



Consumer product recall—Guidelines for suppliers



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 - Australian Industry Group
 - Australian Toy Association
 - CHOICE
 - Consumer Electronics Suppliers Association
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 - National Retail Association
-

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Australian Standard®

Consumer product recall—Guidelines for suppliers

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PREFACE

This Standard was prepared by the Standards Australia Committee CS-106, Consumer Product Management Systems.

The objective of this Standard is to provide practical guidance to suppliers on consumer product recalls and other corrective actions after the product has left the manufacturing facility. Other corrective actions include, but are not limited to, refunds, retrofit, repair, replacement, disposal and public notification.

This Standard is identical with, and has been reproduced from ISO 10393:2013, *Consumer product recall—Guidelines for suppliers*.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this International Standard’ should read ‘this Australian Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

There are no normative references in the source document.

There are mandatory requirements concerning the conduct of a recall in Australia under the Australian Consumer Law.

Information and guidelines are available from the ACCC at www.productsafety.gov.au.

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INTRODUCTION

There is a wide variety of products available to consumers in the global marketplace. Products routinely travel across borders in order to meet increasing consumer demand as suppliers seek to lower cost and expand markets. While many products are safe and fit for intended use, statistics show that, each year, millions of people suffer injuries or illness, or die from unsafe products.

While regulations and standards exist in many countries, and industries do all they can to make products safe and fit for intended use, problems related to design flaws, manufacturing defects, inadequate warnings or instructions still result in unsafe products entering the marketplace. In those instances, it is critical that corrective actions, which include recall, are carried out quickly and effectively. Although many countries have regulatory requirements and guidance for suppliers to conduct product recalls, many do not. Even in countries with well-developed requirements, recalls may be ineffective. As a result, there are inconsistencies in the approaches to product recall and other corrective actions, and products that pose health or safety risks to consumers remain in the marketplace.

This International Standard is designed to provide practical guidance in determining whether corrective actions, including recalls, need to be carried out by the supplier of consumer products. It also provides best practices for conducting a product recall if it is necessary. The guidance provides information and tools that suppliers of all sizes can use to develop a documented and validated product recall programme that will help them implement timely and cost-effective recalls, minimize legal and reputation risks, and reduce health or safety risks to consumers.

Although this International Standard is intended for suppliers, it might also help government agencies in developing or improving product recall policies and guidelines.

Broad application of this International Standard will lead to a more consistent approach to removing unsafe products from the global marketplace, to improving coordination between government and consumer products organizations in different countries, and to increasing consumer confidence in the safety of products available in the marketplace.

This International Standard has been developed in parallel with ISO 10377, which focuses on product safety. The relationship between this International Standard and ISO 10377 is illustrated in [Figure 1](#).

