ISO/FDIS 24096-2:2024(E)

Date: 2024-03-21

ISO/TC 10/SC 6/WG 24,

Secretariat: SAC

Date: 2024-05-06

Formatted: English (United States)

Formatted: English (United States)

Technical product documentation (TPD) — Classification of requirements —

Part 2:
Classification based on severity and susceptibility

Documentation technique de produits (TPD) — Classification des exigences —

Partie 2: Classification en fonction de la gravité et de la susceptibilité

FDIS stage

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: + 41 22 749 01 11
E-mail: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Field Code Changed

Contents

Foreword

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

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

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 10, *Technical product documentation*, Subcommittee SC 6, *Mechanical engineering documentation*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/SS F01, *Technical drawings*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 24096 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document addresses the classification of requirements. It provides a framework for building a system to enable the classification of requirements and an indication of the classification in the functional specification, FUN-SPEC, to support communication of the consequences of nonconformity to functional requirements. FUN-SPEC~~,~~ (see ISO/TS 21619~~,~~) is a part of the technical product documentation (TPD). Other approaches than classification of requirements can be state of the art in achieving the objective of securing the end product.

This document has been developed mainly to be implemented within industry, e.g. the automotive and aerospace industries. However, it can also be used in other engineering fields.

Classification of requirements is a tool by which subsequent parties and stakeholders can be informed of the severity of consequences of nonconformity of requirements. This facilitates the guiding of production and quality assurance resources~~,~~ (e.g. purchasing, production planning, control ~~and,~~ revision~~.~~). The classification system relies on established procedures, regulatory framework and contractual agreements for implementation and follow up as present in all modern industry.

There are several examples of industrial stakeholders that deploy their own or partially self-developed system and methodology for classification of requirements. There has previously not been any ISO document that pragmatically describes "what is" and "how to create" a classification system. This series bridges the identified gap~~,~~ and meets the ~~needs~~need to describe how to introduce and work with a classification system in an industrial and design context.

Knowledge of the consequences of nonconformity with requirements, and actions taken to resolve the source of the deviation from the given requirements, will have a positive effect on product quality, user safety and economy of the product. Production and inspection resources can then be used where they are most needed.

Annex A gives classification examples with severity and susceptibility.

Annex B gives guidance on susceptibility.

Technical product documentation (TPD) — Classification of requirements —

Part 2:
Classification based on severity and susceptibility

1 Scope

This document ~~gives guidance on~~specifies a method for the classification of requirements based on severity and susceptibility. The classification method requires a system in line with the framework described in ISO 24096-1 to form a complete system.

This document:

— gives guidance on the needed elements for a consistent evaluation of the severity over time, and supports a company business model and its brand image;

— gives background to why additional parameters alongside severity are useful as a base for classification;

— adds susceptibility as a viable parameter along with severity;

— gives guidance on the methodology for classification requirements using severity and susceptibility.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8015:2011, *Geometrical product specifications (GPS) — Fundamentals — Concepts, principles and rules*

ISO 10209, *Technical product documentation — Vocabulary — Terms relating to technical drawings, product definition and related documentation*

ISO 24096-1[1)], *Technical product documentation (TPD) — Classification of requirements – Part 1: Framework*

~~ISO 41014:2020, *Facility management — Development of a facility management strategy*~~

~~IEC 60812:2018, *Failure modes and effects analysis (FMEA and FMECA)*~~

43 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8015:2011, ISO 10209, ISO 24096-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

1) Under development.

3.1
susceptibility
degree to which a function is affected by nonconformity of a requirement

Note 1 to entry: While a high susceptibility gives a large effect, a low susceptibility gives a lower effect for the same deviation, see Figures B.1 and B.2.

3.2
severity list
normative assessments of severity within each company or organization

~~5~~4 Basic rules

Severity of a potential consequence at nonconformity shall be used as a parameter when classifying requirements. However, equating classification with severity can lead to an overload of classification indications in the TPD. A classification must therefore encompass more than the severity. In this document, susceptibility to deviation is used in addition to severity to balance classification, see Clause 5 and Annex A.

