Six Sigma Kaizen

ISO 9001 IMPLEMENTATION HUB

Volume 2 • Guide 4 of 7

Clause 8, Part 1: Operational Planning & Customer Focus

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

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

Operational Planning (8.1) • Customer Communication (8.2.1) • Determining Requirements (8.2.2) • Review Before Commitment (8.2.3) • Design & Development (8.3)

How to Use This Guide

This is Guide 2.4 in Volume 2 of the ISO 9001 Implementation Hub. It provides deep-dive coverage of Clause 8, Part 1 — the first half of the Operation clause, covering operational planning and control (8.1), the customer requirements subclauses (8.2.1 through 8.2.3), and design and development (8.3). Clause 8 as a whole is the largest and most operationally intensive section of ISO 9001:2015 — it governs how the organization actually creates and delivers conforming products and services. Part 1 of this guide covers the front end of that value chain: planning what needs to happen, understanding and committing to customer requirements, and developing new products and services under controlled conditions.

Guide 2.5 covers Part 2 of Clause 8: external provider management (8.4), production and service provision (8.5), product and service release (8.6), and control of nonconforming outputs (8.7). Together, Guides 2.4 and 2.5 cover the full operational core of the QMS — the clauses that most directly determine whether products and services meet requirements before they reach customers.

Introduction: Clause 8 as the Value Creation Spine of the QMS

Clause 8 is the "Do" layer of the Plan-Do-Check-Act cycle that structures ISO 9001:2015. Where Clauses 4 through 7 establish the organizational context, governance, planning, and enabling resources of the QMS, Clause 8 governs how the organization uses those resources to actually create and deliver products and services. It is in Clause 8 that the QMS becomes visible to customers — through the quality of what is delivered, the reliability of delivery, and the responsiveness when problems occur.

For most manufacturing organizations, Clause 8 is also where the audit is most intensive. Registrar auditors spend the majority of their shop floor time in Clause 8 territory — observing production processes, tracing material through the production sequence, sampling inspection and release records, examining nonconforming material controls, and evaluating supplier qualification evidence. Getting Clause 8 right means not only having the right documented information but having the right behaviors, the right controls, and the right evidence of both.

The structure of Clause 8 follows the logical sequence of product and service creation from customer requirement through delivered output: determine what the customer needs, plan how to produce it, develop new products under controlled conditions, manage the supply chain, control production, verify conformance, release, and handle nonconformances. This guide follows that sequence for the front-end elements covered here.

Clause 8.1 — Operational Planning and Control

Standard Requirement

ISO 9001:2015, Clause 8.1: "The organization shall plan, implement, control, monitor and review processes needed for the realization of products and services, in accordance with the requirements for the provision of products and services, and to implement the actions determined in Clause 6 by: a) determining the requirements for the products and services; b) establishing criteria for the processes and for the acceptance of products and services; c) determining the resources needed to achieve conformity to product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining, maintaining and retaining documented information to the extent necessary to: 1) have confidence that the processes have been carried out as planned; 2) demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the organization's operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4)."

What Operational Planning Actually Requires

Clause 8.1 is the master operational planning requirement — it frames how all the operational subclauses (8.2 through 8.7) must be approached. The five elements it requires are not sequential steps but parallel dimensions of planning that must all be addressed for any process through which products or services are created:

Planning Element	What It Requires
(a) Determining requirements for products and services	Before producing anything, the requirements that define what conforming output looks like must be determined. This connects to Clause 8.2 (customer requirements determination) and feeds the acceptance criteria in (b). "We know what good looks like" must be formalized into documented criteria, not held informally in experienced employees' judgment.
(b) Establishing criteria for processes and acceptance	Two distinct sets of criteria: process criteria (how the process must be set up and controlled to reliably produce conforming output) and acceptance criteria (what a conforming product or service result looks like). Both must be established before production begins. Process criteria appear in procedures, work instructions, and control plans. Acceptance criteria appear in inspection criteria, drawings, specifications, and first-article inspection requirements.
(c) Determining resources needed for conformity	Planning must identify what people, equipment, materials, and environment are needed to produce conforming product — not just to run the process. This includes identifying when a process capability study is needed before production begins, when specific operator qualifications are required, or when specialized measuring equipment is necessary for a new product type.
(d) Implementing control in accordance with criteria	The process controls defined in (b) must actually be implemented — documented controls that are not followed provide no quality assurance. Control implementation includes verifying that setups meet process criteria before running, that in-process checks are

Planning Element	What It Requires
	conducted at defined intervals, and that final acceptance criteria are applied before release.
(e) Documented information for process confidence and conformance demonstration	Two purposes for records: proving the process ran as planned (process documentation — setup verification, in-process check records, parameter logs) and proving the output conforms (inspection and release records). Both are required; neither alone is sufficient.

