ISO 9001 Documentation
Control Plans

1. Purpose

The purpose of this document is to define the requirements for the development, implementation, maintenance, and control of Control Plans within the organization's Quality Management System (QMS), in accordance with ISO 9001:2015. Control Plans are structured documents that outline the specific controls to be applied during the product and process lifecycle to ensure that product characteristics, process parameters, and quality requirements are consistently met, thereby supporting product conformity, process stability, and customer satisfaction.

Control Plans are a key tool for managing variation, ensuring process control, and driving continual improvement.

2. Scope

This procedure applies to the development and maintenance of Control Plans for all:

- New products and processes
- Modified or updated products and processes
- Existing products and processes subject to change or risk assessment
- Products and processes with critical characteristics, regulatory requirements, or high customer impact

Control Plans cover all phases of the product lifecycle, including:

- Prototype / Pre-production
- Production / Mass manufacturing
- Service / Post-launch / End of Life

They apply to all manufacturing, assembly, inspection, and key support processes that influence product quality, performance, or compliance.

3. References

- ISO 9001:2015 – Quality management systems – Requirements
  (Clauses: 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.5.1, 8.6, 10.2)
- IATF 16949 (if applicable, as a common industry extension of ISO 9001 for automotive)
- Organization's Quality Manual
- Advanced Product Quality Planning (APQP) Procedure
- Failure Mode and Effects Analysis (FMEA) Procedure
- Process Validation Procedure
- Inspection and Testing Procedure
- Document Control Procedure
- Record Control Procedure

4. Definitions

Term	Definition
Control Plan	A structured document that describes the controls to be applied to ensure that product and process characteristics are maintained within specified limits throughout the product lifecycle.
Characteristic	A feature of a material, part, product, or process that can be measured, tested, or verified (e.g., dimension, function, tolerance, performance).
Critical / Significant Characteristic	A product or process characteristic that, if not met, could affect safety, compliance, fit, function, performance, or customer satisfaction.
Special Characteristic	A term often used in regulated or automotive industries to denote features that require specific controls due to regulatory, safety, or customer emphasis (may be designated as "CC" for Critical Characteristic or "SC" for Significant Characteristic).
Control Method	The specific action, test, inspection, or process control used to manage variation and ensure compliance.
Reaction Plan	A predefined response to be taken when a control fails or a deviation is detected (e.g., stop production, quarantine, notify supervisor).

5. Responsibilities

Role	Responsibility
Product / Process Engineers	Lead the development of Control Plans in coordination with cross-functional teams.
Quality Assurance / Quality Engineer	Ensures that Control Plans include appropriate controls, inspection methods, and reaction plans. Reviews and approves Control Plans.
Manufacturing / Production	Implements the controls defined in the Control Plan and provides feedback for continuous improvement.
Project / Program Management	Ensures Control Plans are developed in alignment with product launch timelines and customer requirements.
Supplier Quality	Ensures that supplier Control Plans (for outsourced processes) meet the same requirements.
Management Representative	Ensures that Control Plans support the effectiveness of the QMS and compliance with ISO 9001.

6. Control Plan Requirements (ISO 9001:2015 Clauses 8.3.2–8.3.5, 8.5.1)

6.1 General Requirements

The organization shall:

- Develop a Control Plan for any product or process where variation could affect:
- Product conformity
- Customer requirements
- Safety, regulatory, or performance criteria

Ensure that Control Plans are updated when:

- Products or processes are modified
- New risks are identified
- Customer requirements change
- Nonconformities or quality issues occur
- Tailor the level of control based on the risk, complexity, and criticality of the product/process

Control Plans are living documents and shall be maintained throughout the product lifecycle.

7. Control Plan Content

A typical Control Plan includes, but is not limited to, the following elements:

7.1 Basic Information

- Control Plan Number
- Part Number / Description
- Revision Level
- Date / Effective Date
- Prepared By / Approved By
- Organization / Customer Name

7.2 Product / Process Overview

- Product / Process Name
- Phase (Prototype, Pre-production, Production, etc.)
- Key Process Steps / Operations

7.3 Characteristics

- Product Characteristics (e.g., dimensions, tolerances, features, pin assignment)
- Process Characteristics (e.g., size, contrast, temperatures, resolution)
- Special / Critical Characteristics (clearly identified with symbols such as "CC" or "SC")

7.4 Control Methods

- Control Type: Prevention or Detection
- Control Technique: Inspection, measurement, testing, SPC, mistake-proofing, sorting, etc.
- Sample Size & Frequency: Number of samples and how often the control is applied
- Control Location: Where the control is performed (e.g., operation step, inspection station)
- Measurement / Test Equipment: Tools or gages used for control

7.5 Reaction Plan

Actions to be taken when a deviation or nonconformity is detected

Includes:

- Segregation / Quarantine
- Notification of responsible personnel
- Root cause investigation
- Corrective action
- Customer notification (if required)

7.6 Additional Information

Process Flow Diagram references

FMEA references (linkage to Risk Controls)

Operator instructions or visual aids

Training requirements

Records to be maintained

8. Control Plan Development Process

8.1 Input Sources

Control Plans are developed based on inputs from:

- Design FMEA (for product characteristics)
- Process FMEA (for process risks and controls)
- Process Flow Diagrams
- Engineering Drawings and Specifications
- Customer Requirements
- Regulatory and Industry Standards
- Lessons Learned / Historical Data

8.2 Development Steps

- Identify critical product and process characteristics
- Define control methods for each characteristic
- Determine sample sizes, inspection frequencies, and control points
- Develop reaction plans for nonconformance
- Coordinate with cross-functional teams (engineering, production, quality, etc.)
- Review and approve the Control Plan

9. Control Plan Implementation

Control Plans are communicated to relevant functions, including production, quality, and inspection

Controls are integrated into:

- Work instructions
- Inspection plans
- Training programs
- Operator guidance
- Personnel are trained on the application of controls and reaction plans
- Controls are executed as documented and records are maintained

10. Control Plan Maintenance and Updates

Control Plans are reviewed and updated when:

- There is a change in product design or manufacturing process
- New risks or nonconformities are identified
- Customer requirements are modified
- Process improvements are implemented
- New measurement methods or tools are introduced
- Updates are controlled under the Document Control Procedure
- All changes are reviewed and approved by relevant stakeholders

11. Records and Retention

The following records are maintained:

- Control Plan Documents (master and revised versions)
- Control Plan Review and Approval Records
- Revisions and Change Logs
- Supporting Documents (FMEA, Process Flow, Specifications referenced in the Plan)
- Records are retained per the Controlled Record Retention Policy and are available for audits and reviews.

12. Compliance with ISO 9001:2015

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

- Clause 8.3.2 – Design and development planning (controls for product development)
- Clause 8.3.3 – Design and development inputs (requirements for characteristics)
- Clause 8.3.4 – Design and development controls (risk-based controls)
- Clause 8.3.5 – Design and development outputs (control documentation)
- Clause 8.5.1 – Control of production and service provision (process controls)
- Clause 10.2 – Nonconformity and corrective action (reaction planning)

13. Conclusion

Control Plans are essential tools within the Quality Management System for ensuring that product and process characteristics are effectively controlled to meet customer and regulatory requirements. By defining specific controls, inspection methods, and reaction strategies, Control Plans help prevent defects, reduce variation, and drive continuous improvement.
A well-maintained and consistently applied Control Plan supports product quality, operational efficiency, risk management, and customer satisfaction — fully aligned with the principles and requirements of ISO 9001:2015.

14. 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 - Control Plans

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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