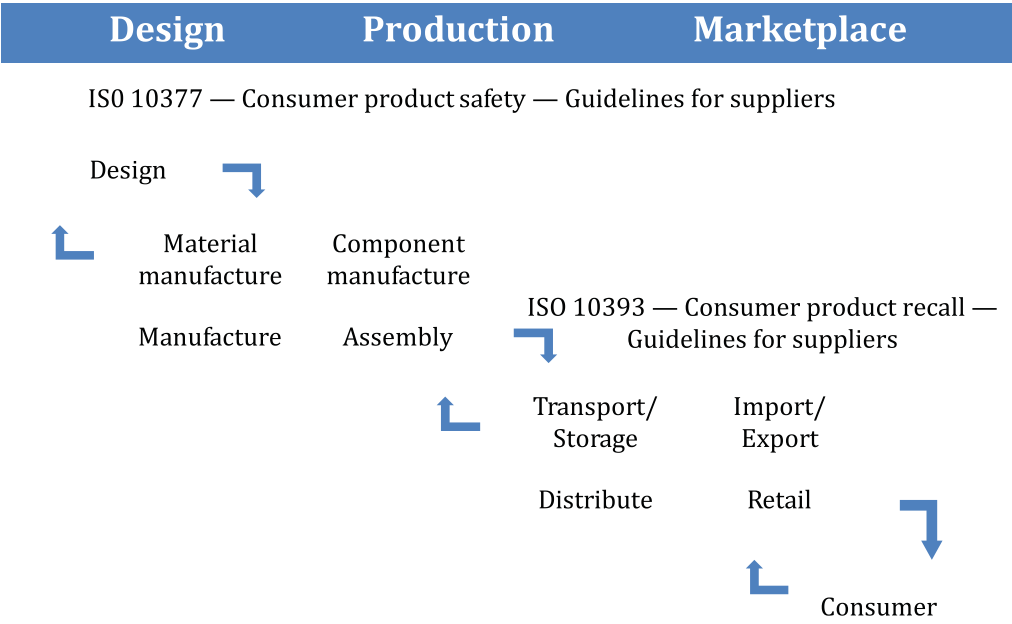


Figure 1 — Relationship between this International Standard and ISO 10377

AUSTRALIAN STANDARD

Consumer product recall—Guidelines for suppliers**1 Scope**

This International Standard provides practical guidance to suppliers on consumer product recalls and other corrective actions after the product has left the manufacturing facility. Other corrective actions include, but are not limited to, refunds, retrofit, repair, replacement, disposal and public notification.

This International Standard is intended to apply to consumer products, but might also be applicable to other sectors.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1**consumer**

individual member of the general public purchasing or using property, products or services for private purposes

[SOURCE: ISO 26000:2010, 2.2]

2.2**consumer product**

product designed and produced primarily for, but not limited to, personal use, including its components, parts, accessories, instructions and packaging

[SOURCE: ISO 10377:2013, 2.2]

2.3**competent**

suitably trained or qualified by knowledge and practical experience to enable the required task or tasks to be carried out

[SOURCE: ISO 22846-1:2003, 2.6]

2.4**corrective action**

action intended to remove potential for harm and to reduce risk

Note 1 to entry: For the purposes of this International Standard, corrective actions are referred to as “recalls” because the public and media more readily recognize and respond to that description.

2.5**foreseeable misuse**

improper or incorrect use of a product that is capable of being known or anticipated in advance, based on a supplier’s best knowledge about the product and human behaviour

EXAMPLE Improper use by children or the elderly.

[SOURCE: ISO 10377:2013, 2.5]

2.6**foreseeable use**

use of a product that is capable of being known or anticipated in advance based on a supplier's best knowledge about the product

[SOURCE: ISO 10377:2013, 2.6]

2.7**harm**

physical injury or damage to the health of people, or damage to property

[SOURCE: ISO/IEC Guide 51:1999, 3.3, modified]

2.8**hazard**

potential source of harm

Note 1 to entry: The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, biological hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

[SOURCE: ISO/IEC Guide 51:1999, 3.5]

2.9**incident**

event or defect that caused or has the potential to cause death, injury or property damage, with respect to a consumer product

Note 1 to entry: "Incident" might be defined differently by law in some countries.

2.10**intended use**

use of a product in accordance with information provided by the supplier

[SOURCE: ISO/IEC Guide 51:1999, 3.13, modified]

2.11**organization**

entity or group of people and facilities with an arrangement of responsibilities, authorities and relationships and identifiable objectives

Note 1 to entry: For the purposes of this International Standard, organization does not include government acting in its sovereign role to create and enforce law, exercise judicial authority, carry out its duty to establish policy in the public interest or honour the international obligations of the state.

[SOURCE: ISO 26000:2010, 2.12, modified]

2.12**product recall**

corrective action taken post production to address consumer health or safety issues associated with a product

2.13**risk**

combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:1999, 3.2]

2.14**risk analysis**

systematic use of available information to identify hazards and to estimate the risk

[SOURCE: ISO/IEC Guide 51:1999, 3.10]

2.15**risk assessment**

overall process comprising a harm and a risk evaluation

[SOURCE: ISO/IEC Guide 51:1999, 3.12]

2.16**risk evaluation**

procedure based on the risk analysis to determine whether the tolerable risk has been achieved

[SOURCE: ISO/IEC Guide 51:1999, 3.11]

2.17**risk management**

coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO Guide 73:2009, 2.1]

2.18**safety**

freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 51:1999, 3.1]

2.19**supplier**

organization or person that provides a product or service

EXAMPLE Designer, producer/manufacturer, importer, distributor, or retailer of a product.

[SOURCE: ISO 9000:2005, 3.3.6, modified]

2.20**supply chain**

network that designs, manufacturers, imports, distributes and sells a product

[SOURCE: ISO 10377:2013, 2.25]

2.21**tolerable risk**

risk which is acceptable for a specific user group based on the current values of society

Note 1 to entry: For the purposes of this International Standard, the terms “acceptable risk” and “tolerable risk” are considered to be synonymous.

[SOURCE: ISO/IEC Guide 51:1999, 3.7, modified]

2.22**traceability**

ability to track a product or component forward through specified stages of the supply chain to the user, and trace back the history, application or location of that product or component

[SOURCE: ISO 9000:2005, 3.5.4, modified]

2.23**user**

person who interacts with the product or service

2.24

vulnerable consumer

consumer who could be at greater risk of harm from products due to their age, level of literacy, physical condition or limitations, or inability to access product safety information

[SOURCE: ISO 10377:2013, 2.30]

3 Purpose and principles

The purpose of this International Standard is to help suppliers develop, implement and improve a product recall programme in order to reduce risk caused by unsafe products in the marketplace.

A product recall programme is a key element of the supplier's overall product safety programme. Suppliers should demonstrate their commitment to consumer product safety by adhering to the principles documented in this International Standard and in ISO 10377. These principles include the following:

- developing and maintaining appropriate processes and systems to prevent product-related incidents that could lead to a recall, including addressing product safety risks at the design stage and allocating appropriate resources for quality management, training, records management and product traceability;
- a commitment to the prompt and effective implementation of a product recall when it is assessed that a product is likely to pose a health or safety risk to consumers;
- promoting a product safety culture by building awareness of the importance of product safety, ensuring product safety programmes are supported and continually improving its product safety programme;
- promoting a product safety culture to others within its supply chain;
- establishing and maintaining compliance with all applicable laws, regulations and standards.

4 General requirements

4.1 General

All suppliers should be prepared to conduct a product recall. The supplier should have in place a product recall plan that includes the following:

- the recall policy (see [4.2](#));
- an outline of the documentation and records that will be created and maintained (see [4.3](#));
- an outline of the legal, industry and regulatory requirements (see [4.4](#));
- identification and explanation of the roles and responsibilities of the recall management team (see [4.5](#));
- a description of the training and exercise requirements for members of the recall management team (see [4.7](#));
- guidance on how product incidents will be investigated and a decision made on whether a recall is necessary (see [Clause 5](#));
- identification of the resources required and processes used to implement a recall (see [Clause 6](#));
- establishing the requirement for continual improvement of the supplier's processes (see [Clause 7](#)).

4.2 Policy

The supplier should develop and maintain a product recall policy and identify how decisions will be made to carry out a product recall. The policy should contain a simple, clear and precise commitment

by the supplier to ensure that products which present, or which have the potential to present, risks or hazards to consumers are effectively removed from the marketplace, or that safety or health issues or concerns are corrected.

4.3 Documentation and record keeping

Management should establish procedures to control and maintain all documents and record data relating to the recall programme for continual improvement, data analysis and facilitation of incident investigation, product identification and traceability, such as the following:

- a copy of the recall policy and procedures;
- records of training and assessment of employee competency;
- records of consumer complaints and product safety incidents;
- records of risk assessment, which may include test reports, and risk analysis;
- records of the recall decision;
- records of communication, including the communication plan, materials, methods used and dates;
- evidence of the effectiveness of the recall, including return rates, effectiveness per method of communication and evidence to show that the recall is working;
- financial records;
- records of repair, refurbishment or disposal.

4.4 Regulatory requirement

The supplier should identify, monitor, understand and comply with applicable legislative, regulatory and standard requirements for recalls, in all markets where a consumer product is produced or sold.

4.5 Expertise required to manage a recall

The supplier should ensure that it has the expertise to investigate the incident, to assess the risk, to make the recall decision and to carry out the recall. In larger suppliers, this may require the establishment of a recall management team made up of staff from a range of functional areas.