Planned vs. Unintended Changes

Clause 8.1 includes a specific requirement about change management: the organization must control planned changes and review the consequences of unintended changes, taking action to mitigate adverse effects. This connects to the Clause 6.3 requirement for planned changes to the QMS — but Clause 8.1 applies specifically to changes in the operational processes themselves.

Planned operational changes — a new machine being introduced into a production sequence, a process parameter being adjusted based on capability data, a new material being substituted — should go through a formal change review before implementation. The review should assess quality implications, update relevant documentation, retrain affected personnel, and verify process capability before running production.

Unintended changes — a process parameter drifting outside specification due to equipment wear, a raw material arriving with different characteristics than expected, a quality characteristic deviating from the historical baseline — require detection, investigation, and mitigation. A production monitoring system (in-process SPC, regular dimensional checks, end-of-shift quality reviews) is what enables unintended changes to be detected before significant nonconforming product is produced.

Kaizen Connection

The SMED (Single Minute Exchange of Die) concept in Lean manufacturing connects directly to Clause 8.1's change management requirement. SMED distinguishes between internal setup activities (performed while the machine is stopped) and external setup activities (performed while the previous job is still running). The quality implication of SMED thinking: change management is more controlled when setup verification activities are separated from production activities. A process that verifies setup criteria before the first production piece is released — not after running 50 pieces — catches unintended changes at the earliest possible point. First-piece inspection, setup approval procedures, and process capability verification are the quality tools that satisfy both Clause 8.1's change management requirement and Lean's objective of building quality into the process at point of setup.

Operational Planning Documentation — Calibrated to Process Risk

The documented information requirement in Clause 8.1(e) must be calibrated to the nature and risk of the process. Not every operational process requires the same depth of documentation. The planning decision about what documentation to maintain and what records to retain should reflect:

- Process complexity and criticality: a simple cutting operation with wide tolerances needs less documentation than a multi-axis CNC machining operation with tight tolerances on flight-safety features
- Operator competence and experience: a well-established process performed by long-tenured, highly competent operators may need less instructional documentation than a new process or one performed by operators in training
- Regulatory and customer requirements: some customers and regulatory bodies specify minimum documentation requirements for specific process types — these override the organization's calibration judgment
- Nonconformance history: processes with a history of producing nonconformances may warrant more extensive documentation and more frequent inspection until the process is stabilized

Clause 8.2 — Requirements for Products and Services

Clause 8.2 covers the front end of the customer interface: how the organization communicates with customers about quality matters, how it determines what customers actually require, and how it reviews and confirms its capability and commitment to meet those requirements before accepting an order. These three activities — communication, determination, and review — form the quality foundation for everything that follows in production.

Clause 8.2.1 — Customer Communication

Standard Requirement

ISO 9001:2015, Clause 8.2.1: "Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant."

Customer communication in ISO 9001:2015 is broader than most organizations initially recognize. It encompasses the full range of quality-relevant interactions between the organization and its customers — not just complaint handling. Each of the five elements has distinct quality management implications:

Communication Requirement	Quality Management Implications
(a) Providing information about products and services	Capability statements, quality certifications, product specifications, and technical data sheets provided to customers must be accurate and current. Providing a customer with an outdated capability statement that claims tolerances the organization can no longer reliably hold creates a requirement that the QMS cannot satisfy. Quality review of customer-facing technical information before distribution is a Clause 8.2.1 responsibility.
(b) Handling enquiries, contracts, orders, and changes	The order intake and contract review process — governed in depth by Clauses 8.2.2 and 8.2.3 — is the mechanism through which requirements are captured and confirmed. But Clause 8.2.1 also requires that changes to contracts and orders be handled systematically. A customer who revises a drawing mid-production must have that change captured, reviewed, and communicated to the production team with the same rigor as the original requirement.
(c) Customer feedback including complaints	The full spectrum of customer feedback — positive and negative, formal and informal — must be systematically captured and processed. Customer complaints must enter the corrective action cycle. Positive feedback provides evidence for customer satisfaction monitoring. Informal customer comments ("we had to spend extra time on incoming inspection of your parts") may indicate a quality issue that has not yet risen to the level of a formal complaint but deserves investigation.
(d) Handling or controlling customer property	Customer-owned tooling, fixtures, materials, drawings, software, and intellectual property held by the organization must be identified, protected, and controlled. Loss, damage, or unauthorized modification of customer property must be reported to the customer. This

Communication Requirement	Quality Management Implications
	connection to Clause 8.5.3 (customer property) is explicit — the communication requirement means the organization must have a defined process for notifying customers when incidents with their property occur.
(e) Contingency actions when relevant	For customers whose supply relationships are critical enough that a supply interruption would have significant consequences, communication about contingency planning may be a customer requirement. This is particularly common in automotive and aerospace supply chains where customers may require suppliers to maintain defined inventory buffers, alternative process qualifications, or documented business continuity plans.

