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INTERNATIONAL STANDARD

ISO 10377

First edition
2013-04-15

Consumer product safety — Guidelines for suppliers

Sécurité des produits de consommation — Lignes directrices pour les fournisseurs

Reference number
ISO 10377:2013(E)

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Foreword

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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 243, *Consumer product safety*.

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Introduction

A number of governments have established laws and requirements for suppliers to place only safe products on the market. In this way, they are trying to deal more broadly with dangers associated with consumer products, rather than developing standards or regulations for every single product.

However, many suppliers have limited experience and few available resources or practical reference documents to guide them through this process, which consists of the following:

— identifying the hazards;

— assessing the risks;

— identifying and implementing risk reduction measures;

— identifying and reducing risks in the production process;

— implementing processes to trace and identify products;

— communicating use and warning information to consumers;

— monitoring the product in the marketplace;

— identifying any safety risks and managing them.

This International Standard provides practical guidance for suppliers of all sizes to assist them in assessing and managing the safety of the consumer products they supply – from the design of the product, to the input of raw materials, to production, to distribution, to retail and to the final product end-user and disposal. This International Standard is intended to be particularly valuable to small and medium-sized enterprises, as well as to suppliers that do not design or produce products, but are still responsible for their safety in many jurisdictions. To assist them, useful information and examples are provided in Annex B.

The supply chain for consumer products is made up of a number of suppliers, often in different parts of the world, where products or product components are being designed, produced and sold in other countries. Therefore, it is important that the guidance provided is aligned with international best practice, easy to understand and applied consistently by suppliers. The overall objective of following internationally consistent guidance is to produce safer consumer products, and thereby:

a) reduce the product safety risks to consumers;

b) reduce the risks to suppliers of product recalls;

c) provide consumers with the information they need in order to make informed choices with respect to the safe use and disposal of consumer products;

d) assist governments by improving the safety of consumer products.

This International Standard does not cover issues such as worker safety, protection of the environment, or social and ethical issues, which are covered extensively by other standards. Instead, this International Standard focuses on consumer products and providing guidance on reducing the risk of harm to consumers and users. It has been developed in parallel with ISO 10393, which focuses on product recall. The relationship between this International Standard and ISO 10393 is illustrated in Figure 1.

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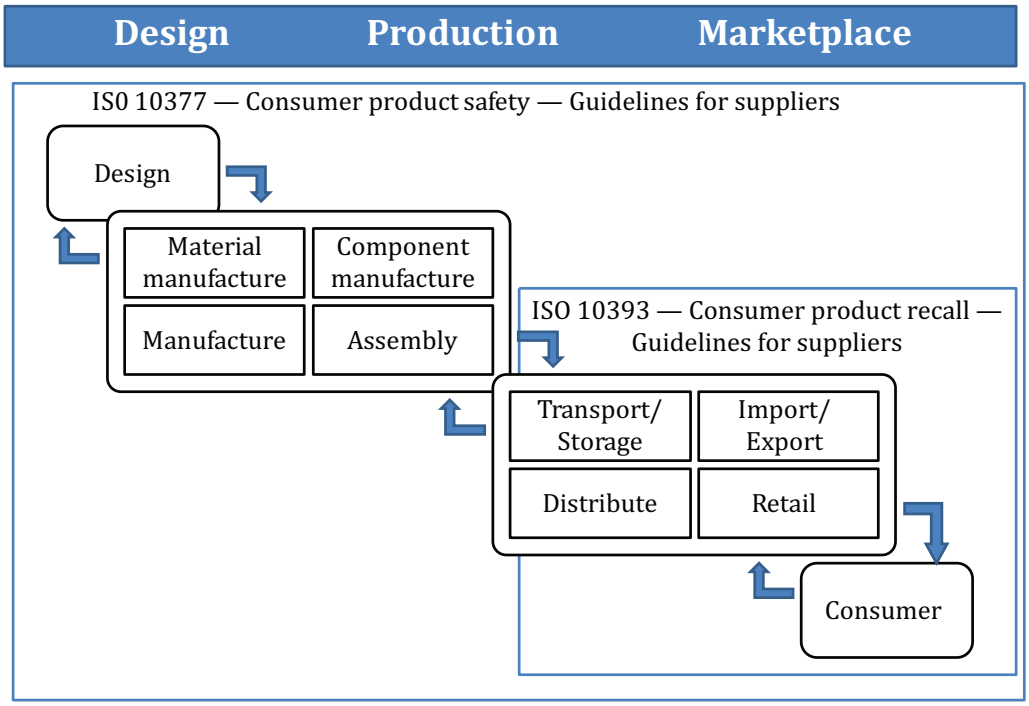

Figure 1 — Relationship between this International Standard and ISO 10393

It is important that suppliers maintain an awareness of and comply with the laws and regulations of the countries where the products are manufactured, imported, distributed or sold.

ISO/IEC Guide 51 and the revisions proposed to it were taken into account in the drafting of this International Standard.

This International Standard is presented in the form of practical guidance. Terms used in this International Standard are defined in Clause 2, although individual countries have established or might establish different specific definitions in law. Clauses 3 and 4 provide principles and general requirements that apply to all members of the supply chain. Clauses 5, 6 and 7 are targeted to specific sectors of the supply chain. Information on relevant International Standards and Guides, useful information for small business, examples related to hazard and risk evaluation, and product safety management plans are provided in Annexes A, B, C and D, respectively.

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Consumer product safety — Guidelines for suppliers

1 Scope

This International Standard provides practical guidance to suppliers on assessing and managing the safety of consumer products, including effective documentation of risk assessment and risk management to meet applicable requirements.

This International Standard describes how to:

— identify, assess, reduce or eliminate hazards;

— manage risks by reducing them to tolerable levels;

— provide consumers with hazard warnings or instructions essential to the safe use or disposal of consumer products.

This International Standard is intended to apply to consumer products, but might also be applicable to decisions concerning safety in other product 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

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.

[SOURCE: ISO 10393:2013, 2.4]

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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.

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

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
harmful event
occurrence in which a hazardous situation results in harm

[SOURCE: ISO/IEC Guide 51:1999, 3.4]

2.9
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]

2.10
hazardous situation
circumstance in which people or property are exposed to one or more hazards

[SOURCE: ISO/IEC Guide 51:1999, 3.6, modified]

2.11
intended use
use of a product in accordance with information provided by the supplier

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

2.12
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]

2.13
product recall
corrective action taken post production to address consumer health and safety issues associated with a product

[SOURCE: ISO 10393, 2.12]

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2.14
protective measure
means used to reduce risk

Note 1 to entry: Protective measures include risk reduction by inherently safe design, protective devices, personal protective equipment, information for use and installation, and training.

[SOURCE: ISO/IEC Guide 51:1999, 3.8]

2.15
residual risk
risk remaining after protective measures have been taken

[SOURCE: ISO/IEC Guide 51:1999, 3.9]

2.16
risk
combination of the probability of occurrence of harm and the severity of that harm

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

2.17
risk analysis
systematic use of available information to identify hazards and to estimate the risk

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

2.18
risk assessment
overall process comprising a risk analysis and a risk evaluation

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

2.19
risk communication
exchange or sharing of information about risk between the decision maker and other stakeholders

[SOURCE: ISO/IEC Guide 73:2002, 3.2.4, modified]

2.20
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]

2.21
risk management
coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO Guide 73:2009, 2.1]

2.22
risk reduction
actions or means to eliminate hazards or reduce risks

2.23
safety
freedom from unacceptable risk

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

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2.24
supplier
organization or person that provides a product or service

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

Note 1 to entry: A supplier can be internal or external to the organization.

Note 2 to entry: In a contractual situation, a supplier is sometimes called “contractor”.

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

2.25
supply chain
network that designs, manufactures, imports, distributes and sells a product

2.26
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]

2.27
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]

2.28
unforeseeable misuse
use of a product in a manner that a supplier cannot reasonably know or anticipate

2.29
user
person who interacts with the product or service

2.30
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

3 Basic principles for addressing consumer product safety

3.1 General

Adherence to the basic principles in 3.2 to 3.7 will assist members of the supply chain to develop and maintain a shared commitment to consumer product safety. This includes a commitment to the prompt implementation of corrective action when hazards are identified as a result of incorrect design, deficiencies in the production process and problems during distribution or storage.

3.2 Promoting a product safety culture within the organization

Consumer product safety should be a key consideration in the organization’s governance structure. This can be accomplished by putting in place a product safety management plan that is implemented and endorsed by the governing body and/or top management. Examples of two different approaches to product safety management plans are presented in Annex D.

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The organization should understand and comply with the laws, regulations and standards that cover the consumer product produced for the marketplace in which the product is manufactured or sold. Responsibility for compliance should be clearly stated and assigned with appropriate resources allocated to develop, maintain, monitor and continually improve the product safety compliance programme.

3.3 Promoting a product safety culture outside the organization

An organization should promote a consumer product safety culture throughout the supply chain. Such promotion may include setting contractual provisions or incentives, promoting good industry-wide practices, forming partnerships with sector organizations and others, sharing of information, and providing consumers with the information they need to assemble, use, maintain and dispose of a consumer product safely (see ISO 26000).

3.4 Committing to providing safe products

Product safety is best addressed at the design stage to reduce the risk from hazards. This will help to avoid the need to expend resources to fund the costs of the recall of unsafe products and the potential of redesign and retooling. Management is accountable for assigning responsibilities for implementing the principles and guidance set out in this International Standard, including providing appropriate resources for training, records management and product traceability.

3.5 Continual improvement

A structured approach for continual improvement that defines objectives for the improvement of consumer products and processes through the analysis of data should be applied to safety in product design, production and the marketplace. Continual improvement activities and their outcomes should be documented and regularly reviewed by management so that continual improvement objectives are being met.

3.6 Precautionary approach

The precautionary approach means that the lack of full scientific certainty should not be used as a reason for postponing risk reduction measures, especially where there are threats of serious or irreversible damage to human health. Due to the increased use of and reference to the precautionary approach, suppliers should consider it when assessing the safety of consumer products.

3.7 Sharing of information

The organization should share information on a continuous basis on the product's performance, compliance, and risks with other members of the supply chain.

4 General requirements

4.1 General

The key issues for all members in the supply chain (designers, manufacturers, importers, distributors and retailers) include the following:

a) designing safety into the consumer product;

b) identifying the potential hazards associated with their products;

c) determining or estimating exposure to the potential hazard;

d) assessing the risks to consumer health and safety;

e) managing these risks by eliminating or reducing them to a tolerable level;

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f) providing consumers with hazard warnings and instructions essential to the safe use and disposal of the products;

g) approving any change or substitution of design, materials, or production processes.

