ISO 9001 Documentation
Impact Analyses

1. Purpose

The purpose of this document is to define the process for managing changes that may affect the Quality Management System (QMS), products, services, processes, or related documented information, in accordance with ISO 9001:2015 requirements. This includes establishing a structured Change Management procedure and conducting Impact Analyses to evaluate the effects of such changes before implementation, to ensure continued conformity, minimize risks, and maintain the effectiveness of the QMS.

2. Scope

This procedure applies to all planned and unplanned changes that may impact:

- The QMS (processes, procedures, controls)
- Products or services (design, functionality, specifications)
- Production or service delivery processes
- Equipment, tools, or technology
- Materials, suppliers, or subcontractors
- Organizational structure, roles, or responsibilities
- Legal, regulatory, or customer requirements
- Documented information (policies, procedures, work instructions, forms)

It encompasses the full lifecycle of a change, including:

- Identification
- Evaluation (Impact Analysis)
- Planning
- Approval
- Implementation
- Verification / Validation
- Review / Post-implementation evaluation

3. References

- ISO 9001:2015 – Quality management systems – Requirements

(Clauses: 4.4, 6.3, 8.1, 8.3.6, 8.5.1, 10.2, 10.3)

- Organization's Quality Manual
- Document Control Procedure
- Risk Management Procedure
- Control of Nonconforming Outputs Procedure
- Corrective and Preventive Action (CAPA) Procedure

4. Definitions

Term	Definition
Change	Any modification, addition, or removal of processes, procedures, resources, tools, systems, materials, or documented information that may affect quality, compliance, or performance.
Change Request	A formal proposal to initiate a change, including the reason, scope, and expected outcomes.
Impact Analysis	A systematic evaluation of the potential effects a proposed change may have on processes, quality, compliance, safety, cost, schedule, or stakeholders.
Change Owner	The individual or department responsible for initiating, managing, and implementing the change.
Change Approver	The authorized person or group who evaluates and approves or rejects the change based on its impact and risk.
Planned Change	A change that is scheduled and evaluated in advance.
Unplanned Change	A change that occurs unexpectedly (e.g., emergency fix, urgent supplier substitution) and is managed retrospectively with proper controls.

5. Responsibilities

Role	Responsibility
Change Initiator / Requester	Identifies the need for change, submits a Change Request, and provides initial information on the nature and rationale.
Change Owner	Leads the change process, coordinates impact analysis, prepares implementation plans, and ensures post-change verification.
Impact Analysis Team	Conducts evaluation of effects across affected areas (quality, safety, cost, compliance, operations, etc.).
Change Approver(s)	Review and approve or reject the change request based on analysis, risk, and benefit.
Implementing Team	Executes the approved change in line with the defined plan.
Quality Assurance / Management Representative	Ensures that the change complies with ISO 9001 requirements and that proper controls are in place.
Document Controller	Updates controlled documentation affected by the change and ensures version control.

6. Change Management Process

6.1 Change Identification and Request

Any individual or department identifying the need for a change shall submit a Change Request that includes:

- Description of the proposed change
- Reason or trigger for the change (e.g., customer request, incident, improvement, regulation)
- Affected processes, products, systems, or documentation
- Expected benefits or objectives
- Urgency / priority level

6.2 Initial Assessment

The Change Owner or QA representative performs an initial assessment to determine:

- Whether the change is necessary
- The scope and magnitude of the change
- Whether a full Impact Analysis is required

6.3 Impact Analysis (Mandatory for Significant Changes)

An Impact Analysis is conducted to evaluate the effects of the proposed change on:

Area	Considerations
Product/Service Quality	Will the change affect specifications, performance, reliability, or customer requirements?
Process Effectiveness	Will it alter workflow, cycle time, resource needs, or controls?
Compliance / Regulations	Does the change align with legal, regulatory, or industry standards?
Risk	Are there new or increased risks (safety, quality, operational)?
Cost & Resources	What are the financial, manpower, or equipment implications?
Schedule / Delivery	Will lead times, delivery, or project milestones be impacted?
Documented Information	Which procedures, work instructions, forms, or records will need updating?
Customers / Suppliers	Will external parties be affected? Do they need to be informed or involved?
Training Needs	Will personnel require new or updated training?

