

Top 5 Major IATF 16949 Nonconformities

PREPARED BY
International Automotive Oversight Bureau



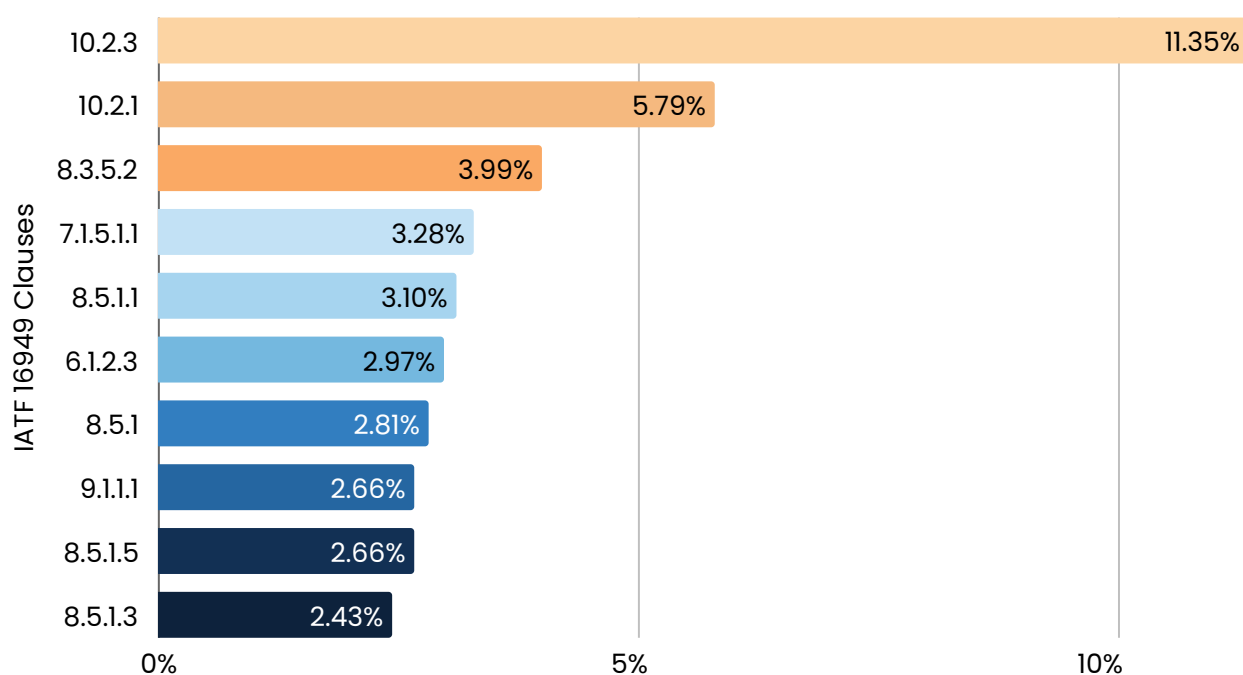
Why Understanding Nonconformities Matters

Every year, Certification Bodies report recurring nonconformities during IATF 16949 audits. These findings often highlight where organizations struggle most – and where targeted improvement can have the biggest impact on performance, compliance, and customer satisfaction.

This guide breaks down the Top 5 Major IATF 16949 Nonconformities with real-world insights into:

