Operation	Characteristic	Spec/Tolerance	Evaluation Method	Sample Size/Frequency	Control Method	Reaction Plan	Responsible
Machining Op 1	length .010"	3.990- 4.000+/- .010"	Calipers	1 pc/4 hours	Record on log	Notify supervisor if out	Operator
Machining Op 2	Surface finish	63 Ra max	Visual + occasional profilometer	Visual 100%, profilometer 1/day	Visual comparison to standard	Adjust speed/feed if rough	Operator
Final In-spec-	All dimensions	Per drawing	CMM	Per sampling plan (AQL)	Inspection report	Reject lot if multiple fails	Inspector
Final In-spec-	Visual defects	No burrs, scratches, damage	Visual	100%	Accept/reject	Rework or scrap	Inspector

Control Plan Development

Steps to Create Control Plan:

1. Identify Characteristics:

- All dimensions and requirements from drawing
- Critical characteristics (affecting fit, function, safety)
- Special characteristics (customer-designated)

2. Classify Characteristics:

- **Critical:** Affects safety or regulatory compliance (100% inspection or tight controls)
- **Key/Major:** Affects fit, function, or customer satisfaction (controlled with SPC or sampling)
- **Minor:** Other dimensions (periodic checks or sampling)

3. Determine Evaluation Methods:

- Select appropriate measurement tools and techniques
- Ensure measurement systems adequate (MSA performed)

4. Establish Sample Size and Frequency:

- Balance risk, cost, and practicality
- Critical: More frequent or 100%
- Stable process with high Cpk: Less frequent

5. Define Reaction Plans:

- Clear instructions for out-of-spec conditions
- Escalation path (operator → supervisor → quality manager)

6. Review and Approve:

- Engineering, Quality, Production review
- Customer approval if required

Control Plan as Living Document: - Update when process changes - Revise based on capability studies (reduce inspection if Cpk improves) - Incorporate lessons learned (increase inspection if problems arise)

Inspection Plans

Inspection Plan: Subset of control plan focused on inspection activities

Inspection Plan Contents: - What to inspect (characteristics) - When to inspect (receiving, in-process, final) - How to inspect (method, equipment) - Acceptance criteria - Records to maintain

Difference from Control Plan: - Control plan covers entire manufacturing process (production + inspection) - Inspection plan focuses only on inspection activities - Some organizations use one document (control plan including inspection); others separate

Example Inspection Plan Sections:

Receiving Inspection: - Material verification (certifications, markings) - Dimensional checks (diameter, length of stock) - Visual inspection (damage, corrosion)

In-Process Inspection: - First-off inspection (setup approval) - In-process checks (dimensions, visual)

Final Inspection: - Dimensional inspection (all characteristics or sampling) - Functional testing (if applicable) - Visual inspection (cleanliness, appearance) - Documentation review (travelers, certifications)

Release Criteria: - All inspections passed - Records complete - Approvals obtained

Summary

Quality planning and documentation form the foundation of an effective QMS. The quality manual provides an overview, procedures document processes, work instructions detail tasks, and forms capture evidence. Document control ensures the right documents are available and current. Control plans guide production and inspection, ensuring consistent quality.

Well-designed documentation is clear, practical, and usable by the intended audience. It balances thoroughness with simplicity, providing enough detail without becoming burdensome. In CNC manufacturing, effective documentation supports consistent processes, reduces errors, facilitates training, and provides evidence of conformance to customers and auditors.

Key Takeaways

1. **Quality Manual** is top-level QMS document; modern approach uses brief descriptions with references to procedures
2. **Documentation hierarchy:** Manual □ Procedures □ Work Instructions □ Records
3. **Procedures (SOPs)** document “how” processes performed; should be clear, concise, and practical
4. **Work Instructions** provide detailed task-level steps; visual format preferred for shop floor
5. **Forms and records** capture evidence of conformance; design for usability and data capture
6. **Document control** ensures current documents available and obsolete removed; electronic distribution preferred
7. **Revision control** tracks changes; use consistent numbering system (Rev A, B, C, etc.)

8. **Master document list** maintains inventory of controlled documents and revisions
 9. **Quality Plans** specify requirements for particular product or project; used for complex or high-risk items
 10. **Control Plans** define characteristics to monitor, measurement methods, frequencies, and reaction plans
 11. **Inspection Plans** detail what, when, and how to inspect
 12. **Control Plans are living documents** updated based on process performance and lessons learned
-

Review Questions

1. What are the advantages of the “reference approach” vs. “descriptive approach” for quality manual content?
 2. Describe the four-level documentation hierarchy in a QMS.
 3. What are the key sections of a Standard Operating Procedure (SOP)?
 4. How do work instructions differ from procedures? When are work instructions needed?
 5. What are best practices for designing forms and records?
 6. What are the key requirements for document control per ISO 9001?
 7. Explain the difference between controlled and uncontrolled copies of documents.
 8. What is a Master Document List and why is it important?
 9. How should obsolete documents be managed?
 10. What is a Quality Plan and when is it needed?
 11. What is a Control Plan and what information does it contain?
 12. How do you determine sample size and frequency for characteristics in a control plan?
-

Practical Exercises

Exercise 1: Write a Simple Procedure

Write a one-page procedure for a process in your shop (or hypothetical): - Choose a process (tool calibration, job setup approval, customer complaint handling) - Use standard SOP format (Purpose, Scope, Responsibilities, Procedure Steps, Records) - Number steps sequentially - Keep language clear and concise

Exercise 2: Create a Visual Work Instruction

Create a visual work instruction for a specific task: - Select a task (measuring with micrometer, setting up fixture, using CMM) - Include photos or illustrations for each key step - Use minimal text (bullet points) - Specify acceptance criteria

Exercise 3: Design a Form

Design a form for capturing quality data: - Choose form type (inspection report, corrective action, audit checklist) - Include header with form number, revision, title - Design fields for data entry

(adequate space, check boxes) - Include signature and date lines - Make it user-friendly and practical

Exercise 4: Develop a Control Plan

Create a control plan for a machined part: 1. Select a part (simple shaft, bracket, housing) 2. List operations (setup, machining, inspection) 3. Identify 8-10 characteristics to control 4. For each characteristic, specify: - Specification/tolerance - Evaluation method - Sample size/frequency - Control method - Reaction plan 5. Format as table or use standard control plan template

Exercise 5: Document Control Audit

Audit document control in your shop (or simulate): 1. Select 5 procedures or work instructions 2. Check: - Are they the current revision? - Are they approved (signatures)? - Are they accessible to users who need them? - Is there a revision history? 3. Check shop floor for obsolete documents 4. List any findings or opportunities for improvement

Additional Resources

Templates and Examples: - ASQ Quality Manual templates - ISO 9001 procedure templates (available from consultants, software vendors) - AIAG Control Plan example (automotive) - AS9102 forms (aerospace FAI)

Software Tools: - Document management systems: MasterControl, ETQ, Intellect, Arena - Microsoft SharePoint with version control - Google Drive or Dropbox Business (for small shops) - ERP/MES systems with integrated document control

Books: - “Documentation for ISO 9001:2015” by Ronna Lehmann - “The ISO 9001:2015 Implementation Handbook” by Kent Keeney - “Control Plan Methodology” by Michael Vorster

Standards: - ISO 9001:2015 Clause 7.5 (Documented Information) - AIAG APQP Manual (Control Plan chapter) - AS9102 (First Article Inspection)

Training: - Document Control training courses (ASQ, online providers) - ISO 9001 Internal Auditor training (includes documentation review) - Technical writing courses (for creating clear procedures)

Module 22 - Quality Management Systems (QMS)

Process control ensures manufacturing processes consistently produce conforming products. This section covers process identification, performance measurement, capability analysis, validation requirements, and specific considerations for CNC machining.

22.5.1 Process Identification and Mapping

Before controlling processes, you must identify and understand them. Process mapping visualizes how work flows through the organization.

Process Identification

Process: Set of interrelated activities that transform inputs into outputs

Process Categories in CNC Manufacturing:

Core Processes (directly create value): - Sales and quoting - Order processing - Production planning and scheduling - CNC programming - Machine setup - Machining operations - Deburring and finishing - Inspection and testing - Packaging and shipping

Support Processes (enable core processes): - Tooling management - Fixture design and maintenance - Preventive maintenance - Calibration - Material handling and storage - Document control - Training

Management Processes (direct and monitor): - Strategic planning - Management review - Internal audits - Corrective and preventive action - Continuous improvement

Process Mapping Tools

High-Level Process Map (SIPOC) SIPOC Diagram: Suppliers, Inputs, Process, Outputs, Customers

Example: CNC Machining Process

Suppliers	Inputs	Process Steps	Outputs	Customers
Material suppliers	Raw material	1. Plan job	Machined parts	Assembly dept
Engineering	Drawings	2. Program CNC	Inspection data	External customers
Tooling vendors	Cutting tools	3. Setup machine	Scrap (waste)	
Customer	Work order	4. Machine part	Records	
Programming	NC program	5. Inspect part		

Purpose: High-level overview, good for initial process understanding or improvement projects

Process Flow Diagram **Process Flow Diagram:** Graphical representation of process steps in sequence

Example: Job Flow from Order to Shipment

Customer PO → Order Entry → Order Review →
Material Available?

↓ No → Purchase Material → Receiving Inspection →
↓ Yes

Programming → Program Verification →

```

Setup → First-Off Inspection →
Approved?
  ↓ No → Adjust Setup → (loop back to Setup)
  ↓ Yes
Production Run → In-Process Checks →
Final Inspection →
Pass?
  ↓ No → Nonconforming Product Process →
  ↓ Yes
Packaging → Shipping → Customer

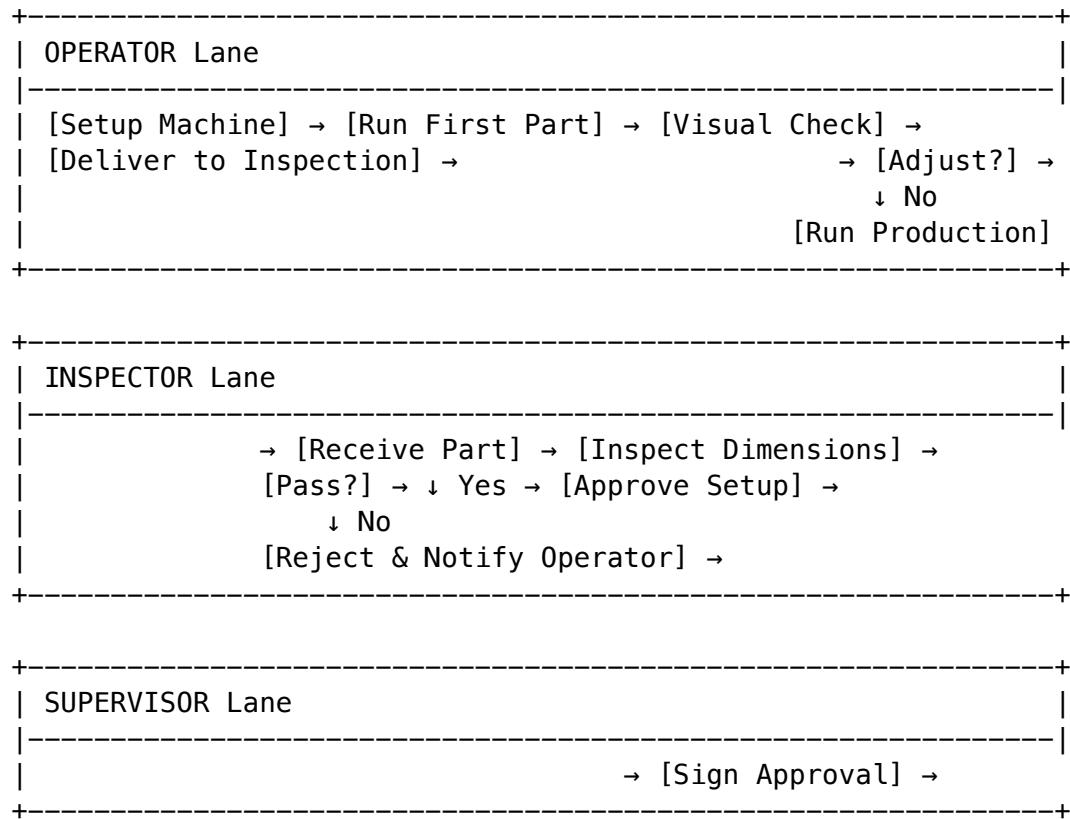
```

Symbols: - Oval: Start/End - Rectangle: Process step - Diamond: Decision point - Arrow: Flow direction

Purpose: Shows sequence, decision points, loops; useful for identifying bottlenecks and inefficiencies

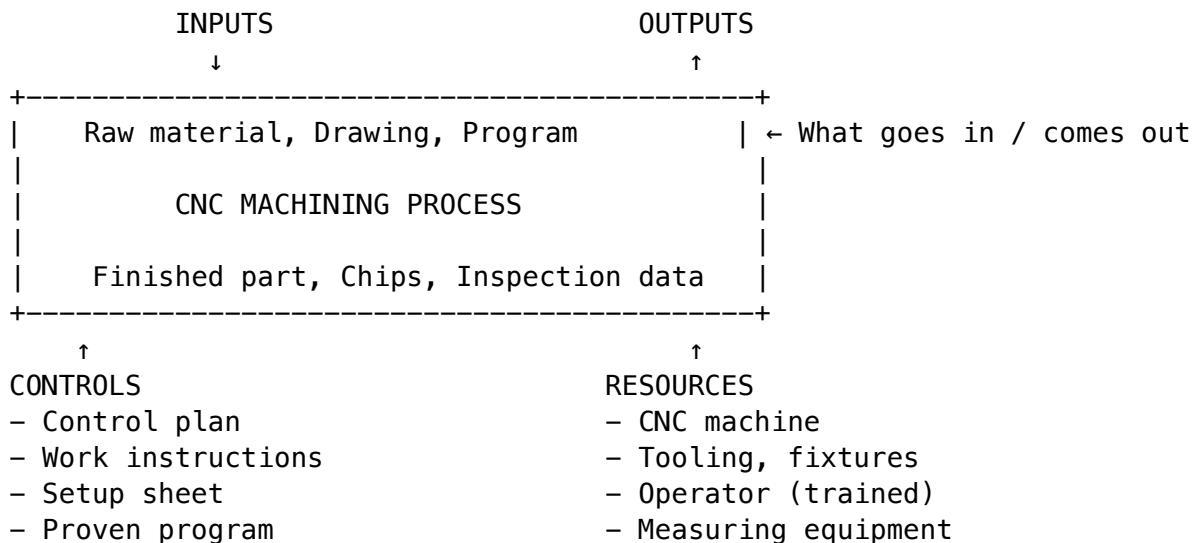
Detailed Process Map (Swim Lane Diagram) **Swim Lane Diagram:** Process flow with responsibilities shown in lanes (rows or columns)

Example: First Article Inspection Process



Purpose: Clarifies roles and handoffs between people or departments; identifies delays and communication gaps

Turtle Diagram **Turtle Diagram:** Shows process inputs, outputs, controls, and resources



Purpose: Comprehensive view of what's needed for process to work; useful for process design and risk analysis

Process Documentation

Processes Should Be Documented:

- Process purpose and scope
- Process inputs and outputs
- Process steps (flow diagram)
- Roles and responsibilities (process owner, participants)
- Key performance indicators (KPIs)
- Controls and monitoring methods
- Interaction with other processes
- Risks and mitigation

Documentation Methods:

- Process procedures (written description)
- Flow diagrams (visual)
- Turtle diagrams
- Process manuals or work instructions

22.5.2 Process Performance Indicators (KPIs)

Key Performance Indicators (KPIs): Metrics that measure how well process is performing

Selecting KPIs

Good KPIs Are:

- **Measurable:** Quantifiable with data
- **Relevant:** Tied to process objectives and customer requirements
- **Actionable:** Can be influenced by process changes
- **Timely:** Measured frequently enough to be useful
- **Understandable:** Clear to everyone involved

Avoid:

- Too many KPIs (focus on vital few)
- Vanity metrics (look good but don't drive improvement)
- Metrics that can't be acted upon

Common CNC Manufacturing KPIs

Quality Metrics 1. Scrap Rate

$$\text{Scrap Rate (\%)} = (\text{Scrap Cost} / \text{Total Production Cost}) \times 100$$

or

$$\text{Scrap Rate (\%)} = (\text{Scrapped Parts} / \text{Total Parts Produced}) \times 100$$

- **Target:** <2% (varies by industry; aerospace often <1%)
- **Frequency:** Monthly
- **Owner:** Production Manager

2. Rework Rate

$$\text{Rework Rate (\%)} = (\text{Rework Hours} / \text{Total Production Hours}) \times 100$$

- **Target:** <3%
- **Frequency:** Monthly
- **Owner:** Production Manager

3. First-Pass Yield (FPY)

$$\text{FPY (\%)} = (\text{Parts Passing Inspection First Time} / \text{Total Parts Inspected}) \times 100$$

- **Target:** >95% (higher for critical parts)
- **Frequency:** Weekly or monthly
- **Owner:** Quality Manager

4. Customer Returns / Parts Per Million (PPM)

$$\text{PPM} = (\text{Defective Parts Returned} / \text{Total Parts Shipped}) \times 1,000,000$$

- **Target:** <100 PPM (aerospace/medical often <10 PPM)
- **Frequency:** Monthly
- **Owner:** Quality Manager

5. Process Capability (Cpk) - Measure of how well process meets specifications - **Target:** Cpk ≥ 1.33 (capable); Cpk ≥ 1.67 (highly capable) - **Frequency:** Quarterly or when process changes - **Owner:** Engineering / Quality

Delivery Metrics 6. On-Time Delivery (OTD)

$$\text{OTD (\%)} = (\text{Orders Delivered On-Time} / \text{Total Orders}) \times 100$$

- **Target:** $\geq 95\%$ (AS9100 requires monitoring)
- **Frequency:** Monthly
- **Owner:** Operations Manager

7. Lead Time

$$\text{Lead Time} = \text{Date Shipped} - \text{Date Order Received}$$

- **Target:** Varies by product; track average and trend
- **Frequency:** Monthly
- **Owner:** Planning / Operations Manager

8. Past-Due Orders

$$\text{Past-Due} = \text{Count of orders past promised delivery date}$$

- **Target:** 0 or minimal

- **Frequency:** Weekly
- **Owner:** Operations Manager

Efficiency Metrics 9. Machine Utilization

Utilization (%) = (Actual Run Time / Available Time) × 100

- **Target:** 60-80% (allows for setup, maintenance, scheduling gaps)
- **Frequency:** Weekly or monthly
- **Owner:** Production Manager

10. Setup Time

Average Setup Time = Total Setup Time / Number of Setups

- **Target:** Reduce over time (SMED projects)
- **Frequency:** Monthly
- **Owner:** Production Manager

11. Cycle Time

Cycle Time = Time to complete one part (or one job)

- **Target:** Minimize while maintaining quality
- **Frequency:** Per job; track trends
- **Owner:** Programming / Production

Cost Metrics 12. Cost Per Part

Cost Per Part = (Material + Labor + Overhead) / Quantity

- **Target:** Reduce or maintain while hitting quality targets
- **Frequency:** Per job or monthly aggregate
- **Owner:** Operations / Finance

13. Tooling Cost Per Part

Tooling Cost Per Part = Total Tool Expenses / Parts Produced

- **Target:** Optimize (not always minimize; better tooling may reduce scrap/cycle time)
- **Frequency:** Monthly
- **Owner:** Production / Tooling Manager

Customer Satisfaction Metrics 14. Customer Satisfaction Score - Survey-based (1-5 scale or NPS) - **Target:** >=4.5/5 or NPS >30 - **Frequency:** Annually or after major projects - **Owner:** Quality / Sales Manager

15. Customer Complaints

Complaints = Count of formal complaints per period

- **Target:** Minimize; track trend
- **Frequency:** Monthly
- **Owner:** Quality Manager

Displaying and Monitoring KPIs

Dashboards: - Visual display of KPIs (charts, graphs, gauges) - Updated regularly (daily, weekly, monthly) - Posted in visible location (break room, office, shop floor) - Digital displays (TV screens, monitors)

Example Dashboard Layout:

ABC Machining – Quality Dashboard (May 2024)	
<hr/>	
Scrap Rate:	1.8% [██████] Target: <2% [check]
First-Pass Yield:	97% [██████] Target: >95% [check]
On-Time Delivery:	93% [██████] Target: >=95% ✘
Customer PPM:	45 [██████] Target: <100 [check]
Cpk (avg):	1.45 Target: >=1.33 [check]
<hr/>	
Actions:	
- OTD below target: Expedite Job #5678, add weekend shift to catch up on backlog	

Review Frequency: - **Daily:** Critical metrics (safety, past-due orders) - **Weekly:** Production metrics (utilization, scrap) - **Monthly:** Quality and delivery metrics (most KPIs) - **Quarterly:** Strategic metrics (customer satisfaction, Cpk) - **Management Review:** All KPIs reviewed semi-annually or annually

22.5.3 Process Validation and Verification

Verification: Confirmation that specified requirements have been met (“Did we build it right?”)

