ISO 9001 Documentation
Validation After Changes

1. Purpose

The purpose of this document is to define the requirements and process for performing Validation After Changes within the Quality Management System (QMS), in accordance with ISO 9001:2015. This ensures that any change made to processes, products, services, systems, or documented information is assessed post-implementation to confirm that it functions as intended, meets specified requirements, and does not adversely affect quality, safety, compliance, or performance.

Validation after changes is a critical control to ensure continued conformity of outputs and the effectiveness of the modified process or system.

2. Scope

- This procedure applies to all changes that have the potential to impact:
- Product or service design, specifications, or performance
- Manufacturing or service delivery processes
- Equipment, tools, machinery, or technology
- Materials, components, or software
- Suppliers or subcontractors
- Process controls, parameters, or methods
- Documented information (procedures, work instructions, forms)
- Organizational structure or responsibilities

It covers the activities required to validate that the change has been implemented correctly and achieves the intended outcome without introducing new risks or nonconformities.

3. References

ISO 9001:2015 – Quality management systems – Requirements
(Clauses: 8.3.6, 8.5.1, 8.6, 10.2, 10.3)

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

4. Definitions

Term	Definition
Validation After Changes	The process of confirming, through objective evidence, that a change has been implemented correctly, functions as intended, and meets all specified requirements after it has been executed.
Change	Any modification to processes, products, systems, tools, materials, or documentation that could affect quality, safety, performance, or compliance.
Intended Outcome	The expected result or performance level that the change was designed to achieve.
Objective Evidence	Quantifiable or observable information (e.g., test results, inspections, data, measurements) that demonstrates conformity or performance.
Post-Implementation Validation	Activities carried out after a change has been implemented to verify its effectiveness and compliance.
Re-Validation	Full or partial repetition of validation activities when significant changes are made to previously validated processes or systems.

5. Responsibilities

Role	Responsibility
Change Owner	Ensures that validation activities are planned, scheduled, and executed after a change is implemented. Coordinates with relevant departments.
Quality Assurance / Quality Control	Defines validation criteria, reviews validation results, and ensures that outputs meet quality and compliance requirements.
Validation Team / Technical Staff	Conducts the actual validation activities, including testing, inspections, trials, or data analysis.
Process Owner	Provides input on operational readiness, supports validation execution, and ensures that validated processes are followed.
Document Controller	Updates any validated documentation reflecting confirmed results or new process parameters.
Management Representative	Ensures that validation after changes aligns with ISO 9001 requirements and supports continual improvement.

6. When Validation After Changes is Required

Validation after changes is mandatory when the change affects:

- Product design, functionality, or customer specifications
- Manufacturing or assembly processes
- Critical process parameters or tolerances
- Equipment, tooling, or software configurations
- Raw materials or component substitutions
- Testing or inspection methods
- Process controls or automation systems
- Safety-related features or regulatory compliance elements

Validation may also be required for non-critical changes, depending on risk assessment outcomes or historical evidence of potential impact.

Note: If the change has already undergone validation as part of the Impact Analysis or Change Approval phase, a post-implementation confirmation is still required to ensure the change was executed as planned and achieves the intended effect.

7. Validation Process After Changes

7.1 Planning the Validation

- The Change Owner, in coordination with Quality Assurance, shall define:
- Validation Objectives: What needs to be confirmed?
- Validation Criteria: What are the pass/fail or acceptance criteria?
- Scope of Validation: Which processes, outputs, or parameters are in scope?
- Methods & Tools: What tests, inspections, data collection, or trials will be used?
- Responsibilities: Who will perform each validation activity?
- Timeline: When will validation occur (typically after change implementation)?
- Documentation: What records will be created and retained?

7.2 Types of Validation Activities

Validation may include one or more of the following, depending on the nature of the change:

Activity	Description
Testing	Conducting trials or operational tests to confirm performance under defined conditions.
Inspection	Visual or dimensional checks to verify compliance with specifications.
Process Trial / Pilot Run	Running the changed process with controlled inputs to evaluate outputs.
Data Analysis	Reviewing performance data, measurements, or statistical evidence.
Customer / End-User Validation	Obtaining feedback or confirmation from customers .
Re-qualification	For equipment or systems, re-qualifying per defined procedures.
Comparative Analysis	Comparing pre-change and post-change results or behaviors.

7.3 Execution of Validation

- Validation is performed after the change has been fully implemented in the operational environment.
- All activities are conducted using controlled methods and documented evidence.
- Personnel involved are qualified and aware of the validation objectives.
- Any deviations or non-conformities observed during validation are recorded and addressed immediately (e.g., through CAPA or rework).

7.4 Documentation of Validation Results

- The following information is recorded in a Validation Report or equivalent document:
- Description of the change validated
- Validation objectives and criteria
- Methods and tools used
- Date and location of validation
- Persons involved
- Test or inspection results
- Data collected
- Conclusions (pass/fail, meets expectations, or requires rework)
- Sign-off by responsible personnel

8. Review and Decision

Based on the validation results:

- If the validation confirms that the change meets all requirements and produces the intended outcome, the change is formally accepted, and the updated process or product is released for normal use.
- If validation fails or identifies issues, the change is not approved for full use. Corrective actions are initiated, and re-validation may be required after the issues are resolved.
- Decisions are documented, and authorization is obtained from the Change Approver or Quality Manager before proceeding.

9. Post-Validation Actions

- Updated procedures, work instructions, or parameters are released based on validated outcomes.
- Training is provided if new methods or controls are introduced.
- Monitoring may continue for a defined period to ensure ongoing stability (e.g., Statistical Process Control, quality trend reviews).
- Lessons learned are captured for future change planning.

10. Integration with Other Processes

Validation after changes is closely linked with:

- Change Management & Impact Analysis – to determine the need and scope of validation
- Risk Management – to focus validation efforts on high-risk areas
- Control of Nonconforming Outputs – if validation reveals issues
- Corrective and Preventive Action (CAPA) – for addressing validation failures
- Document Control – to ensure validated instructions and parameters are current
- Management Review – where significant validation outcomes may be reported

11. Compliance with ISO 9001:2015

This process supports compliance with the following ISO 9001:2015 clauses:

- Clause 8.3.6 – Design and development changes
- Clause 8.5.1 – Control of production and service provision (ensuring changes do not cause nonconformities)
- Clause 8.6 – Release of products and services (ensuring validated outputs are approved)
- Clause 10.2 – Nonconformity and corrective action (addressing validation failures)
- Clause 10.3 – Continual improvement (learning from validation outcomes)

12. Conclusion

Validation after changes is a vital control mechanism within the ISO 9001 Quality Management System to ensure that any modification — whether to processes, products, systems, or documentation — delivers the intended result without compromising quality, safety, or compliance. By systematically verifying the effectiveness of changes through objective evidence, the organization minimizes risk, ensures consistency, and sustains the reliability of its operations and outputs.

A robust validation process reinforces customer confidence, regulatory compliance, and continual improvement, in full alignment with ISO 9001 requirements.

13. 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 - Validation After Changes

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.

End of Document