1. PURPOSE

The purpose of this procedure is to provide the requirements and responsibilities for managing the recall and recovery of LiquiGlide products, including notifications to appropriate clients.

2. SCOPE

2.1. The scope of this procedure is limited to LiquiGlide finished products manufactured either internally or using a Contract Manufacturing Organization (CMO).

3. RESPONSIBILITIES

Role	Responsibility
Management	– Notify the Head of Quality in the event of any potential product recall and recovery situation. – Communication of results from recall/recovery events to all applicable personnel.
Head of Quality:	– Send out notifications to clients related to recall and recovery incidents that indicates a potential risk to customer safety or product quality in a timely manner. – Organizing and determining the frequency of testing of the Recall and Recovery process.

4. DEFINITIONS

N/A

5. PROCEDURE

5.1. A product recall and recovery event may be voluntarily initiated at any time by LiquiGlide, based on any information that indicates a potential risk to customer safety or product quality.

5.2. Management of product recall and recovery events must be conducted by LiquiGlide in a controlled and effective manner.

5.3. In the event that a LiquiGlide partner determines a product recall and recovery is required, LiquiGlide will support the recall and recovery according to the applicable quality agreement.

5.4. All product recall and recovery events must be documented in **[QA-032-FRM-01] Recall and Recovery Form**, including any notifications to regulatory bodies, as required.

5.5. Any member of the Management team who becomes aware of a potential product recall and recovery situation must report the situation to the Head of Quality.

5.6. Management will work with the Head of Quality to determine the specific actions to be taken for the potential recall and recovery event.

5.7. Upon determination of the recall and recovery event, the Head of Quality or designee shall gather the following information:

5.7.1. The lots numbers of product affected

5.7.2. The number of distributed containers affected

5.7.3. The shipping records for the distributed containers

5.8. Each product recall event should be categorized by the Head of Quality and the Management Team. Recall event categories should be recorded **[QA-032-FRM-01] Recall and Recovery Form.** in A recall event can be any of the following categories:

5.8.1. Emergency: A recall event which could lead to severe harm or death.

5.8.2. Major: A recall event which could have some health or safety impact on customers.

5.8.3. Moderate: A recall event which could impact customer satisfaction, but not safety.

5.8.4. Minor: A recall event which is cursory or cosmetic and will not affect the use or safety of the product.

5.9. In a timely manner, the Head of Quality or designee shall notify the appropriate customers and document the event in **[QA-032-FRM-01] Recall and Recovery Form**.

5.9.1. Notification of recall events to customers should include:

5.9.1.1. product name

5.9.1.2. impacted lot numbers

5.9.1.3. date of manufacture and expiration date

5.9.1.4. reason for recall and recovery

5.9.1.5. account of incident/corrective actions taken

5.9.1.6. Risk Assessment/Hazard analysis

5.9.1.7. Recall Event Category

5.9.1.8. name and contact information for point-of-contact

5.9.2. All notification of recall events to customers must be recorded in the **[QA-032-FRM-02] Product Recall Notification Log.** Include the following information:

5.9.2.1. Date of notification.

5.9.2.2. The associated incident number for the recall.

5.9.2.3. The name of the client contact and their title.

5.9.2.4. What information was provided and any additional comments (i.e. were regulatory bodies notified?)

5.10. Returned product must be clearly marked as such, quarantined in a secure location, and physically isolated pending final disposition.

5.10.1. The number of containers returned shall be compared to the number of shipped containers identified in section 5.7 to assess the effectiveness of the recall.

5.11. Non-distributed product impacted by the recall and recovery event must be clearly identified, segregated, and stored in a secure location pending final disposition.

Tests of the Recall and Recovery Procedure

5.12. The Recall and Recovery procedure at LiquiGlide shall be periodically tested. The Head of Quality will determine the frequency of Recall and Recovery tests.

5.13. LiquiGlide Management will communicate the results of Recall and Recovery tests to all applicable LiquiGlide Personnel.

6. ATTACHMENTS

6.1. Attachment 1: Recall and Recovery Form (See QA-032-FRM-01)

6.2. Attachment 2: Product Recall Notification Log (See QA-032-FRM-02)

7. REVISION HISTORY

Revision	Summary of Changes
01	New Document

REVISION HISTORY

Version 01 Effective on 05-Aug-2019
New Document

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

Taylor Farnham
Senior Mechanical Engineer
taylor.farnham@liquiglide.com

I am the author of this document.
Signed 9:19:28 PM UTC 22-Jul-2019

Required Workflow Steps for this Category

Michael Tyo
Quality Assurance Consultant
michael.tyo@liquiglide.com

LiquiGlide Inc / Quality Assurance Approval
I have reviewed and approve this document.
Signed 1:46:49 AM UTC 24-Jul-2019