Clause 8.2.2 — Determining Requirements for Products and Services

Standard Requirement

ISO 9001:2015, Clause 8.2.2: "When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims it makes for the products and services it offers."

Clause 8.2.2 governs the determination of requirements — the foundational understanding of what products and services must achieve before any specific customer order is accepted. It operates at the product and service category level: before the organization offers a product type to market or before it accepts orders for a new category of work, it must have determined what the requirements for that product category are.

The Three Categories of Requirements

ISO 9001:2015 and ISO 9000:2015 (which provides the vocabulary) identify three categories of requirements that must be determined for any product or service:

Stated Requirements

Requirements explicitly communicated by the customer: engineering drawings, specifications, purchase order quality requirements, quality flow-down documents, performance targets, delivery requirements, and any other requirements the customer has articulated. These are the most visible requirements and the ones most organizations handle reasonably well — though the review rigor varies significantly.

Unstated Requirements

Requirements that customers expect to be met even though they have not explicitly stated them. These derive from the product's intended use, industry practice, prior business relationship history, and reasonable expectations of competent professionals in the field. Examples:

- A precision machined aerospace component is expected to be free of machining burrs that could cause assembly interference — even if no drawing note specifies "deburr." This is an unstated requirement derived from the product's intended use and industry practice.
- A customer who has been receiving parts with a specific surface treatment for five years and has not specified it on the drawing expects that surface treatment to continue unless they have explicitly changed the requirement. This is an unstated requirement derived from business relationship history.
- A customer ordering structural components expects that the material used meets the specified alloy and temper condition even if the purchase order does not explicitly require material certification — because this is standard industry practice for structural applications.

Unstated requirements are where quality failures most frequently surprise organizations — they delivered exactly what was specified but not what was expected. The customer requirement review process must explicitly consider what the customer would expect beyond the documented requirements.

Applicable Statutory and Regulatory Requirements

Requirements imposed by law or regulation that apply to the product by virtue of what it is, where it is used, or where it is sold. These apply regardless of whether the customer has specified them and regardless of whether the organization is aware of them. Examples include:

- ITAR (International Traffic in Arms Regulations) for defense articles and defense services
- RoHS (Restriction of Hazardous Substances) for electrical and electronic equipment sold in the European Union
- FAA certification requirements for aviation components
- OSHA requirements for worker safety in manufacturing processes
- Industry-specific standards incorporated by reference into regulatory requirements

An organization that determines its product or service requirements without considering applicable statutory and regulatory requirements has an incomplete requirement determination — and is potentially producing products that are legally nonconforming even when they are technically conforming to the customer's specification.

⚠ Common Pitfall

The most consequential Clause 8.2.2 failure is the "we do what the drawing says" mentality — treating explicitly stated customer requirements as the complete set of requirements without investigating unstated requirements and applicable regulatory obligations. In aerospace and defense manufacturing, this failure has led to products that met every drawing dimension but violated ITAR export control requirements, used non-conforming material that met the specification but not the regulatory material traceability requirements, or were delivered without required first article inspection documentation that the customer's own regulatory obligations required. "The drawing didn't say" is not a defense when the requirement is implied by the product's regulated intended use.

Clause 8.2.3 — Review of Requirements for Products and Services

Standard Requirement

ISO 9001:2015, Clause 8.2.3.1: "The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products or services to a customer, to include: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities; b) requirements not stated by the customer but necessary for specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed."

Clause 8.2.3.2: "The organization shall ensure that contract or order requirements differing from those previously defined are resolved. The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements. The organization shall retain documented information, as applicable: a) on the results of the review; b) on any new requirements for the products and services."

The Customer Requirement Review — Purpose and Scope

The customer requirement review — also called contract review, order review, or feasibility review depending on industry terminology — is the quality gate between receiving a customer requirement and committing to supply. Its purpose is to ensure that before the organization says "yes" to a customer, it has verified that it understands what "yes" means and that it has the capability to deliver it.

The review must occur before commitment to supply — not after. An organization that accepts orders and then discovers during production that it cannot meet a requirement has failed Clause 8.2.3.1. The review must also be genuine — a cursory glance at a purchase order that confirms only that the part number and quantity are correct is not a requirement review. A meaningful requirement review examines whether every element of the requirement is understood and within the organization's capability to deliver.

