



International
Standard

ISO/IEC 5339

Information technology — Artificial intelligence — Guidance for AI applications

*Technologies de l'information — Intelligence artificielle —
Recommandations relatives aux applications de l'IA*

First edition
2024-01

Copyrighted document, no reproduction or circulation
IECNORM FOR review Click to view the full PDF ISO/IEC 5339 WG:2024
Oct 2024



COPYRIGHT PROTECTED DOCUMENT

© ISO/IEC 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Motivations and objectives	2
5 AI application context and characteristics	2
5.1 Establishing approach for AI application context	2
5.2 AI application context	3
5.3 Stakeholders and processes	5
5.3.1 General	5
5.3.2 AI stakeholders	5
5.3.3 Other stakeholders	6
5.3.4 Processes	7
5.4 AI application functional characteristics	8
5.5 AI application non-functional characteristics and considerations	8
5.5.1 General	8
5.5.2 Trustworthiness	9
5.5.3 Risks and risk management	10
5.5.4 Ethics and societal concerns	10
6 Stakeholders' perspectives and AI application framework	11
6.1 General	11
6.2 Stakeholders' perspectives	11
6.3 AI application framework	12
7 Guidance for AI applications	15
7.1 General	15
7.1.1 General	15
7.1.2 AI producer perspective	15
7.1.3 Data provider perspective	16
7.1.4 AI developer perspective	16
7.1.5 AI application provider perspective	17
7.2 Use perspective	18
7.2.1 General	18
7.2.2 AI customer and AI user perspective	18
7.3 Impact perspective	18
7.3.1 General	18
7.3.2 Community perspective	18
7.3.3 Regulator and policy maker perspective	19
Annex A (informative) Use cases	20
Bibliography	27

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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

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

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

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

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

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

Introduction

Artificial intelligence (AI) systems have the potential to create incremental changes and achieve new levels of performance and capability in domains such as agriculture, transportation, fintech, education, energy, healthcare and manufacturing. However, the potential risks related to lack of trustworthiness can impact AI implementations and their acceptance. AI applications can involve and impact many stakeholders, including individuals, organizations and society as a whole. The impact of AI applications can evolve over time, in some cases due to the nature of the underlying data or legal environment. The stakeholders should be made aware of their roles and responsibilities in their engagement. While detailed AI-related standards can serve the interest of technical experts involved in engineering and development, this document provides a macro-level context of the AI application life cycle, to facilitate multi-stakeholder communication, engagement and acceptance.

This document contains guidance for AI applications based on a common framework, to provide multiple macro-level perspectives. The framework incorporates “make”, “use” and “impact” perspectives. It also incorporates AI characteristics and non-functional characteristics such as trustworthiness and risk management. The guidance can be used by standards developers, application developers and other interested parties to provide answers to the question: “What are the characteristics and considerations of an AI application?”. The stakeholders are mapped to various stages of the AI system life cycle, highlighting their roles and responsibilities and making them aware of the processes to follow to enable a coherent stakeholder engagement for the AI application. These stakeholders can have various levels of AI expertise and knowledge. Since AI applications can differ from non-AI software applications due to their continuously evolving nature and aspects of trustworthiness, all stakeholders should be made aware of AI-specific characteristics.

This document provides:

- this document’s motivation and objectives ([Clause 4](#));
- an approach to identifying an AI application’s stakeholders, context, functional characteristics and non-functional characteristics ([Clause 5](#));
- an AI application framework that can be used to answer the question: “What are the characteristics and considerations of an AI application?” ([Clause 6](#));
- guidance for AI applications based on the make, use and impact perspectives ([Clause 7](#)).

The image shows the front cover of an International Electrotechnical Commission (IEC) standard document. The title 'IEC 62368-1:2024' is prominently displayed at the top. Below the title, the text 'Safety of equipment for medical electrical treatment and care procedures - Part 1: General requirements' is written. The cover features a blue and white color scheme with a subtle background texture. A large, diagonal watermark or overlay text is present, reading 'Copyrighted document, no reproduction or circulation' in grey, and 'IECNORM.COM: Click to view the full PDF online' in red, followed by 'IEC 62368-1:2024' in blue, and 'Oct 2024' in grey.

Information technology — Artificial intelligence — Guidance for AI applications

1 Scope

This document provides guidance for identifying the context, opportunities and processes for developing and applying AI applications. The guidance provides a macro-level view of the AI application context, the stakeholders and their roles, relationship to the life cycle of the system, and common AI application characteristics and considerations.

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 22989:2022, *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 22989:2022 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

AI application

use of AI with functional characteristics that operates in stakeholder contexts to deliver an intended result

3.2

cloud service

one or more capabilities offered via *cloud computing* (3.6) invoked using a defined interface

[SOURCE: ISO/IEC 22123-1:2023, 3.1.2]

3.3

private cloud

cloud deployment model (3.5) where *cloud services* (3.2) are used exclusively by a single *cloud service customer* (3.4) and resources are controlled by that cloud service customer

[SOURCE: ISO/IEC 22123-1:2023, 3.2.4]

3.4

cloud service customer

party that is in a business relationship for the purpose of using *cloud services* (3.2)

Note 1 to entry: A business relationship does not necessarily imply financial agreements.

[SOURCE: ISO/IEC 22123-1:2023, 3.3.2, modified —"acting in a cloud service customer role" changed to "in a business relationship for the purpose of using cloud services", Note 1 to entry added]

3.5

cloud deployment model

way in which *cloud computing* (3.6) can be organized based on the control and sharing of physical or virtual resources

Note 1 to entry: The cloud deployment models include community cloud, hybrid cloud, private cloud and public cloud.

[SOURCE: ISO/IEC 22123-1:2023, 3.2.1]

3.6

cloud computing

paradigm for enabling network access to a scalable and elastic pool of shareable physical or virtual resources with self-service provisioning and administration on-demand

Note 1 to entry: Examples of resources include servers, operating systems, networks, software, applications, and storage equipment.

[SOURCE: ISO/IEC 22123-1:2023, 3.1.1, modified — Note 2 to entry deleted]

4 Motivations and objectives

This document establishes guidance based on the question: "What are the characteristics and considerations of an AI application?" It provides a basis for a common understanding among stakeholders to promote communication, engagement and acceptance of an AI application.