Validation: Confirmation that product meets user needs and intended use (“Did we build the right thing?”)

When Validation is Required

ISO 9001 Clause 8.5.1.2: Validation required when **output cannot be verified by subsequent measurement or monitoring** (i.e., defects not detectable until product in use).

Special Processes requiring validation: - **Heat treatment:** Internal structure and properties not visible (must validate process capable of achieving requirements) - **Welding:** Internal weld integrity not fully verifiable by visual inspection (X-ray or UT may be used, but process still validated) - **Plating/coating:** Adhesion and coverage may not be fully verifiable (validate process parameters) - **Cleaning:** Cleanliness level not always verifiable (validate cleaning process removes contaminants) - **Sterilization** (medical devices): Sterility cannot be tested (destroys sample); validate sterilization cycle - **Software:** Output depends on inputs and logic; validate through testing

Non-Special Processes (verification sufficient): - **Machining:** Output fully measurable (dimensions, surface finish) - **Assembly:** Visual and dimensional verification possible - *However, capability studies still valuable even if not “special processes”*

Process Validation Steps

- 1. Define Process Requirements:** - What must process achieve? (e.g., heat treatment: achieve Rc 40-44 hardness) - Specifications and acceptance criteria
- 2. Identify Process Parameters:** - Variables affecting outcome (temperature, time, pressure, flow rate, etc.) - Critical parameters vs. non-critical
- 3. Establish Process Controls:** - Equipment calibration and maintenance - Procedures and work instructions - Monitoring and recording methods
- 4. Qualification of Equipment:** - **Installation Qualification (IQ):** Verify equipment installed correctly per specifications - **Operational Qualification (OQ):** Verify equipment operates per specifications across operational ranges - **Performance Qualification (PQ):** Verify process produces acceptable results consistently
- 5. Process Performance Testing:** - Run process with actual parts or representative samples - Measure outputs and verify meet requirements - Statistical sample size (typically 30+ samples for statistical confidence)
- 6. Documentation:** - Validation protocol (plan) - Test results - Analysis and conclusion - Approval signatures
- 7. Revalidation:** - When process changes (equipment, materials, procedures) - Periodic revalidation (annually or per schedule) - After significant downtime or repairs

Validation Example: Heat Treatment Process

Process: Stress relief heat treatment for aluminum parts (350°F for 3 hours)

Validation Protocol:

- 1. Requirements:** - Temperature: 350°F +/-10°F - Time: 3 hours minimum - Verify stress relief effective (dimensional stability)
- 2. Equipment:** - Oven with calibrated temperature controller and recorder - Thermocouples placed at multiple locations in oven (verify temperature uniformity)
- 3. Installation Qualification (IQ):** - Verify oven installed per manufacturer specs - Verify utilities connected (electrical, ventilation) - Calibration of temperature controller and recorder verified
- 4. Operational Qualification (OQ):** - Run oven empty at 350°F for 3 hours - Record temperature at multiple locations (9 points in oven) - Verify all locations within +/-10°F of setpoint - Result: Temperature uniformity acceptable
- 5. Performance Qualification (PQ):** - Load oven with 30 parts (production configuration) - Run cycle: Heat to 350°F, hold 3 hours, cool - Measure hardness on sample parts (before and after treatment) - Measure dimensional stability (re-measure parts after 30 days, verify no movement) - Result: All parts meet hardness spec, no dimensional changes detected
- 6. Validation Report:** - Document IQ, OQ, PQ results - Conclusion: Process validated for stress relief heat treatment - Approval: Engineering and Quality Manager signatures
- 7. Ongoing Control:** - Each cycle: Record temperature and time (chart recorder or data logger) - Periodic hardness checks (1 part per lot) - Annual revalidation (OQ temperature uniformity check)

22.5.4 Special Processes (Welding, Heat Treatment, Plating)

Special processes require validated procedures, qualified equipment, and trained/certified personnel.

Welding

Why Special Process: - Weld quality (strength, integrity) depends on process parameters (current, voltage, speed, shielding gas) - Internal defects (porosity, lack of fusion) not visible externally - Destructive testing (tensile, bend) or NDT (X-ray, UT) required for verification

Welding Controls:

1. Welding Procedures (WPS): - **Welding Procedure Specification (WPS):** Document specifying welding parameters - Parameters: Base metal, filler metal, joint design, current, voltage, travel speed, preheat, post-weld heat treatment - WPS developed and qualified per code (AWS, ASME, API)

2. Procedure Qualification Record (PQR): - Test record demonstrating WPS produces acceptable welds - Sample welded per WPS, then tested (tensile, bend, impact, macro/micro examination) - PQR supports WPS

3. Welder Qualification: - Welders certified to WPS - Qualification test: Weld sample per WPS, test results meet code requirements - Certification maintained (requalification every 6 months to 3 years depending on code)

4. Weld Inspection: - Visual inspection (100%) - Non-Destructive Testing (NDT): Radiography (X-ray), Ultrasonic Testing (UT), Penetrant Testing (PT), Magnetic Particle Testing (MT) - Frequency per drawing or code requirements

5. Weld Documentation: - Welder identification on part or traveler - WPS used - Inspection results (NDT reports) - Material traceability (weld filler lot number)

Aerospace / Medical: - Strict requirements (Nadcap accreditation for aerospace welding) - 100% NDT often required - Traceability critical

Heat Treatment

Why Special Process: - Internal microstructure and properties changed (not visible externally) - Hardness and mechanical properties depend on time and temperature - Incorrect heat treatment can cause failures (too soft, too brittle, distortion)

Heat Treatment Controls:

1. Heat Treatment Specifications: - Material specification (e.g., AMS 2759 for aluminum, AMS 2750 for steel) - Temperature, time, quench method - Hardness range required

2. Furnace Qualification: - Temperature uniformity survey (TUS): Verify furnace temperature uniform throughout work zone - Frequency: Annually or per AMS 2750 (Class of furnace determines frequency) - Instrumentation calibrated (thermocouples, controllers, recorders)

3. Process Monitoring: - Chart recorder or data logger records temperature vs. time - Thermo-couples in load (for critical parts) - Each load documented (load number, parts, cycle parameters)

4. Verification Testing: - Hardness testing (Rockwell, Brinell): Sample from each load or periodic checks - Tensile or impact testing (for critical applications)

5. Certification: - Heat treatment certification (C of C) for each load - Includes: Load number, material, specification, time/temperature, hardness results - Traceability from part serial number to load number to certification

6. Nadcap Accreditation (Aerospace): - Heat treaters serving aerospace must have Nadcap accreditation (audit by PRI) - Stringent requirements for furnace qualification, instrumentation, procedures, records

Example Heat Treatment Process: Steel parts hardened to Rc 58-62

- Process: Austenitize at 1550°F for 60 minutes, oil quench, temper at 350°F for 2 hours
- Furnace: Class 2 per AMS 2750 (TUS every 6 months)
- Monitoring: Chart recorder captures temperature continuously
- Verification: Hardness test 3 locations on 1 sample part per load
- Certification: Heat treat cert lists load #, parts S/Ns, cycle parameters, hardness results (Rc 60, 61, 59)

Plating and Coating

Why Special Process: - Coating thickness, adhesion, coverage not always fully verifiable (especially complex geometries) - Chemistry and process parameters critical (tank concentration, temperature, current density for electroplating)

Plating Controls:

1. Plating Specifications: - Type of plating (zinc, nickel, chrome, anodize, etc.) - Thickness requirement (e.g., 0.0005" min per QQ-N-290 for nickel) - Appearance and finish

2. Tank Monitoring: - Solution concentration (chemical analysis, titration) - Temperature, pH, current density - Logged per schedule (daily, weekly)

3. Process Parameters: - Rack time (how long parts in tank) - Current density (amps per square inch for electroplating) - Agitation and filtration

4. Verification Testing: - Thickness measurement: Magnetic thickness gage, X-ray fluorescence (XRF), microsection - Adhesion testing: Bend test, tape test (per ASTM standards) - Salt spray testing (corrosion resistance per ASTM B117)

5. Plating Certification: - Batch certification listing parts, specification, thickness results, lot number

6. Nadcap Accreditation (Aerospace): - Platers serving aerospace require Nadcap for many plating types - Chemical analysis, process controls, testing documented

Example: Nickel plating per QQ-N-290, Class 1, .0005" min thickness

- Tank monitored: Nickel concentration 10 oz/gal, pH 4.0, temperature 140°F
- Parts plated for 45 minutes at 30 ASF (amps per square foot)
- Verification: Magnetic thickness gage measures .0006" on test coupon

- Certification: Plating cert lists parts, spec, thickness, lot #, date

Other Special Processes

Painting / Powder Coating: - Film thickness, adhesion, appearance - Oven cure temperature and time validated

Chemical Cleaning / Passivation: - Cleanliness level, passivation effectiveness - Tank chemistry monitored, process validated

Non-Destructive Testing (NDT): - Operator certification required (per ASNT, PCN, or NAS 410) - Procedure qualification - Equipment calibration

22.5.5 Machine Qualification and Capability Studies

Capability studies quantify how well a manufacturing process can meet specifications. Essential for process qualification, continuous improvement, and customer requirements (PPAP, FAI).

Machine vs. Process Capability

Machine Capability (C_m, C_{mk}): - Measures **machine's** inherent capability (short-term, ideal conditions) - Factors affecting machine capability: Accuracy, repeatability, resolution - Measured with: Same operator, same setup, short time period (minimal variation sources)

Process Capability (C_p, C_{pk}): - Measures **process** capability including all normal variation sources - Includes: Machine, operator, material, environment, measurement - Measured with: Production conditions over time

Long-Term Process Performance (P_p, P_{pk}): - Measures process performance over extended period (weeks, months) - Includes: All variation sources plus long-term drift, seasonal effects, lot-to-lot material variation

22.5.5.1 Machine Capability Studies (C_m, C_{mk})

Machine Capability Study: Evaluates machine's ability to produce parts within tolerance under ideal conditions

When to Conduct Machine Capability Study

- New machine purchase (acceptance test)
- After major machine repair or rebuild
- Periodic verification (annually)
- Qualifying machine for new job

Procedure for Machine Capability Study **1. Setup:** - Use best operator - Stable, controlled environment (temperature controlled if applicable) - One setup (no re-setups during study) - Proven program and tooling - Calibrated measurement equipment

2. Sample Collection: - Produce 50-100 parts consecutively (no adjustments) - Measure characteristic of interest (dimension, surface finish, etc.) - Short time period (within 1-2 hours)

3. Data Analysis: - Calculate mean (\bar{x}) and standard deviation (σ) - Calculate Cm and Cmk

Formulas Cm (Machine Capability Index) - Measures spread of process relative to tolerance:

$$Cm = (USL - LSL) / (6\sigma)$$

Where:

USL = Upper Specification Limit

LSL = Lower Specification Limit

σ = Standard deviation of sample

Cmk (Machine Capability Index accounting for centering) - Measures capability considering how centered process is:

$$Cmk = \min[(USL - \bar{x}) / (3\sigma), (\bar{x} - LSL) / (3\sigma)]$$

Where:

\bar{x} = Process mean (average)

Interpretation: - **Cmk ≥ 2.0 :** Excellent machine capability (machine variation uses $\leq 50\%$ of tolerance) - **Cmk ≥ 1.67 :** Good capability (machine acceptable for most applications) - **Cmk ≥ 1.33 :** Adequate (minimum for most customers) - **Cmk < 1.33 :** Inadequate (machine may not hold tolerance consistently)

Example Machine Capability Study Part: Shaft diameter, specification $.500" \pm .002"$ (USL = $.502"$, LSL = $.498"$)

Study: - Machined 50 parts consecutively, no adjustments - Measured diameter on each part with micrometer

Data Summary: - Mean (\bar{x}) = $.5005"$ - Standard deviation (σ) = $.0003"$

Calculate Cm:

$$Cm = (.502 - .498) / (6 \times .0003)$$

$$Cm = .004 / .0018$$

$$Cm = 2.22$$

Calculate Cmk:

$$Cmk = \min[(.502 - .5005) / (3 \times .0003), (.5005 - .498) / (3 \times .0003)]$$

$$Cmk = \min[.0015 / .0009, .0025 / .0009]$$

$$Cmk = \min[1.67, 2.78]$$

$$Cmk = 1.67$$

Conclusion: - Cm = 2.22 (excellent spread) - Cmk = 1.67 (good capability, slightly off-center) - **Machine capable** of meeting specification - **Opportunity:** Center process better (adjust offset) to improve Cmk closer to Cm

22.5.5.2 Process Capability Studies (Cp, Cpk)

Process Capability Study: Evaluates entire manufacturing process (including all variation sources) under normal production conditions

When to Conduct Process Capability Study

- New product launch (PPAP requirement)
- After process change (new machine, tooling, material, method)
- Qualifying process for critical characteristics
- Continuous monitoring (SPC)

Procedure for Process Capability Study **1. Stable Process:** - Process must be in statistical control (no special causes) - Run control chart to verify stability

2. Sample Collection: - Collect 100-125 individual measurements (or 25-30 subgroups of 4-5) - Over time representing normal production (multiple setups, operators, shifts) - Shorter than long-term study (days to weeks, not months)

3. Data Analysis: - Verify normality (histogram, normal probability plot) - Calculate Cp and Cpk

Formulas Cp (Process Capability Index):

$$Cp = (USL - LSL) / (6\sigma)$$

Cpk (Process Capability Index accounting for centering):

$$Cpk = \min[(USL - \bar{x}) / (3\sigma), (\bar{x} - LSL) / (3\sigma)]$$

(Formulas identical to Cm/Cmk, but σ represents process variation including all sources)

Interpretation: - **Cpk >= 2.0:** Excellent process (Six Sigma level, <3.4 defects per million) - **Cpk >= 1.67:** Good process (typical APQP target for critical characteristics) - **Cpk >= 1.33:** Capable process (typical minimum requirement) - **Cpk >= 1.0:** Marginally capable (99.73% of parts within spec, but little margin) - **Cpk < 1.0:** Incapable (producing defects)

Action Based on Cpk: - **Cpk >= 1.33:** Normal sampling inspection acceptable - **1.0 <= Cpk < 1.33:** Increased inspection (100% or tighter sampling) - **Cpk < 1.0:** Corrective action required; may need 100% inspection, sortation, or process improvement before continuing production

Example Process Capability Study **Part:** Hole diameter, specification 10.00 mm +/- 0.05 mm (USL = 10.05, LSL = 9.95)

Study: - Collected 125 samples over 2 weeks (normal production) - 3 operators, 2 machines, multiple setups

Data Summary: - Mean (\bar{x}) = 10.01 mm - Standard deviation (σ) = 0.015 mm

Calculate Cp:

$$Cp = (10.05 - 9.95) / (6 \times 0.015)$$

$$Cp = 0.10 / 0.09$$

$$Cp = 1.11$$

Calculate Cpk:

$$\begin{aligned}Cpk &= \min[(10.05 - 10.01) / (3 \times 0.015), (10.01 - 9.95) / (3 \times 0.015)] \\Cpk &= \min[0.04 / 0.045, 0.06 / 0.045] \\Cpk &= \min[0.89, 1.33] \\Cpk &= 0.89\end{aligned}$$

Conclusion: - Cp = 1.11 (marginal spread) - Cpk = 0.89 (**incapable** - process producing defects)
- **Actions:** - **Immediate:** 100% inspection of this characteristic until process improved - **Short-term:** Center process (adjust offset from 10.01 to 10.00 to improve Cpk) - **Long-term:** Reduce variation (investigate causes: tool wear, machine repeatability, operator technique, material variation)

22.5.5.3 Long-Term Process Performance (Pp, Ppk)

Long-Term Process Performance: Measures process performance over extended period (months), capturing all sources of variation including long-term drift and changes

When to Use Pp, Ppk

- PPAP submissions (initial process study before full production)
- Pre-production or pilot runs
- Long-term monitoring and trending

Difference from Cp, Cpk

Aspect	Cp, Cpk	Pp, Ppk
Time Period	Days to weeks (short-term)	Weeks to months (long-term)
Variation Sources	Normal production variation	All variation including long-term drift, seasonal effects
Purpose	Assess process capability	Assess overall process performance
Standard Deviation	Within-subgroup (short-term σ)	Overall standard deviation

Typical Sequence: 1. **Initial Study (PPAP):** Ppk from initial production (before process fully stabilized) 2. **Ongoing Monitoring:** Cpk from production over time (process should improve as it stabilizes)

Formulas Pp (Process Performance Index):

$$Pp = (USL - LSL) / (6\sigma_{overall})$$

Ppk (Process Performance Index accounting for centering):

$$Ppk = \min[(USL - \bar{x}) / (3\sigma_{overall}), (\bar{x} - LSL) / (3\sigma_{overall})]$$

$\sigma_{overall}$: Overall standard deviation (calculated from all individual measurements, not within-subgroup)

Interpretation: Same as Cpk: - Ppk \geq 1.67 (APQP target for new processes) - Ppk \geq 1.33 (minimum capability)

Relationship Between Pp/Ppk and Cp/Cpk If process is stable and in control: - $P_p \approx C_p$ - $P_{pk} \approx C_{pk}$

If Pp/Ppk significantly lower than Cp/Cpk: - Indicates long-term drift or instability - Process shifting over time (tool wear, temperature changes, material variation) - **Action:** Investigate and address long-term variation sources

Improving Process Capability

If Cpk < Target (typically 1.33), improvement needed:

1. Center the Process (Improves Cpk) If Cp is acceptable but Cpk low: - Process off-center (mean not at nominal) - **Action:** Adjust process mean (offset in CNC program, setup adjustment) - **Result:** Cpk increases toward Cp

Example: - Target: 10.00 mm \pm 0.05 mm - Current: $\bar{x} = 10.025$ mm (off by +0.025 mm) - **Adjustment:** Offset by -0.025 mm to center at 10.00 mm - **Result:** Cpk improves

2. Reduce Variation (Improves Both Cp and Cpk) If Cp is inadequate: - Process variation too large relative to tolerance - **Actions:** - **Machine:** Check machine accuracy (ballbar, laser calibration), improve rigidity, reduce thermal drift - **Tooling:** Better tool holders (hydraulic, shrink-fit vs. collet), tighter runout, replace worn tools sooner - **Fixturing:** Improve work holding (reduce deflection, better location) - **Material:** Tighter control of incoming material (reduce hardness variation, better stock dimensions) - **Operator:** Standardize setup procedures, training, reduce variation between operators - **Measurement:** Improve measurement system (Gage R&R), reduce measurement variation - **Environment:** Control temperature (especially for precision work), reduce vibration

Example: - Cp = 0.90 (inadequate) - Investigation finds tool runout excessive (.003" TIR) - **Action:** Replace tool holder with hydraulic holder (runout <.0002") - **Result:** σ reduced, Cp and Cpk improve to 1.5

3. Widen Tolerance (Last Resort) If process cannot be improved: - Request engineering tolerance revision (if function allows) - Change to more capable process (different machine, method) - **Note:** Widening tolerance reduces quality level; only acceptable if function not compromised

Capability Study Documentation

Capability Study Report Should Include: - Part number, drawing number, characteristic studied - Specification (USL, LSL, nominal) - Sample size and collection period - Data summary (mean, standard deviation, min, max) - Histogram (shows distribution) - Normal probability plot (verifies normality) - Cp, Cpk (or Pp, Ppk) calculations - Control chart (X-bar/R or Individuals) showing stability - Conclusion (capable or incapable) - Actions (if incapable) - Approval signatures

Software Tools: - Minitab (industry standard for statistical analysis) - JMP - Excel with statistical add-ins - QC software (InfinityQS, etc.)