What the Review Must Cover

Clause 8.2.3.1 lists five categories of requirements that must be reviewed:

Review Category	What to Examine
(a) Requirements specified by the customer including delivery and post-delivery	All explicitly stated requirements: drawing and specification revision levels, material requirements, surface finish requirements, dimensional tolerances, delivery quantity and date, packaging requirements, quality documentation requirements (certifications, inspection reports, first article), and any post-delivery obligations (warranty, field support, maintenance).
(b) Requirements not stated but necessary for intended use	Industry-standard practices for this product type; historical requirements that have not been re-specified on the current order; requirements that any competent supplier in this field would be expected to understand and apply without explicit instruction.
(c) Requirements specified by the organization	The organization's own quality standards: minimum inspection requirements, material traceability requirements, minimum surface condition standards, internal quality approvals required before release. These apply to every order regardless of customer specification.

Review Category	What to Examine
(d) Statutory and regulatory requirements	Applicable legal and regulatory requirements for this product in its intended use environment: export control requirements, safety certification requirements, material restriction regulations, product traceability requirements.
(e) Contract or order requirements differing from those previously expressed	This is the change detection element: when an order arrives that differs from a previously accepted order or a previously quoted specification, the difference must be identified, reviewed, and either resolved or flagged before commitment. The most common implementation failure here is in accepting repeat orders without verifying that the current revision matches the last fulfilled revision.

The Review Record — What Must Be Retained

Clause 8.2.3.2 requires retention of documented information on the results of the review and on any new requirements identified. This record must demonstrate that the review was conducted — not merely that the order was accepted. The record must be retrievable and must link to the specific order or contract reviewed.

Common review record formats and their audit implications:

Record Format	Audit Adequacy
Formal order review checklist completed for each order, signed by reviewer, filed with the order record	Fully conforming — demonstrates systematic review, identifies what was reviewed, captures reviewer accountability, and is retrievable with the order
Annotated copy of the purchase order or customer drawing with reviewer initials and date	Conforming if annotations are meaningful (requirements confirmed, concerns noted) rather than merely initialed for signature. Adequate for simple repeat orders with established specifications; less adequate for complex first-article or new product orders.
Email exchange with customer confirming requirements before order acceptance	Conforming as a record of review and confirmation — provided the email is retained and retrievable and demonstrates that requirements were discussed and confirmed, not merely acknowledged
Verbal review with no documentation	Not conforming — no documented information retained as required by Clause 8.2.3.2. The standard requires retained documented information, which verbal review cannot provide
Production traveler creation treated as implicit order review	Partially conforming only if the traveler creation process explicitly addresses all five review categories. Most traveler creation processes do not — they translate order information into production instructions without reviewing capability, regulatory obligations, or unstated requirements

Handling Requirement Changes After Acceptance

Clause 8.2.3 requires that contract or order requirements differing from those previously defined are resolved before commitment. But requirements also change after initial commitment — a customer revises a drawing, changes a delivery date, modifies a specification, or adds a quality requirement mid-production. These post-acceptance changes must be handled with the same rigor as pre-acceptance requirements:

1. The change must be received and formally acknowledged — not verbally communicated without documentation
2. The change must be reviewed for feasibility and impact: can the organization still meet the requirement? Does the change affect the production already in progress? Does it create a compliance obligation that did not previously exist?
3. The change must be communicated to all affected functions — a drawing revision received by the sales team that does not reach the production floor and inspection team in time to affect the job is a change management failure with direct quality consequences
4. The review and communication must be documented — the same record requirement applies to change reviews as to original requirement reviews
5. If the organization cannot meet the changed requirement (due to material in process, equipment constraints, or timeline), the inability must be communicated to the customer before the affected product ships — not after

Auditor Perspective

Registrar auditors evaluate Clause 8.2.3 through a specific evidence-gathering approach that most organizations do not anticipate: they select a product visible on the production floor, trace it back to the customer order, and then ask for the review record for that order. If the review record cannot be produced within a few minutes, or if it is minimal — a date stamp and a signature rather than a structured review — the auditor will probe what the review actually covered. They will ask questions like: "Can you show me where the review confirmed the regulatory requirements for this product?" and "Was there anything in this order that differed from the customer's previous order? How do you know?" The inability to answer these questions from the review record is typically evidence of a minor nonconformance in Clause 8.2.3.

Meridian Case Study

Meridian's Customer Requirement Review Evolution: During the gap analysis, Denise identified that Meridian's estimating and order review process was largely verbal — the estimating team reviewed drawings for feasibility and priced the job, but the review was not structured to address regulatory requirements, unstated requirements, or requirement differences from prior orders. The review procedure (MPC-PRO-004) developed during Phase 3 established a five-category checklist aligned to Clause 8.2.3.1. In the first year post-certification, 312 orders were processed through the formal review. The review identified two noteworthy situations: (1) a repeat order from a defense customer where the drawing revision had changed — the customer had moved from Revision C to Revision D on a critical fastener hole dimension. Without the revision-check step in the review, this change would likely have been missed and parts manufactured to the old revision would have shipped. The review caught it, triggered a conversation with the customer, and resulted in updated production travelers before the job was started. (2) An order for a new component that, upon regulatory review, involved ITAR-controlled technology that required an export license before delivery. The estimating team had no awareness of ITAR implications; the review checklist's regulatory category surfaced the question, which was escalated to legal counsel for evaluation. Both situations were prevented from becoming customer problems because the review process was systematic rather than intuitive.