The functions carried out by members of the supply chain are outlined below and illustrated in Figure 2:

— design: the development of the requirements and specifications to make a consumer product, taking into consideration the product's intended use and foreseeable use and misuse;

— material manufacture: the production of materials to be used in the manufacturing process;

— component manufacture: the production and supply of component products to be used in the manufacture of another product;

— assembly: the production of a consumer product by assembling components that may be used to manufacture another product, or may be a final product;

— manufacture: the production of a product to be supplied to a purchaser;

— transport: the movement of products from one location to another;

— storage: the temporary storage of products, intended for distribution;

— import/export: the movement of products into and out of a country;

— distribute: the logistics function to store and move products, which may employ transport and import/export functions;

— retail: the marketing and sales of products to consumers, which may employ transport, import/export, distribution and storage functions, in getting the product to its final destination;

— consumer: the purchaser and user of a product, who may also install, service, maintain or repair a product, or cause these to be done.

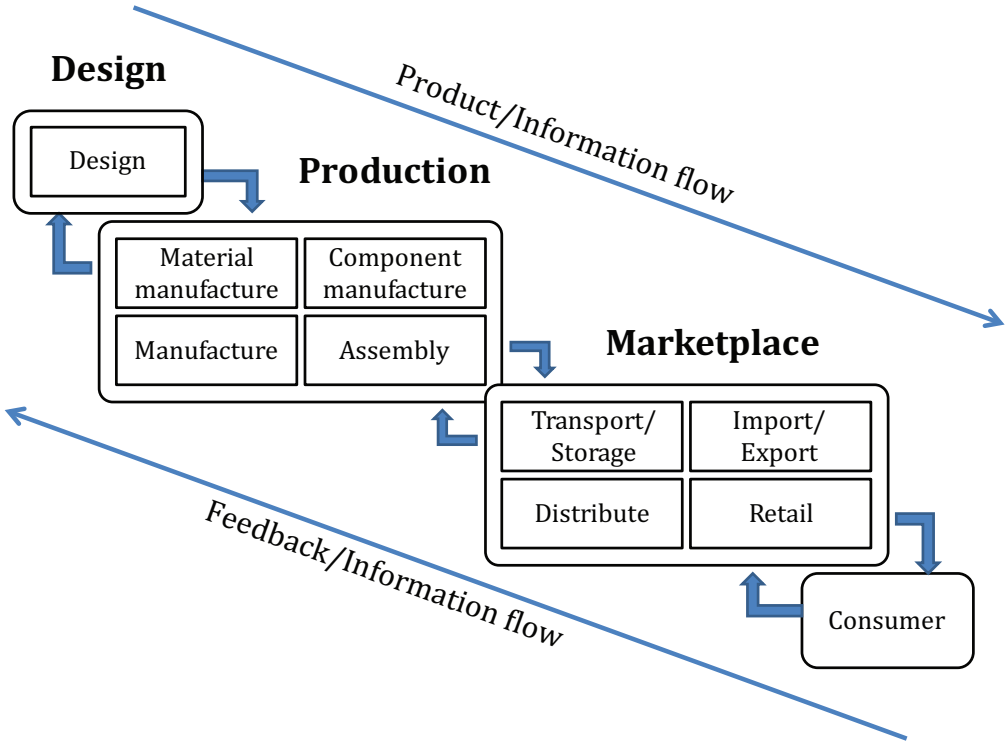

Figure 2 — The supply chain

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4.2 Commitment to providing safe consumer products

4.2.1 Competency and training

The organization should ensure that those involved in consumer product safety, whether they are internal or external to the organization, have the necessary education, training, technical knowledge and experience for carrying out their responsibilities.

The organization should establish and maintain (a) procedure(s) for the following:

a) to define the competency requirements for those responsible for consumer product safety;

b) to ensure competency to carry out duties and responsibilities for consumer product safety, including product safety specifications;

c) to inform those involved in the safety of consumer products about the potential consequences of providing unsafe products.

Training activities may be provided either within the organization or by external sources and should include elements that are:

— based on the competency requirements and the duties and responsibilities for ensuring consumer product safety;

— conducted by competent persons;

— updated as required to ensure that information remains current;

— evaluated and modified as necessary to ensure relevance and effectiveness;

— recorded appropriately and kept by the organization.

4.2.2 Adequate resource allocation

An organization should ensure that appropriate technical, financial and human resources are allocated to safety in design, production and/or the marketplace, e.g.

— financial and human resources;

— access to expertise and relevant reference documents on consumer product safety;

— training of staff on consumer product safety issues;

— records management and document control;

— verification and testing to determine if ongoing production continues to meet safety requirements.

4.2.3 Records management and document control

The organization should establish and maintain procedures to record, control, retain and retrieve all principal documents and data that reflect safety in design, production and the marketplace. These items should include the following:

— records arising from the implementation of this International Standard;

— records required to comply with laws and regulations;

— documents created during management of safety in design (see Clause 5), e.g.

  — hazard analysis and hazard reduction plan;

  — significant design choices and safety decisions;

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- drawings, product specifications and bill of materials;
- product quality tests and approved product samples;
- validation of the design;
- warnings and instructions and language(s) in which they are produced;
- design testing and inspection;
- cost-benefit analysis of corrective action options;
- compliance with regulatory requirements and product specific industry standards;
- third-party testing and conformity assessment, as required;

— documents created during management of safety in production (see Clause 6), e.g.

- good manufacturing practices;
- quality assurance records;
- purchase orders and instructions to the supply chain;
- testing and inspection at the factory;
- third party testing of ongoing production, as required;
- production plan, design validation and creation of the product prototype;
- change requests and subcontracting;
- contamination incidents;
- production readiness, including supply chain management, tooling, commissioning the factory, training and product specifications;

— documents created during management of safety in marketplace (Clause 7), e.g.

- post delivery inspections, audits and consumer product safety testing;
- consumer complaints and consumer product safety incidents;
- records from the sale and distribution of products throughout the supply chain;
- product literature, including advertising, marketing and packaging;
- communications with suppliers and consumers, including product registration, post-sale warnings, market surveys and feedback from buyers;
- reasons for returned products and service records;
- corrective actions.

Documents created should reflect information and records retained from the original design, production and marketplace, as well as those generated as a response to potential hazards, issues, complaints and reviews about the organization's products. All written responses should be placed in the organization's own product files to record that the organization considered all available information about the product, its hazards and its risks. In addition, records related to the expiry date of a product and its useful life should be recorded.

Documents created during all stages in the supply chain should be retained at a minimum for the reasonable life of the consumer product, or as required by law. The documents should be consulted before the next production cycle of the product as part of the organization's continual improvement process.

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4.3 Continual improvement

4.3.1 The organization should ensure that continual improvement of the safety of their consumer product(s) becomes established as a part of the organizational culture. These activities can range from minor to major improvements in the organization and/or its supply chain.

Fundamental to effective and efficient improvement is making informed decisions on the basis of evaluation of information collected and the incorporation of lessons learned. The organization should define objectives for the improvement of its products and processes based on that analysis.

In particular, continual improvement should apply to safety in consumer product design, production and the marketplace, e.g.

— improvement activities in design might include using focus groups to anticipate the product's use in different situations and determining how the product performs or is viewed by different groups (information on focus groups can be found in Annex B);

NOTE Focus groups involve informal discussions using representative consumers to gather or assess information on how they interact or use products in various real-life situations and to determine how the product performs.

— improvement activities in production might include obtaining feedback from staff or testing of ongoing production;

— improvement activities in the marketplace might include, but not be limited to, receiving supplier or consumer comments or complaints and gathering a small team to propose design or production changes or other corrective actions.

All continual improvement activities and their outcomes should be documented and reviewed by management regularly to ensure continual improvement is occurring and that changes do not inadvertently cause another safety problem.

4.3.2 The organization should follow a structured approach for continual improvement, as outlined in its product safety management plan. An example of the main steps in such an approach is illustrated in Figure 3 and includes the following:

a) problem identification and decision making;

b) the development of an action plan;

c) changes to product or processes;

d) monitoring of improvements by all members of the supply chain.

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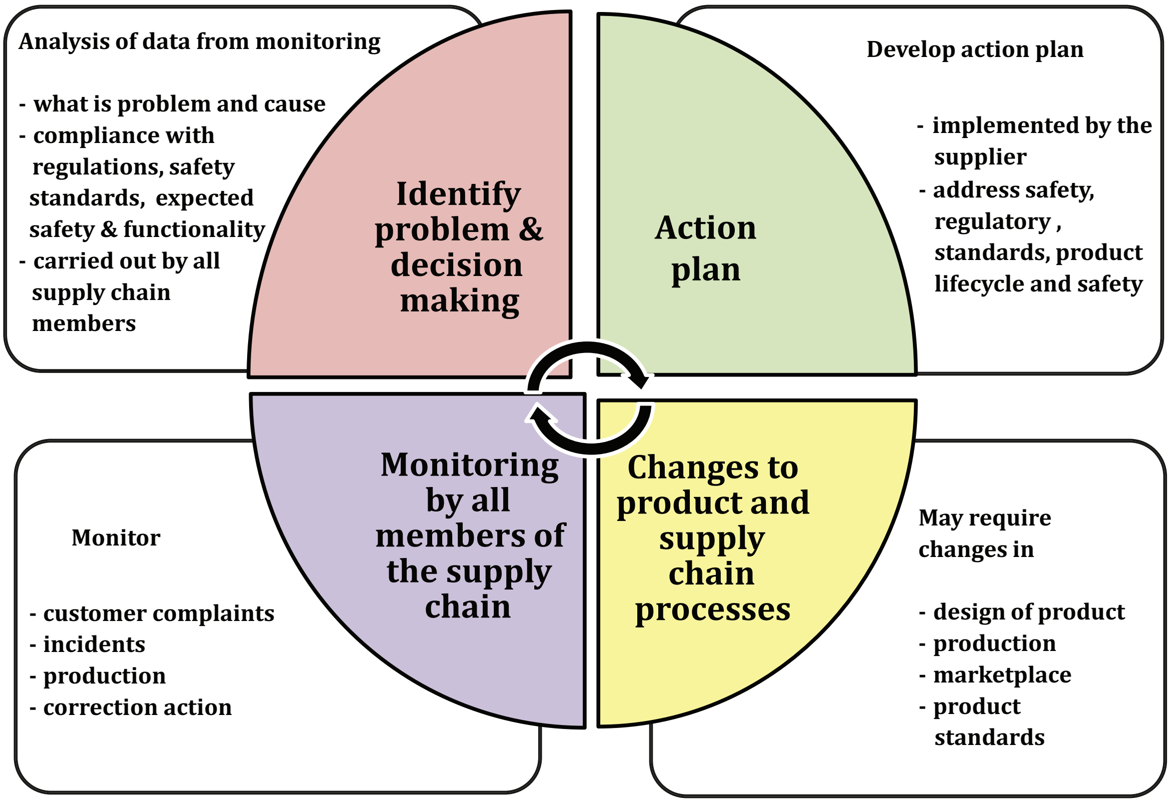

Figure 3 — Example of an approach to continual improvement

Several other models exist, e.g.

