

DOCUMENT NUMBER 90-2000-4.2.4	REVISION L	TITLE Control of Records	REV DATE 12/2016	PAGE 1 of 6
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1.0 Purpose

The purpose of this procedure is to detail the requirements for the storage of Quality records. The procedure details the types of records, responsible departments, locations for storage, and minimum retention times for Product Resources. It also details the conditions for storage.

2.0 Policy

Records shall be gathered and stored by the responsible departments specified below to provide documented evidence that Quality processes have taken place and that products were manufactured to applicable specifications. The records shall be filed in a way that provides for reasonably expedient recall.

3.0 General Requirements

Quality records generated and delivered by the supplier and customer shall also become part of Product Resources' Quality records.

The storage area for Quality records shall be suitable to protect the records from damage, deterioration, and loss. Paper documents shall be stored in a clean, dry area and away from direct sunlight. Clear and legible reference shall be made on the Quality record as to which process or product it refers. Cabinets containing Quality records shall be labeled to identify the contents. Records shall be retained per established minimum record retention schedules. After that, records may be destroyed, but they may also be kept longer if deemed useful.

Records shall be available for review by Product Resources management, Quality Assurance personnel, Quality system registrars, and regulatory bodies for evaluation of the Quality system and for assessment of product conformance. Non-confidential records shall be available for review at the company facility by customers for the determination of conformance to requirements.

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4.0 Procedure

4.1 The Record Storage Chart (below) lists the record types, the storage locations, and the minimum retention times for Quality records for each responsible department.

4.2 This document is summary of Quality records, and we have attempted to make it as complete as possible and as consistent with the rest of the Quality Manual procedures as possible. However, the individual Quality Manual procedures shall always take precedence in the event of factual discrepancies with this document and omissions in this document.

4.3 Procedure 43-2151, Electronic Data Protection, details how Product Resources' electronic documents (which can be Quality records) are protected from loss and damage.

4.4 Procedure 43-4530, Data Backup Plan, details the specifics of the data backup aspects (a subset) of the above Electronic Data Protection procedure.

4.5 Procedure 43-4393, Data Security Policy, details data security policies, implementation of which protects electronic documents from loss, damage, and theft.

4.6 For all handwritten data on all Quality records, any correction or update shall be made by neatly crossing out the incorrect or outdated data, writing in the correct or new data, and signing (or initialing) and dating the entry. In all cases, data and history shall not be destroyed.

4.7 For all electronically-recorded data on all Quality records, any correction or update shall be made by initiating a new entry, indicating the prior entry as superceded, or with entries dated such that the final state is clear. For cases in which the data form does not permit additional entries, change notes shall be added to the record. In all cases, data and history shall not be destroyed.

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5.0 Record Storage Chart

See also Record Storage Chart Notes, which follows the table.

<u>Responsible Department</u>	<u>Record Type</u>	<u>Current Location(s)</u>	<u>Historical Location(s)</u>	<u>Minimum Retention Time (see Note 4)</u>
Engineering, Quality	Product Manufacturing Documents	SyteLine File Server, Document Control Drive	QC Area, Document Control Files	20 yrs.
Engineering, Quality	Device Master Records (medical devices)	SyteLine	N/A	20 yrs.
Sales	Sales Orders (Customer Orders)	SyteLine	N/A	10 yrs.
Sales	Customer Surveys	File Server, Sales Drive	N/A	3 yrs.
Engineering	Project Files	File Server, Engineering Drive	N/A	10 yrs.
Purchasing	Supplier Assessment	QT9	File Server, Purchasing Drive	10 yrs.
Purchasing	SRB Meeting Minutes	File Server, Purchasing Drive	N/A	3 yrs.
Purchasing	Supplier Rating	File Server, Purchasing Drive SyteLine	N/A	3 yrs.
Purchasing	Purchase Orders	SyteLine	N/A	10 yrs.
Production	Serial Number Records	SyteLine	N/A	10 yrs.
Production	Lot Number Records	SyteLine	N/A	10 yrs.
Production	Equipment Maintenance Records	QT9	File Server, Manufacturing Drive	5 yrs.
Test	Device History Records (medical and other devices)	File Server, Device History Record Drive Test Area	File Server, Test and Service Drive	10 yrs.