The formulation of this document is as follows:

- the context of an AI application described with respect to Who (stakeholders), What, When, Where, Why and How at various stages of an AI system life cycle;
- the stakeholders – AI stakeholder roles such as AI provider, AI producer, AI customer, AI partner, AI subject, consumers, community and relevant authorities;
- common AI application functional and non-functional characteristics and considerations.

5 AI application context and characteristics

5.1 Establishing approach for AI application context

This clause describes the approach for establishing the AI application context. This document uses the AI system life cycle stages in accordance with ISO/IEC 22989:2022, Clause 6 and ISO/IEC 5338 [1]. For each of the stages, various stakeholders, processes and relationships are defined and mapped thus:

- Who: The stakeholders (e.g. entities, persons or groups) associated with the context whose interests and values can be served, and whose concerns can be addressed.
- What: Activities associated with the context, such as
 - AI system and application capabilities
 - types of decisions being supported by the AI application.
- How: Specific methods associated with the context, such as
 - degree of human involvement in decision-making (e.g. autonomous or semi-autonomous)
 - AI system in an augmentation role (e.g. decision support, human-system collaboration)

- algorithmic processes
- sources, collection and provision of data
- deployment as a product or service
- When: Associated with the temporal context, i.e. a process in a particular stage of the AI system life cycle, or a temporal activation of a process, such as the frequency of an application. This depends on the context established in “What”.
- Where: Location associated with the context, i.e. where the AI application is used; internal to the organization (e.g. for operations) or external to the organization (e.g. with customers); the deployment mode of the application (e.g. on-premise, as a cloud service or through third parties).
- Why: The external causal and explanatory structures associated with the context, i.e. part of the value proposition to the “Who” such as the customers, users and community, shows the application’s rationale, objectives, benefits, considerations and impacts including economic, social, societal, etc.

5.2 AI application context

Figure 1 shows a typical AI application context with its stakeholders, processes and relationships together with the different stages of an AI system life cycle.

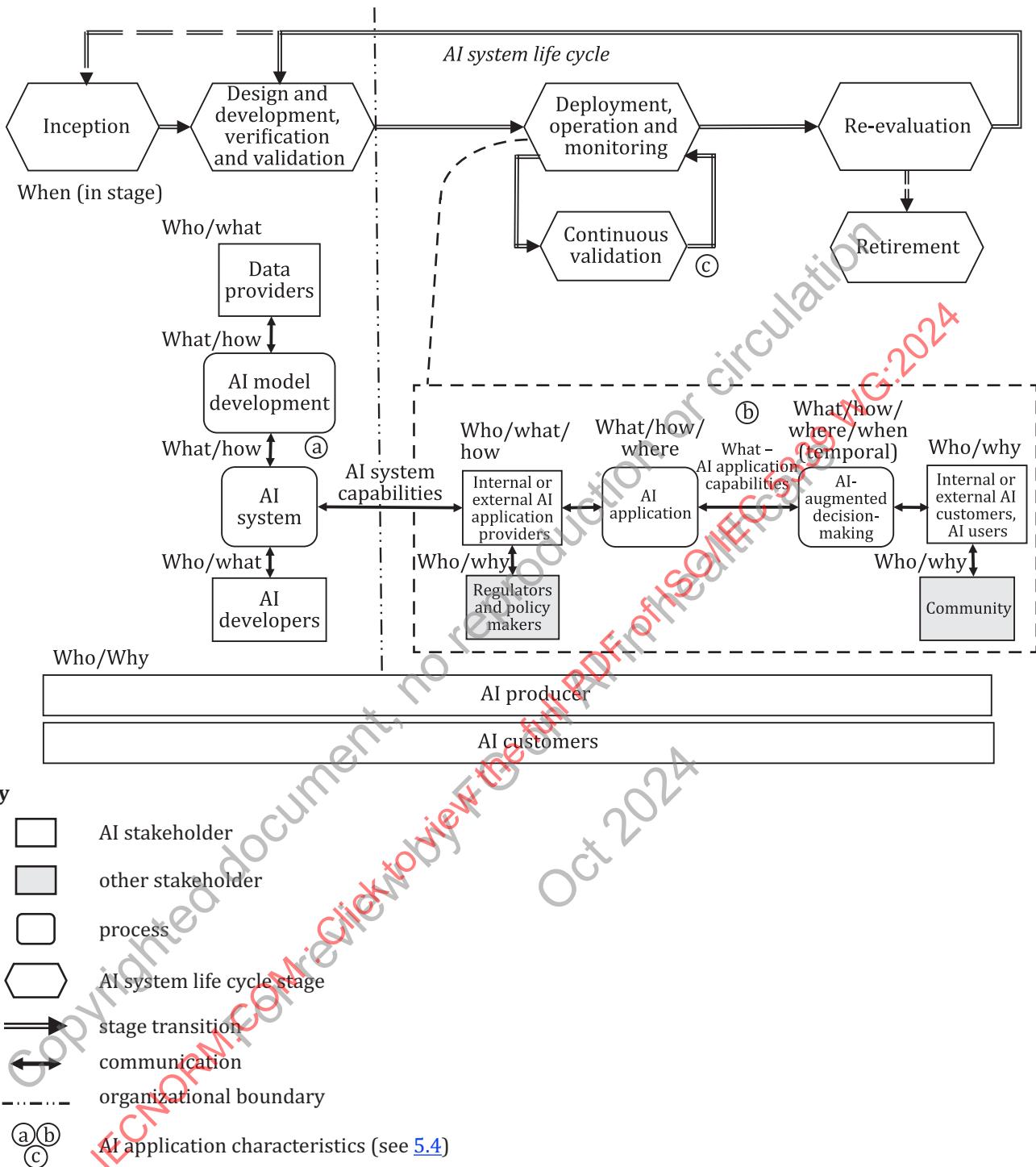


Figure 1 — Typical AI application context

Other stakeholders are those in the community who are not involved with the development or use of the AI application but are still impacted or regulators and policy makers who have impact on the deployment of the application. The relationships between stakeholders include communication and exchanges. The organizational boundary is used to delineate what is inside or outside of the producer's organization (e.g. pre-deployment vs. post-deployment). In certain cases, the AI application provider can be part of the producer's organization but have an external role. The three AI application characteristics (see [5.4](#)) are also reflected in [Figure 1](#).

