INTERNATIONAL STANDARD

ISO 10393

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Consumer product recall — Guidelines for suppliers

Rappel de produits de consommation — Lignes directrices pour les fournisseurs

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is Project Committee ISO/PC 240, *Product recall*.

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.

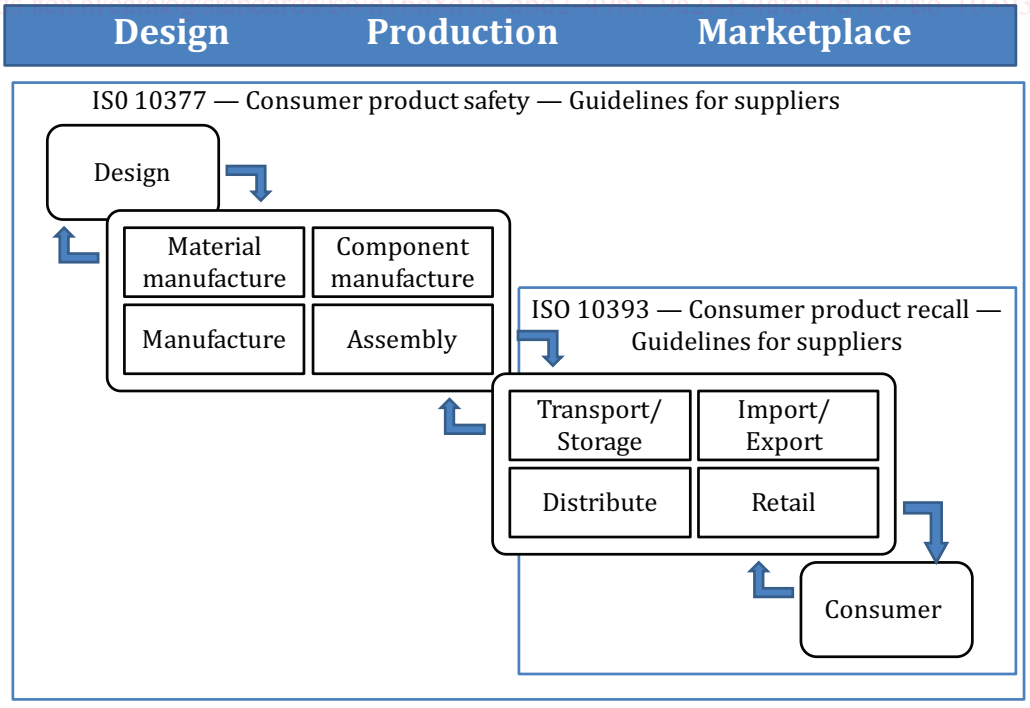

Figure 1 — Relationship between this International Standard and ISO 10377

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.