22.5.6 Setup Approval and First-Off Inspection

Setup Approval: Verification that machine setup is correct before running production, preventing production of nonconforming parts.

Purpose of First-Off Inspection

Benefits: - Catches setup errors early (work offset, tool length, fixture alignment, wrong program) - Prevents scrap (costly to scrap entire lot) - Reduces rework - Verifies process under control before production - Required by most quality systems (ISO 9001, AS9100, IATF 16949)

Cost of Skipping First-Off: - Example: 100-piece lot, \$50 material per piece, setup error causes all 100 scrapped = \$5,000 scrap + labor + schedule impact - First-off inspection cost: 30 minutes inspector time (~\$30) □ **Massive ROI**

First-Off Inspection Procedure

1. **Operator Completes Setup:** - Install tooling, fixtures, work offsets per setup sheet - Load program - Verify program number matches work order
2. **Operator Runs First Part:** - Machine one complete part (or small batch if setup requires multiple parts) - Perform basic checks: - Visual: All features machined? Obvious errors? - Key dimensions: Quick check with calipers or gage (not full inspection)
3. **Operator Submits to Inspection:** - Deliver first-off part, traveler, and drawing to Inspection - Production on hold until approval
4. **Inspector Performs Inspection:** - Retrieve applicable drawing and control plan - Measure characteristics per control plan: - **Critical characteristics:** 100% (all critical dimensions/features) - **Major characteristics:** Representative sample - **Minor characteristics:** Spot check - Record results on traveler or inspection report
5. **Approval or Rejection:** - **If ALL measurements within tolerance:** - Inspector approves (stamps "APPROVED" or signs traveler) - Operator proceeds with production - **If ANY measurement out of tolerance:** - Inspector rejects (stamps "REJECTED") - Inspector notifies operator and supervisor - Operator adjusts setup - Repeat process (Steps 2-5)
6. **Documentation:** - Inspection results retained (on traveler, in inspection log, or electronic record) - Setup approval signature

Setup Approval Frequency

When Setup Approval Required: - **Every setup** (most conservative, recommended for critical parts) - **New job or part** (first time running) - **After tool change** (if tool change affects critical dimensions) - **After significant downtime** (machine off overnight or longer) - **When process unstable** (history of setup errors)

Reduced First-Off (if process proven stable): - Visual and basic check by operator - Full inspection periodic (every 5th setup, weekly, etc.) - Risk-based approach (low-risk parts, proven processes, experienced operators)

Setup Approval Documentation

Traveler / Router: - Job tracking document that follows part through manufacturing - Includes section for first-off inspection results

Example Traveler Section:

FIRST-OFF INSPECTION			
Operation: _____	Setup Date: _____		
Operator: _____	Inspector: _____		
Characteristic	Requirement	Result	OK?
_____	_____	_____	[]
_____	_____	_____	[]
_____	_____	_____	[]
<input type="checkbox"/> APPROVED - Proceed with production			
<input type="checkbox"/> REJECTED - Adjust setup and re-inspect			
Inspector Signature: _____		Date: _____	
Supervisor Approval: _____		Date: _____	

Summary

Process control and validation ensure manufacturing processes consistently produce conforming products. Process mapping identifies activities and interactions. KPIs measure performance and drive improvement. Capability studies quantify process performance relative to specifications. Special processes require validation to ensure outputs meet requirements. Setup approval prevents costly scrap by verifying setup correctness before production.

Effective process control balances rigor with practicality, focusing resources on critical characteristics and processes while avoiding over-control of stable, capable processes. Data-driven decision making (capability indices, SPC, KPIs) enables continuous improvement and builds customer confidence.

Key Takeaways

1. **Process mapping** visualizes workflow; tools include SIPOC, flow diagrams, swim lanes, turtle diagrams

2. **KPIs** measure process performance; select metrics that are measurable, relevant, actionable, timely
 3. **Common CNC KPIs:** Scrap rate, first-pass yield, on-time delivery, Cpk, machine utilization
 4. **Validation required for special processes** where output cannot be verified (heat treatment, welding, plating, sterilization)
 5. **Process validation includes:** IQ (installation), OQ (operation), PQ (performance)
 6. **Machine capability (Cm, Cmk)** measures machine inherent capability (short-term, ideal conditions)
 7. **Process capability (Cp, Cpk)** measures entire process including normal variation (short-to-medium term)
 8. **Long-term performance (Pp, Ppk)** measures process over extended period (months)
 9. **Cpk >= 1.33 minimum** for capable process; >=1.67 for critical characteristics
 10. **Improve Cpk by:** Centering process (if Cp OK) or reducing variation (if Cp inadequate)
 11. **Setup approval (first-off inspection)** prevents production of nonconforming parts; massive ROI
 12. **Special processes** (welding, heat treatment, plating) require qualified procedures, equipment, and personnel
-

Review Questions

1. What is the difference between a process map, flowchart, and turtle diagram? When would you use each?
 2. List five quality KPIs and five delivery/efficiency KPIs relevant to CNC manufacturing.
 3. What is the difference between verification and validation?
 4. When is process validation required per ISO 9001?
 5. Describe the three stages of process qualification: IQ, OQ, PQ.
 6. Why are welding, heat treatment, and plating considered “special processes”?
 7. What is the difference between Cm/Cmk (machine capability) and Cp/Cpk (process capability)?
 8. What is the difference between Cp/Cpk and Pp/Ppk?
 9. If Cpk = 0.9, what does this indicate? What actions should be taken?
 10. How can you improve Cpk if Cp is acceptable but Cpk is low?
 11. What is the purpose of setup approval (first-off inspection)?
 12. When should setup approval be performed?
-

Practical Exercises

Exercise 1: Create a Process Map

Create a process flow diagram for a CNC machining job from order to shipment: 1. List all major steps 2. Identify decision points 3. Draw flowchart with appropriate symbols 4. Identify potential bottlenecks or problem areas

Exercise 2: Select and Define KPIs

For your shop (or hypothetical shop), select 5 key KPIs: 1. Define each KPI (formula, purpose) 2. Set realistic targets 3. Determine measurement frequency 4. Assign ownership (who monitors, who acts) 5. Describe how you would display KPIs (dashboard design)

Exercise 3: Conduct a Capability Study

Perform a simplified capability study on a process: 1. Select a dimension or characteristic 2. Collect 30 measurements (from existing data or measure actual parts) 3. Calculate mean and standard deviation (use Excel AVERAGE and STDEV functions) 4. Calculate Cp and Cpk (use formulas) 5. Interpret results: Is process capable? What actions needed?

Example Calculation: - Spec: 25.0 ± 0.1 mm (USL=25.1, LSL=24.9) - Data: Measure 30 parts - Mean (\bar{x}) = 25.02 mm - Std Dev (σ) = 0.025 mm - $C_p = (25.1 - 24.9) / (6 \times 0.025) = 0.2 / 0.15 = 1.33$ - $C_{pk} = \min[(25.1 - 25.02)/(3 \times 0.025), (25.02 - 24.9)/(3 \times 0.025)] = \min[1.07, 1.60] = 1.07$ - **Conclusion:** Cp adequate but Cpk low due to off-center process; adjust offset to improve Cpk

Exercise 4: Design a Setup Approval Process

Develop a setup approval procedure for your shop: 1. Define when setup approval required 2. List what characteristics to inspect (use example part) 3. Create traveler section or form for recording first-off results 4. Define approval criteria (all in spec? Sample size?) 5. Define reaction plan if rejected

Exercise 5: Validation Protocol for Special Process

Write a simplified validation protocol for a special process: 1. Select process (heat treatment, welding, plating, or other) 2. Define requirements (what must process achieve?) 3. List equipment and parameters 4. Outline IQ, OQ, PQ activities 5. Specify sample size and acceptance criteria 6. Define ongoing controls after validation

Additional Resources

Capability Analysis: - AIAG SPC Manual (Statistical Process Control) - AIAG MSA Manual (Measurement Systems Analysis) - Minitab tutorials (capability analysis, control charts) - "Statistical Process Control" by Douglas Montgomery

Process Validation: - FDA Guidance for Industry: Process Validation (medical devices) - ASME Boiler and Pressure Vessel Code Section IX (welding) - AMS 2750 (Pyrometry for heat treatment) - Nadcap website: www.p-r-i.org (aerospace special processes)

Software: - Minitab (statistical analysis, capability studies, control charts) - JMP - InfinityQS (SPC software) - Excel with Analysis ToolPak

Standards: - ISO 9001:2015 Clause 8.5 (Production and Service Provision) - IATF 16949 (Automotive process requirements) - AS9100 (Aerospace process requirements) - ISO 13485 (Medical device validation requirements)

Training: - ASQ Certified Quality Engineer (CQE) - ASQ Certified Reliability Engineer (CRE) - SPC training courses - Minitab training

Module 22 - Quality Management Systems (QMS)

The quality of purchased materials, components, and services directly impacts final product quality. Effective supplier quality management ensures external providers consistently deliver conforming products and services. This section covers supplier selection, evaluation, monitoring, and control.

22.6.1 Supplier Selection and Evaluation

Supplier Selection: Process of identifying and qualifying suppliers capable of meeting requirements

Importance of Supplier Selection

Quality Risks from Poor Suppliers: - Defective materials (wrong alloy, out-of-spec dimensions) - Inconsistent quality (lot-to-lot variation) - Counterfeit materials (especially in aerospace) - Process failures (heat treatment out of spec, plating defects) - Supply disruptions (late deliveries, shortages)

Your Quality = Supplier's Quality: - Cannot inspect quality into product after materials arrive - Prevention through qualified suppliers more effective than inspection - Customer holds you responsible regardless of supplier issues

Types of Suppliers

Material Suppliers: - Raw materials (bar stock, plate, castings, forgings) - Metal distributors vs. mills - Specialty materials (aerospace alloys, medical-grade)

Outside Service Providers: - Heat treatment - Plating and coating - Welding, grinding, EDM - NDT (non-destructive testing) - Calibration services

Tooling and Consumables: - Cutting tools (end mills, drills, inserts) - Abrasives (grinding wheels, sandpaper) - Coolant, lubricants, chemicals - Gages and measuring equipment

Component Suppliers (if applicable): - Fasteners, hardware - Off-the-shelf components - Sub-assemblies

Supplier Selection Criteria

1. Technical Capability: - Equipment and processes adequate for requirements - Technical expertise and experience - Capacity to meet volume requirements - Lead times acceptable

2. Quality Management System: - ISO 9001 certification (baseline for most suppliers) - Industry-specific certifications: - AS9100 (aerospace suppliers) - ISO 13485 (medical device suppliers) -

IATF 16949 (automotive suppliers) - Nadcap (aerospace special processes) - Quality history and reputation

3. Cost: - Competitive pricing - Total cost of ownership (not just unit price): - Defect costs (inspection, rework, scrap) - Delivery costs (expediting, stock-outs) - Administrative costs (managing problems) - Value vs. price (cheapest != best value)

4. Delivery Performance: - On-time delivery track record - Lead time reliability - Flexibility (expedites, schedule changes) - Geographic location (local vs. overseas)

5. Financial Stability: - Business viability (not at risk of closure) - Credit rating - Years in business - Customer base (sole reliance on one customer risky)

6. Responsiveness and Communication: - Ease of communication - Responsiveness to inquiries and issues - Willingness to collaborate and improve - Customer service quality

7. Risk Factors: - Single-source vs. multiple sources - Critical vs. commodity item - Counterfeit risk (aerospace materials, electronics) - Supply chain stability

Supplier Evaluation Methods

Desktop Evaluation Review Publicly Available Information: - Website (capabilities, certifications, equipment) - Industry reputation (references, online reviews) - Certifications (ISO 9001 certificate, Nadcap listing) - Financial information (Dun & Bradstreet report)

Request Information from Supplier: - Supplier questionnaire (capabilities, certifications, quality system) - Quality manual or procedures (if applicable) - Sample certifications or test reports - Customer references

Supplier Questionnaire Topics: - Company overview (history, ownership, size) - Certifications (ISO 9001, AS9100, Nadcap, etc.) - Equipment list and capabilities - Quality management system overview - Key customers and markets served - Capacity and lead times - Material traceability and control - Calibration and maintenance programs - Nonconformance and corrective action processes

Trial Order Small Sample Order: - Purchase small quantity or pilot lot - Evaluate quality, delivery, communication - Perform incoming inspection (dimensional, material testing) - Assess documentation (certifications, test reports, packaging)

Advantages: - Real-world evaluation (not just paper review) - Low risk (small quantity) - Demonstrates supplier's actual performance

Trial Order Evaluation Criteria: - Quality: Meet specifications? Defect-free? - Delivery: On-time? Packaged properly? - Documentation: Complete certifications? Accurate? - Communication: Responsive to questions?

Supplier Audit (Site Visit) On-Site Assessment: - Visit supplier facility - Evaluate quality system, processes, equipment - Interview personnel - Review records

When Supplier Audit Warranted: - Critical suppliers (high-risk materials, special processes) - High-value contracts - Customer requirement (some aerospace/medical customers require supplier audits) - Supplier lacks certifications (ISO 9001) - Poor performance or major issues

Supplier Audit Checklist Topics:

Management and Quality System: - Quality policy and objectives - Management commitment - Document control - Corrective action system

Personnel: - Training and competence records - Qualifications (welders, inspectors, heat treaters) - Staffing levels and turnover

Equipment and Facilities: - Condition and maintenance of equipment - Calibration program - Cleanliness and organization (5S) - Capacity and capability

Processes: - Process controls (procedures, work instructions) - In-process inspection - Special process validation (heat treatment, plating) - Traceability systems

Quality Records: - Inspection and test records - Nonconformance and corrective action records - Calibration records - Material certifications

Supplier Audit Report: - Summary of findings (conformances, nonconformances, observations) - Score or rating (if using scoring system) - Recommendation (approve, conditional approval, reject) - Corrective actions required (if conditional) - Follow-up plan

Approved Supplier List (ASL)

Approved Supplier List (ASL): Maintained list of qualified suppliers authorized for purchasing

ASL Management: - Only purchase from suppliers on ASL (enforced through purchasing system) - ASL includes: - Supplier name and contact information - Products/services qualified for - Certifications held - Approval date - Evaluation method (audit, trial order, desktop review) - Risk level (critical, major, minor) - Periodic review and update (remove poor performers, add new suppliers)

Adding Supplier to ASL: 1. Supplier evaluation (desktop, trial order, audit) 2. Approval by Quality Manager (and/or cross-functional team) 3. Add to ASL

Removing Supplier from ASL: - Poor performance (quality, delivery) - Loss of certification (ISO 9001, Nadcap) - Business closure or major issues - Notification to purchasing and affected departments

Example ASL Entry:

Supplier Name	Product/Service	Certification	Risk Level	Approval Date	Approved By
ABC Metals	Aluminum bar stock	ISO 9001, AS9100	Medium	2023-05-15	Q. Manager
XYZ Heat Treat Tooling Inc.	Heat treatment	ISO 9001, Nadcap	Critical	2022-08-20	Q. Manager
	Cutting tools	None	Low	2024-01-10	Purchasing

22.6.2 Supplier Audits and Assessments

Supplier audits verify that suppliers maintain quality systems and processes capable of consistently meeting requirements.

Types of Supplier Audits

- 1. Initial Qualification Audit:** - Before approving new supplier - Comprehensive assessment of QMS and capabilities
- 2. Surveillance Audit:** - Periodic audit of approved suppliers (annually, every 2-3 years) - Verify continued compliance and performance
- 3. For-Cause Audit:** - Triggered by problems (defects, delivery issues, nonconformances) - Investigate root causes and verify corrective actions
- 4. Process Audit:** - Focused on specific process (not entire QMS) - Example: Audit heat treatment process at supplier
- 5. Product Audit:** - Inspect product at supplier before shipment - Verify quality before delivery (high-risk or first-time orders)

Supplier Audit Process

- 1. Audit Planning:** - Define audit scope (QMS, specific process, product) - Select audit team (lead auditor, technical expert if needed) - Review supplier information (previous audits, quality manual, recent performance) - Prepare audit checklist - Schedule with supplier (2-4 weeks advance notice) - Send audit plan to supplier
 - 2. Opening Meeting:** - Introductions (audit team, supplier management and escorts) - Confirm scope and schedule - Explain audit process - Tour of facility
 - 3. Audit Execution:** - Interview personnel (management, operators, inspectors, quality) - Observe processes (manufacturing, inspection, testing) - Review documents (procedures, work instructions, control plans) - Review records (inspection records, calibration, training, nonconformances) - Collect evidence (photos, copies of records)
 - 4. Audit Findings:** - **Conformance:** Process meets requirements - **Nonconformance:** Failure to meet requirement (major or minor) - **Observation:** Opportunity for improvement (not yet non-conformance)
- Finding Documentation:** - Describe finding clearly - Cite requirement (ISO 9001 clause, specification, procedure) - Provide objective evidence (what was observed, records reviewed)

Example Findings:

Major Nonconformance: "Three of five heat treatment furnaces have no record of temperature uniformity survey in past 12 months. AMS 2750 requires annual TUS. (Nonconformance to AMS 2750 Section 3.2.2)"

Minor Nonconformance: "Calibration sticker on micrometer S/N 12345 shows due date of 15-MAR-2024, but current date is 22-MAR-2024 (7 days overdue). (Nonconformance to ISO 9001 Clause 7.1.5.1)"

Observation: “Work instructions at machining station are printed on paper and showing wear/staining from coolant exposure. Consider laminating or providing digital display to preserve legibility.”

5. Closing Meeting: - Present findings to supplier management - Discuss nonconformances and observations - Supplier may provide clarifications or immediate corrective actions - Discuss next steps (corrective action plan, follow-up)

6. Audit Report: - Executive summary - Audit scope and dates - Audit team and supplier attendees - Findings (detailed description of each conformance, nonconformance, observation) - Recommendations - Approval and distribution

7. Corrective Action Follow-Up: - Supplier submits corrective action plan (CAP) within specified timeframe (30 days typical) - CAP includes: - Immediate containment (if applicable) - Root cause analysis - Corrective action to prevent recurrence - Completion date - Auditor reviews and approves CAP - Follow-up verification (document review, re-audit, or next surveillance audit)

Supplier Audit Frequency

Frequency Based on Risk:

Risk Level	Audit Frequency	Criteria
Critical	Annually	Special processes (heat treat, plating, welding); safety-critical materials; sole-source; poor performance history
High	Every 2 years	Key suppliers; significant quality impact; moderate performance
Medium	Every 3 years	Routine suppliers; good performance; ISO 9001 certified
Low	As needed	Commodity items; excellent performance; minimal risk

Factors Increasing Audit Frequency: - Lack of certification (ISO 9001) - Quality issues or non-conformances - New supplier (audit within 1st year) - Customer requirement (some aerospace customers require annual supplier audits)

Factors Decreasing Audit Frequency: - Excellent performance (zero defects, on-time delivery) - Strong certifications (ISO 9001, AS9100, Nadcap) - Low-risk commodity items - Long history of satisfactory performance

Remote Audits

Remote (Virtual) Audits: - Conducted via video conference - Became common during COVID-19, now accepted by many standards and customers

Remote Audit Process: - Video call with supplier (Zoom, Teams, etc.) - Supplier uses camera to show facility, equipment, records - Screen sharing to review documents and records - Interviews via video

Advantages: - Lower cost (no travel) - Faster scheduling - Can audit more suppliers

Limitations: - Less comprehensive than on-site - Relies on supplier cooperation (showing what auditor requests) - Difficult to observe processes in detail - May miss issues visible on-site

Best Practice: Combine remote and on-site audits - Initial qualification: On-site preferred - Surveillance audits: Alternate remote and on-site - For-cause audits: On-site (if serious issues)

22.6.3 Supplier Performance Monitoring

Ongoing monitoring of supplier performance ensures continued capability and identifies problems early.