— the approach in ISO 9000, which involves documenting, evaluating the problem, identifying and implementing actions to correct the problem, and monitoring and evaluating the effect of such action: the cycle continues until the problem is resolved;

— the four-step quality model, commonly known as the plan-do-check-act (PDCA) cycle.

Information sources are provided in the Bibliography.

4.4 Applicable laws, regulation and standards

The organization should identify, monitor, understand and comply with applicable legislative, regulatory or standard requirements by:

— identifying all applicable laws, regulations and standards related to the import, export and distribution of the consumer product in the marketplace where it will be sold or manufactured;

— assigning a resource to identify and access the laws, regulations and standards that apply to the product;

— attending training sessions, conferences or monitoring the regulatory and standards environment.

NOTE See Bibliography.

4.5 Consumer product identification and traceability

4.5.1 General

A traceable item is a physical object about which there may be a need to retrieve information about its history, application, or location. For each traceable item, suppliers should be able to trace back to the

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direct supplier of the product (or component) and be able to identify the direct recipient of the product (or component).

Depending on restrictions set out in privacy laws, suppliers may also maintain traceability down to the consumer level, if appropriate or required by law.

Suppliers should use globally unique product identification and product traceability to address the following:

— fulfil business needs, e.g.

  — supporting consumer product safety;

  — ensuring compliance with various legislative or regulatory requirements for product identification, traceability, recall and the establishment and maintenance of records;

— demonstrate control, increase efficiency and reduce the cost of product recall for:

  — compliance with specifications;

  — efficient supply chain management;

  — effective quality management;

  — providing information to consumers and business stakeholders;

  — verifying the presence or absence of product attributes (e.g. organic, child safe);

  — protecting brands;

  — establishing product authentication and anti-counterfeit policies.

Questions to be considered concerning traceability and consumer product identification include the following:

a) Does the supplier know the traceability laws, regulations or standards of the countries to which its products are delivered?

b) Has each supplier advised other members of the supply chain of their unique traceability requirements?

c) Are all the traceable product components or products distributed or received by the supplier identified with a unique identifier?

4.5.2 Traceability across the supply chain

Traceability does not mean that each supplier on its own needs to be able to provide full traceability information across the supply chain. Instead, each member of the supply chain should be able to trace back to the direct source of traceable items and identify the direct recipient of traceable items. This is the “one step up, one step down” principle.

For manufacturers who produce consumer products or components, traceability should be maintained throughout the manufacturing and assembly process. In other words, the manufacturer should be able to determine into which product, component and batch the raw materials or purchased components were incorporated. Records of this linkage should also be maintained for the life of the product to facilitate traceability.

NOTE The supplier might want to have traceability down to the consumer level, if appropriate or required by law, taking into consideration privacy laws.

4.5.3 Consumer product identification

All traceable items should carry a unique identifier and be labelled, marked or tagged at the source (or at their creation), in accordance with applicable legal requirements. The most common supply chain

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practice recommends the use of such identifiers as a barcode with an embedded globally unique number or a combination of serial number, batch or lot number, expiry date and production date. If any of this information is not available, the supplier should request it from those who can provide it.

Suppliers should ensure the true uniqueness of the identification of the traceable item. When sub-contractors or licensees are involved, the supplier should find a way to ensure uniqueness and, in doing so, may depend on contractual agreements.

Product identification should remain on the traceable item or attached to it until the traceable item is consumed, returned, or destroyed. Moreover, it should not be changed unnecessarily.

4.6 Understanding the role of consumers

4.6.1 General

Suppliers should understand the decisions and actions taken by consumers during purchasing, assembling, using, storing and maintaining consumer products, because these consumer actions may have a significant impact on whether or not the product causes harm. In addition, suppliers should provide product information to consumers that will enable consumers to make informed decisions when purchasing a consumer product and to fulfil their responsibilities in using, assembling, maintaining and disposing of the product in a safe manner.

NOTE Further information on drafting information for consumers is given in ISO/IEC Guide 14 and ISO/IEC Guide 37.

4.6.2 Pre-purchase and pre-use

Suppliers should provide information to consumers on the safety features of the consumer product. This may include labelling or advertising that addresses product use. Examples of topics addressed in labelling or advertising are age-appropriate use, potential choking, noise, suffocation, product contents, or other product hazards. Suppliers should identify their name and address on the product packaging. Suppliers should be aware of laws and regulations that require particular labelling or advertising in the jurisdiction where their product will be sold.

Suppliers should instruct consumers to read instructions and examine their consumer products for obvious safety hazards prior to use.

4.6.3 Use

Instructions for assembly, intended and safe use, maintenance, storage, life span and disposal of a consumer product should be provided to consumers. Suppliers can assist consumers in these actions by providing clear and complete instructions, any special instructions and information that is durable and available by means of the following:

— printing it on the product and on the package as space allows;

— including package inserts or other materials distributed with the product;

— providing information through a website or through a telephone contact centre.

It may be necessary to provide personal assistance when information included with the consumer product is not sufficient to minimize safety hazards in use. This assistance should be an integral and routine element of consumer service and may include help in original assembly, installation, hands-on-training and continuing maintenance.

Consumers may also need to be informed on how and where to obtain product servicing, particularly for issues that are potential causes of product safety hazards.

Consideration should also be given to providing adequate information to service personnel on how a product needs to be installed, maintained and repaired to prevent safety hazards (see Reference [55]).

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4.6.4 Post-use

Suppliers should obtain information from consumers about their use of the consumer product. Examples where this information may be obtained include consumer feedback during marketing, consumer complaints to the supplier, consumer information provided during claims and lawsuits, and consumer reports made to regulatory bodies. Suppliers should catalogue this consumer information for use during the continual improvement of the product (see 4.3). Suppliers should provide information on how to report incidents to the supplier and how to detect potential safety hazards, e.g. suppliers should encourage consumers to fill out warranty cards and provide information about national and international product recall databases and other websites on product safety updates.

4.6.5 Vulnerable consumers

Certain vulnerable consumer groups may not be able to fulfil their responsibilities and participate in consumer product safety initiatives or provide feedback about their product use.

Suppliers should work with government officials and civil society groups to help these vulnerable consumers understand and participate in providing feedback about their product use.

NOTE Further information on addressing the needs of vulnerable consumers is given in ISO/IEC Guide 50 and ISO/IEC Guide 71.

5 Safety in design

5.1 General

Safety should be a primary concern at every stage in the supply chain, especially at the beginning of the process, where consumer product design specifications are developed. Lack of consumer product safety considerations at the design state can lead to many product safety failures and result in the following:

— injury to consumers;

— product recalls and the associated costs;

— cost of redesign and retooling;

— product liability litigation and associated costs;

— enforcement and compliance issues with governments.

It is the responsibility of the organization to ensure safety in product design, recognizing that design defects are highly preventable.

5.2 Design specification

5.2.1 The design specification is a critical element to ensure the safety of consumer products. It comprises, but is not limited to, the following:

— drawings, images and photographs;

— description of the product;

— a bill of materials;

— components and parts listing;

— raw material selection and sourcing;

— model name/number and additional traceability information;

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— features, functions, or characteristics of the product;

— product instructions and warnings.

5.2.2 The entire life cycle of the consumer product should be considered in developing the design specification, which should take into account the following:

— product life expectancy;

— environmental factors such as climatic conditions (e.g. temperature, humidity, sunlight, atmospheric pressure);

— packaging;

— transportation to market and storage;

— assembly and the potential for misassembly;

— installation, servicing, maintenance and repair requirements;

— post-use disposal;

— end-of-life failure in a safe manner.

5.2.3 The safety-related considerations that contribute to the design specification should include, but not be limited to, the following:

— description of the product;

— intended use;

— foreseeable use and misuse;

— environmental surroundings of the location where the product will be used (e.g. home/office, indoor/outdoor, fixed/movable);

— compliance with mandatory safety requirements and industry standards;

— exposure analysis;

— hazard identification and characterization;

— risk assessment;

— risk reduction;

— risk communication.

5.2.4 For the purpose of accurate and confident decision making, the organization should undertake market intelligence, gathering and analysing information to identify the markets to be targeted for its product, the potential users and the sources and suppliers of raw materials, components and parts.

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5.3 Safety considerations in design

5.3.1 Foreseeable use

Suppliers should have an understanding and knowledge of the consumer product's intended uses and knowledge of how it will actually be used. This knowledge can be derived from information such as the following:

— the use of a product consistent with its function and design, including technical data on the function and design of the product;

— the use of a product based on factual human behaviour (e.g. a young child explores its surrounding by placing toys in his/her mouth) or measurements of the human body (e.g. a child's head is trapped between the bars of a crib because the child's head is small enough to fit between the slats);

— the use of a product based on feedback from consumers, including their claims, returns, warranties, repairs and lawsuits;

— the use of a product based on the institutional knowledge of the supplier (e.g. actual knowledge held by the supplier and accumulated over many years);

— the use of the product that is consistent with the laws and regulations in the location where the product will be used;

— the use of a product that is consistent with industry knowledge for that particular product.

5.3.2 Foreseeable misuse

Suppliers should have a clear understanding and knowledge of how a consumer product could be misused or misassembled and should make appropriate adjustments to the product design. This knowledge can be derived from information such as the following:

— the use of a product based on factual human behaviour or measurements of the human body (e.g. children, elderly);

— the use of a product based on feedback from consumers, including their claims, returns, warranties, repairs and lawsuits;

— demographics information from marketing and consumer trends;

— the use of a product based on the institutional knowledge of the supplier;

— the use of a product that is consistent with industry knowledge for that particular product;

— reports of failure caused by the consumer improperly assembling, maintaining and caring for the product according to suppliers' directions or instructions.

5.3.3 Unforeseeable misuse

Identifying the misuse of a consumer product that is not intended or readily foreseen is difficult. However, a supplier should establish mechanisms to receive feedback from the marketplace regarding misuse of their products or similar products. This feedback should be monitored and analysed to identify repeatable patterns.

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5.3.4 Risk evaluation

5.3.4.1 General

Risk evaluation is the process of identifying the level of risk associated with a consumer product and normally includes the following steps:

a) hazard identification;

b) exposure analysis;

c) consideration of use conditions;

d) description of potential injury scenarios;

e) evaluation of the severity;

f) evaluation of the probability;

g) risk assessment.

The result of the risk evaluation process determines whether the risk is tolerable and, if not, risk reduction measures, including redesign of the product or introduction of protection measures, should be considered. See Figure 4 for a graphical overview of the process.

