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Artificial intelligence — Functional safety and AI systems

Draft Technical Report stage

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Foreword

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This document was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 42, *Artificial Intelligence*.

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Introduction

The use of artificial intelligence (AI) technology in industry has increased significantly in recent years and AI has been demonstrated to deliver benefit in certain applications. However, there is limited guidance on specification, design and verification of functionally safe AI systems or on how to apply AI technology for functions that have safety-related effects. For functions realized with AI technology, such as machine learning (ML), it can be difficult to explain why they behave in a particular manner and to guarantee their performance. Therefore, special attention can be given whenever AI technology is used in general and especially when it is used to realize safety-related systems.

The availability of powerful computational and data storage technologies makes the prospect of large-scale deployment of ML possible. For more and more applications, adopting machine learning (as an AI technology) is enabling the rapid and successful development of functions that detect trends and patterns in data. This makes it possible to induce a function's behaviour from observation and to quickly extract the key parameters that determine its behaviour. Machine learning can also be used to identify anomalous behaviour or to converge on an optimal solution within a specific environment. Successful ML applications can be found in analysis of financial data, social networking applications and language recognition, image recognition (particularly face recognition), healthcare management and prognostics, digital assistants, manufacturing robotics, machine health monitoring and automated vehicles.

In addition to ML, other AI technologies are also gaining importance in engineering applications. Applied statistics, probability theory and estimation theory have, for example, enabled significant progress in the field of robotics and perception. As a result, AI technology and AI systems are starting to realize applications that can affect safety.

Models play a central role in the implementation of AI technology. The properties of these models can be used to demonstrate the compatibility of AI technology and AI systems with functional safety requirements. For instance, where there is an underlying known and understood scientific relationship between the key parameters that determine a function's behaviour, there is likely to be a strong correlation between the observed input data and the output data. This can lead to a transparent and sufficiently complete model as the basis for AI technology. In this case, compatibility of the model with functional safety requirements can be demonstrated. However, AI technology is often used in cases where physical phenomena are so complex or at such a small scale, or cannot be observed without influencing the experimental data, that consequently there is no scientific model of the underlying behaviour. In this case, the model of the AI technology is possibly not transparent, and its completeness is possibly challenged. In this case, compatibility of the model with functional safety requirements is hard to demonstrate.

Machine learning can be used to create models and thus to extend the understanding of the world. However, machine-learnt models are only as good as the information used to derive the model. If the observed data does not cover important cases, then the derived models can be incorrect. As more known instances are observed they can be used to reinforce a model but this can bias the relative importance of observations, steering the function away from less frequent, but still real, behaviours. Continuous observation and reinforcement can move the model towards an optimum or it can overemphasise common data and overlook extreme, but critical, conditions.

In the case of continuous improvement of the model through the use of AI technology, the verification and validation activities in order to demonstrate its safety integrity can be undermined as the function behaviour progressively moves away from the rigorously tested, ideally deterministic and repeatable behaviour.

The purpose of this document is to enable the developer of safety-related systems to appropriately apply AI technologies as part of safety functions by fostering awareness of the properties, functional safety risk factors, available functional safety methods and potential constraints of AI technologies. This document

also provides information on the challenges and solution concepts related to the functional safety of AI systems.

The purpose of this document is not to define requirements. Descriptions of safety integrity level requirements, for example, safety integrity level (SIL) - or automotive safety integrity level (ASIL) - related requirements, qualifying an AI element to be used within a safety function with a certain SIL or ASIL, is beyond the scope of this document.

Clause 5 provides an overview of functional safety and its relationship with AI technology and AI systems.

Clause 6 introduces different classes of AI technology to show potential compliance with existing functional safety International Standards when AI technology forms part of a safety function. Clause 6 further introduces different usage levels of AI technology depending on their final impact on the system. Finally, Clause 6 also provides a qualitative overview of the relative levels of functional safety risk associated with different combinations of AI technology class and usage level.

In Clause 7, a first method is elaborated to provide a framework for usage of AI technology in safety-related systems, where compliance with existing functional safety International Standards cannot be shown directly.

Clause 8 discusses properties and related functional safety risk factors of AI systems and presents challenges that such use raises, as well properties that can be considered when attempting to treat or mitigate them.

Clauses 9, 10 and 11 show possible solutions to these challenges from the field of verification and validation, control and mitigation measures, processes and methodologies.

Annexes provide examples of application of this document and additional details.

Artificial intelligence — Functional safety and AI systems

1 Scope

This document describes the properties, related risk factors, available methods and processes relating to:

- Use of AI inside a safety related function to realize the functionality;
- Use of non-AI safety related functions to ensure safety for an AI controlled equipment;
- Use of AI systems to design and develop safety related functions.

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/IEC 22989:—[1], *Information technology — Artificial intelligence — Artificial intelligence concepts and terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 22989:— and the following apply.

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

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

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

3.1
safety
freedom from *risk* (3.3) which is not tolerable

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.14]

3.2
functional safety
part of the overall *safety* (3.1) relating to the EUC (Equipment Under Control) and the EUC control system that depends on the correct functioning of the E/E/PE (Electrical/Electronic/Programmable Electronic) safety-related systems and other risk reduction measures

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.1.12]

3.3
risk
functional safety risk
<functional safety> combination of the probability of occurrence of *harm* (3.5) and the severity of that *harm* (3.5)

Note 1 to entry: For more discussion on this concept, see Annex A of IEC 61508-5.

[1] Under preparation. Stage at the time of publication: ISO/IEC FDIS 22989:2022.

[SOURCE: IEC 61508-4, ed. 2.0 (2010-04), 3.1.6, added <functional safety> domain]

3.4
risk
organizational risk
<organizational> effect of uncertainty on objectives

Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both and can address, create or result in opportunities and threats.

Note 2 to entry: Objectives can have different aspects and categories and can be applied at different levels.

Note 3 to entry: Risk is usually expressed in terms of risk sources, potential events, their consequences and their likelihood.

Note 4 to entry: This is the core definition of risk. As risks are specifically focused on *harm* (3.5) a discipline specific definition of *risk* (3.3) is used in this document in addition to the core risk definition.

[SOURCE: ISO 31000:2018, 3.1, added <organizational> domain and added Note 4 to entry]

3.5
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.1.1]

3.6
hazard
potential source of *harm* (3.5)

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.1.2]

3.7
hazardous event
event that can cause *harm* (3.5)

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.1.4]

3.8
system
combination of interacting elements organized to achieve one or more stated purposes

[SOURCE: ISO/IEC/IEEE 15288:2015, 4.1.46, removed the four Notes to entry]

3.9
systematic failure
failure, related in a deterministic way to a certain cause, which can only be eliminated by a modification of the design or of the manufacturing process, operational procedures, documentation or other relevant factors

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.6.6]

3.10
safety-related system
designated system that both

– implements the required safety functions necessary to achieve or maintain a safe state for the EUC; and

– is intended to achieve, on its own or with other E/E/PE safety-related systems and other risk reduction measures, the necessary safety integrity for the required safety functions

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.4.1]

3.11
safety function
function to be implemented by an E/E/PE safety-related system or other risk reduction measures, that is intended to achieve or maintain a safe state for the EUC, in respect of a specific *hazardous event* (3.7)

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.5.1]

3.12
equipment under control
EUC
equipment, machinery, apparatus or plant used for manufacturing, process, transportation, medical or other activities

Note 1 to entry: The EUC control system is separate and distinct from the EUC.

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.2.1]

3.13
programmable electronic
PE
based on computer technology which can be comprised of hardware, software and of input and/or output units

Note 1 to entry: This term covers microelectronic devices based on one or more central processing units (CPUs) together with associated memories, etc.

EXAMPLE The following are all programmable electronic devices:

— microprocessors;

— micro-controllers;

— programmable controllers;

— application specific integrated circuits (ASICs);

— programmable logic controllers (PLCs);

— other computer-based devices (for example smart sensors, transmitters, actuators).

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.2.12]

3.14
electrical/electronic/programmable electronic
E/E/PE
based on electrical (E) and/or electronic (E) and/or programmable electronic (PE) technology

Note 1 to entry: The term is intended to cover any and all devices or systems operating on electrical principles.

EXAMPLE Electrical/electronic/programmable electronic devices include:

— electro-mechanical devices (electrical);

— solid-state non-programmable electronic devices (electronic);

— electronic devices based on computer technology (programmable electronic).

[SOURCE: IEC 61508-4, ed. 2.0 (2010), 3.2.13]

3.15
AI technology
technology used to implement an AI system

Note 1 to entry: Examples of AI technologies are application graph, machine learning framework, machine learning model, machine learning graph compiler.

4 Abbreviations

CPU	central processing unit
CUDA	compute unified device architecture
DL	deep learning
DNN	deep neural network
GPU	graphics processing unit
E/E	electrical and/or electronic
E/E/PE	electrical/electronic/programmable electronic
EUC	equipment under control
FMEA	failure modes and effects analysis
HARA	hazard analysis and risk assessment
HAZOP	hazard and operability analysis
KPI	key performance indicator

5 Overview of functional safety

5.1 Introduction to functional safety

The discipline of functional safety is focused on risks related to injury and damage to the health of people, or damage to the environment and, in some cases, mitigation against damage to product or equipment. The definition of risk differs based on the domain as shown in Clause 3.3, and both are used for AI. This document uses the definition from the functional safety domain as specified in Clause 3 (functional safety risk). Unless otherwise indicated, all references to risk in this document are to this definition.

NOTE ISO 21448:—[2] [7] includes requirements on safety of the intended functionality including aspects such as performance limitation. Annex D describes implications for machine learning.

[2] Under preparation. Stage at the time of publication: ISO/FDIS 21448:2022.

According to IEC 61508-1, control of risk is an iterative process of risk assessment and risk reduction. Risk assessment identifies sources of harm and evaluates the related risks for the intended use and the reasonably foreseeable misuse of the product or system. Risk reduction reduces risks until they become tolerable. Tolerable risk is a level of risk that is accepted in a given context based on the current state of the art.

The IEC 61508 series recognizes the following three-step (prioritised) approach as being good practice for risk reduction:

- Step 1: inherently functionally safe design;
- Step 2: guards and protective devices;
- Step 3: information for end users.

Risk reduction via the provision of functional safety is associated with Step 2.

This document focusses on the aspects of safety functions performed by a safety related system by making use of AI technology, either within the safety related system or during design of the safety related system (Step 2).

This document makes no provision of methodology for AI technology used for Steps 1 and 3.

5.2 Functional safety

IEC 61508-4 [19] defines functional safety as that "part of the overall safety relating to the EUC (Equipment Under Control) and the EUC control system that depends on the correct functioning of the E/E/PE (Electrical/Electronic/Programmable Electronic) safety-related systems and other risk reduction measures." The E/E/PE safety-related system is delivering a "safety function", which is defined in IEC 61508-4 as a "function to be implemented by an E/E/PE safety-related system or other risk reduction measures, that is intended to achieve or maintain a safe state for the EUC, in respect of a specific hazardous event." In other words, the safety functions control the risk associated with a hazard that can lead to harm to people or the environment. The safety functions can also reduce the risk of having serious economic implications.

As the term implies, functional safety - as defined in IEC 61508-4 - aims to achieve and maintain functionally safe system states of an EUC through the provision of safety functions. Based on the inclusion of "other risk reduction measures" in the definition of functional safety and safety functions, non-technical functions are explicitly included. As defined in IEC 61508-4, the EUC is not limited to individual devices but can also be systems.

Following these definitions, functional safety as a discipline is thus concerned with the proper engineering of these technical and non-technical safety functions for risk reduction or risk level containment of a particular equipment under control, from the component level up to the system level, including considering human factors, and under operational or environmental stress.

Functional safety focuses on technical functions for risk reduction and attributes of these functions for risk reduction, (e.g. absence of safety-related failures beyond a defined frequency of occurrence). While the functionality of a safety function is strongly use-case dependent, the properties for risk reduction and related measures are the main focus of functional safety standardization. Prior to the advent of programmable systems, when safety functions were limited to implementation in hardware, the focus of functional safety was to reduce the possibility, consequences of and the likelihood of random hardware failures. With software being increasingly used to implement safety functions, the focus shifts towards systematic failures introduced during design and development. The focus on reliability in functional safety is particularly evident in the narrow definition of functional safety in the automotive domain (ISO 26262-1 [12]): "absence of unreasonable risk due to hazards caused by malfunctioning behaviour of E/E systems".

There is a robust body of knowledge on how to avoid systematic failures in non-AI systems and in software development [138]. This document considers the use of AI technology in the context of safety functions. Functions containing AI technology, especially machine learning, typically follow a different development paradigm to that of non-AI systems. They are less specification-driven and more driven by observation of the data defining the system behaviour. For this reason, the catalogue of available measures for dealing with systematic failures is extended with respect to the specificities of AI technologies: Annex A provides an example of that extension. AI-specific risk reduction measures also differ from non-AI systems from a functional perspective. Functional safety puts a focus on systematic capabilities (IEC 61508-4:2010, Clause 3.5.9) in addition to random hardware and systematic failures throughout the lifecycle.

The relevance of AI technologies when used to realize a safety function is their potential to address new methods for risk reduction. This document examines the use of such technologies for this purpose, while maintaining existing risk reduction concepts, by introducing risk and classification considerations.

In general, achieving an acceptable risk level for increasingly complex and automated systems is likely to depend on advanced safety concepts. This includes the adequate collection of both technical and non-technical risk reduction measures to achieve and maintain safe system states. Assuring the validity of such advanced safety concepts is a great challenge in functional safety. It leads to an increase in the number of functional safety requirements. For all technical risk reduction measures, the distinction is made that hardware random faults and systematic faults are considered, which is done in basic International Standards like the IEC 61508 series or derived International Standards. However, for safety functions including AI technology, it is inevitable that there can be additional focus on the assurance that systematic capabilities of systems that implement these functions are sufficient for the intended use environment.

6 Use of AI technology in safety-related E/E/PE systems

6.1 Problem description

The use of AI technology and AI systems are currently not treated in mature functional safety International Standards (indeed, in some International Standards their use is explicitly forbidden). International Standards that include AI-related contents e.g. include ISO 21448:— [7], ISO/TS 5083 [3] [154] and ISO/PAS 8800 [4] [155].

6.2 AI technology in safety-related E/E/PE systems

Safety-related E/E/PE systems have a set of properties to ensure that they provide the intended safety mitigation measures in a dependable way. These properties are ideally generic and application independent. However, the data and the specifications vary based on application and technology domain. The process in which properties are defined is described in Figure 3 in Clause 7.4 for each of the three stages of the AI framework. The properties can be defined on a case-by-case basis as relevant to the particular application or technology domain data and specifications. Some of these properties can be based on existing International Standards, including the IEC 61508 series [16]-[19], the ISO 26262 series [12]-[15], IEC 62061 [21] and the ISO 13849 series [5], [8]. Others are newly defined. Clause 8 provides a list of typical properties

Satisfying the selected properties is likely to place particular functional safety requirements on the realization, installation, validation, operation and maintenance of such systems. For example, IEC 61508-3 [18] defines such requirements for the software part of E/E/PE systems. However, several AI

[3] Under preparation.

[4] Under preparation.

technologies use different development approaches (e.g. learning-based) compared to the non-AI software engineering lifecycles targeted by IEC 61508-3.

To address the difference between traditional development processes and the approach typical of AI technologies, this Clause provides a general classification scheme for the applicability of AI technology in safety-related E/E/PE systems, based on various contexts of the application of AI technology.

An example of a classification scheme is shown in Figure 1 and in the related Table 1. The scheme is intended to provide insight on how an AI technology can be addressed in the context of functional safety for a specific application. Sector-specific International Standards can be used to translate that general classification scheme into actionable requirements.

Figure 1 — Example of general classification scheme for the applicability of AI in safety-related E/E/PE systems

The classification scheme (see Table 1) is organized along two axes:

— AI Technology Class. This axis considers the level of fulfilment of AI technology in satisfying the identified set of properties, in which:

  — Class I is assigned if AI technology can be developed and reviewed using existing functional safety International Standards, for example, if the properties and the set of methods and techniques leading to achievement of the properties can be identified using existing functional safety International Standards;

  — Class II is assigned if AI technology cannot be fully developed and reviewed using existing functional safety International Standards, but it is still possible to identify the desired properties and the means to achieve them by a set of methods and techniques. For example, it is possible to use complementary methods such as additional verification and validation, so the use of the AI technology can still meet the identified properties;

  — Class III is assigned if AI technology cannot be developed and reviewed using existing functional safety International Standards and it is also not possible to identify a set of properties with related methods and techniques to achieve them.

— AI Application and Usage Level. This axis considers the application of the AI technology and includes, among other things, the way in which it is used. It is classified from A to D, with two intermediate levels for A and B.

NOTE 1 The factors identified in Clause 8 are of high relevance in the context of the classification. These factors are described further in Clause 8 and include the level of automation and control (Clause 8.2), the degree of decision transparency and explainability (Clause 8.3), the complexity of the environment and vague specifications (Clause 8.4), security (Clause 8.5), system hardware issues (Clause 8.6) and the readiness of the technology (Clause 8.7).

An example of a classification of Usage Level is as follows:

— Usage Level A1 is assigned when the AI technology is used in a functional safety-relevant E/E/PE system and where automated decision-making of the system function using AI technology is possible;

— Usage Level A2 is assigned when the AI technology is used in a safety-relevant E/E/PE system and where no automated decision-making of the system function using AI technology is possible (e.g. AI technology is used for diagnostic functionality within the E/E/PE system);

NOTE 2 The evaluation can change depending on the role of the diagnostic function, such as whether the diagnostic is critical to maintaining the functional safety of the system or is merely a minor contributor to functional safety amongst many others.

— Usage Level B1 is assigned when the AI technology is used only during the development of the safety-relevant E/E/PE system (e.g. an offline support tool) and where automated decision-making of the function developed using AI technology is possible;

— Usage Level B2 is assigned when the AI technology is used only during the development of the safety-relevant E/E/PE system (e.g. an offline support tool) and where no automated decision-making of the function is possible:

— Usage Level C is assigned when the AI technology is not part of a functional safety function in the E/E/PE system, but can have an indirect impact on the function:

NOTE 3 An example is an increase in the demand rate placed on a safety system.

— Usage Level D is assigned if the AI technology is not part of a safety function in the E/E/PE system and has no impact on the safety function due to sufficient segregation and behaviour control.

NOTE 4 An example is separation through a “sandbox” or ”hypervisor” in such a way that it cannot affect the safety functionality.

Components containing AI technology are composed of various technology elements (see Clause 7.5). Each element can belong to a different AI technology class. For example, the lower level of abstraction of a neural network can be represented using C++ libraries, which by themselves can be systematically reviewed (e.g. according to the requirements in IEC 61508-3 [18], see the example in Annex A). As such, they can be classified as Class I, though the higher level of abstractions (e.g. deep learning models) can be classified as Class II or Class III.

