

**1. PURPOSE**

The purpose of this procedure is to establish a purchasing process to ensure that purchased product and services conform to specified requirements.

**2. SCOPE**

The requirements of this procedure apply to GT Medical's contract manufacturers, and any other service provider determined to directly affect the quality of the medical device product. This procedure does not apply to MRO items. It is noted that GT Medical does not purchase raw material, components, or equipment for the manufacturing of medical device product.

This procedure covers supplier identification, supplier evaluation/approval, purchase order release, supplier monitoring, and supplier corrective actions.

**3. REFERENCES**

- 21 CFR 820.50 Purchasing Controls
- F-002A, Supplier Qualification Checklist
- F-002B, Supplier Audit Checklist
- F-002C, Consultant Supplier Survey
- F-002D, Approved Supplier List (ASL)
- F-002E, Supplier Corrective Action Request (SCAR)
- F-002F, SCAR Log
- F-002G, Supplier Quality Performance Review

**4. DEFINITIONS**

- 4.1. Critical Supplier:** Supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause a significant degradation in performance. See Appendix B.
- 4.2. MRO Supplier:** Maintenance, repairs, and operation suppliers for items such as HVAC, plumbing, office supplies, and facility support not directly related to finished product.
- 4.3. Non-critical supplier:** Supplier delivering materials, components, or services that have limited risk or influence on the safety and performance of the product. See Appendix B.

**5. RESPONSIBILITY**

- 5.1.** Purchasing shall be performed by Operations personnel or designee. Purchasing shall serve as the primary contact with existing and/or potential suppliers.
- 5.2.** Operations shall create, review and approve/release Purchase Requests. Operations shall maintain purchasing records where required by this procedure.
- 5.3.** Operations is responsible for monitoring supplier performance and issuing Supplier Corrective Action Reports (SCARs) as necessary.

**6. PROCEDURE****6.1. General**

6.1.1. GT Medical's Purchasing and Supplier Controls process contains following subprocesses.

- Evaluation and Approval of Suppliers (Quality Agreements as applicable)
- Ordering of Product and Services
- Ongoing Performance Monitoring
- Supplier Corrective Action Requests (as applicable)

6.1.2. When internal specifications are revised, Operations shall provide applicable suppliers with the revised and approved drawings, specifications, and/or product information.

## **6.2. Evaluation of Suppliers and Consultants**

6.2.1. Suppliers will be evaluated through a combination of the following processes and distinguished by criticality (non-critical vs critical). Appendix B should be used when determining criticality.

6.2.2. As presented in Appendix A, suppliers:

- will be evaluated using F-002A, Supplier Qualification Checklist to be considered a supplier to GT Medical.
  - section 2 need not be completed for suppliers who provide evidence of a quality management system compliant to 21 CFR 820 and ISO 13485 (i.e. quality manual, certificates, etc.).
- will be subject to audits as determined by product criticality, review of quality history, and performance
- if considered as critical, will require the establishment of a Supplier/Quality Agreement. This agreement
  - shall specify that the supplier notify GT Medical of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.
  - Shall include the option of performing a field audit or a desk audit (documented on F-002B, Supplier Audit Checklist, if requested by GT Medical.

6.2.3. Consultants will be required to complete F-002C, Consultant Supplier Survey rather than F002A.

6.2.4. MRO or certain service suppliers providing services not affecting product quality (i.e. office suppliers) do not have to complete the F-002A, Supplier Qualification Checklist.

## **6.3. Consultant Approval**

6.3.1. Approval status shall be determined by management with consideration for the credentials/expertise of the consultant and the work being performed. Conditional approval is not applicable to consultants.

## **6.4. Supplier Approval**

- 6.4.1. Approval status shall be determined by management with consideration for the evaluation results and supplier criticality designation.
- 6.4.2. Suppliers may be approved, conditionally approved, or not approved.
- 6.4.3. For conditionally approved suppliers, the conditions of approval shall be specified. The following table contains two common scenarios, but others may be used. These criteria may be referenced by example number on the F-002A, Supplier Qualification Checklist.

Table 1: Conditional Approval Example Criteria

Example	Criteria
1	Pending results of supplier audit per F-002B, Supplier Audit Checklist. F-002A, Supplier Qualification Checklist is in place and indicates adequate quality controls.
2	The first five batches/lots are conforming to specified requirements.

