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Road vehicles — Functional safety —

Part 7: Production and operation

Véhicules routiers — Sécurité fonctionnelle —

Partie 7: Production et utilisation

ICS 43.040.10

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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.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 26262-7 was prepared by Technical Committee ISO/TC 22, *Road vehicles*, Subcommittee SC 3, *Electrical and electronic equipment*.

ISO 26262 consists of the following parts, under the general title *Road vehicles — Functional safety*:

- *Part 1: Vocabulary*
- *Part 2: Management of functional safety*
- *Part 3: Concept phase*
- *Part 4: Product development: system level*
- *Part 5: Product development: hardware level*
- *Part 6: Product development: software level*
- *Part 7: Production and operation*
- *Part 8: Supporting processes*
- *Part 9: ASIL-oriented and safety-oriented analyses*
- *Part 10: Guideline on ISO 26262*

Introduction

ISO 26262 is the adaptation of IEC 61508 to comply with needs specific to the application sector of E/E systems within road vehicles.

This adaptation applies to all activities during the safety lifecycle of safety-related systems comprised of electrical, electronic, and software elements that provide safety-related functions.

Safety is one of the key issues of future automobile development. New functionality not only in the area of driver assistance but also in vehicle dynamics control and active and passive safety systems increasingly touches the domain of safety engineering. Future development and integration of these functionalities will even strengthen the need of safe system development processes and the possibility to provide evidence that all reasonable safety objectives are satisfied.

With the trend of increasing complexity, software content and mechatronic implementation, there are increasing risks from systematic failures and random hardware failures. ISO 26262 includes guidance to avoid these risks by providing feasible requirements and processes.

System safety is achieved through a number of safety measures, which are implemented in a variety of technologies (for example: mechanical, hydraulic, pneumatic, electrical, electronic, programmable electronic etc). Although ISO 26262 is concerned with E/E systems, it provides a framework within which safety-related systems based on other technologies can be considered.

ISO 26262:

- provides an automotive safety lifecycle (management, development, production, operation, service, decommissioning) and supports tailoring the necessary activities during these lifecycle phases;
- provides an automotive specific risk-based approach for determining risk classes (Automotive Safety Integrity Levels, ASILs);
- uses ASILs for specifying the item's necessary safety requirements for achieving an acceptable residual risk; and
- provides requirements for validation and confirmation measures to ensure a sufficient and acceptable level of safety being achieved.

Functional safety is influenced by the development process (including such activities as requirements specification, design, implementation, integration, verification, validation and configuration), the production and service processes and by the management processes.

Safety issues are intertwined with common function-oriented and quality-oriented development activities and work products. ISO 26262 addresses the safety-related aspects of the development activities and work products.

Figure 1 shows the overall structure of ISO 26262. ISO 26262 is based upon a V-Model as a reference process model for the different phases of product development. The shaded "V"s represents the relations between ISO 26262-3, ISO 26262-4, ISO 26262-5, ISO 26262-6 and ISO 26262-7.