5.3.4.2 Hazard identification

Hazard identification involves the identification of any potential hazards associated with the consumer product that may result in harm (e.g. sickness or injury) from the foreseeable use or misuse of the product, its components and packaging.

Data and information for hazard identification may come from various sources, e.g.

a) consumer complaints and returns from similar products;

b) incident reports, injury data and analysis of databases;

c) recall data from various government and independent sources;

d) requirements in laws, regulations and international, national and industry standards;

e) product or raw material test reports or certificates, as appropriate;

f) state of the art independent industrial, expert and scientific knowledge and advice;

g) relevant ergonomic principles;

h) internet chat groups, forums and social media outlets;

i) other sources of information related to the product and similar products.

There are a number of different types of product hazards associated with consumer products, as presented in Annex C. Hazard identification can be assessed through various types of analysis, e.g. Scenario Analysis, Fault Tree Analysis (FTA), Failure Mode and Effects Analysis (FMEA), Failure Mode, Effects and Criticality Analysis (FMECA), or Event Tree Analysis (ETA). See Bibliography.

When identifying the potential sources of machinery-related hazards (e.g. power tools, lawn mowers), reference can be made to ISO 12100.

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5.3.4.3 Exposure analysis

Exposure analysis refers to identification of the likely user population and its exposure to the hazards associated with the consumer product. This could include the following:

— identification of users that could come into contact with the product, including intended users, potential users and unintended users;

— the physical capabilities and psychological characteristics of the users, e.g. strength, motor skills, experience and physical dimensions;

— identification of users that may be particularly vulnerable to hazards associated with the product, e.g. the elderly, children and those with disabilities;

— the duration that users may be in contact with or exposed to the product;

— how obvious the hazard is to the user, e.g. many will understand the hazard associated with a sharp knife, but a sharp metal edge inside a child's toy may not be as obvious to the intended user.

NOTE Further information on determining the needs and the physical and psychological characteristics of vulnerable consumers is given in ISO/IEC Guide 50 and ISO/IEC Guide 71.

5.3.4.4 Consideration of use conditions

In considering the identification of the hazards and exposure to the hazard, consideration should be given to both foreseeable use and foreseeable misuse, e.g. using electrical equipment in areas of high moisture which could create a shock hazard, or a product that could create a spark in an environment where there are flammable materials, which could result in a fire hazard.

EXAMPLE Electrically-powered appliances used around sources of water, like kitchen and bathroom sinks, where it is possible that they might be immersed in water. Under such circumstances, the person using the appliance is at risk of sustaining an electric shock or even electrocution. In designing this type of product, consideration should be given to providing some type of immersion protection.

5.3.4.5 Description of potential injury scenarios

Suppliers should identify the steps that may lead to harmful events, such as an injury, and be able to describe possible scenarios that could result.

EXAMPLE A potential injury scenario with a consumer electrical product could include the user inserting their hand into an opening while the appliance is live and thereby causing an electrical safety hazard.

5.3.4.6 Evaluation of severity

The severity of the injury is often expressed in qualitative terms such "slight", "minor", "major" and "severe".

EXAMPLE A laceration or cut is a hazard associated with a sharp knife. The severity of the hazard can vary from slight to very serious, depending on the injury scenario. A superficial wound might be regarded as "slight", whereas a deep cut to a vital organ would be regarded as "severe".

5.3.4.7 Evaluation of probability

Probability refers to the likelihood that each step outlined in the injury scenario will occur during the expected lifetime of the product.

As with severity, probability is generally expressed in qualitative terms such as "rare" through to "certain", but often this is based on a numerical ratio or a percentage.

EXAMPLE A probability of one in one million (or 0,000 1 %) might be regarded as "rare", whereas over 50 % probability might be regarded as "highly likely".

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Whether a severe hazard occurs frequently or not, it still may exceed a tolerable risk in relation to most consumer products.

Each step in the injury scenario is given an appropriate probability, with the multiplication of these giving the overall probability of the scenario.

Probability analysis should be substantiated, wherever possible, by test data.

5.3.4.8 Risk assessment

This International Standard makes several references to risk assessment, i.e. the evaluation of any hazards that a consumer product may pose, in order to determine the likelihood that a consumer or user will be exposed to them, and the severity of any harm that may result. In some instances, it may be necessary to do research or obtain further knowledge and expertise in order to carry out the evaluation.

The organization should use the hazard identification and exposure analysis, including conditions of use, and the injury scenario to evaluate the potential risk level. In evaluating the elements associated with risk, the following should be considered as illustrated in Figure 4:

— the product and type of hazard (step 1);

— the conditions of use (step 2);

— the type of consumers using the product including number of and/or vulnerability of those exposed as well as technical and/or human ability to avoid or limit the harm (step 3);

— the injury scenario described in a sequence of steps (step 4);

— the severity of harm caused by the hazard (step 5);

— the probability of exposure (step 6);

— the level of risk (step 7) and whether or not it is acceptable (step 8).

The organization should establish a process for conducting risk evaluation when it is determined that there is a hazard posed which has the potential to cause harm, as described in 5.3.5. The risk evaluation process will generally include the following steps:

a) evaluation of the type of injury that may occur and the corresponding severity level, e.g. fatal versus non-fatal, or serious versus minor injury;

b) estimation of the probability of harm occurring, taking into consideration consumer behaviour and the frequency and duration of use of the product;

c) estimation of the risk to each of the identified consumer groups from the hazards identified;

d) conducting an analysis to see if the level of risk is impacted by changes in assumptions or probabilities;

e) documentation of the risk evaluation;

f) verification by experts of the application of the risk evaluation method and conclusions reached;

g) if the risk is not tolerable, then continuing with risk reduction by redesigning the product or by providing protective measures against the hazard.

A list of potential common hazards is given in Annex C. See also Bibliography.

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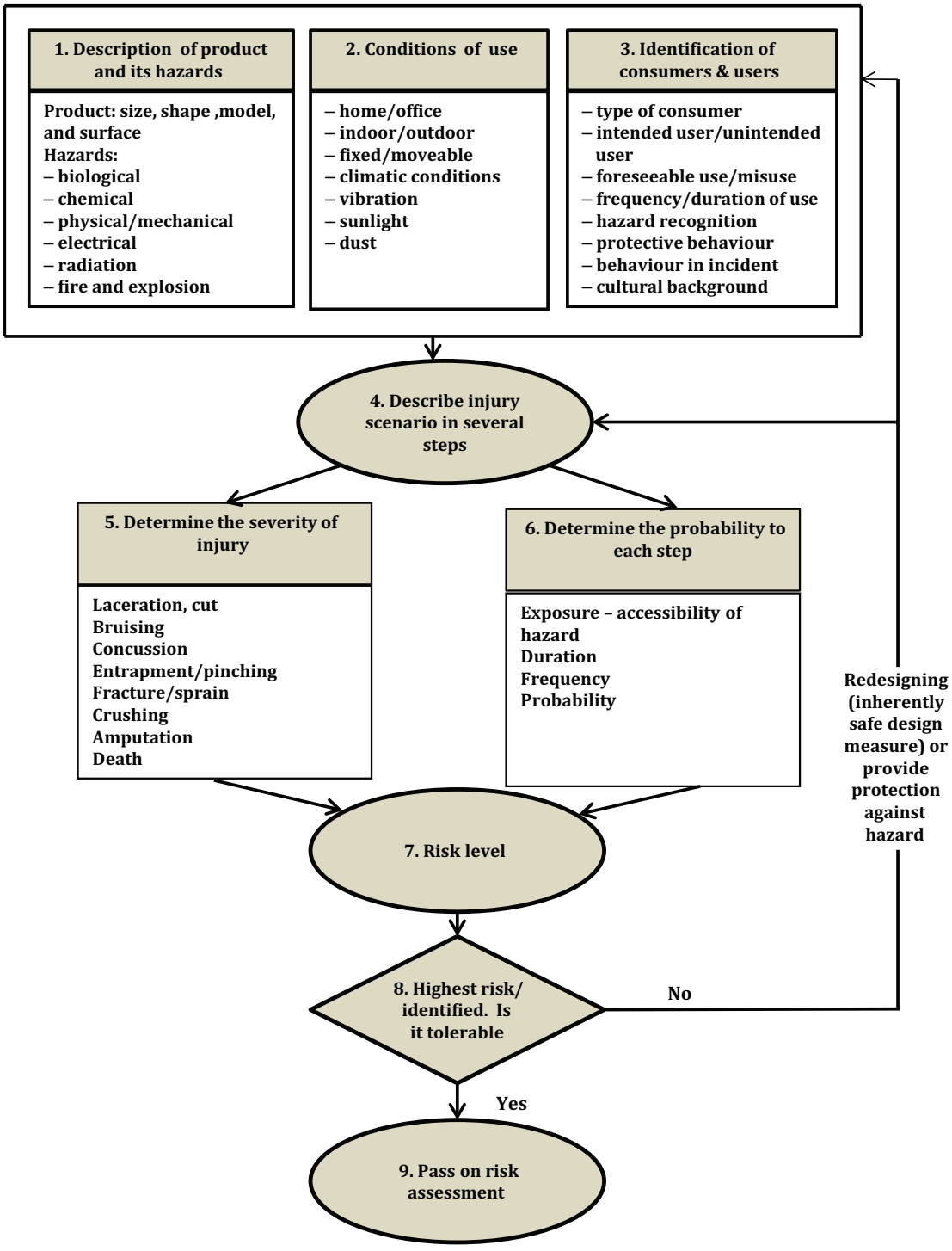

NOTE Figure based on EU risk assessment guidelines for non-food consumer products.

Figure 4 — Diagram illustrating the flow of risk assessment

5.3.5 Risk reduction

The ultimate goal of carrying out risk assessment is to assist the organization in determining how best to reduce the risk and what action needs to be taken. The organization should compare the risk assessment results against what is determined to be tolerable risk, taking into consideration social and public benefits. If a tolerable risk is not achieved, it may be necessary to take further steps to reduce the risk to a tolerable level. If the risk cannot be reduced to a tolerable or acceptable level, the product should

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not be permitted to reach the marketplace. The options to reduce or eliminate the risk may include the following, as illustrated in Figure 5:

a) examining the risk assessment (hazard identification and exposure analysis to determine which aspects of the product are contributing to the risk);

b) evaluating the extent to which the reduction available will reduce the risk;

c) incorporating protective measures into the product at the design stage (e.g. adding a protective cover to a table saw);

d) providing users with safe use information through the provision of instructions for use, assembly and maintenance, and warnings and labels.