5.3 Stakeholders and processes

5.3.1 General

[Figure 1](#) shows the relationship among the stakeholders (Who), their roles (What), (Where) and (When) the processes (What) are employed (How).

[Figure 1](#) also shows that the producer, customer, regulators and community (Who) also have value considerations (Why) at stake in this context.

5.3.2 AI stakeholders

5.3.2.1 General

The AI stakeholders described here play one or more different roles and sub-roles in various stages of the AI system life cycle. The name of the stakeholder is also indicative of its role or sub-role as described in ISO/IEC 22989:2022, 5.19.

5.3.2.2 AI producer

An AI producer (Who) is an organization or entity that designs, develops, tests and deploys products or services that use one or more AI systems. The AI producer takes on these roles as part of its organization's objective (Why, e.g. profit as well as value creation for its customers). These roles span the whole AI system life cycle (When) and include management decisions about the inception and termination or retirement of the AI system.

5.3.2.3 AI developer

An AI developer (Who) is an organization or entity that is concerned with the development of AI products and services for the producer. The roles can include model and system design, development, implementation, verification and validation (What) in the pre-deployment stages of the AI system life cycle (When). An individual AI developer can be a member of the producer's organization or a contractor or partner.

5.3.2.4 AI customer

An AI customer (Who) is an organization or entity that uses an AI product or service either directly or by its provision to AI users. There is a business relationship between an AI application provider (see [5.3.2.6](#)) and an AI customer, e.g. engagement, product purchase or service subscription. The customers' role spans the AI system life cycle (When) since they create the demand, realize the value and sustain the viability of the AI product (Why). They are often consulted by the AI producer during the inception to determine requirements and participate in the verification and validation, deployment, operation and monitoring, retirement stages of the AI system life cycle.

An AI customer or AI user (see [5.3.2.5](#)) can be part of the AI application provider's organization (internal, e.g. a business function department) or have an arms-length relationship (external, e.g. the application provider is a third-party service provider) (Where).

5.3.2.5 AI user

An AI user (Who) is an organization or entity that uses AI products or services. An AI user can be an individual from the community (Who) or a member of the customer organization or entity. A customer can also be a user. An AI user does not have to be an AI customer [i.e. has a business relationship with the AI application provider (see [5.3.2.6](#))]. An AI user's role is usually centred around the operation and monitoring stage of the AI system life cycle (When) to realize value from use of the AI product or service (Why).

5.3.2.6 AI application provider

In general, an AI application provider is an organization or entity that provides products or services that uses one or more AI systems. In the AI application context, an AI application provider (Who) is an organization or entity that provides the capabilities from an AI system (such as reasoning and decision-making) in the form of an AI application (What) as a product or service (How) to internal or external customers as described in ISO/IEC 22989:2022.

NOTE An AI application provider in this document is analogous to an AI product or service provider in ISO/IEC 22989:2022.

An AI application provider can be internal (part of the AI producer's organization) or external (such as a third-party product or service provider). An AI application provider's role is usually centred around the deployment stage in the AI system life cycle (When). They can also participate in earlier stages by contributing about potential application domains, locations, customers and users, decision types and the particularities of the deployment environment.

5.3.2.7 AI partner

An AI partner is an organization or entity that provides services to the AI producer and AI application provider as part of a business relationship.

5.3.2.8 Data provider

A data provider (Who) is an organization or entity that is concerned with providing data used by AI products or services. A data provider either collects or prepares data (What), or both for use by the AI producer's AI model. The data provider can be a partner of the AI producer.

The role of a data provider is usually centred around pre-deployment stages (When). In certain circumstances, such as where the AI system employs machine learning models, the data provider can also be involved in the post-deployment stages to collect and prepare data for continuous validation (When).

5.3.3 Other stakeholders

5.3.3.1 General

Other stakeholders include those in the community that are not involved in the production or use of the AI application but are still impacted, e.g. consumers. Regulators and policy makers whose mandate can have an impact in the AI application context are also in this category.

5.3.3.2 Community

The use of AI technology can have impacts beyond the individual customer and user and affect other community members (Who) (e.g. consumers, family, neighbours, work colleagues, social circle, affiliates).

5.3.3.3 Regulators and policy makers

A regulator (Who) is an authority in the locality where the AI application is deployed and operated, and which has jurisdiction governing the use of AI technology based on existing legal requirements. Even though compliance to legal requirements is assessed by regulators in the deployment, operation and monitoring stages, the AI provider and other early stage stakeholders should identify applicable risks and regulation and provide solutions to avoid barriers to achieve original objectives.

AI applications can be deployed in jurisdictions that have different regulations related to the collection and use of data, as well as their operations.

A policy maker (Who) is an authority in the locality where the AI application is deployed and operated that sets the legal requirements governing the use of AI technology.

5.3.4 Processes

5.3.4.1 General

A process is a function or activity that transforms a specified input into a desired output. In the context of an AI application, the processes described in this clause are related to input data (What) that are transformed (How) by the AI system into its capabilities (What). These capabilities are to be deployed (How, Where) in an AI application (What) to augment a user's decision-making (What, How, When).

5.3.4.2 AI system

An AI system is an engineered system that is designed, developed, verified and validated by the AI producer to perform certain functions such as reasoning and decision-making, as described in ISO/IEC 22989:2022. These functions produce "What the AI system can do", i.e. the AI system capabilities. How these capabilities are produced depends on the configuration and construction of the AI model (see [5.3.4.3](#)) and the field involved, e.g. computer vision, image recognition, natural language processing, machine translation, speech synthesis, data mining and planning.

5.3.4.3 AI model and development

An AI model is a mathematical representation of a process (What) that forms the core of an AI system (see [5.3.4.2](#)). The AI model can be developed from different technologies, such as neural networks, decision trees, Bayesian networks, logic sentences and ontologies. These models are used to make predictions or to compute decisions to support the functions of the AI system as described in ISO/IEC 22989:2022, 8.3.

Information required for the model's development can be derived from machine learning by processing prepared data with an algorithm (How). The data are prepared from sources appropriate for the domain and decision-making environment of the AI application (see [5.3.4.4](#)). Alternatively, information can be derived from human-engineered declarative or procedural knowledge and human expertise can be used in logic programming and rule-based systems for making inferences (How) (see ISO/IEC 23053:2022, 7.1^[13]).

