Six Sigma Kaizen

ISO 9001 IMPLEMENTATION HUB

Volume 2 • Guide 5 of 7

Clause 8, Part 2: Production, Control, and Delivery

Deep-Dive Practitioner Interpretation with Examples, Pitfalls, and Audit Guidance

Clause-by-Clause Practitioner's Guide • ISO 9001:2015

External Providers (8.4) • Production & Service Provision (8.5) • Product Release (8.6) • Nonconforming Outputs (8.7)

How to Use This Guide

This is Guide 2.5 in Volume 2 of the ISO 9001 Implementation Hub. It completes the Clause 8 coverage begun in Guide 2.4, covering the second half of the Operation clause: control of externally provided processes, products, and services (8.4), production and service provision (8.5), release of products and services (8.6), and control of nonconforming outputs (8.7). These subclauses govern the production core and the conformance assurance systems that determine what actually reaches customers.

Together with Guide 2.4, this guide covers the complete Clause 8 operational lifecycle. Clause 8.4 addresses the supply chain that feeds production; Clause 8.5 governs how production is controlled to achieve conformance; Clause 8.6 defines the gate through which only conforming product passes; and Clause 8.7 describes what happens when that gate catches something that should not ship. The quality of an organization's products is ultimately determined by how well these four subclauses function in practice.

Clause 8.4 — Control of Externally Provided Processes, Products, and Services

Clause 8.4 is the supplier management clause — but its scope is broader than the term "supplier management" typically implies. ISO 9001:2015 uses the term "external provider" deliberately to encompass the full range of externally sourced inputs that the organization incorporates into its products and services: raw materials, purchased components, subcontracted processes, and outsourced functions. Every external input that affects the quality of what the organization delivers to customers falls within Clause 8.4 control obligations.

8.4.1 — General: The Extent-of-Control Determination

Standard Requirement

ISO 9001:2015, Clause 8.4.1: "The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization to outsource. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or outputs in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations."

The Three Procurement Scenarios and Their Control Implications

Clause 8.4.1 identifies three distinct scenarios under which external provider control applies, each with different control implications. Understanding which scenario applies to a specific external provider relationship determines the appropriate depth of control:

Scenario	Examples	Control Implication
(a) Externally provided products/services incorporated into the organization's own output	Raw materials, purchased components, subcontracted heat treatment or plating, outside machining operations, purchased calibration services	Strongest control required — these inputs directly determine the quality of the final product delivered to the customer. Incoming inspection, supplier qualification, supplier performance monitoring, and clear purchase order quality requirements all apply.
(b) Products/services provided directly to customers by external providers on behalf of the organization	Third-party logistics providers handling product delivery, installation subcontractors who interface directly with end customers, technical support subcontractors providing service in the organization's name	Control must extend to the customer-facing quality of the externally provided service. The customer's experience with the external provider reflects on the organization. Performance monitoring and customer feedback capture are essential.

Scenario	Examples	Control Implication
(c) Outsourced processes that are part of the organization's QMS scope	Outsourced calibration function, outsourced quality inspection during peak periods, outsourced document management, outsourced training delivery	The organization retains full accountability for these processes even when outsourced. The external provider must operate the process to the organization's QMS requirements, and the organization must verify that it does so.

The Four-Element External Provider Control Framework

Clause 8.4.1 requires the organization to determine and apply criteria for four external provider management activities: evaluation, selection, monitoring of performance, and re-evaluation. These four elements form a cycle that applies to every external provider — not just "critical" suppliers, but all providers of externally sourced inputs that affect product or service quality.

Evaluation and Selection Criteria

Before a new external provider is used, the organization must evaluate its ability to meet the requirements for which it will be responsible. The evaluation criteria must be documented — not applied informally based on the purchasing manager's judgment, however experienced. Common evaluation elements for manufacturing external providers:

- Quality management system: does the provider have an ISO 9001 or sector-specific certification? If not, has their quality system been assessed by the organization or a recognized third party?
- Technical capability: does the provider have the equipment, process expertise, and human resources to reliably produce the required product or service to the required specifications?
- Capacity: does the provider have sufficient capacity to meet the organization's volume and delivery requirements without compromising quality through overloading?
- Financial stability: is the provider financially viable? A supplier who enters financial distress mid-program creates supply chain disruption and quality control failures.
- Track record: what is the provider's quality and delivery performance history with this organization or with similar customers?
- Regulatory compliance: does the provider meet all applicable regulatory requirements for the materials, processes, or services they provide?

