1.0 Purpose

The purpose of this procedure is to describe Product Resources' processes for controlling documents.

2.0 Scope

The scope of this procedure is to describe the releasing of documents to Document Control, issuing documents to the point of use, and changing and re-releasing documents to Document Control. This procedure also includes guidelines for working with computer disks that are submitted as documents. Finally, it addresses the document control of customer labels for packages.

3.0 Process Owner(s)

3.1 Document Control

3.2 Quality Assurance

3.3 Engineering

4.0 Procedure

4.1 Document Status

All documents are controlled in the QMS system. For parties looking to obtain a current document, the QMS system makes only the most current revision of a document available. The QMS system will also show if a document is out for a revision change. The current revision and link to the document for product documents (held in the QMS system) is shown in the ERP system. The ERP system will also show if there is an ECN against a given item.

4.2 Conventions

A document has the same number as the part which it describes. Both the document and the part can be described with a document/part number and a revision level. The revision date in a document should be based on the submission date of the document in the QMS system.

Refer to 91-6003, Identification and Traceability, for guidance on Product Resources' part numbering system and system for document revisions. Refer also to 43-1040, Part Number Prefixes and Categories, as a reference to the prefixes used in the part numbering system.

4.3 Procedure – Releasing Documents (Approval and Publication)

To release a document means to submit it to Document Control with its Product Resources approvals for storage in Document Control, located in the QT9 application, so that it may be issued when needed.

Note that in special, limited cases, there will be a physical master that must be submitted to Document Control. Examples are media such as SSDs, flash drives, flash media, etc. This is done when the physical master must be used in the process wherein a file copy of it will not serve the purpose. In this case there is still an electronic document submitted to the QT9 application along with the physical master submitted to Document Control.

Documents submitted for release shall be reviewed for fitness for use and shall have a minimum of and typically two approvers. QT9 records the revision initiation dates, the date the revision was submitted for approval, and the approvals and their dates. This information is available in the Approval report for each QT9 current document; note that the Timeline must be displayed to see all dates relevant to the document approval process. With the two approvals, the document is approved. The document must then be published to make it the available current document. The final approver or Document Control may publish the document.

Note that in the special case of a physical master, Document Control shall be the publisher so that it can ensure the physical master is simultaneously in place. Document Control will hold these physical masters in a safe location.

The work instructions 43-2500 cover the use of QT9 to accomplish the release of a document.

There are requirements for who may approve which types of documents. See the following table:

Document Type	Approval Requirements	Group with Primary Responsibility
QMS Tier 1 (Quality Manuals) and Tier 2 (Procedures)	The QA Manager must be one of the approvers. The second approver may be any role knowledgeable of the QMS or the process being described by the procedure.	Quality
Manufacturing Documentation Includes assembly drawings and instructions, part detail drawings and specs, in-process and final test procedures, hardware and software for manufacturing or test; rework procedures are listed separately below	One of the approvers must be Engineering and all approvers must be knowledgeable of the part, product, and/or procedure being documented.	Engineering
Rework Procedures	One of the approvers must be Engineering or Quality and all approvers must be knowledgeable of the part or product being reworked. For medical devices, if the rework may have potentially adverse effects, one of the approvers must be Quality.	Engineering

Other Document Types	All approvers must be knowledgeable and/or aware of the part, product, process, procedure, and/or standard being documented.	Varies

In the case of regulated product, the customer or the regulatory body, typically via inclusion by document number and revision in a listing report, also approves of controlled documents prior to their being submitted to Document Control for release into Product Resources' system.

4.4 Procedure – Issuing Documents

To issue a document means to respond to a document request by delivering document copies (hard or electronic) of the document to the point of use.

A document request, in most cases, is handled self-service through the QT9 Document Portal, which will only offer the current revision for any document. Document Control may also issue electronic documents downloaded from QT9 via e-mail.

Job order packages are created and distributed electronically on the company file server. These electronic jobs are accessed by Production personnel on computers at their workstations. The jobs in turn include embedded links in the job operation listing that, when clicked, will open the browser directly to the Document Portal in QT9 and download the document(s) referenced in the routing. These copies are now on the workstation for viewing electronically.

Electronically issued documents are considered valid and current when they are downloaded from the Document Portal, plus seven calendar days or with continued usage, i.e., continuing to build the same job. For Production workstations where job-based download of documents is a regular occurrence, MIS shall configure an automatic pruning of downloads according to this policy.

Purchase orders contain embedded document links as well, and suppliers too are given access to the Document Portal and retrieve their own documents from QT9. Purchasing may also issue electronic documents downloaded from QT9 via e-mail to suppliers.

If a hard copy of a document is needed (paper), users may request it from Document Control or print documents from the QT9 Document Portal and put them into circulation provided they acquire a Document Control Issued stamp from Document Control, which will verify the current revision. Note that the Document Control Issued stamp uses red ink. This copy is to be destroyed (recycled) after its use or returned to Document Control.

Whether electronic or hard copy, issued documents are not to be altered as to the issued content for Production usage. There will sometimes be document errors or ommissions, and a mark-up may be necessary to continue. In that case, Engineering or Quality is to sign/initial and date the change, approving its use, accompanied by the creation of a document change request to capture the needed correction or an ECR if larger in scope.