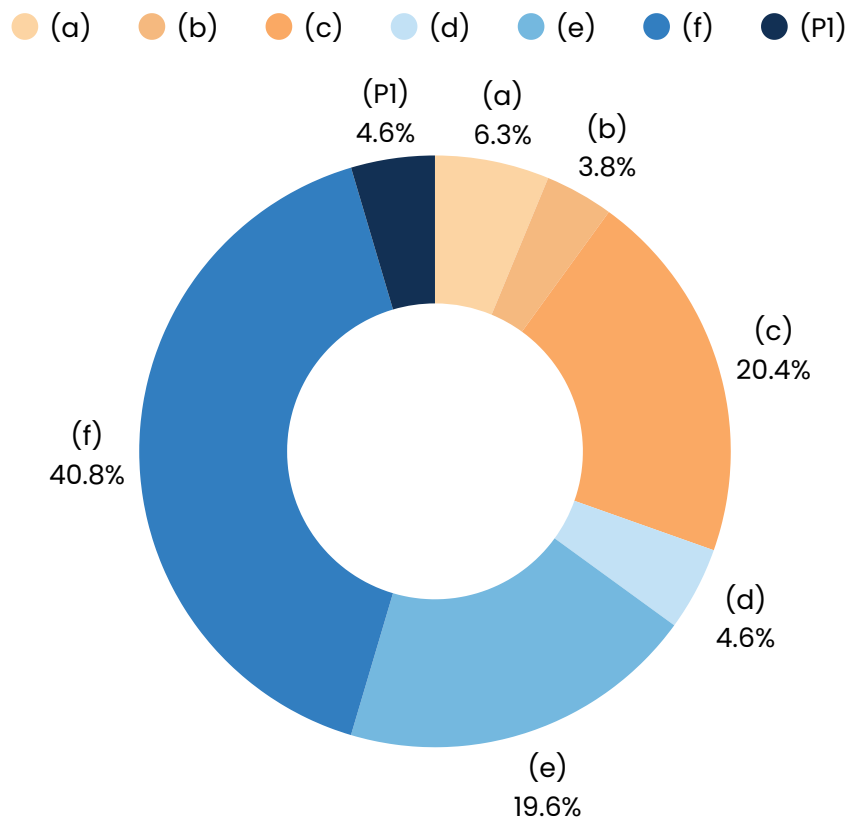
- Sub-clauses where issues occur most often
- Objective evidence observed by auditors
- Root causes identified by organizations
- Systemic corrective actions that lead to improvement

For reference, these are the Top 10 Major NCs:



NC #1: 10.2.3 Problem Solving

Top Sub-Clauses



(f) reviewing and updating the appropriate documented info... (e.g., PFMEA, control plan)

(c) root cause analysis, methodology used, analysis and results

(e) verification of the effectiveness of implemented corrective actions

Objective Evidence Identified by CB Auditors

1. Ineffective Corrective Actions

- Failure to Implement Corrective Actions Effectively: Actions are taken but do not resolve root issues, leading to recurrence.
- Lack of Management Oversight and Verification: No proper review or validation of corrective actions.
- Failure to Consider Impacts on Similar Processes/Products: Actions are applied in isolation without broader impact analysis.

2. Inadequate Root Cause Analysis

- Lack of Root Cause Analysis: Superficial investigations that do not address the true source of problems.
- Customer Complaints & Lack of Process Integration: Repeated issues due to poor problem-solving and lack of systemic improvements.

3. **Documentation and Change Control Failures**

- Failure to Update Documentation (PFMEA, Control Plans): Process changes are not reflected in key documents.
- Lack of PFMEA Updates: Risk assessments and control plans are outdated or incomplete.
- Changes Made Without Proper Documentation and Impact Analysis: Modifications are implemented without traceable records or evaluations.

4. **Process and Measurement Control Issues**

- Calibration/Measurement System Issues: Problems with equipment calibration and measurement reliability.
- Process Control Deficiencies: Inconsistent control over critical process parameters.

5. **Communication and Feedback Loop Gaps**

- Customer Communication & Feedback Loops: Feedback from customers is not used to drive continuous improvement.
- Documentation & Record Keeping Deficiencies: Missing or incomplete records hinder traceability and accountability.

Root cause results determined by organizations

1. **Training & Competency**

- Inadequate training in problem-solving analysis.
- Quality Control personnel lack understanding of problem-solving tools.
- Personnel not properly trained to conduct problem-solving analysis.
- No management verification of problem-solving competencies.
- Human resources lack experience with problem-solving tools.