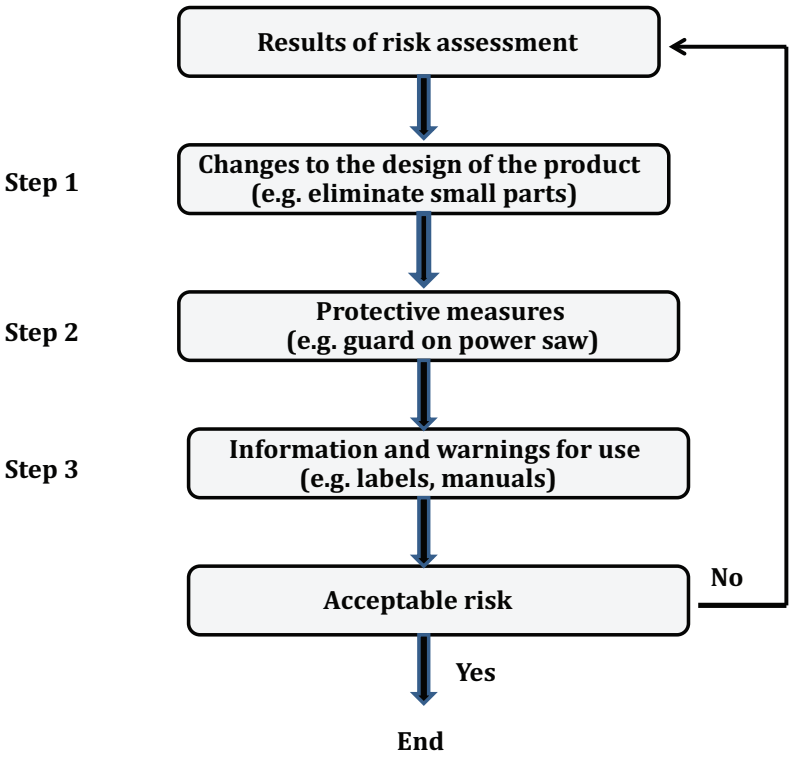

Figure 5 — Example of risk reduction process of an organization

EXAMPLE 1 With a child safety gate, a potential hazard might be the ability of a child to open the catch. The performance criterion for this hazard would be that the catch cannot be opened by any child under five years old. If a hazard cannot be completely "designed out", performance criteria might need to be set for an acceptable level of risk. For instance, a catch on a safety gate that can be opened by 15 % of two-year-old children would be an unacceptable risk, but a mechanism with 0,001 % risk of a bruised finger might be acceptable.

The risk reduction actions could range from redesigning safety into the product to deciding not to manufacturer the product if the risk cannot be reduced to a tolerable level. Safety information, warnings and labelling should be used as the last step in trying to reduce the risk to a tolerable level.

With respect to communicating with the public about risks associated with a consumer product and how they can be avoided, there are two main methods of doing this: warnings and instructions.

Warnings are an integral part of managing consumer product risks. Organizations should warn consumers about products with residual risk. Warnings are brief safety messages about the existence, nature, form, or severity of a product hazard that could adversely affect the health and safety of the user. In addition, the environment and location where a product is used may cause an unforeseen hazard. The content of a warning should describe the product hazard, the harm presented by the hazard and the consequences if the harm is not avoided. Each product hazard should be presented in a separate

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warning. Effective warnings attract attention by using signal words, safety alert symbols and a font in a type size and colour that is suitable to the product hazard. Warnings should be placed on the product in labels that are durable, in product manuals, in safety data sheets and on organization websites.

Instructions are also integral to the safe use of a product. Organizations should provide product users with instructions about the use, assembly, maintenance and disposal of the product. The content of an instruction should give product users the means to avoid a harm presented by a product hazard that has not been reduced or eliminated, and directions to avoid the misuse of the product.

EXAMPLE 2 "In a confined space there are carbon dioxide and flammability hazards. Do not use the camping lantern inside a tent."

Instructions may give direction about action to take if the product is misused, e.g. ingesting bleach. Instructions and warnings with safety messages about product hazards should be written and presented separately to avoid confusing directions about product use.

Other considerations that may govern the content or presentation of a warning or instruction include the following:

— safety messages required by a law or regulation;

— industry standards that give specific guidance about the risk associated with a product or its use;

— other languages in which the warning or instruction should also be given;

— the ability of vulnerable consumers to read and understand the warnings (e.g. children and elderly);

— the location where warnings should be placed on the product;

— the prominence of warnings in the product manual;

— symbols that should be used in product warnings;

— obtaining feedback from a focus group about the content of the warning or instruction;

— whether the product's technology (e.g. software) should provide warnings or instructions to the user.

Where there are no identified regulatory requirements for labelling, or where instructions and guidance are required, the supplier should refer to ISO/IEC Guide 14, ISO/IEC Guide 37, ISO/IEC Guide 74 and ISO 3864.

5.4 Documenting the design specification process

Documentation of the design specification process is important to demonstrate both that it was done and how it was done. The history of the consumer product design and development, including evolution of the product design, the history of other similar products and history of incidents or problems with the product or similar products should be documented. By creating, maintaining and updating these documents, the organization can ensure that information is available to be used during subsequent risk evaluation activities and for traceability, product redesign and legal and regulatory compliance.

The organization should therefore establish and maintain procedures to record, control, retain and retrieve all principal documents and data related to design, production and the marketplace. These should include the following:

— records arising from the implementation of this International Standard;

— documents created during the design stage, e.g.

  — risk assessment including data and information used;

  — significant design choices and safety decisions;

  — drawings, specifications and bill of materials;

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- product quality and safety tests and approved product samples;
- validation of the design;
- validation of warnings and instructions;
- design testing and inspection;
- technical feasibility;
- compliance with regulatory requirements and product specific industry standards;
- third-party testing and conformity assessment, as required;

— the options considered and actions taken to reduce or eliminate any risk.

6 Safety in production

6.1 Basic principles during production

6.1.1 General

The identification and reduction of product safety risks introduced during production will reduce total cost, improve efficiency and improve the overall safety and quality of the final products. Risk assessment (see 5.3.4.8) should be a major concern during all aspects of production, including production planning, production runs, post-production and production support. This clause provides guidance about integrating steps into these phases of production and establishing a culture of product safety, resulting in reduced risks to consumers. The three phases in production are illustrated in Figure 6.

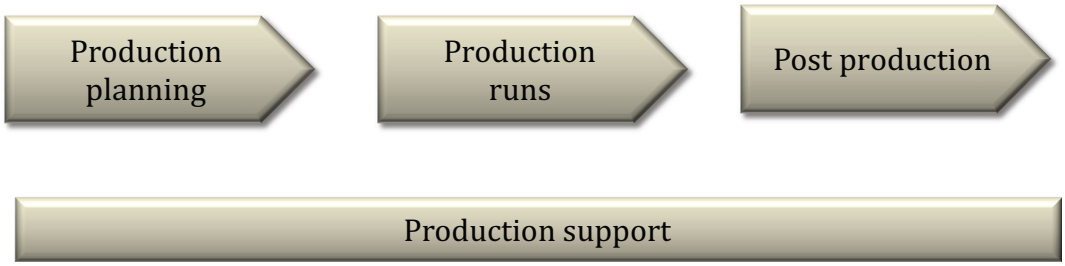

Figure 6 — Phases in production

6.1.2 Development of a culture of product safety in the production facility

Developing a product safety culture in a supply chain with many members will improve consumer product safety. A product safety culture requires organizations to go beyond traditional concepts in the design, prototyping, testing, inspection and training approaches to one where rapidly identifying, managing and mitigating risks in product safety are of paramount importance. The development of a product safety culture should be a priority within the organization and the following practices give evidence of this:

— knowledge of the risks associated with the consumer products they handle and how those should be managed;

— dedication of resources to evaluate supplier practices;

— staying up to date on emerging consumer product safety issues;

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— promoting a value system within the organization that focuses on avoiding any possible injuries or harm as a result of using the company's products;

— communication of compelling and relevant messages about risk reduction activities, and empowering others to put them into practice;

— promotion of effective product safety systems before an incident occurs;

— involvement in standardization work in matters related with consumer product safety (e.g. at the level of technical committees and national mirror committees).

6.1.3 Reduction or elimination of product defects

Defects that affect the safety of products may occur during production and they are preventable. The organization should incorporate actions necessary to reduce or eliminate product defects into every step of production. Examples of actions that could be taken include identifying and controlling the critical steps in the production process, e.g. annealing temperature of glass, torque of screws, or contamination in the facility.

6.1.4 Commitment to consumer product safety

The organization should put in place all the necessary aspects of product safety, including training throughout all phases of its production process. Equally important, the organization should verify that its supply chain providers of raw materials, components and subassemblies have incorporated all the necessary aspects of product safety into their individual production practices.

6.1.5 Best manufacturing practices

The organization should follow industry's best manufacturing practices (BMP) during the production of consumer products. These are practices that provide continual measures of safety and quality, and that can uncover problems due to inconsistency and fluctuations in the production process as they occur and before the product is shipped. Thus, BMPs are a more immediate and consistent way of ensuring that products meet the design specifications.

6.2 Production planning

6.2.1 General

Planning before production begins can reduce the potential for introducing product defects during production. A production facility should plan its production before the start of manufacturing by means of the following:

— confirming it has the final design to be used for actual production;

— reviewing any prototypes built prior to production;

— completing a pre-production run.

These steps should be performed regardless of whether the consumer product is being produced for the first time or if the product design has changed. These steps can help confirm that the product can be consistently manufactured in compliance with the specifications, without the introduction of defects, and at the required production rate.

6.2.2 Production readiness

6.2.2.1 Specifications

The production facility should have the consumer product's specifications, including the final design, performance criteria, the material requirements for production, the raw materials, the components,

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the subassemblies (if any), the bill of materials (if any), assembly requirements, final testing, packaging and labelling.

6.2.2.2 Material procurement

The availability of approved raw materials, components and subassemblies is critical. Organizations should validate that the items provided by its supply chain match the product specifications. In addition, before production begins, the organization should confirm that raw materials, components or subassemblies meet the design specifications, and are neither at their end-of-life nor are unapproved replacements.

6.2.2.3 Tooling

Depending on the consumer product being produced, the production facility will need to ensure that it has the tools necessary for production, including the physical setup within the production facility, specialized machinery, specialized equipment, moulds, fabricators and specialized skills among its staff. It should define and monitor essential aspects that can affect the safety of the products produced, e.g. the critical tolerances, wear on tools and operator actions.

6.2.3 Processes, controls and measures

6.2.3.1 General

The production facility should establish processes, controls and measures during production that are consistent for the production of safe consumer products. It is important that these be recorded in its documents to demonstrate that the production facility meets the agreed safety requirements. The production facility should ensure that employees are aware of the processes, controls and measures. Measuring instruments and equipment should be calibrated.

6.2.3.2 Training

The production facility should ensure employees are trained on existing processes, controls and measures to ensure products are being produced consistently. Suppliers should document the processes, staff certification and staff training.