Clause 8.3 — Design and Development of Products and Services

Clause 8.3 is the most complex and most frequently misapplied clause in ISO 9001:2015. It is misapplied in both directions: organizations that should include it exclude it (treating all manufacturing as production-only), and organizations that include it build elaborate design control systems for activities that are more accurately characterized as process planning. Getting the applicability determination right is the essential starting point.

The Applicability Question — When Does Clause 8.3 Apply?

Clause 8.3 applies when the organization performs design and development activities — the process of establishing the detailed specifications or characteristics of a product or service where the end result is not fully specified by input requirements. The critical distinction is between design (creating something new from requirements) and production (creating to a fully specified design).

ISO 9001:2015 does not define "design and development" narrowly to mean product design. It applies to any activity where the organization is determining — rather than simply executing — the detailed characteristics of a product or service. This broader interpretation catches activities that many manufacturers incorrectly believe are outside the design and development scope:

Activity	Design and Development? Why?	Evidence Required
Customer-designed product manufactured to customer drawings	No — if the customer provides complete specifications (drawing, material specification, tolerance, surface finish) that fully define the product and the organization simply manufactures to those specifications without engineering judgment about product characteristics	Organization must document and justify this exclusion in the QMS scope statement. Must be genuinely complete specifications, not specifications that require engineering interpretation.
Process engineering to achieve customer specifications	Yes — determining the machining sequence, tooling selection, cutting parameters, and process settings required to achieve a customer's dimensional and surface specifications involves design and development of the manufacturing process, even if the product design originates with the customer	Process design records: process design inputs (customer specification), process design reviews, process verification (first article), process validation (production run capability)
Custom fixturing and tooling development	Yes — designing fixtures, jigs, holding devices, and special tooling used in production involves design and development activity. Even if the product being produced is customer-designed, the tooling	Tooling design records: design inputs, design reviews, verification (does the fixture hold correctly), validation (does it produce conforming parts in production)

Activity	Design and Development? Why?	Evidence Required
	to produce it is developed by the organization	
Developing a new service offering	Yes — defining the scope, method, quality criteria, and delivery mechanisms for a new service that does not previously exist involves design and development of that service	Service design records: service requirements, design reviews, service pilots/trials, release criteria
Product configuration engineering based on customer requirements	Yes — selecting from design options to configure a product that meets customer-specific requirements involves engineering judgment about product characteristics even when each option was previously designed	Configuration design records: configuration inputs, selection rationale, compatibility review, customer confirmation
Standard product replication — no engineering content	No — producing an established product to a stable, fully documented specification that has been produced many times before and requires no engineering judgment	Production controls sufficient; no D&D records required provided specifications are truly stable and fully documented

Standard Requirement

ISO 9001:2015, Clause 8.3.1 (General): "The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services."

Clause 8.3.2 (Planning): The organization shall determine: the stages and controls; the design and development reviews, verification and validation activities; responsibilities and authorities; internal and external resource needs; need to involve customers and users in the design process; requirements for subsequent product provision; level of control expected by customers and other relevant interested parties; documented information needed to demonstrate conformance.

Clause 8.3.3 (Inputs): "The organization shall determine the requirements essential for the specific types of products and services to be designed and developed: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services."

Note: Design and development inputs can be contradictory. The organization shall resolve contradictory inputs before proceeding.

Clause 8.3.2 — Design and Development Planning

Design and development planning requires the organization to determine, before beginning the design process, how it will be conducted — the stages, the controls, the review and verification activities, the resources, the customer involvement, and the documentation requirements. This is not a generic quality plan but a project-specific plan that reflects the specific type and complexity of the design activity being undertaken.

The planning requirement is often satisfied through a combination of a standing design and development procedure (governing how all design activities are planned and controlled) and project-specific design plans (defining the stages, reviews, and milestones for a particular design project). The procedure establishes the framework; the project plan applies it to the specific project.

