ISO/IEC FDIS 42001:####(X:2023(E)

ISO/IEC JTC 1/SC 42/WG 1

Secretariat: ANSI

Date: 2023-09-22

Information technology — Artificial intelligence — Management system

~~FDIS stage~~

~~Warning for WDs and CDs~~

~~This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.~~

~~Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.~~

ISO copyright office

CP 401 • Ch. de Blandonnet 8

CH-1214 Vernier, Geneva

Phone: +41 22 749 01 11

Fax: +41 22 749 09 47

Email: copyright@iso.org

Website: www.iso.orgwww.iso.org

Published in Switzerland

Contents

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).

Attention is drawnISO and IEC draw attention to the possibility that some of the elementsimplementation of this document may beinvolve the subjectuse 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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see https://patents.iec.ch).

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) is increasingly applied across all sectors utilizing information technology and is expected to be one of the main economic drivers. A consequence of this trend is that certain applications can give rise to societal challenges over the coming years.

This document intends to help organizations responsibly perform their role with respect to AI systems (e.g. to use, develop, monitor or provide products or services that utiliseutilize AI). AI potentially raises specific considerations such as:

— The use of AI for automatic decision-making, sometimes in a non-transparent and non-explainable way, can require specific management beyond the management of classical IT systems.

— The use of data analysis, insight and machine learning, rather than human-coded logic to design systems, both increases the application opportunities for AI systems and changes the way that such systems are developed, justified and deployed.

— AI systems that perform continuous learning change their behaviour during use. They require special consideration to ensure their responsible use continues with changing behaviour.

This document provides requirements for establishing, implementing, maintaining and continually improving an AI management system within the context of an organization. Organizations are expected to focus their application of requirements on features that are unique to AI. Certain features of AI, such as the ability to continuously learn and improve or lack of transparency or explainability, can warrant different safeguards if they raise additional concerns compared to how the task would traditionally be performed. The adoption of an AI management system to extend the existing management structures is a strategic decision for an organization.

The organization's needs and objectives, processes, size and structure as well as the expectations of various interested parties influence the establishment and implementation of the AI management system. Another set of factors that influence the establishment and implementation of the AI management system are the many use cases for AI and the need to strike the appropriate balance between governance mechanisms and innovation. Organizations can elect to apply these requirements using a risk-based approach to ensure that the appropriate level of control is applied for the particular AI use cases, services or products within the organization's scope. All these influencing factors are expected to change and be reviewed from time to time.

It is important that theThe AI management system isshould be integrated with the organization's processes and overall management structure. Specific issues related to AI need toshould be considered in the design of processes, information systems and controls. Crucial examples of such management processes are:

— determination of organizational objectives, involvement of interested parties and organizational policy;

— management of risks and opportunities;

— processes for the management of concerns related to the trustworthiness of AI systems such as security, safety, fairness, transparency, data quality and quality of AI systems throughout their life cycle;

— processes for the management of suppliers, partners and third parties that provide or develop AI systems for the organization.

This document provides guidelines for the deployment of applicable controls to support such processes.

This document avoids specific guidance on management processes. The organization can combine generally accepted frameworks, other International Standards and its own experience to implement crucial processes such as risk management, life cycle management and data quality management which are appropriate for the specific AI use cases, products or services in scope.

An organization conforming with the requirements in this document can generate evidence of its responsibility and accountability regarding its role with respect to AI systems.

The order in which requirements are presented in this document does not reflect their importance or imply the order in which they are implemented. The list items are enumerated for reference purposes only.

Compatibility with other management system standards

This document applies the harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) developed to enhance alignment among management system standards (MSS). The AI management system provides requirements specific to managing the issues and risks arising from using AI in an organization. This common approach facilitates implementation and consistency with other management system standards, e.g. related to quality, safety, security and privacy.

Information technology — Artificial intelligence — Management system

1 Scope

This document specifies the requirements and provides guidance for establishing, implementing, maintaining and continually improving an AI (artificial intelligence) management system within the context of an organization.

This document is intended for use by an organization providing or using products or services that utilize AI systems. This document is intended to help the organization develop, provide or use AI systems responsibly in pursuing its objectives and meet applicable ~~regulatory~~ requirements, obligations related to interested parties and expectations from them.

This document is applicable to any organization, regardless of size, type and nature, that provides or uses products or services that utilize AI systems.

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

organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.6)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organization is part of a larger entity, the term “organization” refers only to the part of the larger entity that is within the scope of the AI *management system* (3.4).

3.2

interested party
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

Note 1 to entry: An overview of interested parties in AI is provided in ISO/IEC 22989:2022, 5.19.

3.3
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.5) and *objectives* (3.6), as well as *processes* (3.8) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.

3.5
policy
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.3)

3.6
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and environment). They can be, for example, organization-wide or specific to a project, product or *process* (3.8).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as an AI objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of AI *management systems* (3.4), AI objectives are set by the *organization* (3.1), consistent with the AI *policy* (3.5), to achieve specific results.

3.7
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73) and consequences (as defined in ISO Guide 73), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (as defined in ISO Guide 73) of occurrence.

3.8
process
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

Note 1 to entry: Whether the result of a process is called an output, a product or a service depends on the context of the reference.

3.9
competence
ability to apply knowledge and skills to achieve intended results

3.10
documented information
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

—— the *management system* (3.4), including related *processes* (3.8);

—— information created in order for the organization to operate (documentation);

—— evidence of results achieved (records).

3.11
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, *processes* (3.8), products, services, systems or *organizations* (3.1).

Note 3 to entry: In the context of this document, performance refers both to results achieved by using AI systems and results related to the AI *management system*. (3.4). The correct interpretation of the term is clear from the context of its use.

3.12
continual improvement
recurring activity to enhance *performance* (3.11)