

PÕLLU- JA METSAMAJANDUSE TRAKTORID JA MASINAD.  
OHUTUSEGA SEOTUD JUHTIMISSÜSTEEMIDE OSAD. OSA  
4: TOOTMINE, KÄITAMINE, MODIFITSEERIMINE JA  
TUGITEENUSED

Tractors and machinery for agriculture and forestry -  
Safety-related parts of control systems - Part 4:  
Production, operation, modification and supporting  
processes (ISO 25119-4:2018)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 25119-4:2018 sisaldab Euroopa standardi EN ISO 25119-4:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 25119-4:2018 consists of the English text of the European standard EN ISO 25119-4:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.12.2018.	Date of Availability of the European standard is 19.12.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile [standardiosakond@evs.ee](mailto:standardiosakond@evs.ee).

ICS 35.240.99, 65.060.01

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:  
Koduleht [www.evs.ee](http://www.evs.ee); telefon 605 5050; e-post [info@evs.ee](mailto:info@evs.ee)

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage [www.evs.ee](http://www.evs.ee); phone +372 605 5050; e-mail [info@evs.ee](mailto:info@evs.ee)

English Version

Tractors and machinery for agriculture and forestry -  
Safety-related parts of control systems - Part 4:  
Production, operation, modification and supporting  
processes (ISO 25119-4:2018)

Tracteurs et matériels agricoles et forestiers - Parties  
des systèmes de commande relatives à la sécurité -  
Partie 4: Procédés de production, de fonctionnement,  
de modification et d'entretien (ISO 25119-4:2018)

Traktoren und Maschinen für die Land- und  
Forstwirtschaft - Sicherheitsbezogene Teile von  
Steuerungen - Teil 4: Fertigung, Betrieb, Modifikation  
und unterstützende Prozesse (ISO 25119-4:2018)

This European Standard was approved by CEN on 15 October 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

## European foreword

This document (EN ISO 25119-4:2018) has been prepared by Technical Committee ISO/TC 23 "Tractors and machinery for agriculture and forestry" in collaboration with Technical Committee CEN/TC 144 "Tractors and machinery for agriculture and forestry" the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2019, and conflicting national standards shall be withdrawn at the latest by June 2019.

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 supersedes EN 16590-4:2014.

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(s).

For the relationship with EU Directive(s) 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 implement this European Standard: 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 25119-4:2018 has been approved by CEN as EN ISO 25119-4:2018 without any modification.

## Annex ZA (informative)

### Relationship between this European Standard and the essential requirements of EU Machinery Directive 2006/42/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/396 to provide one voluntary means of conforming to essential requirements of the Directive 2006/42/EC on Machinery.

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirement of that Directive, and associated EFTA regulations.

**Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC**

Essential requirements of EU Machinery Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
Annex I, 1.2.1	All normative clauses and sub-clauses	Compliance with the requirements of EN ISO 25119-1:2018, EN ISO 25119-2:2018, EN ISO 2519-3:2018 and EN ISO 25119-4:2018 is required to achieve conformity with essential requirement 1.2.1, paragraph 1, of Directive 2006/42/EC within the limits of the scope of these standards.

**WARNING 1** — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2** — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

# Contents

Page

<b>Foreword</b>	<b>v</b>
<b>Introduction</b>	<b>vi</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>2</b>
<b>3 Terms and definitions</b>	<b>2</b>
<b>4 Abbreviated terms</b>	<b>2</b>
<b>5 Quality management system</b>	<b>3</b>
<b>6 Safety validation and verification</b>	<b>3</b>
6.1 Objectives	3
6.2 General	3
6.3 Prerequisites	3
6.4 Requirements	4
6.4.1 SRP/CS design validation and verification	4
6.4.2 Scope of safety validation and verification	4
6.4.3 Activities	4
6.4.4 Validation and verification plan	4
6.4.5 Validation and verification test specification	5
6.5 Work products	5
<b>7 Configuration management</b>	<b>5</b>
7.1 Objectives	5
7.2 Prerequisites	5
7.3 Requirements	5
7.4 Work products	6
<b>8 Product release</b>	<b>6</b>
8.1 Objectives	6
8.2 General	6
8.3 Prerequisites	7
8.4 Requirements	7
8.4.1 Conditions for product release	7
8.4.2 Documentation of product release	7
8.5 Work products	7
<b>9 Production planning, production and production testing</b>	<b>7</b>
9.1 Objectives	7
9.2 General	7
9.3 Prerequisites	8
9.4 Requirements	8
9.4.1 Production plan	8
9.4.2 Production test plan	8
9.4.3 Personnel	8
9.4.4 Process capability	8
9.4.5 Documentation	8
9.4.6 Non-compliance	8
9.4.7 Storage and transport conditions	9
9.5 Work products	9
<b>10 Operation planning and maintenance (instructions for operating, servicing, repair and decommissioning)</b>	<b>9</b>
10.1 Objectives	9
10.2 General	9
10.3 Prerequisites	9
10.4 Requirements	9