All requirements in the product documentation shall be fulfilled in accordance with ISO 8015:2011, 4.3 and 4.4.

NOTE 1 The classification can be compared with risk assessment where risk is evaluated by combining severity and probability, see Figure 1 and ISO 12100:2010, 5.5.2.1.

Severity is the gravity of possible consequence of nonconformity.

NOTE 2 Severity is defined in ISO 24096-1:—, 3.4.

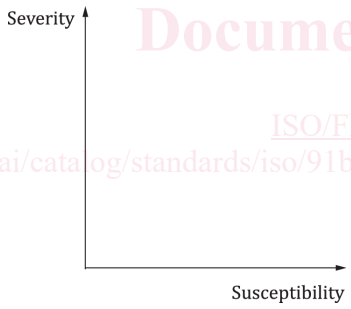


Figure 1 — Example of a template diagram for classification evaluation

Severity of nonconformity with a requirement and susceptibility to deviation are mandatory parameters in a classification system to be assessed in the classification of a requirement.

Due to the variety of already existing solutions, this document is ~~a~~ supporting material which can ~~support~~help individual organizations when deciding on their own classification system and how to use it in the TPD. It is possible to use an already existing system, develop a new one~~,~~ or modify an existing one. Referencing this document in the TPD creates awareness that a classification system for the consequences of nonconformity has been used, and that the classification system used has been developed following the rules and information laid out in this document. The details of the classification itself and the symbology to indicate the classes, however, are not given in this document but in the organization-specific system which shall be referenced in the TPD. In this way, it is possible to use any of the already existing explicit solutions or develop a new one, maybe by modifying an existing one.

~~6~~5 Classification with severity and susceptibility

~~6.1~~5.1 The three steps

~~6.1.1~~5.1.1 General

Classification with severity and susceptibility is made in three main steps. Severity and susceptibility are treated as separate parameters which together determine the final classification of requirements.

The three steps are described in 5.1.2 to 5.1.4 and aspects of them are described in detail in 5.2 to 5.4.

~~6.1.2~~5.1.2 Evaluation of severity

By starting with severity, a screening is achieved. First, it reduces the relevant number of components that can have requirements worthy of classification higher than baseline, see ISO 41014:2020, 3.5.1. Second, it reduces the number of requirements on which the susceptibility needs to be evaluated. Evaluation and grading of the severity should use a severity list for consistency.

In step 1, the evaluation of severity consists of answering three questions:

— 1.1 What are the functions of the design solution?

  — Describe, in detail, what it shall do. List all functions.

— 1.2 What are the effects on the product and for the customer in case of a function deviation?

  — List the effects of function deviation. Remember to include all side effects.

— 1.3 What type of severity heading is each effect associated with?

  — Match each effect to its relevant severity rating. The highest recommended rating is found in the severity list.

This is a bottom-up approach to determine severity, see Annex A for two applied examples.

NOTE When the severity is determined with a top-down analysis, it modifies the analysis to a degree. If the top-down analysis is performed correctly, it identifies the maximum severity for the analysed component. The classification ~~should~~does not still ~~not~~ continue directly at step 2 since different deviations can give different severity and be linked to different requirements.

~~6.1.3~~5.1.3 Evaluation of susceptibility

In step 2, the evaluation of susceptibility consists of answering two questions:

— 2.1 Which requirements affect the function at a nonconformity (most)?

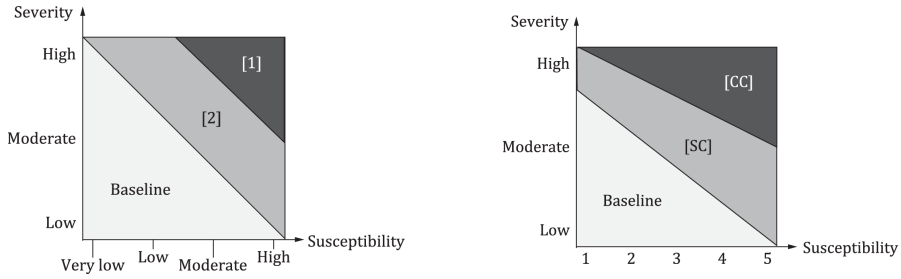
  — List (the most influential) requirements to affect the function.