5.3.4.4 AI application

The AI system capabilities (see [5.3.4.2](#)) are applied to a decision-making environment in a particular domain, including agriculture, transportation, fintech, education, energy, healthcare, manufacturing and many others. This "application" can include incorporating other non-AI capabilities, features and customizations to meet system specifications as well as the needs of customers or users. The AI application provider packages AI system capabilities into a deployable AI application (What), which in turn performs its own unique AI application capabilities. An AI application can be deployed as a product or service by the AI application provider. The level of automation of the AI application is discussed in [5.3.4.6](#). The level of automation can be found in ISO/IEC 22989:2022, 5.13.

An example is an AI system that provides natural language understanding (NLU) capabilities that are packaged with a conversation builder and sentiment analysis functions to create a chatbot deployed as a cloud service for online interaction with users (e.g. the use case in [Clause A.3](#)). Another example is an AI system that provides image processing capabilities with deep learning that is used in a medical diagnostic environment as an anomaly detecting AI application for biomedical imaging. The AI application uses visualization of the training and evaluation data built around the AI system capabilities and interfaces for pathologists in evaluating images^[3].

5.3.4.5 AI service

An AI service is an activity performed for the AI customer or user (How) that is based on an AI application's capabilities. The deployment of the service can be on-premise (e.g. [Clause A.2](#)) or as a cloud service (Where) (e.g. [Clause A.3](#)).

5.3.4.6 AI-augmented decision-making

In a typical decision-making scenario, the decision maker is faced with the following: a set of uncertain events each with a probability of happening; a set of actions that can be taken in response to the events; a set of outcomes based on actions taken and certain events actually happening. To reduce the uncertainty of predicting events, the decision maker can seek to gain a more accurate estimate of the probability of events happening. This can be done by collecting pertinent data about the decision environment and process them within the context of the decision into information to form predictions. Given these predictions and the decision criteria such as to maximize the expected value of the decision, the decision maker's expertise can then be used to determine which action to take based on the expected value of each outcome and take the best course of action. In some cases, external intelligence is also consulted in making the decision.

In the context of an AI application, it is the tool that a decision maker uses to perform some of these tasks. As shown in [Figure 1](#), the collection and preparation of data to be processed by the AI model (see [5.3.4.3](#)) are done for the AI system (see [5.3.4.2](#)). The AI model makes predictions that can contribute to decision-making and courses of action.

The AI application is designed for a certain level of automation. On one end of the spectrum, the decision and action are taken by the AI application without human intervention. On the other end, the recommendation of the AI application is used to augment the knowledge and expertise of the decision maker who ultimately makes the decision and takes the action. The decision-making can occur when scheduled, triggered by sensor or event when needed (When).

5.4 AI application functional characteristics

An AI application can be distinguished from a non-AI application by its possession of one or more of the following functional characteristics:

- a) An AI application is built with the capabilities of an AI system that implements a model to acquire information and processes with or without human intervention by algorithm or programming. The model can be implemented with supervised, semi-supervised, or unsupervised machine learning or programmed rules. The acquisition of information to build the model can also include the processes related to how the information is used.
- b) An AI application applies optimizations or inferences made with the model to augment decisions, predictions or recommendations in a timely manner to meet specific objectives. Other capabilities, features and customization are usually added to uniquely fit the needs of the specific domain and decision environment as well as that of the AI customers and AI users. The form of optimization and inference output to be applied depends on the model being built. The output is used to augment the intelligence of the user in making decisions, predictions and recommendations. The application can react and respond in a dynamic environment, including in real-time.
- c) An AI application is updated in some cases and the model, system or application are improved by evaluation of interaction outcomes. The outcomes from interaction with users are evaluated based on the performance metrics of the model and used for continuous learning and improvement.

The relationship between these three numbered characteristics and the stakeholders within the context of an AI application are reflected in [Figure 1](#).

5.5 AI application non-functional characteristics and considerations

5.5.1 General

The AI application functional characteristics are described in [5.4](#). The non-functional characteristics of an AI application should also be considered by the stakeholders when making decisions about the AI application. This clause introduces AI application-specific non-functional requirements.

5.5.2 Trustworthiness

5.5.2.1 General

Trustworthiness is a non-functional and essential characteristic of an AI system. It refers to the characteristic that signifies that the system meets the expectation of its stakeholders in a verifiable way as described in ISO/IEC 22989:2022, 5.15; as well as expressing its quality as being dependable and reliable^[2]. The trustworthiness of an AI application is based on the trustworthiness of its AI system and any additional incorporated capabilities, features and customization. The different trustworthiness perspectives of stakeholders (make, use, impact) are discussed in [Clause 7](#).

The elements of trustworthiness are briefly introduced in this clause (from ISO/IEC TR 24028:2020^[2]). Further development of trustworthiness has been undertaken in other International Standards such as ISO/IEC 25059^[4].

5.5.2.2 AI robustness

AI robustness is the ability of an AI system to maintain its level of performance, as intended by its developers, and required by its customers and users, under any circumstances (see ISO/IEC 22989:2022, 5.15.2 and ISO/IEC TR 24029-1^[5], ISO/IEC 24029-2^[6] for robustness of neural networks).

5.5.2.3 AI reliability

AI reliability is the ability of an AI system or any of its subcomponents to perform its required functions under stated conditions for a specific period of time (see ISO/IEC 22989:2022, 5.15.3).

5.5.2.4 AI resilience

AI resilience is the ability of an AI system to recover operational condition quickly following a fault or disruptive incident. Some fault tolerant systems can operate continuously after such an incident, albeit with degraded capabilities (see ISO/IEC 22989:2022, 5.15.4).

5.5.2.5 AI controllability

AI controllability is the characteristic of an AI system whose functioning can be intervened by an external agent (see ISO/IEC 22989:2022, 5.15.5).

5.5.2.6 AI explainability

AI explainability is the characteristic of an AI system which can express important factors influencing a decision, prediction or recommendation in a way that humans can understand (see ISO/IEC 22989:2022 5.15.6).

5.5.2.7 AI predictability

AI predictability is the characteristic of an AI system that enables reliable assumptions by stakeholders of its behaviour and the output as described in ISO/IEC 22989:2022, 5.15.7. ISO/IEC TR 24028:2020^[2] discusses this from the perspective of unpredictability.

