## 1.0 Purpose of Document

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

## 2.0 Scope of Process

The document describes records made and stored under Product Resources' QMS.

## 3.0 Process Owner(s)

**3.1** Quality

**3.2** All Departments

## 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 primary 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 and to keep it current. 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** The storage area for physical/paper Quality records shall be suitable to protect the records from damage, degradation, and loss. Paper documents shall be stored in a clean, dry area and away from direct sunlight. Cabinets containing Quality records shall be labeled to identify the contents.

**4.7** Clear reference shall be made on the Quality record as to which process and/or product and/or item it refers.

**4.8** Handwritten data shall be neat and legible. For all handwritten data on all physical/paper Quality records, any correction or update shall be made by neatly crossing out the incorrect or outdated data, writing in the correct or new data, and signing (or initialing) and dating the entry.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.

**4.9** For all recorded data on all electronic Quality records, any correction or update shall be made by initiating a new entry, indicating the prior entry as superseded, 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.

**4.10** For electronic records, file formats should be limited to industry-standard file formats such as PDF and RTF and standard Microsoft Office file formats such as DOC(X), XLS(X), and MSG. PDF is preferred for records.

**4.11** For records that are ultimately kept electronically but originate as paper/physical records, the paper/physical records should be removed from the process and recycled after they are scanned and verified stored in their final electronic location, unless instructions that the paper/physical is to be retained, typically to ship with product based on customer requirements.

**4.12** 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.

**4.13 Product Regulatory Reports**

4.13.1 Quality Assurance maintains all regulatory reports that bear on product manufactured by Product Resources on the Quality drive in the Regulatory directory. Quality Assurance further organizes this space by customer and by current versus obsolete reports.

4.13.2 These reports are referred to by different names depending on the regulatory body, but the following are common names for these reports: Listing Report, Examination Certificate, Listing Constructional Data Report (CDR), and Factory Audit Manual.

4.13.3 As new versions of reports are released periodically, replacing existing versions, it shall be Quality Assurance's responsibility to, on an annual basis, verify that the stored reports are current. This will normally take place each January. For reports found to be out-of-date, they shall be replaced with current versions if the product is still being actively manufactured by Product Resources.

## 5.0 Record Responsibility, Storage, and Retention

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

| **Primary Responsible Department** | **Record Type** | **Current Location(s)** | **Historical Location(s)** | **Minimum Retention Time** |
|---|---|---|---|---|
| Engineering, Quality | Product Manufacturing Documentation | ERP System (parts and routings)<br><br>QMS System (documents) | File Server, Document Control Drive (documents)<br><br>QC Area, Document Control Files (documents) | 20 yrs |
| Engineering, Quality | Device Master Records (medical devices) | ERP System | N/A | 20 yrs |
| Sales | Quotations and Proposals | File Server, Sales Drive | N/A | 5 yrs |
| Sales | Sales Orders (Customer Orders) | ERP System | 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 Surveys (Supplier Assessment Questionnaires) | QMS System | File Server, Purchasing Drive | 10 yrs |
| Purchasing | Supplier Review Board (SRB) Materials: supplier performance, report cards, minutes | File Server, Purchasing Drive > Supplier Review | N/A | 3 yrs |
| Purchasing | Supplier Ratings / Approved Supplier List | ERP System | N/A | 3 yrs |
| Purchasing | Purchase Orders | ERP System | N/A | 10 yrs |
| Purchasing | Service Provider Questionnaires | File Server, Purchasing Drive > Service Provider Questionnaires | N/A | 10 yrs |
| Production | Serial Number Records | ERP System | N/A | 10 yrs |
| Production | Lot Number Records | ERP System | N/A | 10 yrs |

| **Primary Responsible Department** | **Record Type** | **Current Location(s)** | **Historical Location(s)** | **Minimum Retention Time** |
|---|---|---|---|---|
| Production | Equipment Maintenance Records | QMS System | File Server, Manufacturing Drive | 7 yrs |
| Test | Device History Records (medical and other devices) | File Server, Device History Record Drive<br><br>Test Area | File Server, Test and Service Drive | 10 yrs |
| Quality, Test, Service | Product Failure Data | QMS System<br><br>QC Area<br><br>File Server, Quality Drive<br><br>File Server, Test and Service Drive<br><br>File Server, QA Databases (Quality Drive) | Test Area | 7 yrs |
| Stockroom | Job Orders | ERP System Stockroom Area | N/A | 10 yrs |
| Stockroom | Job Order Time Sheets | File Server, Manufacturing Drive | N/A | 10 yrs |
| Production | Packing Checklists | Test Area<br><br>File Server, Test & Service Drive | Stockroom Area | 10 yrs |
| Production | ESD Log | File Server, Manufacturing Drive | Production Floor | 3 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) | ERP System<br><br>File Server, Manufacturing Drive | N/A | 10 yrs |