- 6.4.4. Once suppliers meet the specified conditional approval criteria, they shall be designated as "Approved" on the F-002A, Supplier Qualification Checklist. Objective evidence of the criteria being met shall be attached or referenced (i.e. audit report/date, lot numbers, etc.).
- 6.4.5. At the discretion of management, a conditionally approved supplier who does not meet the criteria may still be approved after supplier corrective actions are taken and verified to be effective. Alternatively, the supplier may be disqualified.

## 6.5. Approved Suppliers List

- 6.5.1. The F-002D, Approved Supplier List (ASL) shall be maintained and updated in a timely manner to reflect changes in supplier and consultant status.

## 6.6. Supplier Contracts

- 6.6.1. Suppliers who manufacture custom or critical components on behalf of GT Medical are required to comply with GT Medical's Quality Agreement.
- 6.6.2. Signed copies of these agreements are maintained in the vendor file.

## 6.7. Ordering Product and Services

- 6.7.1. Operations will use the business operating system or other information sources to determine quantities and dates needed for purchases of product and services.
- 6.7.2. Operations shall have the authority and responsibility to submit purchase orders to suppliers. Purchasing may also occur per other methods defined by a contract/agreement.
- 6.7.3. Other functional areas of the organization should complete the Purchase Request with the items desired and indicate preferred supplier and submit to purchasing for review and approval. Purchasing will then issue a formal Purchase Order.

- 6.7.4. Purchasing will confirm the selected supplier as an approved supplier prior to placing the order. Operations will create the purchase order, which shall clearly describe or reference the requirements for the purchased product (i.e. date, quantity ordered, part number & revisions, etc.).

## **6.8. Ongoing Supplier Monitoring**

- 6.8.1. Reviews of critical supplier performance will be completed, at least annually. Reviews of non-critical supplier performance may be completed at management discretion. The reviews will consider the data sources listed in the F-002G, Supplier Quality Performance Review.
- 6.8.2. In the form F-002G, Supplier Quality Performance Review, suppliers will be given a ranking from A through D, with consideration for the data reviewed. The scoring system will be maintained on the ASL and updated annually. The date of scoring will also be maintained on the ASL.
- 6.8.3. A score of A is the best and D needs improvement. The scoring system is designed to assist purchasing in their ongoing supplier assessment process.
- 6.8.4. Any score of A, B or C will be considered acceptable as-is and will be used as a guide to sourcing strategy.
- 6.8.5. Suppliers who receive a score of a D will be notified, issued a SCAR, and required to implement corrective action prior to supplying more product. An additional Supplier Quality Performance Review may be performed after a specified amount of time (i.e. verification of effectiveness is complete). If performance does not improve, or the supplier will not implement corrective actions, the supplier shall be disqualified and removed from the approved suppliers list..
- 6.8.6. Copies of the supplier notification and their response(s) will be attached to respective F-002A, Supplier Qualification Checklist and placed in that vendor's file.

## **6.9. Settlement of Quality Disputes and Supplier Corrective Action**

- 6.9.1. Purchasing has the responsibility and authority to settle all disputes with suppliers regarding the quality of their material/products/services or matters such as inspection and testing methods.
- 6.9.2. Supplier nonconformances shall be addressed with the supplier in a manner proportionate to the risk associated with the purchased product and compliance with the applicable regulatory requirements. The following, at a minimum, shall constitute the risk-based approach. See Appendix E for the flowchart of the following.
- Form F-002E, Supplier Corrective Action Request (SCAR) shall be used to document all supplier nonconformances.
  - All suppliers shall be notified of nonconformances, the SCAR form may be used for notification purposes.
  - If the nonconformance could affect product safety / efficacy, supplier corrective action is required. Nonconformances not related to product safety or efficacy require corrective action when an adverse trend is identified (i.e. previous nonconformances in

the SCAR log). The F-002E Supplier Corrective Action Request shall be used to document the supplier's actions and the evidence or rationale that the corrective actions will not adversely affect the product.

- If a nonconformance is detected during the product verification or supplier assessment, a SCAR may be issued. A sequential numbering system will be used to assign unique tracking numbers to SCARs issued.

