

Internal Audit Report

Audit Number	A-053
Process or Project	Internal Audit
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 Internal Audit since the previous internal audit (16 Apr 2024).

2 Criteria

Criteria related to this audit includes:

-ISO 9001:2015 primarily section 9.2 Internal Audit.

-SRF-14-PD-001, SRF-14-PR-001 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 Internal Audit
Ashley Mitchell	Management Representative

5 Checklist and Evidence

A-053 Internal Audit Checklist-Internal Audit attached

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	In one Internal Audit (A-037), the auditor did not use the Audit Checklist as required by the procedure.	ISO 9001:2015 - Section 9.2.1 a) 1) SRF-14-PR-001 Section 5.3.3 Audit Checklist
2	In review of CAPA's, CAPA-060 did not have a review of the effectiveness of the corrective action taken as required by the standard.	ISO 9001:2015 Section 10.2.1

6.3 CAPA Reports

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

CAPA	Nonconformity(ies)
CAPA-073	Minor-1
CAPA-074	Minor-2

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) Consider performing and documenting auditor training on the Internal Audit Procedures.
2. 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: 1
2. Number of Records not found or not in compliance: 0
3. Number of Documents not found or not in compliance: 1

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	<u>Ashley Mitchell</u> <small>Ashley Mitchell (Mar 7, 2025 15:50 EST)</small>	7-Mar-2025
Lead Auditor	Debbie Newman	<u>Debbie Newman</u> <small>Debbie Newman (Mar 7, 2025 16:23 EST)</small>	7-Mar-2025
Process Owner of Internal Audit	Ashley Mitchell	<u>Ashley Mitchell</u> <small>Ashley Mitchell (Mar 7, 2025 15:50 EST)</small>	7-Mar-2025
SRF Department Head	Tony Reilly	<u>Tony Reilly</u> <small>Tony Reilly (Mar 24, 2025 08:38 EDT)</small>	24-Mar-2025

Internal Audit Checklist

Audit Number	A-053
Process or Project	Internal Audit

1 Checklist

	Requirement/Question	Evidence	Notes	Findings (C/Mj/Mn)
Review of Prior Audits				
1	NC's from prior audit: None	Audit-038	There were no nonconformances from the previous audit that required verification.	C
2	Status of OFI's from prior audit: None	Audit-038	There were no OFI's identified from the previous audit.	C
Review of Audit Criteria				
3	ISO 9001:2015 – 9.2 Internal Audit	SRF-14-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-14-PD-001 and appears to be adequate for the organization.	C
5	Review of SRF-14-PD-001 Internal Audit Program Description	SRF-14-PD-001 Rev 3	The Program Description refers to audit scheduling, preparation, conducting the audit, audit results, audit report, and post-audit activities. It also refers to responsibilities and authorities. This document adequately addresses the applicable ISO 9001 requirements.	C
6	Review of SRF-14-PR-001 Internal Audit Procedure	SRF-14-PR-001 Rev 5	The Procedure includes all elements required of ISO 9001 and adequately describes the process including roles and responsibilities.	C
Review Objective Evidence in support of Audit Criteria				
7	Review of SRF-01-RF-006 Processes and Process Owners – were they audited once per calendar year?	SRF-01-RF-006 Rev 5	All processes in 2024 were audited per the Audit Register.	C

	Requirement/Question	Evidence	Notes	Findings (C/Mj/Mn)
8	Review of SRF-14-RG-001 Audit Register	SRF-14-RG-001 Rev 20Nov2024	All processes in 2024 were audited per the Audit Register.	C
9	Review a sample of internal audits from 2024	A-042 Infrastructure 18Jul2024 A-037 NC Product 08Apr2024 A-035 Competence 18Mar2024	A-042 had 2 minor nonconformances – CAPA-064 and CAPA-065. CAPA's were generated appropriately. A-037 had 1 minor nonconformance-CAPA-060 A-035 had 1 major nonconformance-CAPA-058 MI NC#1 – Section 5.3.3 in SRF-14-PR-001 requires use of the checklist. A-037 did not utilize the checklist. MI NC#2 – CAPA-060 did not have a review of the effectiveness of the corrective action taken (ISO 9001 10.2.1)	Mi x 2
	Internal Audit results presented to Management Review	Management Review Report 14Jan2025	Section 2.14 discussed internal audit results.	C
	Auditor Qualifications	Aimee Barnard Debbie Newman Ashley Mitchell	AB-30Oct2024 Competence Form included CQA certificate June 9, 2020 DN-ISO 9001 Exemplar Global Certification 22Nov2024 AM-Competence Form included ISO 9001 Lead Internal Auditor 24Jan2023 OBS#1 – Consider performing and documenting auditor training on the Internal Audit Procedures	C

	Requirement/Question	Evidence	Notes	Findings (C/Mj/Mn)
Program Monitoring Method				
	QMS Internal Audit Completion	Management Review Report 14Jan2025	Met goal of 100%	C
	QMS Audit Nonconforming Findings Per Audit	Management Review Report 14Jan2025	No goal. 2024-0.73	C
	QMS Audit Nonconforming Findings Per Year	Management Review Report 14Jan2025	No goal 2024-11	C
	Audit Nonconforming Findings Per Year	Management Review Report 14Jan2025	No goal 2024 0 findings	C

2 Objective Evidence

N/A

3 Approvals

Approved by:	Name:	Signature:	Date:
Lead Auditor	Debbie Newman	<u>Debbie Newman</u> Debbie Newman (Mar 7, 2025 16:23 EST)	7-Mar-2025











A-053 Internal Audit Report_Checklist-Internal Audit

Final Audit Report

2025-03-24

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