If Engineering or Quality provides a draft document for use in Production – not a current document issued from QT9 – this draft must be signed/initialed by Engineering or Quality approving its use. A typical example of this would be a pilot build of a product being built under the watch and instruction of Engineering.

4.5 Procedure – Documents in Distribution

When a document is used so often that the repeated issue of the document becomes impractical, the document may be placed in distribution. A work cell is a common use for documents in distribution. Another common use is the Quality Manual.

Document Control may exclusively put a document in distribution and may do so on paper or electronically as is best for the usage scenario.

On Paper:

A document in distribution follows all the issue rules given above plus these: A label is affixed to the first page of the document. The label states that the document is in distribution as well as the date on which it expires (all documents in distribution expire) and the responsible recipient of the document. The label also states that the document is not to be marked in any way. The expiration date shall be six months from the issue date, or a shorter interval if Document Control has cause. If a collection of documents in a binder, a single label may be placed on the outside of the binder rather than every document individually. An example of this is the Quality Manual.

Electronically:

A copy of the document is placed on a file server location that is read only to the group using the document or otherwise on a Product Resources Internet or intranet site. There is no equivalent in the electronic scenario to the label described above, but the read only nature of the holding space protects the document. There shall be an associated expiration date with the same policy as above.

Maintenance and Tracking:

Whether paper or electronic, Document Control is responsible for tracking the documents in distribution and for updating or removing the documents that have expired or have been obsoleted by an ECN. For paper documents in distribution, the responsible recipient shall be responsible for maintaining the documents in distribution (kept together, kept available) and for being able to locate them for Document Control when needed.

Document Control shall establish a tracking file on the company file server in the Quality share. Entries shall include the document number and revision, the issue and expiration dates, and the responsible recipient (for paper documents in distribution only) or the identity of the electronic location.

4.6 Procedure – Changing Released Documents (ECN Procedure)

The originating department shall be responsible for making and approving changes to documents and documents changes on ECNs, Engineering Change Notices. In the immediate term, the ECN is a vehicle to communicate change to all groups at Product Resources which are stakeholders in the change. Beyond the immediate term, ECNs provide a method by which to track a document's revision history.

Any department may request changes to documents, for example if an error is found, if information is ambiguous, if information is outdated, or if there is an idea for process or product improvement. Change requests are to be made using ECRs in the QMS system. See 43-4758 for instructions on creating an ECR.

Approved ECNs are turned in to Document Control. Document Control shall be responsible for ensuring that the changed documentation described by ECNs is in place before releasing ECNs. Document Control shall file released ECNs on the Quality drive – see ECN Records – and shall distribute released ECNs by email per the ECN's selected distribution. The QA Manager is included on all ECN distributions.

Documents changed by an ECN shall follow the same release procedure as above (see 4.3).

The ECN process has been given its own procedure document. Reference 43-2627.

4.6.1 Procedure – Changing Released Documents (ECN Procedure) – Special Regulatory and/or Customer Requirements

The below sub-sections give additional policy and procedure related to change that would augment the basic ECN process.

Notification of QMS Change

Certain customers or regulatory bodies may choose to be notified on changes to the Quality system. Some may choose to be notified on all changes, and some may choose to be notified only on major changes. The QA Manager assigns the change classification as described in 43-2627. If there is a customer or regulatory body requiring notification for the given class of change, the QA Manager, who is also the Management Representative, is responsible for addressing the change with that party and for fulfilling any requests or instructions related to the change.

ECNs are not created for the documented QMS, specifically Tier 1 Quality Manual, Tier 2 procedure, Tier 3 work instructions, and training material changes, as these changes are tracked via the QMS system. ECNs are created for product/manufacturing documentation.

4.7 Procedure – Document Control for Packaging Labels

In some cases, Product Resources prints and includes on product packaging the customer's inventory label, in the customer's format. In other cases Product Resources must order the product label from the customer.

In the case of Product Resources printing customer-format labels, customer approval of the label content is typically required, and the approval form is submitted to Document Control.

In the case of ordering customer labels from the customer, the ordering information/form is submitted to Document Control.

Quality is responsible for advising on customer-specific procedures and is to be consulted if uncertain.

4.8 Quality, Industry, Regulatory, and Customer Standards (External Standards)

Quality Assurance shall maintain required Quality (including ISO 9001, ISO 80079-34, and ISO 13485), industry, regulatory, and customer standards. Standards are assigned Product Resources part numbers and are maintained in the QMS Document Control system. Standards that are used as part of manufacturing documentation have a manufacturing routing reference to it.

Product Resources employees can access these standards on a “self-service” basis. Only current standards will be made available; if there is a reason to continue to make an obsolete version of a standard available, the given standard will be noted as to its obsolete status.

As new versions of standards are published periodically, and existing versions made obsolete, it shall be Quality Assurance’s responsibility to periodically verify that the published standards are current. This will take place via the QMS system’s document review frequency, 24 months for the external standards category. For standards found to be out-of-date, they shall be replaced with current versions if the standards are required for the compliance of Product Resources’ Quality system or required based on regulatory or customer requirements

5.0 Control of Records

The storage location and retention period for records referenced above is given in 91-6002, Control of Records.