

**ISO 9001 IMPLEMENTATION HUB**

Volume 2 • Guide 2 of 7

# **Clause 6: Risk-Based Thinking & Quality Objectives**

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

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

Risks and Opportunities (6.1) • Quality Objectives (6.2) • Planning of Changes (6.3)

## How to Use This Guide

This is Guide 2.2 in Volume 2 of the ISO 9001 Implementation Hub. It provides deep-dive coverage of Clause 6 — the planning clause — which encompasses risk-based thinking and the management of risks and opportunities (6.1), the establishment and management of quality objectives (6.2), and the planning of changes to the QMS (6.3). Clause 6 is where the foundational understanding built in Clauses 4 and 5 translates into specific forward-looking decisions: what risks must be addressed, what improvement targets will be pursued, and how organizational changes will be managed without compromising quality.

This guide is structured to serve both first-time implementers who need to build these systems from scratch and practitioners who need deeper understanding of a clause area that has generated audit findings or management review questions. Each subclause is covered with the standard's exact requirement language, detailed practical interpretation, multiple implementation examples, a clear explanation of what auditors look for, and the Meridian case study showing how these requirements were implemented in a real manufacturing environment.

## Introduction: Clause 6 in the QMS Architecture

Clause 6 sits at a pivotal position in the ISO 9001:2015 structure. It follows the context and leadership clauses (4 and 5) that establish what the organization is and who governs its quality management, and it precedes the support and operation clauses (7 and 8) that define how quality management is resourced and executed. Clause 6 is the bridge: it translates organizational understanding into forward-looking plans.


The 2015 revision of ISO 9001 introduced two concepts that were either absent or implicit in earlier versions: risk-based thinking as an explicit planning requirement, and quality objectives with the specific planning discipline of defining what will be done, by whom, with what resources, by when, and evaluated how. Both represent a deliberate elevation of planning rigor in the standard — moving from "establish a quality management system" to "plan a quality management system that actively addresses what could go wrong and what improvement is targeted."

Understanding the relationship between the three subclauses of Clause 6 is essential for implementing them as an integrated system rather than three independent compliance exercises:

- Clause 6.1 (Risks and Opportunities) identifies what the QMS must proactively manage — the conditions and events that could undermine its effectiveness or create value if seized
- Clause 6.2 (Quality Objectives) defines where the QMS is headed — the specific, measurable improvement targets that translate the Quality Policy commitments into operational reality
- Clause 6.3 (Planning of Changes) protects what the QMS has built — ensuring that necessary changes to the system are made in a controlled, quality-preserving manner

Together, these three subclauses constitute the QMS planning layer — the forward-looking discipline that distinguishes a proactively managed quality system from a reactively maintained one.

## Clause 6.1 — Actions to Address Risks and Opportunities

 Standard Requirement
ISO 9001:2015, Clause 6.1.1: "When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended results; b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement."
Clause 6.1.2: "The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services."
Note 1: "Options to address risks can include avoiding the risk, taking the risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining the risk by informed decision."
Note 2: "Opportunities can result in the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology."

### The Most Misunderstood Clause in ISO 9001:2015

Clause 6.1 is consistently misunderstood in two opposite directions. Some organizations treat it as a minor documentation exercise — creating a risk register that lists generic organizational risks and then filling it. Others treat it as a mandate for enterprise risk management — attempting to apply complex risk frameworks (ISO 31000, Monte Carlo simulation, full FMEA programs) to every aspect of the business in response to a clause that requires something considerably more focused and proportionate.

The correct interpretation sits between these extremes. Clause 6.1 requires the organization to think systematically about what could prevent the QMS from achieving its intended results, and to plan proportionate actions in response. The standard is explicit about proportionality in Clause 6.1.2: "Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services." A simple 3x3 risk matrix with documented actions is fully conforming for most organizations. A detailed FMEA-driven enterprise risk program may be appropriate for high-risk industries but is not required by the clause.

### Risk-Based Thinking vs. Formal Risk Management

The standard's Note to Clause 6.1 is unusually helpful: it explicitly states that risk-based thinking does not require a formal risk management process. ISO 9001:2015 does not mandate a risk management procedure, a risk management committee, or a formal risk management framework. What it mandates is that the organization considers risk when planning the QMS — that risk awareness is embedded in how QMS decisions are made, not that risk is managed through a separate bureaucratic process.

This distinction matters practically. An organization that documents its risk considerations in a straightforward risk register, reviews and updates that register periodically, and can demonstrate that risk awareness shaped specific QMS design decisions is fully conforming. An organization that conducts elaborate risk workshops but cannot show how the outputs influenced how the QMS was built or operated has invested effort without achieving conformance.