Supplier Performance Metrics

1. Quality Metrics:

Incoming Defect Rate:

Defect Rate (%) = (Rejected Lots or Parts / Total Received) × 100

Parts Per Million (PPM):

PPM = (Defective Parts / Total Parts) × 1,000,000

First-Pass Acceptance Rate:

Acceptance Rate (%) = (Lots Accepted First Time / Total Lots) × 100

2. Delivery Metrics:

On-Time Delivery (OTD):

OTD (%) = (Orders Delivered On-Time / Total Orders) × 100

Lead Time Performance: - Actual lead time vs. quoted lead time - Consistency of lead times

3. Responsiveness: - Response time to inquiries - Flexibility (handling expedites, schedule changes) - Communication quality

4. Cost: - Price competitiveness - Price stability (avoid frequent increases) - Total cost (including defects, delays)

5. Documentation: - Certification accuracy and completeness - Traceability documentation - Timely submission of required documents

Supplier Scorecard

Supplier Scorecard: Report card summarizing supplier performance across multiple metrics

Example Scorecard:

Supplier: ABC Heat Treatment Period: Q2 2024

Metric	Target	Actual	Score	Weight	Weighted Score
Quality (PPM)	<100	45	100	40%	40
On-Time Delivery	>=95%	92%	85	30%	25.5
Responsiveness (1-10)	>=8	9	100	10%	10
Documentation	>=95% complete	98%	100	10%	10
Cost Stability	No increases	1 increase	75	10%	7.5
Overall Score					93

Scoring: - 90-100: Excellent (green) - 80-89: Good (yellow) - 70-79: Marginal (orange) - <70: Unacceptable (red)

Actions Based on Score: - **Green (90-100):** Preferred supplier, consider increased business - **Yellow (80-89):** Acceptable, monitor closely - **Orange (70-79):** Corrective action required, escalate to supplier management - **Red (<70):** Immediate action required, consider alternate sources, place on probation or remove from ASL

Scorecard Distribution: - Share with supplier (quarterly or semi-annually) - Discuss performance (review meeting or call) - Recognize excellent performance - Collaborate on improvement plans for poor performance

Data Collection and Tracking

Incoming Inspection Data: - Record defects found during receiving inspection - Categorize by defect type, supplier, material - Track trends over time

Delivery Data: - Track order date, promised date, actual delivery date - Calculate on-time delivery percentage - Identify chronic late deliveries

Supplier Quality Database: - Software system or spreadsheet tracking supplier performance - Enables reporting and trending - Examples: ERP system supplier module, quality management software, custom database

Periodic Reporting: - Monthly or quarterly supplier performance reports - Review in management review meetings - Share with suppliers

22.6.4 Incoming Inspection and Receiving Procedures

Incoming inspection verifies that purchased materials and services meet specified requirements before use in production.

Purpose of Incoming Inspection

Catch Defects Early: - Prevent defective materials from entering production (causing scrap, re-work, delays) - Less costly to reject at receiving than discover after machining

Verify Supplier Performance: - Confirm supplier quality claims - Detect supplier process problems - Provide data for supplier scorecard

Traceability: - Verify material certifications - Link received material to purchase order and job

Risk Mitigation: - Counterfeit material detection (aerospace) - Regulatory compliance verification (DFARS, RoHS, REACH)

Incoming Inspection Levels

Level of Inspection Depends on Risk:

- 1. No Inspection** (low risk): - Commodity items (office supplies, consumables) - Trusted suppliers with excellent history - Non-critical items
- 2. Document Review Only** (low-medium risk): - Verify packing slip and certifications received - No physical inspection - Suitable for certified suppliers with good history
- 3. Visual and Dimensional Checks** (medium risk): - Visual inspection (damage, correct material, markings) - Basic dimensional checks (diameter, length of stock) - Material certifications reviewed
- 4. Full Inspection** (high risk): - Detailed dimensional inspection - Material verification (chemical analysis, hardness) - First Article Inspection (FAI) for new suppliers or products - Critical materials (aerospace, medical)
- 5. Source Inspection** (critical risk): - Inspect at supplier location before shipment - Used for high-value, critical, or one-time purchases - Ensures quality before expensive shipping

Incoming Inspection Procedure

- 1. Receive Shipment:** - Receiving department accepts delivery - Check for obvious damage (boxes crushed, crate damaged) - Sign delivery receipt
- 2. Verify Shipment:** - Match packing slip to purchase order (PO) - Verify part number, quantity, supplier - Check for required documentation (certifications, test reports)
- 3. Hold for Inspection:** - Material segregated in "Incoming Inspection" area - Tagged "HOLD - AWAITING INSPECTION" - Not released to production until approved
- 4. Perform Inspection:** - Inspector retrieves PO and specifications - Performs inspection per incoming inspection plan

Typical Inspection Checks:

Visual Inspection: - Correct material (verify markings, color, appearance) - Condition (corrosion, damage, defects) - Quantity (count or weigh) - Packaging (adequate protection)

Dimensional Inspection: - Verify stock dimensions (diameter, thickness, length) - Sample inspection (measure representative samples) - Use calipers, micrometer, tape measure

Material Verification: - Review material certification (MTR - Material Test Report) - Verify heat lot number on material matches certification - Confirm alloy, specification (e.g., 6061-T6, AMS 4027) - Check chemical composition and mechanical properties on MTR - Physical/chemical testing (for critical materials): - PMI (Positive Material Identification): XRF analyzer verifies alloy - Hardness testing: Verify heat treatment condition - Tensile testing: For critical applications (sample basis)

Documentation Verification: - Certifications complete and accurate - Traceability information (heat lot, batch number) - Compliance statements (DFARS, RoHS, REACH) - Test reports (if required)

5. Acceptance Decision: - **Accept:** Material meets all requirements - Tag “APPROVED” or “RELEASED” - Move to stock or production area - Update inventory system - **Reject:** Material does not meet requirements - Tag “REJECTED” - Segregate in reject area - Issue supplier corrective action request (SCAR) - Return to supplier or scrap - **Conditional Accept** (use-as-is): - Minor nonconformance - Requires engineering/quality approval - Document deviation and justification

6. Documentation: - Incoming inspection report (paper or electronic) - PO number, supplier, material description - Inspection results (dimensions, visual observations) - Accept/reject decision - Inspector signature and date - Retain certifications with receiving records - Link material lot to jobs where used (traceability)

Reduced Inspection

Reduced Inspection Programs: - For suppliers with proven performance, reduce inspection intensity - Saves time and cost

Criteria for Reduced Inspection: - Supplier certified (ISO 9001, AS9100) - Scorecard rating ≥ 90 for 6-12 months - Zero defects in recent history (e.g., last 20 lots) - Low-risk material

Reduced Inspection Levels: - **Skip-lot inspection:** Inspect every 5th or 10th lot (others dock to stock) - **Sample inspection:** Inspect reduced sample size - **Document review only:** Verify certifications without physical inspection - **Dock-to-stock:** Material released directly to production without inspection (highest trust)

Monitoring: - Continue tracking supplier performance - Return to full inspection if defects found or performance declines

Example Policy: > Suppliers rated ≥ 95 on scorecard for 6 consecutive months with zero defects qualify for skip-lot inspection (inspect 1 in 5 lots, document review only for others). If any lot rejected, return to 100% inspection for 6 months.

Handling Nonconforming Purchased Materials

When Material Rejected at Incoming Inspection:

1. Segregate and Identify: - Move to reject area (bonded cage, separate location) - Red tag “REJECTED” - Do not use in production

2. Document Nonconformance: - Incoming inspection report shows rejection - Nonconformance Report (NCR) issued - Describe defect (dimensions out of spec, wrong material, damaged, missing certification)

- 3. Notify Supplier:** - Contact supplier immediately - Provide details (PO, part number, quantity, defect description) - Request corrective action
 - 4. Disposition:** - **Return to Supplier:** Supplier credits or replaces (most common) - **Use-As-Is:** Engineering determines defect acceptable (with customer concession if required) - **Sort:** Separate good from bad (if some conforming) - **Scrap:** If no value (often supplier pays scrap cost)
 - 5. Supplier Corrective Action Request (SCAR):** - Formal request for corrective action (see next section)
 - 6. Impact Mitigation:** - Check inventory for alternate material - Expedite replacement from supplier - Seek alternate source if critical - Communicate with customer if delivery impacted
-

22.6.5 Supplier Corrective Action Requests (SCAR)

SCAR: Formal notification to supplier of nonconformance requiring corrective action

When to Issue SCAR

Triggers: - Material rejected at incoming inspection - Defect discovered during production (traced to supplier material) - Delivery issues (chronic late deliveries) - Documentation problems (missing or incorrect certifications) - Multiple minor issues indicating systemic problem

Not Every Defect Requires SCAR: - One-time isolated defects may be handled informally (phone call, email) - SCAR for recurring issues or significant problems

SCAR Process

1. Initiate SCAR: - Quality Manager or Purchasing issues SCAR to supplier - SCAR form sent via email (often fillable PDF)

SCAR Form Contents: - SCAR number (tracking) - Date issued - Supplier name and contact - Purchase order number - Material or service description - Description of nonconformance (specific, detailed) - What was wrong? - How discovered? - Quantity affected - Photos or attachments - Immediate action taken (rejected, returned, sorted)

2. Supplier Response Requested: - **Immediate Response** (24-48 hours): Containment actions - Stop shipments if necessary - Inspect remaining inventory - Identify potentially affected shipments to other customers - **Formal Response** (10-30 days): Corrective action plan - Root cause analysis (5 Whys, Fishbone, etc.) - Corrective action to prevent recurrence - Preventive action for similar issues - Timeline for implementation - Effectiveness verification plan

3. Review Supplier Response: - Quality Manager reviews supplier's corrective action plan - **Acceptable:** Approve plan, close SCAR - **Not Acceptable:** Reject, request revised plan (inadequate root cause, corrective action insufficient)

4. Verify Effectiveness: - Monitor subsequent shipments - Verify corrective action implemented - If issue recurs, re-open SCAR or escalate

5. Close SCAR: - Corrective action verified effective - Document closure (date, approval) - Update supplier scorecard

Example SCAR

SUPPLIER CORRECTIVE ACTION REQUEST (SCAR)	
SCAR Number: SCAR-2024-042	

Date Issued: 15-May-2024	
Issued By: Jane Smith, Quality Manager	

Supplier: ABC Metals, Inc.	
Contact: John Doe, Quality Manager	
Email: jdoe@abcmetals.com	

Purchase Order: P0-54321	
Material: 6061-T6 Aluminum bar, 2.0" diameter	
Quantity Received: 50 pieces, 12 ft each	

DESCRIPTION OF NONCONFORMANCE:	
Incoming inspection found diameter of received	
material measures 1.985" to 1.992" (average 1.988").	
Purchase order specified 2.000" +/- .010" (1.990" to	
2.010"). Material is undersized by .008" to .015".	

All 50 pieces inspected, all out of specification.	
Material certification provided (MTR #123456) does	
not list diameter, only confirms alloy 6061-T6.	

IMMEDIATE ACTION TAKEN:	
- All 50 pieces rejected and segregated	
- Material tagged REJECTED, held in bonded cage	
- Production notified, alternate material sourced	
- Request replacement material by 22-May-2024	

SUPPLIER RESPONSE REQUESTED:	
1. Immediate (48 hours):	
- Verify remaining inventory	
- Confirm replacement shipment details/date	
2. Formal corrective action plan (within 30 days):	
- Root cause analysis	
- Corrective actions to prevent recurrence	
- Verification of effectiveness	

Please respond by: 17-May-2024 (immediate)	
14-Jun-2024 (formal CAP)	

Attachments: Incoming inspection report, photos	

SCAR Tracking

SCAR Log: - Maintain register of all SCARs issued - Track status (open, awaiting response, closed) - Aging report (open SCARs past due)

Example SCAR Log:

SCAR #	Date Issued	Supplier	Issue	Status	Due Date	Date Closed
SCAR-2024-041	10-May	XYZ Plating	Coating thickness low	Closed	09-Jun	05-Jun
SCAR-2024-042	15-May	ABC Metals	Diameter undersized	Open	14-Jun	
SCAR-2024-043	20-May	Heat Treat Co	Late delivery	Open	19-Jun	

Management Review: - SCARs reviewed in management review meetings - Chronic issues or unresponsive suppliers escalated - Trends analyzed (repeat issues from same supplier)

22.6.6 Approved Supplier Lists (ASL)

Covered in Section 22.6.1, but reinforced here as ongoing management tool.

ASL Maintenance

Periodic Review (annually or semi-annually): - Review all suppliers on ASL - Update based on performance, audits, certifications - Remove poor performers - Add newly qualified suppliers

ASL Status: - **Approved:** Standard purchasing authorized - **Conditional:** Approved with restrictions (e.g., increased inspection, limited volume) - **Probation:** Poor performance; corrective action required; consider alternate sources - **Removed:** No longer authorized for purchasing

Communication: - Purchasing department has access to current ASL - ERP/purchasing system enforces ASL (blocks POs to unapproved suppliers) - Exception process for emergency purchases (Quality Manager approval required)

22.6.7 Purchase Order Requirements and Flow-Down

Purchase Orders (POs) must clearly communicate all requirements to suppliers, including flow-down of customer and regulatory requirements.

Essential PO Information

Standard PO Elements: - Supplier name and address - PO number and date - Part number and description - Quantity - Unit price and total price - Delivery date and shipping instructions - Payment terms - Buyer contact information

Quality and Technical Requirements

Specifications and Standards: - Engineering drawing number and revision - Material specification (ASTM, AMS, ASME, etc.) - Industry standards applicable (ISO, MIL-STD, etc.) - Workmanship standards

Quality Requirements: - Acceptance criteria - Inspection and testing requirements - Sampling plans (if applicable)

Documentation Requirements: - Material Test Report (MTR) / Certification of Conformance (C of C) - Heat treatment certifications - Plating/coating certifications - Test reports (chemical analysis, mechanical properties, NDT) - First Article Inspection Report (if applicable)

Traceability: - Heat lot traceability required - Serial number requirements - Lot/batch identification

Certifications: - Supplier must hold specific certifications (ISO 9001, AS9100, Nadcap) - Personnel certifications (certified welders, inspectors per ASNT/PCN)

Flow-Down Requirements: - Customer-specific requirements (CSR) from end customer - Regulatory compliance (DFARS, RoHS, REACH, ITAR, EAR) - Right of access (customer or regulatory agency may audit supplier) - Notification requirements (process changes, nonconformances)

Example PO Requirement Section:

QUALITY REQUIREMENTS: 1. Material shall conform to AMS 4911, Ti-6Al-4V, solution treated and aged 2. Material Test Report (MTR) required with heat lot traceability 3. Chemical analysis per AMS 4911 Table 1 4. Material must be DFARS compliant (melted and manufactured in USA) 5. Parts shall be manufactured per AS9100 requirements 6. First Article Inspection per AS9102 required before production shipment; submit FAI package for approval 7. Certificate of Conformance required with each shipment 8. Customer reserves right to access supplier facility for audits or source inspection with 48 hours notice 9. Supplier must notify customer within 24 hours of any nonconformances affecting delivered product

PO Review and Approval

Internal Review Before Issuing PO: - Engineering: Verify specifications correct and complete - Quality: Verify quality requirements and flow-down included - Purchasing: Verify supplier on ASL, pricing, delivery

PO Acknowledgment by Supplier: - Supplier reviews and acknowledges acceptance of PO terms - If unable to meet requirements, supplier notifies immediately (negotiate or cancel)

Changes to PO: - Changes issued as PO revision or Change Order - Both parties agree to changes - Quality review if technical changes

Summary

Supplier quality management is critical to overall product quality and business success. Effective supplier management includes careful selection and qualification, ongoing performance monitoring, incoming inspection, and corrective action when issues arise. Clear communication of requirements through purchase orders and collaboration on improvement ensures suppliers deliver conforming materials and services consistently.

Strong supplier relationships built on mutual trust, transparency, and commitment to quality benefit both parties. Treating suppliers as partners rather than adversaries leads to better quality, innovation, and long-term success.

Key Takeaways

1. **Supplier selection** should evaluate technical capability, quality system, cost, delivery, financial stability, and risk
 2. **Supplier evaluation methods** include desktop review, trial orders, and on-site audits
 3. **Approved Supplier List (ASL)** limits purchasing to qualified suppliers
 4. **Supplier audits** verify QMS and processes; frequency based on risk and performance
 5. **Supplier performance monitoring** uses metrics (quality PPM, on-time delivery, responsiveness) and scorecards
 6. **Incoming inspection** verifies materials meet requirements before use; level based on risk
 7. **Reduced inspection** programs reward excellent suppliers with less inspection burden
 8. **Supplier Corrective Action Requests (SCAR)** formalize nonconformance and require root cause analysis and corrective action
 9. **Purchase orders** must clearly communicate all requirements including specifications, documentation, traceability, and flow-down of customer/regulatory requirements
 10. **Supplier relationships** should be collaborative partnerships, not adversarial
 11. **Material certifications** (MTR, C of C) must be verified for accuracy and traceability
 12. **Counterfeit prevention** especially critical for aerospace; purchase from authorized sources, verify certifications, test materials
-

Review Questions

1. What are the key criteria for selecting a supplier?
2. What are the three main methods for evaluating suppliers before approval?
3. What is an Approved Supplier List (ASL) and why is it important?
4. When should a supplier audit be conducted vs. a desktop evaluation?
5. What are the different types of supplier audits (initial, surveillance, for-cause)?
6. What metrics are commonly used in supplier scorecards?
7. What are the different levels of incoming inspection based on risk?
8. What should be checked during incoming inspection of metal bar stock?
9. When should a Supplier Corrective Action Request (SCAR) be issued?
10. What should be included in a SCAR?
11. What are “flow-down requirements” and why are they important?

12. What quality and technical information should be included on a purchase order?

Practical Exercises

Exercise 1: Supplier Evaluation

Evaluate a hypothetical supplier for approval: 1. Define material or service to be purchased (e.g., aluminum bar stock, heat treatment) 2. List evaluation criteria (capability, quality system, cost, delivery, risk) 3. Choose evaluation method (desktop, trial order, audit) with justification 4. Create supplier questionnaire (10 questions) 5. Define acceptance criteria for approval

Exercise 2: Create Supplier Scorecard

Design a supplier scorecard: 1. Select 5 performance metrics (quality, delivery, cost, responsiveness, documentation) 2. Define calculation method for each metric 3. Set targets for each metric 4. Assign weights (totaling 100%) 5. Create scoring system (0-100 scale) 6. Define actions for different score ranges (excellent, good, marginal, unacceptable) 7. Fill in sample scorecard with realistic data

Exercise 3: Develop Incoming Inspection Plan

Create incoming inspection plan for a material: 1. Select material type (bar stock, castings, purchased components) 2. List inspection checks (visual, dimensional, material verification, documentation) 3. Define acceptance criteria for each check 4. Specify required documentation (MTR, C of C, test reports) 5. Determine sample size (100%, sample, skip-lot) 6. Create inspection form or checklist

Exercise 4: Write a SCAR

Draft a Supplier Corrective Action Request: 1. Identify nonconformance (reject incoming material, late delivery, missing certification) 2. Complete SCAR form with: - Description of problem (specific, detailed) - Quantity affected - Immediate action taken - Response requested from supplier (containment, root cause, corrective action) - Timeline 3. What would you look for in supplier's response?

Exercise 5: Purchase Order Requirements

Create quality requirements section for a purchase order: 1. Select purchased item (machined part, raw material, outside service) 2. List all quality and technical requirements: - Specifications and standards - Documentation required - Traceability requirements - Certifications required - Flow-down requirements (regulatory, customer) 3. Write in clear, specific language suitable for PO

Additional Resources

Standards: - ISO 9001:2015 Clause 8.4 (Control of Externally Provided Processes, Products and Services) - AS9100 Clause 8.4 (Enhanced supplier control requirements for aerospace) - IATF 16949 (Automotive supplier management requirements) - ISO 13485 Clause 7.4 (Medical device supplier control)

Supplier Management Tools: - Supplier questionnaire templates (ASQ, industry associations) - Supplier audit checklists (ISO 9001, AS9100) - Supplier scorecard templates (various sources online) - Supplier management software (ERP modules, standalone QMS software)

Books: - “The ASQ Certified Quality Auditor Handbook” (includes supplier auditing) - “Supplier Management Handbook” by Joseph Cavinato - “Strategic Supplier Management” by Philip Carter

Training: - ASQ Certified Quality Auditor (CQA) - includes supplier auditing - Supplier Quality Management courses (ASQ, online providers) - Auditor training (ISO 9001, AS9100, IATF 16949 Lead Auditor courses)

Industry Resources: - AIAG (Automotive Industry Action Group) - supplier management guidelines - SAE (Society of Automotive Engineers) - aerospace standards - ASQ (American Society for Quality) - tools, templates, training

Module 22 - Quality Management Systems (QMS)

Inspection and testing verify that products conform to specified requirements before release to the customer. This section covers inspection planning, in-process and final inspection methods, First Article Inspection, sampling techniques, and inspection documentation.

22.7.1 Inspection Planning from Engineering Drawings

Effective inspection begins with understanding what to inspect and how to interpret engineering requirements.

Reading and Interpreting Drawings

Key Drawing Elements for Inspection:

Title Block: - Part number and revision level - Material specification - Finish requirements (plating, coating, heat treatment) - Scale - Drawing standards referenced (ASME Y14.5, ISO 1101, etc.)

Dimensions and Tolerances: - Linear dimensions (lengths, diameters, widths) - Angular dimensions - Tolerances (bilateral, unilateral, limit dimensions) - General tolerances (tolerance block)

Geometric Dimensioning and Tolerancing (GD&T): - Feature control frames - Datums and datum reference frames - Geometric tolerances (flatness, perpendicularity, position, profile, etc.) - Material condition modifiers (MMC, LMC, RFS)

Surface Finish: - Surface roughness symbols (Ra, Rz values) - Lay direction - Surface texture requirements

Notes and Specifications: - General notes (break sharp edges, deburr, clean, etc.) - Material specifications (ASTM, AMS, SAE standards) - Process requirements (heat treatment, plating, coating per specific spec) - Inspection requirements (100% inspection, sampling, FAI, source inspection) - Customer-specific requirements

Revisions: - Revision history block - Revision clouds or triangles indicating changes - **Critical:** Always inspect to current revision

Identifying Critical Characteristics

Characteristic Classification:

Critical Characteristics (safety, regulatory, or functional importance): - Identified with special symbols: ▲ (triangle), □ (diamond), or "KEY" notation - Affect safety, fit, or function - Require enhanced controls (100% inspection, SPC, special processes) - Typically customer-designated

Major Characteristics: - Affect fit, function, or performance - Require standard controls (inspection per control plan)

Minor Characteristics: - Less critical dimensions - Periodic sampling acceptable

Example Critical Characteristics: - Hole pattern for mounting (affects assembly) - Bearing bore diameter (affects fit and function) - Wall thickness (affects strength, safety) - Surface finish on sealing surface (affects performance)

Creating Inspection Plans

Inspection Plan Development:

1. Review Drawing and Specifications:

- Identify all dimensions, tolerances, GD&T, finishes, notes
- Note critical and key characteristics

2. List All Characteristics to Inspect:

- Every dimension and requirement from drawing
- Number characteristics sequentially (balloon numbers)

3. Prioritize Characteristics:

- Critical: 100% inspection or tight sampling
- Major: Sample inspection per control plan
- Minor: Periodic checks

4. Select Inspection Methods:

- What equipment/gages needed (micrometer, CMM, gage, visual)
- Who performs inspection (operator, inspector, CMM operator)

5. Determine Frequency:

- When to inspect (first-off, in-process, final)
- Sample size and frequency (every part, 1 per 10, hourly, etc.)

6. Define Acceptance Criteria:

- Tolerance from drawing
- Pass/fail criteria for visual or functional checks

7. Document in Control Plan:

- Formalize inspection plan in control plan (covered in Section 22.4.5)
-

22.7.2 In-Process Inspection

In-Process Inspection: Inspection performed during manufacturing (between operations) to verify conformance before proceeding.

Purpose of In-Process Inspection

Catch Problems Early: - Detect nonconformances before additional work added - Prevent scrapping finished parts (expensive machining already completed) - Reduce rework (easier to correct at intermediate stage)

Verify Process Control: - Confirm setup remains correct - Detect tool wear or process drift - Enable adjustments before defects produced

Example Value: - 5-operation part, defect occurs in Operation 2 - If caught at Operation 2: Scrap value = material + Op 1-2 labor (~\$50) - If caught at final inspection: Scrap value = material + all operations labor (~\$200) - **In-process inspection saves \$150 per scrapped part**

When to Perform In-Process Inspection

Strategic Inspection Points:

After Critical Operations: - Operations affecting critical characteristics - Operations difficult or impossible to inspect later (features hidden by subsequent machining)

Before Expensive Operations: - Inspect before costly operation (multi-axis machining, EDM, coating) - Avoid adding value to defective part

After Setup-Dependent Features: - Features controlled by setup (hole locations, work offsets) - Verify setup correct before continuing

Before Irreversible Operations: - Heat treatment (cannot undo) - Welding - Coating

At Process Capability Limits: - Operations with low Cpk or history of problems - More frequent inspection to monitor stability

Example In-Process Inspection Points:

Shaft Machining (4 operations): 1. **Op 1:** Turn OD and face ends - *In-process check:* Diameter and length (setup-dependent, critical dimensions) 2. **Op 2:** Drill and ream bore - *In-process check:* Bore diameter (critical fit dimension, difficult to inspect after Op 3) 3. **Op 3:** Mill keyway - *In-process check:* Keyway dimensions (before expensive Op 4) 4. **Op 4:** Grind OD (final finish) - *Final inspection:* All dimensions

In-Process Inspection Methods

Operator Self-Inspection: - Operator performs checks using gages at workstation - Quick checks (go/no-go gages, calipers, height gage) - Documented on traveler or in-process log

Roving Inspector: - Inspector circulates through shop floor - Checks in-process parts periodically
- Observes processes and verifies control

Dedicated In-Process Inspection Station: - Parts delivered to inspection area between operations
- More thorough inspection (CMM, precision gages) - Formal approval before next operation

Automated In-Process Measurement: - On-machine probing (measure features without removing part)
- Laser measurement (real-time monitoring) - Vision systems (automated inspection)

In-Process Inspection Documentation

Traveler/Router: - Lists operations and inspection checks - Operator or inspector records results
- Signatures and dates

In-Process Inspection Form: - Dedicated form for recording in-process checks - Part identification, operation, date, operator/inspector - Characteristics inspected and results - Accept/reject decision

Example Traveler Section:

Operation 2: Drill and Ream Bore	
Operator: _____ Date: _____	
IN-PROCESS CHECK (after Operation 2):	
Bore Diameter: .500 +/- .001" (.499 - .501")	
Measured: _____"	[] Accept [] Reject
Depth: 2.00 +/- .010" (1.99 - 2.01")	
Measured: _____"	[] Accept [] Reject
Inspector Signature: _____	
[] APPROVED to proceed to Operation 3	
[] REJECTED - Hold for disposition	

22.7.3 Final Inspection and Testing

Final Inspection: Comprehensive inspection performed after all manufacturing operations complete, before release to customer.

Purpose of Final Inspection

Verify Conformance: - Ensure all requirements met (dimensions, finish, appearance, function) - Catch any defects missed by in-process inspection

Release Authorization: - Formal approval to ship - Evidence of conformance for customer

Quality Assurance: - Final check before product leaves facility - Protects company reputation and reduces returns

Final Inspection Scope

What to Inspect:

Dimensional Inspection: - All critical and key dimensions - Sample of minor dimensions (per control plan) - GD&T characteristics (using appropriate methods: CMM, gage, functional gage)

Visual Inspection: - Surface defects (scratches, dents, burrs, cracks) - Finish quality (plating, coating, paint) - Cleanliness - Identification (markings, labels)

Functional Testing (if applicable): - Assemblies: Fit, function, operation - Pressure testing (leak checks for pressure vessels, hydraulic components) - Electrical testing (continuity, resistance, function) - Performance testing (load, speed, accuracy)

Documentation Review: - Traveler complete (all operations signed off) - In-process inspections passed - Special process certifications received (heat treatment, plating, NDT) - Material certifications present (if traceability required)

Packaging: - Properly packaged to prevent damage - Labeled correctly (part number, quantity, customer info) - Handling instructions included (if applicable)

Final Inspection Methods

Manual Inspection: - Inspector uses hand tools (micrometers, calipers, gages, visual aids) - Records results on inspection report - Time-intensive but versatile

Coordinate Measuring Machine (CMM): - Automated dimensional inspection (especially for complex GD&T) - Generates detailed reports - Fast and accurate for complex parts

Functional Gages: - Go/no-go gages (quick pass/fail check) - Functional fixtures (simulate assembly fit)

Automated Optical Inspection: - Vision systems scan parts for defects - Fast for high-volume production - Requires programming and setup

Sampling vs. 100% Inspection

100% Inspection: - Inspect every part, every characteristic - **When Required:** - Critical characteristics affecting safety or function - Incapable process ($Cpk < 1.0$) - Customer requirement - High-value, low-volume parts - Regulatory requirement (aerospace, medical)

Sampling Inspection: - Inspect representative sample from lot - **When Acceptable:** - Capable process ($Cpk \geq 1.33$) - Non-critical characteristics - High-volume production (100% inspection impractical or costly) - **Sample Size:** Determined by statistical sampling plan (see Section 22.7.5)

Risk-Based Approach: - Critical characteristics: 100% inspection or tight sampling - Major characteristics: Standard sampling - Minor characteristics: Reduced sampling or periodic checks

Final Inspection Documentation

Inspection Report: - Formal record of inspection results - **Contents:** - Part identification (part number, serial number, lot number, quantity) - Drawing number and revision - Date of inspection - Inspector name/signature - Characteristics inspected (dimensions, visual, functional) - Results (measurements, pass/fail) - Overall accept/reject decision - Disposition (released to stock, released to ship, hold, reject)

Certificate of Conformance (C of C): - Statement that parts conform to specified requirements
- Accompanies shipment to customer - Signed by authorized quality representative

Example Certificate of Conformance:

CERTIFICATE OF CONFORMANCE	
Supplier: ABC Precision Machining	
Date: 15-May-2024	
Customer: XYZ Manufacturing	
Customer PO: P0-98765	
Part Number: 1234-5678 Rev C	
Description: Titanium Bracket	
Quantity: 100 pieces	
CERTIFICATION:	
The above parts have been manufactured and inspected in accordance with the specified requirements:	
- Drawing 1234-5678 Rev C	
- Material: Ti-6Al-4V per AMS 4911	
- Heat Treatment: Per customer specification	
- Inspection: Per approved control plan	
All parts conform to specified requirements.	
Supporting Documentation:	
- Material Test Report (MTR) #123456	
- Heat Treatment Cert #HT-2024-042	
- Final Inspection Report #FIR-2024-123	
Authorized Signature: _____	
Name: Jane Smith, Quality Manager	
Date: 15-May-2024	

Data Package (for critical applications): - Comprehensive documentation package - Includes: - Certificate of Conformance - Material certifications (MTR) - Process certifications (heat treatment, plating, NDT) - Inspection reports (dimensional, visual, functional) - Test results - First Article Inspection Report (if applicable) - Traceability records

22.7.4 First Article Inspection (FAI)

First Article Inspection verifies that manufacturing processes can produce parts meeting all design requirements. Covered in detail in Section 22.3.1.3 (AS9102), but reinforced here as general quality practice.

FAI Applications Beyond Aerospace

While AS9102 is aerospace-specific, FAI principles apply broadly:

When to Perform FAI (any industry): - New part introduction - Engineering change affecting form, fit, function - New or significantly modified manufacturing process - Change in supplier or manufacturing location - After extended production break (>1 year) - Customer request

FAI Benefits: - Validates manufacturing process before production - Catches design or manufacturing issues early - Provides confidence to customer - Reduces risk of producing nonconforming lots

FAI Documentation (General Practice)

Even Without AS9102 Requirement: - Document comprehensive inspection of first production part(s) - Measure all dimensions and characteristics - Verify material, finishes, processes - Retain as baseline for future reference

FAI Report Contents: - Part identification - Drawing and specification references - Sample size inspected - Detailed inspection results (all characteristics) - Material and process certifications - Photos (if helpful) - Accept/release decision - Approval signatures (quality, engineering, customer if required)

22.7.5 Sample Size Determination (ANSI/ASQ Z1.4, MIL-STD-105E)

Statistical sampling plans determine how many parts to inspect from a lot to gain confidence in lot quality.

Acceptance Sampling Overview

Purpose: - Inspect sample from lot, accept or reject entire lot based on sample results - Balance risk and cost (100% inspection costly; no inspection risky)

Acceptance Sampling Is NOT: - Process control (SPC charts control processes) - Quality improvement (acceptance sampling only sorts good from bad) - Substitute for capable process (should still aim for $Cpk \geq 1.33$)

Acceptance Sampling IS: - Lot disposition tool (accept or reject lot) - Risk management (balance producer and consumer risk) - Economical alternative to 100% inspection

ANSI/ASQ Z1.4 Standard

ANSI/ASQ Z1.4 (formerly MIL-STD-105E): Most widely used acceptance sampling standard

Sampling Plan Elements: - **Lot Size (N):** Number of parts in lot - **Sample Size (n):** Number of parts inspected from lot - **Acceptance Number (Ac):** Maximum defects allowed in sample to accept lot - **Rejection Number (Re):** Minimum defects in sample to reject lot

Inspection Levels: - **General Inspection Levels:** - Level I: Reduced sample size (less inspection, higher risk) - **Level II:** Standard (most commonly used) - Level III: Increased sample size (more inspection, lower risk) - **Special Inspection Levels (S-1, S-2, S-3, S-4):** Very small samples (use only when small samples justified)

Inspection Types: - **Normal Inspection:** Standard sampling (use at start and when quality acceptable) - **Tightened Inspection:** Stricter sampling (use when quality deteriorates; 2 of 5 lots rejected on normal) - **Reduced Inspection:** Relaxed sampling (use when quality excellent; 10 consecutive lots accepted on normal, optional)

Acceptable Quality Limit (AQL)

AQL: Maximum percent defective (or defects per hundred units) considered acceptable as a process average

Common AQL Values: - **0.065, 0.10, 0.15:** Very critical (aerospace, medical, safety-critical) - **0.25, 0.40, 0.65:** Critical characteristics - **1.0, 1.5, 2.5:** Major characteristics - **4.0, 6.5:** Minor characteristics

AQL Interpretation: - AQL 1.0 means: Accept long-term average of 1% defective - Does NOT mean: Accept any lot with $\leq 1\%$ defective (individual lot may have more or less)

Using ANSI/ASQ Z1.4

Steps to Determine Sampling Plan:

1. **Determine Lot Size (N):** Count of parts in lot (e.g., 500 pieces)
2. **Select Inspection Level:** Usually **Level II** (General Inspection Level II)
3. **Choose AQL:** Based on characteristic criticality (e.g., AQL 1.0 for major characteristic)
4. **Find Sample Size Code Letter:** Use Table I in Z1.4
 - Lot Size 500, Inspection Level II \square Code Letter **H**
5. **Find Sampling Plan:** Use Table II-A (single sampling, normal inspection)
 - Code Letter H, AQL 1.0 \square Sample size **n = 50**, Acceptance number **Ac = 1**, Rejection number **Re = 2**
6. **Interpret:**
 - Inspect 50 parts from lot of 500
 - If ≤ 1 defective found: **Accept lot** (release entire lot)
 - If ≥ 2 defective found: **Reject lot** (100% inspect, return to supplier, scrap, or rework)

Example Sampling Plan:

Lot Size	Level	AQL	Code Letter	Sample Size (n)	Accept (Ac)	Reject (Re)
100	II	1.0	F	20	0	1
500	II	1.0	H	50	1	2
1000	II	1.0	J	80	2	3
100	II	2.5	F	20	1	2

Interpretation: - Smaller lots → smaller samples, but stricter (Ac often 0) - Higher AQL → more lenient (higher Ac for same sample size)

Single vs. Double vs. Multiple Sampling

Single Sampling (most common): - Inspect one sample, make decision (accept or reject) - Simple to administer

Double Sampling: - Inspect first sample; if results inconclusive, inspect second sample - May reduce inspection on average (if quality very good or very bad)

Multiple Sampling: - Up to 7 sequential samples - Complex to administer; rarely used

Recommendation: Use **single sampling, normal inspection, Level II** unless specific reason to deviate.

Sampling Risks

Producer's Risk (α): - Risk of rejecting good lot (false alarm) - Standard: $\alpha = 5\%$ (when process at AQL, 5% chance lot rejected)

Consumer's Risk (β): - Risk of accepting bad lot (defects shipped to customer) - Standard: $\beta = 10\%$ (at Lot Tolerance Percent Defective, LTPD)

Operating Characteristic (OC) Curve: - Graph showing probability of acceptance vs. lot quality - Steep curve = discriminates well between good and bad lots - Included in Z1.4 for each sampling plan

22.7.6 Inspection Records and Certificates of Conformance

Inspection Records

Purpose: - Document evidence of conformance - Traceability (link inspections to specific lots, dates, inspectors) - Quality data for analysis (trends, capability) - Customer and regulatory requirement

Inspection Record Contents: - Part identification (part number, lot/serial number, quantity) - Drawing and revision - Date of inspection - Inspector name/ID - Characteristics inspected - Measurement results - Acceptance criteria (tolerances) - Pass/fail for each characteristic - Overall disposition (accept, reject, rework) - Gage/equipment used (for critical measurements)

Retention: - Per customer contract or regulatory requirement - Typical: 7-10 years for commercial, 10+ years for aerospace/medical - Longer for critical or traceable items (life of product)

Electronic Records: - Preferred over paper (searchable, no physical storage, backup/recovery) - ERP/MES systems capture inspection data - CMM systems generate reports automatically - Ensure data integrity and security (access controls, backups)

Certificates of Conformance

Certificate of Conformance (C of C): Statement that products conform to specified requirements

When C of C Required: - Customer requests on purchase order - Contract requirement - Regulatory requirement (FDA, FAA) - Industry standard practice (aerospace, medical)

C of C Types:

Full C of C: - Statement of conformance to all requirements - Lists specifications and standards met - May include summary data (measurement results) - Signed by authorized quality representative

Partial C of C: - Conforms to some requirements (specific characteristics or tests)

Supplier C of C: - Supplier certifies materials/services provided - Accompanies shipments to customers

C of C vs. Test Reports: - **C of C:** Statement that requirements met (no detailed data) - **Test Report:** Detailed data showing results (chemical analysis, mechanical properties, dimensions) - Some customers require both

Authorized Signatories: - Quality Manager or designated quality representative - List of authorized signatories maintained - Signatures on file with customer (if required)

22.7.7 Gage Calibration and Control

Accurate measurements depend on calibrated gages. Calibration management covered in Section 22.5 (Process Control and Validation), but key points reinforced here.