10.4.1	General	9
10.4.2	Servicing schedule	9
10.4.3	Repair instructions	10
10.4.4	Service technician instructions	10
10.4.5	User information	10
10.4.6	Field observation	10
10.4.7	Storage and transport information	10
10.4.8	Decommissioning and disassembling	10
10.5	Work products	11
<b>11</b>	<b>Modifications (change management)</b>	<b>11</b>
11.1	Objective	11
11.2	General	11
11.3	Prerequisites	11
11.4	Requirements	11
11.4.1	Product modification and improvement procedures	11
11.4.2	Modification request	13
11.4.3	Assessing impact of modification	14
11.4.4	Modification authorization	14
11.5	Work products	14
<b>12</b>	<b>Procedure for suppliers of SRP/CS, subsystems and components</b>	<b>15</b>
12.1	Objectives	15
12.2	General	15
12.3	Prerequisites	15
12.4	Requirements	15
12.4.1	General	15
12.4.2	Scope of requirements	15
12.4.3	Supplier selection	16
12.4.4	Project initiation	16
12.4.5	Project planning	16
12.4.6	Project execution	16
12.4.7	Confirmation measures for the development partners' functional safety	17
12.4.8	System validation	17
12.5	Work products	17
<b>13</b>	<b>Technical documentation</b>	<b>17</b>
13.1	Objectives	17
13.2	Requirements	17
13.2.1	Document retention	17
13.2.2	Document structure	17
<b>Annex A (informative) Technical documentation checklist</b>		<b>19</b>
<b>Bibliography</b>		<b>22</b>

## 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](http://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](http://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 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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 23, *Tractors and machinery for agriculture and forestry*, Subcommittee SC 19, *Agricultural electronics*.

This second edition cancels and replaces the first edition (ISO 25119-4:2010), which has been technically revised. The main changes compared to the previous edition are as follows:

- the introduction has been modified to add specific information on safety standards;
- the scope has been slightly modified;
- and a new Clause 5 (quality management system) has been added;
- the former Clause 5 (configuration management) has been moved after Clause 6;
- Clause 6 has been revised;
- the example of technical documentation checklist has been modified;
- the document has been editorially revised.

A list of all parts in the ISO 25119 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](http://www.iso.org/members.html).



## Introduction

ISO 25119 (all parts) sets out an approach to the assessment, design and verification, for all safety life cycle activities, of safety-related parts comprising electrical and/or electronic and/or programmable electronic systems (E/E/PES) on tractors used in agriculture and forestry, and on self-propelled ride-on machines and mounted, semi-mounted and trailed machines used in agriculture. It is also applicable to mobile municipal equipment.

A prerequisite to the application of ISO 25119 (all parts) is the completion of a suitable hazard identification and risk analysis (e.g. ISO 12100) for the entire machine. As a result, an E/E/PES is frequently assigned to provide safety-related functions that create safety-related parts of control systems (SRP/CS). These can consist of hardware or software, can be separate or integrated parts of a control system, and can either perform solely safety-related functions or form part of an operational function.

In general, the designer (and to some extent, the user) will combine the design and validation of these SRP/CS as part of the risk assessment. The objective is to reduce the risk associated with a given hazard (or hazardous situation) under all conditions of use of the machine. This can be achieved by applying various measures (both SRP/CS and non-SRP/CS) with the end result of achieving a safe condition.

ISO 25119 (all parts) allocates the ability of safety-related parts to perform a safety-related function under foreseeable conditions into five performance levels. The performance level of a controlled channel depends on several factors, including system structure (category), the extent of fault detection mechanisms (diagnostic coverage), the reliability of components (mean time to dangerous failure, common-cause failure), design processes, operating stress, environmental conditions and operation procedures. Three types of failures that can cause E/E/PES malfunctions leading to potential hazardous situations are considered: systematic, common-cause and random.