2. **Process/Procedure Gaps**

- Procedures missing critical steps (e.g., requirements, verification, monitoring, impact assessment).
- No requirement to review and update FMEA, Control Plan, and related documents after corrective actions.
- Processes are overly generic and focus only on implementation, not effectiveness verification.
- Absence of documented lessons learned.
- Responsibilities are not clearly assigned within procedures.
- Initial problem resolution lacks depth, leading to unresolved human error risks.

3. **System/Tool Issues**

- Inconsistent application of problem-solving methodologies.
- Software system limitations (e.g., missing verification notifications, poor tool adoption).
- Confusing formats for documenting corrective actions.

4. **Management Oversight & Accountability**

- Management does not adequately review or confirm corrective action closures to prevent recurrence.
- Process ownership is unclear (e.g., KPIs, review responsibilities).
- Lack of ongoing supervision following problem resolution.

Systemic corrective actions taken by organizations

1. **Procedure Updates & Documentation**

- Adding requirements for follow-up and verification of corrective actions (monthly check-ins, evidence archiving).
- Defining responsibilities for quality department analysis, tracking, and supervisor confirmation.
- Requiring consideration of impact on similar processes & products.
- Clarifying verification stage and documentation.
- Update to include evidence of implementation reasons and corrective measures within process audits.
- Emphasis on using problem-solving tools like 5W analysis.

2. **Training & Communication**

- Training relevant personnel on revised procedures and IATF 16949 requirements.
- Training on problem-solving tools such as 5W analysis.

3. **Process Improvements**

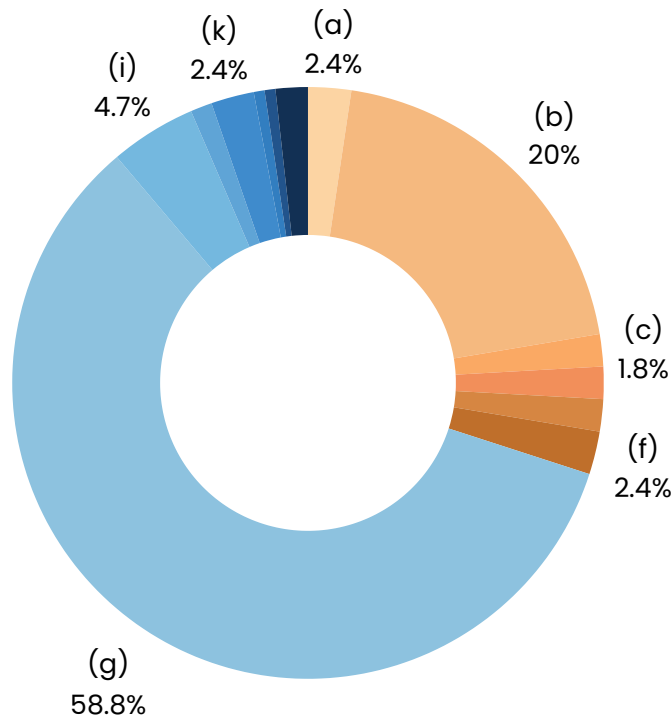
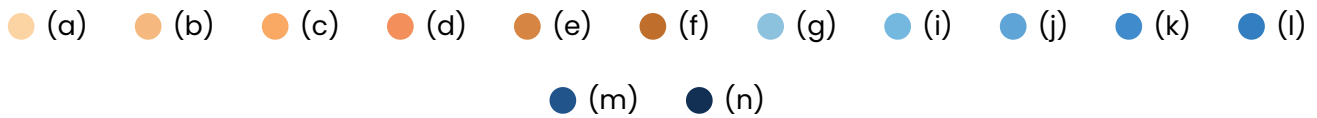
- Formal Verification Stage: Adding a mandatory verification step to the nonconformity management process.
- Organizational Structure: Reviewing and strengthening the quality area of organizational structure.
- Monitoring nonconformities using a new software system.
- Immediate response and tracking of audit issues.
- Add lessons learned from corrective actions into LPA audits.
- Ensuring corrective actions consider the impact on similar processes and products.
- Tracking and evaluating the effectiveness of corrective actions over time.