Table 1 — Example of AI classification table

<table>
<tr><th>AI Technology Class => AI application and usage level</th><th>AI technology Class I</th><th>AI technology Class II</th><th>AI technology Class III</th></tr>
<tr><td>Usage Level A1 (1)</td><td rowspan="5">Application of risk reduction concepts of existing functional safety International Standards possible</td><td>Appropriate set of requirements (5)</td><td rowspan="5">Not recommended</td></tr>
<tr><td>Usage Level A2 (1)</td><td>Appropriate set of requirements (5)</td></tr>
<tr><td>Usage Level B1 (1)</td><td>Appropriate set of requirements (5)</td></tr>
<tr><td>Usage Level B2 (1)</td><td>Appropriate set of requirements (5)</td></tr>
<tr><td>Usage Level C (1,3)</td><td>Appropriate set of requirements (5)</td></tr>
<tr><td>Usage Level D (2)</td><td colspan="3">No specific functional safety requirements for AI technology, but application of risk reduction concepts of existing functional safety International Standards (4)</td></tr>
<tr><td colspan="4">1 Static (offline) (during development) teaching or learning only
2 Dynamic (online) teaching or learning possible
3 AI techniques clearly providing additional risk reduction and whose failure is not critical to the level of acceptable risk.
4 Additionally, other safety aspects (not being addressed with functional safety methods) can possibly be adversely affected by AI usage.
5 The appropriate set of requirements for each usage level can be established in consideration of Clauses 8, 9, 10 and 11. Examples are provided in Annex B.</td></tr>
</table>

7 AI technology elements and the three-stage realization principle

7.1 Technology elements for AI model creation and execution

The creation and the execution of a model involves different technology elements. Table 2 provides a high-level description of the AI landscape and the typical technology elements involved, based on the functional layers of an AI ecosystem as described in ISO/IEC 22989:—, Figure 6. Table 3 is an example of those technology elements for the specific case of machine learning.

Table 2 — Example technology elements

Technology element
AI services
Machine learning — Model development and use — Tools — Data for machine learning
Engineering — Model development and use — Tools
Cloud and edge computing and big data and data sources
Resource pool-compute, storage, network
Resource management-resource provisioning

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526 **Table 3 — Example technology elements involved in model creation and execution for ML**

Technology element (machine learning example)	Example language or tool (not exhaustive)
Application graph	General eXchange Format (GXF) graph in YAML Ain't Markup Language (YAML), recently qualified teacher (rqt) graph in Robot Operating System (ROS)
Machine learning framework[a]	TensorFlow, PyTorch, Keras, mxnet, Microsoft Cognitive Toolkit (CNTK), Caffe`, Theano
Machine learning model	Open Neural Network Exchange (ONNX), Neural Network Exchange Format (NNEF)
Machine learning graph compiler	TensorRT, GLOW, Multi-Level Intermediate Representation (MLIR), nGraph, Tensor Virtual Machine (TVM), PlaidML, Accelerated Linear Algebra (XLA)
Set of calculations	C++
Libraries of calculation operands	CUDA C++, XMMA/SASS kernels, NumPy, SciPy, Pandas, Matplotlib, CUDA Deep Neural Network (cuDNN), SYCL DNN, oneAPI Deep Neural Network (OneDNN), Math Kernel Library (MKL)
Compiler	Gcc, nvcc, clang/llvm, SYCL, dpc++, OpenCL, openVX
Executable machine code	aarch64, PTX, RISC-V, AMD64, x86/64, PowerPC
Computational hardware	GPU, CPU
NOTE This table does not distinguish between elements used for training and those used for inference. [a] A machine learning framework is an end-to-end machine learning platform including tools, libraries and community resources.	

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528 Some technology elements can be addressed with existing concepts of functional safety. For example, one
529 can usually handle the software translating the model to an executable representation with existing
530 concepts of functional safety. All technology elements involved in the model creation and execution can
531 be part of the safety considerations, including those that can be handled with existing concepts of
532 functional safety and those for which new concepts can be defined. Annex A includes an example of how
533 existing concepts of functional safety can be applied to AI technology via assessment of the applicability
534 of IEC 61508-3 [18]. Annex B includes an example of how specific properties, such as the ones described

in Clause 8, can be applied to AI technology for which existing concepts of functional safety cannot be applied.

As shown in Figure 2, elements containing AI technology are used at different levels of a system or application: for the higher-level elements (e.g. application graph) specific properties, such as the ones described in Clause 8, can be applicable; the lower-level elements (e.g. a set of calculations) can be handled with non-AI properties as described in this Clause, such as the properties defined in the IEC 61508 series [16]-[19], the ISO 26262 series [12]-[15] and other International Standards.

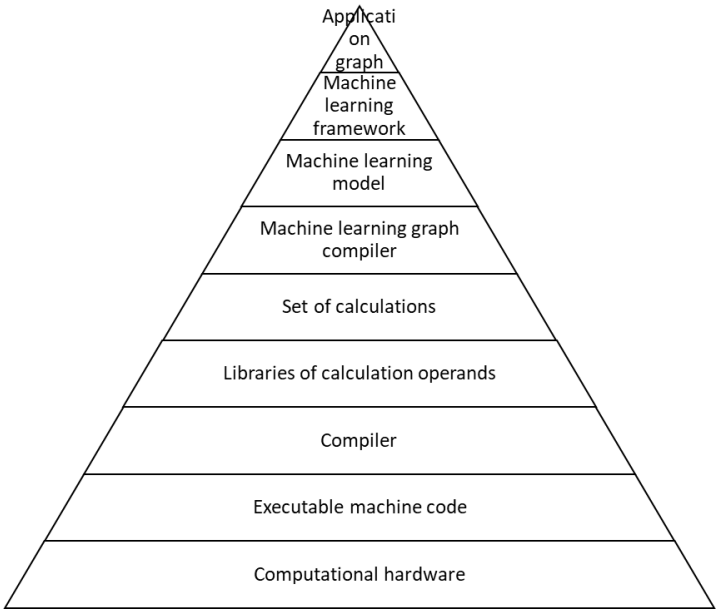


Figure 2 — The hierarchy of technology elements (ML example)

7.2 The three-stage realization principle of an AI system

An AI system can be represented (see Figure 3) by a realization principle comprising three main stages:

— data acquisition;

— knowledge induction from data and human knowledge;

— processing and generation of outputs.

NOTE 1 With respect to ISO/IEC 22989:—, Figure 5, the first stage is mapped to the Inputs task, the second stage is mapped to Learning task and the third stage to the Processing task.

NOTE 2 In this context, human knowledge is derived from a range of different expertise, both in the relevant domain as well as in AI systems.

NOTE 3 The proposed realization principle is general. Specific more detailed examples for AI system are the Monitor-Analyse-Plan-Execute (MAPE) or Sense-Understand-Decide-Act (SUDA).

NOTE 4 The intent of the three-stage realization principle is not to describe a lifecycle (that is described in Clause 11 and includes all stages from concept development and maturation through to development of requirements) but mainly to show that AI includes another point of view (the data).

NOTE 5 Figure 3 does not show feedback loops that can apply for AI systems that are tightly bound into decision loops or that change the real world situation.

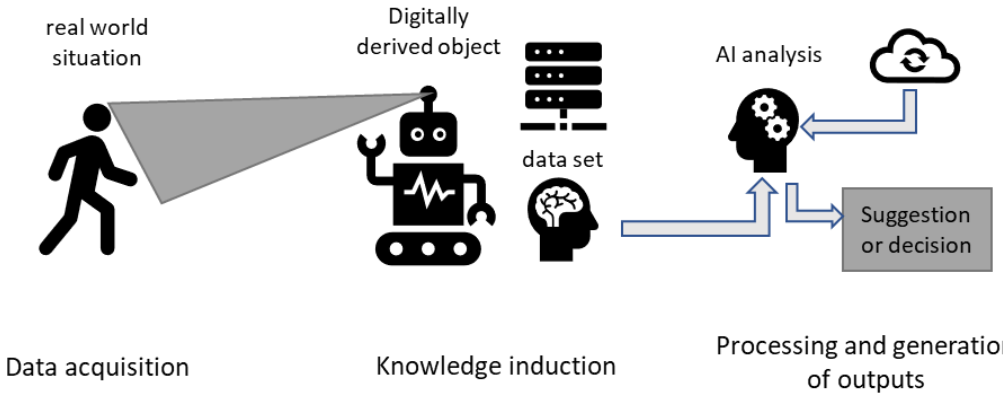


Figure 3—Three-stage realization principle

7.3 Deriving acceptance criteria for the three-stage of the realization principle

The following process (see Figure 4) can be defined to derive acceptance criteria based on the three-stage realization principle:

— Desirable properties are defined for each of the three stages.

— The properties are related to topics and eventually to detailed methods and techniques addressing those topics.

— Acceptance criteria are identified from the set of the detailed methods and techniques.

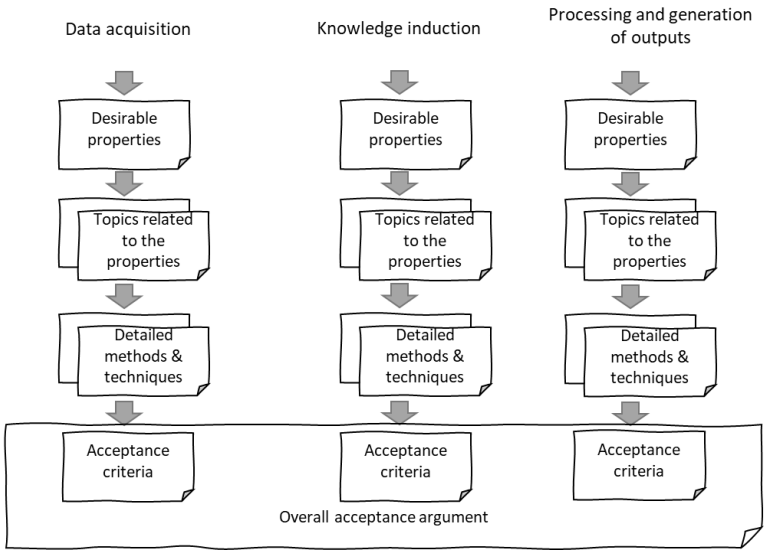


Figure 4 — Processes in each stage

NOTE 1 The properties can be defined on a case-by-case basis or derived from properties listed in existing International Standards, based on the level of the elements containing AI technology. Refer to Clause 8 for the list of considered properties.

NOTE 2 In this context, the acceptance criteria are intended as something that can be identified and confirmed during development.

8 Properties and related risk factors of AI systems

8.1 Introduction

8.1.1 General

Clause 7 describes how the definition of desirable properties is the first step of the three-stage realization principle. The properties are related to topics and eventually to detailed methods and techniques addressing those topics. Acceptance criteria are then identified from the set of the detailed methods and techniques.

This Clause provides guidance on the properties that characterize systems using AI technology and their related risk factors. Such properties and risk factors include degree of automation and control (Clause 8.2), degree of decision transparency and explainability (Clause 8.3), environmental complexity and vagueness of their defining specifications (Clause 8.4), resilience to adversarial inputs (Clause 8.5), system hardware considerations (Clause 8.6) and technological maturity (Clause 8.7).

Details of the properties and risk factors of systems using AI technology, and their related aspects and challenges, are discussed in this Clause.

8.1.2 Algorithms and models

On a technological level, the capability of AI is often achieved by the combination of an algorithm and a model. The model typically represents information that achieves the application's purpose, (e.g. knowledge about how various inputs are to be distinguished and recognized), while algorithms infer information from a model and inputs, (e.g. to make a prediction). This means the functional safety of applications using AI technology depends on both.

Example types of algorithms include linear functions, logical calculi, dynamic Bayesian networks and artificial neural networks. The models can either be handcrafted by an engineer, or can be synthesized from data by machine learning algorithms that themselves use a systematic analysis process. The algorithms are usually implemented as an executable representation, such as machine code (in the case of software), or special hardware, such as field programmable gate arrays (FPGAs).

Usually, algorithms that interact with the models contain only a limited amount of knowledge or implications about the application's goals. This is quite similar to the role of foundational software libraries or programming environments (compilers, etc.) in non-AI software. That is, the algorithm itself does not play a functional safety role, but its correctness is critically important for functional safety to be achieved. In this way, the integrity of algorithms in AI technology can often be handled with existing principles of functional safety as specified in the IEC 61508 series [16]-[19], similar to that of non-AI software components. The same holds for the logic involved in the translation of the algorithm and the model.

By contrast, models often contain knowledge related to the objective of the systems involving functional safety. There are several different ways of constructing models and different approaches can be used for assessing the completion of risk reduction measures to ensure functional safety.

For example, when models are created manually by engineers, the models can likely reflect the engineers' knowledge about the application, which can be assessed during the management processes used within functional safety lifecycles. In these cases, the lifecycle of existing functional safety International Standards can be followed (AI technology Class I as described in Clause 6.2). It is often feasible to create models manually for simple algorithms such as simple linear functions or logical calculi.

In some cases, models derived from data by machine learning algorithms can be analysed and verified after their creation. Alternatively, models derived by machine learning algorithms can be analysed, the

underlying parameters extracted and used to extend general engineering knowledge, that, in turn, can be used to develop further models. With the application of validated engineering knowledge, the lifecycle of existing functional safety International Standards can again be applied (e.g. treating these models as AI technology Class I as described in Clause 6.2).

In other cases, models derived from data by machine learning algorithms can be too complex to be understood, analysed and verified. This is often the case for complex types of models, such as neural networks, because representations of models in these types do not necessarily reflect human understanding or reasoning. The use of different approaches for assessing the risk reduction for functional safety is appropriate in these cases, which and can constitute a major challenge for the use of AI technology in implementation of functional safety systems.

8.2 The level of automation and control

The level of automation (sometimes called "levels of autonomy" in the literature) describes the extent to which an AI system functions independently of human supervision and control. It thus determines not only how much information about the behaviour of the system is available to the operator, but also defines the control and intervention options of the human.

Dimensions of this topic include how high the level of automation is for the respective application, as well as the extent to which the user's control options are restricted. Systems using AI technology with a high-level of automation can exhibit unexpected behaviour that can be difficult to detect and control. Highly automated systems can thus pose risks in terms of their reliability and safety.

Several aspects are relevant in considering whether functional safety is achieved, such as the responsiveness of the AI system and the presence or absence of a "supervisor". In this context, a "supervisor" serves to validate or approve automated decisions of the system. Such a "supervisor" can be achieved by technical control functions, though in some situations such a supervisory function is not feasible, e.g. highly complex decisions or ML systems that have learnt new behaviours. For example, a second safety instrumented system for critical controls (Usage Level C or D as described in Clause 6.2) can be added and assigned to a safety function for redundant components, as in functional safety International Standards like IEC 61508-1 [16].

In turn, this can cause an interoperability problem between the "supervisor" and the automated AI system or between automated AI systems of different levels of automation. The traditional approach, in this case, is, if the levels of automation of the operating AI systems are different, then the general control is carried out according to the level of automation of the system, which has a lower level of automation.

Another way for adding a "supervisor" is to use a human whose task it is to intervene in critical situations or to acknowledge system decisions. In one of the possible ways, this can be addressed by the supervisor aided by an added system (at Usage Level C or D as described in Clause 6.2) to detect possible outcomes of the decision. An example is a simulation system that gives "what if" information for different decisions and can check for outcomes. However, even if humans are in the loop and control the actions of a system, sometimes this cannot reduce such risks to a suitable level and can introduce additional risks.

Furthermore, the adaptability of the AI system can be considered. Here the question arises to what extent can the system change its own behaviour, for example, as can be the case in systems that use machine learning to change their behaviour over time. These systems can adapt to changing environmental conditions (e.g. via feedback loops or an evaluation function) and can even acquire entirely new functions over time. A disadvantage of such learning systems, however, is that they can deviate from the initial specification over time and can be difficult to validate. Therefore, it is appropriate for such systems to be considered very carefully before being used in systems of higher usage levels A-C as described in Clause 6.2.

Table 4 (ISO/IEC 22989:—, Table 1) describes the relationship among autonomy, heteronomy and automation:

Table 4 — Relationship among autonomy, heteronomy and automation (derived from ISO/IEC 22989:—, Table 1).

		Level of automation	Comments
Automated system	Autonomous	Autonomy	The system is capable of modifying its operating domain or its goals without external intervention, control or oversight.
	Heteronomous	Full automation	The system is capable of performing its entire mission without external intervention.
		High automation	The system performs parts of its mission without external intervention.
		Conditional automation	Sustained and specific performance by a system, with an external agent being ready to take over when necessary.
		Partial automation	Some sub-functions of the system are fully automated while the system remains under the control of an external agent.
		Assistance	The system assists an operator.
		No automation	The operator fully controls the system.

NOTE 1 The dividing into levels applies to the control automation functions in any implementation of an automated AI system and taking into account the functions of the components of this system (for example, onboard equipment, floor equipment and control room equipment).

8.3 The degree of transparency and explainability

Often, aspects of transparency and explainability are summarised under the term “transparency”. However, it is beneficial to clearly distinguish these terms.

ISO/IEC 22989 defines explainability as the property of an AI system to express important factors influencing the results of the AI system in a way that is understandable to humans, whereas transparency is defined as the property of a system that appropriate information about the internal processes of an AI system is made available to relevant stakeholders-see also ISO/IEC TR 24028 [11].

In particular, information about the model underlying the decision-making process is likely to be relevant. Systems with a low degree of transparency can pose risks in terms of their fairness, security and accountability. Furthermore, such systems can complicate the assessment of their quality. On the other hand, a high degree of transparency can lead to confusion due to information overload, or can conflict with privacy, security, confidentiality requirements and intellectual properties, and desirable level of explainability can often be achieved without a high-level of transparency. It is therefore important to find an appropriate level of transparency to provide developers with opportunities for error identification and correction, as well as to ensure that a user can trust the AI system.

In non-AI software, the intention and knowledge of the engineer is generally encoded into the system using a logical process, making it possible to trace through the code to determine how and why a certain decision has been made by the software. This can be done by backtracking through and debugging the software or by reverse engineering the software. By contrast, decisions made by AI models, especially by models of high complexity, or models derived from machine learning algorithms, are more difficult to understand for humans. The way knowledge is encoded in the structure of the model and the way decisions are made, are often different from how humans reason about their own decision-making processes [130], [131].

A high-level of explainability protects against unpredictable behaviour of the system but is sometimes accompanied by lower overall performance in terms of the quality of decisions, due to the limitation of current explainability technology (which can limit the amount of information contained in the model to create explanations of reasonable size). Here, a trade-off is often to be made between explainability and the performance of a system. In addition, the relevance of the information about an AI system's decision-making process is likely to be an important factor. It is possible that a system provides clear and coherent information about its decision-making process, but that this information is inaccurate or incomplete.

Explainable AI can also be used to assist with post-incident analysis when the input data, which are sometimes transient, are recorded and reproduced.

Consequently, it can be desirable to include transparency and explainability in the general evaluation of the AI system. Considerations can include:

— whether sufficient information about the system is available;

— whether it is understandable or at least delivers comprehensible information (can be indirectly) to the intended recipient (the intended recipient of an explanation varies depending on the context. It can, for example, be the system developer, first responders of the system in use, or bystanders in some cases);

— whether it delivers correct, complete and reproducible results consistently.

Several evaluation concepts and strategies exist to judge the transparency and explainability of an AI system, such as those reported in References [39] and [40]. Additionally, empirical assessments of the decision-making process of complex models can be carried out, for example, by inspecting a convolutional neural network through visualisation of components of its internal layers [41]. The goal is to make the network's decision process more explainable by determining how input features affect the model output. Reviewing the output of a convolutional neural network by having its internal state inspected by a human expert is an approach that is extended in related work such as Reference [42], [43] and [44]. Even when access to internal model states is completely unavailable, approaches such as randomized input sampling for explanation (RISE) [45] can still provide insights for certain network types.

Even systems traditionally believed to be reasonably explainable with regards to inspection, (e.g. decision trees), can quickly reach a complexity that defies understanding when deployed in real world applications. In situations where an interpretable result is desired, tools such as optimal classification trees [46] or born-again tree ensembles [47] can be applied to reduce complexity and allow for human expert review. See Reference [48] for a further discussion on the relation between AI model types and their interpretability.