In order to guide the designer during design, verification, and to facilitate the assessment of the achieved performance level, ISO 25119 (all parts) defines an approach based on a classification of architecture with different design features and specific behaviour in case of a fault.

The performance levels and categories can be applied to the control systems of all kinds of mobile machines: from simple systems (e.g. auxiliary valves) to complex systems (e.g. steer by wire), as well as to the control systems of protective equipment (e.g. interlocking devices, pressure sensitive devices).

ISO 25119 (all parts) adopts a risk-based approach for the determination of the risks, while providing a means of specifying the required performance level for the safety-related functions to be implemented by E/E/PES safety-related channels. It gives requirements for the whole safety life cycle of E/E/PES (design, validation, production, operation, maintenance, decommissioning), necessary for achieving the required functional safety for E/E/PES that are linked to the performance levels.

The structure of safety standards in the field of machinery is as follows.

- a) Type-A standards (basic safety standards) give basic concepts, principles for design and general aspects that can be applied to machinery.
- b) Type-B standards (generic safety standards) deal with one or more safety aspect(s), or one or more type(s) of safeguards that can be used across a wide range of machinery:
  - type-B1 standards on particular safety aspects (e.g. safety distances, surface temperature, noise);
  - type-B2 standards on safeguards (e.g. two-hand controls, interlocking devices, pressure sensitive devices, guards).
- c) Type-C standards (machinery safety standards) deal with detailed safety requirements for a particular machine or group of machines.

This document is a type-B1 standard as stated in ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

- machine manufacturers (small, medium and large enterprises);
- health and safety bodies (regulators, accident prevention organizations, market surveillance, etc.).

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

- machine users/employers (small, medium and large enterprises);
- machine users/employees (e.g. trade unions, organizations for people with special needs);
- service providers, e.g. for maintenance (small, medium and large enterprises);
- consumers (in case of machinery intended for use by consumers).

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

In addition, this document is intended for standardization bodies elaborating type-C standards.

The requirements of this document can be supplemented or modified by a type-C standard.

For machines which are covered by the scope of a type-C standard and which have been designed and built according to the requirements of that standard, the requirements of that type-C standard take precedence.

# Tractors and machinery for agriculture and forestry — Safety-related parts of control systems —

## Part 4: Production, operation, modification and supporting processes

### 1 Scope

This document sets out general principles for the design and development of safety-related parts of control systems (SRP/CS) on tractors used in agriculture and forestry and on self-propelled ride-on machines and mounted, semi-mounted and trailed machines used in agriculture. It can also be applied to mobile municipal equipment (e.g. street-sweeping machines).

This document is not applicable to:

- aircraft and air-cushion vehicles used in agriculture;
- lawn and garden equipment.

This document specifies the characteristics and categories required of SRP/CS for carrying out their safety-related functions. It does not identify performance levels for specific applications.

NOTE 1 Machine specific type-C standards can specify performance levels (AgPL) for safety-related functions in machines within their scope. Otherwise, the specification of AgPL is the responsibility of the manufacturer.

This document is applicable to the safety-related parts of electrical/electronic/programmable electronic systems (E/E/PES), as these relate to mechatronic systems. It covers the possible hazards caused by malfunctioning behaviour of E/E/PES safety-related systems, including interaction of these systems. It does not address hazards related to electric shock, fire, smoke, heat, radiation, toxicity, flammability, reactivity, corrosion, release of energy, and similar hazards, unless directly caused by malfunctioning behaviour of E/E/PES safety-related systems. It also covers malfunctioning behaviour of E/E/PES safety-related systems involved in protective measures, safeguards, or safety-related functions in response to non-E/E/PES hazards.

Examples included within the scope of this document:

- SRP/CS limiting current flow in electric hybrids to prevent insulation failure/shock hazards;
- electromagnetic interference with the SRP/CS;
- SRP/CS designed to prevent fire.

Examples not included in the scope of this document:

- insulation failure due to friction that leads to electric shock hazards;
- nominal electromagnetic radiation impacting nearby machine control systems;
- corrosion causing electric cables to overheat.

This document is not applicable to non-E/E/PES systems (e.g. hydraulic, mechanic or pneumatic).

NOTE 2 See also ISO 12100 for design principles related to the safety of machinery.