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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

DRAFT INTERNATIONAL STANDARD

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Information technology — Artificial intelligence — AI system impact assessment

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85 **Foreword**

86 ISO (the International Organization for Standardization) is a worldwide federation of national standards
87 bodies (ISO member bodies). The work of preparing International Standards is normally carried out
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89 committee has been established has the right to be represented on that committee. International
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91 collaborates closely with the International Electrotechnical Commission (IEC) on all matters of
92 electrotechnical standardization.

93 The procedures used to develop this document and those intended for its further maintenance are
94 described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the
95 different types of ISO documents should be noted. This document was drafted in accordance with the
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102 constitute an endorsement.

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

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

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

111 Introduction

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

118 The development and use of seemingly minor AI systems has the potential to significantly impact (both
119 positively and negatively) individuals, groups of individuals and the society as a whole. To foster
120 transparency and trustworthiness of systems using AI technologies, an organization developing and
121 using these technologies can take actions to assure affected interested parties that these impacts have
122 been appropriately considered. No single activity can provide this assurance, but AI system impact
123 assessments play an important role in the broader ecosystem of governance, risk and conformity
124 assessment activities which together can create a system of trust and accountability.

125 ISO/IEC 38507, ISO/IEC 23894 and ISO/IEC 42001¹ all form important pieces of this ecosystem, for
126 governance, risk and conformity assessment (via a management system) respectively. Each of these
127 highlights the need for consideration of impacts to individuals and societies. A governing body can
128 understand these impacts to ensure that use of AI systems align to company values and goals. An
129 organization performing risk management activities can understand potential impacts to individuals and
130 societies to appropriately calculate and estimate their overall organizational risk. And an organization
131 developing or using AI systems can incorporate understanding and documentation about these impacts
132 into their management system to ensure that the AI systems in question meet expectations of relevant
133 interested parties as well as internal and external requirements.

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

¹ Under preparation. Stage at the time of publication: ISO/IEC FDIS 42001:2023.

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 22989:2022, *Information technology — Artificial intelligence — Concepts and terminology*

ISO/IEC 23053:2022, *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 22989:2022, ISO/IEC 23053:2022 and the following apply.

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

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

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

3.1

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

the purposes for which an AI system is designed, trained, and tested

3.3

intended users

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

[SOURCE: ISO 20282-1:2006, 3.12, modified to change “people” to “people or information systems”, and “a product” to “an AI system”]

3.4

interested party (preferred term)

stakeholder (admitted term)

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

180 [SOURCE: ISO/IEC 42001:—, 3.2, modified to remove cross references to other definitions in ISO/IEC
181 42001]

182 3.5

183 **reasonably foreseeable misuse**

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

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

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

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

192 [SOURCE: ISO/IEC Guide 51:2014, 3.7, modified to change “a product or system” to “an AI system”, and
193 “supplier” to “AI system developer or provider”]

194 3.6

195 **intentional abuse**

196 willful unauthorized use of an AI system in a way not intended by the AI system developer or provider,
197 that negatively affects the objectives of the AI system provider or user

198 Note 1 to entry: The specific definitions can vary somewhat, depending on the specific application area
199 of the standard or regulation.

200 [SOURCE: ISO/IEC 2382:2015, 2126318, modified to change “willful or negligent” to “willful”, “activity”
201 to “use of an AI system in a way not intended by the AI system developer or provider”, “computer
202 security” to “information security”, and “a data processing system” to “an AI system”]

203 3.7

204 **unintended use**

205 use or application of the AI system in a way not intended by the AI developer or AI provider, including
206 beneficial, negative or neutral impacts

207 3.8

208 **potentially beneficial use**

209 use or application of the AI system in a way not intended by the AI system developer or provider that
210 results in identifiable benefits or opportunities

211 3.9

212 **restricted use**

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

214 3.10

215 **sensitive use**

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

218 4 Implementing an AI system impact assessment process

219 4.1 General

220 Organizations should have a structured, consistent approach for performing and documenting AI system
221 impact assessments. The process used can vary depending on the context, including the organization’s
222 business, strategy, culture, legal requirements and risk appetite. Clause 4 details possible elements of an
223 AI system impact assessment process that organizations can consider when implementing such a process.

4.2 Documenting the process

The process for completing AI system impact assessments in an organization should be documented, and that documentation should be kept up to date and made available to relevant interested parties. Documentation of the process should include information on at least the topics in Clause 4. The outcome of the process documentation can vary depending on the organization's needs and the type of the AI system, and can include, for example:

- documented procedural guidance;
- AI system impact assessment templates (refer to Annex E for an example template);
- 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.