Generally speaking, even when fully "explainable AI" is not immediately achievable, a methodical and formally documented evaluation of model interpretability can be employed in regards to risk , subject to careful consideration of the consequences on functional safety risk that can arise from inappropriate decisions. This can aid in comparability and model selection and can provide insights during an "after the event" failure analysis.

8.4 The complexity of the environment and vague specifications

8.4.1 Overview

AI systems are often used under environmental conditions whose complexity is difficult for humans to fully analyse and describe. AI technology can automatically generate rules, or apply judgement, without reliance on human-generated representations of analytic, detailed and complex environmental conditions. Further, the development lifecycle for AI systems can begin with vague specifications or vague goals.

Vagueness of specifications can lead to difficulty during assurance of functional safety-related properties. The complexity of the environment only worsens the situation. Even the definition of a tolerable level of functional safety is likely to be undermined by a vague specification, because the definition of ”safety function” depends on the given specification.

For functional safety applications, some minimal explanation for the functional completeness (as defined in ISO/IEC 25010-1 [148]) is highly important. Functional completeness can be addressed by seeking an extremely detailed specification or by seeking to cover the whole complex environment (e.g. by training data), or by the combination of the two. Some procedural guidance for the resolution of this topic is given in Clause 9.3.

Another aspect in which AI systems are likely to be called on to perform mainly complex tasks is that, although their models are often deterministic, their output can seem to be probabilistic. For example, since the environment can be very complex such that it can only be represented by a large state space and since the environment can also be subject to constant change and expansion, it can be assumed that even a model that generalises the behaviour well cannot react appropriately to every possible state of the environment.

The effect of operating in complex, not completely defined environments, results in a new type of residual risk beyond the scope of functional safety assessments currently being employed in a domain-specific manner.

The extent to which models are standardized, or their adequateness for the intended application demonstrated, is an important consideration. Additionally, residual risk predicted by the model needs to be considered in terms of behaviour planning and functionality.

Probabilistic assumptions are generally used in the functional safety discipline for the random failures of the hardware and “proven in use” software. Expansion to address the probabilistic concept to address the operational environment is a relatively novel approach to address systematic failures that can also be relevant to AI technologies, see Clause 10.1.6.

A further consideration is the limited ability of translating between different models due to inconsistency of terminology use. Reference [31] provides a survey of the different terms and their varying definitions. This document adopts the terms defined in ISO/IEC 22989.

This Clause covers two prominent types of data issues. For a more comprehensive list of emerging issues, see References [92], [93].

8.4.2 Data drift

A change in the independent variables (covariates or input features) of a model potentially induces a change in the joint distribution of independent variables and dependent variables. Components containing AI technology can be inspected for sources of data drift in the context of a risk analysis and adequate measures can be planned where appropriate. Data drift is often tied to an incomplete representation of the input domain during training. This can be due, for example, to failure to account for seasonal changes in input data, unforeseen input by operators, or the addition of new sensors that become available as input features. Naturally, data drift becomes an issue as soon as a model decays, due to a change in the decision boundaries of the model.

Some examples of data drift can be attributed to failure to apply best practices in model engineering. Common examples include picking inappropriate training data, data whose distribution does not reflect the actual distribution encountered in the application context or omitting important examples in the training data. These problem instances can be fixed by improved modelling and retraining.

Data drift can also be caused by external factors, such as seasonal change or a change in process that induces data drift. Examples include replacement of a sensor with a new variant featuring a different bias

voltage, or the sensor encountering different lighting conditions in training and previously unseen data. It can be appropriate for the model to deal with data drift while already deployed, where retraining is not feasible. In these cases, the model is constructed to estimate correction factors based on features of the input data or allow for supervised correction. Model design is expected to provide safe outputs even in the presence of previously unknown inputs. It is important to understand that following proper model engineering practices, such as establishing a sufficiently diverse training dataset, does not eliminate the need for careful analysis as to whether the resulting model can be generalised to production data. In addition, in the event of the model providing unsafe output, the recoverability of the system from such states needs to be specified and causes analysed.

For example, Reference [32] illustrates the most common sources of data drift and proposes model improvements, such as simpler or computationally more efficient models, even when data drift occurs as simple covariate shift without an apparent effect on classification output. These performance considerations translate to the development and application of modern, deep neural networks [33].

8.4.3 Concept drift

Concept drift refers to a change in relationship between input variables and model output and can be accompanied by a change in the distribution of the input data. For example, the output of a model can be used to gauge the acceptable minimal distance of an operator at runtime based on distance measurements obtained by a time-of-flight sensor (input data). If the accepted safety margins change due to external factors (e.g. increased machine speed not accounted for in the model), concept drift occurs despite both process and inputs having stayed the same.

Systems ideally incorporate forms of drift detection, distinguish drift from noise present in the system and adapt to changes over time. Potential approaches include models like early drift detection method (EDDM) [34], detecting drift using support vector machines [35] or observing the inference error during training to allow for drift detection and potential adaptation [36]. Furthermore, work to quantify drift in machine learning systems is available in Reference [37]. It is noted that drift detection implies some form of runtime monitoring and model updates that can introduce a particular set of system design and safety considerations (e.g. knowing when it is functionally safe to perform an update, detecting failed updates) to be considered at a software or system level.

Concept drift is often handled by selecting subsets of the available training data or by assigning weights to individual training instances and then re-training the model. For reference, Gama et al. provide a comprehensive survey of methods that allow a system to deal with drift phenomena [38].

Some examples of possible mitigation technologies for drift problems are summarized in Reference [94], Chapter 7.8.

8.4.4 Reward hacking algorithms

Reward hacking algorithms refers to methods where AI technology finds a way to “game” its reward function and thus find a more ”optimal” solution to the posed problem. This solution, whilst being more optimal in the mathematical sense, can be dangerous if it violates assumptions and constraints present in the intended real world scenario. For example, an AI system that detects persons based on a camera sweep can decide that it can achieve very high rewards if it constantly detects persons and can thus follow them around with its sensors, potentially missing critical events in other affected areas. This can be countered by employing adversarial reward functions, such as through an independent system that can verify the reward claims made by the primary function using AI technology and subsequently learn and adapt to counter the primary system. Another option is to pre-train a decoupled reward function based solely on the desired outcome and with no direct relationship to the primary function.

8.4.5 Safe exploration

The safe exploration problem is of particular concern when an agent has the capability to explore or manipulate its environment. This does not only pose a problem when referring to, for example, about service robots, unmanned air systems or other physical entities, but also applies to software agents using reinforcement learning to explore their operating space. In these contexts, exploration is typically rewarded, as this provides the system with new opportunities to learn. While it is obvious to see that a self-learning system needs to follow appropriate functional safety protocols when exploring, a system that controls process parameters and employs a random exploration function while not being properly disconnected from the dangerous process can pose equal or greater risks.

8.5 Resilience to adversarial and intentional inputs

8.5.1 Introduction

It is appropriate to determine the integrity of functional safety behaviour against adversarial examples and intentional inputs, such as adversarial attacks, when assessing the trustworthiness of an AI system.

In general, two types of intentional inputs can be distinguished in the field of AI; the first are those inputs that destroy integrity of software execution (such as buffer overflow or integer overflow), and the second are those that cause AI models to compute bad output without causing malfunctions at the software level. For the first class of problems, traditional information technology (IT) security requirements can be considered, see ISO/IEC 27001 [149], ISO/IEC 18045 [150], ISA/IEC 62443 [151] and ISO/IEC TR 19791 [95]. These International Standards provide processes for the audit and certification of horizontal IT security requirements that are also applicable to AI systems and won't be discussed further in this document. However, for the second class of problems, following best practices and observing existing International Standards for non-AI systems are not sufficient. Clause 8.5.3 includes a discussion of the second class of problem with adversarial examples of natural origin affecting the mode of action.

NOTE 1 This document is limited to the achievement of functional safety even in the presence of an AI-specific security threat. It does not address how malevolent action arising from a cyber security threat is controlled. Actions to assure the integrity of functional safety are carried out if a reasonably foreseeable cyber security threat can affect functional safety.

NOTE 2 Properties to assure freedom from intentional malevolent inputs can be contradictory to those that assure functional safety properties. For further information on AI-specific security threats, see Reference [94], Chapter 9.

NOTE 3 Properties that assure resilience to adversarial attacks can be contradictory to those that assure functional safety properties. This is addressed as part of a higher level of system suitability considerations.

NOTE 4 AI also has the potential to reduce the effect of malevolent action on functional safety; this can be considered as part of the higher suitability of the AI system.

8.5.2 General mitigations

Following proper functional safety precautions, a proposed first step in ensuring functionally safe operation is the application of supervision functions that take over the system in the event that a functional safety problem is detected, ensuring no harm can be done by the AI system.

For systems that need high-levels of functional safety, these weaknesses warrant careful consideration in terms of both random failures and systematic errors. Overall, failures and errors can be addressed according to best practices, (e.g. through hardening, robustness, testing and verification). Additionally, specific countermeasures in the field of machine learning can be applied to further mitigate risks for the additional types of failure and error specific to AI technology.

8.5.3 AI model attacks: adversarial machine learning

Models of AI systems, especially those with higher complexities (such as neural networks), can exhibit specific weaknesses not found in other types of systems and thus need additional scrutiny when deployed in a functional safety context. Examples of model-specific problems include adversarial machine learning and others.

Adversarial machine learning is a type of attack on an AI system that has garnered particular interest. Here, an attacker tries to manipulate an AI system model to either malfunction, change the expected model output, or obtain information about the model that can otherwise not be available to the attacker. When trying to manipulate a model, an attacker will typically either modify the input available to the model during inference or try to "poison" the learning process by injecting malicious data during the training phase [127]. It is possible to trick a model into outputting vastly different results by adding miniscule perturbations to the inputs. This noise is, in the case of input images, generally imperceptible to humans and can also be equally well hidden in numeric inputs. While these perturbations are typically non-random and carefully crafted via the means of an optimisation process, it cannot be ruled out that hardware failures or system noise already present in the input cause a non-negligible shift in model output, see Reference [49]. Inputs modified in such a way are called adversarial attacks. Interestingly, adversarial examples generally translate well across different model architectures and intrinsic model components [50], [51]. That, along with the number of well-known model architectures and pre-trained models available in so called "model zoos", makes the practical deployment of adversarial examples seem very likely and hence a significant threat to systems using AI technology [128], [129].

Even a system seemingly resilient against modification of its inputs, (e.g. a system employing a local, non-cloud AI model directly connected to sensors), is not exempt from this type of attack vector. The feasibility of physical attacks on models, even those considered black boxes with no access to internal model details being available, has already been shown in 2017 in Reference [52]. More recently, Reference [53] has shown that it is possible to introduce adversarial examples into the forward inference process of a model, creating the aforementioned perturbations using physical stickers applied to objects and causing a vastly diverging classification result.

When the input to an AI model is susceptible to adversarial attacks, possibility of adversarial attacks in the real system, including input sensing (e.g. camera) and pre-processing, can vary greatly depending on the condition to be deployed. It includes the existence of possible attackers and victims (i.e. if they coincide, it can be appropriate in some cases to omit protection). At the same time, it is noted that this is an emerging technology and is a popular topic of research; a class of adversarial examples that can be realized in the real physical world is already proposed. The net effect of such attacks affecting the functional safety can be precisely evaluated before deciding whether and how much countermeasure is considered appropriate or sufficient.

One proposed countermeasure for these problems is called adversarial training [132]. In essence, adversarial training tries to train an AI system with adversarial examples in an attempt to have the model encode knowledge about the expected output of such an attack. A next natural avenue of action is to attempt to remove the artificially introduced perturbations. Examples of this approach include:

— High-level Representation Guided Denoiser introduced by Reference [56];

— MagNet, which aims to detect adversarial examples and revert them to benign data using a reformer network [57];

— Defence-GAN, employing a generative adversarial network [58].

It is worth mentioning that scenarios exist where both MagNet and Defence-GAN can fail, see Reference [59].

Furthermore, noting that the model types typically affected by adversarial attacks are in general robust against noise, several authors propose randomization schemes to modify the input and increase

robustness against malicious, targeted noise. Approaches include random resizing and padding [60], Random Self-Ensembles [61] and various input transformations such as Joint Photographic Experts Group (JPEG) compression or modifications of image bit depth [62]. While these methods can be effective, recent results show that these transformations are not sufficient measures under all circumstances. In turn, if input transformations are used as a layer of defence against adversarial examples, the efficiency of said protective measures can be evaluated against examples generated using the expectation over transformation (EOT) algorithm presented in Reference [63].

Goodfellow et al. argue that the use of models employing nonlinear components makes them less susceptible to adversarial examples of attack at the cost of increased computational resources [54]. The problem of examining and augmenting the optimisation methods using during training is addressed in Reference [50]. Model ensembles are often applied in order to create a more robust overall model through diversification. However, there are also results in the literature that show that diversification can possibly not sufficiently harden the system against adversarial examples, see Reference [55].

8.6 AI hardware issues

Clearly, AI technology cannot by itself make decisions; it relies on algorithms, software implementing the algorithms and hardware executing the algorithms. Faults in the hardware can violate the correct execution of an algorithm by violating its control flow, causing memory-based errors, interfering with data inputs (such as sensor signals) and generally cause erroneous results or violating the results in a direct way by damaged outputs. This Clause describes some hardware aspects when using AI technology that can affect functional safety. As a short summary, reliable hardware is as important in AI systems as in non-AI systems.

Like hardware used to execute non-AI software, the hardware used to execute AI technology can also suffer from random hardware failure. A list of relevant fault models can be found in International Standards such as IEC 61508-2 [17] and ISO 26262-11 [14].

8.7 The readiness of the technology

Technological maturity describes how mature and error-free a particular technology is in a particular application context. Less mature and new technologies used in the development of an AI system can introduce risks that are unknown or difficult to assess. For mature technologies, a greater variety of experience data are usually available, making risks easier to identify, assess and address. However, mature technologies come with a danger of decreasing awareness of their potential effect on risk over time, so that the positive effects depend on continuous risk monitoring, as well as appropriate awareness training and maintenance.

9 Verification and validation techniques

9.1 Introduction

This Clause describes the difference between verification and validation techniques in AI systems and in non-AI systems, as well as some considerations for solving or mitigating problems arising from these differences applicable to functional safety. This Clause addresses four significant aspects of such differences, although potential differences are not limited to those described in this Clause (see Reference [136] for additional examples). ISO/IEC TR 29119-11:2020 [152], Clauses 7 to 9, are also worthy of consideration.

This Clause focusses particularly on data-driven models created e.g. by machine learning. Clause 7.2 describes this class of models as the main challenge for ensuring the functional safety of an AI system. This is because the functional safety of other types of AI technology can sometimes be achieved by applying the principles of existing functional safety International Standards, as discussed in Clause 7. The

technical content of this Clause is mainly intended to apply to Usage Levels from A1 to C of Class-II AI systems (see Table 1 of Clause 6.2).

When aiming for functionally safe systems containing AI technology created from data, it is taken into account that the AI technology is not constructed by rules as in non-AI developed systems. This means in particular:

— What is not in the data cannot be learned.

— What is in data can likely be learned, but not always perfectly.

Furthermore, just having data in most use cases is not sufficient. Labels are crucial when applying supervised learning techniques. Wrong or erroneous labels are one of primary causes for errors during the learning process. A thoroughly defined data engineering process applied in order to address these aspects.

NOTE The terms "validation" and "verification" can refer to different concepts among different technology areas or domains. In the context of machine learning technology, "validation" means a process step to check convergence of the developing model to terminate the AI training process, which is quite different from that in the verification and validation concepts in the functional safety community. Model convergence is an important precondition for testing, but it does not guarantee the quality of the final product. For example, the "reward hacking" problem arises from a model that is subjectively designed to maximise the given reward function. In this document, the terms verification and validation are almost exclusively used in the context of functional safety.

If the model is derived from a dataset, the content of this Clause is also useful for the training and validation datasets.

9.2 Problems related to verification and validation

9.2.1 Existence of an a priori specification

In the design and development of systems based on machine learning, specifications are often given as a set of data, rather than as a predefined definition of the system behaviour under different operational conditions as in Reference [135]. Although it is a benefit of machine learning that it can derive or acquire knowledge from poorly structured data, the lack of a predefined specification can cause a significant problem for verification and validation, as well as for the evaluation of the residual risk. See Reference [137] for wider discussion.

9.2.2 Non-understandability of particular system behaviour

In development of non-AI software for functional safety-related applications, it is implemented in the way that, for each risk that has been identified during HARA, mitigation in implementation corresponding to the risk can be clearly addressed and its role in maintaining functional safety explained. It is also important that each of such mitigations is designed not to have interference with other mitigations so that effectiveness of each mitigation can be verified, validated and evaluated separately.

On the other hand, many AI technologies can be considered as a "black box", as their internal behaviour and the basis of their decision-making processes are difficult for a human to understand. This means that if the training dataset contains some data that are intended to work as a mitigation for particular risk, its influence to the trained model cannot be certain, nor tested separately for each risk. Furthermore, if some additional training data is added for an additional mitigation, the data can affect existing measures for mitigation of other risks. This makes verification and validation of machine learning models more difficult.

9.2.3 Limitation of test coverage

Testing AI technology is difficult when compared to the process of testing non-AI software. When performing component-level testing on a non-AI software, tests are often designed from both "black box"

and "white box" considerations. In short, "black box" testing focuses on the structure of problem description and "white box" testing focuses on the structure of the implemented software. These concepts are not orthogonal in real world developments and some similarity or correspondence between these two structures is present. For example, boundary testing in "black box" testing implicitly assumes that the boundary (change point) of the behaviour of the implemented software reflects change points in the specification; consequently, testing the boundaries in the specification can often efficiently check the points of discontinuity in behaviour of the software. This assumption is not true for AI technology, because the information of such boundary conditions is not explicitly identified during training. This difference is given careful attention when testing any AI technology (especially those based on machine learning).

9.2.4 Non-predictable nature

As noted in Clause 8.4.1, AI system outputs are often said to be non-predictable or probabilistic in nature, although the algorithm itself can be deterministic. Mitigation can be approached through systematic application of the verification and validation process, with careful considerations for the nature of the AI system. Again, "explainable AI" can be a future solution, but process-supported solutions are more often available.

Further, the apparent non-predictable or probabilistic nature of AI technology, as well as other causes, such as discussed in Clause 9.2.3, decreases the effectiveness or applicability of non-AI testing techniques, especially white box based testing technologies. See ISO/IEC TR 29119-11:2020, Clause 9 for alternative solutions for white box based testing applicable for AI systems.

9.2.5 Long-term stability of risk mitigations

Another possible complication coming from the non-predictable nature can be long-term applicability of the output and lack of maintainability of the implemented system. Even if the problem is subject to systematic and comprehensive analysis of its behaviour in the operational environment, AI technology is derived from real world training data representative of a moment in time. If the real world changes, the ability to represent the correct behaviour can decrease (for example, due to data drift and concept drift – see Clauses 8.4.2 and 8.4.3). To overcome such drift, several methods for re-training and updating the model are proposed for most real world applications of AI systems.

Especially in applications involving functional safety, updating the software is a significant undertaking, with related assessments and procedures considered from the earliest stages of the system design.

9.3 Possible solutions

9.3.1 General

9.3.1.1 Directions for risk mitigation

Generally, there are at least two directions to realize reliable verification and validation of implementations generated from data (that is, machine learned model).