6.2.3.3 Pre-production run

The production facility may wish to do a pre-production run to test its ability to manufacture the final product. The pre-production run can help confirm the safe design and the final assembly, and that the product can be manufactured at the required production rate without introducing defects. Modification of the final design may be necessary before full production begins.

6.2.3.4 Consumer product verification

The units produced during the pre-production run should be assessed for compliance with the specifications and freedom from defects. If possible, the consumer product should be compared to any prototype previously produced, and then tested in an environment that mirrors the eventual use of the product by consumers. If product issues are noted, the various elements above should be reviewed to determine if changes need to be made before the full production run is commenced.

6.3 Full production runs

6.3.1 General

In order to avoid introducing defects in production, the production facility should control all parts of the product during actual production, including the raw materials, components, subassemblies, spare parts, accessories, packaging, warnings, instructions and manuals. Any changes that impact product design,

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raw material, manufacturing process and sourcing should be considered and approved before changes are implemented. Change management is important to ensure product safety.

6.3.2 Raw materials, components and subassemblies

Upon receipt by the production facility, every batch of incoming raw materials, components and subassemblies should be validated to comply with the product's design specifications and to ensure that the quality meets or exceeds the quality used during the pre-production run. Raw materials, components and subassemblies accepted by the production facility should be introduced into its production facility inventory, managed and traced to identify their source, batch, lot and date. Raw materials, components and subassemblies not meeting the specifications should be segregated to ensure that they are not mixed with acceptable material. The production facility should ensure that the raw material, component or subassembly suppliers understand that unapproved raw materials or components or any changes are unacceptable unless approved by the organization.

6.3.3 Production

6.3.3.1 Production scheduling

The scheduling of production provides efficiency, cost savings and planning to produce a final safe consumer product.

6.3.3.2 Production consistency

A production facility should produce final consumer products that are consistent from a safety and quality perspective across one or multiple production runs.

6.3.3.3 Production quality monitoring

Monitoring of production quality ensures safety has been integrated into the final product, based on the design, materials and production planning. Production monitoring may be included as part of the responsibility of the facility's production staff, but the production monitoring processes and execution should be the responsibility of quality staff assigned to the production floor. Production monitoring staff should have established the sampling rate for each production run and document the monitoring. Production monitoring staff should have the ability to stop production if problems have been identified. Production monitoring includes inspections and product testing and should also include the sampling of the product, the manuals and packaging.

6.3.3.4 Finished product testing

Finished product (or batch) testing is integral to assuring the safety of the final product. It includes the complete testing of the finished product and validation of its manual, labels and packaging to the product specifications. Conformity assessment bodies and testing laboratories can assist production facilities in demonstrating that all reasonable steps have been taken to produce a complying product.

6.4 Post production

The production facility should consider the logistics of getting the product from their facilities to the supply chain. If not carried out properly, it could result in damage or the introduction of hazards during shipment, packaging, packing, transportation and storage. Consideration should be given to the following:

— master carton and shipment ready packaging;

— reviewing supply chain logistics requirements, including security and product integrity;

— developing a logistics plan.

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The supply chain should have a shared understanding of the logistics plan to transfer the consumer product to the consumer without being damaged. With this understanding, the supply chain should monitor the transfer in order to ensure that any changes from the plan do not introduce new problems or safety risks into the product.

6.5 Production support

6.5.1 General

The production support function is independent of the production floor function in a production facility. Production support provides the production facility with capabilities such as the following:

— the auditing of production to ensure consistency;

— the monitoring of the regulatory and standards environment to ensure compliance;

— the monitoring of continual improvement processes;

— the meeting of documentation requirements.

6.5.2 Audits

The production facility could be audited by competent persons or competent authorities (e.g. conformity assessment bodies and clients). Production support would facilitate these audits, capturing any input for the continual improvement of the product and processes. When problems in the production process or changes in materials or components are identified, the risk should be assessed. If the risk is not tolerable, removal of the affected products from the marketplace and warehouses should be considered.

6.5.3 Laws, regulations and standards

Production support ensures that the production facility knows the standards, laws and regulations required for the jurisdictions where the products will be manufactured or sold. They should ensure that the final products meet those laws, regulations and standards.

6.5.4 Risk-based testing

Testing conducted by the production facility, conformity assessment bodies and suppliers identify opportunities for continual improvement of products. Production support should ensure that risk reduction or corrective actions arising from product testing are executed and fed back to the organization and through the supply chain.

6.5.5 Documentation

Documentation and record keeping is important for the integrity of the production facility and its processes in order to ensure consistency, as described in 4.2.3.

7 Safety in the marketplace

7.1 General

To improve consumer product safety, suppliers should conduct pre-purchase confirmation, proactive data collection, and ongoing product risk assessment (see 5.3.4.8).

7.2 Pre-purchase assessment

7.2.1 Prior to acceptance, suppliers should confirm that the product ordered meets their requirements in terms of the following:

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— safety for consumers, including vulnerable consumers and those who may be exposed;

— quality attributes that relate to safety;

— compliance with laws, regulations and safety standards;

— suitability for the environment, targeted users and the marketplace.

7.2.2 The right to verify that the consumer product meets requirements should be included in the contract that was reached prior to the production stage. In addition, product specifications should be communicated and agreed during the design stage. Product specifications should include elements such as the following:

— in which marketplace the product will be sold;

— the environment, e.g. an office, nursery and residential home, where the product would be used;

— who the users of the product will be, e.g. in terms of age range and capability.

7.2.3 Compliance can be verified by means such as the following.

— Obtain data from the supplier that the product meets specifications, the applicable laws, regulations and standards and how the compliance was determined. Confirmation can take the form of test criteria and test results generated by internal facilities or third party independent laboratories and, where required, certification results from third party certification bodies.

— Write specific contracts that include the safety, quality and the applicable regulatory compliance requirements for where the products are intended to be manufactured, sold and used. Contracts should also give the supplier the right to verify, require proof of compliance and hold the other members of the supply chain accountable for correction of non-compliant products.

— Review the compliance history of the supplier of the consumer product and the product's history of reported incidents, recalls, lawsuits and consumer complaints.

— Evaluate through sampling and testing. Testing should be done to the test criteria agreed during the safety in design stage and in accordance with applicable regulatory requirements.

— Evaluate through inspection. An alternative or complement to product testing is product inspection, where the product is visually inspected to ensure the requirements are being met and necessary safety certification has been completed.

— Auditing of documentation provided by the supplier of the product can be used as a complement to, or as an alternative to, testing or inspecting. The documentation supplied should present evidence that demonstrates conformance of the product to the requirements. This would include test reports, inspection reports and certification documentation.

7.3 Proactive data collection and analysis

Data collection and analysis provides a supplier with the information necessary to identify trends in consumer product safety, from information such as defects, return rates, repairs, product incidents, complaints, insurance claims and legal actions. Proactive data collection and analysis is also valuable as feedback for the risk reduction and continual improvement processes. Data collection and analysis may also be required by some government regulations. The organization should also consider positive feedback from all sources for continual improvement.

The supplier should establish processes for data collection and analysis by means such as the following:

— establishing, communicating and promoting a consumer complaint system, which is a systematic way of obtaining information on how consumers use products, failure modes and defects, and opportunities to improve the product;

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NOTE Further information on complaints handling in organizations is given in ISO 10002.

— reviewing and analysing products and service records to determine the reason for products being returned and serviced;

— using new data to constantly update the understanding of risks inherent in a product and how to reduce them.

In accordance with ISO 10393, suppliers should establish a process for documenting and investigating incidents and defects involving the product.

7.4 Ongoing assessment of consumer product conformance

Suppliers should verify conformance on an ongoing basis. Ongoing assessment helps to reduce the risks to the health and safety of consumers from variations introduced during multiple productions runs, multiple production lines and multiple factories.

Suppliers can assess the product after it enters the marketplace by means such as the following:

— obtaining products from the marketplace: collecting samples for ongoing assessment as close as possible to, or directly from, the source where a consumer would purchase the product helps to identify and reduce any risks that may have been introduced through the supply chain during transportation, storage and handling;

— verifying compliance of the samples with specifications: as part of auditing documentation, compliance with requirements can be verified by assessing product samples against the product specifications utilized by the manufacturer;

— conducting consumer satisfaction surveys;

— analysing consumer data from various sources including product returns, websites, call centres, in-store feedback and social media;

— establishing a feedback loop through the organization and the supply chain so that data relevant to the compliance of the product is captured during production line and quality control audits;

— conducting factory surveillance at a frequency determined by product risk and the compliance history of the factory;

— including advice that suppliers should monitor their sector of the market by subscribing to recalls websites.

7.5 Warranty and servicing

A supplier may be required to provide continued support after the consumer product is sold to the consumer, including installation, warranty, servicing, repair or providing replacement parts. Suppliers may provide this assistance directly or may delegate this function to other parts of the supply chain or third party service organizations.

Organizations that provide services for products after being sold to the consumer should:

— provide adequate documentation;

— make spare parts available;

— provide training to their staff so that their actions do not reduce the safety level of the product.

Suppliers should also ensure that applicable standards for in-service testing and repair of products are followed.

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Safety hazards can arise in cases of poor product support activities.

EXAMPLE 1 Due to the incorrect installation work for connecting electrical power to a clothes dryer, the connecting point overheated and caused a fire.

EXAMPLE 2 When a safety device on a gas water heater failed, an improper repair was made to restart the product, which generated carbon monoxide that caused a death.

7.6 Product incident investigation

Suppliers should establish a process for documenting and investigating incidents and defects involving the product. See ISO 10393 and Clause B.3 of this International Standard on product incident investigation.

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Annex A
(informative)

Useful International Standards and Guides

The International Standards and Guides listed in this annex, which are also referenced elsewhere in this International Standard, provide advice on how to deal with specific product safety issues, e.g. the safety needs of consumers, developing warnings and instructions and assessing the risk associated with consumer products.

— ISO/IEC Guide 14 specifies what information prospective purchasers (of products or services) require and expect.

— ISO/IEC Guide 37 gives advice on the design and formulation of instructions so that they are helpful to the final users of consumer products and services.

— ISO/IEC Guide 41 provides general recommendations to be taken into consideration when determining the most suitable type of packaging to be used at the point of sale to the consumer.

— ISO/IEC Guide 50 provides a framework for preventing hazards to children from the products and services that they use.

— ISO/IEC Guide 51 is applicable to any safety aspect related to people, property or the environment or a combination of one or more of these, and adopts a risk reduction approach.

— ISO/IEC Guide 71 provides a systematic approach to addressing ageing and disability issues related to the safety of products.

— ISO Guide 73 promotes the coherent description of risk management activities and the use of risk management terminology.

— ISO/IEC Guide 74 explains how to develop graphical symbols aimed at helping the public (e.g. instructions or warnings) and indicates databases for symbols and other valuable resources to assist in that task.

— ISO 9000 describes the fundamentals of quality management systems and defines related terms.

