ISO 9001 Documentation
Traceability of Parts

1. Purpose

The purpose of this document is to define the requirements and processes for ensuring the traceability of parts used in the organization's products or services, in accordance with ISO 9001:2015. This ensures that all parts, components, materials, and sub-assemblies can be uniquely identified, tracked, and linked throughout the entire product lifecycle — from receipt, through production and assembly, to delivery and service — to support quality control, regulatory compliance, customer requirements, and effective incident management.

2. Scope

This procedure applies to all parts, components, raw materials, sub-assemblies, and finished goods that are:

- Used in the manufacture, assembly, or delivery of products or services
- Subject to customer, regulatory, or internal quality requirements
- Capable of impacting product safety, performance, or conformity

It covers the processes for:

- Assigning unique identification to parts
- Recording and maintaining traceability data
- Controlling part identification throughout the supply chain and production process
- Retrieving traceability information for audits, quality investigations, recalls, or customer requests

3. References

- ISO 9001:2015 – Quality management systems – Requirements (Clauses: 8.5.1, 8.5.2, 8.6, 10.2)
- Organization's Quality Manual
- Control of Production and Service Provision Procedure
- Control of Nonconforming Outputs Procedure

- Incoming Inspection and Testing Procedure
- Document Control Procedure
- Record Control Procedure
- Risk Management Procedure

4. Definitions

Term	Definition
Traceability	The ability to trace the history, application, or location of an item (part, material, or product) by means of recorded identification.
Part	Any component, material, sub-assembly, or ingredient used in the production or delivery of a product or service.
Unique Identifier	A code, number, serial number, batch/lot number, or other distinct marker that uniquely identifies a specific part or batch.
Lot/Batch	A defined quantity of parts or materials produced or received under similar conditions, often tracked as a group.
Traceability Record	Documented information that links a part to its origin, usage, inspection data, and destination.
Upstream Traceability	Tracing the origin and supplier information of a part.
Downstream Traceability	Tracing where a part has been used or installed in finished products.

5. Responsibilities

Role	Responsibility
Procurement / Purchasing	Ensures that incoming parts are accompanied by appropriate identification and traceability data from suppliers.
Receiving / Inspection	Verifies part identification and traceability information upon receipt and records it in the system.
Production / Manufacturing	Maintains part traceability during processing, assembly, and internal movement.
Quality Assurance	Ensures traceability controls are implemented, monitors compliance, and supports traceability investigations.
Inventory / Warehouse	Ensures that parts are stored, handled, and issued in a manner that preserves traceability.
Engineering / Design	Defines part identification requirements, especially for critical or regulated components.
Management Representative	Ensures that traceability processes align with ISO 9001 requirements and support product conformity and customer trust.

6. Requirements for Traceability of Parts (ISO 9001:2015 Clauses 8.5.1, 8.5.2, 8.6)

6.1 General Requirements

The organization shall ensure that:

- Each part or batch of parts is uniquely identified or grouped under a controlled lot/batch number
- Identification is maintained throughout all stages of production, storage, and delivery
- Traceability information is recorded, retained, and retrievable as required
- Traceability is extended to suppliers (upstream) and customers / end products (downstream)as applicable

6.2 Identification Methods

- Parts shall be identified using one or more of the following:
- Serial numbers (for individual critical parts)
- Batch or lot numbers (for non-serialized, homogeneous parts)
- Part numbers (as defined in engineering or procurement documentation)
- Barcodes / QR codes / RFID tags (for automated tracking where applicable)
- Date codes (for shelf life or production date tracking)
- Supplier part numbers (with cross-reference to internal codes)

All identification markings must be legible, durable, and resistant to wear or environmental factors where applicable.

6.3 Traceability Data to Be Maintained

For each part or batch, the following information shall be recorded and maintained:

- Unique part or batch identifier
- Supplier / source information
- Date received or manufactured
- Quantity received or produced
- Inspection or test results
- Location in storage or production
- Usage in specific assemblies, jobs, or orders
- Destination / customer information (for finished goods)

- Date of issue or use
- Any deviations, nonconformities, or corrective actions related to the part

7. Traceability Process

7.1 Incoming Part Traceability

- All purchased parts must include supplier part numbers, batch/lot numbers, or serial numbers, as applicable
- Upon receipt, the Receiving / Inspection function verifies and records the identification data in the material receiving log or ERP system
- Incoming inspection records are linked to the specific part or batch identifiers

7.2 In-Process Traceability

- During production or assembly, parts are tracked through work orders, job numbers, or production batches
- Operators or systems record which parts or batches are used in which assemblies or jobs
- Movement of parts within the facility is controlled to prevent mix-ups or loss of identity
- Barcoding, scanning, or manual logging is used to maintain real-time traceability

7.3 Finished Goods Traceability

- Finished products are linked to the specific parts, batches, or serial numbers used in their assembly
- A finished goods record or certificate of conformity includes full traceability details of critical components
- Shipping or delivery records reference the traceability data of the products shipped

7.4 Downstream / Customer Traceability

- Where required by customer contracts, regulations, or product safety standards, the organization ensures that products can be traced back to every component used

- Traceability data may be provided to customers upon request or for recalls, audits, or warranty claims

8. Control of Nonconforming or Suspect Parts

If a part is found to be nonconforming, defective, or suspect, its unique identifier or batch/lot number is used to quickly identify:

- Where it was used
- Which products or batches are affected
- Whether corrective action (e.g., quarantine, recall, rework) is required
- This enables targeted containment and minimizes disruption or customer impact

9. Recordkeeping and Retention

All traceability records are maintained as controlled quality records

Records include:

- Part identification logs
- Inspection and test records
- Production and assembly records
- Material receipts and issues
- Shipping and delivery documentation
- Traceability reports or queries
- Records are retained for the duration specified in the Controlled Record Retention Policy, in accordance with legal, regulatory, and customer requirements

10. Critical or Regulated Parts

For safety-critical, high-value, or regulated parts (e.g., medical, aerospace, automotive, electronics), enhanced traceability controls are applied, including:

- 100% serialization or unique tracking
- Enhanced supplier documentation requirements
- Strict segregation and labeling
- Additional verification and audit controls

Such parts are identified in risk assessments, control plans, or product specifications.

11. Benefits of Part Traceability

- Ensures product conformity and quality assurance
- Enables rapid response to quality issues, recalls, or customer complaints
- Supports regulatory compliance and customer audits
- Enhances supply chain transparency and accountability
- Facilitates continuous improvement and root cause analysis

12. Compliance with ISO 9001:2015

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

- Clause 8.5.1 – Control of production and service provision (ensuring traceability during operations)
- Clause 8.5.2 – Identification and traceability (core requirement for part and material identification)
- Clause 8.6 – Release of products and services (ensuring traceable, conforming outputs)
- Clause 10.2 – Nonconformity and corrective action (using traceability for effective resolution)

13. Conclusion

Traceability of parts is a fundamental requirement in a robust Quality Management System, ensuring that every component used in production or service delivery can be tracked throughout its lifecycle. By implementing structured identification, recording, and control processes, the organization enhances quality, safety, compliance, and customer trust, while enabling fast and effective responses to quality issues or regulatory requirements.

Maintaining full traceability aligns with ISO 9001:2015 and supports the organization's commitment to delivering reliable, high-quality products and services.

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 - Traceability of Parts

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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