One direction, generally the more difficult, is to analyse the generated model to extract human-understandable knowledge of the model's expected behaviour. Theoretically, if the behaviour becomes completely human-explainable, these can then enable AI technology and systems to be treated as Class-I AI. This direction of approach is further discussed in Clause 9.4.

The other approach is to explain functional safety-related quality indirectly by analysing how the AI system is constructed during the development process. Although testing of machine learning-based AI is not always complete, additional analysis and assurance on the development processes and its inputs can mitigate the risks of unwanted behaviour systematically. The rest of Clause 9.3 is mainly focused on this approach.

9.3.1.2 AI metrics and safety verification and validation

In the context of usual AI developments, several metrics such as accuracy are used for the training process of machine learning algorithms. These metrics are essential for managing the progress of AI training, and can often be used in the AI "verification and validation" phase (meaning not the same as the term "validation" elsewhere in this document). Although better accuracy suggests better quality for functional safety-related applications, it is not generally enough for ensuring required functional safety properties. For example, an average accuracy metric only reflects the probability part of risks, not the value part of the risks. The mitigation proposed in this Clause is to be applied in parallel or in sequence to the evaluation using AI technology metrics, especially in data design, data preparation and testing phases.

9.3.2 Relation between data distributions and HARA

In the data-driven process of system developments for functional safety-related tasks, relationship between risks and data distribution is critically important. In safety-related systems, it is assumed that HARA is always taken beforehand. Then, the question is, for a given use case, whether an AI system is given sufficient training data and test data to develop a particular behaviour during the training phase. A logical understanding of the specific HARA activity is important in order to ensure the dataset is understood in relation to the outcome of HARA activity. This approach can be considered similar to that of non-AI safety-related software for which a set of risk mitigations has been identified.

Whether the initial specification is predefined, or derived from example data instances, the first priority is to define and bound the operational domain of the system as precisely as possible. The boundary can be defined either as an input data space or as a profile of real world usage. Establishing metrics for checking dataset and verification and validation activities are corresponding to the defined domain at an early stage of development is important to the relevance of the activities.

Hence, it is also important that logical analysis of the input data distribution is performed in addition to collection and learning from the given dataset. Such an analysis relates to the outcome of the HARA activity, so that data distribution points in the dataset are identified as corresponding to each identified risk—see, for example, ISO/IEC 5259 series [125], which highlights that data quality is key for AI technologies.

In addition, even if the input dataset is well-designed, there is no guarantee that the training process can derive the behaviour corresponding to each identified risk from the data distribution observations. Both systematic errors and random errors can occur during training, which can cause functional safety goal violations. While detecting such failures to the best degree possible is one of the intentions of testing activities in the verification and validation phase, a means of mitigating training errors is also important during the training phase.

9.3.3 Data preparation and model-level validation and verification

Given that the design target for training and test datasets is determined in relation with HARA results, the next step is to ensure that these datasets actually satisfy such determined criteria. This data requirement can be further divided into four important criteria:

a) Whether all functional safety relevant scenarios identified during HARA have corresponding data included in the given tests.
b) For each identified risk in a), whether the test data cover all reasonable variations of situations which cause such a risk.
c) For each risk-causing situation in b), whether the given test data have enough diversity and amount for supporting the outcome of training.
d) For each risk-causing situation in b), whether the test results by given test samples can be considered to be a stable test result for the set of possible inputs.

Any given test activities are expected to give answers for each of the four criteria. The following considerations are one possible set of answers for the criteria, applicable to any AI technology for which test data are attributed with clear, correct and expected answers ("test oracles"). In these examples, bias in the data is also considered, see Reference [10].

For a):

— Clearly specify the sets of data attributes corresponding to each identified risk in the HARA.

For b):

— For each identified set of data attributes for an identified risk, check the existence of the test data within test dataset.

— For the subset of test data extracted for each identified risk, check the distribution of other attributes and assess whether the data are unintentionally biased toward specific situations; for this purpose, existing technology for test designs for non-AI software (e.g. combinatorial testing) can be used. See ISO/IEC TR 29119-11:2020, Clause 8.1 and ISO/IEC/IEEE 29119-4 for further details.

— If it is suspected there is unintended bias in the dataset, consider collection of additional test data; in some cases synthesis of test data from simulations can be a solution, if sufficient diversity, representativity and coverage cannot be obtained from real data. See ISO/IEC TR 29119-11:2010, Clause 8.4 for some examples. The developer can also remove real data to rebalance the dataset.

For c):

— For diversity that can be addressed by existing attribute values, the mitigations identified in bullet 2) can be used.

— Furthermore, assess the data collection and preparation processes so that any unwanted bias is not likely to be included in the test dataset; see ISO/IEC TR 24027 [10].

— The amount of test data are determined from the intended probability of risk mitigation (derived from the HARA) and the amount of data needed for training (derived from monitoring the accuracy indicator for the subset of training data). In addition, complexity of the operational domain is better considered in order to mitigate data distribution shifts occurring by many uncontrolled factors (e.g. time, weather, location).

For d):

— Ensure that over-fitting to the training data can be detected within the development process. One way of achieving this is to ensure the independence between training data and test data, which can be enforced through development process management and assessment, tool-based approaches, or even using a level of independence in the teams or organizations carrying out the testing (see IEC 61508-1 [16], Clause 8 or of BS EN 50128 [23], Clause 5). Cross-validation, which is a method for evaluating machine learning models by training several other machine learning models on subsets of the available input dataset and then cross-correlating between them on the subset of the dataset. Several methods are available, see Reference [82].

— Ensure that trained models have sufficient robustness in terms of the given problem, using the following approaches:

  — generating multiple models of different sizes, using smaller models so long as other objectives are met (large models can lead to excess sensitivity);

— applying a technology that improves robustness, (e.g. regularisation or randomized training);

— numerically and directly evaluating the robustness, (e.g. using safe radius [84]—this is an emerging discipline).

— Search for possible data that affect stability: (e.g. metamorphic testing [85], data augmentation [86], generative adversarial networks [87], adversarial training [88], adversarial example generation [89] or adversarial example detection [90]).

— Ensure that the training dataset and test dataset are free of malicious modifications or alterations; this entails reviewing the credibility of data source or data collection processes.

There are several references available for proposing some concrete technologies and techniques representing these criteria. Annex C gives some examples for applicable procedures and techniques.

The costs for implementing these mitigations can vary considerably on the depth of investigations e.g. on used levels of combination in b), and chosen technology. It is appropriate to plan verification and validation according to the required level of functional safety and other application criteria.

9.3.4 Choice of AI metrics

The performance and KPIs of a system containing AI technology can be thoroughly evaluated. In the area of machine learning often single metrics are used to achieve that goal. While metrics are essential, the following coherences can be considered:

— The significance and trustworthiness of a metric is connected to the amount of data available for training, validation and testing—the amount of data has a bearing on how much trust can be placed in a metric with a defined confidence level (e.g. 95 %) based on n executed test cases.

— Metrics reduce information – such a reduction of information can cover safety issues. Various metrics can be used to cover dedicated aspects such as e.g. safety related misclassifications to assess the targeted performance or KPIs.

— Field monitoring is applied to evaluate whether the performance and KPIs still can be kept in the operational phase – intervening actions is taken in case those assumptions cannot be met.

— Metrics are not typically the only measure to assess the safety of a system containing AI but only one aspect.

ISO/IEC TR 24029-1 [153] separates the robustness assessment into 3 core categories: statistical, formal and empirical-based tests

9.3.5 System-level testing

In complex systems using AI technology as a partial component, system-level testing is an important complement to verification and validation at the detailed level. Some of the criteria described in Clause 9.3.3 e.g. criteria b), are also applicable for system-level testing. System-level testing can be either data-based or scenario-based (e.g. running a test vehicle in test fields with simulated risks). System-level testing can be carried out in simulations, as a digital twin, or in the real world application. Real world testing is expensive and not always possible (due in part to risks to safety) but it is useful for validating KPIs and unveiling unidentified hazardous unknowns to mitigate against incomplete HARA. Simulation is useful for exploring large numbers of scenarios in both software-in-the-loop and hardware-in-the-loop settings. The quality and realism of simulators is important for achieving good verification and validation results. See Clause 9.4.2 and 9.4.3 for more descriptions.

9.3.6 Mitigating techniques for data-size limitation

Preparing sufficiently large test oracles to test all outcomes is infeasible within development lifecycles. Back-to-back testing, as described by ISO/IEC TR 29119-11:2020, Clause 8.2, can be used to annotate test oracles with the expected answers. The extent of independence between the different versions of the system to be tested is assessed carefully. Back-to-back testing with AI technology generated from the same source of training data can likely fail to address criteria a) and b).

Another solution, where a large test oracle can be used to address the full range of operation, is to use simulation as a test data generator.

For some AI systems it is difficult for engineers to construct a reliable test oracle (e.g. AI systems constructed using reinforced learning with "AI-versus-AI" competitions; i.e. Generative Adversarial Network). The general conditions for testing in these cases are similar; however, additional criteria for reliability of tests can apply. For example, well-tested alternative implementations can be used to undertake back-to-back testing. Alternatively, a design change can be implemented to separate any risks from influence from the model-driven AI technology, effectively converting to Usage Level C as described in Clause 6.2.

9.3.7 Notes and additional resources

— See ISO/IEC TR 29119:2020, Clause 9 for alternative solutions for white box based testing applicable for AI systems.

— The training data is a significant part of the specification, but the loss function is also important. There are also approaches that require all domain-specific knowledge to be encoded during the training.

9.4 Virtual and physical testing

9.4.1 General

Functional safety approaches for AI technology tend to focus on elements of the AI system that can be shown to assure functional safety attributes, for example functional safety or rule monitors that can override the primary control system to inhibit unsafe action. An effective and objective way to demonstrate a system's performance is via virtual testing or simulation, where a curated set of well-chosen stress-test scenarios can be exercised during the qualification and certification activities. Individual components can be tested, as well as multiple components at a system level. Such approaches can use constrained random selection of scenario parameter values, scenario testing based on parameter distribution or importance sampling when constructing the scenarios to be tested (see ISO 21448:— [7], Clause C.5).

Physical tests also have their place as a tangible way to correlate simulation results, validate KPIs and uncover unknown unknowns. Physical tests are far more limited than simulation in their ability to probe the domain space due to cost and time limitations but do test some aspects that are difficult to emulate in a simulation, for example, the effect of hardware delays on feedback loops and cascade effects. Structured tests can take place in which tests are set up for known scenarios, such as on a test track for automated vehicle applications.

9.4.2 Considerations on virtual testing

The use of simulation for testing has long been an integral part of functional safety. Established methods such as timing simulation and fault injection have direct extension to AI systems, and their use is encouraged. For the complex, high dimensional models featured in many AI solutions (such as neural networks for perception or decision-making tasks), simulation offers many additional benefits:

— For certain applications, simulation can provide more complete test coverage than real world testing. Examples include scenarios where real world testing is dangerous or prohibitively expensive to conduct at large scale over the possible input space. For models with high dimensional inputs, simulation can be used to automate over the input space and produce correlated results in ways infeasible by traditional testing.

— Simulation can greatly speed up development time, allowing greater access to functional safety products and updates. Newly discovered hazards can be incorporated into the functional safety solution with much improved turnaround time. For highly complex environments, this reduced latency in the development and update cycle can be critical.

— Simulation can provide multiple entry points for fault injection. Faults can be introduced at the system, component or subcomponent level, and they can be introduced in combinations that can be inaccessible by real world testing.

— Simulation can provide accurate ground truth, which negates the potential of systematic errors induced by real world measurements and setup.

— Simulation environments can be well-controlled and can track all metadata associated with a particular test. This can prevent any random bias introduced in a real test, or loss of relevant metadata.

The following items are worthy of consideration when introducing simulation or in general virtual testing as part of the verification and validation process of AI technology in functional safety systems.

— Fidelity of simulation. Consider the underlying models, toolchain, simplifications, assumptions. A risk assessment of the simulation environment addresses the implications of inaccuracies, imprecision or incompleteness of the simulation environment. Evidence can be used to support the claims of the simulation output, such as a simulation to real world correlation. For example, a simulator used to justify a functional safety component used for perception can include arguments about the realistic rendering of the scene, metrics to correlate the two, indistinguishableness by human observers, etc. See Clause 9.4.3 for more discussion.

— Type of simulation. No one virtual testing tool can be used to test all aspects of an AI system. This is why multiple tools sometimes are used to develop confidence in the functional safety of the full AI system. A virtual testing toolchain can include the following tools: Model-in-the-Loop (MiL), Software-in-the-Loop (SiL), Hardware-in-the-Loop (HiL).

— Test-coverage approach. Approaches can include random test sampling, constrained test sampling based on certain justification of the input space, distribution-based test sampling based on a user profile, criticality or importance test sampling based on functional safety analysis, stress-based sampling based on edge cases or expected conditions that can stress the system, etc (see ISO 21448:—[7], Clause C.5). For multi-dimensional inputs, this can also address what combination of factors are tested.

— Test coverage size. What amount of simulation is sufficient to justify the functional safety argument.

Before virtual testing tools can be used to validate or approve an AI system, the toolchain itself is verified and validated. Confidence in a virtual testing toolchain can be achieved by assessing four key attributes:

— Fit for Purpose: how suitable are the tools for the AI system assessment. A clear description of the test objective and a definition of all boundary conditions of the AI system is provided. The operating environment is analysed and described to derive the requirements for the individual simulation models. The complexity and level of detail for each model can vary depending on the relevance, significance and range of each factor. For example, if the operating environment excludes night operation, then the sensor models is not validated against low-light conditions.

— Capability: what the virtual tests can do, and what are the risks associated. This involves defining assumptions, limitations and fidelity levels of the toolchain, ways to assess the fidelity (KPIs), and reasonable tolerance for the KPIs. It provides justification that the tolerance for simulation to real

world correlation is acceptable for the test objective. Note that the chosen fidelity level for the models and the assumptions made play a major role in defining the limitations of the toolchain.

— Correctness (verification): how sound and robust are tools' data and algorithms. This looks into the implementation of the conceptual or mathematical models building up the toolchain. This verification provides assurance that the toolchain does not exhibit unrealistic behaviour for a set of inputs that cannot be tested during the validation phase. The procedure is grounded on a multi-step approach that can include code verification, calculation verification and sensitivity analysis.

— Accuracy (validation): how well do the virtual tests reproduce the target data. This includes generating data that can be used to demonstrate the accuracy of the virtual testing tools with respect to the real world. Toolchain validation consists of 4 main steps. The exact methodology depends on the structure and purpose of the toolchain. The validation can consist of one or more of the following:

  — Validate Subsystem models e.g. environment model (infrastructure, weather conditions, user interaction), sensor models (RADAR, Camera, Light Detection and Ranging (LIDAR)), chassis model (actuation, powertrain);

  — Validate chassis system (chassis model together with the environment model);

  — Validate sensor system (sensor model together with the environment model);

  — Validate integrated system (sensor model plus environment model with influences from chassis model).

Applying the same scenarios across all tool levels (MiL, SiL and HiL) allows effective validation of the system without requiring an impossible number of physical tests to be carried out.

The usage of virtual testing tools can depend on the virtual validation and verification strategies implemented during their development. Therefore, the simulation design and the toolchain is not typically standardized but rather explained and reviewed during the certification process. In addition, simulation toolchains can contain intellectual property and therefore are left technology neutral.

Therefore, the overall assessment of a virtual testing toolchain requires a unified method to investigate these properties and gain confidence in the data generated by the tools. It is important that simulation models and the simulation tools used in the overall toolchain are investigated in terms of their impact in case of a safety error in the final product. The proposed approach for criticality analysis can be derived from IEC 61508-3 or ISO 26262-8, which requires qualification for some of the tools used in the development process.

9.4.3 Considerations on physical testing

Physical testing has a complementary role to simulation testing. Testing the system in a real world environment, or final operating environment, can provide the highest fidelity of real use validation. For real world testing, some additional considerations include:

— Use of structured tests, setting up known scenarios, or use case tests. Examples include test track cases for autonomous vehicle applications, or defined scenes for sensor perception tasks. Such tests can be well specified and provide controlled measurements that can be tracked and compared over time. Structured tests can be derived from many different inputs, such as safety, technology and product level analysis. A comprehensive test plan requires good understanding of the final application.

— Combination of real world testing with simulation. Physical tests are far more limited than simulation in their ability to probe the input domain space due to cost and time limitations, but provide the highest real use fidelity and automatically capture random phenomena that cannot or are not able to be modelled in simulation. In contrast to structured tests, which typically test "known knowns", both real and simulated testing can uncover different types of "known unknowns".

— Correspondence of real world testing to simulation. Real world tests can be used to validate the models used in simulated tests.

— Continuous testing and feedback. Real world testing can also uncover "unknown unknowns" over time. Once an AI system is approved and in operation, its own incident statistics can provide ongoing evidence of safety performance. Reported incidents can provide information to continuously advance the qualification simulation scenario suite. However, for the core functions where inductive or deductive absolute proof is not possible, then acceptable failure rates are derived from system failure rate goals and justified. If this is demonstrated empirically, the test methodology and results are recorded. Plans for continuous improvement, incident tracking and feedback mechanisms, are included as part of the safety planning stage.

— Operational design domain or Real world Usage Profile. The boundaries of operation are defined, and can include limits of use, environmental limits, location and temporal limits, and responsibilities between the system and users, and if appropriate, other systems. Testing parallels the defined operation, with metrics to show coverage of the design domain (this applies to both simulation and real world testing).

— Statistical significance. Test procedures and results are derived from sound statistical principles. For example, a final on-site validation test of a safety stopping function is carried out multiple times and relevant parameters fall within a predefined limit based on statistical analysis. In contrast, verification tests of a perception function for human detection can be carried out on a large test database, with size and coverage determined from target failure rates and confidence intervals.

9.4.4 Evaluation of vulnerability to hardware random failures

Certain features regarding testing of AI technology are known. For example, it has been shown that vulnerability of deep neural networks to soft errors is low (see References [25], [83]). Evaluation of the fraction of failures leading to safe behaviour (as opposed to unsafe behaviour), is useful for certain types of networks. Possible methods include fault injection on weights as a proxy for faults in underlying hardware. For example, it is possible to analyse classification models to determine with confidence the only vulnerable parts of the AI technology with respect to soft errors (see References [26], [78]).

9.5 Monitoring and incident feedback

Once an AI system is approved and in operation, its own incident statistics can be used to provide ongoing evidence of safety performance. Reported incidents can be used to feedback information on which to continuously enhance the scenario suite used during the testing activities. However, for the core functions where inductive or deductive absolute proof is not possible, acceptable failure rate targets are derived from system failure rate goals, together with suitable justifications to substantiate the functional safety. If this is demonstrated empirically, the test methodology and results can also be recorded.

Operational design domain and real world usage profiles can be used to define and bound the problem scope, creating metrics for coverage of testing (both simulated and real).

Statistical significance considerations derive test dataset size and test coverage from target failure rates and confidence intervals, providing guidance for acceptable confidence levels.

9.6 A note on explainable AI

A type of evolving AI technology, known as "Explainable AI", aims to provide important factors influencing a decision in a way that humans can understand (see ISO/IEC 22989). Sufficiently explainable AI technology, if successfully realized, can be able to provide factors that enables developers to understand its decision-making algorithms and can pave the way for assurance of functional safety of machine-learnt algorithms in a similar way to current functional safety International Standards. Alternatively, some knowledge can sometimes be extracted from models generated by human and then a similar behaviour can be implemented as non-AI software through typical programming processes.