## The Four Purposes of Clause 6.1 Risk Identification

The clause requires the organization to identify risks and opportunities that need to be addressed for four specific purposes — each represents a different type of forward-looking planning concern:

Purpose	What It Requires and Why It Matters
(a) Give assurance the QMS can achieve its intended results	Identify the risks that could prevent the QMS from functioning as designed — risks to system integrity rather than product quality outcomes. Examples: turnover of key QMS knowledge holders, inadequate management review participation, breakdown of document control discipline. If these risks are not identified and managed, the QMS infrastructure may fail even when individual processes are performing well.
(b) Enhance desirable effects	Identify opportunities to improve QMS performance beyond the minimum standard — conditions or events that, if leveraged, could advance quality objectives, strengthen supplier relationships, or build organizational quality capability. A new technology adoption, a regulatory change that creates a competitive advantage for quality-certified suppliers, or a customer's shift to preferred supplier status create opportunities the QMS can be positioned to seize.
(c) Prevent or reduce undesired effects	The most commonly understood purpose — identifying risks to product conformance and customer satisfaction. Supplier quality failures, process capability gaps, seasonal production surges that stress quality controls, single-source material dependencies. These are the operational quality risks that most organizations have some informal awareness of; Clause 6.1 requires that awareness to be explicit and documented.
(d) Achieve improvement	Identify the conditions under which improvement is most needed and most achievable. Where is the gap between current quality performance and what customers need or what competitors deliver? Where are the recurring nonconformances that represent the highest-impact improvement opportunity? This purpose connects risk and opportunity thinking directly to the quality objectives in Clause 6.2.

## Building the Risk and Opportunity Register

The risk and opportunity register is the primary tool for satisfying Clause 6.1. It does not need to be elaborate — it needs to be current, connected to the context analysis (Clause 4.1) and interested parties (Clause 4.2), and demonstrate that risks and opportunities were considered in QMS planning decisions. The following structure covers all required elements:

#	Risk / Opportunity Description	Likelihood (1-3)	Impact (1-3)	Priority Score	Planned Action	Owner
R-01	Key quality engineer (22 years experience) approaching retirement — critical process knowledge at risk	3 — Likely within 2 years	3 — Major QMS disruption	<b>9 — High</b>	Organizational knowledge documentation (Clause 7.1.6); cross-training of backup; structured knowledge transfer plan	MR + HR
R-02	Single-source raw material supplier (titanium bar stock) serving defense customers — no qualified alternative	2 — Possible	3 — Customer delivery impact	<b>6 — Medium</b>	Qualify alternate supplier within 12 months; maintain 90-day safety stock; include in management review	Purchasing
R-03	Customer adoption of model-based definition (MBD) replacing 2D drawings — inspection procedure competency gap	3 — Already occurring with 2 customers	2 — Moderate — affects inspection reliability	<b>6 — Medium</b>	MBD interpretation training for inspection staff; update inspection procedure; evaluate MBD-capable CMM software	Quality + Engineering
R-04	Production incentive structure rewards throughput over quality — operator behavior risk during high-volume periods	2 — Occasional	2 — Moderate — first-pass yield impact	<b>4 — Low-Medium</b>	Supervisor reinforcement of quality-stop authority; first-pass yield included in team performance metrics; QMS awareness training	Operations + MR
O-01	ISO 9001 certification enables access to aerospace customer program tier previously closed to non-certified suppliers	3 — Confirmed by customer	3 — Significant revenue potential	<b>9 — High</b>	Accelerate certification timeline; brief sales team on newly accessible program opportunities immediately upon certification	MR + Sales
O-02	Competitor quality failure with shared customer creates	2 — Possible	3 — Significant revenue	<b>6 — Medium</b>	Customer relationship management	Sales + MR

#	Risk / Opportunity Description	Likelihood (1-3)	Impact (1-3)	Priority Score	Planned Action	Owner
	preferred supplier opportunity if Meridian can demonstrate quality advantage		and relationship value		plan; ensure quality metrics are available to share; proactive outreach with quality performance data	

## Risk Scoring Methods — Choosing the Right Approach

ISO 9001:2015 does not prescribe a specific risk scoring method. Organizations may use any approach that is proportionate to their size, complexity, and the nature of the risks they face. The most commonly used methods, from simplest to most comprehensive:

Method	How It Works	Best For
Simple Likelihood x Impact Matrix (3x3 or 5x5)	Score each risk on likelihood (1-3 or 1-5) and impact (1-3 or 1-5). Multiply scores to get priority. High scores receive planned actions; low scores may be monitored or accepted. Document the scoring criteria so scores are consistent across raters and over time.	Most manufacturing QMS applications. Simple, auditable, sufficient for ISO 9001:2015 conformance, and produces results that non-specialists can understand and use.
Bowtie Analysis	Maps a risk event in the center (the "knot"), with causes leading to the event on the left (threats) and consequences flowing from the event on the right (impacts). Controls are placed on both sides — preventive controls on the left reduce likelihood; mitigating controls on the right reduce impact. Provides a visual, systemic view of risk and control relationships.	Complex risks where cause chains and consequence chains are both important — major product liability risks, supply chain disruption scenarios, regulatory compliance failures. Particularly useful for communicating risk to leadership and for identifying control gaps.
Process FMEA (Failure Mode and Effects Analysis)	For each process step, identifies potential failure modes (what could go wrong), their effects (what would happen), and their causes (why they would happen). Each combination is scored on Severity (S), Occurrence (O), and Detection (D). Risk Priority Number = S x O x D. High RPN combinations receive corrective or preventive actions.	High-risk manufacturing processes, new product launches, processes with complex failure modes. Particularly aligned with Clause 8.5 operational controls. Already required by AS9100, IATF 16949, and other sector-specific quality standards that sit above ISO 9001.

Method	How It Works	Best For
ISO 31000 Framework	The international standard for risk management — a comprehensive framework covering context establishment, risk identification, risk analysis, risk evaluation, risk treatment, and ongoing monitoring. More structured and rigorous than the above approaches.	Organizations with regulatory requirements for formal risk management, or those pursuing integrated risk management beyond QMS scope. Generally more than ISO 9001:2015 requires, but compatible with it and adds value in high-stakes environments.

## The Proportionality Requirement — Matching Actions to Risk Level

Clause 6.1.2 explicitly requires that actions to address risks be proportionate to their potential impact on product conformance and customer satisfaction. This proportionality principle has two dimensions that must both be honored:

- High-priority risks require substantive planned actions — not monitoring alone. A risk scored as high likelihood and high impact cannot be addressed solely by noting it in the register. It requires a concrete action plan: who will do what, by when, to reduce either the likelihood or the impact or both.
- Low-priority risks do not require elaborate treatment. The standard explicitly notes (in the Note to Clause 6.1.1) that "retaining the risk by informed decision" is a valid option. An organization that has considered a low-likelihood, low-impact risk, has documented its assessment, and has concluded that no action beyond monitoring is warranted is fully conforming. Not every risk requires an action plan.

## The Effectiveness Evaluation Requirement

Clause 6.1.2(b)(2) requires the organization to evaluate the effectiveness of the actions taken to address risks and opportunities. This is a frequently overlooked element — organizations build risk registers and define actions but never close the loop by assessing whether those actions worked.

Practical effectiveness evaluation approaches:

- Include risk register review in the management review agenda. If a risk action was implemented since the last review, report on whether the risk likelihood or impact changed as a result. Has the alternate supplier qualification (R-02 in the example) been completed? Has the material dependency risk actually been reduced?
- Include risk register items as internal audit targets. When auditing the processes associated with specific risks, verify that the planned risk actions were implemented and observe whether the risk conditions have improved.
- Update risk scores annually based on action effectiveness and changes in the risk environment. A risk whose score has not changed over two years — despite actions being taken — either indicates the actions were ineffective or the risk was not well-understood.

## Opportunities — The Underused Half of Clause 6.1

The word "opportunities" appears in Clause 6.1's title and requirements but rarely receives the same attention in implementation as risks. ISO 9001:2015's Note 2 explicitly expands on what opportunities can encompass: adoption of new practices, new products, new markets, new customers, partnerships, and new technology. Organizations that treat Clause 6.1 as purely a risk management requirement miss half of its designed value.

Opportunity identification in the QMS context should ask: where are the conditions in our environment, our capabilities, or our customer relationships that could be leveraged to improve quality performance, advance quality objectives, or create competitive advantage through quality? The answers to these questions should feed both the risk register and the quality objectives development process in Clause 6.2.

### Common Pitfall

The three most persistent Clause 6.1 failures: First, the generic risk register — filled with risks like "regulatory changes may affect operations" and "customer requirements may change" that apply to every organization in every industry and demonstrate no specific understanding of the organization's actual risk environment. Second, the static register — completed during implementation and never reviewed or updated despite significant organizational and environmental changes. Third, the disconnected register — risks identified that have no evident connection to how the QMS was designed; auditors routinely ask "can you show me how risk R-03 influenced this procedure?" If the answer is "it didn't," the register is not functioning as planned. The test of a useful risk register is not whether it exists but whether it demonstrably shaped decisions.

### Kaizen Connection

The Process FMEA is the most powerful bridge between ISO 9001:2015's risk-based thinking requirement and Lean Six Sigma methodology. A well-executed PFMEA for a key production process simultaneously satisfies Clause 6.1 risk identification, directly informs the Clause 8.1 operational control plan, identifies the measurement and monitoring needs captured in Clause 9.1, and generates improvement priorities for the Clause 10.3 CI agenda. Organizations that maintain current PFMEAs for their highest-risk processes and link those PFMEAs to their ISO 9001 control plans and risk register have integrated risk-based thinking at the deepest operational level — far exceeding what a stand-alone risk register achieves.


### Meridian Case Study

Meridian Risk Register in the First Certification Year: Meridian's initial risk register, built in Phase 1 of the implementation, contained 11 risks and 4 opportunities. By the end of Year 1 post-certification, the register had been reviewed twice — once at the Month 10 management review (during the implementation) and once at the Month 18 post-certification management review. The review at Month 18 produced three significant updates: R-01 (knowledge transfer risk) was partially mitigated — the organizational knowledge documentation was complete and cross-training was underway, reducing likelihood from 3 to 2; O-01 (certification enabling new program tier access) had been realized — Meridian was awarded a bid on one of the newly accessible programs, so the opportunity was reclassified as achieved; and two new risks were added based on operating experience — an identified capacity constraint in CMM inspection during peak production periods (a new risk not visible at implementation) and a documentation compliance risk in the design change control process revealed by the Stage 2 audit finding. The management review output that authorized the CMM capacity risk action plan — purchase of a second CMM — was the first direct risk-register-to-capital-investment linkage in Meridian's history. Denise cited this connection in her post-Year-1 quality report as evidence that the risk register had become a genuine management tool rather than a compliance document.

### Auditor Perspective

Registrar auditors evaluate Clause 6.1 through three lines of inquiry. First, existence and currency: is there a risk register, and is it current? A register with a creation date but no review or update date is a red flag. Second, specificity and authenticity: are the risks specific to this organization's actual situation, or are they generic? Specific risks reference named suppliers, specific process vulnerabilities, identified customer requirements, and named regulatory requirements. Generic risks do not. Third, connection: can the Management Representative trace from a risk in the register to a specific QMS design decision, process control, or improvement action that addresses it? If the answer is no for the highest-priority risks, the register has not functioned as Clause 6.1 intends.

## Clause 6.2 — Quality Objectives and Planning to Achieve Them

 Standard Requirement
ISO 9001:2015, Clause 6.2.1: "The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate."
Clause 6.2.2: "When planning how to achieve its quality objectives, the organization shall determine: a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated."

### Quality Objectives as Management Tools, Not Compliance Items

The quality objective requirement is where many organizations reveal the clearest gap between conforming documentation and genuine quality management. An objective that is listed in a register, assigned a target number, and then never reviewed between management reviews is technically conforming to Clauses 6.2.1(b) and (e) — until an auditor asks for the monitoring data and finds it does not exist, or asks about the most recent results and finds that management cannot describe them.

Genuine quality objectives are active management tools: they define where the QMS is headed in measurable terms, they are reviewed regularly against actual performance, and they trigger informed decisions when performance is off-track. The difference between a compliance objective and a management objective is not in the documentation — it is in whether the organization actually manages to them.

### The Seven Requirements for Quality Objectives

Clause 6.2.1 lists seven requirements that every quality objective must meet. Each has implementation implications:

Requirement	What It Means and Common Implementation Failures
"Consistent with the quality policy"	Objectives must logically derive from the policy's commitments — a policy that commits to customer satisfaction must have a customer satisfaction objective; a policy that commits to continual improvement must have improvement objectives. Inconsistency between policy and objectives signals that one or both was developed without consideration of the other. Auditors routinely ask to see the connection between specific policy language and specific objectives.
"Be measurable"	Every objective must have a defined metric with a numeric or otherwise verifiable target. "Improve customer satisfaction" is not measurable. "Achieve a customer satisfaction score of 4.2 out of 5.0 on the annual survey" is measurable. The target must be specific

Requirement	What It Means and Common Implementation Failures
	enough that any observer can determine at any point whether the objective has been achieved or not.
"Take into account applicable requirements"	Objectives should reflect the requirements of relevant interested parties — particularly customers' quality expectations and applicable regulatory standards. An objective to reduce rework should reflect the customer's tolerance for quality escapes, not just the organization's internal cost preferences. An objective for regulatory compliance reporting accuracy should reflect the specific regulatory deadline requirements.
"Relevant to conformity of products and services and to enhancement of customer satisfaction"	Both of these relevance dimensions must be addressed across the set of objectives. An objective set that focuses entirely on internal process metrics without any customer-facing outcome measures fails the customer satisfaction relevance requirement. An objective set that focuses only on customer satisfaction without addressing product conformance metrics misses the product conformance dimension.
"Be monitored"	Monitoring must be active and regular — not annual. Monthly monitoring against a defined baseline is the minimum meaningful frequency for operational quality objectives. Some objectives (daily production yield, for example) warrant daily monitoring. The monitoring record must be retrievable to demonstrate to auditors that monitoring actually occurred.
"Be communicated"	Objectives must reach the people whose work affects whether they are achieved — not just the quality manager and senior leadership. A first-pass yield objective that operators are unaware of cannot influence operator behavior. Communication must be specific: not "we have quality objectives" but "our first-pass yield target is 95%, we are currently at 92%, and here is what that means for your work."
"Be updated as appropriate"	Objectives must evolve as circumstances change. An objective that has been achieved should be replaced by a more ambitious target or a different quality dimension. An objective whose target was set based on incorrect assumptions should be revised when better information is available. Annual review and update is standard practice; significant organizational or customer changes may warrant interim updates.

## Clause 6.2.2 — The Achievement Plan

Clause 6.2.2 is the planning discipline that turns a list of objectives into a managed program. Each quality objective must have a documented plan addressing five specific questions. This is not bureaucratic formality — it is the difference between an aspiration and a commitment:

Planning Element	What Must Be Determined and Why It Matters
(a) What will be done	The specific actions — not vague intentions — that will drive performance toward the target. "Improve supplier quality" is not an action. "Conduct quarterly supplier quality reviews with the top five suppliers by volume, with documented action plans for any supplier below 98% on-time delivery" is an action. Actions must be specific enough that progress can be verified.

Planning Element	What Must Be Determined and Why It Matters
(b) What resources will be required	The investment — time, money, equipment, personnel — needed to execute the actions. Objectives without resource allocation are organizational wishes. Identifying required resources forces a realistic assessment of whether the objective is achievable given what the organization is willing to invest. Resource requirements should be approved and tracked against actuals.
(c) Who will be responsible	A named role or individual — not a department or committee — who owns the objective's achievement. Ownership without a name attached is diffused responsibility that no one manages. The responsible person should have sufficient authority over the processes that affect the objective to be genuinely accountable for performance against target.
(d) When it will be completed	A specific target date for objective achievement — typically the end of the planning period (annual), with intermediate milestones for objectives with long achievement timelines. An objective without a date has no urgency and no mechanism for detecting whether progress is on schedule.
(e) How the results will be evaluated	The method for determining whether the objective has been achieved at the target date. For quantitative objectives, the evaluation method is straightforward: compare the metric at evaluation date to the target. For more complex objectives, the evaluation method should be defined in advance — not left to post-hoc interpretation.

## Setting Objectives at Relevant Functions, Levels, and Processes

The standard requires quality objectives to be established at "relevant functions, levels, and processes" — meaning objectives should exist not only at the organizational level but should cascade to the functions and process levels where they can drive operational behavior change.

The cascading objective model translates organizational-level quality targets into function-level performance expectations that individual department managers and supervisors can be held accountable for:

Organizational-Level Objective	Function-Level Cascade	Process-Level Cascade
Reduce customer-reported nonconformance rate from 2,200 PPM to under 1,000 PPM by Year-end	Operations: Reduce internal first-pass rejection rate from 8.3% to under 5% by Year-end Quality: Achieve 100% completion of First Article Inspection for all new jobs within 30 days of first production run Engineering: Complete design review documentation within 5 business days of design freeze for all projects	CNC Machining: Reduce dimensional rejection rate for critical features from 4.2% to under 2% by Q3 Inspection: Achieve 100% first-piece inspection completion on Line 1 and Line 2 by Q2
Achieve on-time delivery rate of 95% by Q3	Operations: Achieve schedule attainment (production to plan) of 97% or higher on monthly basis Purchasing: Achieve supplier on-time delivery rate of 98% for critical material suppliers Sales:	Production Planning: Issue production travelers to shop floor minimum 5 days before required start date for all jobs Purchasing: Place purchase orders for long-

Organizational-Level Objective	Function-Level Cascade	Process-Level Cascade
	Complete customer order review within 24 hours of order receipt 100% of the time	lead materials minimum 10 days before required delivery

## Baseline Setting — The Starting Point for Every Objective

Every quality objective requires a defined baseline — the current performance level from which improvement will be measured. An objective without a baseline cannot be evaluated for achievement: "reduce customer returns" says nothing if you do not know the starting rate. Baseline setting has practical implications for implementation timing: the baseline should be established from real performance data, which means the measurement system must be operational before the objective can be validly baselined.

When an organization is establishing objectives for the first time during QMS implementation, some metrics may not have historical data available. In these cases, the approach is to establish the measurement system and data collection process, collect a defined period of baseline data (typically 30 to 90 days), and set the improvement target against the documented baseline. An objective whose baseline is "not currently tracked" should be accompanied by an interim plan to establish the measurement before the target-setting cycle.

## Quality Objectives and the Management Review Connection

Quality objectives are a mandatory input to the management review (Clause 9.3.2(e)) and a primary mechanism through which the management review drives organizational quality improvement. The management review should examine not only current performance against each objective but the trend — is performance improving, stable, or declining? And for objectives that are off-track, the management review should produce a documented decision: is the action plan adequate, does it need adjustment, or does the target need to be revised?

A management review that examines quality objectives and produces no decisions or actions reveals one of two problems: either all objectives are being achieved (which should prompt a discussion about whether the targets are ambitious enough) or the review is not engaging substantively with performance gaps. Either way, the management review output should document the conclusion and any resulting decisions.

### Best Practice

Build a quality objectives dashboard as a controlled document that is updated monthly and reviewed at every management review. The dashboard should show each objective with five data points: the policy commitment it supports, the baseline, the current performance, the target, and a RAG status indicator (Green = on track or achieved, Amber = within 10% of target, Red = more than 10% below target). Make the dashboard visible beyond the quality team — post it on the production floor for operational objectives, share it with department managers for their function-level objectives, and present it at all-hands meetings for organizational-level objectives. Visibility creates accountability that no amount of private reporting can achieve.

### Meridian Case Study

Meridian Quality Objectives in Year 1 Post-Certification: Six objectives were established at certification. By Month 18 (the second management review post-certification), four had been achieved, one was on track, and one required intervention. The achieved objectives: (1) On-time delivery reached 94% against a 95% target — within measurement variability of the target and trending upward, reclassified as achieved with a revised target of 96.5% for Year 2; (2) first-pass yield improved from 8.3% to 5.6% against a 5% target — achieved; (3) corrective action on-time closure reached 91% against a 90% target — achieved; (4) all implementation milestones completed on or before schedule — achieved and retired. The on-track objective: supplier on-time delivery at 94.8% against a 96% target, improving consistently month over month. The intervention objective: customer PPM at 1,240 against a 1,000 PPM target — not achieved, but the rate had improved from 2,200 PPM at baseline, representing a 44% improvement. The management review decision: revise the Year 2 target to 1,100 PPM (achievable given current trend) rather than resetting to the original 1,000 PPM target (which analysis suggested required a supplier quality improvement that was already in progress but not yet complete). This was a genuine management decision based on real data — exactly what quality objectives are designed to produce.

## Clause 6.3 — Planning of Changes

### Standard Requirement

ISO 9001:2015, Clause 6.3: "When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner. The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the assignment or reassignment of responsibilities and authorities."

### What Clause 6.3 Is and Is Not Requiring

Clause 6.3 is specifically about planned changes to the QMS itself — not changes to products, designs, or production processes (those are addressed in Clause 8.5.6). It requires that when the organization decides to change its quality management system — revising a procedure, restructuring process ownership, adding a new QMS process, changing the scope — those changes be made in a controlled, planned manner that preserves QMS integrity.

The clause does not require a formal change management procedure (though many organizations create one) or a change control board. It requires that the four considerations listed — purpose and consequences, QMS integrity, resources, and responsibility assignment — be thought through before changes are implemented. Evidence of this planning can be as simple as a documented discussion in a management review, a procedure revision request form that captures these considerations, or a structured change proposal submitted for approval.

### The Four Change Planning Considerations

Consideration	What It Requires and Why It Matters
(a) Purpose of the change and potential consequences	Every QMS change should have a documented rationale — why is this change being made? What problem does it solve, what improvement does it enable, or what requirement does it address? Equally important: what are the potential unintended consequences of the change? A procedure revision that simplifies one process may create a gap in another. A restructuring of process ownership may leave previously assigned responsibilities uncovered. Thinking through consequences before implementing prevents rework.
(b) The integrity of the quality management system	Changes to one part of the QMS can affect others in ways that are not immediately obvious. A change to the document control procedure affects every procedure it governs. A change to the corrective action process affects how audit findings, customer complaints, and internal nonconformances are handled. Clause 6.3 requires that QMS integrity — the system's ability to function as a coherent whole — be considered and protected through each change.
(c) Availability of resources	Changes to the QMS require resources to implement and sustain. A new monitoring requirement requires someone's time. A revised

Consideration	What It Requires and Why It Matters
	<p>procedure requires training of affected personnel. A restructured process ownership requires the new owner to develop competence. If resources are not available to support the change through its full implementation cycle, the change will be planned but not effectively executed — producing a documented QMS that diverges from actual practice.</p>
(d) Assignment or reassignment of responsibilities and authorities	<p>QMS changes frequently affect who is responsible for what. A new process requires an owner. A reorganization may move responsibility for a quality function from one manager to another. These responsibility changes must be explicitly addressed — not assumed to follow naturally from an organizational chart update. The Clause 5.3 requirements for communicated and understood responsibilities apply to the post-change state as much as to the original system.</p>

## When Does Clause 6.3 Apply?

Practitioners frequently ask where the threshold is for applying Clause 6.3 — which changes are significant enough to require the planning considerations, and which are routine enough to be handled under normal document control? The practical answer:

Change Type	Clause 6.3 Application
QMS scope changes — adding or removing products, services, sites, or clause applicability	Always apply Clause 6.3. Scope changes affect the entire certification boundary and require structured evaluation of all four considerations before implementation. Scope changes also require notification to the registrar.
Significant procedure revisions — changing how a core process operates	Apply Clause 6.3. Document the rationale for the change, assess the impact on related processes and records, ensure training resources are available, and confirm that the revised procedure is owned by an appropriate role.
New QMS processes — adding a process not previously in the QMS	Apply Clause 6.3. New processes require ownership assignment, procedure development, training, records system setup, and performance measure definition — all resource-dependent planning decisions.
Minor procedure corrections — correcting a typographical error, updating a form version number, correcting a document reference	Normal document control is sufficient. These changes do not affect how processes operate and do not require the full Clause 6.3 planning consideration.
Organizational restructuring affecting QMS process ownership	Apply Clause 6.3. Role changes, department restructuring, and management changes that affect who owns QMS processes require the responsibility/authority consideration and often the resource and consequence considerations as well.
Technology changes affecting QMS tools — new document management	Apply Clause 6.3. Technology changes can significantly affect document control, records accessibility, and process execution. The integrity consideration is particularly important

Change Type	Clause 6.3 Application
system, new ERP system affecting records management	— ensuring the QMS functions correctly in the new technical environment before the old one is decommissioned.

## Integrating Clause 6.3 with Document Control

Most organizations implement Clause 6.3 through two integrated mechanisms: a procedure change request process and the document control system. When a change to a QMS procedure is proposed, the change request form captures the four Clause 6.3 considerations — purpose, integrity assessment, resources needed, and responsibility assignment. The completed form routes through the appropriate approval authority. Once approved, the change is implemented through the document control procedure: the revised document is issued, the previous version is archived, and affected personnel are trained before the effective date.

This integration means Clause 6.3 planning is embedded in the normal operational workflow rather than being a separate bureaucratic layer. The change request form is a Clause 6.3 planning record. The document control approval workflow is the Clause 6.3 authorization mechanism. The training record created when personnel are briefed on the revised procedure is the evidence that resource requirements were met. One coherent workflow satisfies both clauses.

## The Planning Integration — How Clauses 6.1, 6.2, and 6.3 Work Together

Clause 6 is most powerful when its three subclauses function as an integrated planning system rather than three independent compliance requirements. The integration logic:

- The context analysis (Clause 4.1) and interested party review (Clause 4.2) feed identified risks and opportunities into the Clause 6.1 risk register. The risk register in turn generates two types of outputs: actions to reduce high-priority risks (risk treatment actions) and improvement targets for high-priority opportunities (which become quality objectives in Clause 6.2).
- Quality objectives (Clause 6.2) define where the QMS is going in measurable terms. The achievement plans for each objective include planned changes to processes, procedures, or resources. When those planned changes affect the QMS itself, they trigger the Clause 6.3 change planning consideration.
- Changes to the QMS (Clause 6.3) may generate new risks (a changed process introduces new failure modes) and new opportunities (a new capability enables pursuit of previously unavailable customers), which feed back into the Clause 6.1 risk register. The planning cycle is continuous.

QMS Element	Feeds Into	Example Connection
Clause 4.1 Context Analysis	Clause 6.1 Risk Register	Context identifies MBD adoption trend as an external technological issue (R-03 in Meridian example) → risk register entry → training action and procedure update planned
Clause 6.1 Risk Register	Clause 6.2 Quality Objectives	High-priority risk of knowledge loss (R-01) → opportunity to improve knowledge documentation as QMS capability → quality objective: complete organizational knowledge documentation for 5 critical process areas by Q2
Clause 6.1 Risk Register	Clause 8.1 Operational Controls	Process FMEA for CNC machining identifies high RPN for dimensional nonconformance on critical features; control plan updated with increased first-piece inspection frequency; connects to Clause 8.5 production control
Clause 6.2 Quality Objectives	Clause 6.3 Change Planning	Objective to reduce customer PPM requires implementing Statistical Process Control for critical machining dimensions → new QMS monitoring process → Clause 6.3 change planning for new SPC procedure and monitoring responsibility assignment
Clause 6.3 Change Planning	Clause 6.1 Risk Register	New ERP system implementation changes records management approach for production records → new risk entry: records accessibility during system transition → planned action to maintain parallel systems during transition period
Clause 9.3 Management Review	All of Clause 6	Management review evaluates risk register currency and objective performance → decisions to update risk scores, revise objective targets, or authorize changes to QMS processes → outputs feed directly back into all three Clause 6 subclauses