4. **Assigning Specific Responsibilities**

- Assigning a coordinator for complaint management.
- Assigning responsibilities for immediate actions to be taken related to specific complaints.

NC #2: 8.3.5.2 Manufacturing Process Design Output

Top Sub-Clauses



(g) manufacturing process FMEA

(b) special characteristics for product and manufacturing process

Objective Evidence Identified by CB Auditors

1. Missing or Incomplete Documentation

- Control Plans, Process Flow Charts, SOPs, and Work Instructions missing or inconsistent.
- FMEAs incomplete or incorrect severity grading.
- Production Capacity Analysis and Process Capability Studies absent.
- Special Characteristic Lists incomplete; layouts and assembly documentation missing.
- No records for trial production verification.

2. Non-Compliance & Process Control Issues

- Deviations in process parameters and equipment settings.
- Lack of equipment validation.
- Failure to meet customer performance requirements.
- Missing compliance testing and incomplete MSA.

3. Specific Process Gaps

- Missing critical process controls (e.g., inspection, appearance checks).
- Uncontrolled key parameters (pressure, temperature, mold settings).
- Undefined acceptance criteria for appearance and moisture testing.

4. Organizational & Systemic Weaknesses

- Inconsistent severity grading methodology.
- Gaps in understanding and applying APQP elements.

Root cause results determined by organizations

1. **General APQP Process & Documentation Deficiencies**

- APQP procedure is lacking detail, being too vague and not outlining sufficient requirements for critical steps.
- Lack of Integration between design, manufacturing, and quality. Siloed processes lead to misalignment and missed requirements.
- Lack of Enforcement/Verification of procedures.

2. **Control Plan Specific Issues**

- Control plans not developed in conjunction with drawing requirements, process flow, and special characteristics lists.
- Lack of cross-functional input by a project team.
- Missing control plan checklist including completeness of control plan elements.

3. **Special Characteristics**

- Special characteristics not identified, documented, and tracked.
- Failure to include special characteristics in drawings and documentation.

4. **Process Capability & Validation**

- Process capability studies not conducted.
- process capabilities not included in documentation.

5. **New Product Development & Customer Transfers**

- Failure to follow design process requirements for customer transfers with changes.
- Lack of documentation for capacity analysis.

6. **FMEA Specific Issues**

- Insufficient understanding of the purpose of FMEA and how to perform it effectively.
- FMEA not aligned with customer transfer projects.

Systemic corrective actions taken by organizations

1. **Process Definition & Control**

- Revisions focused on clarifying and controlling procedures related to product planning, development, and quality.
- Emphasis on integrating manufacturing process requirements early in planning stages.
- Updates to standard operating procedures and work instructions to improve consistency.

2. **Customer Requirement Management**

- Actions aimed at ensuring customer-specific requirements (e.g., special characteristics, regulatory compliance) are properly identified, documented, and maintained throughout the process.
- Improvements to traceability and verification of customer requirements in planning and execution.

3. **Documentation & Training**

- Enhancements to documentation practices, including control plans, procedures, and requirement records.
- Implementation of training programs to ensure personnel understand and follow updated procedures.

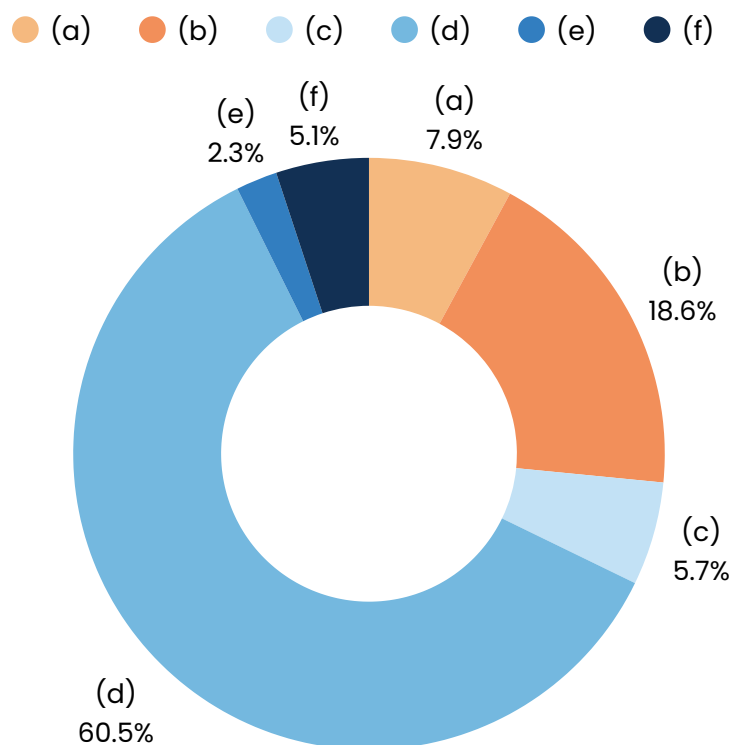
- Standardization of templates and checklists to reduce variability in reporting and execution.

4. Risk & Failure Analysis

- Increased focus on consistent application of failure mode and effects analysis (FMEA) principles.
- Definition of roles and responsibilities for conducting risk assessments.
- Integration of risk analysis into planning and review processes.

NC #3: 10.2.1 Nonconformity and Corrective Action

Top Sub-Clauses



(d) review the effectiveness of any corrective action taken

(b) evaluate the need for action to eliminate the cause(s) of the nonconformity...

Objective Evidence Identified by CB Auditors

1. Ineffective Corrective Action Management

- Evidence of recurring issues previously flagged in audits or complaints.
- Corrective actions failed to eliminate root causes, leading to repeated findings.
- Actions focused on symptoms rather than systemic problems.

2. Root Cause Analysis Deficiencies

- Audit records show missing or shallow root cause investigations.
- Lack of structured methodologies for identifying and resolving underlying issues.

3. Implementation & Follow-Up Gaps

- Corrective actions were not consistently executed.
 - No verification steps documented to confirm effectiveness.
 - Absence of clear accountability for action completion.
4. **Documentation & Record Control Issues**
- Missing inspection records and planning data.
 - Inconsistencies between documented procedures and actual practices.
 - Improper or absent use of required forms and templates.
5. **Process Control Failures**
- Poor maintenance and application of risk analysis tools.
 - Non-adherence to standard operating procedures.

Root cause results determined by organizations

1. **Procedural & Documentation Deficiencies**
 - Missing, unclear, or insufficient procedures.
 - Inconsistent documentation and lack of standardized forms or templates.
2. **Weak Monitoring & Execution**
 - Inadequate follow-up and verification of corrective actions.
 - Poor accountability and inconsistent implementation of defined actions.
3. **Training & Competency Gaps**
 - Lack of training on quality procedures and problem-solving tools.
 - Limited understanding and application of structured methodologies (e.g., 5 Whys, 8D).
4. **System & Tool Limitations**
 - Ineffective or missing systems for tracking corrective actions.
 - Lack of integration between quality systems and operational processes.
5. **Organizational & Leadership Issues**
 - Weak communication, limited management engagement, and shifting priorities.
 - Structural issues such as high turnover and unclear roles affecting consistency.

Systemic corrective actions taken by organizations

1. **Process Documentation & Control**
 - Updating procedures including verification steps, management review, and records.
 - Addition of management verification of corrective actions.
 - Including read-across, referencing for traceability in reports.
 - Training on updated continuous improvement procedures.
2. **Action Plan Monitoring & Effectiveness**
 - Defining KPIs for action plan progress in 8D problem-solving.
 - Creating lists of executed action plans versus results for effectiveness validation.
 - Implementing monthly meetings to discuss action plan advances and communicate effectiveness.
3. **Management Review & Accountability**
 - Requiring management to lead evaluation of continuous improvement projects.
 - General manager supervision of meetings and involvement in escalating issues.

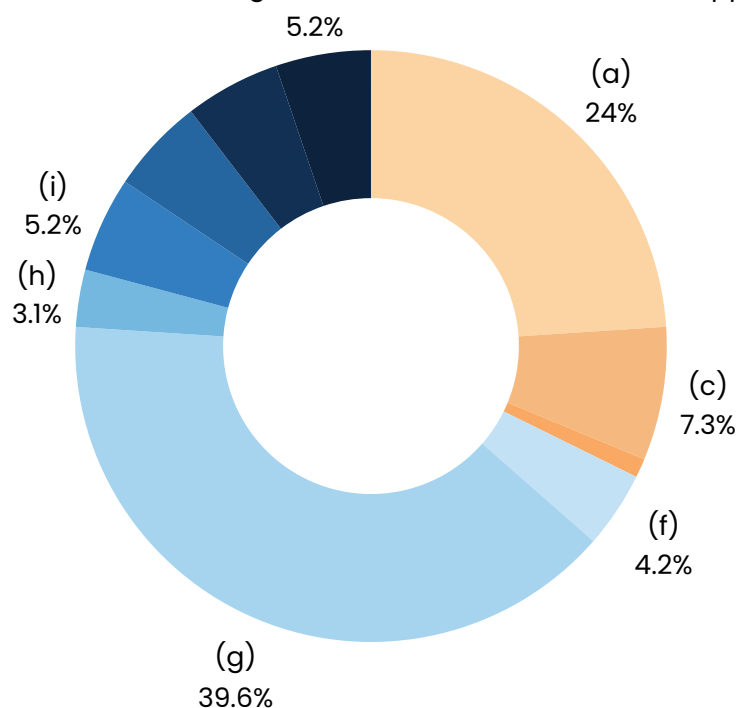
NC #4: 8.5.1.1 Control Plan

Top Sub-Clauses

● (a) ● (c) ● (d) ● (f) ● (g) ● (h) ● (i)

- The organization shall develop control plans (in accordance with Annex A) at the syste...
- The organization shall have a control plan for pre-launch and production that shows lin...
- If required by the customer, the organization shall obtain customer approval...

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(g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA)...

(a) controls used for the manufacturing process control, including verification of job set-ups

Objective Evidence Identified by CB Auditors

1. Missing Process Steps in Control Plans

- Key manufacturing or assembly steps not documented.
- Critical parameters (e.g., time, temperature, pressure) for specific operations are missing.
- Supporting sub-processes and intermediate steps are omitted.

2. Control Plan Incompleteness / Insufficient Detail

- Critical process parameters are not defined.

- Monitoring methods/tools for special characteristics are absent.
- Special characteristics are not identified or marked.
- 3. **Discrepancies Between Control Plan & Actual Practice**
 - Documented parameters differ from actual operating values.
 - Inspection and verification frequencies are inconsistent.
 - Actual operations deviate from documented procedures.
- 4. **Lack of Alignment Between Control Plan & Risk Analysis (FMEA)**
 - Operations listed in risk analysis are not reflected in control plans.
 - Operation numbering is inconsistent between documents.
- 5. **Control Plan Versions & Updates**
 - Control plans are not revised after process changes.
 - Updated parameters are not incorporated into documentation.

Root cause results determined by organizations

1. **Lack of Clear Documentation & Procedures**
 - Missing Requirements in Control plans.
 - No established rules for when control plans need to be reviewed and updated.
2. **Unclear Roles & Responsibilities**
 - Not clear who is responsible for creating, reviewing, updating, and ensuring adherence to control plans.
3. **Change Control**
 - Process changes and design changes are not reflected in the control plan.
 - Poor communication about changes.
 - Control plans not properly integrated with other crucial processes such as engineering changes, FMEA revisions, and production process management.
4. **Lack of skills or training**
 - Personnel lack a clear understanding of control plan requirements, documentation needs, and procedures.
 - Reviews are conducted without appropriate expertise.
5. **Lack of Ownership and Accountability**
 - No responsibility assigned for the overall health and effectiveness of the control plan.
 - Lack of management oversight and direction.

Systemic corrective actions taken by organizations

1. **Control Plan Procedure Update**
 - Process parameter control to include machine settings within the control plan.
 - Incorporating customer requirements for process controls and special characteristics.
 - Ensuring all relevant process activities are documented and supervised.
 - Adding a review step after control plan completion.
 - Documenting the rationale for inclusion of specific controls.
2. **APQP (Advanced Product Quality Planning)**

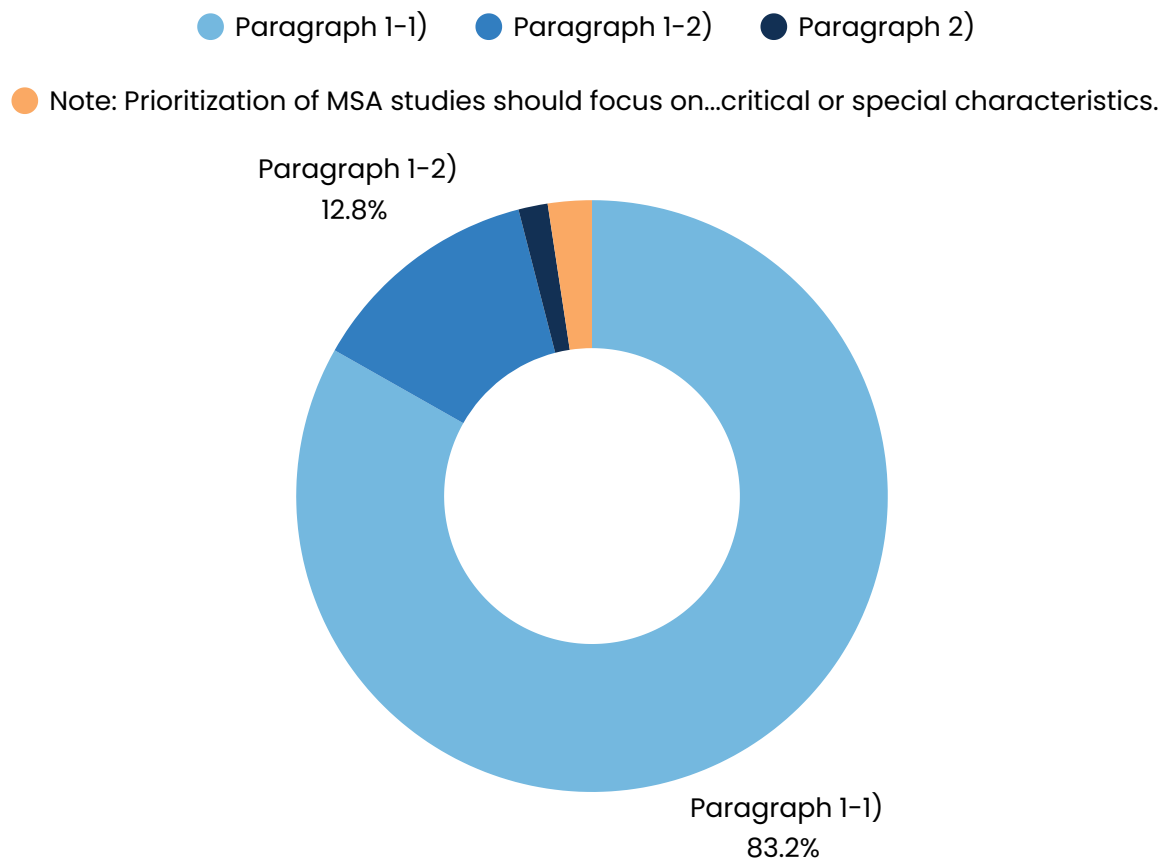
- Integrate control plans as a core element within the APQP process, including the planning and review phases.
- Creating a stage work summary and review form before quality planning is recognized by senior managers.
- Ensuring proper sign-off on technical information developed and integrating it with the production process.

3. Training & Communication

- Provide training on APQP procedures.
- Improve communication of the changes in procedures to relevant departments.
- Defining roles and responsibilities within the Quality Department.

NC #5: 7.1.5.1.1 Measurement system analysis

Top Sub-Clauses



Paragraph 1-1) Statistical studies shall be conducted to analyze the variation present in...

Paragraph 1-2) The analytical methods and acceptance criteria used shall conform to those

Objective Evidence Identified by CB Auditors

1. Lack of Measurement System Analysis Execution

- Many measurement systems used in inspection and testing have not undergone MSA.
- This gap spans multiple tools and processes, impacting overall measurement reliability.
- 2. **Methodological Inconsistencies**
 - MSA studies often apply incorrect or incomplete methodologies.
 - Key metrics and study types are frequently overlooked.
- 3. **Missing Study Components**
 - Critical MSA elements such as stability and linearity studies are often omitted.
 - Repeatability and reproducibility (R&R) evaluations are incomplete or invalid due to methodological gaps.
- 4. **Planning and Knowledge Limitations**
 - There is no structured approach for MSA planning or record keeping.
 - Personnel lack sufficient understanding of MSA requirements and their link to quality documentation.

Root cause results determined by organizations

1. **Knowledge/Training**
 - Lack of knowledge about the AIAG MSA manual, and general understanding of MSA principles.
 - New technicians unfamiliar with requirements, lack of understanding leads to incorrect spreadsheet/software usage.
 - Insufficient initial training, lack of ongoing updates on standards, new employee onboarding issues.
2. **Procedures/Documentation**
 - Lack of clear requirements to perform MSA on all instruments identified in the control plan.
 - Missing procedures for customer MSA requirements.
 - Lack of archiving requirements for MSA reports.
 - Missing review requirements for customer-provided monitoring documents.
 - Lack of clarity regarding what data tables must include.
 - Lack of definition on what measuring equipment require MSA studies.
 - Procedures do not specify a review process for MSA reports.
3. **Execution/Responsibility**
 - Lack of defined responsibility for performing and reviewing MSA studies.
 - Lack of oversight and inspection of MSA plans.
 - Failure to confirm MSA after mold repair.
4. **Systemic/Process**
 - Lack of integration with project management for MSA activities.
 - Alternate methods being used without proper justification.
 - Lack of process for filing and retrieving MSA data.

Systemic corrective actions taken by organizations

1. **Scope Expansion**

- Extend MSA coverage to all inspection, measurement, and testing systems listed in control plans and customer requirements.
- Prioritize MSA for key and special characteristics.
- Include non-traditional systems such as visual, counting, and customer-provided methods.
- Review and align with customer requirements to ensure compliance and completeness of reports.

2. Documentation and Record Updates

- Revise procedures and work instructions to incorporate expanded MSA requirements.
- Add review steps for customer-provided data and ensure report completeness.
- Update data tables to include full instrument identification details.

3. Process and System Improvements

- Develop and formalize MSA plans detailing methodology, timelines, responsibilities, and frequency.
- Implement a systematic approach for conducting and managing MSA studies.
- Standardize handling and review of customer-provided data and methods.

4. Training and Competency

- Mandate training on revised procedures, applicable standards, and new tools/software.
- Assess personnel capabilities to ensure alignment with process control requirements.

Driving IATF 16949 Compliance

The Top 5 Nonconformities highlight common challenges – but also clear opportunities to strengthen systems and improve consistency. Addressing root causes, enforcing accountability, and maintaining process discipline are key to lasting improvement.

Questions about any of the information? Send us an email: Contact_Us@iaob.org