It is possible that a midpoint exists between the data-driven and explainable approaches. Although it is currently impractical to enforce sufficient explanation of decision-making for every class-II AI system development, there are some currently achievable approaches to interpretability or explainability of the model structure, which can possibly help in the verification and audit processes. For example, heat maps on the internal nodes contributing to specific decisions can be useful for understanding the causes of decisions [96]. Such techniques, sometimes called "grey box" approaches, are useful for the understanding of the behaviour of an AI system, especially when it differs in its decision-making from the implementors' intentions. In these cases, careful consideration is needed when the meaning of the extracted explanation is inconsistent with functional safety requirements. For example, an explanation extracted from some mid layers of DNN cannot be well-suited for safety purposes, because unexplained processes in the following layers can hinder the intended feature.

Refer to Clause 8.3 and ISO/IEC TR 24028:2020 [11] for further information on AI explainability.

10 Control and mitigation measures

10.1 Introduction

The failure of an AI system that can be tolerated by a robust architecture without loss of safety properties is preferable and the result of a good architecture not a method for improving AI quality. The architectural design principles for safe systems are not changed by machine learning (ML), though they impose new challenges in defining and guaranteeing their reliability properties and failure behaviours.

This Clause considers the methods of enhancement for ML models as components of AI systems and discusses how subsystems around them can be used to improve non-functional properties of reliability, availability and quality. Clause 10.2 describes AI subsystem architectural considerations, Clause 10.3 proposes methods to increase reliability of components while Clause 10.4 summarizes mitigation and control models. The failure mechanisms from Clause 8 have highlighted differentiating challenges for ML components and Clause 9 the through-life process of verifying and validating these components. Measures introduced in this Clause are directed by knowledge of these failure modes and are introduced as part of a robust ML process described in Clause 11.

10.2 AI subsystem architectural considerations

10.2.1 Introduction

Safety assessment at a system level can determine the appropriate subsystem reliability of a function incorporating ML components. The subsystem architecture can incorporate complementary technologies in assemblies to meet these demands. The existence of the following features of the problem drives different possible solutions:

a) Safe (suboptimal) back-up function to the ML component can be designed with "non-AI" techniques. This can be a failsafe null action. The back-up action allows the use of detection methods to switch the output when unsafe conditions are detected.

b) A safe subset of the action space can be determined (a priori or online) using a supervisor function with constraints or limits.

c) ML redundancy with output voters or aggregators can also be considered.

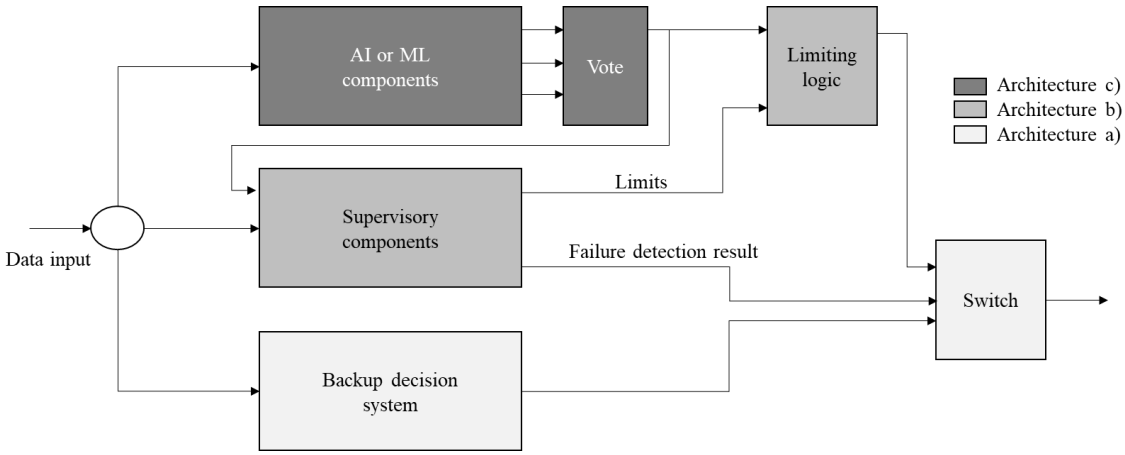


Figure 5 — Architectural patterns for systems using AI technology components

The inclusion of AI technology introduces specific challenges to each of these architectural options. Clause 10.2.1 describes how detection mechanisms for abnormal input, output or internal state (e.g. its neuron activation strength) can be used to identify situations of possible failure. Clause 10.2.2 describes how to use supervision functions using elements of control theory to minimally bound AI operation. Clause 10.2.3 shows different ways of establishing redundancy with AI technologies. Finally, Clause 10.2.5 discusses AI system design with statistical evaluation.

10.2.2 Detection mechanisms for switching

The architecture as given in Figure 5 is often denoted as passive (diverse) redundancy in fault-tolerant systems literature. For example, a supervisory monitor can detect when an AI technology is producing potentially unsafe actions, either due to internal or external faults. Following detection, an action can be taken to maintain the system in a safe state. The monitor can be developed using either non-AI technology or using AI technology. In the latter case, considerations of the level of independence between the monitor and the primary system can be used to justify the approach.

Acceptable behaviour of AI technology can be evaluated within the distribution of its training data (Figure 6, a). No knowledge of out-of-distribution (OOD) input data behaviour can typically be verified, and thus the behaviour can depend on the unknown generalization properties of the model. The distribution can depend on both the parameters in a single sample and their evolution in time (i.e. dynamics). Simple boundaries on acceptable inputs are not able to detect gaps in the training data, particularly for high dimensional systems. In absence of training data improvements, anomaly detection methods (see Reference [97]) can, in some cases, be selected based upon the data properties (dimensionality, linearity of parameter correlations, dynamics, seasonality drift, etc.) (see References [98] and [99]). However, adversarial methods have shown the extreme sensitivity of deep networks to small, seemingly random perturbations (e.g. misclassification of images by adding noise, making reliable input parsing challenging).

Adversarial examples detection checks, at runtime, whether incoming data are adversarial or not (References [100] and [101]).

Output monitoring can detect undesirable behaviour resulting from OOD or in-distribution input data. Monitoring against a known boundary (Figure 6, b) or alternative model, is well known in fault detection literature (e.g. statistical or model-based residual detection). Boundaries can be adaptive to the system input or state (Figure 6, c). For dynamic systems, the detection decision can also consider that a safe state is reachable by the switched in controller (i.e. inertia or instability do not prevent dangerous states being entered). Where the output distributions defy conventional modelling techniques, using ML to create a monitor can be required. One example is to train a (simpler) secondary network (in a student–teacher architecture) on the output generated by the ML model and use this with labelled data to predict confidence in the output [97].

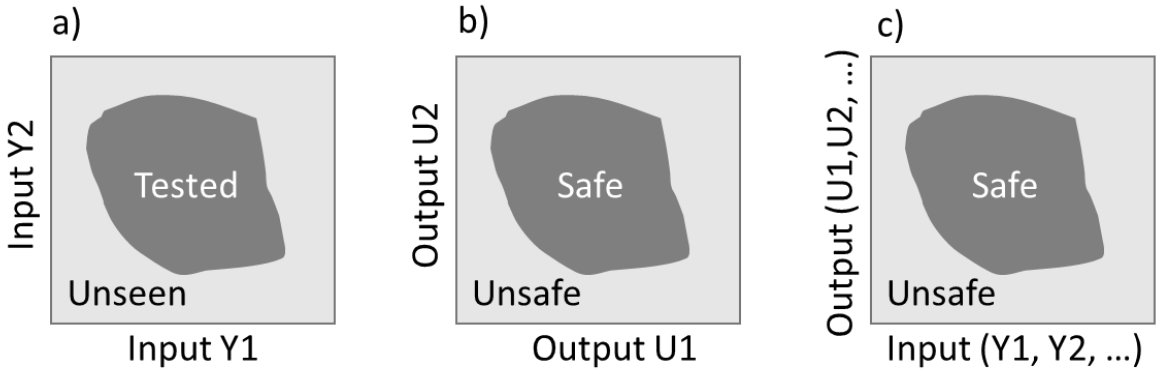


Figure 6 — Evaluation of acceptable behaviour of AI technology

Meta-information from the model can also be used, such as the internal neuron activations or by designing uncertainty measures into the network. Uncertainty measures in ML can be explicitly derived (Bayesian Neural Network) or approximated (dropout, ensembles, softmax output layer). Confidence of output (strength of activation) can be useful but requires careful calibration to a probability and is subject to risks. These risks include overconfidence (classifiers often fail silently by providing incorrect but confident outputs), not only at extremes or beyond bounds of training space but also to small perturbation of adversarial examples.

Four points are considered for development of monitors:

— the type of AI technology faults that can be detected;

— the ways in which AI technology faults can be revealed at runtime;

— the performance benchmarks of different runtime monitors;

— the types of intervention that can be used to circumvent a fault after detection and potential hazards invoked.

Examples related to machine learning are provided in Reference [75].

Uncertainty wrappers as described in Reference [139] that evaluate the quality of the decision can also be instrumented for either automated decision-making or as input for humans to decide if the AI system proposes valid decisions.

10.2.3 Use of a supervision function with constraints to control the behaviour of a system to within safe limits.

It is possible that an AI system can be constrained to work within a predefined safe envelope. Safe limits require that a subset of the action space (safe envelope) can be determined and are minimally restrictive on safe ML component behaviour. Simple limits on output can overly inhibit an ML component to mimic the limiter itself therefore negating the benefit. This subsystem architecture is sometime referred to as a safety cage, which enforces behaviour onto the subsystem.

For example, as shown in Figure 7 a), an AI system can be used as part of the Intelligent Control to provide an optimal decision. In this architecture, the non-AI safety function outputs acceptable range of outputs for a given input and limits the Intelligent Control output.

Constraining the output based on a function of input is not appropriate for systems with dynamics, where the system state (x) defines the unsafe regions but does not instantly respond to change in controller.

Formally, minimal bounds can be designed for dynamic and hybrid systems through control theory methods such as barrier functions approaches (Reference [102]), which determine an invariant set under the control of the non-AI system, see Figure 7 b). These approaches can guarantee that the system does not exceed an operating region deemed safe for some limited worst-case control input (the subset *u* of all possible control signals *U*). These sets are typically conservative as they do not actively look to recover a system back towards safer regions, thus control barrier functions can also be used as detection mechanisms to switch in conventional stabilizing controls (producing control signal *u**, if they are available with suitable AI monitoring, as described in Clause 10.2.1). For systems with particularly complex safety requirements, for example multichannel measuring systems that use AI technology, checking functions such as metrological self-check or self-validation can be considered, see Reference [71].

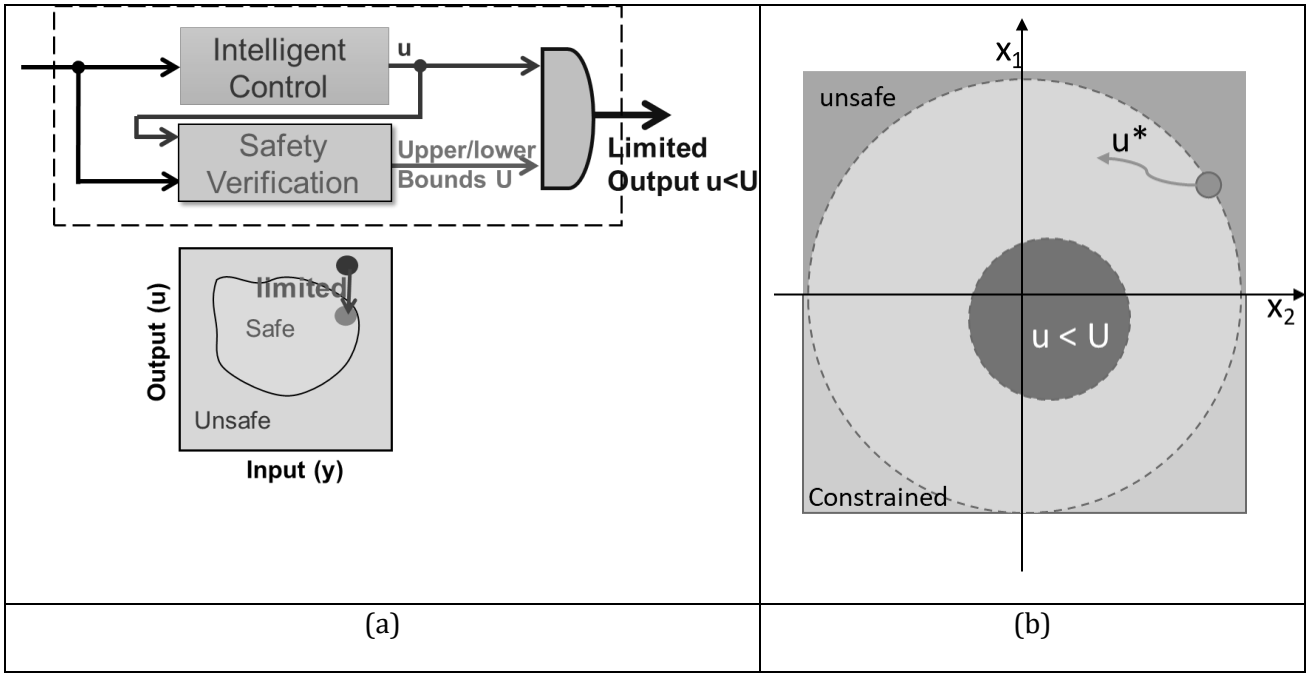


Figure 7 — Safer application of AI technology to control: a) through supervisory constraints on discrete outputs. Or b) on continuous control output through barrier certificates

10.2.4 Redundancy, ensemble concepts and diversity

Redundancy can be of different types: structural (spatial), temporal (frequency), functional (informational), or combined. When using neural networks for example, redundancies for AI technologies include:

— Using analytical redundancy (see Reference [64]): Quantitative model-based failure detection and isolation (FDI) methods rely on the comparison of a system's available measurements, with a-priori information represented by the system's mathematical model. There are two main trends of this approach, namely analytical redundancy or residual-generation methods and parameter estimation.

— Time-redundant multiple computation (see Reference [65]): For example, concurrent error correction can be achieved by using time redundancy based on recomputing with triplication with voting (RETWV).

— N-version programming (see Reference [66]): In this method, several simplex models are trained independently, such that these models are unlikely to produce erroneous results for the same test cases. In this way, it is possible to design a fault-tolerant system whose output is determined by all these models cooperatively.

— Using redundant deep architectures (see Reference [67]).

— The ensemble use of neural networks to build reliable classifiers (see Reference [68]): The idea is to combine several "weak" classifiers to obtain a "strong" one, so that the classifier can still work reliably if one of its members fails.

— Use of algorithm-based fault tolerance for neural networks (see Reference [69]).

Methods of metrological self-check (including self-validation, self-diagnosis) that have found application in control systems for critical equipment, such as References [70]–[74], can be also considered and adapted for use with AI technology.

For higher effectiveness, redundancy is combined with diversity to reduce the likelihood of systematic failures during development. This is related to multiple AI technologies exhibiting the same behaviour, but implemented:

— by different teams;

— using separate labelling rules;

— using different problem formulations;

— using different training data;

— executing on diverse hardware (also valid for non-AI technology specific failure modes);

— with diversity of sensing;

— with diversity of self-check or self-validation methods;

— with diversity of AI technology itself.

Due to its complex and indefinite nature, diversity can be expressed by a multitude of metrics. It is important to evaluate these metrics carefully to answer the following basic questions: to what extent can AI technologies with the same training conditions differ in their performance and robustness? And are diversity metrics suitable for selecting members to form a more robust ensemble?

Another possible approach is to identify and eliminate false detections by comparing key point decisions from different neural networks [76]. This form of diverse comparison is often combined with monitoring (see Reference [77]).

When relying on redundancy as part of a safety argument and considering the explainability of DNNs it can be possible to rely on an analytical argument for freedom from common cause failures. In this case it can be relevant to base the argument on verification and validation and demonstrate through simulation the absence of common cause failures between redundant networks.

10.2.5 AI system design with statistical evaluation

AI technology is normally characterised using probabilistic measures, therefore it can be considered predictable in a statistical sense for the given test data. Note that this predictive behaviour is not a deterministic behaviour, but a statistically predictable behaviour. For a specific application under specified operating conditions, a system containing AI technology can be evaluated for functional safety with consideration of the statistical distribution of its output. A key assumption is that these statistics rely on the distribution of testing data being sufficiently similar to the production data.

An assessment approach can then be based on the following steps:

— Analysing the AI technology, e.g. the ML model.

— Treat the AI system as a normal mathematical model, but only with probabilistic behaviour.

Example of a model can be found e.g. in Reference [2]. The more flexible the model, the more complicated its analysis can be. An example of a comparable analysis can be found in Reference [24].

The use of this statistical information needs careful consideration in the justification especially for Class II and Class III AI technologies.

10.3 Increase of the reliability of components containing AI technology.

10.3.1 Introduction to AI component methods

As a complement to architectural considerations in Clause 10.2, this Clause identifies AI supporting technologies to increase the reliability of trained systems when deployed. Clause 10.3.2 provides examples of methods that make AI technology less sensitive to intended and unintended input data perturbations. Simplification of trained networks is proposed as a class of methods to remove dormant or unused element of a network in Clause 10.3.3 while Clause 10.3.4 uses attention analysis methods to identify risks in the learnt structures. Clause 10.3.5 describes the mechanisms to protect the input and model data during training and run-time.

10.3.2 Use of robust learning

To improve robustness against disturbances of noises, device failures and possibly malicious (adversarial) inputs, several methods can be used at both testing and learning stages. Possibly applicable techniques include:

— Regularization is a methodology to mitigate the over-fitting problem, and thus to improve stability. This technique can be considered as analogous to the methods used in regression fitting, where the weight magnitude or non-zero values in the training loss function is penalised or given a prior distribution. This is generally preferred to post training pruning of low valued weights. Alternative methods include structuring the network to share weights on node connections e.g. on repeated filter elements in a convolutional neural network (CNN), i.e. to simplify the structure of the model. Dropout is often considered good practice to reduce overfitting in DNNs, at the cost of an additional "dropout rate" hyperparameter. This technique randomly turns off parts of the network for a small proportion of training. Since the network cannot exclusively rely on a single node to model a particular data feature, the dropped-out regions do not overspecialise. See References [80], [103], [104].

— When the AI system disturbances are predictable (e.g. for hardware errors), fault-aware training that includes error modelling during neural network training, to make neural networks resilient to specific fault models on the device (see Reference [81]). Adversarials are not predictable, however.

— Adversarially robust training is a learning method that minimises or limits the worst-case error under the training data augmented by a model of an attacker's possible perturbations. The simultaneous maximisation of adversarial perturbation effect and minimisation of error leads to the extension of standard gradient descent training algorithms, (see Reference [105]. Other approaches can provide robustness guarantees for output invariance, e.g. formally proving that no change in classification can occur when perturbations are within given bounds. See Reference [106]. However, scaling these guarantees to large scale and heterogenous networks remains a challenge.

— Randomization approaches, such as randomized smoothing, provides efficient equivalent to multiple

modes all trained with the augmentation of data with randomized noise, so as to calculate the final result value to be a mean with respect to the noise distribution. See Reference [107].

— Robustness to out of distribution input is also important for applications subject to limited training data or data drift or concept drift. Data augmentation and enrichment reduces the distances that the AI system needs to extrapolate from training data. For example, higher performance is obtained if images are translated and rotated in the training data. This richer learning often has the complementary effect of increasing robustness. See Reference [108].

10.3.3 Optimisation and compression technologies

Optimisation and compression technologies, such as quantisation of parameters and computations (i.e. reduction of parameter bandwidth), pruning (i.e. removal of less important parameters from the model) and knowledge distillation to simpler surrogate models have their origin in achieving hardware-specific compute acceleration (i.e. by using more efficient hardware technology), can provide secondary benefits to the system. As with all modifications to a system, the risks in performance loss are carefully analysed. See References [133], [134].

The low dimensional embedding of the training data into a lower dimensional as an integral part of modern deep networks is often preferred to more non-AI techniques (linear and non-linear principal components, clustering, feature extraction, etc.). The risk of discarding information by non-AI techniques is traded off against the complexity of the ML solution.

Simplified models have a reduced dimensionality of weights and (perhaps) inputs can make training easier and can reduce the risk of non-convexity in the loss landscape. As well as capacity for convergence improvements, reduced network dimensions intuitively make interpretability more tractable. However, the dimension can still certainly exceed the capacity to understand the function of each parameter in relation to its contribution to requirement satisfaction (i.e. its traceability). Emerging visualization methods have shown promise, particularly for image classification, but completeness is not yet proven (see Reference [110]). Modularising the network is another pragmatic way to help understand its traceability and ease verification (including potential to make formal verification approaches computationally feasible).

Knowledge distillation was originally designed to create simpler surrogates and more computationally tractable models. The concept produces a secondary simpler model trained on the output of larger model rather than on training data. The potential for the complex model to create a lower dimensional embedding than the raw data has been shown to allow increased performance with interpretable linear models. Non-linear secondary models can contribute less to interpretability but can aid in smoothing gradients. Smoother gradients can provide gradient masking protection against adversarial attacks, making the change in output smaller for a given input perturbation. This is achieved by creating probabilistic labels in a first training path with the complex model and then retaining a simpler model with these ”non-crisp” probabilistic labels (see Reference [109]).

Network neuron pruning can defend against training-time attacks by post-training analysis of the neuron activation with clean inputs, iteratively removing those that have low activation and retesting. This reduces the risk of operational discovery of unwanted behaviours. Of course, a sophisticated attacker can design a network with neurons sensitive to both clean and poisoned data thus ensuring they are not pruned. Data protection is thus also suitable to address these challenges (see Clause 10.3.5).

10.3.4 Attention mechanisms

There are several considerations on attention mechanisms:

— Attention mechanism to learn global context: The attention mechanism (see Reference [111]) is aiming to improve the prediction performance in sequence-to-sequence models such as language translation models, speech-to-text converters and image captioning models. The attention mechanism learns the relationship between a sequence of features (e.g. words in a sentence) using a weighted combination of all encoded input vectors. Similarly, in machine vision applications, attention weights can learn a global weighting over the entire image to solve more complex tasks such as image captioning (see Reference [112]) in which convolution layers are not capable. Later, Image transformers (see Reference [113]) have been proposed to capture the context in images without any sequential data (e.g. text) available for training. Lastly, the attention mechanism is being used as a suitable solution for training models on multi-domain data especially combinations of sequential and spatial data.

— Post-hoc attention maps for sanity checking and feature manipulation: Attention map (also known as saliency map or sensitivity map) is a common type of machine learning explanation to point out the most important feature in a given prediction. Attention map is a type of local explanation that is limited to individual model predictions, regardless of overall model behaviour, but still suitable for investigating the edge cases for model debugging. Attention maps can be obtained in different ways such as local approximation of deep models (see References [114], [115], [116]) using shallow interpretable models. To generate saliency maps for DNNs, various gradient-based methods (see References [118], [119]), convolution-based (see References [120], [121]), deconvolution and perturbation-based (see Reference [122]) methods have been proposed. Note that attention map explanations can be either post-hoc or integrated with the network (see Reference [123]).

— Benefits of attention maps: Reviewing machine learning explanations has benefits for designers to improve a given model in multiple stages of the machine learning lifecycle. For example, identifying issues in model structure (see Reference [122]), features engineering (see References [116], [117]) and training data improvement. Additionally, assuming that model explanations are consistent with the end-user reasoning and understanding of data, human review of attention maps for building an appropriate level of trust to autonomous systems.

— Trainable attention: Trainable attention mechanisms have attention weights that are learned during training to improve attention efficiency. For example, Reference [114] uses a multiple attention-estimator module for different network layers to encourage more refined attention maps and higher prediction performance. Explicit human supervision (e.g. gaze tracking) for attention models has been also experimented in Reference [115] but carries high data annotation costs.

— Explanations truthfulness: Since model explanations are always incomplete estimation of the black box models, the correctness and completeness of explanations is greatly influenced by factors like the heuristic technique, input example, and training data size and quality. For example, model overfitting (i.e. a statistical model that contains more parameters than can be justified by the data) can be reduced as the training data size increases.

10.3.5 Protection of the data and parameters

Data and model parameters are potentially vulnerable to random and intentional disturbances and loss, with causes from hardware failure to data poisoning in adversarial attacks. As with all data used in a system the use of data risk assessment and management processes (Clause 11) can help to drive the protection measures used with consideration for particular challenges associated with data-intensive AI technology (e.g. volume, variety, velocity, variability).

Information assurance of data used for machine learning follows guidance from bodies such as National Institute of Standards and Technology (see for example Reference [140]). Configuration control of data is maintained throughout model lifecycle, including provenance, access rights and quality metrics of the data. A configuration process similar to ISO 26262-6:2018 [13], Annex C can be used. Data information assurance at run-time and offline training needs to consider a multitude of properties (integrity,

completeness, accuracy, resolution, etc.), see Reference [141], Section 6.4, which also suggests measures to maintain these properties.

In addition to data control measures, pre-processing of the input data stream to remove unfeasible inputs patterns is a sensible precaution, e.g. filters transparent to physical system bandwidth to remove adversarial noise, complement detection mechanisms avoiding out-of-distribution data.

The high compute demands of ML can drive developers to use third party high-performance computing to train a model, where information assurance is a higher risk. It is not sufficient to only mitigate intellectual property leakage (e.g. encryption, obfuscation of labels and data distribution). Training data manipulation (poisoning) can be designed by an attacker to circumvent local testing, where the network behaves correctly on normal test data with dormant problems (e.g. neurons not activated by normal training). Complementing pruning techniques, the (light weight) retraining on a locally protected data source can help reduce the sensitivity to adversarial examples. See Reference [124].

11 Processes and methodologies

11.1 General

From a functional safety point of view, many lifecycle issues are common to AI systems and non-AI systems. These commonalities are described in Clause 11.2.

The level of functional safety a system needs to achieve is independent of whether AI technology is used or not. AI technologies can be used in some part of the system, but not the whole system. Other parts of the system can be built using non-AI software approaches. The methodology commonly used to develop AI models has inherent gaps from a functional safety International Standards requirement perspective. This can then lead to investigations in approaches to address these gaps.

To ensure functional safety, it is important to consider safety throughout the whole lifecycle of a system.

11.2 Relationship between AI lifecycle and functional safety lifecycle

Traditionally the term "lifecycle" has been used for several objectives. One objective is to provide a defined set of processes within a system or hardware or software lifecycle, as well as to facilitate communication amongst stakeholders of that lifecycle. ISO/IEC 22989 describes a high-level lifecycle model of AI systems while ISO/IEC 5338:—[5] [1] defines the lifecycle processes of AI systems. Software lifecycle processes are also described in Reference [4].

An additional objective is that achieved by the functional safety lifecycle described in the IEC 61508 series [16]-[19] and other functional safety International Standards. The objective in this case is to clarify what is to be achieved at each phase throughout the whole lifecycle to implement a certain level of functional safety. To this end the IEC 61508 series defines a functional safety lifecycle that includes a hazard and risk analysis phase and an overall functional safety requirements allocation phase described in the general requirements of IEC 61508-1 [16]. Additional specific requirements are given for hardware in IEC 61508-2 [17] and for software in IEC 61508-3 [18].

In this document the view is taken that it is reasonable, therefore, to start from a traditional functional safety lifecycle and to modify and adapt the functional safety lifecycle to take into account AI system-specific issues that affect functional safety. The hazard and risk analysis phase can be based on the IEC 61508 series or other functional safety International Standards, modified to address the AI specific particularities listed in ISO/IEC 5338 [1] as properties important for functional safety (see Clause 8).

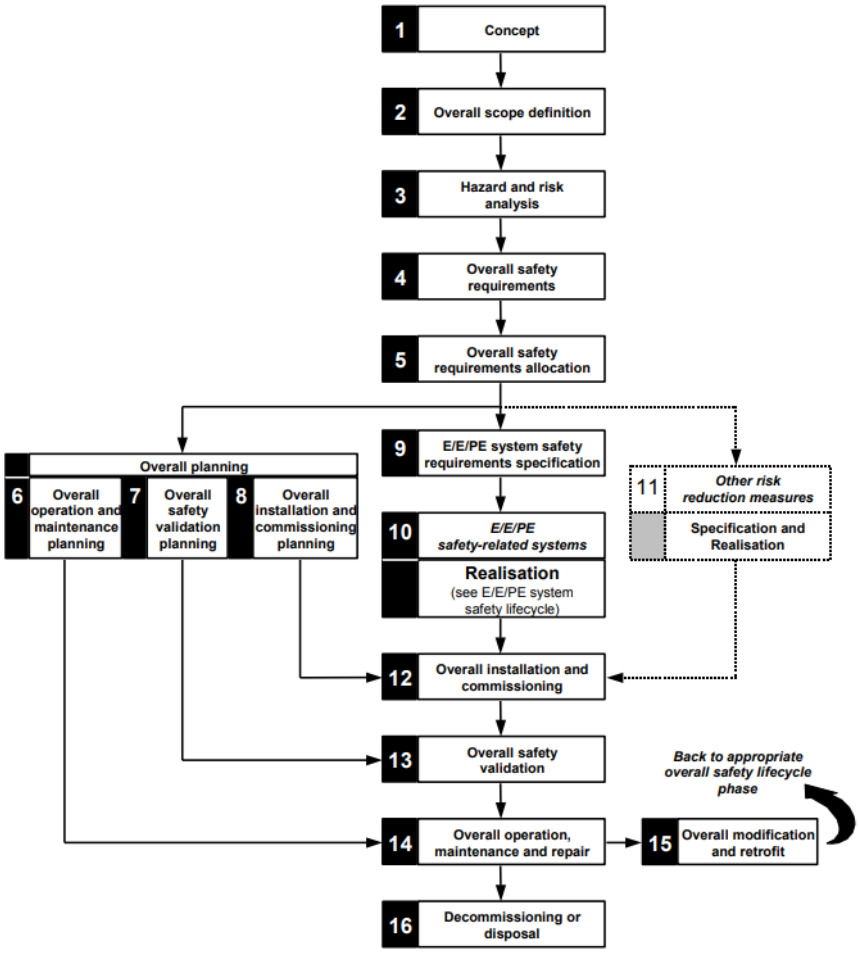
5 Under preparation. Stage at the time of publication: ISO/IEC CD 5338:2022.

The IEC 61508 series and other functional safety International Standards mention the V-model as the basis of the lifecycle, although certain International Standards (including the IEC 61508 series [16]-[19], [22] and IEC 61511 [20]) do recognize that the lifecycle can be tailored to the specific implementation technology.

A functional safety lifecycle for the development of an AI system is selected during functional safety planning (see Figure 8).

It is acceptable to tailor the V-model for incremental development models to fit with the AI-specific particularities for example as shown in ISO/IEC 5338 [1]. When performing iterative and incremental development (e.g. iterative learning cycles), regression validation is important.

Figure 8 — Lifecycle model taken from the IEC 61508-1:2010 Figure 2



11.3 AI phases

An example of mapping between ISO/IEC 5338 [1] and the IEC 61508 series is provided in Annex D.

11.4 Documentation and functional safety artefacts

Documenting sufficient information for each phase of the chosen system and software functional safety lifecycles contributes to subsequent phases and of verification activities.

Issues specific to AI systems include learning processes, data relevance and sufficient documentation of training, validation and test data.

11.5 Methodologies

11.5.1 Introduction

This Clause describes some of the most critical methodologies to be considered with respect to AI technologies.

11.5.2 Fault models

The concept of fault models is intended to enable systematic and possibly automated analysis of an elements´ behaviour in the presence of faults. The idea of fault models is to cover the many folded details of reality by a sufficiently high abstraction level. Especially in the area of machine learning it is crucial to raise fault awareness: fault models are a key for achieving that.

A fault model is a simplifying abstraction of real effects likely to cause errors that is intended to enable a systematic analysis. Often different effects are covered by one fault. In reality, fault propagation is quite complex, but frequently different chains of propagation lead to similar errors. Sometimes the fault model seems to be more pessimistic than reality, but often the reality is much more “creative” than a human brain can foresee.

When defined precisely enough the impact of faults can be simulated or analysed manually. This is essential to judge functional safety. By applying the fault model to all elements, the completeness with respect to the fault model abstraction level is ensured.

To create a fault model, a description and design, of the system with the corresponding elements is required. For each of these elements the failure modes are identified, e.g. by a guide work method such as the HAZOP.

For machine learning the following aspects are covered by fault models:

— Datasets used for training, validation and test;

— machine learning model;

— learning process;

— connection of the machine learning lifecycle with the safety lifecycle (also consider performing a Process FMEA).

Validation and verification aspects are discussed in Clause 9

11.5.3 PFMEA of offline training of AI technology

FMEA can be applied at the process level, the functional level or the element level, for example, it can be applied during the offline training of the AI technology.

Process FMEA (PFMEA) can be used to analyse and eliminate possible sources of bias and limitation within the offline training process. Additional methods of analysis can also be considered, such as classification FMEA (CFMEA), which is a technique specialized to assess classification-based perception (see Reference [79]).

Annex A
(informative)

Applicability of IEC 61508-3 to AI technology elements

A.1. Introduction

This Annex aims to provides an example on whether and how a proposed selection of the techniques and measures listed in IEC 61508-3:2010 [18] Annex A (and the relevant tables from Annex B of IEC 61508-3:2010, with the descriptions from Annexes B and C of IEC 61508-7 [22]) can be applied for the technology elements of an AI system that can be shown to be compliant to current functional safety International Standards.

NOTE With respect to the classification scheme described in Clause 6, this Annex applies to Class I AI technology elements, while Annex B applies for Class II elements.

A.2. Analysis of applicability of techniques and measures in IEC 61508-3:2010 Annexes A and B to AI technology elements

Tables A.1 to A.19 provide an approach to interpreting the IEC 61508-3 Annex B and Annex C Tables for the technology elements of an AI system that can be shown to be compliant to current functional safety International Standards.

NOTE In the Tables A.1-A.19, the "B.x.x.x", "C.x.x.x" references in the second column of each table (with header "Ref.") indicate detailed descriptions of techniques or measures given in Annexes B and C of IEC 61508-7 [22].

Table A.1 — Interpretation of Software safety requirements specification (Reference: IEC 61508-3 Table A.1)

Technique or Measure		Ref.	Interpretation for AI technology elements
1a	Semi-formal methods	Table A.17	There are several research papers working on this direction, see Reference [142]. Moreover, AADL [27] provides formal modelling and semantics. Its use for formal verification of certain system behaviours has been documented in literature, such as [29] and [30]. Regarding semi-formal methods for ML, just about every ML paper uses semi-formal methods to describe their architecture, in the form of block diagrams, layer descriptions and links and input flow behaviour.
1b	Formal methods	B.2.2, C.2.4	

	Technique or Measure	Ref.	Interpretation for AI technology elements
2	Forward traceability between the system safety requirements and the software safety requirements	C.2.11	For the use case independent technology elements: applicable as for non-AI system elements. For the use case dependent technology elements, in some cases it is difficult to define a safety requirements specification for AI model. (e.g. the safety need can be to detect all pedestrian on the road), but how to clearly define all possible use cases for pedestrians, (e.g. a person on a wheelchair). On the other hand, IEC TS 62988-1 [143] and IEC 61496 [144] for instance define a person detection function that can be decomposed into software functions and traced. For instance, a certain number of pixels or measurement samples return a value with a specified tolerance. This can be used regardless of underlying software technology, including AI technology.
3	Backward traceability between the safety requirements and the perceived safety needs	C.2.11	Applicable as for non-AI system elements.
4	Computer-aided specification tools to support appropriate techniques or measures above	B.2.4	Applicable as for non-AI system elements.

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1784 **Table A.2 — Interpretation of Software design and development –**
1785 **software architecture design (Reference: IEC 61508-3 Table A.2)**

	Technique or Measure	Ref.	Interpretation for AI technology elements
	Architecture and design feature		
1	Fault detection	C.3.1	There are several possible methods for AI fault detection, for both runtime (inference) and offline (training), including: • Checking the operational domain for distributional shifts; • Checking for new concepts (e.g. new objects, different behaviour, new rules); • Changes occurring in the world (domain drifts, new objects, changing rules). So it is differentiated between fault detection during training and during inference.
2	Error detecting codes	C.3.2	Applicable to AI technology elements as well.
3a	Failure assertion programming	C.3.3	This is possible also for AI technology elements (see Reference [28]).
3b	Diverse monitor techniques (with independence between the monitor and the monitored function in the same computer)	C.3.4	This is possible also for AI technology elements: monitor can be either a traditionally developed mechanism or another AI technology (e.g. trained differently or implementing another AI algorithmic approach); or having a N-modular architecture with diverse DNN solving the same problem and voted. Consider not only the diversity between the software and the AI algorithm, but also the diversity between the data on which ML algorithm is trained.
3c	Diverse monitor techniques (with separation between the monitor computer and the monitored computer)	C.3.4	
3d	Diverse redundancy, implementing the same software safety requirements specification	C.3.5	

Technique or Measure		Ref.	Interpretation for AI technology elements
3e	Functionally diverse redundancy, implementing different software safety requirements specification	C.3.5	To consider also hardware diversity is relevant for software and it can include diversity in lower-level software implementation, diversity of compiled instruction, instruction execution, etc.
3f	Backward recovery	C.3.6	It is also used for AI technology in principle (subject to sufficient storage state space) and can increase the robustness of an AI result as well since such a methodology introduces a kind of redundancy (slight changes in the input vector).
3g	Stateless software design (or limited state design)	C.2.12	Not appropriate for AI technology elements.
4a	Re-try fault recovery mechanisms	C.3.7	It is also used for AI technology in principle (subject to sufficient storage state space) and can increase the robustness of an AI technology result as well since such a methodology introduces a kind of redundancy (slight changes in the input vector).
4b	Graceful degradation	C.3.8	For AI technology elements, graceful degradation can be applied in case of a lowered certainty of an output value.
5	Artificial intelligence – fault correction	C.3.9	This requirement of the IEC 61508 series is under review for future editions of IEC 61508-3 in line with the work of ISO/IEC JTC 1/ SC 42 / WG 3.
6	Dynamic reconfiguration	C.3.10	This requirement of IEC 61508 series is under review for future editions of IEC 61508-3 in line with the work of ISO/IEC JTC 1/ SC 42 / WG3. This is essential for future open systems beside AI. There are different considerations based on the specific AI system element. For example, active learning being dynamic reconfiguration of weights due to individual robot learning, while regular updates are process managed.
7	Modular approach	Table A.19	Applicable to AI technology elements as well.
8	Use of trusted or verified software elements (if available)	C.2.10	Applicable to AI technology elements as well. To be noted that verified software it is not needed for all steps of AI model development. It is relevant for inference, but not for data collection process.
9	Forward traceability between the software safety requirements specification and software architecture	C.2.11	Applicable to AI technology elements as well.
10	Backward traceability between the software safety requirements specification and software architecture	C.2.11	Applicable to AI technology elements as well.
11 a	Structured diagrammatic methods	C.2.1	Applicable to AI technology elements as well.
11 b	Semi-formal methods	Table A.17	Applicable to AI technology elements as well.
11 c	Formal design and refinement methods	B.2.2, C.2.4	Applicable to AI technology elements as well.
11 d	Automatic software generation	C.4.6	Basic principle of software development appropriate also for AI technology elements as well.
12	Computer-aided specification and design tools	B.2.4	Applicable to AI technology elements as well.

Technique or Measure		Ref.	Interpretation for AI technology elements
13 a	Cyclic behaviour, with guaranteed maximum cycle time	C.3.11	Applicable to AI technology elements as well.
13 b	Time-triggered architecture	C.3.11	Applicable to AI technology elements as well.
13 c	Event-driven, with guaranteed maximum response time	C.3.11	Applicable to AI technology elements as well.
14	Static resource allocation	C.2.6.3	Applicable to AI technology elements as well.
15	Static synchronisation of access to shared resources	C.2.6.3	Applicable to AI technology elements as well. This can be managed through the associated embedded software (e.g. runtime environment).

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Table A.3 — Interpretation of Software design and development – support tools and programming language (Reference: IEC 61508-3 Table A.3)

Technique or Measure		Ref.	Interpretation for AI system technology elements
1	Suitable programming language	C.4.5	Those measures are applicable for use case independent elements (e.g. CUDA C++ libraries) while very difficult for the use case dependent elements (i.e. the models). In other words, the code running on the target still fulfils the objective of those measures that are not applicable for the rest of the AI system.
2	Strongly typed programming language	C.4.1	
3	Language subset	C.4.2	
4a	Certified tools and certified translators	C.4.3	It can be difficult because Commercial Off-the-Shelf (COTS) software is typically involved. However, a distinction can also be made about training vs. inference. COTS like TensorFlow are used for model development and training, but TensorRT converts the models into a runtime engine for inference and it is certified.
4b	Tools and translators: increased confidence from use	C.4.4	This measure is very important for AI technology development.

Table A.4 — Interpretation of Software design and development – detailed design (Reference: IEC 61508-3 Table A.4)

Technique or Measure		Ref.	Interpretation for AI system technology elements
1a	Structured methods	C.2.1	Also appropriate for AI technology, limited to the software aspects (i.e. the use case independent elements) and architecture (ML model architecture is usually described using diagrams, connections, etc. Modular approach can also be used in ML models). Rather not applicable for the data related elements.
1b	Semi-formal methods	Table A.17	
1c	Formal design and refinement methods	B.2.2, C.2.4	
2	Computer-aided design tools	B.3.5	
3	Defensive programming	C.2.5	
4	Modular approach	Table A.19	
5	Design and coding standards	C.2.6 Table A.11	Design standards are applicable to AI technology elements as well. Coding standard (white box approach) is applicable for use case independent elements (e.g. CUDA C++ libraries) while very difficult for the use case dependent elements (i.e. the models).
6	Structured programming	C.2.7	
7	Use of trusted or verified software elements (if available)	C.2.10	Applicable to AI technology elements as well.
8	Forward traceability between the software safety requirements specification and software design	C.2.11	Applicable to AI technology elements as well.

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1794 **Table A.5 — Interpretation of Software design and development –**
1795 **software module testing and integration (Reference: IEC 61508-3 Table A.5)**

	Technique or Measure	Ref.	Interpretation for AI system technology elements
1	Probabilistic testing	C.5.1	Applicable to AI technology elements as well. AI technology learns by available data: given that it is obvious that data are suitable for the desired task (in terms of amount and distribution). Attributes include: — definition of target probability; — definition of test set used for measuring the actual probability; — systematic specification of the test set (aiming for completeness to achieve the desired task, but also considering unintended behaviour).
2	Dynamic analysis and testing	B.6.5 Table A.12	Applicable to AI technology elements as well.
3	Data recording and analysis	C.5.2	Applicable to AI technology elements as well. Scope for AI: Data Engineering (e.g. Setup, Management, Specification of Training, Validation and Test Datasets)
4	Functional and black box testing	B.5.1 B.5.2 Table A.13	Applicable to AI technology elements as well.
5	Performance testing	Table A.16	Applicable to AI technology elements as well.
6	Model based testing	C.5.27	Applicable to AI technology elements as well.
7	Interface testing	C.5.3	Applicable to AI technology elements as well.
8	Test management and automation tools	C.4.7	Applicable to AI technology elements as well.
9	Forward traceability between the software design specification and the module and integration test specifications	C.2.11	Applicable to AI technology elements as well.
10	Formal verification	C.5.12	Some level is possible, but hardly possible for the whole AI system.

1796

Table A.6 — Interpretation of Programmable electronics integration (hardware and software) (Reference: IEC 61508-3 Table A.6)

	Technique or Measure	Ref.	Interpretation for AI system technology elements
1	Functional and black box testing	B.5.1 B.5.2 Table A.13	Applicable to AI technology elements as well.
2	Performance testing	Table A.16	Applicable to AI technology elements as well.
3	Forward traceability between the system and software design requirements for hardware and software integration and the hardware and software integration test specifications	C.2.11	Applicable to AI technology elements as well.

Table A.7 — Interpretation of Software aspects of system safety validation (Reference: IEC 61508-3 Table A.7)

	Technique or Measure	Ref.	Interpretation for AI system technology elements
1	Probabilistic testing	C.5.1	See Table A.5, row 1.
2	Process simulation	C.5.18	Applicable to AI technology elements as well.
3	Modelling	Table A.15	Applicable to AI technology elements as well.
4	Functional and black box testing	B.5.1 B.5.2 Table A.13	Applicable to AI technology elements as well.
5	Forward traceability between the software safety requirements specification and the software safety validation plan	C.2.11	Applicable to AI technology elements as well.
6	Backward traceability between the software safety validation plan and the software safety requirements specification	C.2.11	Applicable to AI technology elements as well.

1803 **Table A.8 — Interpretation of Modification (Reference: IEC 61508-3 Table A.8)**

Technique or Measure		Ref.	Interpretation for AI system technology elements
1	Impact analysis	C.5.23	Applicable to AI technology elements as well. Addition: It is likely the normal case that AI technology changes can happen very often. Change management planning considers all foreseeable trigger events that can possibly imply a change, such as explicitly planned continuous changes, changes due to detected anomalies, or changes due to aging of demands. Since changes can already be foreseen during development, change management is explicitly considered in the safety planning already. (e.g. by defining a model change protocol and defining the actions to be performed in such a case). Events that can trigger change are also important.
2	Reverify changed software module	C.5.23	Applicable to AI technology elements as well.
3	Reverify affected software modules	C.5.23	Applicable to AI technology elements as well.
4a	Revalidate complete system	Table A.7	Also appropriate for AI technology elements as well depending on the impact of a change.
4b	Regression validation	C.5.25	Applicable to AI technology elements as well.
5	Software configuration management	C.5.24	Applicable to AI technology elements as well.
6	Data recording and analysis	C.5.2	Applicable to AI technology elements as well.
7	Forward traceability between the Software safety requirements specification and the software modification plan (including reverification and revalidation)	C.2.11	Applicable to AI technology elements as well.
8	Backward traceability between the software modification plan (including reverification and revalidation) and the software safety requirements specification	C.2.11	Applicable to AI technology elements as well.

1804

1805 **Table A.9 — Interpretation of Software verification (Reference: IEC 61508-3 Table A.9)**

	Technique or Measure	Ref.	Interpretation for AI system technology elements
1	Formal proof	C.5.12	Some level is possible, but hardly possible for the whole AI application (due to the size of executable code, formal analysis works only for portions of the code)
2	Animation of specification and design	C.5.26	Applicable to AI technology elements as well.
3	Static analysis	B.6.4 Table A.18	Those measures are applicable for use case independent elements (e.g. CUDA C++ libraries) while can be more difficult for the use case dependent elements (i.e. the models). The expressiveness is not the same as in traditional code.
4	Dynamic analysis and testing	B.6.5 Table A.12	
5	Forward traceability between the software design specification and the software verification (including data verification) plan	C.2.11	Applicable to AI technology elements as well.
6	Backward traceability between the software verification (including data verification) plan and the software design specification	C.2.11	Applicable to AI technology elements as well.
7	Offline numerical analysis	C.2.13	Applicable to AI technology elements as well.

1806

1807 **Table A.10 — Interpretation of functional safety assessment (Reference: IEC 61508-3 Table**
1808 **A.10)**

	Assessment or Technique	Ref.	Interpretation for AI system technology elements
1	Checklists	B.2.5	Applicable to AI technology components as well, specialities of AI are addressed
2	Decision tables and truth tables	C.6.1	Applicable to AI technology elements as well.
3	Failure analysis	Table A.14	Applicable to AI technology elements as well.
4	Common cause failure analysis of diverse software (if diverse software is actually used)	C.6.3	Also appropriate for AI on system level.
5	Reliability block diagram	C.6.4	Applicable to AI technology elements as well.
6	Forward traceability between the requirements of Clause 8 and the plan for software functional safety assessment	C.2.11	Applicable to AI technology elements as well.

1809

1810 **Table A.11 — Interpretation of Design and coding standards (Reference: IEC 61508-3 Table B.1)**

Technique or Measure		Ref.	Interpretation for AI system technology elements
1	Use of coding standard to reduce likelihood of errors	C.2.6.2	These measures are applicable for use case independent elements (e.g. CUDA C++ libraries) while very difficult for the use case dependent elements (i.e. the models). Furthermore, some of the IEC 61508-3 requirements (e.g. 2, 3a, 3b) are sometimes not suitable for state-of-the-art software development like object-oriented programming languages.
2	No dynamic objects	C.2.6.3	
3a	No dynamic variables	C.2.6.3	
3b	Online checking of the installation of dynamic variables	C.2.6.4	
4	Limited use of interrupts	C.2.6.5	
5	Limited use of pointers	C.2.6.6	
6	Limited use of recursion	C.2.6.7	
7	No unstructured control flow in programs in higher level languages	C.2.6.2	
8	No automatic type conversion	C.2.6.2	

1811

1812 **Table A.12 — Interpretation of Dynamic analysis and testing (Reference: IEC 61508-3 Table B.2)**

Technique or Measure		Ref	Interpretation for AI system technology elements
1	Test case execution from boundary value analysis	C.5.4	Applicable to AI technology elements as well.
2	Test case execution from error guessing	C.5.5	Applicable to AI technology elements as well.
3	Test case execution from error seeding	C.5.6	Applicable to AI technology elements as well.
4	Test case execution from model-based test case generation	C.5.27	Applicable to AI technology elements as well.
5	Performance modelling	C.5.20	Applicable to AI technology elements as well.
6	Equivalence classes and input partition testing	C.5.7	Applicable to AI technology elements as well.
7a	Structural test coverage (entry points) 100 %	C.5.8	Those measures are applicable for use case independent elements (e.g. CUDA C++ libraries) as also for the code descripting the model, even if the expressiveness is not the same as in traditional code. However, it can be difficult to achieve adequate test coverage of the input space.
7b	Structural test coverage (statements) 100 %	C.5.8	
7c	Structural test coverage (branches) 100 %	C.5.8	
7d	Structural test coverage – modified conditions and decisions, (Modified condition/decision coverage – MC/DC) 100 %	C.5.8	

1813

Table A.13 — Interpretation of Functional and black box testing (Reference: IEC 61508-3 Table A.13)

Technique or Measure		Ref	Interpretation for AI system technology elements
1	Test case execution from cause consequence diagrams	B.6.6.2	Applicable to AI technology elements as well.
2	Test case execution from model-based test case generation	C.5.27	Applicable to AI technology elements as well.
3	Prototyping or animation	C.5.17	Applicable to AI technology elements as well.
4	Equivalence classes and input partition testing, including boundary value analysis	C.5.7 C.5.4	Applicable to AI technology elements as well.
5	Process simulation	C.5.18	Applicable to AI technology elements as well.

Table A.14 — Interpretation of Failure analysis (Reference: IEC 61508-3 Table B.4)

Technique or Measure		Ref	Interpretation for AI system technology elements
1a	Cause consequence diagrams	B.6.6.2	Applicable to AI technology elements as well. Failure analyses also considers data engineering aspects.
1b	Event tree analysis	B.6.6.3	
2	Fault tree analysis	B.6.6.5	
3	Software functional failure analysis	B.6.6.4	

Table A.15 — Interpretation of Modelling (Reference: IEC 61508-3 Table B.5)

Technique or Measure		Ref	Interpretation for AI system technology elements
1	Data flow diagrams	C.2.2	Applicable to AI technology elements as well.
2a	Finite state machines	B.2.3.2	Applicable to AI technology elements as well.
2b	Formal methods	B.2.2, C.2.4	Applicable to AI technology elements as well.
2c	Time Petri nets	B.2.3.3	Applicable to AI technology elements as well.
3	Performance modelling	C.5.20	Applicable to AI technology elements as well.
4	Prototyping or animation	C.5.17	Applicable to AI technology elements as well.
5	Structure diagrams	C.2.3	Applicable to AI technology elements as well.

1821 **Table A.16 — Interpretation of Performance testing (Reference: IEC 61508-3 Table B.6)**

Technique or Measure		Ref	Interpretation for AI system technology elements
1	Avalanche or stress testing	C.5.21	Applicable to AI technology elements as well.
2	Response timings and memory constraints	C.5.22	Applicable to AI technology elements as well.
3	Performance requirements	C.5.19	Applicable to AI technology elements as well.

1822

1823 **Table A.17 — Interpretation of Semi-formal methods (Reference: IEC 61508-3 Table B.7)**

Technique or Measure		Ref	Interpretation for AI system technology elements
1	Logic or function block diagrams	See IEC 61508-3 Table B.7 Note 1	Applicable to AI technology elements as well.
2	Sequence diagrams	see IEC 61508-3 Table B.7 Note 1	Applicable to AI technology elements as well.
3	Data flow diagrams	C.2.2	Applicable to AI technology elements as well.
4a	Finite state machines or state transition diagrams	B.2.3.2	Applicable to AI technology elements as well.
4b	Time Petri nets	B.2.3.3	Applicable to AI technology elements as well.
5	Entity-relationship-attribute data models	B.2.4.4	Applicable to AI technology elements as well.
6	Message sequence charts	C.2.14	Applicable to AI technology elements as well.
7	Decision tables or truth tables	C.6.1	Applicable to AI technology elements as well.
8	Unified Modelling Language (UML)	C.3.12	Applicable to AI technology elements as well.

1824

Table A.18 — Interpretation of Static analysis (Reference: IEC 61508-3 Table B.8)

Technique or Measure		Ref	**Interpretation for** AI system technology elements
1	Boundary value analysis	C.5.4	Those measures are applicable for use case independent elements (e.g. CUDA C++ libraries) as well as for the code descripting the model, even if the expressiveness is not the same as in traditional code. However, it can be difficult to achieve adequate test coverage of the input space.
2	Checklists	B.2.5	
3	Control flow analysis	C.5.9	
4	Data flow analysis	C.5.10	
5	Error guessing	C.5.5	
6a	Formal inspections, including specific criteria	C.5.14	
6b	Walk-through (software)	C.5.15	
7	Symbolic execution	C.5.11	
8	Design review	C.5.16	Applicable to AI technology elements as well.
9	Static analysis of run time error behaviour	B.2.2, C.2.4	Those measures are applicable for use case independent elements (e.g. CUDA C++ libraries) as well as for the code descripting the model, even if the expressiveness is not the same as in traditional code. However, it can be difficult to achieve adequate test coverage of the input space.
10	Worst-case execution time analysis	C.5.20	Applicable to AI technology elements as well.

Table A.19 — Interpretation of Modular approach (Reference: IEC 61508-3 Table B.9)

Technique or Measure		Ref	**Interpretation for** AI system technology elements
1	Software module size limit	C.2.9	Those measures are applicable for use case independent elements (e.g. CUDA C++ libraries) as also for the code descripting the model, even if the expressiveness is not the same as in traditional code. While it can be difficult for test coverage of input space. About software size, the criteria are likely not a size but rather a number of parameters (e.g. such as a limited number or neural network nodes or connections or layers). Complexity can also be redefined for ML. Can be combined with size, or types of connectivity between layers, since DNNs do not typically have branching statements.
2	Software complexity control	C.5.13	
3	Information hiding or encapsulation	C.2.8	
4	Parameter number limit, fixed number of subprogram parameters	C.2.9	
5	One entry one exit point in subroutines and functions	C.2.9	
6	Fully defined interface	C.2.9	Applicable to AI technology elements as well.

Annex B
(informative)

Examples of applying the three-stage realization principle

B.1 Introduction

This Annex describes non-exhaustive examples on how to apply the classification scheme described in Clause 6 and the three-stage realization principle described in Clause 7.

B.2 Example for an automotive use case

The example described in this Clause is an automotive system comprised of two layers:

- the mission layer, is responsible for charge of perceiving the environment, taking decisions including planning routes and commanding actuation including steering, braking;
- the protection layer, which provides safety functions such as identifying conditions under which to execute a protective stop or brake command.

NOTE 1 The mission layer can be referred to as the "item" using ISO 26262-1 [12] terminology or the "control function" using IEC 61508-4 [19] terminology. The protection layer can be referred to as the part of the system guaranteeing the "safety goal" using ISO 26262-1 terminology or the "safety-related system" using IEC 61508-4 terminology.

It is assumed that the system includes cameras and the related data are processed by a perception algorithm based on deep learning (DL) algorithm like a DNN. An example of this type of DNN is DriveNet [91].

A typical representation of this system is shown in Figure B.1.

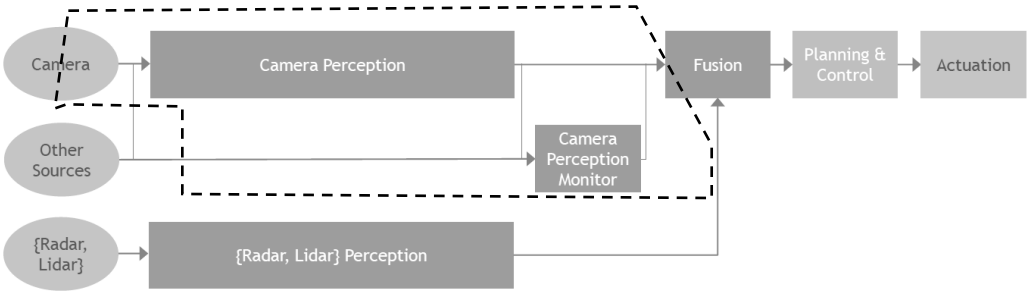

Figure B.1 — Example of an automotive system

NOTE 2 In Figure B.1 light grey boxes represent sensing inputs, actuators; dark grey represent perception related functions and related monitors.

The scope of the example is limited to the area outlined by the dashed line in Figure B.1, i.e. the camera perception DNN, the related sensing path (i.e. the camera) and related monitors. The other perception paths (lidar, ladar) that can be involved in the system, the related fusion and the planning and actuation functions are not in scope.

The AI technology used in this system can be considered of a Usage Level A1 as described in Clause 6.2, because it is used in a safety relevant E/E/PE system and automated decision-making of the AI system is possible. Based on the principles described in Clause 8, the following properties can be identified for this use case:

— Specifiability: How to specify pedestrian appearance in an image?

— Interpretability: How to get insight into design?

— Generalisation: Can the DNN interpolate across input domain?

— Domain shift: Is the DNN operating in training data domain?

— Robustness-safeness: Can small perturbations (malicious or not) change output?

— Diversity: What does diversity mean in the context of DL and how to ensure that diversity is sufficient (e.g. different DL architectures, different training datasets)?

