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# 1.0 Purpose

To provide a documented procedure that defines the controls needed for the identification, storage, protection, retrieval, retention & retention time and disposition of documented information that is retained (records) by FDI.

# 2.0 Scope

All quality management system (QMS) related records retained by or required to be retained by FDI.

# 3.0 References

- FDI Quality Management System Manual <7.5.2>
- FDI Quality Policy (Quality Management System Manual Addendum D)
- All FDI documented procedures (SOP's)
- ALL FDI documented work instruction (SWI's)

# 4.0 Requirements

- 4.1 Identification
- 4.1.1 Forms, records and containers used to store records are clearly marked or otherwise identified to make their retrieval and status evident. A list of typical records affected is maintained and retained at the end of this documented procedure.
- 4.1.2 Care is taken to ensure that forms and records are legible. The use of correction fluid or tape is prohibited on purchase orders, certifications and test reports.
- 4.1.3 Corrections to records are made with line outs, initials and dates where appropriate.
- 4.2 Storage
- 4.2.1 Records are temporarily stored in folders and file cabinets located indoors and throughout the facility.
- 4.2.2 Records are stored for the long term in bankers boxes, located in the warehouse, and maintained and retained above the floor.

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- 4.3 Protection
- 4.3.1 Folders and steel file cabinets provide adequate short term protection for records. These records are carefully handled to ensure that they remain identifiable, legible, useful, and retrievable.
- 4.3.2 FDI records considered confidential or of particular importance may be retained off site, as authorized by the FDI Vice President, so long as they remain readily retrievable.
- 4.3.3 Care is taken when records are transported, ensuring that efforts are made to keep them dry and damage free.
- 4.3.4 For Documented Information that does not require retention, FDI conducts weekly collection of hard copy Internal & External Documented Information for eventual Shredding. This activity includes temporary staging and eventual delivery of documented information to the Secured Container deployed for slightly longer storage, and the eventual hand off to the Disposal provider (every other month).
- 4.4 Retrieval
- 4.4.1 Proper identification, storage, and handling of records ensures that they remain retrievable. Records are retained in areas familiar and easily accessible by those FDI employees who require access to the records.
- 4.5 Retention & Retention time
- 4.5.1 Unless otherwise specified, records related to the QMS are retained for a period of no less than 10 years, and as required by the FDI Purchase Order Requirements.
- 4.5.2 Records are retained indefinitely unless otherwise authorized by the FDI Vice President. Typical records affected are listed at the end of this documented procedure, with retention and retention time repeated.
- 4.6 Disposition
- 4.6.1 Once a record's retention period has expired, FDI Top Management may consider its destruction as final disposition. This is accomplished by shredding.

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- 4.7 Flow down to the Supply Chain
- 4.7.1 Communication of record control requirements to external providers is demonstrated through inclusion of the requirements on the FDI Purchase Order template.
- 4.7.2 External Providers

Confidence in supply chain control of records in accordance with FDI flow down requirements is achieved through on-site assessment and/or performance evaluation of external providers.

If an external provider maintains third party QMS registration with an accredited certification body, confidence in its control of records throughout the supply chain is enhanced.

## 4.8 Identification & retention sample registry

Typical Records affecting or affected by the FDI QMS:	Retention period	
Manufacturer, distributor, repair station, test and inspection reports (as applicable)	Minimum 10 years	
Original certificates of conformity (Manufacturer, sub-tier distributor), copies of Airworthiness Certificates (As applicable)	Minimum 10 years	
Nonconformity, concession, and corrective Action Records	Minimum 10 years	
Lot traceability records	Minimum 10 years	
Environmental or shelf life condition records	Minimum 10 years	
Purchase Orders & Contracts (FDI and Customer)	Minimum 10 years	
Certifications (product, services, personnel)*	Minimum 10 years	
Training & competency / qualifications	Minimum 10 years	
Nonconformity (Product, Process or System)	Minimum 10 years	
Approvals of Documented Information	Minimum 10 years	
Official shipping and handling records	Minimum 10 years	
Management review	Minimum 10 years	
Regulatory reporting	Minimum 10 years	

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Preventive Action / Continual Improvement Log

Minimum 10 years

\* Exception - calibration recall records

Minimum 1 cycle

4.8 All documented information, including but not limited to tags and other forms, work instructions, procedures and manuals referred to herein are subject to the requirements of FDI documented procedure SOP 7.5.1.