Internal Audit Report

Audit Number	A-054
Process or Project	Nonconforming Product
Principal Auditee	Ashley Mitchell
Date of Audit	11 February 2025

1 Objectives and Scope

The two main objectives of this audit are to evaluate conformity of actions to SRF Operations' QMS and to evaluate compliance of the SRF Operations' QMS to the requirements of the ISO 9001:2015 standard. This will be accomplished by reviewing the identified scope, related documentation, and review of records to obtain objective evidence to determine if any nonconformity or areas of improvement exist in complying with applicable regulatory standards.

The scope of this audit encompasses the QMS documented information, and records related to Nonconforming Product since the previous internal audit (08 Apr 2024).

2 Criteria

Criteria related to this audit includes:
-ISO 9001:2015 primarily section 8.7 Nonconforming Product.
-SRF-12-PD-001, SRF-12-PR-001, SRF-12-PR-002 and any other support criteria as documented in the SRF-01-ML-001 SRF Operations Quality Manual.

3 Team Members

Name	Role
Debbie Newman	Lead Auditor

4 Attendees and Contacts

Name	Title or Role
Debbie Newman	Lead Auditor (External)
Ashley Mitchell	Process Owner for Nonconforming Product
Ashley Mitchell	Management Representative
Mike Dickey	Sr. Production Support Technician

5 Checklist and Evidence

A-054 Internal Audit Checklist-Nonconforming Product

6 Results

6.1 Major Nonconformities

The following major nonconformities were identified during this audit. Major nonconformities are considered significant breakdowns in the process. CAPA Reports must be initiated for these.

	Major Nonconformity	Criteria
1	N/A	N/A

6.2 Minor Nonconformities

The following minor nonconformities were identified during this audit. Minor nonconformities are considered marginal deviations or oversights from an otherwise well implemented process. Corrective Action Reports may or may not be initiated for these.

	Minor Nonconformity	Criteria
1	N/A	N/A

6.3 CAPA Reports

The following CAPA Reports are initiated to address the nonconformities identified during the audit.

CAPA	Nonconformity(ies)
N/A	N/A

6.4 Observations and Comments

The following observations were made during the audit. These are not related to a nonconformity but may provide opportunities for improvement.

1. OBS#1 – (OFI) The SRF-12-PR-001 could better describe the handoff to SRF-02-PR-002 Customer Satisfaction when nonconformances are identified after the delivery of products.
2. OBS#2 – (OFI) Consider creating a log and/or method to aggregate and trend nonconforming products detected after delivery.
3. Other than the observations and comments listed above, this audit finds the Internal Audit processes meet the requirements of the audited criteria.

6.5 QMS Process Monitoring Findings

1. Number of Opportunities for Improvement (OFIs) identified: 2
2. Number of Records not found or not in compliance: **0**
3. Number of Documents not found or not in compliance: **0**

7 Audit Report Distribution

1. Tony Reilly, SRF Department Head
2. Ashley Mitchell, Principal Auditee
3. Ashley Mitchell, Process Owner of Internal Audit
4. DocuShare folder, QMS Records

8 Approval

Approved by:	Name:	Signature:	Date:
Principal Auditee	Ashley Mitchell	Ashley Mitchell Ashley Mitchell (Mar 7, 2025 15:59 EST)	7-Mar-2025
Lead Auditor	Debbie Newman	Debbie Newman Debbie Newman (Mar 7, 2025 16:22 EST)	7-Mar-2025
Process Owner of Internal Audit	Ashley Mitchell	Ashley Mitchell Ashley Mitchell (Mar 7, 2025 15:59 EST)	7-Mar-2025
SRF Department Head	Tony Reilly	Tony Reilly Tony Reilly (Mar 24, 2025 08:37 EDT)	24-Mar-2025