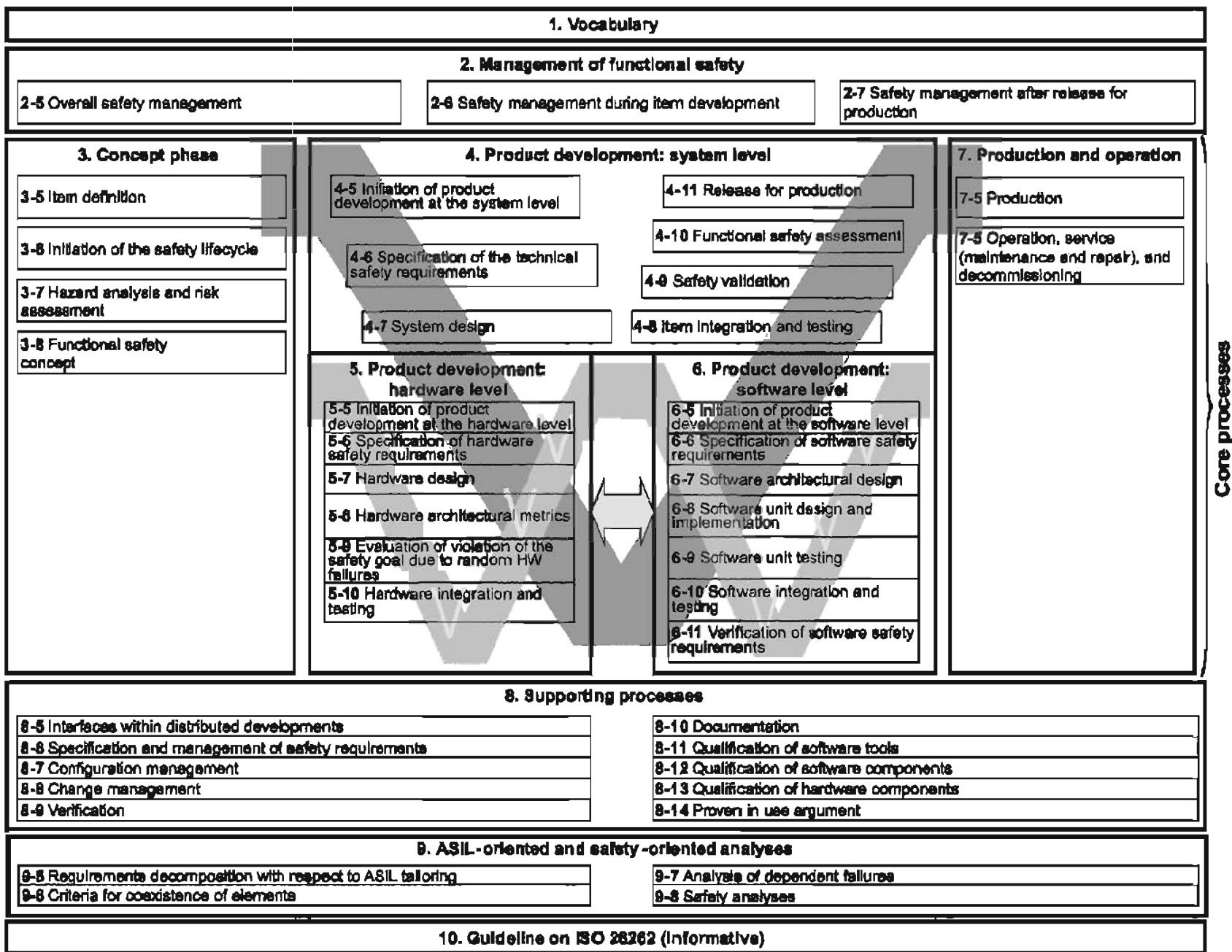


Figure 1 — Overview of ISO 26262

Road vehicles — Functional safety — Part 7: Production and operation

1 Scope

ISO 26262 is intended to be applied to safety-related systems that include one or more E/E systems and that are installed in series production passenger cars with a max gross weight up to 3,5 t. ISO 26262 does not address unique E/E systems in special purpose vehicles such as vehicles designed for drivers with disabilities. Systems developed prior to the publication date of ISO 26262 are exempted from the scope.

ISO 26262 addresses possible hazards caused by malfunctioning behaviour of E/E safety-related systems including interaction of these systems. It does not address hazards as 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 safety-related systems.

ISO 26262 does not address the nominal performance of E/E systems, even if dedicated functional performance standards exist for these systems (for example active and passive safety systems, brake systems, ACC).

This part of the International Standard specifies the requirements on production as well as operation, service and decommissioning.

2 Normative references

The following referenced documents are indispensable for the application 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 26262-1: —¹ *Road vehicles – Functional Safety — Part 1: Vocabulary*

ISO 26262-2: —¹ *Road vehicles – Functional Safety — Part 2: Management of functional safety*

ISO 26262-3: —¹ *Road vehicles – Functional Safety — Part 3: Concept phase*

ISO 26262-4: —¹ *Road vehicles – Functional Safety — Part 4: Product development: system level*

ISO 26262-5: —¹ *Road vehicles – Functional Safety — Part 5: Product development: hardware level*

ISO 26262-6: —¹ *Road vehicles – Functional Safety — Part 6: Product development: software level*

ISO 26262-8: —¹ *Road vehicles – Functional Safety — Part 8: Supporting processes*

ISO 26262-9: —¹ *Road vehicles – Functional Safety — Part 9: ASIL-oriented and safety-oriented analyses*

¹ To be published

3 Terms, definitions, abbreviated terms

For the purposes of this document, the terms, definitions and abbreviated terms given in ISO 26262-1 apply.