4.3 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 how it fits into an AI management system (ISO/IEC 42001) or other organizational management or governance structure, and can include considerations such as:

- how the organization integrates the AI system impact assessment with organizational risk assessment;
- how the organization integrates the AI system impact assessment with other types of impact assessments;
- organizational governance, risk and compliance processes that are in place or planned for the treatment of potential impacts.

NOTE Annexes A, B and D provide additional information.

4.4 Timing of AI system impact assessment

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 risk 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:

- applicable legal requirements;
- risk level of the AI system (the organization can consider ISO/IEC 23894:2023, 6.3.4 for additional guidance);
- expectations of relevant interested parties;
- internal AI system life cycle processes.

Triggers for a reassessment can include:

- change in use of the AI system;
- change in sensitivity of data;
- change in complexity or type of AI system.

NOTE Risk levels can be predetermined by external requirements. Risk or impact levels can be pre-determined by external requirements (e.g. AI in automobiles can be high impact due to safety concerns)

Timing considerations can include:

- how often AI system impact assessments are performed;
- at what stage of the AI system life cycle they are performed;
- how frequently they are updated;
- what triggers the need for a new AI system impact assessment or an update.

268 The organization should consider whether they use tools for triaging when an AI system impact
 269 assessment is required. For example, if the organization determines that AI system impact assessments
 270 are only to be done on “high-risk” AI systems, they should document as part of the process what
 271 constitutes a “high-risk” AI system and what triggers the need for an impact assessment (e.g. certain
 272 system features, purpose, consequence, context, affected interested parties, model type, data type, level
 273 of automation or type of output). A triaging process can require a briefer version of the AI system impact
 274 assessment to determine if the AI system is high-risk and requires a full AI system impact assessment.

275 **4.5 Guidance for determining the scope of the AI system impact assessment**

276 The organization should define and document the scope of AI system impact assessments by document
 277 the scope of an AI system by providing clear guidance for the AI system impact assessments based on the
 278 needs of the organization in question and the potential impacts on relevant interested parties. The scope
 279 of an AI system impact assessment can include, but is not limited to:

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

284 NOTE Changes to a system component can have implications to the overall system impact on various
 285 interested parties.

286 **4.6 Allocating responsibilities**

287 There can be several responsibilities for an organization to allocate. These depend on the nature of the
 288 AI system impact assessment, its length and other factors, and can include responsibilities for:

- 289 — documentation of the AI system impact assessment;
- 290 — relevant interested parties who contribute to the completion of the assessment and those
 291 responsible for coordinating their involvement (e.g. research and development, marketing and
 292 sales, security and operations, legal, labour representatives and other relevant interested
 293 parties);
- 294 — communication of the results;
- 295 — approvals;
- 296 — escalations.

297 AI system impact assessment responsibilities should be allocated commensurate with relevant
 298 experience, competency, role and access to information.

299 Multi-disciplinarity is recommended to ensure that impacts are reasonably foreseen and addressed
 300 throughout the AI system’s life cycle.

301 NOTE Diverse expertise can be relevant to an effective assessment process. Disciplines can include
 302 people with training in human rights and social sciences such as anthropology, sociology and psychology.

303 **4.7 Establishing thresholds for sensitive uses, restricted uses and impact scales**

304 A critical part of AI system impact assessments is ensuring that defined thresholds, particularly around
 305 AI system use, are documented. Prior to this, the organization should define and document those
 306 thresholds, based on the context in which they operate. This can include considerations such as:

- 307 — applicable legal requirements;
- 308 — expectations of relevant interested parties;
- 309 — state of the art;
- 310 — benefits of the AI system;
- 311 — cultural, labour and societal norms;
- 312 — 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 potential misuses are sensitive or prohibited by organizational policy. Legal or other external requirements can further determine the sensitivity of uses or 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 system designed to automate lending decisions.

EXAMPLE 2 A step to take if a sensitive or restricted use is identified can be escalation 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 system due to adverse impact.

The organization should also consider how overall impact scales are determined and potential 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 factor into the impact scale and next procedural steps the organization determines in the AI system impact assessment process.

The organization should consider the magnitude of potential impacts when defining the various pieces of the AI system impact assessment. The organization should have criteria for the types of potential impacts that can be an outcome of the AI system. For example, to assess the magnitude of potential impacts, the AI system impact assessment can include criteria for rating impacts as severe or catastrophic if they can lead to high adverse consequences for the organization, for groups of individuals or to societies. See, for example, Section 3.2 of [16].

4.8 Performing the AI system impact assessment

For each intended use and reasonably foreseeable misuse of an AI system, the organization should consider, as appropriate:

- a) identification of reasonably foreseeable AI system impacts to all identified individuals, groups of individuals and to societies, as outlined in 5.7 and in other resources as appropriate. Both beneficial impacts and harmful impacts should be considered;
- b) multiple types or dimensions of AI system impacts to groups of individuals, organizations and to societies, e.g. as outlined in Section 3.2 of [16], including but not limited to:
 - 1) identify reasonably foreseeable potential impacts to individuals, groups, organizations and societies. It is important to consider how such impacts also translate into organizational risks. 5.8 provides further guidance on the types of potential benefits and harms that should be considered for each identified interested party;
 - 2) frequency of assessing and reassessing risks and impacts;
- c) impacts to fundamental rights, as part of identifying impacts to individuals or groups of individuals as outlined in [16] and in Section 3.3 of [16], including but not limited to:
 - 1) identify impacts to human rights periodically or as appropriate, e.g. as early as possible and at identified stages of the AI system life cycle. Non-exhaustive examples of rights to be considered are non-discrimination, right to life and personal security, privacy and freedom of expression;
 - 2) determine how impacts to fundamental and human rights will be addressed;
- d) assessment of the magnitude and likelihood of identified impacts.

4.9 Analysing the results of the AI system impact assessment

The results of the AI system impact assessment can play a crucial role in the responsible use and development of AI systems. The assessment should be analysed and incorporated into both technical and management decisions.

361 On a technical level, analysis can be used, for instance, to improve product or service quality, building-in
 362 safeguards against unintended use or misuse, improve safety and robustness of AI systems etc. It can also
 363 include determining the types of measures to address benefits and harm as detailed in 5.8.2. Additionally,
 364 the results of the assessment should be compared to the thresholds established in 4.7 and if the
 365 thresholds are not met, identify an action plan to remediate.

366 On a management level, analysis can be used to inform the organizational risk management processes on
 367 foreseeable impacts of AI systems. This can include consideration of individual system impact
 368 assessments, but also analysing several assessments holistically to determine how trends can affect
 369 organizational risks and objectives at a broad level.

370 **4.10 Recording and reporting**

371 The organization should define and document expectations for how the AI system impact assessment is
 372 to be recorded, as well as expectations for reporting the results of the AI system impact assessment. The
 373 format of the assessment can depend on the needs of the organization, and can be captured in a document
 374 template, a system, or through any other method that enables recording and reporting.

375 The organization can have both internal and external reporting needs. Internal reporting considerations
 376 can include reporting to:

- 377 — upper management;
- 378 — worker's representatives;
- 379 — system developers;
- 380 — system owners.

381 External reporting considerations can include reporting to:

- 382 — regulatory authorities;
- 383 — customers;
- 384 — individuals affected by the AI system.

385 Reporting of AI system impact assessment to relevant interested parties can include:

- 386 — actual or potential impact information related to the intended AI system use cases, as well as other
 387 potentially beneficial uses, reasonably foreseeable misuses and intentional abuses (at least at a
 388 broad level);
- 389 — as many dimensions of identified impacts as appropriate, including as many of the types of
 390 impacts outlined in 5.8 as reasonably possible.

391 When reporting information on misuses or abuses, the organization may omit details that can be useful
 392 to attackers.

393 **NOTE** For resources on what details can provide attackers with inappropriate information, see [22].

394 Reports should be structured and worded such that they can provide the information needed by a
 395 relevant interested parties to assess where necessary the AI system's compliance with legal requirements
 396 related to impact assessments. They should also be structured and worded in a way that, where certain
 397 portions are unavailable for intellectual property protection, they remain comprehensible.

398 **4.11 Approval process**

399 The organization should document any approvals required as part of the AI system impact assessment
 400 process. This can include approvals related to exceeding established thresholds (see 4.7) or a final
 401 approval of the overall AI system impact assessment. Considerations can include:

- 402 — when approvals are required (e.g. when a threshold is exceeded, after the AI system impact
 403 assessment is completed);
- 404 — who has the responsibility for approval (this can vary depending on the type of approval).