| **Primary Responsible Department** | **Record Type** | **Current Location(s)** | **Historical Location(s)** | **Minimum Retention Time** |
|---|---|---|---|---|
| Human Resources | Employee Training Records | QMS System | Training Manager Software (data on file server, Training drive) | 10 yrs, life of employment plus 1 yr, see Note 3 |
| Quality | Calibration Records | QMS System | QC Area | 10 yrs |
| Quality | Inspection Reports (Incoming / Outgoing) | ERP System<br><br>File Server, Quality Drive<br><br>QC Area | N/A | 10 yrs |
| Quality | Audit Noncompliance Reports | QMS System | File Server, QA Databases (Quality Drive) | 10 yrs |
| Quality | External Standards | QMS System | Intranet Site<br><br>File Server, Quality Drive | 3 yrs (following discontinuation) |
| Quality | Supplier Corrective Action Requests | QMS System | File Server, Quality Drive<br><br>File Server, QA Databases (Quality Drive) | 10 yrs |
| Quality | Management Review Minutes | File Server, Quality Drive | N/A | 10 yrs |
| Quality | Reject Tags, Reject Tag Data | QC Area<br><br>File Server, Quality Drive | N/A | 10 yrs,<br><br>(3 mos paper originals) |
| Quality | Customer Complaint Reports | QMS System | File Server, QA Databases (Quality Drive) | 10 yrs |
| Quality | Corrective Action Requests | QMS System | File Server, QA Databases (Quality Drive) | 10 yrs |
| Quality, Engineering | ECRs (formerly ECNRs) | QMS System | Customer Process System Database; File Server, Engineering Drive | 5 yrs |

| **Primary Responsible Department** | **Record Type** | **Current Location(s)** | **Historical Location(s)** | **Minimum Retention Time** |
|---|---|---|---|---|
| Quality | ECNs | ERP System (ECNs)<br><br>File Server, Quality Drive (released ECNs)<br><br>Mail Server, ECN Public Folder (ECN actions) | N/A | 10 yrs |
| Quality | Risk Assessments | QMS System | N/A | 5 yrs |
| Quality | Change Controls | QMS System | N/A | 5 yrs |
| Quality | Product Deviation and Change Requests (PDs) | File Server, Quality Drive | N/A | 10 yrs |
| Quality | Quality System Documents (Quality Manual and associated procedures and forms) | QMS System | Intranet Site<br><br>File Server, Document Control Drive<br><br>QC Area, Document Control Files | 10 yrs |
| Quality | Quality System Document Revision Change History | QMS System | N/A | 10 yrs |
| Quality | Internal Audit Reports | QMS System | File Server, Quality Drive | 10 yrs |
| Quality | Internal Audit Plan | QMS System | File Server, Quality Drive | 10 yrs |
| Quality | Product Regulatory Reports | File Server, Quality Drive | N/A | 10 yrs |
| Quality | Process Analysis and Process FMEA (PFMEA)<br><br>(see also Note 7) | File Server, Engineering Drive > By Customer > [customer] > [product] > Current Product Definition > Risk | N/A | 5 yrs |
| Quality | Process Validation<br><br>(see also Note 8) | File Server, Engineering Drive > By Customer > [customer] > [product] > Current Product Definition > Risk | N/A | 5 yrs |

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 servers and their names used for the file and mail servers, 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 date of manufacture. For records related to systems, the time given is the time from the date of last applicability.

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

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

(7) This describes for process analysis and PFMEA the final storage location post project that brought the product into production. While the project is active, it will be found here: File Server, Engineering Drive > By Customer > [customer] > [product] > Projects > [project] > Risk Mgmt.

(8) This describes for process validation the final storage location post project that brought the product into production. While the project is active, it will be found here: File Server, Engineering Drive > By Customer > [customer] > [product] > Projects > [project] > V&V > Process Validation.