6.9.3. When supplier corrective action documentation is required, the form F-002E, Supplier Corrective Action Request (SCAR) will be used to document the investigation, root cause, and actions needed to correct and prevent the recurrence of the nonconformity. The form will assist in the verification of the corrective action, its effectiveness, and that product quality was not adversely affected by any changes.

6.9.4. Purchasing will obtain a SCAR number from the log F-002F, SCAR Log. SCAR's will be logged and tracked to closure on F-002F, SCAR Log.

## **7. APPENDICES**

**7.1.** Appendix A – Initial qualification and re-qualification requirements

**7.2.** Appendix B – Supplier Classification Flowchart

**7.3.** Appendix C – F-002E SCAR Flowchart

## 8. DOCUMENT HISTORY

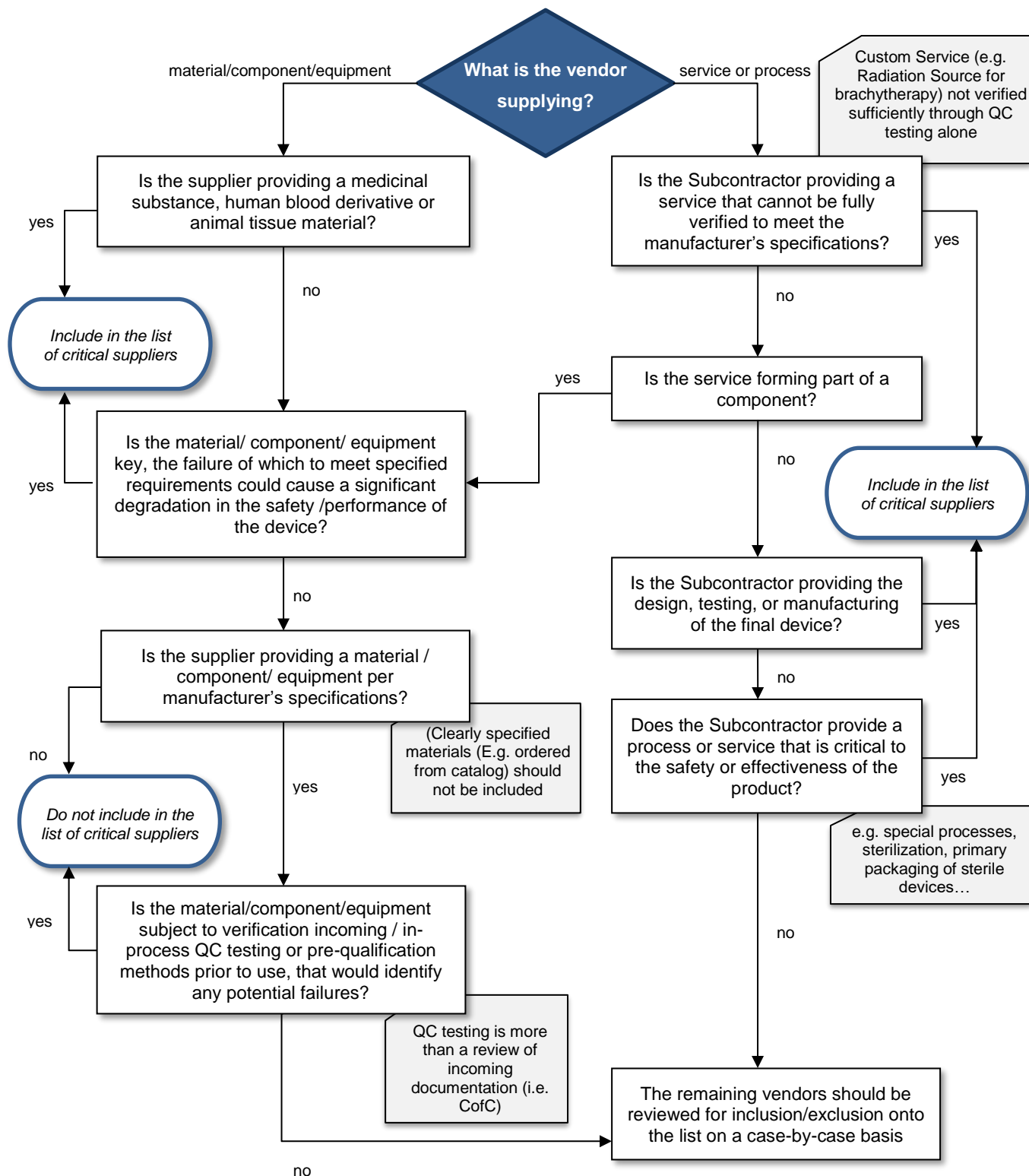
Functional Area	Signature & Date
Operations	<p>Hernan Lopez  <i>Hernan Lopez</i> 30 Nov 2018 05:22:030-0800            REASON: I am approving this document.            72eef047-7bbe-4092-82b1-f04e00c2e31e</p>
Quality	<p>Michelle Lott  <i>Michelle Lott</i> 26 Nov 2018 11:41:023-0800            REASON: I am approving this document.            f7e7590f-6690-4b5c-92a2-9498dd850663</p>
Regulatory	<p>Jessica Newhard  <i>Jessica Newhard</i> 03 Dec 2018 06:49:022-0800            REASON: I am approving this document.            3bd17091-2c34-4925-88ed-391ad6b1da50</p>

