TECHNICAL REPORT

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Safety of machinery - Relationship with ISO 12100 - Part 1: How ISO 12100 relates to type-B and type-C standards (ISO/TR 22100-1:2015)

Sécurité des machines - Relation avec l'ISO 12100 - Partie 1: Relation entre l'ISO 12100 et les normes de type B et type C (ISO/TR 22100-1:2015)

This Technical Report was approved by CEN on 27 June 2017. It has been drawn up by the Technical Committee CEN/TC 114.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (CEN ISO/TR 22100-1:2017) has been prepared by Technical Committee ISO/TC 199 "Safety of machinery" in collaboration with Technical Committee CEN/TC 114 “Safety of machinery” the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Report: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/TR 22100-1:2015 has been approved by CEN as CEN ISO/TR 22100-1:2017 without any modification.

Annex ZA
(informative)

Relation of this document to the Machinery Directive 2006/42/EC

ZA.1 General

CEN ISO/TR 22100-1 (identical to ISO/TR 22100-1:2015) provides for the first time a transparent guideline how to choose the appropriate machinery safety standard(s) representing the state of the art and to apply it/them correctly in order to achieve at a given time a level of tolerable risk by adequate risk reduction for an actual machine. In this document, the term tolerable risk should be read as residual risk as defined in ISO 12100-1 to be compliant with European Union (EU) legislation.

NOTE While the residual risk is defined as the risk remaining after risk reduction measures have been implemented (see ISO/IEC Guide 51:2014, 3.8), tolerable risk is the level of risk that is accepted in a given context based on the current values of society (see 3.2). It is generally accepted that the residual risk is equal or lower than the tolerable risk.

Compared to the international level (where no common legal framework for machinery safety exists) at the European Union (EU) machinery safety standards are developed by CEN and CENELEC within the legal framework of the *New Approach (New Legislative Framework)*[1)] to provide presumption of conformity with relevant Essential Requirements of the *EU Machinery Directive 2006/42/EC*[2)].

Those standards are harmonized and provide presumption of conformity to 2006/42/EC when cited in the *Official Journal of the EU*[3)].

ZA.2 Special relevance of this document for harmonized standards (type-C) providing presumption of conformity

The methodology as specified in Clause 6 of this document provides detailed guidance for the machine manufacturer how to choose and evaluate harmonised standards (type-C) in order to achieve presumption of conformity with Essential Requirements of 2006/42/EC for his actual machine in accordance with the following statement given in §111 of the Guide to the application of the Machinery Directive 2006/42/EC:

"Application of the specifications of a C-type standard confers a presumption of conformity with the essential health and safety requirements of the Machinery Directive covered by the standard provided the manufacturer has determined in his risk assessment that the scope and the significant hazards covered by the standard correspond with his actual machinery. Further practical guidance is provided by ISO/TR 22100-1:2015."

1) Further information to the New Approach (New Legislative Framework) are provided in the Blue Guide: http://ec.europa.eu/DocsRoom/documents/18027

2) http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32006L0042

3) Example for a citation of Harmonized Standards to 2006/42/EC see http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv:OJ.C_.2016.173.01.0001.01.DEU&toc=OJ:C:2016:173:TOC

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Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 199, Safety *of machinery*.

ISO/TR 22100 consists of the following parts, under the general title *Safety of machinery — Relationship with ISO 12100*:

— *Part 1: How ISO 12100 relates to type-B and type-C standards*

— *Part 2: How ISO 12100 relates to ISO 13849-1*

The following parts are under preparation:

— *Part 3: Implementation of ergonomic principles in safety standards*

Introduction

This Technical Report is written to assist the designer/manufacturer of machinery and related components in understanding and navigating the different types of ISO machinery safety standards. It identifies the different kinds of documents in ISO (see Table B.1) and explains the type-A, type-B and type-C structure of machinery safety standards and their interrelationship with regard to the practical design of machinery subjected to adequate risk reduction to achieve tolerable risk.

This part of ISO/TR 22100 might be helpful for standard writing committees (type-B and type-C), too. However, it does not provide specification of the general content that is expected to be included in the different types of machinery safety standards. This specification is given in ISO Guide 78.

This part of ISO/TR 22100 includes a visual representation of many ISO machinery safety standards to assist in improving understanding of the interrelationships and linkages between these documents.