4 Requirements for compliance

4.1 General requirements

When claiming compliance with ISO 26262, each requirement shall be complied with, unless one of the following applies:

- 1) Tailoring in accordance with ISO 26262-2 has been planned and shows that the requirement does not apply.
- 2) A rationale is available that the non-compliance is acceptable and the rationale has been assessed in accordance with ISO 26262-2.

Information marked as a "NOTE" is only for guidance in understanding, or for clarification of, the associated requirement and shall not be interpreted as a requirement itself.

4.2 Interpretations of tables

Tables may be normative or informative depending on their context.

The different methods listed in a table contribute to the level of confidence that the corresponding requirement shall apply.

Each method in a table is either a consecutive entry (marked by a sequence number in the leftmost column, e.g. 1, 2, 3) or an alternative entry (marked by a number followed by a letter in leftmost column, e.g., 2a, 2b, 2c).

For consecutive entries all methods are recommended in accordance with the ASIL. If methods other than those listed are to be applied a rationale shall be given that they comply with the corresponding requirement.

For alternative entries an appropriate combination of methods shall be applied in accordance with the ASIL, independently of whether they are listed in the table or not. If methods are listed with different degrees of recommendation for an ASIL the higher one should be preferred. A rationale shall be given that the selected combination of methods complies with the corresponding requirement. If all highly recommended methods listed for a particular ASIL are selected a rationale needs not to be given.

For each method, the degree of recommendation to use the corresponding method depends on the ASIL and is categorized as follows:

"++" The method is highly recommended for this ASIL.

"+" The method is recommended for this ASIL.

"o" The method has no recommendation for or against its usage for this ASIL.

4.3 ASIL dependent requirements and recommendations

The requirements or recommendations of each subclause shall apply to ASIL A, B, C and D, if not stated otherwise. These requirements and recommendations refer to the ASIL of the safety goal. If ASIL decomposition has been performed at an earlier stage of development in accordance with ISO 26262-9—: Clause 5 the ASIL resulting from the decomposition will apply.

If an ASIL is given in parentheses, the corresponding subclause shall be read as a recommendation rather than a requirement for this ASIL.

5 Production

5.1 Objectives

The first objective of the requirements in this Clause is to develop a production plan for safety-related products.

The second objective is to ensure that the required functional safety is achieved during the production process by the relevant product manufacturer or the person or organisation in charge of the process (vehicle manufacturer, supplier, sub-supplier etc.).

5.2 General

It is common for some characteristics of the product or process to be safety-related, i.e. a deviation of these characteristics outside the authorised range during production can adversely affect functional safety. These safety-related conditions, derived from the development phase of the product, are defined as safety-related special characteristics, e.g. temperature range for specific processes, material characteristics, expiration date, fastening torque, production tolerance, and configuration.

By including these safety-related special characteristics in production planning and checking, this phase defines requirements to ensure that functional safety is achieved during the production process as well.

The requirements and recommendations of this clause apply to the production of safety-related elements, systems or the whole item and its installation in the vehicle

5.3 Inputs to this clause

5.3.1 Prerequisites

The following information shall be available:

- requirements for production, operation, service and decommissioning (see ISO 26262-4—: 7.5.3, ISO 26262-5—: 7.5.4)
- specification of dedicated measures for hardware components (see ISO 26262-5—: 9.5.2)
- release for production report (see ISO 26262-4—: 11.5)

5.3.2 Further supporting information

The following information may be considered:

- production plan (from external source)
- production control plan (from external source)

5.4 Requirements and recommendations

5.4.1 Production Planning

5.4.1.1 The production process shall be planned by evaluating the item and considering the following:

- a) The requirements for production

EXAMPLE 1 assembly instructions (e.g. the calibration and setup of a sensor), safety-related special characteristics (e.g. the tolerance for the selection of elements)

- b) the conditions for storage, transport and handling of hardware elements;

EXAMPLE 2 Allowed storage time for the element

- c) the approved configurations defined in the release for production documentation
- d) the lessons on the capability, learnt from previously released production plans
- e) the suitability of the production process, means of production, tools and test equipment concerning the safety-related special characteristics
- f) the competences of the personnel.