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<u>Responsible Department</u>	<u>Record Type</u>	<u>Current Location(s)</u>	<u>Historical Location(s)</u>	<u>Minimum Retention Time (see Note 4)</u>
Quality, Test, Service	Product Failure Data	QT9 QC Area File Server, Quality Drive File Server, Test and Service Drive File Server, QA Databases (Quality Drive)	Test Area	5 yrs.
Production	Job Orders	SyteLine Stockroom Area	N/A	10 yrs.
Production	Packing Checklists	Test Area File Server, Test & Service Drive	Stockroom Area	10 yrs.
Quality	Component Calibration Records	File Server, Quality Drive	Stockroom Area	10 yrs.
Receiving	Packing Slips, Quality Docs, Certificates of Compliance (from suppliers)	File Server, Manufacturing Drive	Stockroom Area	10 yrs.
Shipping	Certificates of Compliance (to customers)	SyteLine File Server, Manufacturing Drive	N/A	10 yrs.
Human Resources	Employee Training Records	QT9	Training Manager Software (data on file server, Training drive)	10 yrs., life of employment plus 1 yr., see Note 3
Quality	Calibration Records	QT9	QC Area	10 yrs.
Quality	Inspection Reports (Incoming/Outgoing)	SyteLine File Server, Quality Drive QC Area	N/A	10 yrs.
Quality	Audit Noncompliance Reports	QT9	File Server, QA Databases (Quality Drive)	10 yrs.

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<u>Responsible Department</u>	<u>Record Type</u>	<u>Current Location(s)</u>	<u>Historical Location(s)</u>	<u>Minimum Retention Time (see Note 4)</u>
Quality	Standards	QT9	Intranet Site File Server, Quality Drive	3 yrs. (following discontinuation)
Quality	Supplier Corrective Action Requests	QT9	File Server, Quality Drive File Server, QA Databases (Quality Drive)	10 yrs.
Quality	Management Review Minutes	File Server, Quality Drive	N/A	10 yrs.
Quality	Nonconformity Reports	QC Area File Server, Quality Drive	N/A	10 yrs., (3 mos. paper originals)
Quality	Customer Complaint Reports	QT9	File Server, QA Databases (Quality Drive)	10 yrs.
Quality	Corrective Action Requests	QT9	File Server, QA Databases (Quality Drive)	10 yrs.
Quality	ECNs	QT9 SyteLine File Server, Quality Drive	N/A	10 yrs.
Quality	Product Deviation and Change Requests (PDs)	File Server, Quality Drive	N/A	10 yrs.
Quality	Quality System Documents	QT9 Company Website	Intranet and Internet (Company Website) Sites File Server, Document Control Drive QC Area, Document Control Files	10 yrs.
Quality	Internal Audit Reports	QT9	File Server, Quality Drive	10 yrs.
Quality	Internal Audit Plan	QT9	File Server, Quality Drive	10 yrs.

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Record Storage Chart Notes:

(1) If a department / functional area name is given as the storage location, it is implied that the document is a paper document stored within the offices or areas of the stated group.

(2) Procedure 43-4530, which is maintained by MIS, gives specific and up-to-date information on the current server(s) and its/their name(s) used for the file server(s), for the storage of ERP system data, and for the storage of intranet and Internet site data.

(3) Training records are maintained for 10 years minimum, though training records for active employees are never discarded and are maintained for a minimum of one year beyond the termination of employment. Thus 10 years or the life of employment plus one year, whichever is greater is the minimum retention time.

(4) For records related to product, the time given is the time from the date of the last unit manufactured. For records related to systems, the time given is the time from the date of last applicability.

(5) QT9 is Product Resources' electronic QMS software, a system supported by an on-premises application server and database server.

(6) Infor ERP SL (a.k.a. SyteLine) is Product Resources' ERP software. This is a system supported by an on-premises application server and database server.