Regardless of size, suppliers may need outside assistance from advisors and consultants. Arrangements should be made with advisors and consultants so that they can develop an understanding of its recall programme before an incident occurs.

The objectives of the people responsible for managing the recall are as follows:

- assess all available information and determine the actions necessary to do the following:
 - protect the health or safety of consumers;
 - maintain relationships with consumers and stakeholders;
 - protect the reputation of the supplier;
 - fulfil all relevant legal obligations (e.g. mandatory reporting) in all countries of distribution;
- liaise with relevant government and industry authorities;
- ensure that key stakeholders are kept informed of the supplier's decisions and actions, including forthcoming media communications;

- ensure that decisions and recall actions are implemented effectively with least disruption to the normal operation of the supplier's day-to-day business.

[Table 1](#) lists the typical expertise required for a product recall.

4.6 Authority for key decision

The supplier should identify the person or people who have the authority to make the decision to recall the product.

The key decisions that may need to be made are as follows:

- make a product recall decision and determine the scope of that recall, as discussed in [5.1](#);
- stop production and place product on hold during a product recall investigation, as discussed in [5.3](#);
- stop the sale of a product at any point in the supply chain, as discussed in [5.6](#);
- notify the regulator(s) about a product recall incident, comply with applicable regulatory requirements, and report the progress of the recall to regulator(s), as discussed in [6.3.3](#);
- notify the supply chain about a product recall incident, as discussed in [6.3.4](#);
- communicate to consumers about actions that should be taken during a product recall, as discussed in [6.3.5](#);
- execute the logistical requirements of the product recall, as discussed in [6.4](#);
- assess the effectiveness of the recall to make recommendations about its progress, as discussed in [6.6](#);
- bring an end to the monitoring phases of the product recall by the regulator and cease active recall operations, as discussed in [6.7.2](#).

4.7 Training and recall simulation

The staff responsible for the recall should be familiar with the supplier's product recall plan and have the capabilities and personal attributes needed to implement the recall.

Planning, training and conducting recall simulations will help to better prepare people for a recall and also increase the likelihood that agreed processes are implemented quickly and effectively under conditions that can be stressful. In addition, these activities may be required to meet contractual, legal and insurance requirements.

Table 1 — Typical expertise required for product recall

Expertise required	Activities or responsibilities
Recall coordination and leadership	- First point of contact for incidents - Initial sorting and escalation of the incident - Ensure notifications are made to appropriate people - Gather people with the appropriate expertise - Facilitate meetings and ensure required actions are carried out - Ensure information needed is collected in a timely manner and appropriate people are updated regularly - Ensure timely decisions are made - Ensure all communications are consistent and controlled - Ensure appropriate external notifications and briefings are performed - Ensure all required reports are prepared and distributed - Facilitate continual improvement process and ensure follow up responsibilities are delegated
Technical/Engineering	- Lead the investigation of the recall incident - Review internal records, quality systems and traceability of the affected product - Establish contact with laboratories and testing authorities and other experts performing the risk analysis or risk assessment - Lead the risk analysis or risk assessment process - Act as a liaison with suppliers - Provide technical advice about the product to the team - Participate in the recall decision
Operations	- Gather distribution records, ensure they are accurate and create distribution register - Manage collection, retrieval, replacement, repair and disposal of product - Ensure accurate records are kept to measure recall effectiveness - Manage the logistical requirements necessary to remove product from the marketplace, to repair or replace product in the marketplace and to destroy defective product that was the subject of the recall
Sales and marketing/ Accounts	- Establish and maintain liaison with affected consumers - Ensure consumer enquiries and concerns are addressed in a timely manner - Establish consumer needs for replacement products and arranges credits, refunds, or replacements for the subject product - Participate in the recall decision
Finance/ Risk management	- Estimate costs of proposed actions, sources of funding and potential impact on business - Notify insurer where required - Establish budget and monitor costs - Keep records for claims - Work with sales & marketing/accounts to arrange credits and refunds - Participate in the recall decision

Table 1 (continued)

Expertise required	Activities or responsibilities
Legal counsel	Ensure compliance with regulators' requirements Ensure compliance with contractual requirements with buyers and licensors Provide advice to minimize organization's liabilities arising from recall decision and from day-to-day execution of recall plan Participate in the recall decision
Communications	Identify key audiences, with special focus in vulnerable groups Assist in the development of the communication strategy and key messages Establish and manage resources to handle enquiries (call centre, product recall consultant) Prepare communications and gain approval for release Monitor clarity and usefulness of communications and recommend any changes necessary to improve effectiveness.