5.4.1.2 The production plan shall describe the sequence and methods of the production steps required to achieve the functional safety of the item, systems or elements. It shall include, as applicable:

- a) the production process flow and instructions
- b) the production tools and means,
- c) the implementation of the traceability measures,

EXAMPLE Labelling for the element

- d) the implementation of dedicated measures applying to hardware parts and specified during hardware development

NOTE The production process also includes processes or operations required to rework the item.

5.4.1.3 There shall be a procedure designed to ensure that the correct embedded software and the associated calibration data are loaded into the ECU as part of the production process.

EXAMPLE 1 This verification can be done through the use of a checksum, so that the checksum of the loaded executable and configuration data is compared to the correct checksum for this particular model and vehicle configuration.

EXAMPLE 2 Read back and comparison of the part number from the software loaded into the ECU with target part number or calibration from the bill of material for that specific vehicle; as well as read back and comparison of the loaded calibration data

5.4.1.4 When the production control plan is developed, the controls description and criteria for the item, systems or elements as well as the safety-related special characteristics shall be considered

5.4.1.5 The sequence and methods of the control steps, as well as necessary test equipment, tools and test criteria, shall be described in the production control plan

5.4.1.6 Reasonably foreseeable process failures and their effects on functional safety shall be identified and the appropriate measures shall be implemented to address the findings.

5.4.1.7 The requirements on the producibility at system, hardware or software development level arising during production planning shall be specified and directed to the persons in charge (see ISO°26262-4, ISO°26262-5 and ISO°26262-6). If changes to the product are required during the production process, the change management process described in ISO 26262-8—: Clause 8 shall be applied

5.4.2 Production of samples or pre-production series

5.4.2.1 The production process for samples, or pre-production series, should correspond to the target production process, as well as its control measures.

NOTE Samples or pre-production series are items, systems or elements, produced before release for production.

5.4.2.2 Deviations from the target production process shall be analysed in order to identify which part of the production process can already be assessed and for which part an assessment of the target production will be required.

NOTE If the production of samples equals the target production process the result of assessments (e.g. proof of capability of the production process) can be used when performing the safety assessment.

EXAMPLE Deviations can concern the sequence and methods of the production or control steps, as well as necessary means of production, test equipment, and tools

5.4.3 Production

5.4.3.1 The production process, as well as its control measures, shall be implemented and maintained as planned.

NOTE The appropriate training of the personnel involved in production is part of this implementation.

5.4.3.2 Process failures occurring during production (including deviation of safety-related special characteristics from their authorised range) and their potential effects on functional safety shall be analysed and the appropriate measures shall be taken and monitored.

EXAMPLE Such measures can include performing further control measures, sorting, processing, and exchange of elements.

5.4.3.3 The capability of the production process, means of production, tools and test equipment shall be assessed and maintained.

NOTE The capability of the process can be proven by periodic process audits or periodic qualification measures for each person performing the process steps.

5.4.3.4 The test equipment shall be subject to test equipment monitoring.

5.4.3.5 The execution of controls in accordance with the production control plan shall be documented. The related control documentation shall include the following information: control date, identification of controlled object, and control results. This shall ensure that the safety-related special characteristics of the product meet their specifications in the production process.

NOTE 1 In the case of manually performed controls, the identification of the controlled object and control results are sufficient.

NOTE 2 The controlled object's identification can be a vehicle identification number or a production number for a vehicle-level control measure or a part number or a serial number for a controlled component.

NOTE 3 The control results can consist of either a single status (e.g. pass or fail) or the evaluation of a collection of data against boundary limits.

5.4.3.6 Only approved configurations shall be produced, as defined in release for production documentation

5.4.3.7 If changes to the production process concerning the item, systems or elements are initiated during the production phase, they shall comply with Clause 5.

5.5 Work products

5.5.1 Production plan (refined) resulting from requirements 5.4.1.1, 5.4.1.2, 5.4.1.3, and 5.4.1.6

5.5.2 Production control plan (refined) including test plan, resulting from requirement 5.4.1.4 and 5.4.1.5

5.5.3 Documentation of performed control measures resulting from requirement 5.4.3.5.

5.5.4 If applicable, **requirements on the producibility at system-, hardware or software development level** resulting from requirement 5.4.1.7

5.5.5 Assessment report for capability of the production process, resulting from requirement 5.4.2.2 and 5.4.3.3.

6 Operation, service (maintenance and repair), and decommissioning

6.1 Objectives

The first objective of this Clause is to define the scope of customer information, maintenance and repair instructions regarding the safety-related products in order to maintain the required functional safety during operation of the vehicle.