Calibration Program Requirements

ISO 9001 Requirements (Clause 7.1.5.1): - Measuring equipment calibrated or verified at specified intervals - Calibrated against traceable standards (national or international standards: NIST, PTB, etc.) - Identified with calibration status (label showing due date) - Safeguarded from adjustments that would invalidate results - Protected from damage and deterioration

Calibration Intervals: - Based on: Manufacturer recommendation, stability, usage frequency, criticality - Common intervals: 6 months, 1 year, 2 years - Review and adjust based on history (if always in-tolerance, may extend; if out-of-tolerance, shorten)

Calibration Process

- 1. Identify Equipment Requiring Calibration:** - Micrometers, calipers, indicators, height gages
- CMM, vision systems, profilometers - Test equipment (torque wrenches, pressure gages, multi-meters) - Environmental monitoring (thermometers, humidity gages)
- 2. Master Calibration Schedule:** - List of all equipment, serial numbers, calibration intervals, due dates - Updated as equipment calibrated - Alerts generated before due (2 weeks advance notice typical)
- 3. Send for Calibration:** - **External Lab:** Accredited calibration lab (ISO/IEC 17025) - **In-House:** If have standards and trained personnel (less common)
- 4. Receive Calibration Certificate:** - Calibration certificate shows: - Equipment ID and serial number - Date of calibration - Standards used (with traceability) - "As Found" condition (measurements before adjustment) - "As Left" condition (measurements after adjustment/calibration) - Pass/fail (in tolerance or out of tolerance) - Uncertainty of measurement - Calibration lab accreditation (ISO/IEC 17025 logo) - Next calibration due date
- 5. Affix Calibration Label:** - Sticker on gage showing: - Calibration date - Due date (or month/year due) - Calibration lab or ID - Green/Yellow/Red labels (green = current, yellow = due soon, red = overdue)
- 6. Return to Service:** - If passed calibration, return to use - Update calibration schedule - File calibration certificate
- 7. Out-of-Tolerance Action:** - If gage found out-of-tolerance at calibration: - Investigate impact (what was measured since last calibration?) - Notify affected customers if parts shipped (may need recall or re-inspection) - Adjust or repair gage - Re-calibrate
- 8. Overdue Action:** - If gage used past due date: - Remove from service immediately - Quarantine (tag "OUT OF CALIBRATION - DO NOT USE") - Send for calibration - Investigate impact (measurements since due date are suspect) - Preventive action (improve alert system, training)

Gage Management Best Practices

Gage Inventory: - Assign unique ID to each gage (engraved or labeled) - Maintain database (gage type, serial number, location, calibration due date, history)

User Training: - Train personnel on proper use of gages - Handling, storage, maintenance - Recognize calibration status (check label before use)

Gage Storage: - Protective cases - Climate-controlled storage (precision gages sensitive to temperature, humidity) - Clean and dry environment

Gage R&R (Measurement Systems Analysis): - Periodically verify gage repeatability and reproducibility - Covered in Section 22.14 (MSA)

Summary

Inspection and testing are the final gatekeepers ensuring only conforming products reach customers. Effective inspection starts with understanding drawing requirements, uses strategic in-

process checks to catch problems early, and concludes with thorough final inspection before release. First Article Inspection validates new processes. Statistical sampling plans (ANSI/ASQ Z1.4) balance inspection cost with risk. Inspection records provide traceability and evidence of conformance. Calibrated gages ensure measurement accuracy.

A robust inspection program, combined with capable processes (high Cpk), provides confidence that products consistently meet requirements.

Key Takeaways

1. **Inspection planning** begins with understanding drawing requirements and identifying critical characteristics
 2. **In-process inspection** catches problems early, reducing scrap and rework costs
 3. Strategic in-process inspection points: After critical operations, before expensive operations, before irreversible operations
 4. **Final inspection** provides comprehensive verification before release to customer
 5. **First Article Inspection (FAI)** validates manufacturing process for new parts or changes
 6. **Sampling inspection** uses statistical methods to balance cost and risk; ANSI/ASQ Z1.4 most common standard
 7. **Acceptable Quality Limit (AQL)** defines acceptable process average; lower AQL for critical characteristics
 8. **Sampling plan** determined by lot size, inspection level, and AQL; results in sample size (n) and acceptance number (Ac)
 9. **100% inspection** required for critical characteristics, incapable processes, or customer requirements
 10. **Inspection records** document evidence of conformance and provide traceability
 11. **Certificate of Conformance (C of C)** certifies products meet requirements; accompanies shipments
 12. **Gage calibration** essential for measurement accuracy; calibrate at specified intervals against traceable standards
-

Review Questions

1. What key elements on an engineering drawing must be reviewed for inspection planning?
2. How do you identify critical vs. minor characteristics on a drawing?
3. What is the purpose of in-process inspection, and when should it be performed?
4. Give three examples of strategic in-process inspection points.
5. What should be included in a final inspection?
6. What is the difference between 100% inspection and sampling inspection? When is each appropriate?
7. What is First Article Inspection (FAI) and when is it required?
8. What is an Acceptable Quality Limit (AQL)? How does AQL relate to sampling plans?
9. Using ANSI/ASQ Z1.4: For a lot of 500 parts, inspection level II, AQL 1.0, what is the sample size and acceptance number?
10. What is a Certificate of Conformance (C of C) and when is it required?

11. What information must be on an inspection record?
 12. What are the requirements for gage calibration per ISO 9001?
 13. What should be done if a gage is found out-of-tolerance at calibration?
-

Practical Exercises

Exercise 1: Create Inspection Plan from Drawing

Obtain or create a simple engineering drawing: 1. Identify all dimensions and requirements to inspect 2. Number characteristics sequentially (1, 2, 3...) 3. Classify each characteristic (critical, major, minor) 4. For each characteristic, specify: - Inspection method (gage/tool) - Inspection frequency (first-off, in-process, final) - Sample size (100%, sample) 5. Create inspection checklist or form

Exercise 2: Design In-Process Inspection Strategy

For a multi-operation machined part: 1. List all operations (Op 1, 2, 3...) 2. Identify strategic in-process inspection points 3. For each inspection point, justify why (catches critical dimension, before expensive operation, etc.) 4. Specify what to inspect at each point 5. Design traveler section for recording in-process inspection results

Exercise 3: Sampling Plan Determination

Using ANSI/ASQ Z1.4 (tables available online or in standard): 1. Determine sampling plans for following scenarios: - Lot size 150, Level II, AQL 1.0 - Lot size 800, Level II, AQL 2.5 - Lot size 50, Level II, AQL 0.65 2. For each, specify: - Sample size code letter - Sample size (n) - Acceptance number (Ac) - Rejection number (Re) 3. Interpret: "Inspect ___ parts; accept lot if <=___ defective; reject if >=___ defective"

Exercise 4: Final Inspection Report

Create a final inspection report template: 1. Design form layout (headers, fields, tables) 2. Include all required information (part ID, drawing, date, inspector, etc.) 3. Section for dimensional results (characteristic, requirement, result, pass/fail) 4. Section for visual inspection 5. Section for documentation review (traveler, certs) 6. Acceptance decision and signature 7. Fill in sample data for hypothetical part

Exercise 5: Calibration Schedule

Create a calibration schedule for inspection department: 1. List 10 pieces of measurement equipment (micrometers, calipers, CMM, etc.) 2. Assign unique ID numbers 3. Determine calibration interval for each (6 months, 1 year, 2 years) 4. Create schedule table (ID, description, serial number, interval, last cal date, next due date) 5. Determine which gages due for calibration this month

Additional Resources

Standards: - ANSI/ASQ Z1.4 (Sampling Procedures and Tables for Inspection by Attributes) - ISO 2859-1 (International equivalent to Z1.4) - ASME Y14.5 (Geometric Dimensioning and Tolerancing) - AS9102 (First Article Inspection Requirement - Aerospace)

Books: - "Fundamentals of Dimensional Metrology" by Connie Dotson, Ted Busch - "Inspection and Gaging" by Kennedy, Hoffman, Bond - "GD&T: Application and Interpretation" by ASME - "Acceptance Sampling in Quality Control" by Edward Schilling, Dean Neubauer

Software: - CMM software (PC-DMIS, Calypso, MeasureM ind) - Inspection data management systems (QC-CALC, DataPage, InfinityQS) - Statistical software for sampling plans (Minitab, JMP)

Training: - GD&T training (ASME Y14.5 courses) - CMM operation training (equipment-specific) - Inspection techniques courses (ASQ, community colleges) - AS9102 FAI training (aerospace-specific) - Acceptance sampling courses

Online Resources: - NIST (National Institute of Standards and Technology): Measurement science resources - ASQ (American Society for Quality): Inspection and measurement resources - ASME: GD&T standards and training - ISO: Standards and technical resources

Module 22 - Quality Management Systems (QMS)

When products fail to meet specified requirements, systematic controls prevent unintended use or delivery. This section covers identification, segregation, disposition, and documentation of nonconforming products.

22.8.1 Identification and Segregation of Nonconforming Product

Nonconforming Product: Product that does not conform to specified requirements (dimensions out of tolerance, wrong material, damage, missing processes, etc.)

Immediate Actions When Nonconformance Detected

1. Stop Production (if nonconformance could affect additional parts): - Prevent producing more defective parts - Investigate root cause before continuing

2. Identify Nonconforming Product: - Tag or mark clearly: "NONCONFORMING", "REJECT", "HOLD" - Red tags common (universal signal for reject) - Include: - Part number and quantity - Description of nonconformance - Date discovered - Who identified

Example Reject Tag:

+-----+	
△ NONCONFORMING PRODUCT △	
DO NOT USE – DO NOT SHIP	

Part Number: 1234-5678	

Quantity: 25 pcs	
Nonconformance:	
Hole diameter .505" (spec .500+/- .002)	
Discovered: 15-May-2024	
By: J. Smith, Inspector	
NCR Number: NCR-2024-042	
Disposition: _____	
Approved By: _____	

3. Segregate Physically: - Move to designated nonconforming product area - Separate from conforming product (prevent mix-up) - **Bonded Cage/MRB Area:** Locked or controlled access area for rejects - Do not release until disposition determined and approved

4. Update Status (if using ERP/MES system): - Change lot status to “HOLD” or “REJECT” in system - Prevents accidental shipment or use

Segregation Methods

Physical Barriers: - Separate room or caged area - Red-marked floor area - Dedicated shelving or racks

Visual Identification: - Red tags attached to parts or containers - Red bins or totes - Warning signs (“NONCONFORMING PRODUCT AREA - DO NOT USE”)

System Controls: - ERP system status prevents transactions (picking, shipping) - Barcode scanning rejects quarantined lots

22.8.2 Nonconformance Reporting (NCR) Process

Nonconformance Report (NCR): Formal documentation of nonconformance

When to Issue NCR

Internal Nonconformances: - Parts rejected at inspection (in-process or final) - Defects discovered during production - Incorrect processes performed - Material received not meeting specifications

External Nonconformances: - Customer returns or complaints - Defects discovered at customer location - Field failures

Thresholds: - Some organizations issue NCR for any reject - Others only for significant issues (quantity, cost, recurrence) - Define policy (e.g., “NCR required for rejects >\$500 value or affecting critical characteristics”)

NCR Form Contents

NCR Header: - NCR number (unique identifier, sequential) - Date issued - Issued by (name, department) - Priority (critical, major, minor)

Product Identification: - Part number and description - Quantity affected - Lot number, serial number, work order number - Customer (if external)

Nonconformance Description: - What is wrong? (specific, detailed) - Where discovered? (operation, inspection stage, customer) - How discovered? (inspection, testing, visual observation, customer complaint) - Acceptance criteria (specification or requirement) - Actual condition (measurement or observation) - Photos or sketches (if helpful)

Containment (immediate action): - What done immediately? (stopped production, segregated parts, notified customer)

Disposition (see Section 22.8.3): - Scrap, rework, repair, use-as-is, return to supplier - Disposition authority and approval

Root Cause Analysis (if performed): - Why did nonconformance occur? - Root cause findings

Corrective Action (if required): - Actions to prevent recurrence - Link to Corrective Action Report (CAR) if separate

Closure: - Disposition completed - Verification performed - Closed by (signature, date)

NCR Example

NONCONFORMANCE REPORT (NCR)	
NCR Number: NCR-2024-042 Date: 15-May-2024	
Issued By: Jane Smith, QA Inspector	
Priority: [] Critical <input checked="" type="checkbox"/> Major [] Minor	
<hr/>	
PRODUCT IDENTIFICATION:	
Part Number: 1234-5678 Rev C	
Description: Aluminum Bracket	
Quantity: 25 pcs (Lot 2024-0515)	
Work Order: WO-55443	
Customer: XYZ Manufacturing	
<hr/>	
NONCONFORMANCE DESCRIPTION:	
Discovered: Final inspection, 15-May-2024	
Characteristic: Hole diameter (Dwg Item 4)	
Specification: $\varnothing 0.500 \text{ +/- } .002" (.498 - .502")$	
Actual: $\varnothing 0.505"$ (measured on all 25 pcs)	
Nonconformance: Diameter oversize by $.003"$	
<hr/>	
[Photo attached showing hole and measurement]	
<hr/>	
CONTAINMENT:	

| - All 25 pcs segregated in MRB area, red-tagged |
 | - Checked previous lot (W0-55442, 50 pcs) - OK |
 | - Notified production supervisor and customer |
- Machine taken out of service pending investigation
DISPOSITION: [] Scrap [] Rework Repair
[] Use-As-Is [] Return to Supplier

Disposition Details:
Approved for repair: Bore to next size (\varnothing .520")
and install oversized bushing (customer approved
Engineering Change ECN-2024-123).

Disposition Approved By:
Engineering: _____ Date: _____
Quality: _____ Date: _____
Customer: _____ Date: _____ (if required)

ROOT CAUSE: (see CAR-2024-042 for full analysis)
Drill bit worn beyond life; no tool life tracking
system in place.

CORRECTIVE ACTION: (see CAR-2024-042)
Implement tool life tracking in ERP system.

CLOSURE:
Repair completed 20-May-2024, re-inspected - OK
All 25 pcs shipped to customer 22-May-2024

Closed By: _____ Date: _____
 +-----+

NCR Tracking

NCR Log: - Register of all NCRs (spreadsheet or database) - Enables trending and analysis

NCR Log Fields: - NCR number - Date opened - Part number - Nonconformance type (dimensional, material, damage, process) - Disposition - Status (open, awaiting disposition, closed) - Date closed

Reporting: - Monthly NCR summary (count, cost, trends) - Pareto analysis (most common non-conformances) - Review in management review meetings

22.8.3 Disposition Options

Disposition: Decision on what to do with nonconforming product

Disposition Authority

Material Review Board (MRB): - Cross-functional team reviews nonconformances and determines disposition - Members: Quality Manager, Engineering, Production, sometimes customer representative - Formal meetings (weekly or as needed) or virtual approvals

Disposition Approval Levels: - **Minor nonconformances:** Quality Manager or supervisor approval - **Major nonconformances:** MRB approval - **Critical/safety nonconformances:** Engineering and customer approval required

Disposition Options

1. Scrap Definition: Part cannot be salvaged; discard

When to Scrap: - Beyond economical repair - Critical characteristic out of spec (safety, regulatory) - Customer will not accept repair or use-as-is - Material defect (wrong alloy, contamination)

Process: - Document scrap decision on NCR - Physically destroy or mark "SCRAP" (prevent accidental use) - Remove from inventory (adjust quantities in ERP) - Analyze scrap cost for metrics (scrap rate) - Scrap material may have salvage value (sell to recycler)

Example: Titanium part with crack discovered during final inspection. Cannot be repaired (crack indicates material defect or process issue). **Disposition: Scrap**

2. Rework Definition: Bring product into full conformance with original requirements

When to Rework: - Possible to correct defect and meet all original specs - Economical (rework cost < scrap + replacement cost)

Rework Approval: - Rework procedure must be approved (Engineering and Quality review) - Defines rework steps, acceptance criteria, verification method

Re-Inspection: - After rework, re-inspect per **original requirements** (full conformance required) - If passes, release for use - If fails, scrap or evaluate for repair

Examples: - Dimension undersized Cannot rework (cannot add material) - Dimension oversized Rework by machining to spec - Missing hole Rework by drilling hole - Burrs or sharp edges Rework by deburring - Wrong coating Strip and re-coat

Rework Procedure (example): > **Rework Procedure for NCR-2024-042** > Part: 1234-5678, Quantity: 10 pcs > Nonconformance: Chamfer on hole missing >> Rework Steps: > 1. Inspector verifies chamfer missing (visual inspection) > 2. Operator uses chamfer tool (82° countersink, .020" depth) to add chamfer to each hole > 3. Inspector verifies chamfer per drawing (visual and depth check) > 4. If OK, remove reject tag and release to stock > 5. If not OK, scrap part >> Approved: Engineering _____ Quality _____

3. Repair Definition: Alter product to meet intended use, but **not** to original requirements

Key Difference from Rework: - **Rework:** Brings to full original specification - **Repair:** Alters to alternative specification acceptable for use

When to Repair: - Cannot meet original spec, but alternative acceptable - Economical - Customer agrees (concession required)

Approval Required: - Engineering evaluates if repair acceptable (fit, form, function, safety) - Customer approval (deviation or concession) - Document deviation in NCR and on part/record

Re-Inspection After Repair: - Inspect to **repair specification** (not original drawing) - Document that part repaired per approved deviation

Examples: - Hole diameter .505" (spec .500+/-0.002"): Repair by boring to .520" and installing oversized bushing (customer approves Engineering Change) - Surface finish rougher than spec: Repair by additional grinding to improve finish (may not meet original Ra, but acceptable to customer)

Important: Repair requires customer notification and approval (concession, deviation, or engineering change). Without approval, cannot ship repaired parts.

4. Use-As-Is Definition: Accept product without correction, even though it does not meet original requirements

When Use-As-Is: - Nonconformance minor and does not affect fit, form, function, safety - Customer agrees nonconformance acceptable - Economical (avoid scrapping usable parts)

Approval Required: - Engineering evaluates impact - Customer approval (concession or waiver) - Document justification

Examples: - Cosmetic defect (scratch on non-visible surface): Use-as-is if function unaffected - Dimension slightly out of spec but still functions: Engineering analysis shows acceptable, customer approves - Missing non-critical marking: Use-as-is if marking not required for traceability

Use-As-Is vs. Repair: - **Use-As-Is:** No changes made to product (ship as-is) - **Repair:** Product altered before shipment

Customer Communication: - Notify customer of nonconformance - Request concession or waiver - Document approval in NCR - Ship with notation (e.g., "Shipped per customer waiver dated 20-May-2024")

5. Return to Supplier Definition: Nonconforming purchased material or service returned to supplier

When Applicable: - Material or purchased parts received nonconforming - Outside process (heat treatment, plating) defective

Process: - Document nonconformance (NCR or Supplier Corrective Action Request - SCAR) - Notify supplier - Obtain Return Material Authorization (RMA) from supplier - Return for credit, replacement, or rework by supplier

Example: Aluminum bar stock received with diameter 1.985" (spec 2.000"+/-0.010"). **Disposition:** **Return to supplier for credit and replacement.**

6. Sort/Segregate Definition: Inspect 100% to separate conforming from nonconforming (when sample inspection detects defects)

When Applicable: - Sample inspection rejected lot - Portion of lot may be conforming

Process: - 100% inspect all parts in lot - Segregate good (conforming) from bad (nonconforming)
- Release conforming parts - Disposition nonconforming parts separately (scrap, rework, etc.)

Example: Sample inspection found 3 defective parts in sample of 50 from lot of 500. **Disposition:** **100% sort remaining 450 parts, separate good from bad.**

22.8.4 Material Review Board (MRB)

MRB Purpose

Material Review Board (MRB): Cross-functional team that reviews nonconformances and determines disposition

Benefits: - Multiple perspectives (quality, engineering, production) - Consistent dispositions - Ensures decisions technically sound and economical - Customer representation (for critical customers/applications)

MRB Membership

Typical MRB Members: - **Quality Manager** (chair) - **Engineering Manager or Lead Engineer** - **Production Manager or Supervisor** - **Purchasing** (for supplier issues) - **Customer Representative** (aerospace, medical often require customer participation)

Quorum: Minimum members required for valid decisions (e.g., Quality + Engineering minimum)

MRB Process

- 1. NCR Submitted to MRB:** - NCR issued by Quality or Inspector - Nonconforming product segregated - NCR forwarded to MRB for disposition
- 2. MRB Reviews NCR:** - Review nonconformance details - Evaluate options (scrap, rework, repair, use-as-is) - Consider: - Technical feasibility (can it be reworked? Will repair work?) - Safety and function (does defect affect performance?) - Cost (scrap vs. rework cost) - Customer requirements (will customer accept?) - Schedule impact (time to rework vs. scrap and remake)
- 3. MRB Determines Disposition:** - Decide on disposition (scrap, rework, repair, use-as-is) - Document decision on NCR - Approve rework/repair procedure (if applicable) - Identify if customer concession required
- 4. MRB Approvals:** - MRB members sign NCR approving disposition - If customer concession required, obtain before proceeding
- 5. Execute Disposition:** - Production or Quality executes disposition (scrap, rework parts) - Re-inspect if reworked/repaired
- 6. Close NCR:** - Verify disposition completed - Update NCR status to closed

MRB Meeting Frequency

Options: - **Scheduled Meetings:** Weekly or bi-weekly MRB meetings to review all open NCRs - **As-Needed:** MRB convenes when significant NCR arises (for critical issues requiring immediate

decision) - **Virtual/Electronic**: MRB reviews and approves NCRs via email or electronic workflow (no formal meeting)

Best Practice: Combination approach - Routine NCRs: Electronic review and approval (fast turnaround) - Complex or critical NCRs: In-person MRB meeting (discussion and collaboration)

22.8.5 Rework and Repair Procedures

Rework Procedures

Rework Procedure Requirements: - Document steps to correct nonconformance - Specify tools, equipment, methods - Define acceptance criteria (original requirements) - Identify verification method (re-inspection) - Approve before execution (Engineering and Quality)

Rework Procedure Template:

REWORK PROCEDURE

NCR Number: _____

Part Number: _____ Quantity: _____

Nonconformance: [Description]

Rework Steps:

1. [Step 1 with details]
2. [Step 2]
3. [...]