Design and Development Stages

A design and development process typically progresses through defined stages, each with specific inputs, activities, outputs, and review requirements. The stages appropriate to a manufacturing process engineering context (the most common form of D&D in contract machining) differ from those in a product design context but share the same structural logic:

Stage	For Process Engineering (Contract Manufacturing)	For New Product Design (Product Developer)
Input capture	Customer drawing, specification, and tolerance requirements; material requirements; delivery requirements; previous similar process experience	Customer or market requirements; regulatory requirements; interface requirements from other systems; lessons learned from prior designs
Concept development	Determine machining sequence, process routing, tooling approach, fixturing concept; identify critical process variables and their tolerances; estimate process capability	Generate design concepts; evaluate against requirements; select preferred concept; preliminary feasibility assessment
Detailed design	Develop CNC programs, tooling specifications, setup documentation, in-process inspection criteria, control plan; complete process FMEA	Complete engineering drawings and specifications; material selection; tolerance analysis; detailed FMEA; design verification planning
Verification	First article inspection against customer specification; process capability study for critical characteristics; measurement system analysis for critical gages	Prototype testing against design requirements; analysis, simulation, or calculation verification; engineering review of test results against requirements
Validation	Production trial run to confirm process can consistently produce conforming product at production volume; customer review and acceptance of first articles if required	Field testing or customer piloting under representative conditions; demonstration that the design meets user needs in actual use
Transfer to production	Complete process documentation package (travelers, work instructions,	Release of approved design documentation to manufacturing;

Stage	For Process Engineering (Contract Manufacturing)	For New Product Design (Product Developer)
	control plan, setup sheets); operator training; production release	production readiness review; production qualification

Clause 8.3.3 — Design and Development Inputs

Design inputs are the requirements that the design must satisfy — the specifications, constraints, regulatory obligations, and performance targets that define what a successful design looks like. Five categories of inputs must be determined:

- Functional and performance requirements: what the product or process must do and how well it must do it — dimensional accuracy, surface finish, material properties, structural performance, dimensional repeatability
- Information from previous similar activities: lessons learned from prior design projects, existing process capability data, known failure modes from similar designs, documented experience from analogous products or processes
- Statutory and regulatory requirements: legal obligations that apply to the design — material restrictions, safety standards, export control classifications, sector-specific standards incorporated by regulation
- Standards and codes of practice committed to: applicable industry standards referenced in contracts or organizational procedures — ASME, AWS, ASTM, AMS, MIL-SPEC, industry best practice guides that the organization has committed to follow
- Potential consequences of failure: what happens if the design fails in service? For flight-critical components, a dimensional error might cause structural failure. For food-contact equipment, a surface finish specification violation might cause bacterial contamination. Understanding the consequence of failure shapes how rigorous the design controls must be.

The standard's note about contradictory inputs is particularly important. Design inputs frequently conflict: a tight tolerance may be required for functionality but may be at the edge of the organization's process capability; a material specified for performance may not be compatible with the selected manufacturing process; a customer delivery requirement may conflict with the lead time for necessary process qualification. These contradictions must be identified and resolved before design proceeds — otherwise the design is attempting to satisfy mutually exclusive requirements, which will inevitably produce a conformance failure at verification or validation.

Clause 8.3.4 — Design and Development Controls

Standard Requirement

ISO 9001:2015, Clause 8.3.4: "The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs have met the design and development input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities shall be retained."

The Three-Control Hierarchy: Review, Verification, and Validation

Clause 8.3.4 requires three distinct types of design quality control activities — review, verification, and validation — each serving a different purpose in confirming that the design will deliver conforming products and services:

Control Activity	Definition and Purpose	Manufacturing Context Example
Design Review	A structured evaluation of the design at defined stages to assess whether it is on track to meet requirements. Involves relevant stakeholders — engineering, quality, production, customer where applicable. Identifies issues before they become embedded in the design.	Mid-process development review: engineering, quality, and production supervisor review the proposed machining sequence and process parameters against the customer specification, capability data, and production constraints. Issues identified and resolved before CNC program is written.
Design Verification	Confirms that the design outputs (the specifications, process settings, programs, and documents produced by the design activity) meet the design inputs (the requirements that the design was supposed to satisfy). Answers: "Did we design what we said we would design?"	First Article Inspection: dimensional verification of the first production parts against the customer drawing and specification. CMM inspection report demonstrating that all critical dimensions are within tolerance confirms that the machining process produces output meeting the specified requirements.
Design Validation	Confirms that the product or service resulting from the design meets the needs of the intended user under real conditions of use. Answers: "Did we design the right thing?"	Customer first article acceptance: customer receives and inspects the first article parts, installs them in the assembly, and confirms that they function as intended. Or production capability run: a production trial batch is produced and its performance in subsequent assembly or use is evaluated.

The distinction between verification and validation is one of the most consistently confused aspects of Clause 8.3. The common summary: verification asks "did we build the design right?" (does the output match the specification?); validation asks "did we build the right design?" (does the product actually work as the customer intends?). Both are required. A product that meets its specification (verified) but does not function in the customer's assembly (not validated) has failed design and development controls.