5.5.2.8 AI transparency

AI transparency enables the stakeholders to be informed of the purpose of the AI system, how it was developed and deployed (see ISO/IEC 22989:2022, 5.15.8). This involves communicating information such as goals, limitations, definitions, assumptions, algorithms, data sources and collection, security, privacy and confidentiality protection and level of automation. A discussion of traceability, an element of transparency, as a potential source of ethical concern can be found in ISO/IEC TR 24368:2022^[7].

5.5.2.9 AI verification and validation

AI verification is the confirmation that an AI system was built right and fulfils specified requirements. AI validation is the confirmation with objective evidence that the requirements for a specific intended use of the AI application have been fulfilled (see ISO/IEC 22989:2022, 5.16). ISO/IEC 25059^[4] describes software engineering validation and verification methods that are applicable to an AI system.

5.5.2.10 AI bias and fairness

A biased AI system can behave unfairly to humans (or certain subgroups). Fairness is a human perception and is based on personal and societal norms and beliefs. Unfair behaviour of AI systems can have negative, even harmful and devastating, impact on individuals or groups (see ISO/IEC 22989:2022, 5.15.9, see also discussion in ISO/IEC TR 24027:2021^[8]).

5.5.3 Risks and risk management

5.5.3.1 General

Risks, as with trustworthiness, are non-functional property of AI systems. AI systems, such as traditional software systems, operate within a spectrum of risk^[9], which is determined by the severity of the potential impact of a failure or unexpected behaviour and the impacted individuals or societies.^[2] Risks can be mitigated by risk management practices. The extent of risk management undertaken by an organization depends on its “risk appetite”. In some cases where the adversity level is high the “concern” can become a risk management “objective” at all stages of the AI system life cycle. In this clause, the elements of risks and risk management are introduced (see ISO/IEC 23894^[9]).

5.5.3.2 Risk management framework and processing

A risk management framework “to assist the organization in integrating risk management into specific activities and functions” that are specific to the development, provision or offering, or use of AI systems is introduced in ISO/IEC 23894:2023, Clause 5^[9]. The processes associated with the AI-specific activities and functions include systematic application of policies, processing and practices in assessing, treating, reporting and mitigating the risks are detailed in ISO/IEC 23894:2023, Clause 6^[9].

5.5.4 Ethics and societal concerns

5.5.4.1 General

On the one hand, AI technology has the potential to provide huge benefits to societies, organizations and individuals. On the other hand, the application of AI technology also gives rise to potential and wide-ranging ethical and societal concerns. Common ethical concerns relate to the means of collecting, processing and disclosing of personal data, conceivably with biased opinions, that feed opaque machine learning decision-making algorithms which are not explainable (see ISO/IEC TR 24368:2022, 6, 8^[7]).

5.5.4.2 Ethical framework

An AI ethical framework can be built on existing ethical frameworks such as virtual ethics, utilitarianism, deontology and others (see considerations in ISO/IEC TR 24368:2022^[7]). This clause describes the approach for establishing an AI application context as described in ISO/IEC TR 24368:2022, 7.2^[7]). Organizations contemplating the development and use of AI in responsible ways can consider adoption of various AI principles (ISO/IEC TR 24368:2022, 6.2^[7] and further discussed in Clause 8). Key themes associated with the AI principles include accountability, safety and security, transparency and explainability, fairness and non-discrimination, human control of technology, professional responsibility, promotion of human values, international human rights, respect for international norms of behaviour, community involvement and development, respect for the rule of law, sustainable environment and labour practices (see also examples of how to build socially acceptable AI in ISO/IEC TR 24368:2022, Clause 8^[7]).

5.5.4.3 Societal concerns

The use of AI technology has the potential to impact a wide range of societal stakeholders beyond the customers and users. These stakeholders can be members of the community where the AI technology is deployed or even future generations who will live with the impact of the technology on the quality-of-life of the physical and work environment. It is the responsibility of the organization contemplating the development and use of AI technology to recognize its social responsibility and undertake stakeholder identification and engagement to address the impact of the technology (see ISO 26000:2010^[10]).

5.5.4.4 Legal requirements and issues

AI technology is new and the legal requirements associated with its development, deployment and use are not yet widely defined. Some regions have instituted legal requirements governing certain aspects of AI technology and applications (e.g. facial recognition for law enforcement), and a wide range of proposals has been made and debated. Currently there are no coordinated and cohesive legal requirements at the domain, regional, national or international levels concerning AI technology.

6 Stakeholders' perspectives and AI application framework

6.1 General

The AI application context described in [5.2](#) forms the foundation of the AI application framework defined in this clause. The AI application framework can be used to answer the question: "What are the characteristics and considerations of an AI application?"

6.2 Stakeholders' perspectives

The AI application framework described here incorporates the perspectives of different groups of stakeholders. These groups have dissimilar perspectives on the AI application based on their intentions and objectives. They are "make", "use" and "impact" and are shown in [Figure 2](#). An organizational boundary is used in [Figure 2](#) as a demarcation between the different groups of stakeholders. These perspectives focus on the AI application and its functional characteristics, non-functional characteristics and considerations.

