

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

IATF 16949:2016 Quality management in automotive series production, requirements supplementing ISO 9001

The automotive supplement to ISO 9001

103 requirements. This standard can be certified against by an accredited body. As of 07/2026.

This list contains only the automotive-specific supplementary requirements of IATF 16949. The IATF standard does not stand on its own, it applies together with ISO 9001. For a complete preparation, also work through the ISO 9001 checklist, both sit side by side in the bundle. Self-assessment without any examining character, no proof for a certification. What gets audited is a single manufacturing site, and only a certification body additionally recognised by the IATF may issue the certificate. Pure development, warehouse and logistics sites are not eligible for certification.

Company

Date

Prepared by

4 Context of the Organization, Automotive Supplemental Requirements

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4.3.1 The scope of the management system covers all sites, processes and products of series and service part production. Support functions and manufacturing process development are included, and any non-applied requirement carries a factual justification that is filed in a traceable way.

What proves it: Scope statement in the manual or in a separate document listing sites, product families and a table of non-applied clauses together with the justification. Also useful: the draft certificate or the application form of the certification body, since it states the same scope. A small operation manages with a single page: address, what is manufactured, what is explicitly excluded and why.

Open In progress Met Not applicable

Evidence / justification

4.3.2 Customer-specific requirements agreed in contracts are collected in full, mapped to the matching clauses of the management system and reflected in the scope. For every requirement it is visible who implements it and where it is governed.

What proves it: Customer-specific requirements (CSR) per customer as a matrix: source with revision level from the customer portal, affected clause number, internal rule, owner, review date. Plus the downloaded customer documents in a version-controlled location. Small operations keep a single table for all customers and fix one date every six months on which the portals are checked for new revision levels.

Open In progress Met Not applicable

Evidence / justification

4.4.1.1 For purchased parts, materials and outsourced processes there is evidence that they meet the specified product and process requirements. Responsibility for conformity stays with your own organization, even where the work is performed externally.

What proves it: Supplier approval records with part submission status (PPAP), initial sample and incoming inspection reports, material certificates, and contracts or purchase order requirements for outsourced processes such as heat treating, plating or welding, including the required special process approvals. A small operation keeps one folder per supplier holding the valid approval, the latest inspection report and a note on who granted the approval.

Open In progress Met Not applicable

Evidence / justification

4.4.1.2 Products and manufacturing processes with safety relevance are identified as such and marked, and a written procedure governs how they are handled. It names responsibilities and deputies, the special approvals and inspections, traceability across the supply chain, the training of the people involved and the notification path to customer and authority in the event of an incident.

[Document](#)

What proves it: Product safety procedure, list of safety-related parts and characteristics with markings in the drawing, the FMEA and the control plan, a written appointment of the responsible person with proof of qualification, training records of the affected staff and an escalation and notification plan with contact details. A small operation keeps this on two pages: who decides which parts are affected, what happens immediately on suspicion, and which phone numbers are called in which order.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

5 Leadership, Automotive Supplemental Requirements					5
5.1.1.1	The organization has established binding rules on responsible conduct, covering as a minimum the prevention of bribery and corruption, the behaviour expected of employees, and a protected reporting route through which breaches of law or of internal rules can be escalated without detriment to the person reporting them.				Document
What proves it: An approved anti-bribery and anti-corruption policy, a code of conduct for employees and a described escalation or whistleblowing route, each dated and demonstrably communicated to the workforce (notice board, training attendance list, intranet). A small site can cover all three points in a two page document, together with a named reporting contact (for example the managing director with an external person of trust as an alternative) and an acknowledgement of receipt signed by staff.					
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Evidence / justification					
5.1.1.2	Top management evaluates the processes of the quality management system not only on whether they achieve their intended results, but also on the time, people and material consumed in achieving them, and the outcome of that evaluation feeds into the management review.				
What proves it: A process map that assigns to each process at least one effectiveness indicator (for example on time delivery, defect rate) and one efficiency indicator (for example lead time, rework hours, scrap cost), plus the evaluation recorded in the management review minutes. For a small site a monthly one page indicator sheet with five to ten lines, discussed and signed off in the leadership meeting, is sufficient.					
OpenIn progressMetNot applicable					
Evidence / justification					
5.1.1.3	Each process of the quality management system has a named owner who steers the process and its interfaces, is accountable for the related indicators and holds the competence and decision making authority required to do so.				
What proves it: A list of processes with a named owner for each, supplemented by a short role description setting out authority. Auditors cross check this in interviews: the named person must be able to explain their process, their indicators and their interfaces. In a small site one person may own several processes, but the assignment must be written down and known to that person.					
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Evidence / justification					
5.3.1	Persons responsible for conformity to product requirements are assigned by name, their authority extends to stopping production and shipment when nonconformities occur, the assignment is known at all levels and applies equally across all shifts.				
What proves it: An organization chart or responsibility matrix naming persons per shift, a written stop authority (halting production and shipment) and evidence that this was communicated, for example through a training attendance list or a notice at the line. A documented case in which production was actually stopped and escalated is strong evidence. Small sites capture this as a shift plan with deputy arrangements plus a notice at the line.					
OpenIn progressMetNot applicable					
Evidence / justification					
5.3.2	It is defined who ensures that customer specific requirements reach the shop floor and are implemented, who assigns and maintains special symbols for safety and regulatory characteristics, who triggers corrective action and who halts production or shipment in the event of a nonconformity.				
What proves it: A responsibility matrix that assigns an owner to each item of the customer requirements (the customer specific requirements matrix for the respective customer), together with the rule for assigning special symbols in drawings, FMEA and control plan, and records of corrective actions that were triggered. In a small site one table per customer is enough: requirement, source in the customer portal, owner, evidence of implementation.					
OpenIn progressMetNot applicable					
Evidence / justification					

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6 Planning: Risk, Contingency and Objectives in the Automotive Context

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6.1.2.1 Risk analysis draws demonstrably on your own experience with the product: recalls, findings from product audits, field returns, repairs, customer complaints, scrap and rework have been evaluated and have fed into how the risks are rated.

What proves it: A risk register or risk matrix that names the source behind each risk, together with the underlying evaluations: complaint statistics, scrap and rework figures, product audit reports, 8D reports, a field return overview. In a small operation a maintained spreadsheet is enough, listing every complaint and every larger scrap event with date, cause and the resulting risk rating, reviewed together once a quarter.

Open In progress Met Not applicable

Evidence / justification

6.1.2.2 For failures that have not yet occurred, there is a defined way to identify possible causes, rate their effect and eliminate them through action; the effectiveness of that action is verified and the lesson learned is carried over to comparable processes, products and equipment.

What proves it: A form or process description for preventive action covering trigger, assessment of the possible effect, action, due date, evidence of effectiveness and one line on transfer to similar parts. Useful sources include FMEA results (Core Tools reference manual), near misses, lessons from other plants or recalls elsewhere in the industry. A small operation simply adds a column to its existing action sheet or 8D sheet asking whether the case could arise elsewhere, plus the outcome of that check.

Open In progress Met Not applicable

Evidence / justification

6.1.2.3 Documented contingency plans exist for situations in which supply to the customer falters; they cover failure of key equipment, missing deliveries from suppliers, shortage of staff, fire, recurring natural events and disruption of utilities, IT and infrastructure, define how the customer is notified, are tested for effectiveness, are reviewed at least annually and ensure that the product still meets customer specification after restart.

[Document](#)

What proves it: One contingency plan per critical process with trigger, immediate action, owner, alternative source or alternative machine and the notification path to the customer, plus records of the testing (simulation or dry run) and of the annual review with a visible revision status. In a small operation a two page sheet per bottleneck is enough, naming second source, backup machine, deputy arrangement and phone numbers, extended by a short note after every exercise and after every real incident.

Open In progress Met Not applicable

Evidence / justification

6.2.2.1 Quality objectives and the related performance targets are set for the relevant functions, processes and levels, derived from customer requirements and from the results of considering interested parties, refreshed at least annually and cascaded far enough that they can be influenced where they apply.

What proves it: An objective sheet or metrics overview per area with target value, reference period, owner and actual status, together with a traceable derivation from customer requirements (for example ppm limit, delivery performance, response time) and from the analysis of interested parties. A small operation keeps a single board with five to seven metrics, updated monthly in the production meeting and reset once a year in the management review.

Open In progress Met Not applicable

Evidence / justification

7 Support, Automotive Additions

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7.1.3.1 Planning and improvement of the plant, floor space, machines and equipment are carried out by a cross-functional team. Risks are named explicitly and backed by actions. Manufacturing feasibility, available capacity and the effectiveness of the existing operations are part of this planning.

What proves it: Layout plan showing material flow, capacity calculation for each bottleneck machine, minutes of the planning session listing participants from production, quality, logistics and maintenance, plus a risk list for the planning. A small operation keeps this as a one-page record with a layout sketch, a takt calculation and three named risks.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

7.1.4.1 For production, inspection and storage areas, cleanliness, order, state of maintenance and the suitability of the ambient conditions for the respective product are defined and checked at regular intervals.

What proves it: Walk with a 5S checklist including date and photos, cleaning schedule with named owners, plus records of temperature, humidity or particles wherever the product calls for it. Small operations tie the walk to the weekly shift handover and post the result on a board in the area.

Open In progress Met Not applicable

Evidence / justification

7.1.5.1.1 For every type of inspection, measuring and test equipment system listed in the control plan, the variation in the measurement results has been studied. Study methods and acceptance criteria are defined up front, and any deviating method is agreed with the customer.

What proves it: Measurement systems analyses per characteristic and per gauge, with date, appraiser and evaluation, run as repeatability and reproducibility studies for variable characteristics and as attribute agreement studies for attribute characteristics. Methods and criteria follow the MSA reference manual. Customer approvals for deviating methods are on file in writing. A small operation runs the study in a spreadsheet and files it with the drawing for the characteristic concerned.

Open In progress Met Not applicable

Evidence / justification

7.1.5.2.1 For all inspection, measuring and test equipment that supports evidence of product conformity, records of calibration and verification exist, including traceability to recognized standards. Where equipment is found to be out of tolerance, it is documented what happened to the parts inspected since the last valid check and whether the customer was informed.

[Document](#)

What proves it: Calibration certificate per gauge showing results before and after adjustment, statement of traceability, gauge number and next due date, plus a gauge register with a due list. Where equipment was found out of tolerance, the traceback of the affected lots and the customer notification belong in the same file. For software-driven equipment, the version in use is part of the record.

Open In progress Met Not applicable

Evidence / justification

7.1.5.3.1 Where an in-house inspection or measurement facility exists, its scope of work is defined in writing and forms part of the management documentation. The definition covers at minimum the permitted test methods, the competence of the personnel, the measuring equipment and the required ambient conditions.

[Document](#)

What proves it: A laboratory scope document listing the tests that may be performed, plus test instructions, competence records for the personnel and an equipment list with calibration status. An internal laboratory can also be a single measuring station, and a small operation states the scope for it on two pages.

Open In progress Met Not applicable

Evidence / justification

7.1.5.3.2 Where testing, calibration or measurement is placed with an outside party, the suitability of that provider is evidenced, either through accreditation to the relevant laboratory standard or through separate evidence that the provider meets the customer requirements.

What proves it: Accreditation certificate of the laboratory together with the annex stating the accredited scope, or alternatively an in-house assessment of the laboratory as a supplier with customer approval. The external laboratory reports carry the reference to the order, the part and the equipment used.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

7.2.1	A defined process determines training needs, creates awareness of each person's role in quality, and ensures the competence of everyone performing work that affects product and process. People holding special assignments, for example on special processes, are covered explicitly.	Document
What proves it: Documented competence process, a skills matrix per workstation showing target and actual, an annual training plan and records of the training delivered. Small operations keep a single matrix with names in the rows and workstations in the columns and mark the gaps in color.		
Open In progress Met Not applicable		
Evidence / justification		
7.2.2	Newly hired or reassigned people are trained on the job, including the customer requirements. The depth of the training is driven by prior knowledge and by how much the activity matters. Temporary agency staff likewise know what defective work means for the customer.	
What proves it: On-the-job training record per person and workstation with date, content, trainer and signature, plus the customer-specific points covered. A card at the workstation naming the concrete consequence of a defect, for example a line stop at the customer, adds to the evidence and in small operations replaces a separate training package.		
Open In progress Met Not applicable		
Evidence / justification		
7.2.3	A defined process evidences that internal auditors are competent for the audit type they perform. It covers understanding of the process approach, of the quality methods expected in the sector, of the customer-specific requirements and, for product audits, of the product requirements themselves. A list of qualified auditors is maintained, and auditors keep their knowledge current.	Document
What proves it: Competence profile per auditor with training records covering the APQP, PPAP, FMEA, MSA and SPC reference manuals, the number of audits observed and of audits led, plus annual evidence of maintained competence and the current auditor list. Anyone too small to hold their own auditors buys in an external auditor by the hour and files that auditor's competence record.		
Open In progress Met Not applicable		
Evidence / justification		
7.2.4	Whoever audits suppliers on behalf of the organization is demonstrably competent to do so. Competence covers audit methodology, knowledge of the quality management system requirements used in the sector, knowledge of the customer-specific requirements and an understanding of the audited supplier's processes.	
What proves it: Competence record per supplier auditor, audit reports naming the auditor, and a comparison of that auditor's experience with the audit scope. Small operations engage an external auditor for supplier audits and file that auditor's certificate together with the audit reports.		
Open In progress Met Not applicable		
Evidence / justification		
7.3.1	There is evidence that all employees know what effect their work has on product quality, what they contribute to reaching the quality objectives and what risks defective parts create at the customer. This awareness is refreshed at regular intervals.	Document
What proves it: Briefing records with date, topics and signatures, quality information at the line stating the concrete customer consequences, and quality items minuted from the shift meeting. A small operation collects the signed annual briefing covering customer consequences and real complaint examples from its own house.		
Open In progress Met Not applicable		
Evidence / justification		
7.3.2	A defined process motivates employees to take part in improvement and to reach the quality objectives, and builds an understanding of the commercial contribution their own work makes.	Document
What proves it: Documented improvement process with response deadlines, a list of suggestions submitted and implemented, a participation measure and a posting on the cost of quality. Small operations run an improvement board on the wall plus a short weekly format in which suggestions are decided. Photos of the cards and the implementation list then serve as the evidence.		
Open In progress Met Not applicable		
Evidence / justification		

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7.5.1.1 A manual or an equivalent document structure describes the management system. It contains the scope with justification for any exclusion, the processes with their sequence and interaction, and a mapping showing where in the system each standard requirement and each customer-specific requirement is covered.

[Document](#)

What proves it: Quality management manual or a set of linked documents, plus a process map and a cross-reference table from clause number to document or process, with its own column for the customer-specific requirements. A small operation realizes the manual as a folder structure with an overview page pointing to the individual documents.

Open In progress Met Not applicable

Evidence / justification

7.5.3.2.1 Retention periods and the disposal of records are governed in writing. The rule meets at minimum the statutory and the customer-specific requirements. Records on production part approval, tooling and supplier approval stay available and legible beyond the life of part production and service part supply.

[Document](#)

What proves it: Retention matrix listing record type, period, storage location, owner and disposal route, extended by the periods taken from the customer requirements, plus disposal records. Small operations keep the matrix to one page and, for digital storage, refer to the backup plan with its restore test.

Open In progress Met Not applicable

Evidence / justification

7.5.3.2.2 A defined process governs how customer drawings, standards and specifications and their changes are reviewed, distributed and implemented. The review is prompt, normally within ten working days. The date of implementation in series production is recorded, and the affected documented information is updated with the change.

[Document](#)

What proves it: Receipt note and distribution list per customer specification, change record stating the date of series implementation, plus updated control plan, updated FMEA and updated inspection instructions. Small operations keep a simple change list with receipt date, review date, implementation date and the documents affected.

Open In progress Met Not applicable

Evidence / justification

8 Operation, additional requirements for automotive production

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8.1.1-a Planning of the operational processes takes in customer requirements and the technical specifications the customer refers to, so that both can be traced into production planning, process descriptions and inspection settings.

What proves it: Customer requirement specification, list of applicable specifications per part number with revision level, reference to the specification inside the process plan or the work instruction. A small shop keeps a customer specification column in its part master list, with source and revision, so that every change makes clear which papers have to follow.

Open In progress Met Not applicable

Evidence / justification

8.1.2-a Products developed or manufactured on customer order, together with the related project files and development states, are kept confidential unless the customer releases them.

What proves it: Non-disclosure agreements with customers and a confidentiality clause in employment contracts, access rules for project folders, marking of confidential drawings. A small shop handles this with an access-restricted customer directory and one short rule on which photos and samples never leave the site.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.2.1.1-a Communication with the customer takes place in the language and form the customer asks for, and the ability to exchange design data in the data format the customer requires is in place.

What proves it: Overview of the data and CAD formats required per customer, evidence of the software used or of a contracted conversion service, examples of correspondence and portal entries in the customer language. A small shop buys the conversion in and documents the customer portal access together with the person responsible.

Open In progress Met Not applicable

Evidence / justification

8.2.2.1-a When product requirements are determined, recyclability, environmental impact and the characteristics known from the product and its manufacture are considered as well; the statutory requirements of the country of manufacture and of the country of destination are included.

What proves it: Requirements list per project with fields for material and recycling targets and for target markets, substance reporting in the usual industry material database, list of the applicable legal requirements per country of destination with the date of the last check.

Open In progress Met Not applicable

Evidence / justification

8.2.3.1.1-a Customer requirements are reviewed before an order is accepted, and this formal review is waived only with the explicit agreement of the customer.

What proves it: Quotation and order review record with date and initials of the functions involved, and, where the review is waived, the written customer agreement; an email is enough. A small shop uses a one-page review form per enquiry, signed off by engineering, production and sales.

Open In progress Met Not applicable

Evidence / justification

8.2.3.1.2-a Special characteristics defined by the customer are carried into the own documented information with the customer symbol, and they run through risk analysis, control plan, inspection instruction and the release and change records without a break.

What proves it: Drawing or specification carrying the customer symbols, a legend per customer that maps those symbols to the own marking, and the carry-through into the inspection record. A small shop keeps a characteristics list per part that brings customer symbol, own marking, inspection point and gauge together.

Open In progress Met Not applicable

Evidence / justification

8.2.3.1.3-a Before an order is accepted it is analysed and recorded that the product can be made in the required volume, cycle time and quality with the equipment available or planned; the same applies to changed orders and to new manufacturing technologies.

Document

What proves it: Feasibility analysis per enquiry covering capacity, tooling and process risks, with a clear result: feasible, feasible with actions, not feasible. The functions involved sign it off and the sheet stays with the quotation. A small shop gets by with a one-page feasibility sheet attached to the enquiry.

Open In progress Met Not applicable

Evidence / justification

8.3.1.1-a The design and development requirements apply to product design as well as to manufacturing process design, and the emphasis lies on error prevention rather than on error detection.

What proves it: Process description of design and development covering both strands, evidence of preventive methods such as risk analyses and poka-yoke solutions. Where the site carries no product design responsibility, the process part still applies, and the exclusion of product design is recorded with a justification.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.3.2.1-a Design and development planning is carried by a team that includes engineering, production, quality, purchasing and logistics, and it takes account of timing, cost and feasibility targets.

What proves it: Project plan with milestones, owners and dates, attendance lists of project meetings showing several functions, status overview per milestone. The APQP reference manual serves as a frame, but its forms are not mandatory. In a small shop a fixed project round of three or four people and a maintained schedule are enough.

Open In progress Met Not applicable

Evidence / justification

8.3.2.2-a The people entrusted with product design master the tools and methods needed for it, and that competence is evidenced.

What proves it: Competence matrix with rows for CAD, tolerance stack-up, risk analysis and design of experiments, training records, work samples from earlier projects. Where design is bought in, the competence of the service provider is evidenced in the contract or through its own records.

Open In progress Met Not applicable

Evidence / justification

8.3.2.3-a For products with embedded software a separate documented development process including quality assurance is in place, and the own software development capability is self-assessed against a recognised assessment model and recorded.

[Document](#)

What proves it: Description of the software life cycle, result of the self-assessment with date and action plan, version control, test cases and test reports per software level. Where no product contains software, that fact is recorded with a justification instead of leaving the item blank without comment.

Open In progress Met Not applicable

Evidence / justification

8.3.3.1-a The inputs to product design are captured completely and cover functional and performance targets, special characteristics, the interfaces to the environment of the part, targets for service life and reliability, and the knowledge gained in earlier projects.

What proves it: Customer requirement specification and the requirements list derived from it, with a source stated per line, design FMEA as evidence of the risk review, lessons learned list from predecessor projects. Customer requirements that cannot be met are clarified with the customer in writing and the clarification is filed.

Open In progress Met Not applicable

Evidence / justification

8.3.3.2-a The inputs to manufacturing process design are captured and cover the outputs of product design, targets for productivity, process capability and cost, experience from comparable processes, and the settings made for error prevention at machine and workstation.

What proves it: Process design sheet with target values, layout and flow sketch, list of the process alternatives examined with the reason for the choice, process FMEA. A small shop keeps one process sheet per part family with cycle time, output target and the planned safeguards.

Open In progress Met Not applicable

Evidence / justification

8.3.3.3-a A defined and documented process determines how special characteristics are identified, defined, marked in the documented information and safeguarded through risk analysis, production control plan and inspection, even where the customer has named none.

[Document](#)

What proves it: Procedure for special characteristics with an own symbol set, a traceable chain from the drawing symbol through the FMEA into control plan and inspection instruction, customer approval wherever the customer asks for it. A spot check on a running part is the fastest way to see whether the chain holds.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.3.4.1-a Development progress is reviewed at defined milestones against agreed measurements, the results are reported to management and, where required, aligned with the customer.

What proves it: Milestone report with figures on open items, risks and dates, minutes of the project reviews with the decisions taken, status reports to the customer. In a small shop a milestone list with open items, owners and dates, walked through in every project round, is enough.

Open In progress Met Not applicable

Evidence / justification

8.3.4.2-a Design validation is carried out according to the customer requirements including the timing the customer sets, and the results are recorded.

What proves it: Test plan with standard and customer requirements per characteristic, test reports from the own laboratory or from one recognised by the customer, customer release note. A small shop places life and environmental testing with an external test provider and assigns those reports unambiguously to the project.

Open In progress Met Not applicable

Evidence / justification

8.3.4.3-a Where the customer asks for prototypes, a documented prototype programme and a matching control plan exist, and the same suppliers, tooling and processes as in later series production are used as far as possible.

[Document](#)

What proves it: Prototype control plan, part and tooling list with a note where a deliberate deviation from series production is made, statement of work for outsourced prototype scopes. Where no customer asks for prototypes, this is recorded as a note instead of leaving the item open.

Open In progress Met Not applicable

Evidence / justification

8.3.4.4-a A documented process governs the approval of product and manufacturing process according to the customer requirements, and bought-in scopes are themselves approved before the own submission to the customer takes place.

[Document](#)

What proves it: Approval file per part number with initial sample inspection report, measurement records, capability evidence, control plan and the customer approval letter, plus the approval status of the suppliers involved. The PPAP reference manual or the process named by the customer serves as a frame; the retention period follows the customer requirement.

Open In progress Met Not applicable

Evidence / justification

8.3.5.1-a The outputs of product design are described so that they can be verified, and they cover the design risk analysis, results on reliability and service life, the special characteristics, error prevention solutions, and the complete product definition with models and drawings.

What proves it: Drawing set and model data with an unambiguous release and change level, design FMEA, reports on service life and reliability, bill of materials, requirements for service, marking and packaging. What matters is that every output can be traced back to a requirement from 8.3.3.

Open In progress Met Not applicable

Evidence / justification

8.3.5.2-a The outputs of manufacturing process design are documented and cover the process flow, the process risk analysis, the production control plan, work and inspection instructions, the acceptance criteria for process capability, and the methods for error prevention and for rapid feedback when deviations occur.

[Document](#)

What proves it: Process flow diagram, process FMEA, production control plan and work instructions carrying the same change level, capability targets set in writing, commonly Ppk $\geq$ 1.67 for the production launch and Cpk $\geq$ 1.33 for ongoing production, unless the customer states otherwise. Add the description of the poka-yoke solutions and the evidence that their function is checked at regular intervals.

Open In progress Met Not applicable

Evidence / justification

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8.3.6.1-a Changes to product or manufacturing process are evaluated for their effects, verified and, where needed, validated before they are implemented; the customer approval required is in hand before series implementation, including for changes that originate at a supplier.

What proves it: Change request with an assessment of the effects on form, fit, function, durability and process, evidence of the customer approval, FMEA and control plans updated to match, and for software the documented version level. A simple change list per part number shows which level has been running since when.

Open In progress Met Not applicable

Evidence / justification

8.4.1.1-a All externally provided products, components and services that affect customer requirements are covered by supplier control, including outsourced processes such as heat treatment, coating, welding, testing or calibration.

What proves it: List of the suppliers and outsourced processes subject to control, with scope, risk rating and the type of evidence chosen in each case. A small shop keeps this in a table with the columns supplier, service, risk, evidence and last evaluation.

Open In progress Met Not applicable

Evidence / justification

8.4.1.2-a A documented supplier selection process considers the risk to product conformity and to delivery reliability, past quality and delivery performance, the assessment of the quality management system, and, where applicable, design and software capability and product safety concerns.

[Document](#)

What proves it: Procedure for supplier selection with criteria and weighting, completed assessment sheets for the approved suppliers, approval decision with date and signature. A small shop uses a one-page assessment sheet per new supplier and files it in the supplier folder.

Open In progress Met Not applicable

Evidence / justification

8.4.1.3-a Where the customer directs the source, responsibility for the quality of the purchased parts stays with the own site, and the performance of those sources is monitored just as for freely chosen suppliers.

What proves it: Marking of these suppliers in the supplier list, running performance data on complaints and delivery reliability, correspondence with the customer where problems persist. A different arrangement on responsibility only holds if it is agreed with the customer in writing.

Open In progress Met Not applicable

Evidence / justification

8.4.2.1-a The type and extent of control over externally provided processes and products is set on a risk basis, so that for every scope it is clear whether incoming inspection, certificates, approvals or audits are required, and the effectiveness of that control is reviewed.

What proves it: Control matrix per commodity group with the type of evidence set, incoming inspection instruction with the inspection scope, examples of mill certificates and approval reports. Where deviations pile up in one scope, the tightened inspection scope is documented with a date.

Open In progress Met Not applicable

Evidence / justification

8.4.2.2-a Externally provided products, materials and services meet the statutory requirements of the country of manufacture, of the receiving country and of the country of destination named by the customer, and the suppliers are bound to this.

What proves it: Purchase order or framework contract clause on prohibited substances and declaration duties, declarations of conformity and substance data from the suppliers, evidence of the report in the usual industry material database. An annual enquiry with the relevant suppliers keeps the status current.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.4.2.3-a A development stage of the quality management system is set for suppliers, with a traceable path from self-declaration through certification to ISO 9001 up to further automotive requirements, unless the customer has agreed otherwise.

What proves it: Supplier list with the current certification status, target stage and target date, certificates on file with their validity date, written customer approval for justified exceptions. A reminder before the certificates expire prevents gaps going unnoticed.

Open In progress Met Not applicable

Evidence / justification

8.4.2.3.1-a Suppliers of software or of components with embedded software are required to operate and maintain a process for the quality assurance of their software, and their capability for this is assessed and taken into account in the supplier evaluation.

What proves it: Contractual obligation in the quality assurance agreement, result of the supplier self-assessment or of an assessment against a recognised model, version and test evidence for the software levels delivered. Where the item does not apply to the site, the exclusion is recorded with a justification.

Open In progress Met Not applicable

Evidence / justification

8.4.2.4-a Supplier performance is tracked continuously against defined measurements, covering at least the conformity of the parts delivered, disruptions at incoming goods and at the customer including field returns, delivery reliability, and special status notifications from customers or certification bodies.

What proves it: Supplier evaluation on a fixed rhythm with the measurements named, an escalation rule when target values are missed, minutes of the supplier talks with the actions agreed. In a small shop a table with complaints, ppm value and delivery deviations per supplier, updated every six months, is enough.

Open In progress Met Not applicable

Evidence / justification

8.4.2.4.1-a A documented process defines when an audit at the supplier is needed, what type and scope it has and how often it takes place; the risk rating and the past performance of the supplier form the basis of the decision, and the audit reports are retained.

[Document](#)

What proves it: Audit programme with the reason for the selection, audit reports with findings, actions and dates, evidence that effectiveness was checked. A small shop audits one critical supplier on site per year and records the result and the action list on two pages.

Open In progress Met Not applicable

Evidence / justification

8.4.2.5-a For suppliers where a need for action has been identified, development actions are set by urgency, type and extent, given owners and dates, and their effect is followed up.

What proves it: Action plan per supplier, derived from the evaluation or the audit, evidence of the support given such as training, joint problem solving or a process walk, and the trend of the measurements before and after the action as evidence of effectiveness.

Open In progress Met Not applicable

Evidence / justification

8.4.3.1-a The requirements passed on to suppliers contain all applicable statutory requirements as well as the special product and process characteristics, and the suppliers are obliged to cascade these requirements down their own supply chain.

What proves it: Purchase order documents and drawings with the special characteristics marked, quality assurance agreement with a cascade clause, supplier confirmation that the requirements were passed to its sub-tier suppliers. A spot check on one purchase order shows whether the marking really travels with it.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.5.1.1 A control plan exists for every product family and every manufacturing site, covering prototype, pre-launch and production. It names the characteristics to be monitored, the gauges used, the sample sizes and the inspection frequencies, defines a reaction for every deviation, and is updated whenever the product, the process or the inspection method changes.

[Document](#)

What proves it: Control plan per part family with revision status and change history, linked to the process FMEA and the work instruction, plus the reaction plan that the shop floor actually follows when something goes wrong. The plan is described in the APQP and PPAP reference manuals; what is required here is the plan itself. At launch a capability demonstration is customary, typically $Ppk \geq 1.67$, in ongoing production $Cpk \geq 1.33$, unless the customer specifies otherwise. Small operations keep the plan as one table per part family, one row per characteristic.

Open In progress Met Not applicable

Evidence / justification

8.5.1.2 Standardised work descriptions, operator instructions and visual aids exist for the activities performed. They are accessible at the workstation, understandable in the language of the people doing the work, and demonstrably known to the employees.

[Document](#)

What proves it: Work instruction with a picture or boundary sample right at the workstation, revision and release date visible, plus the training record of the employees. Small operations tape a laminated sheet with photos of a good part and a bad part to the machine; that serves the purpose better than a binder in the office.

Open In progress Met Not applicable

Evidence / justification

8.5.1.3 Setups are verified. At every job and material changeover the first part is inspected and released, the last part of the previous job is assessed, and where boundary samples apply the comparison is made against them. The results of the setup verification are recorded.

[Document](#)

What proves it: Setup record per job with first part approval, time, inspector and measured values, plus the retained first and last parts in the setup rack. Small operations use a form at the machine that the setter signs off before the run starts.

Open In progress Met Not applicable

Evidence / justification

8.5.1.4 For restart after planned and unplanned production shutdowns it is defined how conformity of the first products is ensured, and the defined actions are carried out.

What proves it: Startup checklist for restart after a weekend, a plant shutdown or a breakdown, signed off by production management, plus the inspection results of the first parts after startup. Small operations tie this to Monday morning and to the setup that is needed anyway.

Open In progress Met Not applicable

Evidence / justification

8.5.1.5 A maintenance system is in place for the equipment needed to meet the production plan: critical equipment is identified, spare parts for it are available, preventive maintenance is planned and performed, maintenance objectives are measured, and predictive methods are used where they add value.

[Document](#)

What proves it: Equipment list with criticality, maintenance schedule with due dates and sign-off, spare parts list for bottleneck items, and a metric tracked over time such as unplanned downtime or equipment availability. Small operations keep the maintenance schedule as a recurring calendar entry per machine. What matters is the sign-off, not the tool.

Open In progress Met Not applicable

Evidence / justification

8.5.1.6 Production tooling, fixtures and inspection and test equipment are inventoried. Condition, location and tool life are known, wear is monitored, repair and modification are governed, and tooling stored off site or held at a service provider is subject to the same monitoring.

What proves it: Tooling register with number, location, tool life, last repair and owner, plus unambiguous identification of customer-owned tooling. Small operations keep this as a table plus a label on the tool. What matters is that the counter of strokes or parts produced is kept up to date.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.5.1.7 Production is planned order by order and aligned to the customer release. Planning takes due dates, lot sizes and capacity into account, and the information needed for it is accessible at the decisive points in the process.

What proves it: Production schedule or order list showing customer release, delivery date and lot size, visible to production and shipping, plus on-time delivery as a metric. Small operations work with a planning board or a shared spreadsheet, as long as it reflects the current release.

Open In progress Met Not applicable

Evidence / justification

8.5.2.1 For every automotive product it is analysed and recorded how far traceability has to reach so that in the event of a defect the affected scope can be bounded. The defined identification runs from incoming goods through production to delivery, allows batch, lot and time of manufacture to be assigned, and the retention period of the records is determined.

[Document](#)

What proves it: Documented traceability analysis per product with its result, plus batch labels, the production order and the link from delivery note to batch. A useful test is a recall drill: starting from a delivery note number, name the batches built in and the further affected shipments within a few hours. Safety-related characteristics may call for finer granularity.

Open In progress Met Not applicable

Evidence / justification

8.5.4.1 Product and material are protected against damage, mix-up and expiry during storage, internal transport and shipping. Packaging and labelling are defined, stock is assessed at defined intervals for condition and usability, and material with limited shelf life is controlled against its expiry date.

What proves it: Packaging specification per part, stock assessment with date and result, labelling of shelf-life-limited goods with expiry date, and a first in, first out rule that is actually lived. Small operations mark shelf-life-limited goods with colour and check them during every stocktake.

Open In progress Met Not applicable

Evidence / justification

8.5.5.1 Feedback from the field, complaints and the results of returned part analyses reach production, logistics, development and design and flow back into the risk assessment, into the FMEA and into the control plan.

What proves it: Returned part report with failure mode and root cause, plus the revision of the FMEA and the control plan that follows from that report. Small operations log every customer report of a field problem in a list and take that list into the management review.

Open In progress Met Not applicable

Evidence / justification

8.5.5.2 Where a service agreement with the customer exists, it is verified whether the service centres used, the tools and gauges deployed for the purpose and the qualification of the service staff match the agreement.

What proves it: Service agreement, evidence of the tools and gauges used in a service case, and training records of the service personnel. If no service agreement exists, that is recorded with a rationale instead of passing over the point in silence.

Open In progress Met Not applicable

Evidence / justification

8.5.6.1 Changes to product, process, material, manufacturing location or supplier are evaluated before implementation, their effect on product and process is demonstrated, customer approval is obtained where it is required, and after implementation the effectiveness of the change is verified.

[Document](#)

What proves it: Change request with evaluation, verification and validation results, customer approval and effective date, plus the resulting resubmission according to the PPAP reference manual. Small operations keep a change register with one row per change. What matters is the date, the approval and the link to the first changed lot.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.5.6.1.1 For the process controls it is recorded which method is the primary one and which alternate or fallback method is permitted. Use of an alternate method is approved, limited in time and risk assessed, and the return to the primary method is confirmed before the temporary control ends.

[Document](#)

What proves it: List of process controls with the primary and the permitted alternate method, plus an approval form for temporary use showing start, planned end, approver and risk assessment. A frequent case: the poka yoke device fails and the operation falls back to 100 percent visual inspection. Exactly that case belongs described up front, not improvised once the failure occurs.

Open In progress Met Not applicable

Evidence / justification

8.6.1 Product is released only once the inspections planned in the control plan have been performed and passed. Where the customer requires a release, it is on hand before delivery, and any deviation from the planned inspection is approved.

What proves it: Inspection records for the lot referencing the control plan, release note with person and date, and, where needed, the customer release. Small operations tie the release to the delivery note: no delivery note without a signed-off inspection.

Open In progress Met Not applicable

Evidence / justification

8.6.2 At defined intervals the product is inspected in full against all dimensions and requirements of the drawing and, where required, tested for its function. Scope and frequency follow the customer requirement, and the results are available for the customer to review.

What proves it: Full dimensional report covering all dimensions of the drawing with date, gauge and inspector, plus the functional test report and the schedule showing the agreed interval. Small operations outsource the full dimensional inspection to an accredited measuring lab and file the report with the part family.

Open In progress Met Not applicable

Evidence / justification

8.6.3 For products with appearance requirements, valid boundary or reference samples are available, the lighting at the inspection station is suitable for the assessment, the inspecting personnel are qualified for appearance evaluation, and the evaluation criteria are defined.

What proves it: Approved boundary samples with validity date, a statement of the illuminance at the visual inspection station, and qualification records of the visual inspectors, including an eyesight test where required. Small operations keep a good sample and a bad sample as a pair right at the inspection station; that replaces long descriptions.

Open In progress Met Not applicable

Evidence / justification

8.6.4 For purchased products and services it is defined how their conformity is ensured, for instance through incoming inspection, through evaluated inspection data from the supplier, through an audit at the supplier or through another agreed method. The chosen method is justified and is applied.

What proves it: Incoming inspection plan per material group with the chosen method and its rationale, plus inspection records or the evaluated supplier data. Small operations grade by risk: safety-related parts are inspected in house, standard parts are covered by the supplier mill certificate.

Open In progress Met Not applicable

Evidence / justification

8.6.5 Before purchased products enter own production it is evidenced that they meet the applicable statutory and regulatory requirements of the country of manufacture and of the destination countries named by the customer.

What proves it: Supplier declaration or conformity evidence per material, evidence on substance restrictions and reporting duties such as material data sheets and the entry in the industry material data system. Small operations file the declaration in the supplier folder and set a reminder where it is time limited.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.6.6	The acceptance criteria of the inspections are unambiguously defined and, where the customer requires it, approved by the customer. For attribute inspection by sampling, the acceptance criterion is zero defects.
	What proves it: Inspection plan or control plan with an unambiguous acceptance criterion per characteristic, plus the customer approval where it is required. A sampling instruction that permits an acceptable defect rate greater than zero contradicts this requirement and is replaced.
	Open In progress Met Not applicable
	Evidence / justification
8.7.1.1	Before product that deviates from specification is processed further or shipped, a customer concession is on hand. The released quantity and the period of validity are recorded, the affected product is identified, and once the concession ends the original specification applies again.
	What proves it: Customer deviation permit with number, released quantity and expiry date, plus identification of the affected lots and a register that tracks consumption of the approved quantity. The same applies to material that a supplier ships under a concession: passing it on to the own customer is not permitted without that customer's agreement.
	Open In progress Met Not applicable
	Evidence / justification
8.7.1.2	Procedures prescribed by the customer for handling nonconforming product are applied, and the customer specific requirements that apply are known at the own site and assigned to a responsible function.
	What proves it: Overview of the customer specific requirements per customer with the reference to where they are covered in the own system, plus the records from the procedures the customer demands, such as notifications in the customer supplier portal. Small operations maintain a matrix of customer to requirement to own rule, otherwise the requirements get lost in daily business.
	Open In progress Met Not applicable
	Evidence / justification
8.7.1.3	Product with unclear or uninspected status is treated as nonconforming product, put on hold and stored separately. The people in production are instructed to recognise suspect material as such and to handle it accordingly.
	What proves it: Quarantine area with unambiguous identification, hold note with date, quantity and trigger, and training records on handling suspect material. For small operations a red-marked, lockable area is enough. What matters is that nobody takes anything out of it without documenting the release.
	Open In progress Met Not applicable
	Evidence / justification
8.7.1.4	Rework follows an approved procedure whose risks are assessed and for which customer agreement is on hand where required. Reworked product is re-inspected, and quantity, decision, date and the traceability of the reworked parts are recorded.
	What proves it: Rework instruction including the inspection step after rework, plus the rework record with quantity, lot, date and responsible person. The risk assessment belongs in the process FMEA, because rework is a process step of its own with failure modes of its own.
	Open In progress Met Not applicable
	Evidence / justification
8.7.1.5	Repair, meaning restoration of usability without full conformity to specification, is carried out only with a customer concession. The procedure is approved and risk assessed, repaired product is re-inspected, and quantity, decision, date and traceability are recorded.
	What proves it: Customer concession for the repair, repair instruction with the subsequent inspection, and the repair record with quantity, lot and date. The distinction between rework and repair is recorded in writing; it is the most frequent point of dispute in an audit.
	Open In progress Met Not applicable
	Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

8.7.1.6 If nonconforming product has been shipped or is suspected of having been shipped, the customer is informed without delay. The notification and the actions initiated are recorded.

What proves it: Notification to the customer with timestamp and recipient, plus the bounding of the affected shipments from traceability and an escalation rule stating who notifies when. Small operations define the contact for quality notifications per customer in advance, so that nobody has to start searching in an emergency.

Open In progress Met Not applicable

Evidence / justification

8.7.1.7 For nonconforming product that is neither reworked nor repaired, the handling is governed: it is rendered unusable before disposal, it does not reach a secondary market without the customer's agreement, and the decision taken is recorded.

[Document](#)

What proves it: Scrap record with quantity, lot and date, plus a definition of how parts are rendered unusable, for example by destroying the functional surface. Small operations photograph the scrapped parts and attach the picture to the hold notice.

Open In progress Met Not applicable

Evidence / justification

9 Measuring and evaluating performance, automotive-specific additions

12

9.1.1.1 Process capability or performance is demonstrated for every new manufacturing process and is monitored on an ongoing basis, the characteristics, measurement methods and sample sizes defined in the control plan are followed, and the agreed or internally defined acceptance limits such as Cpk $\geq$ 1.33 or Ppk $\geq$ 1.67 serve as the benchmark.

What proves it: Capability studies per special characteristic with sampling plan, data series and calculated index, linked to the corresponding line of the control plan. A small operation takes 25 subgroups of 5 parts from a stable run and calculates the indices in a spreadsheet, which is sufficient evidence as long as gauge and operator are recorded.

Open In progress Met Not applicable

Evidence / justification

9.1.1.1-b When a manufacturing process is unstable or fails to reach the required capability, a predefined reaction plan takes effect that covers containment of the product, 100 percent inspection where needed and a corrective action plan with due dates, the implementation of which is tracked by responsible management.

What proves it: Reaction plan column in the control plan, plus records of triggered cases: hold tag, inspection report of the tightened inspection, action plan with due date and owner, release after effectiveness has been demonstrated. If the customer requires approval of the plan, the customer response belongs in the file.

Open In progress Met Not applicable

Evidence / justification

9.1.1.2 Which statistical tools are used for which characteristic is defined during product development, justified in the risk analysis and carried over into the control plan.

What proves it: Assignment list of characteristic to tool, for example control chart, capability study or attribute inspection, visible in the process FMEA and the control plan. The SPC reference manual and, where the customer requires it, the customer's own specification form the basis for the selection.

Open In progress Met Not applicable

Evidence / justification

9.1.1.3 The people working with the data understand the underlying concepts such as variation, a process in statistical control, capability and the consequences of overadjustment, and this understanding is also embedded across the supply chain.

What proves it: Training material and attendance records on basic statistics, competence matrix with an entry for control chart interpretation, plus a matching item in supplier development. In a small operation a half-day in-house session using examples from the company's own production is enough, recorded with date and signatures.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

9.1.2.1 Automotive customer satisfaction is tracked using hard performance data, including delivery schedule performance with premium freight, reported quality incidents, complaints and field returns, customer scorecards and portal notifications, plus any special status or escalation issued by the customer.

What proves it: Monthly performance overview per customer with ppm, delivery schedule performance, number of premium freight shipments and their cost, printouts or extracts from the customer portal, list of open complaints. Anyone without a portal connection records the ratings sent by the customer via email in a simple overview.

Open In progress Met Not applicable

Evidence / justification

9.1.3.1 The analysed data is reviewed over time, compared with the targets that were set and, where available, with competitive benchmarks, and the actions derived from it are prioritised by their effect on the customer and on risk.

What proves it: Trend charts covering at least twelve months, target comparison with a comment on any deviation, prioritised action list with the reasoning behind the ranking. Customer targets or industry reference values are sufficient as a comparison when no benchmark is available.

Open In progress Met Not applicable

Evidence / justification

9.2.2.1 A documented internal audit process exists, its programme is built on a risk basis and takes internal and external performance trends, complaints and process risks into account, and the programme is adjusted when significant events such as customer complaints or process changes occur.

[Document](#)

What proves it: Documented audit process, three-year audit programme with a risk rationale per process, change history of the programme showing what triggered each adjustment. A small operation keeps the programme as a single table with process, risk rating, planned date and actual date.

Open In progress Met Not applicable

Evidence / justification

9.2.2.2 All management system processes are audited within a three-year cycle, and the requirements of this automotive standard together with the customer-specific requirements are explicitly part of the audit scope.

What proves it: Coverage matrix of process against audit year, audit checklists referencing the clauses of the standard and the relevant customer requirement list, audit reports with findings. The matrix shows at a glance which processes are still open in the current cycle.

Open In progress Met Not applicable

Evidence / justification

9.2.2.3 Every manufacturing process is audited within a three-year cycle across all relevant shifts and at the handover points for effectiveness and efficiency, including implementation of the control plan and any approach required by the customer.

What proves it: Process audit reports per manufacturing line stating shift, equipment and the parameters checked, comparison of the machine settings in use against the control plan, tracking of actions. If the customer requires a particular process audit method, the completed questionnaire of that method is attached.

Open In progress Met Not applicable

Evidence / justification

9.2.2.4 Products are checked against the agreed requirements at defined stages of manufacture and delivery, covering dimensional accuracy, function, packaging and labelling, and the frequency is driven by risk and by customer requirements.

What proves it: Product audit plan with a frequency per part family, audit reports with measured values, photos of packaging and labelling, nonconformity reports with follow-up actions. A small operation checks one finished part per order completely against drawing and customer specification and files the record.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

9.3.1.1 Top management reviews the management system at least once a year and more frequently when customer ratings, complaints or internal performance data indicate an increased risk of failing to meet customer requirements.

What proves it: Schedule of the reviews, invitation and attendance list including top management, minutes of each meeting. The trigger for an additional meeting, for example a customer escalation, is named in the minutes.

Open In progress Met Not applicable

Evidence / justification

9.3.2.1 In addition to the general inputs, the management review takes in the cost of poor quality, measures of process effectiveness and efficiency, the results of feasibility reviews, achievement of the maintenance objectives, warranty and field failure data as well as the customer scorecards, and a documented action plan is created wherever customer targets have not been met.

[Document](#)

What proves it: Review minutes with one page per input topic, backed by a cost of poor quality breakdown, OEE or availability data, warranty analysis, customer scorecard and field feedback. The action plan exists as a separate document with action, owner, due date and effectiveness check and is followed up in the next meeting.

Open In progress Met Not applicable

Evidence / justification

10 Improvement, automotive supplemental requirements

5

10.2.3 A defined and documented problem solving process exists that classifies problems by type and significance, determines the root cause using a recognised methodology, separates immediate containment actions that protect the customer from permanent corrective actions, demonstrates the effectiveness of the actions taken and feeds the lessons learned back into documented information such as the FMEA and the control plan.

[Document](#)

What proves it: Documented procedure for problem solving plus closed case files, typically as an 8D report or in a customer prescribed format, containing root cause analysis, effectiveness verification and a reference to the updated FMEA or the revised control plan. Small organisations manage with a lean 8D template and a simple open issues list, what matters is the evidenced feedback into the documents, not the size of the form.

Open In progress Met Not applicable

Evidence / justification

10.2.4 A documented process governs the use of error proofing by technical means (poka yoke), the devices in use are identified in the control plan, inspection instructions including challenge parts exist for verifying their function, these functional checks are carried out and recorded at defined intervals, and the handling of a failure or malfunction of such a device is defined.

[Document](#)

What proves it: Documented procedure for error proofing, control plan identifying the devices, an inspection instruction per device, retention of the known good and known bad challenge parts (red rabbit or limit samples) and records of the functional checks, for example per shift or per changeover. Small organisations record this evidence as a signed line in the setup or shift log, together with a reaction rule stating what happens to the parts produced since the last successful check when a device is found to have failed.

Open In progress Met Not applicable

Evidence / justification

10.2.5 Where a warranty arrangement with the customer applies, a warranty management process exists that includes physical analysis of returned parts, defines the handling of parts with no fault found and takes the customer specific warranty rules into account.

What proves it: Description of the warranty process, analysis reports for returned parts, a defined approach for no trouble found parts including depth of analysis and alignment with the customer, plus an evaluation of cost and quantity per failure mode. Small organisations cover this point with a returns list stating the finding, the cause and the action initiated for each part, linked to the problem solving file.

Open In progress Met Not applicable

Evidence / justification

Supplement only. Without the ISO 9001 list next to it, this preparation is incomplete.

10.2.6 Customer complaints and field concerns are analysed, affected parts are examined using the tests and within the time limits specified by the customer, the results including the analysis lead time are reported to the customer and internally, and the findings lead to corrective actions whose effectiveness is demonstrated.

What proves it: Complaint statistics with failure modes and trends, test reports for field returns showing the dates of receipt, analysis and feedback, evidence of customer communication, for example via portal or report, and the associated corrective actions. Small organisations run a single complaint overview from which the receipt date, the due date, the finding and the closure are visible.

Open In progress Met Not applicable

Evidence / justification

10.3.1 A documented process for continual improvement exists that names the methods and tools used, defines when improvement projects are triggered, provides for an effectiveness check of the actions implemented and explicitly includes the reduction of variation and waste in manufacturing processes.

Document

What proves it: Documented procedure with trigger criteria, for example process capability below the agreed target value, scrap rate or recurring complaints, plus an improvement plan or action list with owner, due date and result evaluation, and evidence of effectiveness through the indicator before and after. Small organisations satisfy this with an improvement board or a simple table per process, provided the trigger, the action, the due date and the verified effect are visible in it.

Open In progress Met Not applicable

Evidence / justification