— ISO 10002 provides guidance on the process of complaints handling related to products within an organization, including planning, design, operation, maintenance and improvement.

— ISO 10393 provides an international model code of good practice for consumer product recalls and other corrective actions after the product has left the manufacturing facility.

— ISO 12100 specifies basic terminology, principles and a methodology for achieving safety in the design of machinery including those intended for consumers.

— ISO 26000 provides guidance to all types of organizations, regardless of their size or location, on concepts, terms and definitions related to social responsibility.

— ISO 31000 provides principles and generic guidelines on risk management.

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Annex B
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Information and guidance for small businesses

B.1 General

This International Standard is intended for organizations of all sizes. However it is recognized that many small to medium-sized organizations may have limited experience or resources to do the following:

— to identify hazards and the cause of the hazards in consumer products;

— to evaluate risks;

— to establish the procedures and policies that will assist them in meeting mandatory legal requirements and best practices to supply safe consumer products.

The purpose of this annex is to provide such information and examples to assist suppliers in implementing the guidance outlined in this International Standard.

B.2 Questions for suppliers to consider when designing, producing or supplying consumer products

B.2.1 General

This clause lists a number of questions that a supplier may wish to consider. These questions are only examples of the types of questions that a supplier may ask and do not necessarily cover all aspects of supplying a product that does not cause harm.

B.2.2 General questions

— Do my staff or external contractors have the necessary education, training, technical knowledge and experience to carry out their responsibilities related to consumer product safety? (see 4.2.1)

— Have I allocated enough financial and human resources to design, produce or supply safe consumer products? (see 4.2.2)

— Does my company have a system in place to record retain, retrieve and analyse information received from incidents, complaints, service records and test reports, complaints and incidents? (see 4.2.3)

— Does my company know and understand the laws, regulations and standards with which my product(s) need(s) to comply in the country where the product(s) will be manufactured or sold? (see 4.4)

— Does my company know the traceability regulations or standards of the countries to which my products will be distributed? (see 4.5)

— Does my company know the traceability requirements of the other members of the supply chain involved with my product? (see 4.5)

— Are all the product components or products distributed by the supplier, which need to be traced, identified with a unique identification and description? (see 4.5)

B.2.3 Questions related to design

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— Do my staff or external contractors have the necessary education, training, technical knowledge, and experience to identify the potential hazards in a consumer product design, to evaluate the potential risks and to determine what changes need to be made to the design to remove the risk? (see 4.2.1)

— Who are the possible users of the consumer product, and who could come into contact with it, i.e. intended users, potential users, unintended users, and vulnerable users? (see 5.3.2)

— What are the physical capabilities and psychological characteristics of the users, e.g. strength, motor skills, experience and physical dimensions? (see 5.3.2)

— What potential hazards may be associated with the consumer product? (i.e. try to anticipate everything about your product that could go wrong or be dangerous to the eventual user) (see Annex C)

— Will the user actually be exposed to the hazard? (e.g. a sharp edge in a product may not be accessible to the user) (see 5.3.4)

— How long will the users be in contact with or exposed to the hazard associated with the product? (see 5.3.4)

— What possible injuries may be caused by each of the hazards identified? (see Annex C)

— How serious could the injuries or harm be for each of the hazards identified? (see Annex C)

— How likely is it that an incident caused by each consumer product hazard will actually happen? (see 5.3.4)

— If the risk is not acceptable, can it be reduced by changing the design of the consumer product to eliminate the cause of the hazard? (see 5.3.5)

— If the design cannot be changed to reduce the risk, can the risk be reduced by adding protective devices? (e.g. a guard on a power saw) (see 5.3.5)

— Can any risk that remains be addressed through information or warnings to the consumer or user? (see 5.3.5)

— Are clear instructions for assembly provided? (see 5.3.5)

B.2.4 Questions related to production

— Is the consumer product design specification faulty and does it result in an unsafe or illegal product? (see 6.2.2)

— Did the product designer carry out and provide a copy of a risk assessment? (see 6.2.2)

— Is it possible for the production facility to mass produce the consumer product as designed? (see 6.2.2)

— Does my facility have the tools, processes and trained employees needed to produce the product? (see 6.2.3)

— Does my facility have the tools and trained staff to maintain and calibrate the production equipment? (see 6.2.3)

— Do we have processes in place to prevent contamination of the product by chemical or biological agents? (see 6.1.3)

— Have the steps in the process been identified that are critical to producing a safe product? (see 6.2)

— Can suppliers provide a consistent supply of the raw materials, components or subassemblies that are required to produce the product? (see 6.3.2)

— Do we have procedures in place to verify that the raw materials, components and subassemblies meet specifications? (see 6.3.2)

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— Has a plan for testing the consumer product during production been established and implemented? (see 6.3.3)

— Will corrective actions arising from testing during production be executed? (see 6.3.3)

B.2.5 Questions related to the marketplace

— Does the consumer product ordered meet my company's requirements for safety, quality, compliance with regulations and suitability for consumers and the marketplace where I intend to distribute and/or sell the product? (see 7.2)

— Do I have confidence that the company will consistently supply compliant product? (see 7.2)

— Does my company have the right to verify that the consumer product meets its safety requirements? (see 7.2. and 7.4)

— Has my company established processes to collect data from complaints, returns, service records and monitoring products in the marketplace? (see 7.6)

— Does my company have the ability to analyse the data collected? (see 7.6)

— Does my company know and understand the requirements for reporting incidents and actions to correct defects that exist where I plan to distribute the product? (see Clause B.3)

B.3 Consumer product incident investigation

A process for documenting and investigating reports of incidents and defects involving the consumer product should be established. Reference should be made to ISO 10393, which gives the following guidance:

— the organization should make it easy for users of the product to file product incident reports;

— document the product incident or defect details, the investigation, the findings and the actions taken;

— assign competent staff to investigate the incident or defect, and to check for trends; determine if the incident or defect report is valid and, if possible, acquire the product involved in the actual incident for review;

NOTE Harm can be created directly or indirectly if the product does not function as intended, e.g. a smoke alarm which fails to detect smoke.

— provide regulators or competent authorities, certification bodies and other stakeholders with product incident and defect reports, the investigation findings and the actions taken at the frequency and level of detail required by legal and contractual requirements;

— perform a risk assessment if the evaluation identifies a harm or potential harm;

— if the risk assessment concludes that corrective action is required, identify means to reduce the potential harm: corrective actions include repair or rebuilding the product, removing the product from the marketplace, scrapping the product or conducting a product recall;

— identify the root cause for the defect that created the potential harm;

— identify and implement corrective actions to eliminate or reduce the reoccurrence of the defect, e.g. depending on the level of risk, this can be accomplished by redesign of the product to remove the potential harm, guarding against the potential harm or by informing the users of the potential harm;

— determine if the defect is common to other products and, if so, require that similar corrective actions be implemented;

— check that the corrective actions achieve the desired goal in reducing the potential for the defect to reoccur.

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As far as possible, the steps in the process should be carried out in parallel, rather than sequentially, in order to reduce the time needed to reach a decision on the product's potential to create harm and to implement corrective actions.

B.4 Planning and carrying out a focus group

In simple terms, focus groups consist of a small number of people (six to ten people) brought together to discuss and provide their views on a pre-defined issue. Normally, the purpose of such groups is to find a solution to a problem or to provide information on a specific subject. Some of the main considerations to be taken into account when planning a focus group are as follows.

As a technique, focus groups can be very useful for:

— generating ideas on new products or services, or for improving existing ones;

— carrying out exploratory investigations about attitudes, motivations or beliefs;

— learning the concerns and language of consumers, and integrating them into warning labels, instructions or advertising messages;

— evaluating packaging and product information.

The success of this technique is heavily dependent on several key aspects, i.e.

a) the willingness and motivation of the people to participate in the session;

b) the agreement between the participant and moderator for the participant to tell the truth about the topic in question, and for the moderator not to influence the opinion of the participants by asking leading questions;

c) a clearly defined objective for holding the focus group;

d) selection of participants that ensures that they have adequate experience in the topic of analysis and do not know one another;

e) the impartiality of the moderator, who is external to the organization.

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Annex C
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Hazard and risk evaluation

Risk evaluation is the logical identification and evaluation of any hazards that a product may pose, and the determination of the likelihood that a consumer or user will be exposed to them. Once the potential hazards and their cause have been identified, it is then possible to determine the risk posed and, if required, to redesign the product or add protective devices before the product is produced or reaches the consumer. In some instances, but not all, it may be necessary to carry out research or obtain knowledge and expertise in order to help with the evaluation.

Table C.1 provides a number of examples to illustrate how hazards are identified.

Table C.1 — Identification of hazards

Hazard	Product property	Injury scenario	Injury
Abrasion	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
Adhesion	Exposed adhesive	Traumatic removal of skin that is attached to a product by an adhesive.	Avulsion, laceration
Avulsion	Catch points	Teeth or fingernails caught in narrow channels	Removal of tissue (e.g. teeth, nails) by tearing
Burn (cold)	Cold surfaces	Person does not recognize the cold surface and touches it; the person sustains frostbite	Burn
Burn (thermal)	Hot surfaces	Person does not recognize the hot surface and touches it; the person sustains burns	Burn
Burn (thermal)	Hot liquids	Person handling a container of liquid spills some of it; the liquid falls on the skin and causes scalds	Burn, scald
Burn (thermal)	Open flames	A person near the flames may sustain burns, possibly after clothing catches fire	Burn
Burns (chemical)	Chemicals with caustic properties	Burn caused by a caustic or corrosive chemical contacting the skin.	Burn
Burns (cold)	Objects or areas with greatly reduced temperatures	Burn caused by contact with a cold solid, liquid, or gas.	Burn
Burns (thermal)	Objects or areas with elevated temperatures, hot liquids and steam	Including scald burn caused by contact with a hot liquid or steam, hot surface burn caused by contact with a hot solid, and electrical burn or tissue damage caused by electric current passing through the tissue.	Burn
Burns (thermal)	Heat production	Product becomes hot; a person touching it may sustain burns; or the product may emit molten particles, steam, etc., that hits a person	Burn