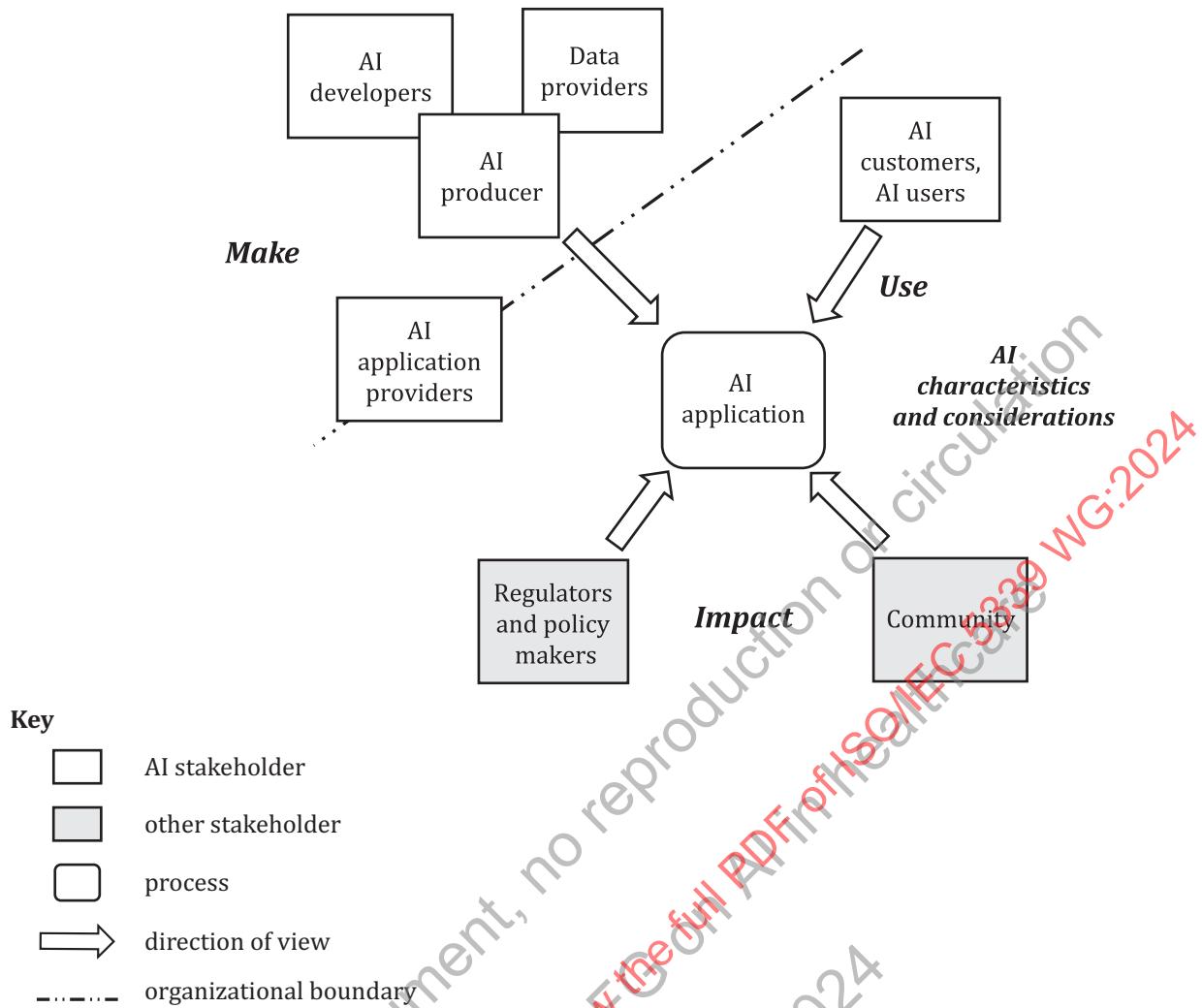


Figure 2 — AI application – stakeholders' perspectives

The "make" perspective emanates from the AI producers, AI developers and data providers who produce the AI application. The AI provider shares some of this perspective since they can have a role in both the production and deployment of the AI application. The AI customer and AI user have the "use" perspective since they are the ones who employ the AI application to augment their decision-making. The community's perspective is from the view of how it is being impacted by the deployment of the AI application. The regulator's perspective is on whether the deployment of the AI application complies with legal requirements (promulgated by policy makers) of the locality and jurisdictional impact on the product or service if non-compliant.

6.3 AI application framework

The AI application framework is represented in [Figure 3](#). [Table 1](#) establishes the relationship between the stakeholders (rows) and their make and use perspectives (columns). [Table 2](#) establishes the relationship between the stakeholders (rows) and their impact perspective (column). [Table 3](#) expands on the AI characteristics of the processes (How) and the context of the stakeholders' involvement. The AI application framework as a combined view from [Tables 1, 2](#) and [3](#) is shown in [Figure 3](#).

Perspectives		Make	Use	Impact
Stakeholders				
Context	Who			
	What			
	How			
	When			
	Where			
	Why			
	Subclause references			
All non-functional	Characteristics			
	Considerations			
Subclause references				

AI characteristics	Processes	What	How	Subclause references

Figure 3 — AI application framework as combined view with [Table 1](#), [Table 2](#) and [Table 3](#)

Table 1 — AI application framework — Make and use perspectives

Perspectives		Make				Use	
Stakeholders		AI producers	Data providers	AI developers	AI application providers	AI customers	AI users
Context	Who	•	•	•	•	•	•
	What (see AI characteristics in Table 3)	•	•	•	•	•	•
	How (see AI characteristics in Table 3)	Build, apply, update	Build	Build	Build	Apply	Apply
	When	All stages	Design and development; Verification and validation	Design and development; Verification and validation	Deployment, operation and monitoring	All stages	Deployment, operation and monitoring
	Where	•	•	•	•	•	•
	Why	•	•	•	•	•	•
	Subclause references	7.1.2	7.1.3	7.1.4	7.1.5	7.2.2	7.2.2
AI non-functional	Characteristics	Trustworthiness, risks and management					
	Considerations	Ethics, societal concerns, legal requirements and issues					
Subclause references		5.5.2 , 5.5.3 , 5.5.4					
• = Stakeholder's role(s) in context.							

Table 2 — AI application framework — Impact perspective

Perspectives		Impact	
Stakeholders		Community	Regulators and policy makers
Context	Who	•	•
	What	•	•
	How	•	•
	When	Deployment, operation and monitoring	Deployment, operation and monitoring
	Where	•	•
	Why	•	•
	Subclause references	7.3.2	7.3.3
AI non-functional	Characteristics	Trustworthiness, risks and management	
	Considerations	Ethics, societal concerns, legal requirements and issues	
Subclause references		5.5.2 , 5.5.3 , 5.5.4	
• = Stakeholder's role(s) in context.			

Table 3 — AI application framework — AI characteristics

AI Characteristics	Processes	What	How	Subclause references
Built with the capabilities of an AI system that implements a model to acquire information and processes with or without human intervention by algorithm or programming	AI model development, AI system	■	■	
Applies optimizations or inferences made with the model to augment decisions, predictions or recommendations in a timely manner to meet specific objectives	AI application, AI-augmented decision-making	■	■	5.4
Updates and improvements made to the model, system or application by evaluation of interaction outcomes	Continuous validation	■	■	

■ = AI characteristics in context.

7 Guidance for AI applications

7.1 General

This clause provides recommendations for the stakeholders to recognize their roles and responsibilities as well as be made aware of opportunities in making, using or responding to the impact of the AI application. The functional characteristics (see [5.4](#)) and non-functional characteristics (see [5.5](#)) of the AI application are considered in this guidance.

The guidance is formulated as a set of questions that each type of stakeholder should be asking as part of their roles and responsibilities based on the perspectives in [Figure 2](#) and the framework in [Table 3](#). Some of these questions can lead to opportunities for the stakeholders to explore further aspects of an AI application such as applicability of relevant International Standards for the specific application. [Annex A](#) provides two use cases where answers to some of the questions recommended here are used to fill in the AI application framework in [Table 3](#).

7.1.1 General

The stakeholders with the make perspective are those that work for or partner with the AI producer to design, develop, verify, validate and provide data for the AI system, which in turn is deployed as an AI application.

7.1.2 AI producer perspective

The AI producer should at least address the following considerations:

- Who are the AI customers and AI users?
- Who are the AI developers? Are they qualified and skilled employees or contractors?
- Who are the AI application providers and their relationship with the AI producer?
- Who are the stakeholders in each stage of the AI system life cycle (see ISO/IEC 22989:2022, Clause 6)? What is the AI system and its capabilities? What algorithm is the AI model based on?
- What are the AI characteristics of the AI application?
- What data are used to create the AI model? What is the source of these data? Who are the data providers and their partners?

- What are the trustworthiness and risk concerns of the AI application? What is being done to assess and mitigate these concerns? Is a risk management system in place for the organization? ([2],[9])
- What are the ethics, societal concerns, security, confidentiality, privacy and other legal requirement considerations in producing and deploying the AI application? How are they being addressed [5]?
- What is the technological ecosystem for the accessible deployment of the AI application?
- What is the overall quality of the AI system? [4],[5]
- How is the AI application built, applied and updated? How is the AI model trained or programmed? How robust is the AI model [6],[7]? When (in which stage of AI system life cycle) the model building, application and updates will be reviewed? Where is the model built, applied and updated, on site or using a cloud service? When (in which stage of AI system life cycle) should the AI producer be involved to reassess AI characteristics in context?
- Where is the AI application to be deployed, on-premise or as a cloud service? Where will the AI application be developed? Where are the AI developers located? Where are the data sources located? Where, in terms of, geographical location will the AI application be deployed?
- Why is the AI application being developed into a product or service? What is the potential value for the AI producer and AI customer? What are the opportunities and courses of action?

7.1.3 Data provider perspective

The data provider should at least address the following considerations:

- Who is the AI producer? Employer, partner or customer?
- What data are being collected and what is the source? How are the data collected, stored, processed, provisioned and fed into the AI model (for machine learning applications, see ISO/IEC 5259-4:—¹⁾ [14])? Is a data management system employed (for machine learning applications, see ISO/IEC 5259-3:—²⁾ [15])?
- What is the domain, geographical and other providence of the data being collected? What are the applicable boundary conditions of the AI model developed from these data?
- What are the sources and nature restrictions for gathering the required training data?
- How is the quality of the collected data measured and validated (for machine learning applications see ISO/IEC 5259-2:—³⁾ [11])? What are the trustworthiness and bias concerns of the data? What is being done to assess and mitigate these concerns (see ISO/IEC TR 24028:2020, [2] ISO/IEC TR 24027:2021 [8])?
- How are data being collected, validated and used to update the AI model during the operation and maintenance stage? How are collected data secured, protected and used appropriately in compliance with internal policies and data sovereignty requirements?
- When (in which stages of AI system life cycle) the data availability and quality need to be reassessed?
- Where is the source location of the data? Where are the data to be processed, on-premise or using a cloud service? In which geographic location?
- Why specific data are needed in the context of the AI application?

7.1.4 AI developer perspective

The AI developer should at least address the following considerations:

- Who is the AI user, data provider and AI producer?

1) Under preparation. Stage at the time of publication: ISO/IEC DIS 5259-4:2023.

2) Under preparation. Stage at the time of publication: ISO/IEC DIS 5259-3:2023.

3) Under preparation. Stage at the time of publication: ISO/IEC DIS 5259-2:2023.

- What is the relationship between the AI developer and AI producer? Employee or contractor?
- What are the qualifications and skills required of the AI developers?
- What AI model is employed, trained or programmed? How is the AI model being designed, developed, validated and verified into the functional characteristics of the AI system? What processes are involved?
- What are the technological and ecosystem requirements needed to deploy the AI system as an accessible AI application?
- What are the algorithms used for data processing? What are the criteria for data quality? What are the criteria for output quality? What are criteria for validation and verification? What are the criteria for model update?
- How are data pre-processed? How is the quality of data determined? How is the algorithm selection done? How are the model requirements adapted?
- When (in which stage of AI system life cycle) are the context and requirements assessed?
- Where the AI application can be deployed, locally or as a cloud service?
- Why is the AI application being developed into a product or service? Why the specific model is used?

7.1.5 AI application provider perspective

The AI application provider should at least address the following considerations:

- Who are the AI customers and AI users and how do they employ the AI application?
- What is the relationship between the AI producer and the AI application provider? Employer or partner?
- What are the AI characteristics of the application? What are its capabilities, capacity and throughput as well as constraints and limitations?
- What are the technological and ecosystem requirements for the AI customers and AI users to access and use the AI application? What are the failure recovery provisions?
- What are the operational analytics of the AI application and how are they monitored?
- What are the impacts of the AI application on its customers, users and community?
- How is the AI application built, applied and updated? How is the AI model trained or programmed? How robust is the AI model^[5] ^[6]? When (in which stages of AI system life cycle) the model building, application and updates are to be reviewed? Where is the model built, applied and updated, on site or as a cloud services? When (in which stages of AI system life cycle) should the producer be involved to reassess AI characteristics in context?
- How are risks managed in the deployment of the AI application?
- When (in which stage of AI system life cycle) are the context and requirements assessed?
- Are there any applicable boundaries for the recommended, acceptable or responsible use of the AI application? Are these part of the legal requirements in the software license?
- Where is the AI application being deployed? What legal requirements apply to the functional and non-functional characteristics of the AI application's domain? Who are the regulators?
- Why is the AI application being developed into a product or service?

