



Complaint Handling SOP

1. Purpose

To define the process for identifying, documenting, investigating, escalating, correcting, and closing incidents, non-conformances, and external complaints using the approved **Incident Report and CAPA forms**, in accordance with Good Documentation Practice (GDP) and ALCOA principles.

2. Scope

This SOP applies to all incidents, potential non-conformances, and external complaints related to company services, shipments, or deliveries.

This SOP applies to all employees involved in reporting, investigating, approving, implementing, or closing incidents and CAPAs.

3. Policy

3.1 Incident and Complaint Identification

Incidents and complaints may originate from:

- External customers
- Internal personnel
- Identification of actual or potential non-conformances

All identified incidents or complaints shall be documented using the approved **Incident Report Form**.

3.2 Incident Report Completion

The individual identifying the incident or complaint shall complete the Incident Report Form as soon as possible and in a contemporaneous manner.

The following information shall be completed, where applicable:

- Incident Date
- Incident Taken By
- Customer Name, Phone, and Address
- Contact Name and Position



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- SLL Job Number and Client Reference Number
- Concise description of the non-conformance, potential non-conformance, or external complaint
- Initial remedial action taken
- Suspected root cause
- Corrective action person(s)
- Corrective action follow-up
- Steps to avoid repeating the problem
- CAPA escalation decision (Yes/No) with justification
- Name and date of person completing the form

Completed Incident Reports shall be submitted to the Quality Manager within **24 hours** of identification.

3.3 Initial Remedial Action

Where required, immediate remedial action may be taken to mitigate or correct the issue. All such actions shall be documented in the **Initial Remedial Action** section of the Incident Report.

3.4 Incident Review and CAPA Escalation

The Quality Manager shall review each Incident Report and determine whether escalation to CAPA is required.

The escalation decision shall be documented by selecting **Yes or No** on the Incident Report and providing justification. When CAPA is required, the Quality Manager shall initiate the CAPA process.

3.5 CAPA Investigation

When CAPA is initiated, the CAPA section of the form shall be completed by the Quality Manager or an assigned team member and shall include:

- Confirmation of whether initial remedial action was taken (or justification if none)
- Details of the investigation
- Identification of one or more root causes

Investigations shall be appropriate to the severity and complexity of the issue and supported by objective evidence.



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3.6 Corrective and Preventive Actions

Corrective and preventive actions shall be defined, documented, and tracked within the CAPA form, including:

- Corrective actions to prevent recurrence of an existing non-conformance
- Preventive actions to prevent potential future non-conformances
- Assigned action owners
- Due dates and completion dates

Actions shall be implemented and monitored until completion.

3.7 CAPA Classification and Timeframes

Each CAPA shall be classified by the Quality Leader in **Part C: Problem Identification and Evaluation** as:

- **Minor** – target closure within **7 working days**
- **Major** – target closure within **5 working days**
- **Critical** – target closure within **2 working days**

CAPA open and close dates shall be recorded in the CAPA Log.

3.8 Review and Approval

Proposed corrective and preventive actions shall be reviewed and approved by:

- An SLL Team Member reviewing and approving the actions
- An SLL Manager reviewing and submitting the actions

Names, job titles, and approval dates shall be documented on the CAPA form prior to implementation.

3.9 CAPA Monitoring and Closure

The Quality Leader shall:

- Assign a CAPA Log Reference Number
- Monitor CAPA progress and completion
- Verify implementation and effectiveness of actions



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CAPA may be closed only when all actions are completed, verified, and approved. Closure shall be documented with the **CAPA Closed Date** and **QA Name**.

3.10 Communication

Where applicable, customers shall be informed of complaint receipt and resolution. All customer communications shall be documented within the Incident Report and/or CAPA records.

3.11 Records, Documentation Control, and Data Integrity

All Incident Reports, CAPA forms, and CAPA Logs are quality controlled and shall be completed in accordance with **Good Documentation Practice (GDP)** and **ALCOA principles** (Attributable, Legible, Contemporaneous, Original, Accurate).

- Records shall be completed legibly and contemporaneously using permanent ink or approved electronic systems.
- All entries shall be attributable to the individual completing them.
- Errors shall be corrected by drawing a single line through the original entry, entering the correct information, and initialing and dating the correction.
- Records shall not be obscured, erased, or deleted.

All records shall be retained for a minimum of **three (3) years**, unless a longer retention period is required by regulatory, contractual, or customer requirements.

3.12 Training and Review

Relevant personnel shall be trained in this SOP. Incident and CAPA trends shall be reviewed periodically by Quality Management. This SOP shall be reviewed at least every **two years**, or sooner if required.



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REVISION CONTROL

The following is the revision history for this document.

Version	Change Description	Eff Date	Approver	Approver
1.0	Creation	24 AUG 2023		
1.1	Logo Updated	19 JUN 2024		
2.0	Complete revision of SOP. Updated structure, clarified responsibilities, aligned complaint handling practices with GDocP and ALCOA+ principles. Supersedes all previous versions.	04 MAR 2026	DocuSigned by: <i>Bill Maloney</i> C34D253392F940F... 3/4/2026	Signed by: <i>Vince Lambert</i> 213BC8E41A9D48A... 3/4/2026

Certificate Of Completion

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 Subject: Complete with Docusign: SLL Complaint Handling SOP 2.0.pdf
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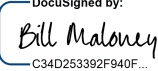
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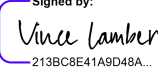
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 vlambert@myrushdelivery.net
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Electronic Record and Signature Disclosure:

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 ID: 3a6f0e88-2bca-4e75-883c-413790892534

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/4/2026 8:15:35 AM
Certified Delivered	Security Checked	3/4/2026 2:22:11 PM
Signing Complete	Security Checked	3/4/2026 2:23:19 PM
Completed	Security Checked	3/4/2026 2:23:19 PM

Payment Events

Status

Timestamps

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