



Change Control SOP

1. Purpose

The purpose of this SOP is to ensure that all changes to controlled documents, systems, and critical business components are assessed, approved, implemented, and documented in a controlled manner. This process ensures traceability, consistency, and compliance with Good Documentation Practices (GDP) and ALCOA principles and maintains the integrity of the Quality Management System (QMS).

2. Scope

This SOP applies to all changes affecting:

1. **Controlled QMS documents**, including SOPs, forms, policies, and records.
2. **Critical business components**, including:
 - o IT software and systems (e.g., Xcelerator shipment tracking, Samsara vehicle tracking, Thermo King TCV monitoring, QMS).
 - o Critical facility changes impacting operations.
3. **Internal and external process changes** that could impact service delivery, compliance, or customer satisfaction.

All changes, regardless of source, must be submitted, reviewed, and approved according to this SOP.

3. Policy

3.1 Responsibilities

Step	Responsible	Accountable	Consulted	Informed
Initiate Change Request	Requester / Employee	N/A	QA, Operations	Manager
Review & Define Options	Change Control Committee	Manager	QA, IT, Operations	Customer (if applicable)
Approval of Change	Manager / Senior Staff	CEO / VP / Director of Operations	QA, Operations	Requester / Affected Departments



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Step	Responsible	Accountable	Consulted	Informed
Implementation	Assigned Owner	Manager	QA	All impacted staff
Verification & Closure	QA / Change Control	Manager	None	Requester / Affected Staff

Change Control Committee manages the overall process and ensures compliance with this SOP. The **Quality Manager** ensures records are complete and retained.

4. Policy & Procedure

4.1 Change Request Submission

- All changes must be submitted using the Change Request Form (CRF) or an approved electronic system.
- The CRF must include:
 1. Unique Change Request ID
 2. Date of submission
 3. Requester name and department
 4. Description of the requested change
 5. Reason for the change
 6. Expected benefits or value
 7. Proposed timeline / expected completion
 8. Conditions of success / acceptance criteria
- Emails or informal communication are not sufficient for documenting change requests.

4.2 Review and Options

- The Change Control Committee reviews each CRF within a defined turnaround time (e.g., 3 business days).
- At least two options for implementing the change shall be evaluated, including:
 1. Option number and name



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2. Proposed solution and steps to implement
 3. Estimated timeline
 4. Impacts to documents, processes, or systems
 5. Expiration date for customer or internal approval
- All impacts on quality, compliance, and customer satisfaction must be assessed.

4.3 Approval

- Minor changes may be approved by the Manager.
- Major or critical changes require approval by Senior Staff (CEO, VP, Director of Operations).
- Approval must be documented with name, title, signature, and date in the CRF or electronic system.

4.4 Implementation

- Once approved, the assigned owner implements the change.
- All activities must be documented and traceable.
- A verification step by QA or designated personnel must confirm the change is implemented correctly and meets acceptance criteria.

4.5 Communication and Training

- All impacted personnel must be notified of the change.
- Training is required for any procedural or system changes that affect personnel tasks.
- Communication and training records must be maintained.

4.6 Recordkeeping

- All CRFs, supporting documents, approvals, and verification records are controlled quality records.
- Records must comply with GDP and ALCOA principles:
 - **Attributable:** Identify who performed and approved each step
 - **Legible:** Entries must be readable and permanent



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- **Contemporaneous:** Completed at the time of action
- **Original:** Use original forms or approved electronic records
- **Accurate:** Reflect true events and decisions
- Errors must be corrected by striking through with a single line, entering the correct information, and initialing and dating the correction.
- All records shall be retained for a minimum of three (3) years, unless regulatory or contractual obligations require longer retention.

4.7 Closure

- QA verifies that the change was implemented and the CRF is complete.
- Closure of the CRF must be documented with date, name, and signature.
- The CRF is then filed in the Change Control Log for audit purposes.

4.8 Monitoring and Review

- The Change Control Committee shall periodically review change trends and metrics to identify process improvement opportunities.
- This SOP shall be reviewed at least every two years or earlier if required.

5. References

- QMS: Incident, Complaint, and CAPA Handling SOP
- GDP / ALCOA Principles



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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	18 July 2023		
1.1	QMS added to the Scope as a business component.	9 JAN 2024		
1.2	Company Name and Logo Updated	19 JUN 2024		
2.0	Comprehensive revision to clarify process flow, strengthen role and approval requirements, and align with QMS and related SOPs. Supersedes Version 1.2 in full.	04 MAR 2026	DocuSigned by: <i>Bill Maloney</i> C34D253392F940F... 3/4/2026	Signed by: <i>Vince Lambert</i> 213BC8E41A9D48A... 3/4/2026

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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 8:14:01 AM
Certified Delivered	Security Checked	3/4/2026 2:13:13 PM
Signing Complete	Security Checked	3/4/2026 2:21:05 PM
Completed	Security Checked	3/4/2026 2:21:05 PM

Payment Events

Status

Timestamps

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