

## Product Recall in North America

**Note:** Due to security concerns, some information in this chapter has been removed or replaced with XXX.

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**Attachment(s):**

- Customer List Worksheet
- Recall Record
- Using Customer List Worksheet
- Using Recall Record



## Overview

**Product recalls initiated to protect stakeholders** A Product Recall is initiated when BOC notifies users, purchasers, distributors or transporters of a defective product or service that, if not addressed, will most likely affect the occupational health and safety of people involved in, or in the vicinity of, product use, storage or transport.

Most Product Recalls are initiated voluntarily but government agencies such as the FDA are able to initiate compulsory recalls if a voluntary recall has not been initiated, or is considered to be inadequate.

## Purpose and Scope

**Purpose** This chapter provides a framework and reference for the Product Recall process.

**Scope** This chapter applies across BOC North America:

- All Gas Products, including
  - ISP: Food, Medical, Industrial, Special
  - PGS: Process Operations, Distribution, Engineering & CES
  - EM: Electronic gases
- All Equipment provided or distributed to Customers, including
  - ISP: Medical, Home Therapy, Welding & Safety, Hospital, Containers, Valves and Labeling
  - PGS: Process , Customer Equipment
  - EM: Process, Containers, Valves and Labeling

## About Product Recalls

**Initiation of Product Recalls** Most Product Recalls are initiated in several ways:

- Voluntarily by suppliers who have discovered a serious defect with their product.
- Compulsory recalls may be initiated by a government agency if a voluntary recall has not been made, or is considered inadequate.
- Customer complaints and internal non-conformances

**Recall phases** The Product Recall process consists of the following major phases:

- *Assessing the Impact of the Problem (Page 5)*
- *Deciding to Proceed with Product Recall (Page 6)*
- *Developing the Product Recall Action Plan (Page 7)*
- *Recall Communications and Notifications (Page 7)*
- *Implementing the Product Recall Action Plan (Page 8)*
- *Disposal and Replacement of Recalled Product (Page 9)*
- *Post Product Recall Actions (Page 10)*

**Operational readiness** Given the critical importance of this process, it is essential that all appropriate staff can perform the roles defined in this chapter. This **must** be achieved by training, see *Process Awareness (Page 11)*, and by conducting *Mock Product Recalls (Page 11)*.

**Product Recall Priority** Product Recalls may be categorized by priority as follows:

<b>Recall Priority</b>	<b>Description</b>
<i>P1 – Serious Risk</i>	<ul style="list-style-type: none"> <li>• Emergency crisis situation</li> <li>• A situation in which there is reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.</li> <li>• Potential to lead or has lead to a P1 Incident</li> <li>• Regulatory mandate</li> </ul>
<i>P2 – High Risk</i>	<ul style="list-style-type: none"> <li>• A situation in which use or exposure to a product may cause temporary or medically reversible adverse health consequences</li> <li>• Probability of serious adverse health consequences or death is remote.</li> <li>• Potential to lead or has lead to a P2 Incident</li> </ul>
<i>P3 – Medium Risk</i>	<ul style="list-style-type: none"> <li>• A situation in which use or exposure to a product is not likely to cause adverse health consequences</li> <li>• Potential to lead or has lead to a P3 Incident</li> </ul>
<i>P4 – Low Risk</i>	<ul style="list-style-type: none"> <li>• Insignificant or no hazard situation</li> <li>• No Recall Required or Passive Recall</li> </ul>

*Note:* See *IMS-24-05 : Accident/Incident Investigation and Reporting in Gases America* for information on Incident Categories

**Crisis situations** In a crisis situation, the time frame is very short and the pressure to resolve a problem may be very intense. In these situations, some of the roles and responsibilities defined in this chapter may be combined. Similarly, Product Recall assessments, decisions and the performance of the Action Plan (preliminary) may be "intertwined".

# Product Recall Ownership and Responsibility

**Business process ownership** The following positions are responsible for the Product Recall process execution and P1 and P2 Product Recalls in their area of responsibility:

- ISP: VP of Operations
- PGS: VP of Process Operations
- PGS: VP of Distribution and Logistics

**Product Recall Steering Committees** The VP SHEQ will assemble a Product Recall Steering Committee when a potential recall is initiated. The committee will be comprised of members, aligned with businesses, for example Industrial Products, Medical Products, Special Products, Bulk, Customer Engineering Services (CES), from the following functions:

- Business Unit(s) involved or affected (Sales/Marketing/Management)
- Communications
- Legal
- Engineering & Technology
- Operations (Production/Distribution)
- Container Asset Management
- Safety/ Health/ Environment/ Quality (SHEQ)

Product Recall Steering Committees are similar to Assessment Teams. In addition, they become involved in the Action Plan and implementation of remedial actions.