— Confidence: How to consider confidence levels in the context of DL?

These properties can be mapped to the three stages of the realization principle as shown in Table B.1.

Table B.1 — Mapping of properties to the realization principle stages

	Acquisition from inputs and data	**Knowledge induction from training data and human knowledge**	**Processing and generation of outputs**
Specifiability	-	X	X
Interpretability	-	-	X
Generalisation	-	-	X
Domain shift	-	X	X
Robustness-safeness	X	-	X
Diversity	X	X	X
Confidence	-	-	X

The AI technology used in this system can be considered of a Class II, because, as shown in Table B.2, it is still possible to identify a set of available methods and techniques satisfying the properties (e.g. it is still possible to use certain compensation methods of verification and validation), so that the AI technology can meet outlined criteria and the development follows suitable processes

Table B.2 provides an example of the analysis of the properties in the applicable stages of the framework, and identifies the topic, the KPIs and the available techniques and measures to satisfy those properties.

1882 **Table B.2 — Example property analysis**

Stage: knowledge induction from training data and human knowledge **Desirable property**: Specifiability			
Topic	**Details**	**KPI**	**Available methods with references**
specification of the dataset	• amount of data. • type of data needed (e.g. object classes, object data definition, weather conditions, geographic domain, background scene). • division of data between training, validation and testing.	• dataset coverage. • dataset distribution. • example: the dataset contains images acquired for different road types during differing weather conditions and the data acquisition takes place during daytime.	• manual curation. • active learning.
specification of labelling policy	• data annotation. • treatment of occluded objects. • number of annotators annotating the same data.	• labelling quality distribution. • example: the road lane boundaries are marked pixel by pixel. Each image is annotated by two independent annotators. The amount of 10 % of randomly selected data is additionally annotated by a third annotator.	

1883

1884 B.3 Example for a robotics use case

1885 The example described in this Clause is an autonomous mobile platform that transports materials around
1886 an industrial warehouse.

1887 The system is separated between application and safety domain:

1888 — The application domain includes wireless communication with the fleet management system to
1889 receive tasks and updates, and local on-device software for carrying out the tasks (localization,
1890 navigation, mapping).
1891 — The safety domain provides safety functions such as Emergency Stop, Protective Stop, Speed
1892 Limitation and Muting.

1893 The overall system can be classified as a driverless industrial truck under ISO 3691-4 [145] and industrial
1894 mobile robot (type B) under ANSI/RIA R15.08-1 [146].

1895 The scope of the example is limited to the implementation of the Protective Stop safety function, as this
1896 is the only safety function that utilizes machine learning. It is assumed that each safety function is
1897 independent of each other, and that the application domain is isolated from the safety domain.

1898 A simplified representation of this system, limited to the components relevant to the Protective Stop
1899 safety function, is shown in Figure B.2. Camera sensors around the robot provide images to a neural

network, which produces a depth image. The depth image is converted into a 3D view of the scene. A check is made to see if a safety violation occurs. If so, a protective stop output is sent to the motor. While additional sensors are shown on the robot, it is assumed the safety function can be implemented on each sensor independently (rather than a "system of systems").

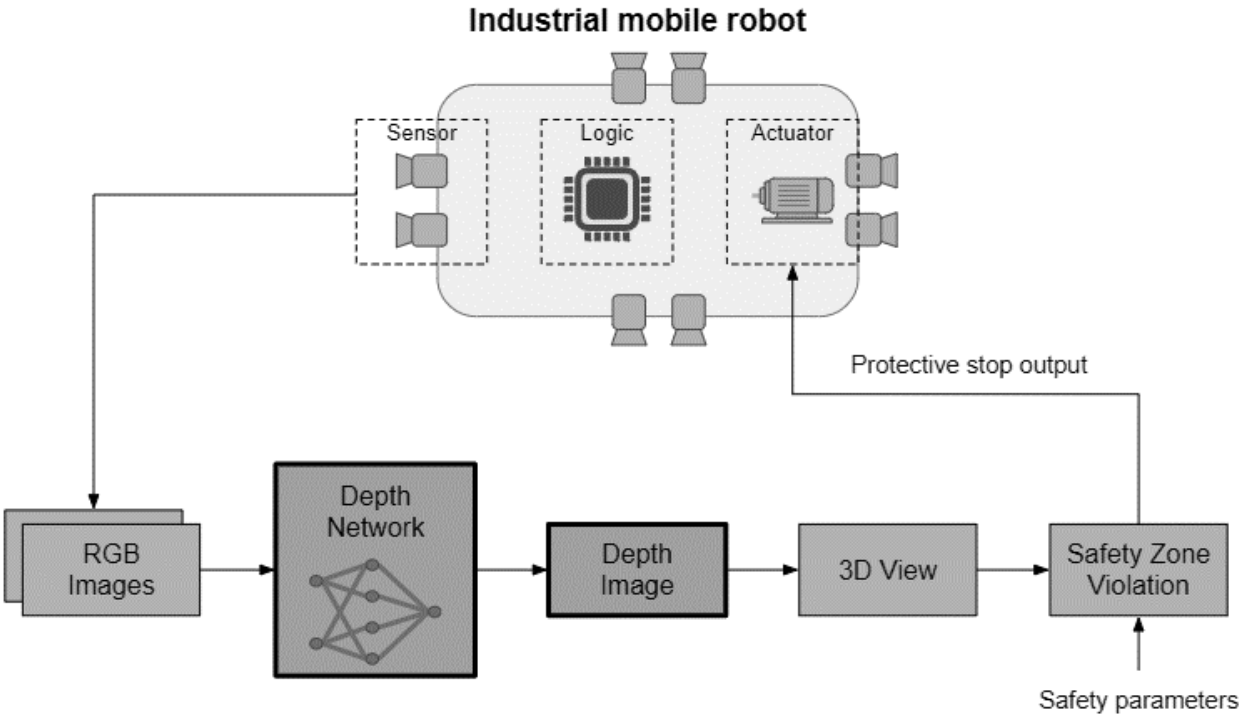

Figure B.2 — Example of industrial mobile robot

The software components in dark grey with bold black outline (i.e. depth network and depth image) represents logic and outputs directly produced by the machine learning model. All other components in grey are not within the scope of this document and can be validated using existing International Standards. The dark grey components can be considered Usage Level A1 as described in Clause 6.2, since they are used in a safety relevant E/E/PE system and automated decision-making of the AI is possible.

Based on the principles described in Clause 8, the following properties for this application that can appropriately be addressed by the AI components are:

- Specifiability: What are the requirements of the network? How do those requirements map to existing International Standards for safety sensors, such as IEC 61496-1 [144] and IEC TS 62998-1 [143]? What constitutes the training images for the neural network, how are those images mapped to the operating environment? How many images, across different classes, are sufficient for training?
- Domain shift: What if the deployment environment is different than the environment used during training?
- Verifiability: How is the neural network performance assessed? How does this assessment map to existing International Standards for safety sensors, such as IEC 61496-1 [144] and IEC TS 62998-1 [143]?
- Robustness: How robust is the neural network to different noise sources (hardware, environmental factors, operational changes, ageing, etc.)?
- Interpretability: Are the results produced by the network understandable? Do the produced results correspond to the expected results, as defined by the safety requirements?

— Explainability: Are the components that make up the machine learning model understood? Is there a reason for design choices? Do those choices map to input requirements?

Table B.3 maps the properties to the three-stage realization principle of Clause 7.

Table B.3 — Mapping of properties to the realisation principle stages

	Acquisition from inputs or data	**Knowledge induction from training data and human knowledge**	**Processing and generation of outputs**
Specifiability	X	X	X
Domain shift	-	X	X
Verifiability	-	X	X
Robustness	X	-	X
Interpretability	-	X	X
Explainability	-	X	-

Table B.4 provides an example analysis from the third stage of the three-stage realization principle in relation to the verifiability property.

Table B.4 — Example property analysis

Stage: processing and generation of outputs **Desirable property:** verifiability		
Topic	**Details**	**Compliance criteria**
How is the neural network performance assessed?	• For a given input, definition of what constitutes a "correct" output by the network. • Definition of what range of inputs is evaluated.	• Pixel level KPIs. • Image level KPIs. • Sequence level KPIs. • Dataset level KPIs.
How does the network performance map to existing safety International Standards and metrics?	• Mapping of measured network performance criteria to existing standard criteria. • Requirement tracing from standards performance requirements to network requirements.	• Requirement traceability or mapping documents.
How to determine verification process is accurate (e.g. unexpected behaviour due to combination of factors that	• Single-dimensional vs multi-dimensional testing. • Statistical analysis of random variate testing. • Independent verification process.	• Test plans. • Independently reviewed results. • Statistical analysis. • Tool qualification • Process FMEA.

Stage: processing and generation of outputs **Desirable property:** verifiability		
cannot be seen by testing across single factors)?	• Evaluation and or certification of verification tools • Evaluation and or certification of verification tools	
How to determine when verification is complete?	• Amount of verification data • Type of verification data and how its split into relevant parameters • Frequency with which verification is carried out • Frequently with which verification data is refreshed • Stopping criteria for verification	• Test plans • Predetermined stopping criteria • Process FMEA

1935

1936 The same analysis can be applied to all other identified properties from Table B.3, identifying a set of
1937 available methods and techniques to satisfy the property. As such, the AI technology used in this system
1938 can be considered Class II as defined in Clause 6.2.

Annex C
(informative)

Possible process and useful technology for verification and validation

C.1 General

This Annex is to complement the content of Clause 9.3 to provide examples of possible process and technical methods to be used. The content is mainly quoted with rearrangement from Reference [94].

C.2 Data distribution and HARA

To keep sufficient levels of relation between data distributions and hazard and risk analysis as described in Clause 9.3.2 and 9.3.3 a), the following measure can be taken.

- For low-level requirements:
  - Examine and record the major cause of possible deterioration of safety.
  - Based on the examination results, design data and reflect it in applicable attributes.
- For middle-level requirements:
  - Analyse risks of deterioration of quality in use in overall system and their impact with a certain level of engineering coverage and record the results in documents.
  - Analyse if any measure applies to any of those risks, and analyse attributes related to the risk that are contained in an input to machine learning components.
  - Analyse and record the application-specific characteristics of environments that can generate machine learning input, with regards to the difficulty for machine learning and other aspects.
  - Examine sets of attributes and attribute values, based on the results of those analysis and record the background of such decisions.
- For high-level requirements, in addition to what described for low-level and middle-level requirements:
  - Investigate documents on own past examination results and those of others with regard to elements to be extracted as characteristics of system environment and record the background of examinations leading to the extraction of applicable subsets.
  - Investigate past examination results in line with application fields of systems with regard to deterioration risks of qualities in use of overall systems and record the examination results including the background of selection.
  - Moreover, extract deterioration risks of qualities in use of overall systems using engineering analysis such as fault tree analysis and record their results.

For identifying attribute sets related to identified risk, the following things are better to be consulted:

- Basic knowledge on the existing functional safety design, the existing hazard lists in each application domain, or brainstorming results based on existing International Standard hazard list, for example in ISO 12100 [3] or one from NASA [126].
- Analysis cases on prior systems and similar machine learning based systems.

— Domain knowledge by brainstorming with users.

— Knowledge about data employed preliminarily and exceptional cases identified in the trials of the training in the proof of concept stage.

C.3 Coverage of data for identified risks

Having enough and well-diverse data for each identified risk is the next step. Checking existence of one datum for an identified risk is easy, but the rest of things are difficult to ensure. If the subset of data related to a specific risk is determined, it is relatively easy to check the distribution of the attribute values. However, as number of attributes are often become tens or more in typical machine-learning use cases, checking for all combinations of attribute values to be included are unlikely; so, some kind of coverage metrics can be useful. In the area of software testing study, several metrics for test coverage are used; one possible solution is to reuse such a concept for defining the coverage, especially a concept of combinatorial testing.

In this way, some possible measures for this subproblem can be set as follows:

— For low-level requirements:

  — Ensure having some inputs for each of attributes corresponding to major risk factors.

  — Moreover, ensure some input for corresponding to combinations of composite risk factors.

  — Furthermore, extract attributes of differences in particularly important environmental factors and prepare data corresponding to combinations with serious risk factors.

— For middle-level requirements, in addition to what described for low-level requirements:

  — Ensure data corresponding to particularly important risk factors to satisfy, in principle, the International Standards for pair-wise coverage. To be more specific, a case of combining an attribute value of combination of those factors and individual attribute values included in all attributes other than those to which the attribute value belongs are to be included.

— For high-level requirements:

  — Based on engineering consideration, set standards for coverage of attributes and establish sets of combinations of attribute values that satisfied standards for coverage.

  — The level of strictness of the standards for coverage (pair-wise coverage, triple-wise coverage, etc.) to be set taking into account system usage and risk severity. Standards can be set individually for each risk where appropriate.

C.4 Data diversity for identified risks

Data collection process management is used to achieve diversity of data having similar attribute values, because little is known about such data diversity beforehand in usual machine-learning application. Data source and its processing is carefully examined to ensure that the data are not biased to some specific input conditions.

Some possible measures for this subproblem can be set as follows:

— For low-level requirements:

  — Consider the source and method of acquiring test datasets to ensure that no bias is found in application situations.

  — Extract samples without bias from original data for each case to ensure that no bias is found.

2019 — Record activities carried out to prevent bias from entering.

2020 — Check that there are sufficient training data and test data for each analysed case in the
2021 training phase, validation phase, etc.

2022 — When sufficient training data cannot be acquired for any case, review and loosen the
2023 coverage standards and record what is to be checked individually by system integration
2024 tests in line with the original standards.

2025 — For middle-level requirements, in addition to what described for low-level requirements:

2026 — Grasp an approximate probability of occurrence for each attribute value or each case.

2027 — Check if acquired data is not deviated from the expected distribution.

2028 — Positively check other than acquisition methods made regarding the coverage of the data
2029 included in each case. For example, in each case, when there is any attribute not included
2030 in that case, extract the distribution related to that attribute and check if there is no
2031 significant bias.

2032 — For high-level requirements, in addition to what described for middle-level requirements:

2033 — Acquire certain indicators for coverage of data included in each case. For example, check
2034 if there is no correlation between data other than attribute values included in
2035 combinations of cases using feature extraction or any other technique.

2036 Refer to Clauses 9.3.6 and 9.4 for using data augmentation and simulators for expanding the data
2037 size.

2038 C.5 Reliability and robustness

2039 For reliability and robustness of the generated machine learning model, usual AI metrics and test
2040 dataset are typically used. However, ensuring robustness in machine learning is currently a
2041 difficult problem.

2042 The text in Clause 9.3.3, d), gives some hints about what method can be used. For applications
2043 with lower-level requirements, such general cautions are often sufficient. For those high-level
2044 requirements, some forms of numerical or formal analysis for stability can be expected.

2045 Some of the following technologies can be used:

2046 – For low-level requirements:

2047 — Regularization.

2048 — Cross validation.

2049 — Randomized training.

2050 — Model size exploration.

2051 – For middle-level requirements:

2052 — Adversarial training.

2053 — Smoothing.

2054 — Adversarial example generation or detection tests.

2055 – For high-level requirements:

2056 — Evaluation of maximum safe radius.

2057 — Formally checked robust training and smoothing.

Annex D
(informative)

Mapping between ISO/IEC 5338 and IEC 61508 series

ISO/IEC 5338 [1] describes a lifecycle for AI systems. The IEC 61508 series describes a safety lifecycle. Both International Standards define a set of processes and phases throughout the whole lifecycle within a system. Both International Standards allow to tailor the sequence of execution of each process or phase and also to repeat a process or phase is possible as long as the impact of the additional work is also taken into account according all the other process or phase that are being affected by the additional work.

The Table D.1 provides a mapping for the technical processes of ISO/IEC 5338 [1] and the IEC 61508 series lifecycle phases. Other processes of ISO/IEC 5338 [1] are taken into account also, especially the risk management process of ISO/IEC 5338 [1].

Table D.1 — Mapping between IEC 61508 series to ISO/IEC 5338

Safety lifecycle (IEC 61508)	**AI system lifecycle (ISO/IEC 5338)**
	Technical processes
Concept (IEC 61508-1:2010 Figure 2: 1 Concept)	— Business or mission analysis process. — Stakeholder needs and requirements definition process.
Overall scope definition (IEC 61508-1:2010 Figure 2: 2 Overall scope definition)	— Stakeholder needs and requirements definition process. — System requirements definition process.
Hazard and risk analysis (IEC 61508-1:2010 Figure 2: 3 Hazard and risk analysis)	— Risk management process.
Overall safety requirements (IEC 61508-1:2010 Figure 2: 4 Overall safety requirements)	— Stakeholder needs and requirements definition process. — System requirements definition process.
Overall safety requirements allocation (IEC 61508-1:2010 Figure 2: 5 Overall safety requirements)	— Architecture definition process. — Stakeholder needs and requirements definition process. — System requirements definition process.
Overall operation and maintenance planning (IEC 61508-1:2010 Figure 2: 6 Overall operation and maintenance planning)	— Operation process. — Maintenance process.
Overall safety validation planning (IEC 61508-1:2010 Figure 2: 7 Overall safety validation planning)	— Validation process.
Overall installation and commissioning planning (IEC 61508-1:2010 Figure 2: 8 Overall installation and commissioning planning)	— Transition process.
System safety requirements specification (IEC 61508-1:2010 Figure 2: 9 System safety requirements specification)	— Stakeholder needs and requirements definition process. — System requirements definition process.
System design requirements specification (IEC 65108-1:2010 Figure 3: 10.1 System design requirements specification)	— Architecture definition process. — Design definition process. — System analysis process.
System safety validation planning (IEC 65108-1:2010 Figure 3: 10.2 System safety validation planning)	— Validation process.

Safety lifecycle (IEC 61508)	**AI system lifecycle (ISO/IEC 5338)**
	Technical processes
System design and development (IEC 65108-1:2010 Figure 3: 10.3 System design and development)	— System analysis process. — Implementation process.
Software safety requirements specification (IEC 65108-1:2010 Figure 4: 10.1 Software safety requirements specification)	— Stakeholder needs and requirements definition process. — System analysis process.
Software design and development (IEC 65108-1:2010 Figure 4: 10.3 Software design and development)	— Knowledge acquisition process. — AI data engineering process. — Implementation process.
Validation plan for software aspects of safety system (IEC 65108-1:2010 Figure 4: 10.2 Validation plan for software aspects of safety system)	— Verification process. — Validation process.
Integration (hardware and software) (IEC 65108-1:2010 Figure 4: 10.4 PE Integration)	— Integration process.
Software operation and maintenance procedures (IEC 65108-1:2010 Figure 4: 10.5 Software operation and maintenance procedures)	— Operation process. — Maintenance process.
Software aspects of system safety validation (IEC 65108-1:2010 Figure 4: 10.6 Software aspects of system safety validation)	— Validation process.
System installation, commissioning, operation and maintenance procedures (IEC 65108-1:2010 Figure 3: 10.5 System installation, commissioning, operation and maintenance procedures)	— Transition process.
System safety validation (IEC 65108-1:2010 Figure 3: 10.6 System safety validation)	— Validation process. — Continuous validation process.
Overall operation, maintenance and repair (IEC 61508-1:2010 Figure 2: 14 Overall operation, maintenance and repair)	— Operation process. — Maintenance process.
Overall modification and retrofit (IEC 61508-1:2010 Figure 2: 15 Overall modification and retrofit)	— Maintenance process.
16 Decommissioning or disposal (IEC 61508-1:2010 Figure 2: 16 Decommissioning or disposal)	— Disposal process.

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