The second objective of this Clause is to provide the requirements concerning activities addressing safety issues before disassembly.

6.2 General

This Clause provides requirements for developing repair instructions and user information, and the planning, execution and monitoring of the maintenance work, taking into account the safety-related special characteristics of the item.

During decommissioning the phases "before disassembling", "disassembling", and "after disassembling" can be distinguished. This Clause addresses only those activities before disassembling.

6.3 Input to this clause

6.3.1 Prerequisites

The following information shall be available:

- requirements for production, operation, service and decommissioning (see ISO 26262-4:—, 7.5.3, ISO 26262-5:—, 7.5.4);
- release for production report (see ISO 26262-4:—, 11.5);
- warning and degradation concept, included in the functional safety concept (see ISO 26262-3:—, 8.5.1).

6.3.2 Further supporting information

The following information may be considered:

- maintenance plan (from external source)

6.4 Requirements and recommendations

6.4.1 Planning of operation, service (maintenance and repair), and decommissioning

6.4.1.1 The processes concerning operation, repair and maintenance shall be planned by evaluating the item and considering the following:

- a) the requirements for operation;
- b) the warning and degradation concept;
- c) the measures for field data collection and analysis;

NOTE The data collected from field monitoring can be used for proven in use arguments.

- d) the conditions for storage, transport and handling of the hardware elements;

EXAMPLE 1 Allowed storage time for the element

- e) the approved configurations defined in the release for production documentation;

EXAMPLE 2 Allowed configurations of hardware, software and software calibration data during repair

- f) the competence of the personnel involved.

6.4.1.2 The maintenance plan shall describe the sequence and methods of the maintenance steps or activities, maintenance intervals, as well as the necessary means of maintenance and the necessary tools.

6.4.1.3 The maintenance and repair instructions shall describe the following:

- a) the work steps and procedures, diagnostic routines and methods,
- b) the description of maintenance tools and means,

EXAMPLE 1 Programming, sensor calibration/setup and diagnostic equipment

- c) If applicable, a description of the sequence and methods of the control steps and control criteria used to verify the safety-related special characteristics,
- d) the relevant configuration of the product, including the traceability measures,

NOTE This includes features in the maintenance tools used to ensure that the correct version of software is loaded into the vehicle, if such an operation is performed during maintenance.

EXAMPLE 2 Labelling for the element is a means to ensure traceability

- e) the permissible deactivation of item, systems or elements and necessary changes in the vehicle;
- f) the driver information in the case of permissible deactivations and changes; and
- g) the provision of replacement parts through new parts or released replacement parts.

6.4.1.4 The user manual shall include relevant usage instructions and warnings concerning the item, and the following information shall be included:

- a) The relevant functions and operating modes, how to use them in the intended way, status information (warning concept) and user reaction required. This includes the expected actions from the customer in the case of a failure and its associated warning to ensure controllability;

- b) The required maintenance activities and corresponding warning signals in the case of malfunction;
- c) The warnings regarding known hazards resulting from interactions with third party products; and
- d) The warnings regarding safety-related innovative features of the item that could lead to driver's misunderstanding or misuse.

EXAMPLE Innovative feature: automatic park brake when compared to manual park brake

6.4.1.5 The requirements regarding the decommissioning activities shall be developed. They shall describe the measures to be taken before disassembling the vehicle, with emphasis on deactivating the systems, or elements, which would violate a safety goal if activated during disassembly or decommissioning.

EXAMPLE decommissioning of airbags

6.4.1.6 The requirements regarding the operation, repair, maintenance and decommissioning at the system, hardware or software development level arising during the planning of operation, service (maintenance and repair), and decommissioning, shall be specified and directed to the persons in charge (see ISO°26262-4, ISO°26262-5 and ISO°26262-6).

6.4.2 Operation, service (maintenance and repair), and decommissioning

6.4.2.1 The field monitoring process for functional safety events related to the item shall be implemented as planned (see ISO°26262-2—: 7.4.5). The data collected by this process shall be analysed to detect the presence of any safety issues and, if found, actions to address those issues shall be initiated. This process shall be capable of providing the evidence required by the proven in use argument if it is intended to use this argument (see ISO°26262-8—: Clause 14).