Monitoring of Performance

Supplier qualification is not a one-time event — it is the beginning of an ongoing performance monitoring relationship. Once a provider is qualified, the organization must monitor its continuing performance against the criteria that justified qualification. Common performance monitoring metrics in manufacturing environments:

Metric	Definition	Monitoring Approach
On-time delivery rate	Percentage of deliveries received on or before the required date	Track against each purchase order; calculate monthly; review trend in supplier scorecard
Incoming quality rate	Percentage of incoming lots accepted at first inspection (without rejection or waiver required)	Record incoming inspection results by supplier; calculate rejection rate; analyze rejection trends by defect type
Material certification accuracy	Percentage of shipments with complete, accurate, and conforming material certifications	Review certifications at receiving; flag discrepancies; track by supplier
Corrective action responsiveness	Time to provide a corrective action plan following a quality notification, and effectiveness of the corrective actions submitted	Track CAR issuance and response dates; evaluate root cause adequacy; verify effectiveness after implementation
Process audit results (for process suppliers)	Findings from periodic process audits conducted at the supplier's facility or by verified audit report	Audit frequency determined by performance level and process criticality; findings tracked to closure

Re-evaluation

ISO 9001:2015 requires periodic re-evaluation of external providers. Re-evaluation is the formal reassessment of a provider's continued qualification — answering the question "are we confident this provider still meets our qualification criteria?" Re-evaluation frequency should be determined by performance level: a consistently high-performing supplier may need only annual re-evaluation; a supplier with recurring quality issues may need quarterly re-evaluation or re-qualification of specific processes.

Re-evaluation triggers beyond scheduled periodic review include: a major quality escape, a significant delivery failure, a change in the supplier's certification status, a change in the supplier's ownership or key personnel, evidence of financial instability, or a material change in the supplier's process or facility. These events should trigger an unscheduled re-evaluation regardless of when the last scheduled review occurred.

8.4.2 — Type and Extent of Control

Standard Requirement

ISO 9001:2015, Clause 8.4.2: "The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall: a) ensure that externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; 2) the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements."

Clause 8.4.2 requires the organization to design its external provider controls proportionately — matching the depth of control to the potential quality impact of the externally provided input. A raw material from a commodity supplier with a long, clean quality history requires different controls than a single-source specialty heat treatment process that is critical to the mechanical properties of a structural component.

External Provider Criticality	Appropriate Controls	Verification Activities
Critical — directly affects key product characteristics; no alternative source; history of variability	Detailed purchase order quality requirements; process audit at supplier's facility; first-article qualification for each new job; statistical sampling at incoming; supplier-resident quality representative for major programs	Full dimensional and material verification at incoming; chemical and physical testing of material certifications; process capability data from supplier; independent testing of critical characteristics
Significant — affects product quality; alternatives available; generally reliable performance	Standard purchase order quality requirements; annual supplier evaluation; incoming sampling inspection; supplier corrective action requirements for escapes	Sampling inspection per AQL plan; review of material certifications; periodic process audits or survey questionnaires
Standard — commodity or low-criticality input; multiple qualified alternatives; consistent performance	Purchase order specification requirements; approved supplier list qualification; performance monitoring via delivery and quality records	Reduced incoming inspection based on supplier performance history; certification review; periodic re-qualification
Outsourced QMS process — calibration, inspection, training	Service agreement with QMS requirements; performance metrics defined; output review	Review of output records for compliance; periodic audit of the outsourced process; competence verification of outsourced personnel

8.4.3 — Information for External Providers

Standard Requirement

ISO 9001:2015, Clause 8.4.3: "The organization shall ensure the adequacy of requirements before their communication to external providers. The organization shall communicate to its external providers its requirements for: a) the processes, products and services to be provided; b) the approval of: products and services, methods, processes and equipment, and the release of products and services; c) competence, including any required qualification of persons; d) the external providers' interactions with the organization's quality management system; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises."

Clause 8.4.3 requires that purchase orders and supplier agreements communicate the organization's requirements with sufficient completeness and clarity to enable the external provider to understand and meet them. The standard explicitly requires that requirements be adequate before communication — not adequate in the buyer's mind but adequate for the supplier to understand and act on.

A purchase order that says "produce to drawing" without specifying the drawing revision, the acceptable material specifications, the required quality documentation at shipment, the sampling and inspection requirements, and the corrective action obligations is not adequate. A purchase order that specifies all of these elements is adequate. The test: if the supplier reads only the purchase order, can they understand everything they need to do to deliver a conforming shipment?

Kaizen Connection

Lean supply chain thinking and ISO 9001:2015 Clause 8.4 are profoundly aligned in their view of supplier relationships. Both reject the adversarial, transactional model of supplier management in favor of a partnership model where the organization invests in its suppliers' quality capability as a direct investment in its own quality performance. The Toyota Production System's concept of "yokoten" — horizontal deployment of best practices across the supply chain — is the manufacturing equivalent of what Clause 8.4.2(d) requires: determining what verification activities ensure that externally provided inputs meet requirements. In both frameworks, the answer is not simply incoming inspection but systematic engagement with suppliers' processes to build quality in before shipment rather than inspect it in upon receipt.

Meridian Case Study

Meridian Supplier Management Year 1: Meridian's approved supplier list at certification contained 34 suppliers across six categories: raw material (bar stock, sheet, plate), heat treatment, surface finishing (plating and coating), hardware (fasteners, inserts), special processes (NDT, welding), and calibration services. The supplier qualification procedure (MPC-PRO-006) established three qualification tiers: (1) Critical suppliers requiring on-site audit or current ISO 9001/AS9100 certificate plus first-article qualification; (2) Standard suppliers requiring completed supplier survey questionnaire plus quality performance references; (3) Low-criticality commodity suppliers requiring only approved supplier list registration and purchase order acceptance. Of the 34 suppliers at certification, 8 were Critical tier, 18 were Standard, and 8 were Low-criticality. In Year 1 post-certification, two supplier events tested the program: (1) A critical heat treatment supplier (Category 1 tier) produced a batch with hardness below specification due to a furnace calibration failure — the escape reached Meridian in incoming materials. The supplier corrective action process was initiated, a CAPA was received and evaluated, and the supplier was re-audited before they were cleared to supply further. The batch was held and subjected to 100% hardness testing; 12 of 47 pieces failed and were scrapped. (2) The supplier qualification program identified through the annual re-evaluation that one Standard-tier raw material supplier's quality management had degraded significantly — their ISO 9001 certificate had lapsed 8 months earlier. The supplier was notified that they could not remain on the approved supplier list without reinstatement within 60 days. They achieved re-certification within the window; no supply disruption occurred.