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Table C.1 *(continued)*

Hazard	Product property	Injury scenario	Injury
Chemical	CMR substance	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets onto skin; and/or person inhales substance as gas, vapour or dust	Cancer, mutation, reproductive toxicity
Drowning	Holds liquid and is large enough to admit the head or face	Obstructing the passage of air by submersion of mouth and nose in a fluid.	Drowning, anoxia
Electric shock	Accessible electric current	Sudden stimulation of the nerves or convulsion caused by the passage of electric current through any portion of the body.	Cardiac Arrest, muscle damage, electric shock
Electric shock	High/low voltage	Person touches part of the product that is at high voltage; the person receives an electric shock	Electric shock
Entrapment	Parts moving against one another	Person puts a body part between the moving parts while they move together; the body part gets trapped and put under pressure (crushed)	Bruising; dislocation; fracture; crushing
Ergonomic strain	Components or products which are not sized or shaped to their purpose	Poor body mechanics during tasks	Strains and fatigue in muscles, joints and tendons.
Explosion	Explosive mixtures	Person is near the explosive mixture; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear
Explosion (chemical)	Violent chemical reaction	Sudden release of chemical energy in a sudden and often violent manner, usually with the generation of high temperature and release of gases.	Impact, Burn
Explosion (mechanical)	Parts under spring tension	Sudden release of mechanical energy in a sudden and often violent manner.	Impact, laceration
Fall	High position of user	Person at high position on the product loses balance, has no support to hold on to and falls from height	Bruising; dislocation; fracture, concussion; crushing
Foreign object insertion (non-airway)	Small or slender products or components	Objects lodged in ears or other non-airway body cavities.	Irritation Infection, discomfort
Impact	Slippery surface	Person walks on surface, slips and falls	Bruising; fracture, concussion
Impact (moving object)	Pressurized liquid or gas, or vacuum	Liquid or gas under pressure is suddenly released; person in the vicinity is hit; or implosion of the product produces flying objects	Dislocation; fracture, concussion; crushing; cuts (see also under fire and explosion)
Impact (moving object)	Elastic element or spring	Elastic element or spring under tension is suddenly released; person in the line of movement is hit by the product	Bruising; dislocation; fracture, concussion; crushing
Impact with moving object	Significant kinetic energy	Force or impetus transmitted to the body by a collision from a moving object.	Fracture or bruising
Infrared	Electromagnetic radiation with wavelength between 780 nm and 1 mm.	Sufficient time exposure to intense infrared light, e.g. heat lamps. Hazard is dependent on time and intensity.	Tissue damage through a thermal mechanism (burn).

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Table C.1 *(continued)*

Hazard	Product property	Injury scenario	Injury
Interference with safe activity	Small eyeholes, ill-fitting footwear, loud sounds or dim lights	Sensory distraction or masking leading to the creation of a hazard condition.	Various injuries
Internal airway obstruction	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Choking, internal airway obstruction
Internal airway obstruction/ aspiration	Small light aerodynamically shaped objects	Inhalation of (a) small object(s) into the airway.	Acute (anoxia) or chronic (infection)
Internal airway obstruction/ choking	Small parts which fit in the mouth	Objects lodged in the mouth or oral airway.	Anoxia
Internal airway obstruction/ insertion	Small parts which fit into the nostrils	Objects lodged in the nasal passages.	Infection or aspiration.
Laceration	Sharp edge	Person touches sharp edge; this lacerates the skin or cuts through tissues	Laceration, cut; amputation
Microwave	Electromagnetic radiation with wavelength between about 1 mm and 1 m.	Ineffective shielding on microwave transmission and generating devices	Tissue damage through heating or of interfering with implanted medical devices.
Noise-induced hearing loss	High Intensity impulsive or continuous noise	Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance	Permanent or temporary complete or partial loss of hearing
Positional asphyxia	Tilting infant environments/ conditions	Children's heads may tilt forward placing their airways under compression.	Anoxia
Puncture	Sharp corner or point	Person bumps into sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Puncture
Puncture	Sharp points	Penetration injury of the skin caused by contact with a sharp point.	Bleeding open wounds
Repetitive motion	Poor design of control interfaces	Human interface requiring repetitive motion, e.g. frequently repeated tasks	Carpal tunnel syndrome muscle and joint strain. Nerve damage
Strangulation (neck)	Strings, cord or edges of products that can come into contact with the throat.	Caused by external pressure obstructing the passage of air through the airway or by preventing the flow of oxygenated blood to the brain.	Anoxia
Suffocation	Flexible films and circular cross-section rigid containers that can cover the nose and mouth	Caused by obstructing the passage of air by sealing the mouth and nose with an external object (example: plastic films, containers).	Anoxia
Suffocation	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child)	Suffocation
Ultraviolet	Electromagnetic radiation between about 100 nm and 400 nm.	Exposure to intense UV for sufficient duration,, e.g. tanning booths.	Tissue damage through photochemical effect.

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Table C.1 *(continued)*

Hazard	Product property	Injury scenario	Injury
Ultraviolet	Ultraviolet radiation	Skin or eyes of a person are exposed to radiation emitted by the product	Burn, scald; neurological disorders; eye injury; skin cancer, mutation
Vibration	Eccentrically mounted motors	Hand-Arm Vibration (HAV) (usually associated with the use of vibrating hand tools) and Whole-Body Vibration (WBV), which is experienced when the operator or driver sits on or in a vibrating machine, usually a vehicle such as a forklift, or one of muscle and joint strain. Nerve damage the numerous kinds of vehicles used in agriculture, transport, materials handling, mining and forestry.	Muscle and joint strain. Nerve damage

The examples in Table C.2 illustrate how hazards such as those identified in this annex are identified and are evaluated.

Table C.2 — Examples of identification and evaluation of hazards

Type of hazard	Scenario	Evaluation of hazard	Type of injury
Mechanical hazard: sharp edges that are accessible to the body or part of the body	Child reaches through a small hole or guard with a hand or finger	Measure hole and compare against data on the size of children's fingers at various ages (anthropometric data) to make sure a child's finger will not fit in the hole	Cut, amputation
Entrapment between moving parts, parts of structure or an opening	A child's head is caught between the slats of a crib. Fingers trapped between supports of a folding chair.	Data on size of children's heads or fingers at different ages (anthropometric data) Use of head forms to evaluate entrapment hazards Computer simulations	Crushing, strangulation, amputation
Stability hazard: a product such as a clothes cabinet tips	The cabinet hits a person causing injury. The cabinet hits an electrical product which breaks and live electrical parts become exposed.	Stability test where drawers in the cabinet are loaded and opened.	Bruising, fracture, concussion Electrical shock, burn
Thermal: Hot surfaces	A child or person touches the surface and sustains a contact burn	Measure the temperature of the surface Burn data provides information on the time for skin to be burned at various temperatures.	1st to 3rd degree burn depending on duration of contact with hot surface

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Annex D
(informative)

Product safety management plans

D.1 General

This annex provides examples of two approaches that could be used to develop a product safety management plan. Clause D.2 describes a quality management approach through the development of a product safety management plan quality assurance manual. Clause D.3 outlines a checklist that could be used to assist a supplier in developing such a plan.

D.2 Product safety management plan based on a quality assurance manual

Figure D.1 provides a schematic view of a product safety management plan based on a quality assurance manual.

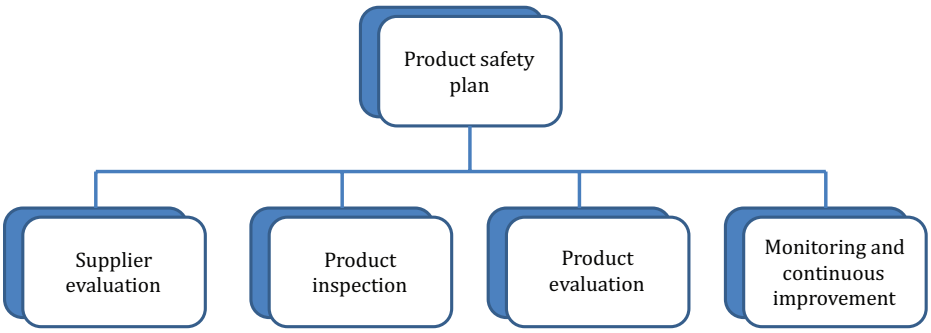

Figure D.1 — Schematic view of product safety management plan based on quality assurance manual

In this approach, as illustrated in Figure D.1, the quality assurance manual could be expected to contain the following main elements of a product safety plan:

a) introduction;

b) objective:

   1) organization's responsibilities:

      i) structure of product safety in the organization (policies; accountabilities; governance);

      ii) compliance to standards and regulatory requirements;

      iii) documentation;

   2) supplier responsibilities:

      i) product level risk evaluation/management and risk mitigation plan;

      ii) compliance to standards and regulatory requirements;

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iii) design and hazard analysis;

c) supplier evaluation;

d) factory audit;

e) social accountability;

f) product inspection:

1) in-process inspection;

2) pre-shipment inspection;

3) inspection reports;

g) product evaluation;

h) sample submission:

1) test protocols;

2) test reports;

3) sample disposal/return;

4) hold notification;

i) monitoring and continual improvement:

1) market surveillance;

2) recall management;

j) forms:

1) service request form;

2) vendor (supplier) letter.

D.3 Checklist for development of a product safety management plan

D.3.1 Management commitment to product safety:

a) mission statement;

b) corporate culture.

D.3.2 Develop a product safety policy commensurate with company tolerance of risk:

a) continual improvement of process and system.

D.3.3 Appoint and empower a safety officer to be responsible for:

a) strategic planning of safety and quality processes;

b) tactical resolution of existing issues;

c) appropriate allocation of technical, financial and human resources.

D.3.4 Implement and document safety process:

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a) design:

   1) risk analysis:

      i) ensure compliance with laws, regulations and standards;

      ii) identify product characteristics, features and functions that may impact its hazard or exposure;

      iii) conduct incident data and recall analysis for hazard identification;

      iv) predict reasonably foreseeable uses of the product;

      v) apply human factor analysis to summarize hazard types and severity;

   2) risk management:

      i) compare risk level with organization's risk tolerance;

      ii) risk treatment (if needed);

   3) risk communication for residual risk to stakeholder and consumers;

b) production:

   1) institute a quality policy within and across the supply chain;

   2) develop a proactive quality assurance process:

      i) all key processes and procedures are documented;

      ii) indicators are defined to monitor these following processes:

         — procurement management including traceability;

         — sampling;

         — measurements;

         — analysis (statistical analysis/process control);

         — reporting;

      iii) corrective procedures are implemented in case the processes are found to be outside of acceptable tolerance;

   3) implement the quality assurance system throughout the product development cycle, i.e. from raw material to final product finishing, assembly and packaging;

c) marketplace:

   1) establish a post market surveillance system;

   2) identify key safety indicators;

   3) reverse flow analysis for early detection of emerging issues;

   4) risk analysis for informed decision making (e.g. product withdrawal/recall).

D.3.5 Develop a communication system/safety manual:

a) safety manual that reflects:

   1) management statements concerning product safety;

   2) policies of the organization and the support of these policies by the management;

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3) standard operating procedures;

4) responsibilities of personnel involved;

5) procedures detailing the processes running in the organization and across its supply chain;

6) mechanisms to intervene if deviations from the procedures are detected;

7) information technology infrastructure that serves as a document database (including safety manual and reports);

b) communication with stakeholders and consumers.

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