**Initiator and notification** The initiator is the person who receives the initial enquiry or becomes aware of a problem or non-conformance. Immediate notification **must** be made to:

- VP SHEQ or Director Quality Assurance – Murray Hill
- 1-800-XXX-XXXX if these individuals are not available

**Corporate legal team** Corporate Legal provides ongoing legal support to the Recall Team and Steering Committee, including:

- Review all legal requirements as appropriate
- Review contractual commitments to customers
- Product Warranty considerations
- Product Liability considerations
- Assessment of potential claims from customer.

**Medical product expert** The Director of Quality Assurance – Murray Hill ensures that all GMP requirements are met. This includes:

- Contact Regulatory Authority such as FDA
- Advise details of recall
- Advise duration of recall action and completion date.
- Advise recall implementation plan
- Document all aspects of the Product Recall process, including any agreements or follow up with Regulatory Agency.
- Provide recall updates to Regulatory Agencies such as the FDA
- Request termination approval of recall from Regulatory Agency such as the FDA

**Recall Assessors** Recall Assessors are staff with appropriate knowledge and experience who are directed by the VP SHEQ, after consultation with the appropriate Business Process Owners, to investigate product problems or non-conformances in order to arrive at a recommendation to recall or not.

They will usually be from the part of the business that the product impacts, for example:

- Business Managers
- Key Customer Account Managers
- Container Asset Managers
- Production and Distribution
- CES
- SHEQ Specialist or QA Manager
- Legal
- Communications
- Engineering/Technical

**Product Recall Manager** Product Recall Manager (appointed and empowered) is a competent person with the responsibility to coordinate and carryout all functions of the recall process.

**Product Recall Team** Product Recall Team consists of resources close to the action, as required by the Recall Manager to carry out the action plan.

## Product Recall Process

### Assessing the Impact of the Problem

**Review failures against specifications** Recall Assessors review product failures against product specifications and advise VP SHEQ with a recommended course of action. The timeliness of this assessment is critical and it should take between 24 to 48 hours to complete.

*Note:* Additional Assessors may be required to meet the timeline.

Step	Action
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Step	Action	
1	<p>Collect and record details of the problems, including:</p> <ul style="list-style-type: none"> <li>Name, telephone, fax of person reporting the problem</li> <li>Date and time of report</li> <li>Physical location of problem</li> <li>Nature of problem</li> <li>Number of reports received</li> <li>Results of tests and other investigations on suspect and other samples</li> <li>Other relevant factors.</li> </ul>	<input type="checkbox"/>
2	<p>Collect and record details of the product, including:</p> <ul style="list-style-type: none"> <li>Product name and description</li> <li>Batch or serial number</li> <li>Manufacturer/BOC Site contact name, phone and fax</li> <li>Date manufactured</li> <li>Date released</li> <li>Quantity of the batch and amount released</li> <li>Quantity estimated to be in Distribution channels</li> <li>Local/overseas distribution</li> <li>Distribution information, including the number of direct and other accounts and, where necessary, the identity of the accounts.</li> <li>Number of complaints received</li> <li>Product part order code.</li> </ul>	<input type="checkbox"/>
3	<p>Collect and record details of other relevant information including:</p> <ul style="list-style-type: none"> <li>Availability for investigation of suspect sample or other samples</li> <li>Type of hazard, and assessment of risk to user</li> <li>Action proposed (including communication)</li> <li>Proposed recall Priority (1, 2, 3 or 4).</li> </ul>	<input type="checkbox"/>
4	<p>Prepare a detailed report for VP SHEQ advising for or against a recall. The report will include identified hazards, assessed risks and a review of consequences. In addition, the following <b>must</b> be included:</p> <ul style="list-style-type: none"> <li><b>Recall Record (see attachment)</b></li> <li><b>Customer List Worksheet (see attachment)</b></li> </ul>	<input type="checkbox"/>
5	<p>Proposals for the correction of the problems under investigation should be included in the report, even if a recall is not recommended.</p>	<input type="checkbox"/>

## Deciding to Proceed with Product Recall

### Determining if recall is necessary

The VP SHEQ will call an immediate meeting with the Product Recall Steering Committee. The committee **must** review all available information from the Recall Assessor(s). A decision will be made as quickly as possible to decide one of the following:

- No action is required
- Possibility of product recall exists; more data required
- Product recall is indicated

- Proceeding with a recall** When the Product Recall Steering Committee makes a decision to proceed with a Product Recall they will initiate the following:
- Communication to all stakeholders affected by the recall decision
  - Appointment of a Recall Manager and Recall Team to co-ordinate and execute all functions
  - Contingency planning process, if appropriate
  - Development of a Recall Strategy and Plan
  - Role Map: Internal and external (customers)

- Documenting the decision** Any of the above three decisions **must** be documented as follows:
1. If no action is required, the rationale and data to support that decision **must** be a part of the documentation.
  2. If more data is required the following **must** be documented:
    - Reason data is required
    - Clear ownership of what is required
    - Person responsible for securing data
    - Plan to be executed with data
    - Date plan will be available

If product recall is indicated, documentation **must** indicate the rationale for the decision, including appropriate data and records as per *Recall Record (see attachment)* and *Customer List Worksheet (see attachment)*. Documentation **must** also include the agreed to Product Recall Strategy.