The Impact Analysis shall be documented, including:

- Assumptions made
- Identified risks and mitigations
- Recommended actions
- Approval recommendations

Note:Not all changes require a full impact analysis. Minor or low-risk changes may be pre-approved or managed through a simplified process, but must still be controlled.

6.4 Change Evaluation and Approval

Based on the Impact Analysis, the Change Approver(s) will:

- Review the justification, risks, benefits, and readiness
- Approve, reject, or request further information
- Define any conditions or constraints for the change

Approval is documented with:

- Name and title of approver(s)
- Date
- Approval decision and comments

6.5 Change Planning and Implementation

For approved changes, a Change Implementation Plan is developed, covering:

- Tasks and responsibilities
- Timeline and milestones
- Resource requirements
- Communication plan
- Documentation updates
- Training needs
- Risk mitigation actions

The plan is executed according to schedule, with oversight by the Change Owner.

6.6 Verification and Validation

After implementation, the change is verified to ensure:

- ❖ It has been properly executed
- ❖ The expected outcomes are achieved
- ❖ No adverse effects have occurred

Where applicable, validation is performed to confirm fitness for purpose (e.g., new product design, process capability).

6.7 Post-Implementation Review

A review is conducted to assess:

- ❖ The success of the change
- ❖ Any unintended consequences or issues
- ❖ Lessons learned
- ❖ Opportunities for further improvement

Findings are documented and, if necessary, lead to corrective actions or adjustments.

7. Control of Emergency / Unplanned Changes

In cases where a change must be implemented urgently (e.g., safety issue, equipment failure, supply disruption), the following applies:

The change is implemented with immediate containment or corrective action

- ❖ A retrospective Change Request and Impact Analysis is completed as soon as possible
- ❖ Approval is obtained retrospectively or by authorized emergency personnel
- ❖ The change is monitored and formally reviewed afterward

All emergency changes are logged, tracked, and controlled to prevent recurrence or nonconformance.

8. Documentation and Records

The following records are maintained as part of the Change Management and Impact Analysis process:

- Change Request Forms
- Impact Analysis Reports
- Change Approval Records
- Change Implementation Plans
- Verification / Validation Results
- Post-Implementation Review Reports
- Training Records
- Communication Logs

These records are retained per the Controlled Record Retention Policy and are subject to internal audit and management review.

9. Integration with Other Processes

Change Management is integrated with:

- Risk Management – to identify and mitigate risks associated with change
- Corrective and Preventive Action (CAPA) – when changes arise from incidents or nonconformities
- Document Control – to ensure all affected documentation is updated
- Training Management – to ensure personnel are trained on new or revised processes
- Management Review – where significant changes and their impacts are discussed

10. Compliance with ISO 9001:2015

This Change Management and Impact Analysis process supports compliance with the following ISO 9001:2015 clauses:

- Clause 4.4 – Understanding the organization and its context; QMS and its processes
- Clause 6.3 – Planning of changes to the QMS
- Clause 8.1 – Operational planning and control (managing changes to processes)
- Clause 8.3.6 – Design and development changes (if applicable)

- Clause 8.5.1 – Control of production and service provision (ensuring changes do not cause nonconformities)
- Clause 10.2 – Nonconformity and corrective action (changes resulting from incidents)
- Clause 10.3 – Continual improvement (changes to enhance performance)

11. Conclusion

A structured Change Management and Impact Analysis process is essential to proactively manage modifications within the Quality Management System and ensure that all changes contribute positively to quality, efficiency, and compliance. By assessing risks, understanding impacts, planning carefully, and reviewing outcomes, the organization ensures that changes are implemented safely, effectively, and in full alignment with ISO 9001 requirements.

12. Revision History of This Document

Rev No.	Date	Revised By	Approved By	Description
v1.0	2025-10-29	John Wang	Janice Lee	Initial release of ISO 9001 Documentation - Impact Analyses

Note: All controlled documents must be accessed through authenticated and approved channels. Employees must notify QA/Document Control in case they identify outdated or conflicting versions.

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