7.2 Use perspective

7.2.1 General

The stakeholders with the use perspective are those AI customers and AI users that employ the AI application to augment their decision-making (see [5.3.4.6](#)).

7.2.2 AI customer and AI user perspective

The AI customer and AI user should at least address the following considerations:

- What is the relationship between the AI application provider and AI customer or AI user?
- What are the AI customers' and AI users' (and as community members) considerations in using the AI application? What are some of the governance implications involved in organizations where the AI application is employed (see ISO/IEC 38507:2022[\[12\]](#))?
- What data are collected in using the AI application and how are they being used (for machine learning applications, see Reference [\[11\]](#))? What are the data governance policies in place? Are the data being fed back into the AI model for continuous learning and improvement?
- What are the trustworthiness and risk considerations of the AI application being used? What is being done to assess and mitigate these concerns[\[2\]](#)?
- What are the transparency and explainability aspects of the AI application supplied by the AI provider?
- What are the ethical and societal concerns in using the AI application? How are they addressed?
- What decision-making will be augmented by the AI application? What is the level of automation? Who is going to evaluate the effectiveness of the AI application and what metrics are being used?
- How do the AI customers and AI users access the output of the AI application to augment their decision-making? How are the performance and effectiveness of the AI application being measured?
- When (in which stage of AI system life cycle) are the context and requirements assessed? Where is the AI application deployed and accessed? What are the legal requirements for deployment?
- Why is the AI application being employed? What are the potential values in employing the AI application?

7.3 Impact perspective

7.3.1 General

The community in which the AI application is deployed and its consumers in it can be impacted by its use. Examples include the use of AI applications in surveillance, loan application, delivery of health care, information dissemination in social media. The deployment of an AI application can be impacted by the regulator who is an authority in the locality and has jurisdiction governing the use of AI technology based on legal requirements promulgated by policy makers.

7.3.2 Community perspective

The community in which the AI application is deployed should at least address the following considerations:

- Who are the consumers? What are their particular concerns as a member of the community?
- What data are collected in using the AI application and how are they being used? What are the privacy concerns?
- How is the community and consumers in it being impacted by the employment of the AI application? How is this impact being measured, how often and by whom? What are the community's recourses for adverse impacts?

- When (in which stage of AI system life cycle) the AI customer feedback or requirements are to be assessed and reassessed?

7.3.3 Regulator and policy maker perspective

Regulators and policy makers should at least address the following considerations:

- Who are the consumers? What are their particular concerns as a member of the community?
- What is the mechanism through which legal requirements are made for the deployment of the AI application (e.g. top-down or bottom-up)? How is the AI application being used and how does the employment impact the community? Who is the responsible party (e.g. AI provider, AI customer, AI user)?
- When (in which stage of AI system life cycle) are the legal requirements assessed or reassessed?
- Where is the AI application being deployed? What are the applicable legal requirements? How is the deployment going to be monitored for compliance? Who is the responding party for a violation?
- Why is the AI application being employed? What are the potential values in employing the AI application? What are potential, positive or adverse impacts on the community?

Annex A

(informative)

Use cases

A.1 General

Two use cases are presented to illustrate the applicability of this document based on the context (see [5.2](#)), stakeholders and processes (see [5.3](#)), AI characteristics (see [5.4](#)) captured in the AI application framework (see [Clause 6](#), [Table 2](#) and [Table 3](#)). Some of the cells are filled in with answers from questions suggested in [Clause 7](#).

A.2 Fujitsu^{TM 4)} Limited – detecting defects in wind turbine blades

The use case from Fujitsu Limited deals with an AI application that uses deep learning to train an algorithm to detect defects in a wind turbine blade to augment quality control and inspection decision-making. The stakeholders, context and AI characteristics of this application are shown in [Table A.1](#), [Table A.2](#) and [Table A.3](#) based on the AI application framework (see [6.3](#)) (refer to [Figure 3](#) for a combined view of the framework).

Table A.1 — AI application framework — Make perspective for Fujitsu Limited use case

Perspectives		Make			
Stakeholders		AI producers	Data providers	AI developers	AI application providers
Context	Who	Fujitsu Limited	Ultrasonic scanner vendor	Fujitsu Limited	Fujitsu Limited
	What (see AI characteristics in Table A.3)	Responsible for the entire system	Provides data from ultrasonic scanners	Develops the AI system including the trained model	Takes the developed AI system and provides it as an AI application
	How (see AI characteristics in Table A.3)	Build, apply, update	Build	Build	Build
	When	All stages	Design, develop, verify, validate	Design, develop, verify, validate	Deploy, operate, monitor
	Where		Producer	Producer	Customer premises
	Why	The producer is expected to provide a good AI application for the customer because of a good understanding of the objective and requirements of the AI application through dialogues with the customer			

Empty cells denote no information was provided.

4) FujitsuTM is a trademark of Fujitsu Limited. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of this product.

Table A.2 — AI application framework — Use and impact perspectives for Fujitsu Limited use case

Perspectives		Use		Impact	
Stakeholders		AI customers	AI users	Community	Regulators and policy makers
Context	Who	Wind turbine manufacturer	Professional quality controller, inspector of manufacturer	Utility companies, users and neighbours of wind turbine	For example, for the EU market: the European Commission's Director-General (DG) for internal market, industry, entrepreneurship and SMEs
	What				
	How	Apply	Apply		
	When	Deploy, operate, monitor	Deploy, operate, monitor	Deploy, operate, monitor	Deploy, operate, monitor
	Where	Customer premises	Customer premises		
	Why	Any defects when a blade is in operation cannot only prove catastrophic but also inflict major damage to the manufacturer's reputation. The manufacturer produces over 5 000 wind turbine blades every year for use in on and offshore wind farms. Each blade can be up to 75 m in length and takes a highly skilled professional quality controller up to 6 h to evaluate the scanning data in the quality assurance process. With the AI system the evaluation time is reduced by 80 %, which translates into cost savings, reduced production lead times, and increased productivity	Professional quality controllers and inspectors of the manufacturer are interested in their increased productivity with the AI application as well as the performance (accuracy) of the AI application	Neighbours of the wind turbine sites are apprehensive about any damage caused by a defective wind turbine	The regulator ensures the safety of products with applicable requirements for the manufacturing process of huge products such as wind turbine blades and liability of defective products

Empty cells denote no information was provided.