## Developing the Product Recall Action Plan

- Developing the Recall Plan** The Recall Manager and Product Recall Team gather any additional information required and develop the Recall Action Plan. The plan must be approved by the Product Recall Steering Committee and must include:
- Accountability
  - Timeframe for completion
  - Logistics
  - Communication
  - Areas of impact
  - Disposal
  - Closure

## Recall Communications and Notifications

- Medical recall notification** If the recall is categorized as P1 or P2, the Director of Quality Assurance – Murray Hill, **must** contact the FDA district office with a notification of the intended product recall action.
- If the FDA is notified, BOC will submit the Product Recall Action Plan for review. The agency may agree or recommend changes as appropriate.

- Product recall communication guidelines**
- Product Recall communication should be written in accordance with the following guidelines:
- Brief and to the point.
  - Product, size, lot number(s), code(s) and any other pertinent descriptive information **must** be clearly identified for accurate and immediate identification of the product.
  - Reason for the product recall and the hazard involved **must** be explained.
  - Specific instructions on how the recalled products need to be handled.
  - A ready means for the recipient of the communication to report to BOC whether it has any of the products. For example, by sending a postage-paid self-addressed postcard or by allowing the recipient to place a collect call to BOC.
  - Patient Health Risk Assessment

- Corporate communication**
- Corporate Communications prepares media release(s) and provides ongoing communication support to the Recall Manager and Team. This will include appropriate media release(s) or other forms of communication targeted at:
- Regulatory authorities such as the FDA
  - BU Managing Directors
  - SHEQ General Managers
  - Designated Media Spokesperson(s)
  - Customers
  - Internal staff
  - Suppliers.
  - Public Warnings

*Note:* Some customers may require (or prefer) their first contact for matters of this nature to be with a specific “head office” person.

- Public warnings**
- All communication **must** be cleared through general counsel prior to transmission. The recall strategy **must** specify whether a public warning is needed; if so, the following forms of public warning may be used:
- Mass media to reach total population (radio, TV, newspaper, etc.)
  - Personal calls by the BOC sales force.
  - Telephone communication followed by letter.
  - Telegraph communication followed by letter.
  - First class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: **Drug, Medical Device, Recall**, etc. The letter and the envelope should also be marked **Urgent**.
  - Distributors free bulletin services.

## Implementing the Product Recall Action Plan

**Implementing the recall plan** The Recall Manager and Recall Team implement the Recall Action Plan and follows up on progress. The team collects further data on the extent & location of product subject to recall and identifies by location each suspect item to be recalled: During the recall process the team should:

- Review all data available and decide whether further data is required.
- Monitor and report potential claims by customers
- Listen to comments by customers
- Check quality of products recalled
- Monitor impact on customers/markets
- Conduct effectiveness checks

**Effectiveness Checks** Verification of investigations by direct visits, telephone calls, letters or other verified methods to ensure that consignees have been notified of the recall and have taken appropriate action. The Effectiveness Check Level represents the depth of consignee contact:

- **P1 Recall:** 100% of the total number of consignees **must** be contacted.
- **P2 Recall:** A percentage of the total number of consignees to be contacted. The percentage is to be determined on a case-by-case basis, but **must** be greater than 10% and less than 100% of the total number of consignees.
- **P3 Recall:** 10% of the total number of consignees **must** be contacted.

**Status Reports** The Recall Manager **must** provide weekly progress reports to the Product Recall Steering Team until closure of the recall. The Recall Status Reports should contain the following information:

- Number of consignees notified of the product recall, and date and method of notification.
- Number of consignees responding to the product recall communication and quantity of products on hand at the time it was received.
- Number and identity of consignees that did not respond
- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
- Number and results of effectiveness checks that were made.
- Estimated time frames for completion of the product recall.

**Product recall progress** The Product Recall Steering Team monitors the progress of the recall and are responsible for:

- Specifying modifications to plan, if required
- Approving the closure of the recall campaign and transition to the Post Recall phase

## Disposal and Replacement of Recalled Product

**Disposal and replacement approval** The Recall Manager will submit a proposal for proper disposal and replacement of recalled product to the Product Recall Steering Committee for approval.

