



Deviation and Nonconformance Management SOP

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to establish a controlled and consistent process for identifying, documenting, investigating, classifying, correcting, and preventing deviations, nonconformances, and complaints related to transportation, storage, handling, and distribution activities. This SOP supports compliance with Good Distribution Practice (GDP), Good Documentation Practices (GDocP), and ALCOA+ principles. All issues are first recorded as Incident Reports; CAPAs are initiated only if warranted by QA review or client request.

2. Scope

This SOP applies to all operational, quality, safety, and compliance deviations and complaints, including those received from internal or external sources. It covers:

- Temperature excursions
- Delivery errors or delays impacting product quality
- Chain of custody breaks
- Documentation errors or missing records
- Vehicle or equipment failures
- Security incidents
- SOP non-compliance
- Client-specific requirement failures

All deviations that require CAPA are managed in accordance with the CAPA SOP. This SOP applies to all employees, contractors, and departments involved in regulated transport operations.



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3. Policy

3.1 All Personnel

- Immediately report deviations, suspected deviations, or complaints
- Provide accurate and timely information
- Participate in investigations when requested

3.2 Drivers, ICs, and Field Personnel

- Report incidents, deviations, and complaints to Dispatch immediately
- Document facts in job records and system notes
- Preserve shipment integrity while awaiting instruction

3.3 Dispatch / Operations

- Record initial Incident Report details in Xcelerator CASE and job memo
- Notify Operations Management and QA

3.4 Operations Manager

- Ensure Incident Reports, deviations, and complaints are logged and assigned
- Support investigation and fact gathering
- Verify operational corrective actions are implemented

3.5 Quality Assurance (QA)

- Owns deviation, complaint, and CAPA processes
- Reviews of all Incident Reports to determine if CAPA is warranted
- Initiates CAPA per CAPA SOP when required or upon client request
- Reviews and classify deviations and complaints (Minor, Major, Critical)
- Approves root cause analysis and CAPA closure



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- Ensure client communications are completed for complaints

4. Identification and Reporting

All deviations and complaints are first documented as an Incident Report. Sources include:

- Temperature alarms or excursions
- Dispatch or driver reports
- Client complaints (verbal or written)
- Audit findings
- Monitoring system alerts (Samsara, Thermo King)
- Documentation review
- Equipment or vehicle failures
- Training gaps

Incident Reports must be submitted immediately to the manager and forwarded to QA for review.

5. Investigation and CAPA Decision

1. QA reviews the Incident Report to determine:
 - Whether the deviation or complaint warrants a CAPA
 - Classification of Minor, Major, or Critical per CAPA SOP
2. CAPA is automatically created if requested by the client or if the deviation/complaint is Major or Critical.
3. Investigations follow CAPA SOP methodology, including root cause analysis using 5 Whys and or Fishbone when applicable.
4. Investigation outcomes feed directly into CAPA action plans if applicable.



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6. Classification

Classification	Description	CAPA Action
Minor	Low-risk deviation or minor complaint; no expected impact	CAPA may be initiated based on trend or client request; investigate within 7 working days per CAPA SOP
Major	Potential or confirmed impact to product quality, compliance, or complaint	CAPA required; investigate and implement actions within 5 working days per CAPA SOP
Critical	Confirmed product compromise, regulatory/client-reportable, or serious complaint	CAPA required; immediate investigation and implementation within 2 working days per CAPA SOP

7. Corrective and Preventive Actions (CAPA)

- CAPA is initiated per the CAPA SOP if QA determines it is required or if client requests.
- Corrective and preventive actions are documented, implemented, and verified for effectiveness (30 days post-closure) per CAPA SOP.
- CAPA records are linked to the originating Incident Report.
- Effectiveness checks may trigger additional CAPA if actions are found ineffective.

8. Client Notification

- Client notification follows CAPA SOP guidance: immediate or per client agreement.
- QA ensures documentation of communication.



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9. Documentation and Records

Records must include:

- Incident Reporting recorded in CASE and in SLL Portal
- Investigation notes
- Supporting data
- CAPA records (if applicable)
- Client communications (if applicable)
- QA approval and closure documentation

All records follow ALCOA+ principles and company retention requirements.

10. Trending and Review

- QA reviews deviations and complaints quarterly.
- Trend analysis identifies recurring causes, gaps, and improvement opportunities.
- CAPA actions feed into trend reports and continuous improvement initiatives.

11. Training

- Personnel involved in deviations, complaints, or CAPA processes must be trained and records maintained.

12. Definitions

- **Incident Report:** Initial documented record of a deviation, complaint, or issue, regardless of severity.
- **Deviation:** Departure from an approved procedure, requirement, standard, or expected outcome.



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- **Nonconformance:** Failure to meet a specified requirement (regulatory, client, SOP, or contractual).
- **Complaint:** Any issue reported from internal or external sources, verbal or written, relating to service, shipment, or delivery.
- **Minor Deviation:** Low-risk deviation or minor complaint issue; no expected impact on product quality or compliance.
- **Major Deviation:** Deviation or complaint with potential or confirmed impact to product quality, compliance, or client requirements.
- **Critical Deviation:** Deviation or complaint resulting in confirmed impact to product quality, data integrity, or regulatory/client-reportable events.
- **Root Cause:** The underlying reason for a deviation or complaint occurred.
- **CAPA:** Corrective and Preventive Action initiated in accordance with the CAPA SOP to remediate and prevent recurrence.
- **ALCOA+:** Attributable, legible, contemporaneous, original, accurate, + complete, consistent, enduring and available

13. References

- SIR LANCELLOT LOGISTICS CAPA SOP
- Shipment Lifecycle SOP
- GDP Guidelines
- Complaint Handling SOP



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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	02 MAR 2026	DocuSigned by: <i>Bill Matton</i> 2026 C34D253392F940F...	Signed by: <i>Vince Lambert</i> 2026 213BC8E41A9D48A...

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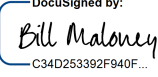
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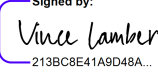
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Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
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Signing Complete	Security Checked	3/2/2026 11:38:25 AM
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