Clause 8.5 — Production and Service Provision

Clause 8.5 governs the execution layer of the QMS — the conditions under which production and service delivery actually occur. It is the clause that most directly determines whether the quality planning done in Clauses 8.1 through 8.4 translates into conforming products and services. The subclauses of Clause 8.5 address the full range of production and service provision controls: controlled conditions for process execution (8.5.1), identification and traceability (8.5.2), customer and external provider property (8.5.3), preservation (8.5.4), post-delivery activities (8.5.5), and control of changes (8.5.6).

8.5.1 — Control of Production and Service Provision

Standard Requirement

ISO 9001:2015, Clause 8.5.1: "The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that process or output acceptance criteria have been met, and that products and services conform to requirements; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities."

What "Controlled Conditions" Means in Practice

Controlled conditions means that the process environment is managed to reliably produce conforming output — that the right information, the right equipment, the right measurements, the right environment, and the right people are consistently in place whenever the process runs. Each of the eight elements of Clause 8.5.1 represents one dimension of process control:

Control Element	Implementation Guidance
(a) Documented information defining characteristics and results	Work instructions, travelers, drawings, control plans, and acceptance criteria must be available at the point of use — not filed in the quality office. An operator who must stop production and walk to the quality office to find the acceptance criterion for a borderline dimension is working in an inadequately controlled process.
(b) Suitable monitoring and measuring resources	Measurement equipment calibrated and suitable for the precision required; appropriate for the measurement technique; available at the point of measurement. An inspector who must share a single micrometer among three inspection stations or who uses a caliper to measure a tolerance that requires micrometer precision is working without suitable measuring resources.
(c) Monitoring and measurement at appropriate stages	First-piece inspection before running, in-process checks at defined intervals, final inspection before release — each at the stage where detection of a nonconformance prevents the largest

Control Element	Implementation Guidance
	amount of nonconforming work from proceeding. The inspection plan must be executed at the defined stages, not skipped when production pressure builds.
(d) Suitable infrastructure and environment	Temperature, cleanliness, lighting, humidity, and other environmental conditions that affect process and product quality are controlled. Critical measurement operations in thermally unstable environments produce unreliable results. Assembly operations in contaminated environments produce field failures.
(e) Competent persons with required qualifications	Not just trained — competent. The distinction from Clause 7.2 is directly applied here: processes must be performed by people whose competence to perform them has been verified, not just trained. For regulated processes (welding, NDT, special process operations), formal qualification credentials may be required.
(f) Validation of special processes	For processes where output cannot be verified by measurement — the output is inside a product, the property develops over time, or the measurement is destructive — the process capability to consistently achieve the intended result must be validated before production and revalidated periodically. Welding, heat treatment, adhesive bonding, and coating processes are common examples.
(g) Actions to prevent human error	Poka-yoke (mistake-proofing) devices, checklists, dual-verification requirements, sequential work instructions with checkpoint sign-offs, color coding, and other human factors engineering controls that make correct execution easier than incorrect execution. The control plan and FMEA should identify where human error risk is highest and what controls are in place.
(h) Release, delivery, and post-delivery activities	Defined release criteria applied before shipment; proper packaging and preservation for delivery; defined post-delivery obligations (warranty, maintenance, installation support) communicated to the relevant functions.

Special Processes — Clause 8.5.1(f) in Depth

Clause 8.5.1(f) addresses a specific and often under-controlled category of manufacturing processes: those where the conformance of the output cannot be verified by subsequent monitoring or measurement, or where the nonconformance becomes apparent only in use. These "special processes" require process validation rather than product inspection as the primary quality assurance mechanism — because by the time an inspection could detect a problem, it is too late.

Special Process Type	Why Output Cannot Be Fully Verified / Validation Approach
Welding	Internal weld quality (fusion, porosity, cracking) cannot be fully evaluated by surface inspection. The weld may appear conforming on the surface while internal defects compromise structural integrity. Validation approach: welder qualification to AWS, ASME, or equivalent standard; welding procedure specification qualification; periodic weld procedure requalification; destructive testing of test specimens to verify weld quality.

Special Process Type	Why Output Cannot Be Fully Verified / Validation Approach
Heat treatment	Material properties resulting from heat treatment (hardness through-section, microstructure, residual stress) cannot be fully verified without destructive testing. Surface hardness testing provides partial verification but does not confirm case depth, core properties, or absence of adverse microstructural conditions. Validation approach: furnace calibration and uniformity surveys; qualified heat treatment procedure qualification per AMS or equivalent; process monitoring records; periodic testing of witness specimens or destructive verification of production samples.
Adhesive bonding and potting	Bond strength and integrity between bonded surfaces cannot be evaluated without destructive testing of the assembled joint. Visual inspection of the adhesive fillet line provides only surface conformance evidence. Validation approach: bonding procedure qualification; qualified personnel performing bonding operations; defined and controlled adhesive storage, mixing, and application conditions; bond strength testing of coupon specimens processed with each production batch.
Chemical and electrochemical surface treatments (plating, anodizing, passivation)	Coating thickness, adhesion, porosity, and chemical composition are not fully verifiable by visual inspection. Dimensional effects of thick coatings on precision features may also require pre/post measurement rather than post-coating verification alone. Validation approach: qualified plating procedure; process chemistry control records; periodic test panel processing and property verification; coating thickness measurement using calibrated gauges at defined frequency.
Non-destructive testing (NDT)	The ability of an NDT process to detect a given defect type depends on procedure qualification, equipment calibration, and inspector qualification — not just the execution of the technique. An unqualified NDT procedure may miss defect types it is intended to detect. Validation approach: NDT procedure qualification per ASNT, NAS 410, or customer-specified standard; Level II or III certified inspector performing and reviewing NDT; calibrated equipment; periodic procedure requalification.

8.5.2 — Identification and Traceability

Standard Requirement

ISO 9001:2015, Clause 8.5.2: "The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. When traceability is a requirement, the organization shall control the unique identification of the outputs and retain documented information necessary to enable traceability."

Identification and traceability serve two related but distinct quality purposes. Identification tells you what a piece of product is and where it is in the inspection sequence. Traceability tells you where a piece of product came from and lets you trace quality problems back through the production and supply chain to their source.

Identification — What Is Required

Every piece of product moving through the production process must be identifiable — you must be able to determine what it is and what its inspection status is. Identification serves two functions:

- Product identity: what part number, drawing revision, and lot or job number does this product belong to? This prevents mixing products from different jobs, different revisions, or different customers.
- Inspection status: has this product been inspected? What was the result? Is it accepted, rejected, awaiting inspection, or on hold for engineering disposition? Uninspected product must not be confused with inspected and accepted product.

Identification methods vary by product type and production environment: part marking (engraving, stamping, labeling), tagging (travelers, job tags attached to work-in-process), container identification (labeled bins, boxes, pallets), and location-based identification (designated areas for different inspection statuses). The method must be "suitable" — appropriate to the product type, the environment, and the need to maintain identification through all production stages including heat treatment, plating, and other processes that might remove or damage labels.

Traceability — When It Is Required and What It Demands

ISO 9001:2015 requires traceability "when traceability is a requirement" — meaning when the customer, the organization, or applicable regulations require that the production history of a product can be reconstructed from available records. In practice, traceability is required in:

- Aerospace and defense manufacturing: lot traceability from raw material certification through all production operations and special processes is typically required by AS9100 and customer flow-down requirements
- Medical device manufacturing: FDA requirements and ISO 13485 demand device history record traceability to raw materials, component lots, and production equipment
- Safety-critical components: structural fasteners, pressure vessels, lifting equipment, and other safety-critical products typically require raw material lot traceability
- Regulated materials: ITAR-controlled materials, conflict minerals, RoHS-compliant materials — traceability demonstrates regulatory compliance
- Customer contractual requirements: many customers specify traceability requirements in their purchase orders or quality flow-down documents

When traceability is required, unique identification must be maintained for each traceable unit (lot, serial number, or batch), records must link each unit to its raw material lot and certification, all processing operations with their dates and operator records, inspection results, and disposition. The traceability chain must be complete and unbroken — a gap in the chain at any point (heat treatment records showing the batch number but not linking to the incoming material lot, for example) breaks the traceability that the requirement demands.

⚠ Common Pitfall

The most common identification and traceability finding in manufacturing audits is what practitioners call the "traceability break" — a point in the production sequence where the physical connection between a piece of

product and its associated documentation is lost. Classic traceability break scenarios: parts removed from a job lot for separate processing (heat treatment, plating) and returned without re-association to their original lot documentation; in-process work-in-progress stored without job identification between operations; subcontracted operations that return product with the subcontractor's lot reference but without linkage to the original job traceability record. The audit test is simple: the auditor selects a finished part and asks to trace it back to raw material. Any point in that trace where the connection must be assumed rather than demonstrated is a traceability gap.

8.5.3 — Property Belonging to Customers or External Providers

Standard Requirement

ISO 9001:2015, Clause 8.5.3: "The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer or external provider property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred."

Customer property is broader than most organizations initially recognize. In addition to physical tooling and fixtures (the most commonly considered category), customer property includes: customer-provided materials incorporated into production, customer intellectual property (drawings, specifications, CAD data, manufacturing processes), customer-provided test equipment, customer-owned software, and any other asset the customer has entrusted to the organization for use in fulfilling the contract.

The Four Obligations for Customer Property

- Identify: Know what you have received from the customer and be able to distinguish it from the organization's own property at any time. Customer tooling should be tagged and recorded in a customer property register.
- Verify: Confirm that customer-provided materials, tooling, or information are suitable for the intended use before incorporating them into production. Receiving damaged customer tooling and proceeding to use it is a quality risk; receiving a customer drawing at an old revision and using it without verifying currency is a requirement conformance risk.
- Protect: Handle and store customer property in a way that prevents damage, deterioration, or loss. Customer-owned tooling may represent significant value and may be irreplaceable for the customer's production program — its protection is a contractual and quality obligation.
- Report: When customer property is lost, damaged, or found unsuitable, report this to the customer immediately and document the incident. Attempting to conceal damage to customer property or to use damaged property without customer notification is a serious breach of the supply relationship and of this clause requirement.

8.5.4 — Preservation

Standard Requirement

ISO 9001:2015, Clause 8.5.4: "The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Note: Preservation can include

identification, handling, contamination control, packaging, storage, transmission or transportation, and protection."

Preservation requirements apply from the point of production through delivery — and in some cases, beyond delivery if the organization provides installation or maintenance services. The preservation controls must be appropriate to the product's sensitivity and the risks of the production and delivery environment. A precision machined surface finish can be degraded by improper handling. A heat-treated component's mechanical properties can be compromised by exposure to hydrogen-bearing environments. An electronic assembly's integrity can be destroyed by electrostatic discharge. Preservation planning must account for these vulnerabilities.

Key preservation control areas in precision manufacturing:

- In-process handling: designated lifting points for large parts; protective packaging for precision surfaces; ESD-safe handling for sensitive assemblies; separation of dissimilar metals to prevent galvanic corrosion
- Storage: defined storage conditions (temperature, humidity, cleanliness); FIFO (first in, first out) material rotation to prevent material aging; protection from contamination and physical damage; segregation by material type or heat treat condition
- Packaging for shipment: customer or industry-standard packaging requirements; corrosion protection for machined surfaces (oil, VCI paper, nitrogen purge); cushioning against transit shock; labeling requirements; quantity verification before sealing
- Transportation: selection of carriers with appropriate handling capabilities; temperature control for heat-sensitive products; vibration control for precision assemblies; chain-of-custody documentation for high-value or security-classified shipments

8.5.5 — Post-Delivery Activities

Standard Requirement

ISO 9001:2015, Clause 8.5.5: "The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback."

Post-delivery activities encompass all quality-related obligations that extend beyond the point of delivery: warranty, maintenance, field service, technical support, product end-of-life obligations, recall processes, and customer training. Many manufacturers assume that their quality obligations end at delivery — this assumption is incorrect under ISO 9001:2015 wherever post-delivery activities are relevant.

The five considerations that determine the extent of required post-delivery activities:

- Statutory and regulatory requirements: warranty requirements, consumer protection laws, product liability recall obligations, and sector-specific post-delivery regulations that apply regardless of customer preference

- Potential consequences of failure: a product whose in-service failure has safety implications requires more robust post-delivery monitoring and response than a non-safety-critical product
- Nature, use, and intended lifetime: a component designed for a 25-year service life requires different post-delivery tracking than a consumable with a 6-month service life
- Customer requirements: warranty terms, maintenance service agreements, field support obligations, and technical assistance commitments contracted with customers
- Customer feedback: how the organization learns about in-service quality performance and uses that information to improve future production quality

8.5.6 — Control of Changes

Standard Requirement

ISO 9001:2015, Clause 8.5.6: "The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review."

Clause 8.5.6 is the production-side change control requirement — distinct from Clause 6.3 (QMS system changes) and Clause 8.3.6 (design changes). It governs changes to how production or service provision is carried out: changes to process parameters, substitution of tooling or fixtures, material substitutions, changes to inspection methods or frequencies, changes to operator assignments for qualified processes, and changes to production equipment.

The change control review must assess: whether the change maintains conformance to all relevant requirements; whether the change requires design and development re-review (Clause 8.3.6); whether the change requires customer or regulatory approval before implementation; what documentation must be updated; what training is required for affected personnel; and whether re-verification of process capability or product conformance is needed after the change.

The documented information requirements for production changes — results of review, authorization, and actions — mean that verbal change decisions are not conforming. A supervisor who informally changes a setup parameter to address a quality problem without creating a documented change record has made an unauthorized change that cannot be traced in future quality investigations. Production change control must be embedded in the daily workflow, not treated as a bureaucratic exception.

Clause 8.6 — Release of Products and Services

Standard Requirement

ISO 9001:2015, Clause 8.6: "The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release."

The Release Gate — Purpose and Design

Product release is the quality gate between production and the customer — the point at which the organization formally asserts that what it is delivering meets the requirements it committed to. Clause 8.6 requires that this gate function reliably: that the planned verification arrangements are completed before release, that release is authorized by a designated person, and that a retrievable record of both the conformance evidence and the authorization is retained.

The three core requirements of Clause 8.6 are:

1. Planned arrangements must be completed: the inspection plan, acceptance criteria, and sampling requirements defined in the control plan and inspection procedure must be fully executed before release is authorized. Partial inspection does not constitute a completed release arrangement.
2. Release must be authorized by a designated person: someone with defined release authority must specifically approve shipment. A part that passes inspection but where no one has specifically authorized its release against the acceptance criteria is not released under Clause 8.6 — it has been inspected but not released.
3. Release records must capture conformance evidence and the releasing authority: "conforming" or "accepted" alone is not adequate evidence of conformity. The record must show what was measured, against what criteria, and with what result.

Release Authorization — Roles and Documentation

The "relevant authority" who may approve release is defined by the organization — typically the quality inspector, quality engineer, or quality manager for standard release decisions, with escalating authority levels for special release situations. The release authorization system should define:

- Who may authorize standard release (conforming product, all inspection requirements met): typically inspection personnel who performed or reviewed the inspection
- Who may authorize conditional release (product requiring engineering disposition, customer concession, or limited release): typically quality engineer or quality manager with technical authority to evaluate the nonconformance
- Who may authorize customer-deviated release (product released under a customer-approved concession or waiver): typically quality manager with documented customer authorization

- What the release record must contain to be acceptable: conformance to acceptance criteria, identification of the product released (quantity, lot number, drawing revision), date of release, and name or signature of the authorizing individual

The Release Record — What Constitutes Adequate Evidence

Release records are among the most intensively scrutinized records during certification audits and customer audits. Auditors trace production orders from the shop floor to the release record and evaluate whether the record demonstrates that conformance was actually verified — not merely assumed or asserted. Common release record types and their audit adequacy:

Release Record Type	When Adequate	Common Deficiencies
Dimensional inspection report (bubble drawing or tabular)	When all required dimensions are listed with measured values, tolerances, and accept/reject determinations; inspector identified; date included; drawing and revision referenced	Missing measured values (only "pass" notation); incomplete balloon coverage; no drawing revision reference; no inspector identification
Certificate of Conformance (CoC)	When explicitly references the specifications, drawing revision, material certifications, and other applicable requirements; states that all requirements have been met; signed by authorized quality representative; traceable to specific lot or serial number	Generic CoC that does not reference specific requirements; signed by non-quality personnel without release authority; no traceability to specific lot; no reference to drawing revision
Production traveler with inspection sign-offs	When each required inspection step is specifically signed off by an inspector with a date; traveler identifies the job, part number, and drawing revision; final release signature is by authorized quality representative	Sign-offs by operators (not inspectors) for quality verification steps; missing final quality release signature; no distinction between operator checks and quality verification
Electronic quality record with digital release authorization	When the system captures who performed each inspection step, when, the results of each measurement, the acceptance criteria applied, and who authorized final release with date and electronic signature	System-generated "passed" flag without captured measured values; electronic signatures not authenticated or traceable to specific individuals; audit trail not available

Auditor Perspective

The release record audit is one of the most reliable quality indicators registrar auditors have encountered. An organization whose release records are complete, specific, and retrievable has almost certainly built a quality-disciplined production system. An organization whose release records are minimal, generic, or inconsistently maintained typically has a production culture where quality is managed informally rather than systematically. The auditor's typical approach: select a recently shipped lot from the shipping records, locate the associated release record, and evaluate whether the record demonstrates that conformance was verified against specific criteria by an identified authorized individual. If the record says "inspected and

> approved" with a signature but no measured data, the auditor will ask what was inspected, against what criteria, and with what result — and the release record cannot answer. That is a finding.

Clause 8.7 — Control of Nonconforming Outputs

Standard Requirement

ISO 9001:2015, Clause 8.7.1: "The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery. The organization shall deal with nonconforming outputs in one or more of the following ways: a) correction; b) segregation, containment, quarantine or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected."

Clause 8.7.2: "The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity."

The Nonconforming Output Control Cycle

Clause 8.7 requires a systematic approach to every nonconforming output — from the moment of detection through final disposition. The cycle has six stages, each with specific requirements:

Stage	Action Required	Documentation Requirement
1. Detection and identification	Identify the nonconformance — what requirement was not met, by how much, in which pieces. Mark the nonconforming product with a clear nonconforming status identifier.	Initial NCR created identifying the product (part number, quantity, lot), the nonconformance (what characteristic failed, what the measured value was, what the requirement is), and the date and person discovering the nonconformance.
2. Segregation and containment	Physically separate nonconforming product from conforming product. Move to a designated nonconforming material hold area. Prevent accidental release by ensuring the nonconforming identification is durable and unambiguous. If the nonconformance is systemic, contain the concern across any production already in process.	NCR notes segregation action taken; hold tag or label applied to product identifying the NCR number and hold status.

Stage	Action Required	Documentation Requirement
3. Notification	Notify relevant personnel: the process owner (how did this happen?), the quality manager (is there a systemic issue?), and where applicable, the customer (if they have received product that may be affected, or if the disposition will require their approval).	NCR identifies who was notified and when; customer notification documented if applicable.
4. Evaluation and disposition decision	Evaluate the nonconformance to determine the appropriate disposition: rework to bring product into conformance, scrap, use-as-is if the nonconformance does not affect form, fit, or function, or return to supplier. This evaluation requires technical judgment by a qualified person with defined authority.	NCR records the disposition decision, the technical rationale, and the identity and authority of the person making the disposition decision.
5. Disposition execution	Execute the authorized disposition: perform the rework, scrap the product, process the deviation or concession request. If rework is performed, verify that the rework has brought the product into conformance before re-releasing it.	NCR records the disposition executed and the verification result confirming conformance (for rework) or recording destruction (for scrap).
6. Root cause and corrective action (when appropriate)	For significant or recurring nonconformances, initiate a corrective action to address the root cause. Not every NCR requires a CAPA — isolated, minor, low-risk nonconformances may be corrected without formal CAPA. Recurring patterns and high-risk escapes always require CAPA.	NCR references the CAPA if one was initiated; CAPA record number cross-referenced.

Disposition Options — What Each Means and When to Use It

The four disposition options listed in Clause 8.7.1 are not mutually exclusive — multiple may apply to a single nonconformance event. Their appropriate use:

Disposition	When Appropriate	Quality Considerations
Correction (rework, repair, adjustment)	When the nonconformance can be corrected to bring the product within specification — a dimension that is slightly undersized can be corrected; a surface scratch can be polished out; an incorrect marking can be restamped	Rework must be performed to a defined process; re-inspection after rework must verify conformance; rework adds cost and may affect other characteristics (a rework operation on one dimension may affect an adjacent dimension)
Segregation, containment, quarantine	Immediately upon identification of any nonconformance; prevents unintended use of nonconforming product while disposition decision is made; also used for quarantine of product pending investigation when systemic concern exists	Physical segregation must be effective — marking alone is not sufficient if nonconforming product could be confused with conforming product in the same storage area; quarantine area should have controlled access
Informing the customer	When nonconforming product may have already been delivered; when the disposition (use-as-is or deviation) requires customer approval; when the nature of the nonconformance may affect the customer's product or assembly	Customer notification triggers the customer's own quality processes; documentation of customer notification and response is required; customer-directed disposition supersedes the organization's unilateral decision
Concession (acceptance under deviation or waiver)	When the product does not conform to specification but engineering analysis determines it is functional and acceptable for the intended use; requires authorization by a qualified technical authority; may require customer approval if the nonconformance affects a customer-specified characteristic	Concessions must be technically justified — not simply convenient; the concession record must document the technical rationale, the authorized approver, and any conditions (use restrictions, limited quantities); customer concessions must be requested before use, not after delivery

Nonconforming Output Detected After Delivery

Clause 8.7.1 explicitly states that the nonconforming output control requirements apply to nonconformances detected after delivery. This is one of the most significant and most frequently ignored aspects of the clause. When a customer reports a quality problem with already-delivered product, or when the organization discovers a quality issue in released product through its own quality monitoring, the nonconforming output control process must be applied:

4. Investigate the scope: how many units are affected? What lots were impacted? Is the nonconformance limited to the reported units or is it likely systemic across multiple shipments?
5. Contain the concern: identify all affected product at the customer's facility and in transit; request a hold on use of affected product pending investigation

6. Notify the customer: with a preliminary assessment, a containment plan, and a timeline for root cause analysis and corrective action
7. Assess safety and regulatory implications: does the nonconformance create a safety risk? Does it require regulatory notification? Do customer's end users need to be informed?
8. Determine and implement disposition: repair in place, replacement, field modification, or use-as-is with customer acceptance
9. Complete root cause analysis and corrective action: the escape is a QMS failure — how did nonconforming product pass the release gate? The CAPA must address both the nonconformance cause and the release control failure

Meridian Case Study

Meridian Nonconforming Output Management Year 1: During the first post-certification year, Meridian processed 47 internal nonconformance reports. Of these, 31 (66%) were reworked and released; 11 (23%) were scrapped; 4 (9%) were accepted under use-as-is concession with engineering documentation; and 1 required customer notification and return for credit. The single customer notification involved a case where 6 pieces were released with dimensional deviations that were outside specification on a feature with functional implications. The root cause analysis revealed a gap in the first-piece inspection procedure — the inspection traveler did not require verification of this dimension at first piece, only at final inspection. The corrective action updated the control plan to add first-piece verification of this dimension for all future jobs of this family. The corrective action also resulted in an update to the risk register (Risk R-04 — human error in inspection due to inspection plan completeness) with an updated action: monthly review of control plan completeness for active jobs as part of the quality engineer's standard work. This closed loop from customer escape through root cause through risk register update illustrates the integrated quality system functioning as designed.

Quick Reference: Clause 8 Part 2 Audit Readiness

Clause 8.4 Conformance Checklist

	Conformance Item
☐	Approved supplier list maintained with current qualification status for all external providers of quality-affecting inputs
☐	Supplier evaluation criteria documented — not applied informally based on purchasing experience alone
☐	Supplier performance monitoring active — on-time delivery, incoming quality, corrective action responsiveness tracked and reviewed
☐	Supplier re-evaluation conducted periodically and documented — performance-based frequency rather than fixed calendar regardless of performance
☐	Outsourced QMS processes (calibration, inspection, training) controlled with same rigor as direct-supply external providers
☐	Purchase orders communicate requirements adequately — not just part number and quantity, but specification revision, quality requirements, documentation requirements
☐	Control depth proportionate to external provider criticality — critical providers receive more intensive control than commodity suppliers

Clause 8.5 Conformance Checklist

	Conformance Item
☐	8.5.1: Work instructions, travelers, drawings, and acceptance criteria available at point of use — not filed in the quality office
☐	8.5.1: First-piece inspection consistently executed at required stages — not skipped under production pressure
☐	8.5.1: Special processes validated before production use and revalidated periodically — procedure qualification, equipment qualification, personnel qualification records current
☐	8.5.1: Human error prevention controls identified in control plan and implemented — poka-yoke, checklists, dual verification for high-risk steps
☐	8.5.2: Product identification maintained through all production stages including special processes (heat treatment, plating, etc.)
☐	8.5.2: Inspection status clearly visible for all work-in-process — uninspected product not confused with inspected/accepted product
☐	8.5.2: Traceability records complete and unbroken where traceability is required — no gaps in the trace chain from raw material to final release

	Conformance Item
☐	8.5.3: Customer property register maintained — all customer-owned tooling, materials, and intellectual property identified and controlled
☐	8.5.3: Process for notifying customer of lost, damaged, or unsuitable customer property is documented and operational
☐	8.5.4: Preservation controls implemented through production and delivery — packaging, storage, handling, and transportation requirements defined and followed
☐	8.5.6: Production change control process documented — all process changes reviewed, authorized, documented, and communicated before implementation

Clause 8.6 Conformance Checklist

	Conformance Item
☐	Release criteria defined for each product and service type — what must be verified before release is authorized
☐	Release authority defined by role — who may authorize standard release, conditional release, and customer-deviated release
☐	Release records retain evidence of conformity — not just "passed" but measured values, acceptance criteria, and pass/fail determination
☐	Release records identify the authorizing individual — not just an anonymous signature but a name or identifier traceable to a specific person
☐	No product shipped without documented release authorization by an authorized quality representative

Clause 8.7 Conformance Checklist

	Conformance Item
☐	Designated nonconforming material hold area is physically separate from conforming product — marked, controlled, and not accessible for unauthorized removal
☐	NCR created for every nonconforming condition — not handled informally without documentation
☐	NCR records describe the nonconformance specifically — what characteristic failed, measured value, specified requirement, and quantity affected
☐	Disposition decision documented with technical rationale and authorizing person identified by name and role
☐	Reworked product re-inspected against acceptance criteria before release — rework alone is not release authorization

	Conformance Item
☐	Concessions (use-as-is dispositions) technically justified and authorized at appropriate level — customer concession obtained before use where required
☐	Customer notification process operational for nonconformances affecting delivered product — triggering investigation, containment, and CAPA
☐	NCR trends analyzed periodically — recurring nonconformances identified and prioritized for corrective action

Most Common Clause 8 Part 2 Audit Findings

Finding Area	Clause	Typical Finding Statement
Supplier evaluation not documented	8.4.1	Three suppliers on the approved supplier list were added based on verbal recommendation without documented qualification evaluation. No evaluation criteria, survey results, capability assessment, or qualification rationale records exist for these suppliers.
Supplier performance not monitored	8.4.1	Approved supplier list was established at certification. No supplier performance monitoring records (scorecards, quality metrics, delivery tracking) exist for any supplier since certification. The organization is unable to demonstrate how it monitors external provider performance.
Purchase order requirements inadequate	8.4.3	Purchase order PO-2024-178 for heat treatment processing specifies part number and quantity but does not reference the applicable specification (AMS 2759), the required hardness range, the documentation required at delivery (heat treat certification), or the applicable special process qualification requirements.
Special process not validated	8.5.1	Production welding is performed on structural aluminum components. The organization uses outside welding contractors but cannot provide evidence of welding procedure qualification per AWS D1.2 or equivalent standard. Welder qualification records for the contracting welders are not maintained by the organization.
Traceability break	8.5.2	Tracking a component through production from raw material to finished part, a traceability break was identified at the heat treatment operation. Parts are sent to an outside heat treatment supplier by lot number, but return documentation references only the supplier's internal lot ID. No documented link exists between the incoming material lot (and its material certification) and the heat-treated part lot as returned.
Release record inadequate	8.6	Release records for 3 of 5 lots sampled show a quality inspector signature and "accepted" notation on the traveler. No measured inspection data is recorded — only the accept/reject determination. The records do not demonstrate conformity to acceptance criteria; they demonstrate only that an inspector reviewed the product.

Finding Area	Clause	Typical Finding Statement
NCR quarantine ineffective	8.7	Two nonconforming parts are in the designated quarantine area with NCR tags. Three additional parts with the same visible nonconformance were observed in a production work-in-process bin adjacent to the quarantine area without NCR identification. The physical segregation of the quarantine area does not prevent nonconforming material from being inadvertently mixed with in-process product.
Rework not re-inspected	8.7	Review of NCR records for the past 6 months identified 4 instances where the disposition was "rework." In 2 of 4 cases, the NCR shows rework was performed but does not contain a re-inspection record confirming that the rework brought the product into conformance. Both lots were released and shipped without documented verification of post-rework conformance.

Next in Volume 2: Guide 2.6 — Clause 9: Performance Evaluation. Deep-dive coverage of monitoring, measurement, analysis, and evaluation (9.1) including customer satisfaction monitoring (9.1.2), internal audit requirements (9.2), and management review (9.3) — the Check layer of the PDCA cycle that converts QMS activity data into organizational decisions and improvement actions.