**Disposal and replacement process**

Recall Team organizes disposal and replacement of recalled product. They **must**:

- Ensure all products or services to be recalled are identified by location and reconcile the return of each item.
- Contact customers (as per Communication Plan) to communicate appropriate action steps for collection/disposal of recalled product.
- Coordinate collection/disposal with:
  - Customer Service Center (CSC)
  - ISP Distribution
  - National Scheduling Center (NSC)
  - Customer Engineering Services (CES)
  - Others (as appropriate).
- Dispose of defective product taking into account pollution, noise, space, etc.
- Maintain supply logistics.
- Maintain/meet safety requirements for disposal
- Arrange for delivery of replacement product (if and where required).
  - Ensure availability of sufficient stocks of replacement items
  - Where necessary, find alternative sources, and/or, methods of supply

## Post Product Recall Actions

**Final Report**

The Recall Manager **must** prepare a final report on the Recall. The report is to include relevant portions of the following information:

- Copies of recall correspondence with customers
- Circumstances leading to the recall
- Extent of distribution of the relevant batch
- Result of the recall including quantity of stock returned, corrected, outstanding, etc. (recall records, customer lists)
- Confirmation, where applicable, that customers have received the recall letter
- Method of destruction or disposal of recalled goods
- Proposed corrective and preventive actions

**Termination of a recall**

If applicable, BOC will send updates to FDA as described in Recall Plan/Strategy. The BOC Recall Steering Committee will determine when recall is closed, and the FDA will be notified accordingly.



**Closing meeting**

Recall Manager calls a Post Recall Review meeting to review the final report and to review the effectiveness of the Product Recall process. Attendees should include the Product Recall Steering Committee.

Agreement **must** be reached on corrective and preventive actions. See *IMS-14-02 : Corrective and Preventive Action Process for Gases America*

## Process Awareness

**Induction** All new manager level staff or staff promoted to manager level **must** complete the training contained in the Learning and Assessment Guide (LAG) contained in this chapter.

**Maintaining process awareness** All managers **must** include the topic of “Product Recall Process” in their Team meetings at least every three years.

## Mock Product Recalls

**Purpose** Mock Product Recalls are conducted to:

- comply with legislative or customer requirements
- ensure the readiness of managers to handle actual Product Recalls should they occur
- demonstrate compliance at medical gas locations using computer systems to keep distribution records

**Mock Recall for cylinder locations** A Mock Product Recall **must** be performed once per quarter at all BOC sites involved in the distribution of Medical Gases.

The recall will be conducted by the Location Manager or designee as follows:

- Randomly select at least three lots that will be included in each mock recall.
- Only lots with more than 25 cylinders will be used
- Each cylinder size will be included a minimum of once per year
- Lots selected will be no older than 6 months
- At least twice per year, one of the lots should be a bulk gas lot number
- In general, the steps outlined in this chapter will be followed. However, actions such as customer notification and product segregation will not be required. The forms attached to this chapter should be used as needed.
- Record the results of the mock recall and maintain the record on site.

**Mock Recall for PGS locations** A Mock Product Recall **must** be performed at all BOC sites involved in the distribution of Medical and Beverage Gases:

- Semi-annually for PGS ASU sites
- Annually for PGS CO2 beverage sites.

A Mock Recall **must** include:

- Randomly select at least three lots that will be included in each mock recall.
- Lots selected will be no older than 6 months
- In general, the steps outlined in this chapter will be followed. However, actions such as customer notification and product segregation will not be required. The forms attached to this chapter should be used as needed.
- Record the results of the mock recall and maintain the record on site.

**Evaluating Recall Results** The Location Manager or designee is responsible for:

- evaluating the results
- investigating quantity discrepancies
- initiating corrective or preventive actions
- documenting results

*Note:* The overall effectiveness of the recall will be evaluated during internal audits

**Documenting the Mock Recall** The Mock Product Recall documentation will include the following information and will be maintained on site for three years:

- Lot distribution report and customer list worksheet or other appropriate equivalent reports generated from electronic systems, such as GOLD, SAP, etc.
- Diamond or PCR reports (ISP only)
- Recall Record – with the notation at the top of the form indicating ‘Mock’

## Recordkeeping

**Retention** The Recall Record and the Customer List Worksheet **must** be maintained for six years. The Mock Recall Record **must** be maintained for three years.

## Forms and Attachments

**Forms** The following forms are used in this chapter:

- *Recall Record (see attachment)*
- *Customer List Worksheet (see attachment)*

**Attachments** The following attachments are used in this chapter:

- *Using Recall Record (see attachment)*
- *Using Customer List Worksheet (see attachment)*