

Basic elements for a common understanding of use conditions in standards

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Introduction

This document contains basic elements for a common understanding of terms that describe use conditions of products mentioned in various standards and regulations.

It is mainly intended for experts in standardization and has been developed as an attempt to align the different interpretations regarding the terms being used. This document does not specify requirements for products and is not intended to be used as a mandatory guide, while it may be useful as input to a possible future revision of ISO/IEC Guide 51 (to be decided upon by ISO and IEC).

This document does not offer definitions, but is limited to the “common” understanding of some essential terms since definitions of these terms differ from each other across industries as they are currently used. The specific understanding of terms and requirements can also differ depending on the product category, the intended use environment of the product, and the area which they are dealing with (safety, EMF, EMC, security etc.). Therefore, whenever relevant, the responsible Technical Committees should consider to establish appropriate definitions or understandings, taking into account these circumstances as relevant for their expected use.

Terms for normal conditions, abnormal conditions and fault conditions were discussed. As they are already specified in many product standards, and as the use depends on the area, it was agreed that the individual Technical Committees should define those terms that are needed for their use. This document should be considered as a common ground for using and understanding some terms, and at the same time leaving room for a technology-specific adaption wherever needed. Therefore, this document doesn't offer definitions of terms but rather common understandings of terms.

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Use-related terms

2.1 Product function

Any assessment of whether a product complies with the requirements of a European Directive/Regulations needs to take into account the typical conditions which exist when the product is used. Therefore, any definition of “use-conditions” to be made by the responsible Technical Committee needs to take into account the user behaviour and the functioning of the product.

2.2 Intended use

2.2.1 Common understanding

Use of a product in accordance with the information for use provided by the manufacturer.

2.2.2 Explanatory information

Intended use assumes that the product is properly stored, installed, maintained and used for its intended purpose.

Intended use includes only those uses for which the product is designed.

Intended use is determined by the information supplied by the manufacturer on the label, in the instructions for use, in product markings or in promotional or sales materials or statements. In the absence of such information, the intended use is the use of the product as can be generally expected.

Intended use should also take into account the type of user that is expected to use the product, for example, ordinary users, instructed users, skilled persons or laymen.

In some cases, user training is provided. When provided, this is considered to be a part of the information for use. Providing user training is not mandatory. For some products, mainly in the professional area, user training is commonly applied. This user training should be seen as

additional information that helps to describe the intended use of the product in addition to the information or instructions in the user manual.

2.3 Other expected use

2.3.1 Explanatory information

Next to the intended use as described in the information provided by the manufacturer, there can be additional uses that cannot be regarded as misuse.

In addition, some areas or industries may use a slightly different term for a part of this use. In the medical area for example, the term normal use is defined in addition to the term intended use. For medical equipment, the term intended use is reserved for the purpose of intended medical device use only, while normal use includes activities like maintenance as well. See IEC 62366-1 for other specific use terms for medical equipment.

2.4 Reasonably foreseeable use

2.4.1 Use of the term

Different EU Directives and Regulations use this term in slightly different ways, and use different terminologies, which is confusing for the reader and makes it hard to have a common understanding of the term. Some of the terms found in the legislative documents are:

- conditions of use which can be reasonably foreseen,
- reasonably foreseeable conditions,
- reasonably foreseeable conditions of use,
- foreseeable by the manufacturer as representative of normal use in the intended applications,
- realistic assumptions about normal conditions and purposes of use.

In this document it is assumed that the meaning of these terms are all similar and for a harmonized view the term 'reasonably foreseeable use' has been chosen.

2.4.2 Common understanding

Reasonably foreseeable use always includes the intended use (see 2.2) and the other expected use (see 2.3). Depending on the area and the applicable regulation, it may or may not also include reasonably foreseeable misuse (see 2.6).

Whether reasonably foreseeable use should or should not include reasonably foreseeable misuse in a certain standard is a decision of the responsible standards committee, taking into account the relevant EU Directives and Regulations for the standard.

2.4.3 Explanatory information

There are several terms used by standards and regulations as if they were equivalent, but they all have a slightly different meaning (for example, reasonably foreseeable use, reasonably foreseeable conditions, conditions of reasonably foreseeable use).

When the term reasonably foreseeable use is used, more focus seems to be given to the foreseeable ways the product is used by the user. When the term reasonably foreseeable (use) condition is used, more focus is given to the external conditions in which the product can be used. In this document, the term reasonably foreseeable use is intended to cover both of the above meanings. Usually, the manufacturer will define parameters, probably including limit values, that can be used to describe reasonably foreseeable use, but the manufacturer is maybe not in a position to set, configure or check the parameters for a specific situation when a product is used. The resulting use conditions can include, for example:

- use of the product under environmental conditions that are outside the manufacturer's influence, for example defined by temperature and humidity, or even the knowledge of the user;
- use of the product inside or outside its intended purpose, provided that it could reasonably be foreseen.

It is up to the individual technical committees to decide which of these conditions should be considered, if any, depending on the product scope and the intended use of the products. Depending on the product under consideration, elements such as the environmental conditions, system installation parameters and technical circumstances can also need to be assessed to determine the reasonably foreseeable use (conditions).

The assessment whether a specific use can be considered as reasonably foreseeable use should take into account the behavior of all types of users, including vulnerable persons. It can also depend on the persons that are expected or allowed to use the product (for example, professional versus ordinary person using the product).

2.5 Misuse

2.5.1 Common understanding

Use of a product which is NOT in accordance with the information for use provided by the manufacturer and outside the normally expected use of the product.

NOTE Misuse is either reasonably foreseeable misuse (see 2.6) or other misuse such as intentional abuse (see 2.7).

2.5.2 Explanatory information

Misuse is any use of the product in a way that is not intended by the manufacturer or which is unlawful. Misuse can either be intentional or unintentional.

2.6 Reasonably foreseeable misuse

2.6.1 Common understanding

Use of a product which is not in accordance with the information for use provided by the manufacturer, but which could be known or anticipated based on common knowledge of the product and conditions of use that could result from lawful and readily predictable human behavior.

Whether reasonably foreseeable misuse should be taken into account in a certain standard, is a decision of the responsible standards committee, taking into account the relevant EU Directives and Regulations for the standard.

2.6.2 Explanatory information

Reasonably foreseeable misuse can also be determined as the use of a product in a way not intended by the manufacturer, but which is the result of the use in good faith. Reasonably foreseeable misuse can either be intentional or unintentional, but the user does not have the intention to use the product in an unlawful manner.

To determine reasonably foreseeable misuse conditions, standards writers should take into account experience acquired through the past use of the same or a similar type of product, accident information and knowledge about common human behaviour.

The assessment whether a specific use can be considered as reasonably foreseeable misuse should also take into account the type of users, for example, ordinary persons, instructed persons, skilled persons, layman and professional users.

2.7 Other misuse (Abuse)

2.7.1 Common understanding

Use of a product in a way that the manufacturer could not reasonably know or anticipate or in a way where the user is fully aware that it is unlawful.

NOTE A similar type of misuse is defined as abnormal use in IEC 62366-1.

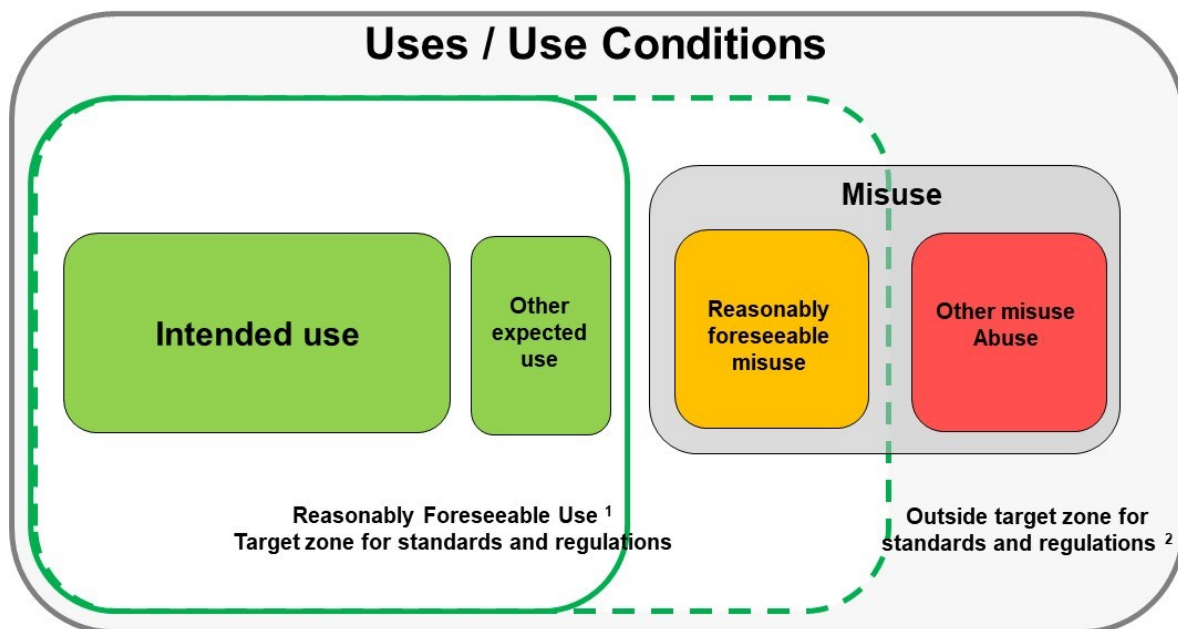
2.7.2 Explanatory information

In contradiction to reasonably foreseeable misuse, this kind of misuse is the use of a product in bad faith. In this case, the user, or any other party, intentionally misuses the product in order to do something beyond reasonable use or in an unlawful manner. These situations are not considered reasonable or lawful and therefore are a clear abuse of the product. With the exception of some areas (for example: security), these use cases do not need to be taken into consideration by standardizers or by the manufacturer when developing a product.

2.8 Graphical overview

Figure 1 provides a graphical overview of the different use conditions. Product requirements should at least cover the normal expected use of a product, which is indicated by a surrounding full green line.

Depending on the applicable EU Directives and Regulations, product standard writers can be required to go beyond 'intended' and address other uses (for example, reasonably foreseeable misuse) or conditions (for example, reasonably foreseeable product or system configurations), which is indicated by the dashed green line.



¹ Depending on the area and the applicable regulation, reasonably foreseeable use conditions may or may not include reasonably foreseeable misuse.

² While abuse is in general outside the target zone for standards and regulations, it should be noted that some specific areas focus on this misuse, such as the area of security.

Figure 1 - Graphical overview on how the different use terms relate to each other