Clause 8.3.5 — Design and Development Outputs

Standard Requirement

ISO 9001:2015, Clause 8.3.5: "The organization shall ensure that design and development outputs: a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance

> criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper use. The organization shall retain documented information on design and development outputs."

Design outputs are the deliverables of the design and development process — the specifications, programs, procedures, tooling designs, control plans, and other documents that define how the product will be produced and verified. In a manufacturing process engineering context, the design output package for a new job typically includes:

- CNC programs and tooling lists
- Process routing and operation sequence
- Setup sheets with fixture configuration and datum references
- In-process inspection criteria and frequency
- First article inspection requirements
- Control plan identifying critical characteristics and their control methods
- Work instructions for any non-standard operations
- Packaging and preservation requirements

The requirement that outputs "meet the input requirements" creates a traceability obligation: it must be demonstrable that each output was developed to satisfy a specific input requirement. This is the link that makes verification possible — if you cannot trace an output to an input, you cannot verify that the output satisfies the input.

Clause 8.3.6 — Design and Development Changes

Standard Requirement

> ISO 9001:2015, Clause 8.3.6: "The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts."

Design change control is where many organizations' design and development systems are most fragile. The Stage 2 audit finding at Meridian — incomplete design change records — is representative: an organization that has a reasonable design development process often has a weak change control process, because changes feel less significant than the original design and receive less disciplined treatment.

Change control must apply to both changes made during design development (before the design is released to production) and changes made after release. Post-release design changes are often the most quality-critical because they affect product already being produced — sometimes product already shipped to customers. The change control process for post-release changes should address:

- Whether the change affects in-process product — do in-progress jobs need to be stopped, reworked, or dispositioned?

- Whether the change affects already-shipped product — do customers need to be notified of the change and its quality implications?
- Whether the change requires re-verification — does the changed design output still satisfy all design inputs, or does the change create a new verification requirement?
- Whether the change requires re-validation — does the changed product still function as the customer intends in its application?
- How the change is documented, authorized, and communicated to production, quality, and customer service

Meridian Case Study

Meridian Design and Development in Year 1 Post-Certification: The design and development procedure (MPC-PRO-005) was the most challenging procedure developed during implementation, requiring external consultant involvement and three revision cycles. In Year 1 post-certification, MPC-PRO-005 was applied to 23 new-job process engineering activities. The most significant application was the development of the machining process for a new aerospace customer (Northfield Systems) component — a titanium structural bracket with 14 critical dimensions including 3 GD&T geometric tolerances requiring precision CMM verification. The design process for this job took 6 weeks: input capture from Northfield's engineering drawings and specification package, process development including a preliminary process FMEA, a design review attended by the engineering manager, production supervisor, and quality engineer, first-article inspection producing 47 measured results against 14 critical dimensions, and customer first-article acceptance by Northfield's supplier quality engineer. The documented design records from this activity — inputs, review minutes, FAI report, customer acceptance record — became the reference package for all future Northfield jobs of similar complexity. The organizational knowledge captured in this package (process parameters, gage selection, setup notes, lessons learned from the FAI process) directly addressed the R-01 knowledge risk identified in the context analysis.

Quick Reference: Clause 8 Part 1 Audit Readiness

Clause 8.1 Conformance Checklist

	Conformance Item
☐	Acceptance criteria established for products and services before production begins — not determined after production reveals a problem
☐	Process criteria (setup requirements, in-process parameters, control frequencies) documented in control plans or equivalent
☐	Resources needed for process execution and product conformance determined and provided for each process type
☐	Planned changes to operational processes reviewed for quality impact before implementation, with documentation
☐	Monitoring system in place to detect unintended process changes — in-process checks, SPC, or equivalent
☐	Process records (setup verification, in-process checks) retained as evidence that processes ran as planned

Clause 8.2 Conformance Checklist

	Conformance Item
☐	Clause 8.2.1: Customer communication process covers all five required elements — information provision, order handling, feedback/complaints, customer property, and contingency requirements
☐	Clause 8.2.1: Customer drawing and specification changes communicated to all affected functions before affecting production
☐	Clause 8.2.2: Requirement determination addresses stated requirements, unstated requirements, and applicable statutory and regulatory requirements
☐	Clause 8.2.3: Formal review conducted before commitment to supply for every new order — not only new products but repeat orders where revision levels may have changed
☐	Clause 8.2.3: Review covers all five categories: customer-specified, unstated, organization-required, regulatory, and differences from previous orders
☐	Clause 8.2.3: Review records retained and retrievable — linked to specific orders, demonstrating what was reviewed and by whom
☐	Clause 8.2.3: Post-acceptance requirement changes reviewed, documented, and communicated to all affected functions before production proceeds