A supplier should do the following:

- identify the people and organizations that may be needed to carry out recall activities, provide them with the recall plan and make them aware of their responsibilities and authority to act during a recall;
- train people so that they understand their responsibilities and have the skills to carry out those responsibilities during a product recall,
- practise the implementation of the recall plan through a simulated recall, in order to verify that the recall plan is likely to be useful in a real recall situation;
- document and implement what has been learned from the simulation to improve the recall programme;
- conduct ongoing reviews of the recall programme and simulations, in order to keep it current and effective and to retain and improve skills for preventing and managing recalls.

It may be difficult for smaller organizations to conduct a recall simulation. In such cases, key managers should review their recall plan annually and discuss potential incidents and how the plan will be implemented if a recall becomes necessary. This should include involvement of an external consultant or advisor whose expertise has been identified as necessary (see [Table 1](#)).

5 Assessing the need for a product recall

5.1 General

In order to determine the need for a product recall, the supplier should have in place a process for acting upon receipt of information that a product has created harm, or has the potential to create harm, in accordance with [5.2](#) to [5.6](#), as illustrated in the flowchart in [Figure 2](#), and the timeline required by the applicable regulatory requirements.

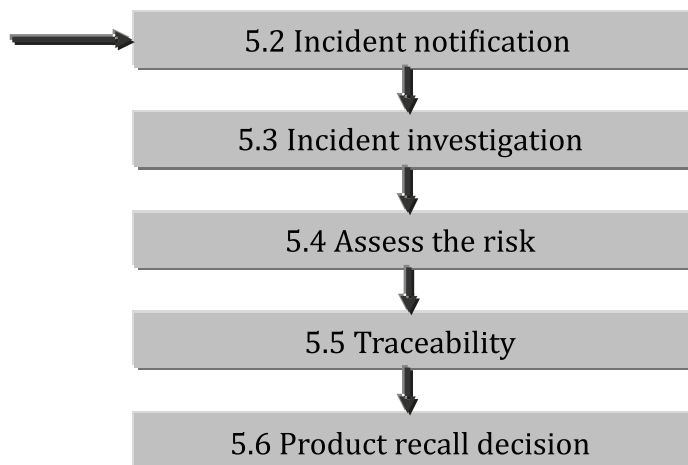


Figure 2 — Assessing the need for product recall

For situations where very serious injury or substantial property damage could occur, consideration should be given to implementing a product recall, even if the probability of risk cannot be accurately determined.

5.2 Incident notification

Suppliers should have in place a system for collecting information on product incidents and communicating these to stakeholders, as necessary.

As required by regulatory requirements and contractual obligations, the supplier should notify regulators, certification bodies and other organizations of reports that a product has created harm, or has the potential to create harm.

5.3 Incident investigation

The supplier should establish a process for investigating product incidents or potential incidents. The process will generally include the following steps:

- document the key elements of the investigation, including the findings and the actions taken;
- conduct an initial assessment to determine the urgency and the priority of the investigation;
- assign competent staff to conduct the investigation;
- determine if the incident report is valid and accurate, which could also involve acquiring the actual product or a sample to use for testing and review purposes;
- determine if the product report is valid and accurate, which could also involve acquiring the actual product or a sample to use for testing and review purposes, in accordance with appropriate sampling procedures;
- identify the root cause for the defect that created the harm or potential harm, and use this information in the continual improvement process outlined in ISO 10377; in addition, the supplier should determine if the defect is common to other products and therefore require that similar recalls be implemented;
- assess the risk in accordance with [5.4](#);
- determine if there have been any other incidents regarding the product in question, including those related to similar products.