Internal Audit Checklist

Audit Number	A-054
Process or Project	Nonconforming Product

1 Checklist

	Requirement/Question	Evidence	Notes	Findings (C/Mj/Mn)
Review of Prior Audits				
1	NC's from prior audit: 1-CAPA-060-Traveler noted product was "use as is", but not approved by customer.	Audit-037 CAPA-060	CAPA-060 is closed with no verification of effectiveness required.	C
2	Status of OFI's from prior audit	Audit-037	There were OFI's identified and many of those improvements were seen during this assessment	C
Review of Audit Criteria				
3	ISO 9001:2015 – 8.7 Control of Nonconforming Outputs	SRF-12-PD-001 Rev 3	This document adequately addresses the applicable ISO 9001 requirements.	C
4	Review of SRF-01-ML-001 SRF Operations Quality Manual related to the specific process	SRF-01-ML-001 Rev 2	The Quality Manual refers to SRF-12-PD-001 and appears to be adequate for the organization.	C
5	Review of SRF-12-PD-001 Nonconforming Products Program Description	SRF-12-PD-001 Rev 3	The Program Description refers to establishing dispositioners and notifications, nonconforming product, detours, deviations and discrepancies, analyzing data, and records.	C
6	Review of SRF-12-PR-001 Nonconforming Product Procedure	SRF-12-PR-001 Rev 3	How do you describe nonconforming products detected after delivery of products? – SRF-02-PR-002 Customer Satisfaction Procedure OBS#1 – Further describe the handoff to SRF-02-PR-002 when nonconformances are identified after the delivery of products.	C

	Requirement/Question	Evidence	Notes	Findings (C/Mj/Mn)
			OBS#2-Consider creating a log and/or method to aggregate and trend nonconforming products detected after delivery.	
7	Review of SRF-12-PR-002 Detours, Deviations and Discrepancies Procedure	SRF-12-PR-002 Rev 2	The procedure appears to adequately describe the current process.	C
8	Review SRF-11-PR-002 Work Control Document Register for NCR related information	SRF-11-PR-002 Rev 2	The WCD tab provides a list of all documents needed. The NCR dispositioner is a limited permission.	C
Review Objective Evidence in support of Audit Criteria				
9	Review of nonconforming products in Pansophy.	-L2HE NCR 674-Closed 2025-01-23 -ER5C NCR 1092 – Still open -L2HE NCR 656 – Closed 11/18/24 -L2HE NCR 657 – Still open -L2HE-BPMFTSN-10 had a rejected tag referring to D3, but no entry in Pansophy. PRIMeS does correctly note it as rejected and it was correctly located on the Rejected shelving.	Pansophy is the software that captures NCR's and NCR's are linked to the products / projects. NCR's are resolved during the project.	C
10	Review of Detours, Deviations and Discrepancies in Pansophy	-L2HE D3 216 11/13/2024 -C100R-D3-123, D3-118 -ER5C D3-714-NCR created	Pansophy is the software that captures D3's and they are linked to the product/projects. D3's are resolved during the project.	C
11	Review of WCD-Work Control Documents to see evidence of who should be notified when an NCR is initiated and modified, and who is authorized to determine the resolution and close the NCR. -Trace the information into Travelers within the Pansophy systems.	L2HE-RG-001-R3 L2HE WCD Register -Traveler L2HE-CWI-UCM -Traveler L2HE-CLNRM-CST-ASSY	Review of L2HE WCD includes names of personnel as NCR informative and NCR dispositioners. It is noted that the current NCR names on the WCD are not always kept current, nor is the list on Page 1 of the traveler. This is not a requirement of the procedure.	C
12	Review a sample of Quality Review meetings to see data from the NCRs and D3s.	2/10/2024 Quality Review Meeting 9/9/2024 Quality Review Meeting	Meetings include data from NCR's and D3's.	C

	Requirement/Question	Evidence	Notes	Findings (C/Mj/Mn)
13	Review of NCR traveler STP-NCR-R13	STP-NCR-R13 06Jan2025	This is a document that describes the coding of the NCR Traveler in Pansophy. It appears current.	C
Program Monitoring Method				
14	NCR Category Pareto	2/10/2024 Quality Review Meeting	Informative only.	C
15	NCR Resolution Pareto	2/10/2024 Quality Review Meeting	Informative only	C
16	NCR Timeliness	2/10/2024 Quality Review Meeting	Informative only	C
17	Significant NCRs	2/10/2024 Quality Review Meeting	New metric that has not been reported in Quality Review or Management Review yet. Updates to Pansophy occurred in Jan 2025.	C

2 Objective Evidence

N/A

3 Approvals

Approved by:	Name:	Signature:	Date:
Lead Auditor	Debbie Newman	Debbie Newman Debbie Newman (Mar 7, 2025 16:22 EST)	7-Mar-2025

A-054 Internal Audit Report_Checklist-Nonconforming Product

Final Audit Report 2025-03-24

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