Clause 8.3 Applicability Decision Guide

Before proceeding to the Clause 8.3 conformance checklist, confirm applicability using this decision framework:

Question	If Yes: D&D Applies; If No: Continue to Next Question
Does the organization develop new products or services with engineering content?	Yes: Clause 8.3 applies. All product design activities require D&D controls.
Does the organization perform process engineering to achieve customer specifications — determining machining sequences, tooling, process parameters?	Yes: Clause 8.3 applies to process design activities. The product design may be customer-provided, but the process design is the organization's.
Does the organization design fixtures, tooling, or special devices used in production?	Yes: Clause 8.3 applies to tooling and fixture design activities.
Does the organization perform configuration engineering or selection from design options?	Yes: Clause 8.3 applies where engineering judgment is exercised in selecting product configurations.
Does the organization produce only to fully specified, stable customer designs with no engineering judgment required?	If genuinely yes to all of the above: Clause 8.3 may be legitimately excluded. Document the justification in the scope statement.

Clause 8.3 Conformance Checklist

	Conformance Item
☐	8.3.1 and 8.3.2: Design and development procedure establishes the planning framework — stages, controls, review and verification activities, resources, and documentation requirements
☐	8.3.3: Design inputs are determined and documented before design proceeds — covering functional requirements, prior experience, regulatory requirements, applicable standards, and consequences of failure
☐	8.3.3: Contradictory inputs are identified and resolved before design proceeds — not discovered at verification
☐	8.3.4: Design reviews conducted at defined stages — attendees, issues identified, and dispositions documented
☐	8.3.4: Verification activities conducted — FAI, dimensional inspection, or equivalent demonstrating outputs meet inputs
☐	8.3.4: Validation activities conducted where applicable — customer acceptance, production trial, or functional testing demonstrating product meets intended use requirements
☐	8.3.5: Design outputs documented — complete package including process documentation, inspection criteria, and control plans traceable to design inputs
☐	8.3.6: Design change control process applied to both pre-release and post-release changes — changes documented, reviewed, authorized, and communicated

	Conformance Item
☐	8.3.6: Post-release changes assessed for impact on in-process and shipped product — customer notification process defined for changes with product quality implications

Most Common Clause 8 Part 1 Audit Findings

Finding Area	Clause	Typical Finding Statement
No review record for orders sampled	8.2.3	Review of three production orders selected from active work-in-process found that two have no customer requirement review records. Production travelers were created and production is underway but no documented evidence of pre-commitment review was found for either order.
Repeat order review missing revision check	8.2.3	Order MP-2024-047 for Northfield Systems component NC-884 was accepted and production is in progress to Drawing Revision C. Customer purchasing records show that the current drawing is Revision D, issued by the customer 6 weeks prior. No revision comparison step was performed during order review; the organization has been manufacturing to a superseded revision.
Regulatory requirements not in review scope	8.2.3	Requirement review procedure (MPC-PRO-004) addresses drawing and specification requirements, delivery, and packaging. There is no step addressing applicable statutory and regulatory requirements. One active production order is for a defense customer involving ITAR-controlled technology; the organization is unable to demonstrate that ITAR applicability was reviewed before order acceptance.
D&D exclusion not justified	8.3	QMS scope excludes Clause 8.3 on the basis that the organization manufactures to customer specifications. Review of the engineering function reveals that process engineers develop machining sequences, tooling configurations, and CNC programs for all new jobs. These activities constitute design and development of the manufacturing process and cannot be excluded from Clause 8.3 scope.
Design review records incomplete	8.3.4	Design review records for three active design projects reviewed. Records confirm that design reviews occurred (meeting dates and attendees are documented) but do not capture issues raised during the review, the disposition of those issues, or who was responsible for resolving open items. Records demonstrate attendance at a meeting, not the conduct of a controlled design review.
Verification and validation conflated	8.3.4	The organization describes its first article inspection process as satisfying both design verification and design validation requirements. First article inspection confirms that produced dimensions meet drawing requirements (verification), but there is no evidence of validation — no customer acceptance of the first article, no functional testing, and no production trial

Finding Area	Clause	Typical Finding Statement
		confirming that the process reliably produces conforming parts at production volume.
Design change control not applied	8.3.6	Engineering manager confirmed that process parameters for job NC-884 were modified during production Month 3 after first-article acceptance when dimensional variation was observed. The modification was made informally — no change record, no re-verification that the modified parameters produced conforming output, no customer notification. The change affected all 47 pieces produced after the modification.

Next in Volume 2: Guide 2.5 — Clause 8, Part 2: Production, Control, and Delivery. Deep-dive coverage of external provider management (8.4), production and service provision including identification and traceability (8.5), product and service release (8.6), and control of nonconforming outputs (8.7) — the production control and conformance assurance subclauses that determine quality at the point of delivery.