6.4.2.2 The maintenance, repair or decommissioning of the item, its systems or its elements should be conducted and documented in accordance with the maintenance plan or the maintenance and repair instructions.

NOTE This includes the application of repair and maintenance procedures and the documentation of this application in paper or electronic form by the performer of these procedures.

6.4.2.3 The supply of parts and their storage and transport conditions shall be implemented as planned.

6.4.2.4 If changes to the item for subsequent production are initiated by operation, field monitoring, maintenance, repair or decommissioning, a change management process in accordance with ISO 26262-8—: Clause 8 shall be applied.

6.5 Work products

6.5.1 Maintenance plan (refined) resulting from requirement 6.4.1.1, 6.4.1.2, 6.4.1.3,

6.5.2 Repair instructions resulting from requirement 6.4.1.3.

6.5.3 User manual resulting from requirement 6.4.1.4.

6.5.4 Instructions regarding field observations resulting from requirement 6.4.2.1.

6.5.5 Instructions for decommissioning resulting from requirement 6.4.1.5.

6.5.6 If applicable, **requirements concerning operation, maintenance and decommissioning at system-, hardware or software development level** resulting from requirement 6.4.1.6

Annex A (informative)

Overview on and document flow of production and operation

This Annex represents a digest of "Production and operation" by Table A.1.

Table A.1 provides an overview on objectives, prerequisites and work products of the particular phases of production and operation.

Table A.1 — Production and operation: overview

Clause	Title	Objectives	Prerequisites	Work products
7-5	Production	<p>The first objective of the requirements in this Clause is to develop a production plan for safety-related products.</p> <p>The second objective is to ensure that the required functional safety is achieved during the production process by the relevant product manufacturer or the person or organisation in charge of the process (vehicle manufacturer, supplier, sub-supplier etc.).</p>	<ul style="list-style-type: none"> — requirements for production, operation, service and decommissioning (see ISO 26262-4, 7.5.3, ISO 26262-5, 7.5.4) — specification of dedicated measures for hardware components (see ISO°26262-5, 9.5.2) — release for production report (see ISO°26262-4, 11.5) 	<p>5.5.1 Production plan (refined) resulting from requirements 5.4.1.1 to 5.4.1.3, and 5.4.1.6</p> <p>5.5.2 Production control plan (refined) including test plan, resulting from requirement 5.4.1.4 and 5.4.1.5</p> <p>5.5.3 Documentation of performed control measures resulting from requirement 5.4.3.5.</p> <p>5.5.4 If applicable, requirements on the producibility at system-, hardware or software development level resulting from requirement 5.4.1.7</p> <p>5.5.5 Assessment report for capability of the production process, resulting from requirement 5.4.2.2 and 5.4.3.3.</p>
7-6	Operation, service (maintenance and repair), and decommissioning	<p>The first objective of this Clause is to define the scope of maintenance, customer information and repair instructions regarding the safety-related products in order to maintain the required functional safety during operation of the vehicle.</p> <p>The second objective of this Clause is to provide the requirements concerning activities addressing safety issues before disassembly.</p>	<ul style="list-style-type: none"> — requirements for production, operation, service and decommissioning (see ISO 26262-4:—, 7.5.3, ISO 26262-5:—, 7.5.4); — release for production report (see ISO°26262-4:—, 11.5); — warning and degradation concept, included in the functional safety concept (see ISO°26262-3:—, 8.5.1). 	<p>6.5.1 Maintenance plan (refined) resulting from requirement 6.4.1.1 to 6.4.1.3,</p> <p>6.5.2 Repair instructions resulting from requirement 6.4.1.3.</p> <p>6.5.3 User manual resulting from requirement 6.4.1.4.</p> <p>6.5.4 Instructions regarding field observations resulting from requirement 6.4.2.1.</p> <p>6.5.5 Instructions for decommissioning resulting from requirement 6.4.1.5.</p> <p>6.5.6 If applicable, requirements concerning operation, maintenance and decommissioning at system-, hardware or software development level resulting from requirement 6.4.1.6</p>

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- [1] IEC°61508 (all parts), *Functional safety of electrical/electronic/programmable electronic safety-related systems*
- [2] ISO°TS°16949, *Quality management systems -- Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations*