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Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviated terms	2
5 Developing and implementing an AI system impact assessment process	3
5.1 General	3
5.2 Documenting the process	3
5.3 Integration with other organizational management processes	4
5.4 Timing of AI system impact assessment	4
5.5 Scope of the AI system impact assessment	5
5.6 Allocating responsibilities	5
5.7 Establishing thresholds for sensitive uses, restricted uses and impact scales	6
5.8 Performing the AI system impact assessment	7
5.9 Analysing the results of the AI system impact assessment	7
5.10 Recording and reporting	7
5.11 Approval process	8
5.12 Monitoring and review	9
6 Documenting the AI system impact assessment	9
6.1 General	9
6.2 Scope of the AI system impact assessment	9
6.3 AI system information	10
6.3.1 AI system description	10
6.3.2 AI system functionalities and capabilities	10
6.3.3 AI system purpose	10
6.3.4 Intended uses	10
6.3.5 Unintended uses	11
6.4 Data information and quality	11
6.4.1 General	11
6.4.2 Data information	11
6.4.3 Data quality documentation	12
6.5 Algorithm and model information	12
6.5.1 General	12
6.5.2 Information on algorithms used by the organization	12
6.5.3 Information on algorithm development	13
6.5.4 Information on models used in an AI system	13
6.5.5 Information on model development	14
6.6 Deployment environment	14
6.6.1 Geographical area and languages	14
6.6.2 Deployment environment complexity and constraints	14
6.7 Relevant interested parties	15
6.7.1 General	15
6.7.2 Directly affected interested parties	15
6.7.3 Other relevant interested parties	15
6.8 Actual and reasonably foreseeable impacts	16
6.8.1 General	16
6.8.2 Benefits and harms	16
6.8.3 AI system failures and reasonably foreseeable misuse	19
6.9 Measures to address harms and benefits	20
Annex A (informative) Guidance for use with ISO/IEC 42001	21
Annex B (informative) Guidance for use with ISO/IEC 23894	23

ISO/IEC FDIS 42005:2025(en)

Annex C (informative) Harms and benefits taxonomy	25
Annex D (informative) Aligning AI system impact assessment with other assessments	27
Annex E (informative) Example of an AI system impact assessment template	31
Bibliography	38

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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*.

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

The growing application of systems, products, services and components of such that incorporate some form of artificial intelligence (AI) has led to a growing concern about how AI systems can potentially impact all levels of society. AI brings with it the promise of great benefits: automation of difficult or dangerous jobs, faster and more accurate analysis of large sets of data, advances in healthcare etc. However, there are concerns about reasonably foreseeable negative effects of AI systems, including potentially harmful, unfair or discriminatory outcomes, environmental harm and unwanted reductions in workforce.

The development and use of seemingly benign AI systems can have the potential to significantly impact (both positively and negatively) individuals, groups of individuals and the society as a whole. To foster transparency and trustworthiness of systems using AI technologies, an organization developing and using these technologies can take actions to assure affected interested parties that these impacts have been appropriately considered. AI system impact assessments play an important role in the broader ecosystem of governance, risk and conformity assessment activities, which together can create a system of trust and accountability.

ISO/IEC 38507, ISO/IEC 23894 and ISO/IEC 42001 all form important pieces of this ecosystem, for governance, risk and conformity assessment (via a management system) respectively. Each of these highlights the need for consideration of impacts to individuals and societies. A governing body can understand these impacts to ensure that the development and use of AI systems align to company values and goals. An organization performing risk management activities can understand reasonably foreseeable impacts to individuals and societies to appropriately incorporate into their overall organizational risk assessment. An organization developing or using AI systems can incorporate understanding and documentation about these impacts into its management system to ensure that the AI systems in question meet expectations of relevant interested parties, as well as internal and external requirements.

The act of performing AI system impact assessments and utilizing their documented outcomes are integral to activities at all organizational levels to produce AI systems that are trustworthy and transparent. To this end, this document provides guidance for an organization on how to both implement a process for completing such assessments and promote a common understanding of the components necessary to produce an effective assessment.

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Information technology — Artificial intelligence — AI system impact assessment

1 Scope

This document provides guidance for organizations performing AI system impact assessments for individuals and societies that can be affected by an AI system and its foreseeable applications. It includes considerations for how and when to perform such assessments and at what stages of the AI system life cycle, as well as guidance for AI system impact assessment documentation.

Additionally, this guidance includes how this AI system impact assessment process can be integrated into an organization's AI risk management and AI management system.

This document is intended for use by organizations developing, providing or using AI systems. This document is applicable to any organization, regardless of size, type and nature.

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, *Information technology — Artificial intelligence — Artificial intelligence concepts and terminology*

ISO/IEC 23053, *Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 22989, ISO/IEC 23053 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 system impact assessment

formal, documented process by which the impacts to individuals, groups of individuals and societies are considered by an organization developing, providing, or using products or services utilizing artificial intelligence

3.2

intended use

use for which an AI system is designed

3.3

unintended use

use for which an AI system is not designed

3.4

intended users

groups of people or information systems for which an AI system is designed

[SOURCE: ISO 20282-1:2006, 3.12, modified — “people” has been replaced with “people or information systems” and “a product” has been replaced with “an AI system”.]

3.5

interested party

stakeholder

person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

[SOURCE: ISO/IEC 42001:2023, 3.2]

3.6

reasonably foreseeable misuse

use of an AI system in a way not intended by the AI system developer or provider, but which can result from readily predictable behaviour of intended users

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. the elderly, children and persons with disabilities. For more information, see ISO 10377.

Note 2 to entry: In the context of consumer safety, the term “reasonably foreseeable use” is increasingly used as a synonym for “intended use”, and “unintended use” as a synonym for “reasonably foreseeable misuse.”

Note 3 to entry: The specific definitions can vary somewhat, depending on the specific application area of the standard or regulation.

[SOURCE: ISO/IEC Guide 51:2014, 3.7, modified — “a product or system” has been replaced with “an AI system”, and “supplier” has been replaced with “AI system developer or provider”.]

3.7

restricted use

use of an AI system that is constrained by laws, organizational policies or contractual agreements

3.8

sensitive use

use of an AI system that can have a significant adverse impact on individuals, group of individuals or societies

3.9

top management

person or group of people who directs and controls an organization 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 covers only part of an organization, then top management refers to those who direct and control that part of the organization.

[SOURCE: ISO/IEC 42001:2023, 3.3]

4 Abbreviated terms

AI	artificial intelligence
BIA	business impact assessment
EIA	environmental impact assessment
FIA	financial impact assessment
HRIA	human rights impact assessment

IT	information technology
ML	machine learning
PIA	privacy impact assessment
PII	personally identifiable information
SIA	security impact assessment

5 Developing and implementing an AI system impact assessment process

5.1 General

5.1.1 The organization should have a structured and consistent approach for performing and documenting AI system impact assessments. The process used can vary depending on a range of factors.

5.1.2 Internal factors include:

- a) organizational context, governance, objectives, policies and procedures;
- b) contractual obligations;
- c) intended use of the AI system to be developed or used;
- d) risk appetite.

5.1.3 External factors include:

- a) applicable legal requirements, including prohibited uses of AI systems;
- b) policies, guidelines and decisions from regulators that have an impact on the interpretation or enforcement of legal requirements in the development and use of AI systems;
- c) incentives or consequences associated with the intended use of AI systems;
- d) culture, traditions, values, norms and ethics with respect to development and use of AI systems;
- e) competitive landscape and trends for new products and services using AI systems;

5.1.4 Clause 5 details possible elements of an AI system impact assessment process that the organization can consider when implementing such a process.

5.2 Documenting the process

The organization should document the process for completing AI system impact assessments. Such documentation should be kept up to date and made available, where appropriate, to relevant interested parties. Documentation of the process should include information on the topics in Clause 5. The intended results of the process documentation can vary depending on the organization's needs and the type of the AI system, and can include, for example:

- a) documented procedural guidance;
- b) AI system impact alignment guide or template (refer to [Annex D](#)) or for a standalone template (see [Annex E](#));
- c) use cases for awareness-raising and training;
- d) input in various management reviews in the related AI management system;

- e) completed AI system impact assessments and other artefacts from the assessment process.

Documentation should be maintained throughout the AI system impact assessment process within the data retention policies of the organization and its legal obligations related to data retention, i.e. at the stages of design, redesign, deployment and evaluation.

5.3 Integration with other organizational management processes

The organization should document how the AI system impact assessment is integrated with other organizational processes. This can include considerations such as:

- a) how the organization integrates the AI system impact assessment with organizational risk assessment;
- b) how the organization integrates the AI system impact assessment with other types of impact assessments;
- c) which organizational governance, risk and compliance processes are in place or planned for the treatment of reasonably foreseeable impacts.

NOTE [Annexes A, B and D](#) provide additional information.

5.4 Timing of AI system impact assessment

5.4.1 As part of establishing the AI system impact assessment process, the organization should determine and define when such assessments should be performed and to what level, or when a previous AI system impact assessment can be reused, repurposed or revised, and to what extent. Determining the timing of the AI system impact assessments can be impacted by factors such as, but not limited to:

- a) applicable legal requirements;
- b) contractual and professional obligations and duties;
- c) internal structures, policies, processes, procedures and resources, including technology;
- d) risk level of the AI system (the organization can consider ISO/IEC 23894:2023, 6.3.4 for additional guidance);
- e) expectations of relevant interested parties, including customers;
- f) internal AI system life cycle processes;

For additional guidance on the timing of AI system impact assessments and how they can be connected or aligned with other impact assessments conducted by the organisation, see [Annex D](#).

5.4.2 The organization should consider reassessment when changes arise in factors such as, but not limited to:

- a) change in intended use of the AI system, including changes to the users of the AI system;
- b) change in customer expectations;
- c) change in the AI system itself, including changes to:
 - 1) the data used;
 - 2) the complexity or type of the AI system;
 - 3) the performance of the AI system;
- d) changes in the operational environment of the AI system;

- e) change in context surrounding the AI system, including changes to:
 - 1) the applicable legal requirements;
 - 2) contractual obligations;
 - 3) internal policies;
 - 4) the relevant interested parties of the AI system;
 - 5) the locations and sectors in which the organization operates or anticipates operating.

AI risk assessments and AI system impact assessments should be conducted prior to implementing the change triggering reassessment.

5.4.3 Timing considerations can include:

- a) how often AI system impact assessments are performed;
- b) at what stage of the AI system life cycle the AI system impact assessment is performed;
- c) how frequently the AI system impact assessment is updated;
- d) under what circumstances a new AI system impact assessment or an update is needed;
- e) what other impact assessments are linked to the AI system impact assessment.

5.4.4 The organization should consider whether it uses tools for triaging when an AI system impact assessment is required. For example, if the organization determines that AI system impact assessments are only to be done on “high-risk” AI systems, they should document as part of the process what constitutes a “high-risk” AI system and what triggers the need for an impact assessment. A triaging process can require a briefer version of the AI system impact assessment to determine if the AI system is high-risk and requires a full AI system impact assessment.

5.5 Scope of the AI system impact assessment

The organization should define the scope of the AI system impact assessment, including the applicability and the boundaries of the AI system impact assessments considering the internal and external factors provided in [5.1](#), the expectations of relevant interested parties and the reasonably foreseeable impacts on individuals, groups of individuals or societies. The scope of an AI system impact assessment can include, but is not limited to:

- a) the entire AI system or a component of the AI system that provides functionalities explicitly useable by users (e.g. when a change is made to one or more components of the AI system);
- b) a description of the role of the organization within the AI ecosystem (e.g. data provider, model provider, service provider or product provider).

If a system is composed of interconnected AI systems, the organization should consider whether to perform a single AI system impact assessment.

NOTE Changes to an AI system component can have implications to the overall AI system impact on various interested parties.

5.6 Allocating responsibilities

The organization should ensure that the responsibilities for the AI system impact assignment are assigned and communicated within the organization. The relevant responsibilities depend on multiple factors, including the nature of the AI system impact assessment, its scope and its extent, the existence of a previous assessment, and can include responsibilities for:

- a) establishing the scope of the assessment;

- b) ensuring the allocation of appropriate resources;
- c) ensuring the availability of documented information;
- d) liaising with the relevant interested parties that can contribute to the assessment (e.g. groups and personnel responsible for research and development, marketing and sales, security and operations, legal personnel, labour representatives and other relevant interested parties);
- e) reporting and communication of the results or any relevant information to other organizational process or functions;
- f) establishing approvals process and escalations;
- g) ensuring the availability of the AI system impact assessment to relevant management reviews within the AI management system and the organization;

The assignment of responsibilities should consider the required experience and competency, the relevance of the role and the necessary access to information.

The organization should ensure that the assignment of responsibilities takes into account the relevant need for a multidisciplinary approach to consider impacts that can be reasonably foreseen and addressed throughout the AI system's life cycle.

NOTE Relevant disciplines can include engineering, health and safety, human rights, ethics and social sciences such as anthropology, sociology and psychology.

5.7 Establishing thresholds for sensitive uses, restricted uses and impact scales

A critical part of the AI system impact assessments processes is ensuring that thresholds, particularly around AI system use, are documented. The organization should define those thresholds, based on the context in which they operate. This can include considerations such as:

- a) applicable legal requirements;
- b) expectations of relevant interested parties;
- c) state of the art;
- d) benefits of the AI system;
- e) cultural, labour and societal norms;
- f) applicable AI ethical frameworks.

Depending on the types and amounts of thresholds, the organization can implement additional processes, including reviews and approvals. For example, the organization can decide that certain uses or reasonably foreseeable misuses are sensitive or prohibited by organizational policy. Legal or other external requirements can further determine the sensitivity of uses or reasonably foreseeable misuses of an AI system. If an AI system impact assessment indicates that its planned use falls under a "sensitive" or a "restricted" category, the organization should document what the next steps are as part of the overall process.

EXAMPLE 1 An example of a sensitive use case can be an AI systems designed to automate lending decisions, as such systems can have significant adverse financial impacts on individuals.

EXAMPLE 2 If a sensitive or restricted use is identified, then such uses can be escalated to management (including approvals). Consider an AI system which heavily impacts rights, particularly those of children, and with adverse impacts that cannot be mitigated by technical improvements. Such issues can be escalated to decide whether to review the development of this AI system due to adverse impact.

The organization should also consider how overall impact scales are determined and reasonably foreseeable impacts are calculated. The results of an AI system impact assessment can indicate, for example, that intended uses for an AI system are not sensitive but can affect a large population of users, and that should