Acceptance Criteria: [Original drawing requirements]

Verification Method: [Re-inspection method and tools]

Rework Performed By: _____ Date: _____

Re-Inspection Results: [] Accept [] Reject

Inspector: _____ Date: _____

Approved By:

Engineering: _____ Date: _____

Quality: _____ Date: _____

Re-Inspection After Rework: - Must meet **all original requirements** (no compromise) - Use same inspection methods as original - If passes, release - If fails, scrap (further rework usually not economical; indicates rework procedure inadequate)

Repair Procedures

Repair Procedure Requirements: - Document altered specification (repair standard) - Engineering analysis shows repair acceptable (fit, form, function maintained) - Customer concession ob-

tained (formal approval) - Define verification method (inspect to repair standard, not original)

Customer Concession Process: 1. Engineering prepares concession request: - Describe nonconformance - Propose repair - Justify acceptability (analysis, testing, experience) 2. Submit to customer for approval 3. Customer reviews and approves or rejects 4. Document approval on NCR 5. Proceed with repair per approved procedure

Tracking Repairs: - Parts repaired should be identifiable (serial number, lot number) - Traceability: Link repaired parts to NCR and customer concession - If performance issues later, can trace back to repair

22.8.6 Customer Notification and Approval

When Customer Notification Required

Notify Customer When: - Nonconforming product already shipped - Nonconforming product requires repair or use-as-is disposition (concession needed) - Delivery delayed due to nonconformance (scrapped lot, need to reproduce) - Safety or regulatory concern - Customer contract specifies notification (e.g., "Notify customer within 24 hours of any nonconformance affecting delivered product")

Do Not Wait: - Notify promptly (within 24-48 hours) - Delayed notification damages trust and may allow customer to use defective parts

Notification Content

What to Include: - Description of nonconformance (part number, quantity, defect) - Impact assessment (safety, function, performance) - Parts affected (lot numbers, serial numbers, delivery dates) - Proposed disposition (repair, return, use-as-is) - Request for approval (if concession needed) - Corrective action to prevent recurrence (if known)

Communication Methods: - Email (common, provides documentation) - Phone call followed by written confirmation - Formal letter (for serious issues) - Customer portal or system (if available)

Customer Concession Request

Concession/Waiver/Deviation: Customer approval to accept nonconforming product

Concession Request Format:

CONCESSION REQUEST

To: XYZ Manufacturing, Attn: Quality Manager

From: ABC Machining, Quality Manager

Date: 20-May-2024

Subject: Concession Request for Part 1234-5678, NCR-2024-042

Part Number: 1234-5678 Rev C

Description: Aluminum Bracket

Quantity: 25 pcs (Lot 2024-0515)

Purchase Order: P0-98765

Nonconformance:

Hole diameter measures $\varnothing .505"$ (specification $\varnothing .500+/- .002"$).
Diameter oversize by $.003"$ ($.001"$ beyond tolerance).

Impact Assessment:

Engineering analysis indicates oversized hole acceptable for assembly. Bushing can accommodate diameter range $\varnothing .500-.510"$ per assembly drawing 9999-1111. No impact to fit, function, or safety.

Proposed Disposition: Use-As-Is

Request: We request concession to ship parts as-is.

Justification:

- Hole diameter within bushing tolerance
- Assembly fit verified with sample part
- No safety or functional impact
- Parts urgently needed for your production (due 22-May-2024)

Corrective Action:

Root cause identified as worn drill bit. Implemented tool life tracking system to prevent recurrence (see CAR-2024-042).

Approval Requested:

- Approved – Ship as-is
 Rejected – Scrap and replace

Customer Approval: _____ Date: _____
(Signature)

Customer Response: - Approved: Proceed with disposition, document approval on NCR - Rejected: Scrap or pursue alternative disposition, notify customer of revised plan

22.8.7 Traceability of Nonconforming Material

Why Traceability Matters

Scenario: Nonconformance discovered after parts used in production or shipped

Need to Answer: - Which specific parts affected? - Where are they now? (stock, in-process, shipped to customer) - What jobs or assemblies used affected material?

Traceability Enables: - Targeted containment (isolate affected parts, not entire inventory) - Customer notification (identify which customers received affected parts) - Recall (if necessary)

Traceability Methods

Lot/Batch Tracking: - Group of parts produced together (same date, machine, setup, material heat lot) - Lot number links parts to production records, material certifications, inspection results

Serial Number Tracking: - Unique identifier for each part - Enables tracking of individual part (where it went, what assembly it's in) - Required for aerospace, medical, automotive (critical parts)

Material Heat Lot Traceability: - Link finished parts to material heat lot - If material defect found (wrong alloy, contamination), can identify all parts from that heat lot

Traveler/Router: - Job tracking document follows part through manufacturing - Records operations, inspections, nonconformances - Retained for traceability

ERP/MES System: - Electronic tracking of lots, serial numbers, genealogy - Enables rapid queries ("Which jobs used material from heat lot H-123456?")

Nonconformance Traceability Example

Scenario: Heat treatment found out-of-spec for Lot 2024-0515 (hardness too low)

Traceability Investigation: 1. **Identify affected parts:** Lot 2024-0515 = 100 parts, part number 1234-5678 2. **Check disposition:** - 25 pcs in finished goods stock (quarantine immediately) - 50 pcs shipped to Customer A on 10-May (notify customer) - 25 pcs shipped to Customer B on 12-May (notify customer) 3. **Containment:** - Quarantine stock (25 pcs) - Notify customers (provide lot number, serial numbers if available) - Request customers inspect and quarantine 4. **Disposition:** - Engineering evaluates: Low hardness = reduced strength, safety concern - Disposition: Scrap (cannot use-as-is for safety-critical application) 5. **Customer Actions:** - Customer A: 50 pcs not yet used, return to supplier - Customer B: 25 pcs already installed in assemblies, customer disassembles and replaces 6. **Corrective Action:** Investigate heat treatment process, implement controls to prevent recurrence

Without Traceability: Would not know where parts went, cannot contain issue, risk of failures in field

Summary

Nonconforming product control ensures defective parts are identified, segregated, and properly dispositioned to prevent unintended use or delivery. Nonconformance Reports (NCRs) document defects and disposition decisions. The Material Review Board (MRB) provides cross-functional review for consistent, technically sound dispositions. Options include scrap, rework (to original spec), repair (to altered spec with customer approval), or use-as-is (customer concession). Customer notification and approval required when nonconformances affect shipped product or require concessions. Traceability enables targeted containment and recall when defects discovered after shipment.

Effective nonconforming product control protects customers, reduces risk, and drives corrective action to prevent recurrence.

Key Takeaways

1. **Immediately identify and segregate** nonconforming product to prevent unintended use
 2. **Red tags and bonded cages** provide visual and physical controls
 3. **Nonconformance Reports (NCRs)** formally document defects, disposition, and closure
 4. **Material Review Board (MRB)** provides cross-functional review and disposition approval
 5. **Disposition options:** Scrap, rework (to original spec), repair (altered spec), use-as-is, return to supplier, sort
 6. **Rework** brings part into full conformance with original requirements; must re-inspect to original spec
 7. **Repair** alters product to meet intended use but not original spec; requires customer concession
 8. **Use-as-is** accepts product without correction; requires customer concession
 9. **Customer notification** required when nonconformances affect shipped product or delivery
 10. **Customer concessions** (waivers, deviations) must be obtained before shipping nonconforming product
 11. **Traceability** essential for containment when defects discovered after shipment
 12. **NCR tracking and trending** identifies recurring issues driving corrective action
-

Review Questions

1. What immediate actions should be taken when a nonconformance is detected?
 2. How should nonconforming product be identified and segregated?
 3. What information should be included on a Nonconformance Report (NCR)?
 4. What is the purpose of a Material Review Board (MRB)?
 5. Who should be on the MRB?
 6. What are the six disposition options for nonconforming product?
 7. What is the difference between rework and repair?
 8. When is customer approval required for disposition?
 9. What is a concession (or waiver), and when is it needed?
 10. What should be included in a customer concession request?
 11. Why is traceability important for nonconforming product control?
 12. What should be done if nonconforming product already shipped to customer?
-

Practical Exercises

Exercise 1: Complete an NCR

Create a Nonconformance Report for a scenario: 1. Define nonconformance (dimensional defect, wrong material, damage, etc.) 2. Complete NCR form with: - Product identification - Nonconformance description - Containment actions - Disposition (with justification) - Approvals 3. Determine if customer notification required

Exercise 2: MRB Disposition Decision

Scenario: Final inspection found 20 parts with hole diameter .505" (spec .500+/-0.002"). Cost: \$50/part material and labor.

MRB Review: 1. Identify disposition options (scrap, rework, repair, use-as-is) 2. For each option, evaluate: - Feasibility (can it be done?) - Cost (estimate) - Time (impact to delivery) - Customer acceptance 3. Recommend disposition with justification 4. Determine if customer approval needed

Exercise 3: Write Rework Procedure

For a nonconformance (missing chamfer, rough surface finish, burrs, etc.): 1. Write rework procedure with: - Steps to correct defect - Tools and methods - Acceptance criteria (original spec) - Verification method 2. Identify who must approve procedure 3. Define re-inspection requirements

Exercise 4: Customer Concession Request

Draft a concession request letter for a nonconformance: 1. Select nonconformance (dimension slightly out, cosmetic defect, missing non-critical feature) 2. Write formal request including: - Description of nonconformance - Impact assessment (why it's acceptable) - Proposed disposition - Justification - Corrective action to prevent recurrence 3. Include signature blocks for customer approval

Exercise 5: Traceability Investigation

Scenario: Material defect discovered in heat lot H-55443 after parts shipped.

Conduct traceability investigation: 1. Identify what information needed (lot numbers, serial numbers, shipment dates, customers) 2. Determine where affected parts are (stock, in-process, shipped) 3. List containment actions for each location 4. Define customer notification requirements 5. Propose disposition for affected parts

Additional Resources

Standards: - ISO 9001:2015 Clause 8.7 (Control of Nonconforming Outputs) - AS9100 Clause 8.7 (Aerospace nonconforming product control) - ISO 13485 Clause 8.3 (Medical device nonconforming product)

Forms and Templates: - NCR form templates (available from ASQ, consultants, online) - MRB meeting minutes templates - Concession request templates

Books: - "Root Cause Analysis: The Core of Problem Solving and Corrective Action" by Duke Okes - "Nonconformance Management Systems" by various quality publications

Training: - ASQ Certified Quality Auditor (CQA) - includes nonconformance management - Internal auditor training (ISO 9001, AS9100) - covers NCR systems - MRB training (industry-specific courses)

Software: - Quality management software (ETQ, MasterControl, Intellect) - NCR tracking and workflow - ERP systems with quality modules - NCR and disposition management

Module 22 - Quality Management Systems (QMS)

Corrective and Preventive Action (CAPA) is the systematic process for investigating problems, identifying root causes, implementing solutions, and preventing recurrence. CAPA drives continuous improvement by learning from defects, nonconformances, and near-misses.

22.9.1 Root Cause Analysis Methodologies

Root Cause: The fundamental reason a problem occurred; eliminating the root cause prevents recurrence

Symptoms vs. Root Causes: - **Symptom:** Shaft diameter out of tolerance - **Immediate Cause:** Tool worn - **Root Cause:** No tool life tracking system in place

22.9.1.1 5 Whys Analysis

5 Whys: Simple technique asking “Why?” repeatedly to drill down to root cause

Process: 1. State the problem 2. Ask “Why did this happen?” 3. For each answer, ask “Why?” again 4. Repeat 5 times (or until root cause identified) 5. Root cause reached when asking “Why?” no longer provides useful information

Example 1: Part Scrapped Due to Dimension Error

Problem: Shaft diameter .510" (spec .500+/-0.002")

Why? Tool wore beyond life

 Why? Operator didn't change tool when due

 Why? Operator didn't know tool life limit

 Why? No tool life tracking system

 Why? Management didn't implement tracking system (cost, priority)

ROOT CAUSE: No tool life tracking system implemented

Corrective Action: Implement tool life tracking in ERP; establish tool replacement intervals based on testing; train operators

Example 2: Late Delivery

Problem: Order shipped 3 days late

Why? Machining took longer than planned

 Why? Machine broke down mid-job

 Why? Spindle bearing failed

 Why? Preventive maintenance not performed

 Why? Maintenance schedule not followed (technician out sick, no backup)

ROOT CAUSE: No backup plan for preventive maintenance when technician unavailable

Corrective Action: Cross-train additional technician on preventive maintenance; implement maintenance scheduling system with alerts

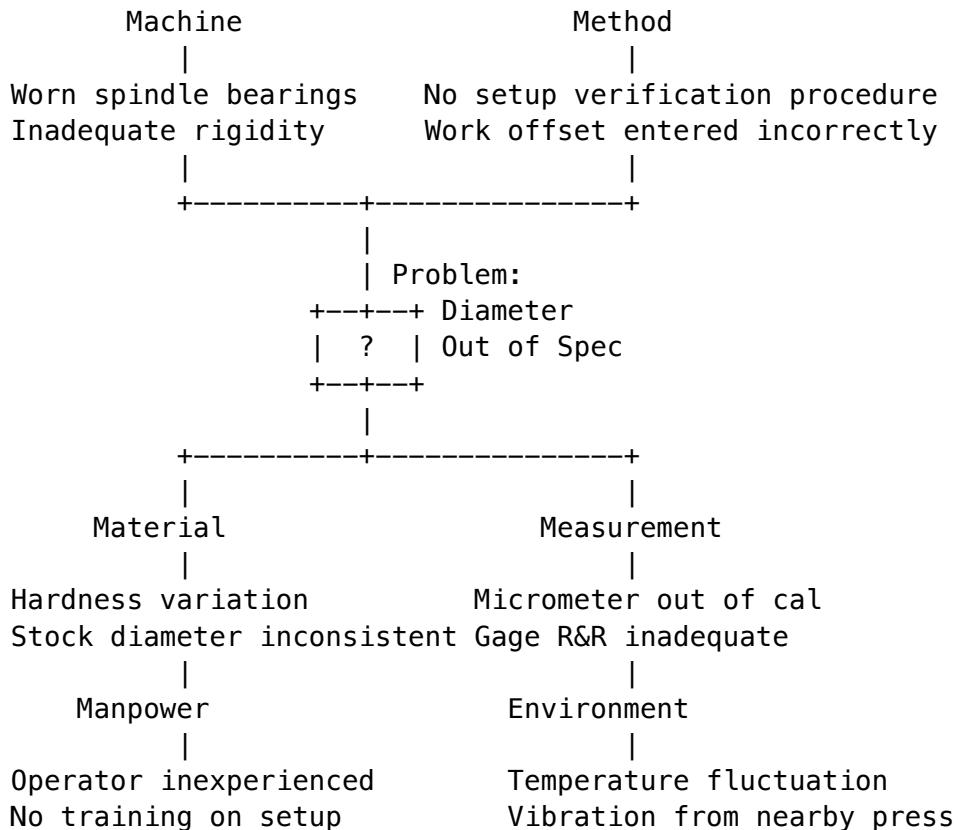
5 Whys Best Practices: - Don't stop too early (symptoms, not root cause) - Don't go too far (beyond organization's control) - Involve people who know the process - Focus on process/system, not blame individuals - Verify root cause (will eliminating it prevent recurrence?)

22.9.1.2 Fishbone (Ishikawa) Diagrams

Fishbone Diagram: Visual tool organizing potential causes into categories

Categories (6 Ms): - **M**achine (equipment, tools) - **M**ethod (processes, procedures) - **M**aterial (raw materials, supplies) - **M**anpower (people, training, skill) - **M**easurement (gages, inspection methods) - **M**other Nature (environment: temperature, humidity, vibration)

Example Fishbone Diagram: Shaft Diameter Out of Tolerance



Process: 1. Define problem (head of fish) 2. Draw main bones (6 M categories) 3. Brainstorm potential causes for each category 4. Ask "Why?" for each cause to dig deeper 5. Identify most likely root causes (circle or mark) 6. Verify root causes with data or testing

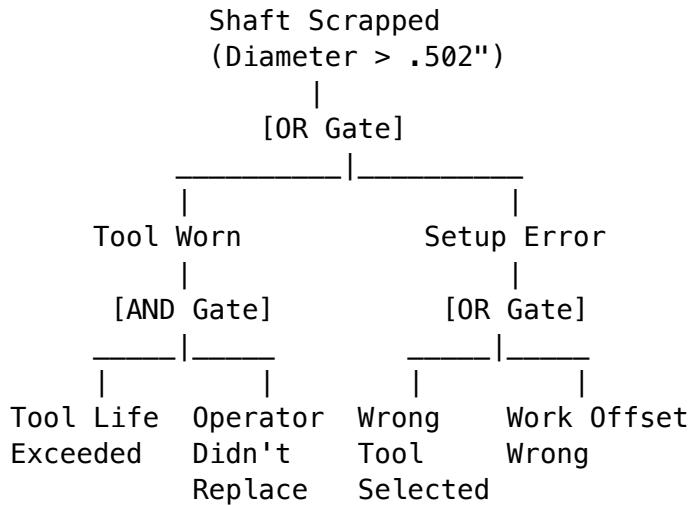
Advantages: - Structured brainstorming - Considers multiple categories (avoids tunnel vision) - Visual representation easy to understand - Good for complex problems with multiple contributing factors

22.9.1.3 Fault Tree Analysis

Fault Tree Analysis (FTA): Top-down, deductive analysis using Boolean logic to identify combinations of failures leading to problem

Logic Gates: - **AND Gate:** All inputs must occur for output to occur - **OR Gate:** Any input causes output

Example Fault Tree: Shaft Scrapped (Oversized Diameter)



Interpretation: - Shaft scrapped if EITHER tool worn OR setup error - Tool worn requires BOTH tool life exceeded AND operator didn't replace - Setup error from EITHER wrong tool selected OR work offset wrong

Use Cases: - Complex systems with multiple failure modes - Safety-critical applications (identify single points of failure) - Understanding interactions between failures

Advantages: - Rigorous, logical analysis - Identifies combinations of failures - Quantitative (can assign probabilities to estimate overall failure rate)

Disadvantages: - Time-consuming for complex systems - Requires understanding of system

22.9.1.4 Failure Mode and Effects Analysis (FMEA)

FMEA: Systematic method for identifying potential failure modes, their effects, and prioritizing corrective actions

FMEA Types: - **Design FMEA (DFMEA):** Identifies design weaknesses - **Process FMEA (PFMEA):** Identifies process risks

FMEA Process (for PFMEA):

1. **Identify Process Steps:** List operations in manufacturing process
2. **Identify Potential Failure Modes:** What could go wrong at each step? - Dimensional error - Surface damage - Wrong material - Missing operation
3. **Identify Effects:** What happens if failure occurs? - Scrap part - Customer complaint - Field failure - Safety hazard

4. Identify Causes: Why might failure occur? - Tool wear - Setup error - Operator error - Material variation

5. Rate Severity, Occurrence, Detection (1-10 scale):

Severity (S): How serious is the effect? - 1: No effect - 5-6: Moderate (rework, customer dissatisfaction) - 9-10: Critical (safety hazard, regulatory violation)