— 2.2 How closely outside the requirements will the function start to deteriorate?

  — Evaluate the susceptibility of each listed requirement.

~~6.1.4~~5.1.4 Weighing severity and susceptibility together

In step 3, the results from step 1 and step 2 are combined. The combination of severity and susceptibility yields the classification for each requirement. A simple diagram, as exemplified in Figure 2, can be used.



a) Uniform distribution of severity – susceptibility relation

b) Non-uniform distribution of severity – susceptibility relation

Key

[CC] critical characteristics

[SC] significant characteristics

NOTE [1], [2~~], Baseline~~] and baseline, and [SC], [CC~~], Baseline~~] and baseline are classes used in two different example systems.

Figure 2 — Examples of diagrams weighing severity and susceptibility together for final classification

~~6.2~~5.2 Severity and severity lists

~~6.2.1~~5.2.1 General

Severity is the first parameter to assess. To assess it, a firm understanding of the function of the design is required. To get a consistent assessment of severity, a normative table is needed: this is called the "severity list". This should be a list of affected areas with its maximum potential severity rating. This reduces the risk for arbitrary and personal views and assessments. The grading of the severity preferably has the same number of steps as the final classification for easy evaluation. The severity list is built up in two steps, see 5.2.2 and 5.2.3.

~~6.2.2~~5.2.2 Severity description

Step 1.1 is determining how different effects are viewed, see Table 1.

Table 1 — Example of severity description in three levels

Level	Description
High severity level	At nonconformity to requirements, there is a risk for function deviation resulting in: — personal injury; — considerable damage which can cause unpredictable and unforeseeable stop and inability to complete intended task; — financial damage; — environmental impact.
Moderate severity level	At nonconformity to requirements, there is a risk for function deviation resulting in: — loss of product function;

Level	Description
	— inability to continue production; — necessity of immediate repair.
Normal severity level (Baseline)	At nonconformity to requirements, there is no risk for the effects listed above. Little or no effect on important characteristics for the customer.

~~6.2.3~~5.2.3 Severity list

Step 1.2 is determining which effects different areas can have and the severity level to which each effect correlates. Starting with a coarse survey to identify the main parameters, see Table 2, is often useful.

Table 2 — Example of a severity list

Important customer requirement and/or product requirements	Severity
Safety effect	High severity level
Financial effect	High severity level
Environmental effect	High severity level
Comfort effect	Moderate severity level
Company or product image	High severity level

The severity list is a breakdown evaluation of customer demands, development targets, product requirements, and organization business model and philosophy.

The severity list contains the highest recommended classification for a failure effect. The severity lists can be unique for each product section and should reflect the organization business model, including aspects as image, model for profitability and customers' expectations.

The severity lists may need to be company internal documents (confidential) as they reflect business trade-offs, strategies and considerations.

~~6.3~~5.3 Function as the route to severity

~~6.3.1~~5.3.1 Function description

The function description shall express what the design "does", not what it "is". By clarifying all functions, they can all be evaluated and secured. This constitutes step 1.1 in 5.1.2.

~~6.3.2~~5.3.2 Effects of deviating functions

Based on the function description, the effects of deviating or failing functions can be deduced and described. This corresponds to the sum of all failure effects for the classified item in a design failure mode and effects analysis (FMEA), see IEC 60812:2018. It is important to find all the ultimate effects everywhere to ensure that the worst effects are always detected even when they affect other systems or cause a chain of events. This constitutes step 1.2.

~~6.3.3~~5.3.3 Final severity

The described effect can be associated to different categories or headings in appropriate severity list. This gives the final severity. This constitutes step 1.3.