REVISION HISTORY		
Rev. #	Released Date (YYYY-MM-DD)	Author
1	2018-05-14	Michelle Lott
2	2018-11-26	Raines DeMint

### APPENDIX A – Initial qualification and re-qualification requirements

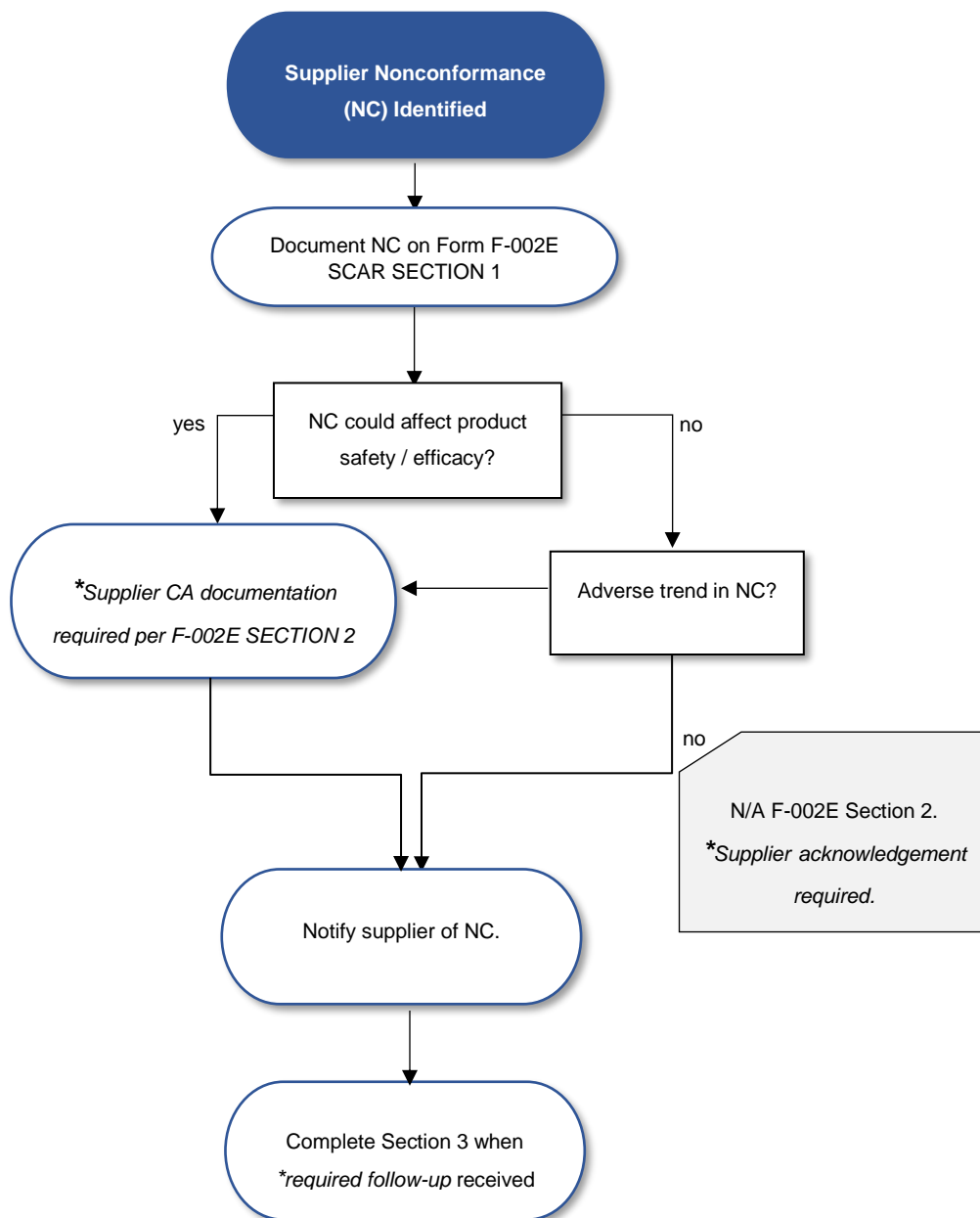
	<b>Non-critical Supplier</b>	<b>Critical Supplier</b>
Initial qualification	<p>Documented on:</p> <p>F-002A, Supplier Qualification Checklist Section 1</p> <p>F-002C, Consultant Supplier Survey</p>	<p>Documented on:</p> <p>F-002A, Supplier Qualification Checklist Sections 1 &amp; 2</p> <p><b><u>and</u></b></p> <p>Service/Quality Agreement</p> <p><b><u>And optionally</u></b></p> <p>Field Audit or Desk Audit (documented on F-002B, Supplier Audit Checklist)</p>
Re-qualification	<p>Annually using:</p> <p>F-002G, Supplier Quality Performance Review (optional for non-critical suppliers)</p>	

## APPENDIX B - Supplier Classification Flowchart





### APPENDIX C F-002E SCAR Flowchart




# MySignatureBook V3.12


Validation Report as of: 04 Dec 2018 13:37:043-0800


1



Subject CN MSB  
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Email operations@msbdocs.com  
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Signing Time 03 Dec 2018 06:49:022-0800

 The Certificate chain was successfully built to a Trusted Root Certificate.

 The Signer's identity is valid.

 The Document has not been modified since the signature was applied.

This page was added to the original document by the MySignatureBook Validation Service (SVS) as part of the process to convert active signature block content into inactive text. A full validation report of each signature is generated and cross-referenced using a numeric footnote annotation.

# Audit Trail Report

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26 Nov 2018 11:22:055-0800	Raines DeMint		RequestSent	Sign request sent to ePak recipient. User UUID : 2ee4a9ef-4d1a-4598-bb7f-8eeac6189470
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03 Dec 2018 06:49:059-0800	Jessica Newhard	SOP-004 Labeling and Unique Device Identification (UDI) Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 40b9fbb3-45bd-4dd4-b84b-f390cbe81db
03 Dec 2018 06:50:019-0800	Jessica Newhard	SOP-005 Electronic Tools Procedure Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 9ae0e0f0-81dd-4206-84cb-7e83a707d8fe
03 Dec 2018 06:50:043-0800	Jessica Newhard	SOP-006 Order Entry Process Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 5b065ba7-7993-4140-9097-ecedababd14b
03 Dec 2018 06:51:019-0800	Jessica Newhard	TSS-001_2018-11-26_JNewhard.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 9732b790-2038-4f44-80b8-fcfcf2f949bc
03 Dec 2018 19:43:053-0800	John Baker	TSS-001_2018-11-26_JBaker.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : bb1eb73e-fbbf-45f9-a42e-142e3a2717b5 Document UUID : 5278beff-309d-4378-8cae-cf40ad9de034
04 Dec 2018 13:20:059-0800	Matt Likens	TSS-001_2018-11-26_MLikens.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4 Document UUID : 6e427ba3-e577-42c7-9352-5d9b984a124c
04 Dec 2018 13:20:059-0800	Maria Laitenberger		Completed	The ePak completed the workflow successfully custodian. User UUID : fff18bac-7002-4b20-9ce3-567169aab764