## Quick Reference: Clause 6 Audit Readiness

### Clause 6.1 Conformance Checklist

	Conformance Item
<input type="checkbox"/>	Risk and opportunity register exists and is specific to this organization — no generic risks that could apply to any company in any industry
<input type="checkbox"/>	Risks and opportunities are traceable to the context analysis (Clause 4.1) and interested party analysis (Clause 4.2)
<input type="checkbox"/>	Both risks (threats to QMS effectiveness) AND opportunities (conditions to be leveraged for improvement) are included
<input type="checkbox"/>	Each risk and opportunity has a documented priority assessment (likelihood, impact, or equivalent scoring)
<input type="checkbox"/>	High-priority risks have substantive planned actions — not just monitoring — with owners and target dates
<input type="checkbox"/>	Actions are proportionate to potential impact — not every risk has an elaborate action plan; low-priority risks may legitimately be monitored or accepted
<input type="checkbox"/>	Effectiveness of risk actions is periodically evaluated — scores updated and actions assessed for impact
<input type="checkbox"/>	Risk register reviewed and updated at each management review — management review minutes reference the risk register
<input type="checkbox"/>	Can demonstrate connection between specific risks in the register and specific QMS design decisions or process controls

### Clause 6.2 Conformance Checklist

	Conformance Item
<input type="checkbox"/>	Quality objectives established at organizational, function, and process levels — not only at the top level
<input type="checkbox"/>	Each objective is measurable with a numeric or otherwise verifiable target and a defined baseline
<input type="checkbox"/>	Objectives logically connect to the Quality Policy commitments — the policy-to-objective chain is traceable
<input type="checkbox"/>	Objectives address both product conformance and customer satisfaction dimensions
<input type="checkbox"/>	Each objective has a documented achievement plan: what will be done, resources, responsible owner, completion date, evaluation method
<input type="checkbox"/>	Objectives are monitored on a regular cadence (monthly minimum for operational objectives) with retrievable monitoring records

	Conformance Item
<input type="checkbox"/>	Objectives are communicated to the personnel whose work affects them — not just to the quality team and senior leadership
<input type="checkbox"/>	Off-track objectives generate management review discussion and documented decisions — not passive acceptance
<input type="checkbox"/>	Objectives are reviewed and updated at each planning cycle — achieved objectives are replaced or elevated, not left as permanent fixtures

## Clause 6.3 Conformance Checklist

	Conformance Item
<input type="checkbox"/>	A mechanism exists for planning changes to the QMS before implementing them — whether a formal change request form, a documented management review decision, or a procedure revision process that captures the four considerations
<input type="checkbox"/>	QMS changes document the purpose and rationale — not just what changed but why
<input type="checkbox"/>	Impact on related QMS processes and documents is considered before changes are implemented — no change is treated as isolated from the rest of the QMS
<input type="checkbox"/>	Resources required to implement and sustain the change are identified and secured before implementation
<input type="checkbox"/>	Responsibility assignments affected by the change are explicitly updated — not assumed to follow automatically from organizational changes
<input type="checkbox"/>	Training records exist for affected personnel following QMS procedure changes

## Most Common Clause 6 Audit Findings

Finding Area	Clause	Typical Finding Statement
Generic risk register	6.1	Risk register contains risks stated at a level of generality that applies to any organization in any industry (e.g., "customer requirements may change," "regulatory environment may evolve"). No risks are specific to this organization's processes, suppliers, customers, or operational environment.
Static risk register	6.1	Risk register shows creation date during QMS implementation with no subsequent review or update. Significant organizational changes (two new aerospace customers, one key supplier financial distress situation) since creation are not reflected in the current register.
No risk-to-QMS connection	6.1	Management Representative was unable to demonstrate a connection between any risk in the register and a specific QMS process control, procedure design decision, or quality objective. Risk register appears to exist as a compliance

Finding Area	Clause	Typical Finding Statement
		document without functional integration into QMS decision-making.
Objectives not measured	6.2	Quality objectives are documented with numeric targets but no monitoring data was available. Management Representative confirmed that the "on-time delivery" objective metric has not been captured monthly as the procedure requires — measurement has not been consistently conducted.
No achievement plan	6.2	Three of five quality objectives do not have documented achievement plans addressing what will be done, who is responsible, what resources are required, the completion date, and how results will be evaluated, as required by Clause 6.2.2.
Objectives not communicated	6.2	Five operators and two supervisors interviewed in the production area were unable to describe any quality objectives relevant to their work. One supervisor stated "I think there are some quality targets but I do not know what they are."
QMS change without planning	6.3	Review of procedure change records revealed that MPC-PRO-008 (Machining Process) was revised in Month 15 post-certification. No change request record or equivalent documentation captures the Clause 6.3 planning considerations — purpose, QMS integrity assessment, resources, and responsibility assignment — for this change.

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*Next in Volume 2: Guide 2.3 — Clause 7: Support. Deep-dive coverage of resources (7.1) including infrastructure and calibration (7.1.5), organizational knowledge (7.1.6), competence (7.2), awareness (7.3), communication (7.4), and documented information (7.5) — the full support layer that enables every other QMS element to function with adequate capability, evidence, and control.*

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