Occurrence (O): How likely is the cause? - 1: Remote (<1 in 1,000,000) - 5-6: Moderate (1 in 1,000) - 9-10: Very high (>1 in 10)

Detection (D): How likely to detect before reaching customer? - 1: Almost certain to detect - 5-6: Moderate detection chance - 9-10: Cannot detect

6. Calculate Risk Priority Number (RPN):

$$RPN = \text{Severity} \times \text{Occurrence} \times \text{Detection}$$

High RPN = High priority for corrective action (typically RPN >100 or >125)

7. Identify Actions: Corrective actions to reduce S, O, or D

8. Re-Calculate RPN: After actions implemented, verify RPN reduced

FMEA Example: CNC Turning Operation

Process Step	Failure Mode	Effect	Current Severity	Cause	Occurrence	Controls	Detection	RPN	Action	Recommended Responsibility
Turn OD	Diameter over-size	Scrap 6	Tool wear	5	Visual tool checks	3	90	Implement tool life tracking	Production Mgr	
Turn OD	Diameter under-size	Scrap 6	Setup error (work off-set)	3	First-off inspection	2	36	(Acceptable, - no action)		
Drill hole	Hole location wrong	Scrap, 8 customer complaint	Program error	2	Program verification, FAI	4	64	Implement program approval checklist	Engineering	
Drill hole	Hole diameter over-size	Scrap 6	Worn drill	4	Periodic checks	4	96	Establish drill life limits	Production Mgr	

Actions Based on RPN: - RPN >100: Action required - RPN 50-100: Action recommended - RPN <50: Acceptable risk (monitor)

After Actions Implemented (Re-calculate): - Turn OD, diameter oversize: Occurrence reduced to 2 (tool life tracking prevents excessive wear) \square RPN = $6 \times 2 \times 3 = 36$ [check] - Drill hole, diameter

oversize: Occurrence reduced to 2, Detection reduced to 2 (tighter checks) \square RPN = $6 \times 2 \times 2 = 24$
[check]

FMEA Benefits: - Proactive (identifies risks before failures occur) - Prioritizes actions (focus on highest RPN) - Structured and comprehensive - Documents risk analysis

FMEA Standards: - AIAG FMEA Manual (automotive) - AIAG & VDA FMEA Handbook (2019) - latest standard

22.9.2 8D Problem Solving Process

8D (Eight Disciplines): Structured problem-solving methodology developed by Ford, widely used in automotive and manufacturing

8D Steps:

D0: Prepare for 8D

- **Purpose:** Determine if 8D appropriate for problem
- **Activities:**
 - Assess problem severity and scope
 - Collect initial data
 - Decide if 8D required (or simpler method sufficient)

D1: Establish the Team

- **Purpose:** Form cross-functional team with knowledge and authority
- **Activities:**
 - Identify team members (quality, engineering, production, customer rep if applicable)
 - Assign team leader
 - Define roles and responsibilities
- **Team Skills Needed:** Process knowledge, technical expertise, problem-solving skills, authority to implement actions

D2: Describe the Problem

- **Purpose:** Clearly define the problem using data
- **Activities:**
 - Use **5W2H** method:
 - * **What** is the problem?
 - * **When** did it occur? (first occurrence, frequency)
 - * **Where** discovered? (operation, location, customer)
 - * **Who** discovered? affected?
 - * **Why** is it a problem? (impact)
 - * **How** many affected? (quantity, scope)
 - * **How** detected?
 - Quantify problem (defect rate, scrap cost, customer complaints)

- **Example:** “25 parts from Lot 2024-0515 have hole diameter .505” (spec .500+/-0.002”), discovered at final inspection on 15-May-2024. Parts scrapped, cost \$1,250. Customer delivery delayed 1 week.”

D3: Implement Interim Containment Actions (ICA)

- **Purpose:** Protect customer from defective product while root cause investigated
- **Activities:**
 - Sort/inspect remaining inventory (separate good from bad)
 - Increase inspection frequency (100% inspection until problem resolved)
 - Notify customer (if product shipped)
 - Recall or screen product at customer (if necessary)
- **ICA Not Permanent:** Temporary until corrective action implemented

D4: Identify Root Cause

- **Purpose:** Determine why problem occurred
- **Activities:**
 - Use root cause analysis tools (5 Whys, Fishbone, Fault Tree)
 - Brainstorm potential causes
 - Test hypotheses with data or experiments
 - Verify root cause (recreate problem by introducing root cause; eliminate problem by removing root cause)
- **Example:** Root cause = No tool life tracking; verified by testing (tool life exceeded → oversize parts; tool changed on time → parts in spec)

D5: Choose and Verify Permanent Corrective Actions (PCA)

- **Purpose:** Select actions that eliminate root cause and verify effectiveness
- **Activities:**
 - Brainstorm potential corrective actions
 - Evaluate options (cost, feasibility, effectiveness)
 - Select best action(s)
 - Test on small scale (pilot) to verify effectiveness
- **Example PCA:** Implement tool life tracking system in ERP; establish tool replacement interval (200 parts); train operators

D6: Implement and Validate Permanent Corrective Actions

- **Purpose:** Implement PCA broadly and verify long-term effectiveness
- **Activities:**
 - Roll out PCA to all affected areas
 - Update procedures, work instructions, forms
 - Train personnel
 - Monitor performance (verify problem does not recur)
 - Remove Interim Containment Actions (return to normal inspection)
- **Validation Period:** 30-90 days typical (monitor for recurrence)

D7: Prevent Recurrence (Preventive Actions)

- **Purpose:** Apply lessons learned to prevent similar problems elsewhere
- **Activities:**
 - Identify similar processes or products at risk
 - Apply corrective action to those areas
 - Update standards, design guidelines, training materials
- **Example:** Tool life tracking implemented for problematic operation; expand to all operations using cutting tools

D8: Recognize the Team and Close

- **Purpose:** Acknowledge team's efforts and formally close 8D
- **Activities:**
 - Document 8D process and results
 - Share lessons learned (bulletin, training, management review)
 - Recognize team contributions (thank team, celebrate success)
 - Archive 8D report
- **8D Report:** Comprehensive documentation of all steps (D0-D7)

8D Report Template: Single document capturing all disciplines, used for tracking and communication

8D Benefits: - Structured and thorough - Team-based (leverages diverse expertise) - Customer-focused (interim containment protects customer) - Prevents recurrence (D7 applies lessons broadly) - Widely recognized (especially in automotive)

22.9.3 Corrective Action Planning and Implementation

Corrective Action Report (CAR)

CAR: Document that initiates and tracks corrective action process

CAR vs. NCR: - **NCR** (Nonconformance Report): Documents nonconforming product and disposition - **CAR** (Corrective Action Report): Documents root cause analysis and corrective action to prevent recurrence - Often linked: NCR identifies problem, CAR investigates and corrects

CAR Triggers: - Nonconformances (internal, customer) - Audit findings - Customer complaints - Process performance issues (scrap, rework, low Cpk) - Near-misses (problems caught before causing defects) - Management review action items

CAR Contents (similar to 8D): 1. **Problem Description:** What happened? (clear, specific, data-driven) 2. **Containment:** Immediate actions taken 3. **Root Cause Analysis:** Why did it happen? (method used, findings) 4. **Corrective Action Plan:** What will be done to prevent recurrence? - Specific actions - Responsible person - Target completion date 5. **Implementation:** Actions completed (evidence) 6. **Effectiveness Verification:** Did corrective action work? (monitoring results) 7. **Closure:** Verified effective, closed (signature, date)

CAR Approval: - Quality Manager reviews and approves root cause analysis - Action owners approve action plans - Quality Manager approves closure (after verification)

Corrective Action Implementation

Typical Corrective Actions: - **Process Changes:** Modify process parameters, add controls, automate - **Procedure Updates:** Revise work instructions, add steps, clarify requirements - **Training:** Educate personnel on proper methods, new procedures - **Equipment:** Repair, upgrade, replace equipment or tooling - **Inspection:** Add inspection points, increase frequency, improve gages - **Design Changes:** Modify product design to eliminate issue (if design-related) - **Supplier Actions:** Change suppliers, increase incoming inspection, implement supplier corrective action

Implementation Steps: 1. **Plan:** Define specific actions, responsibilities, timelines, resources 2. **Communicate:** Notify affected personnel, explain changes 3. **Execute:** Perform actions (procedure updates, training, equipment changes) 4. **Document:** Record evidence of implementation (training records, procedure revisions, photos) 5. **Verify:** Check that actions implemented correctly

Example Corrective Action Implementation:

Problem: Holes drilled oversize due to worn drills

Root Cause: No drill life tracking

Corrective Action Plan: 1. Establish drill life limits (Action: Engineering conducts tool life study; Due: 30-May) 2. Implement tracking in ERP (Action: IT configures ERP module; Due: 15-Jun) 3. Create work instruction for drill replacement (Action: Quality writes WI-120; Due: 10-Jun) 4. Train operators (Action: Supervisor conducts training; Due: 20-Jun) 5. Monitor drill life compliance (Action: Supervisor spot-checks; Ongoing)

Implementation Evidence: - Tool life study report (drills last 500 holes +/-10%) - ERP system configured (screenshot showing drill counter) - WI-120 Rev A approved and distributed - Training records (10 operators trained on 20-Jun) - Spot-check log (shows drill changes at proper intervals)

22.9.4 Preventive Action and Risk Mitigation

Preventive Action: Action taken to eliminate causes of potential nonconformances (before they occur)

ISO 9001:2015 Approach: - No separate “Preventive Action” clause (was in ISO 9001:2008) - Preventive action integrated through **Risk-Based Thinking** (Clause 6.1) - Identify risks proactively, implement actions to mitigate

Sources of Preventive Action

Risk Assessments: - Identify potential problems during process design or product introduction - FMEA highlights risks requiring preventive action

Trend Analysis: - Monitor metrics (scrap rate, customer complaints, Cpk) - Increasing trends signal need for preventive action

Lessons Learned: - Apply corrective actions from one area to similar areas (D7 in 8D) - Industry trends or competitor issues

Near-Misses: - Problems caught before causing defects (close call) - Investigate and prevent actual occurrence

Audit Observations: - Non-critical findings (observations) may become nonconformances if not addressed

Example Preventive Actions: - Tool life tracking implemented after one operation had issues □ Apply to all operations (prevent similar issues elsewhere) - Temperature swings observed affecting precision □ Install climate control (prevent dimensional issues) - Supplier quality deteriorating (trend in reject rate) □ Audit supplier, implement corrective action (prevent shipment of defective material)

22.9.5 Effectiveness Verification

Effectiveness Verification: Confirm that corrective action eliminated problem and prevented recurrence

Why Verification Critical: - Ineffective corrective actions waste resources - Problem recurs, damaging customer confidence - Verify = learning (if not effective, revise action)

Verification Methods

1. Monitor Metrics: - Track performance data after corrective action implemented - Compare before vs. after - Example: Scrap rate 5% before, 1% after (30-day monitoring) □ Effective

2. Audit/Inspection: - Verify corrective action implemented correctly (procedure followed, equipment functioning) - Example: Audit shows operators following new drill replacement procedure □ Effective implementation

3. No Recurrence: - Problem does not recur over monitoring period (30-90 days typical) - Example: No oversized holes detected in 60 days □ Effective

4. Customer Feedback: - Customer complaints stop or reduce - Example: Customer complaint about late deliveries; after action, OTD improves to 98%, no complaints for 3 months □ Effective

5. Statistical Verification: - Cpk improves (capability increased) - Control charts show process stable and in control - Example: Cpk before 0.9 (incapable), Cpk after 1.5 (capable) □ Effective

Verification Period

Typical Timeframes: - **Short-term** (30 days): Immediate verification (procedure followed, problem stopped) - **Long-term** (90 days): Sustained effectiveness (no recurrence over time)

When to Verify: - Not immediately (allow time for action to take effect) - Not too late (problem may recur if action ineffective) - Risk-based (higher risk □ longer monitoring)

If Corrective Action Ineffective

Signs of Ineffective Action: - Problem recurs - Metrics do not improve - Root cause was incorrect (addressed symptom, not root cause)

Actions if Ineffective: 1. **Re-open CAR:** Do not close; action ineffective 2. **Re-analyze Root Cause:** Was root cause identified correctly? 3. **Revise Corrective Action:** Modify action or implement additional actions 4. **Re-verify:** Monitor again after revised action implemented

Example: - **Problem:** Holes drilled oversize - **Corrective Action:** Train operators on proper drill use - **Verification (30 days):** Problem recurs (3 more lots with oversized holes) - **Conclusion:** Ineffective (training alone insufficient) - **Revised Action:** Implement tool life tracking (more robust solution) - **Re-verification (60 days):** No recurrence Effective

22.9.6 CAPA Documentation and Tracking

CAPA Records

Required Records (ISO 9001, FDA, aerospace, medical): - Problem description - Root cause analysis - Corrective/preventive actions - Implementation evidence - Effectiveness verification - Approval and closure

Retention: Per regulatory or customer requirements (7-10 years typical)

CAPA Tracking System

CAPA Log/Database: - Register of all CARs - Status tracking (open, in-progress, awaiting verification, closed) - Aging report (overdue CARs)

CAPA Log Fields: - CAR number - Date opened - Problem description (brief) - Source (NCR, audit, complaint, etc.) - Assigned to (action owner) - Target completion date - Status - Date closed

Example CAPA Log:

CAR #	Date Opened	Problem	Source	Assigned To	Due Date	Status	Date Closed
CAR-2024-041	10-May	Late delivery	Audit finding	Ops Mgr	10-Jun	Closed	05-Jun
CAR-2024-042	15-May	Holes oversize	NCR-2024-042	Prod Mgr	15-Jul	In Progress	
CAR-2024-043	20-May	Customer complaint	Complaint	Quality Mgr	20-Jun	Awaiting Verification	

Reporting: - Monthly CAPA summary (count, aging, closure rate) - Review in management review meetings - Trend analysis (repeat issues, common root causes)

CAPA Software

Options: - **Spreadsheet:** Simple, low-cost (suitable for small shops with few CARs) - **Quality Management Software:** ETQ, MasterControl, Intellect (workflow, notifications, reporting) - **ERP**

System: Quality module within ERP (integrated with NCRs, audits)

Software Benefits: - Automated workflow (email notifications, approvals) - Centralized repository (all CARs in one place) - Reporting and analytics (dashboards, trends) - Audit trail (who did what, when)

Summary

Corrective and Preventive Action (CAPA) drives continuous improvement by systematically investigating problems, identifying root causes, implementing solutions, and verifying effectiveness. Root cause analysis tools (5 Whys, Fishbone, Fault Tree, FMEA) identify why problems occur. The 8D problem-solving process provides structured approach emphasizing team collaboration and customer protection. Effectiveness verification ensures corrective actions work. Preventive actions eliminate potential problems before they occur. CAPA documentation and tracking ensure accountability and enable trend analysis.

A strong CAPA system transforms problems into opportunities for improvement, building a learning organization that continually enhances quality and performance.

Key Takeaways

1. **Root cause analysis** identifies why problems occur, not just symptoms; correcting root cause prevents recurrence
 2. **5 Whys** simple technique asking “Why?” repeatedly to drill down to root cause
 3. **Fishbone diagrams** organize potential causes into categories (Machine, Method, Material, Manpower, Measurement, Environment)
 4. **FMEA** (Failure Mode and Effects Analysis) proactively identifies risks; prioritizes actions using RPN (Severity × Occurrence × Detection)
 5. **8D problem solving** structured 8-step process emphasizing team approach and customer protection
 6. **Interim Containment Actions** (D3 in 8D) protect customer while root cause investigated
 7. **Corrective Action Reports (CAR)** document problem, root cause, actions, verification, and closure
 8. **Preventive actions** eliminate potential problems before they occur; integrated through risk-based thinking
 9. **Effectiveness verification** essential to confirm corrective action works; monitor metrics, no recurrence
 10. **If action ineffective**, re-open CAR, re-analyze root cause, revise action
 11. **CAPA tracking** enables monitoring status, aging, trends
 12. **Strong CAPA system** drives continuous improvement and organizational learning
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Review Questions

1. What is the difference between a symptom and a root cause?

2. How does the 5 Whys technique work? Provide an example.
 3. What are the “6 Ms” in a Fishbone diagram?
 4. What is FMEA, and what is it used for?
 5. How is RPN calculated in FMEA? What does a high RPN indicate?
 6. What are the 8 disciplines (8D) in the 8D problem-solving process?
 7. What is the purpose of Interim Containment Actions (D3) in 8D?
 8. What is the difference between a Nonconformance Report (NCR) and a Corrective Action Report (CAR)?
 9. What should be included in a Corrective Action Plan?
 10. What is preventive action? How does it differ from corrective action?
 11. How do you verify that a corrective action is effective?
 12. What should be done if a corrective action is found to be ineffective?
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Practical Exercises

Exercise 1: 5 Whys Analysis

Conduct a 5 Whys analysis for a problem: 1. Select a problem (late delivery, scrap, customer complaint, equipment failure) 2. Ask “Why?” and answer 3. Ask “Why?” for each answer, repeat 5 times 4. Identify root cause 5. Propose corrective action addressing root cause

Exercise 2: Fishbone Diagram

Create a Fishbone diagram for a quality problem: 1. Define problem (head of fish) 2. Draw 6 main bones (Machine, Method, Material, Manpower, Measurement, Environment) 3. Brainstorm potential causes for each category (draw sub-bones) 4. Identify most likely root causes (circle) 5. Recommend corrective actions

Exercise 3: FMEA (Simplified)

Create a simple Process FMEA for a machining operation: 1. List 3-5 process steps 2. For each step, identify 1-2 potential failure modes 3. For each failure mode: - Describe effect - Rate Severity (1-10) - Identify cause - Rate Occurrence (1-10) - Describe current detection method - Rate Detection (1-10) - Calculate RPN 4. For high RPN (>100), recommend actions to reduce risk

Exercise 4: Complete a CAR

Draft a Corrective Action Report: 1. Select a problem (real or hypothetical) 2. Complete CAR sections: - Problem description - Containment actions - Root cause analysis (use 5 Whys or Fishbone) - Corrective action plan (specific actions, responsibilities, due dates) 3. Describe how you would verify effectiveness

Exercise 5: 8D Problem Solving

Apply 8D process to a problem: 1. Select significant problem (customer complaint, major non-conformance) 2. Complete each discipline (D1-D8): - D1: Identify team members - D2: Describe problem (5W2H) - D3: List interim containment actions - D4: Perform root cause analysis - D5:

Propose permanent corrective actions - D6: Describe implementation plan - D7: Identify preventive actions for similar areas - D8: Outline closure and recognition 3. Create 8D report summarizing findings

Additional Resources

Standards and Guidelines: - ISO 9001:2015 Clause 10.2 (Nonconformity and Corrective Action) - FDA 21 CFR Part 820.100 (CAPA for medical devices) - ISO 13485 Clause 8.5 (CAPA for medical devices) - AIAG FMEA Manual (FMEA methodology) - Ford 8D Manual (8D problem solving)

Books: - "Root Cause Analysis: The Core of Problem Solving and Corrective Action" by Duke Okes - "The Problem Solving Memory Jogger" by GOAL/QPC - "5 Whys: The Ultimate Root Cause Analysis Tool" by Karn Bulsuk - "FMEA: Failure Mode and Effects Analysis" by D.H. Stamatis

Software: - Quality management software (ETQ, MasterControl, Intellect) - CAPA workflow - FMEA software (ReliaSoft XFMEA, IQS FMEA) - Mind mapping software (for Fishbone diagrams): XMind, MindManager

Training: - ASQ Certified Quality Engineer (CQE) - includes root cause analysis and CAPA - Root Cause Analysis courses (ASQ, online providers) - FMEA training (AIAG, consulting firms) - 8D training (automotive industry associations) - Problem-solving courses (Lean Six Sigma Green Belt, Black Belt)

Online Resources: - ASQ (American Society for Quality): Problem-solving tools and resources - AIAG (Automotive Industry Action Group): FMEA guidelines - iSixSigma: Problem-solving articles and tools - Quality Digest: CAPA and root cause analysis articles
