

# AI Act:

# AFNOR unveils the first ISO/IEC 42001 certifiable standard on the management of artificial intelligence

Companies designing, supplying or using artificial intelligence should very soon turn to the international voluntary and certifiable standard ISO/IEC 42001, either voluntarily to demonstrate that they are controlling the risks of this technology, or to comply with the European AI Act.

- The voluntary ISO/IEC 42001 standard is the world's first repository of best practices for managing risks linked to AI, approved by 170 countries.
- The initiative is aimed at designers, suppliers and users alike.
- It is recognized internationally.
- As part of a certification, auditors will pay particular attention to the quality and governance of data, the management of risks and impacts linked to the algorithms designed or used.

### Regulations and standards, very distinct roles

The publication of this standard comes in a context of States becoming aware of the need to regulate AI, after a year 2023 marked by the accelerated emergence of generative AI. Thus, twenty-eight states signed the Bletchley declaration on November 2, 2023, recognizing the risks linked to AI and committing to developing policies to limit the risks linked to its use.

Part of the answer lies in a regulatory framework, the European AI Act, currently being adopted, but also in the establishment of voluntary standards, proposing standardized good practices. The ISO/IEC 42001 standard is the result. "The regulations set the requirements. On the standardization side, our role has been to listen to the market and all its stakeholders – AI designers, AI providers, users and end users – in order to bring together their best risk management practices in a shared document, so that 'they are representative of their operational reality and help them meet these requirements', explains Morgan Carabeuf, AFNOR rapporteur for France at ISO and IEC, the duo of international organizations which lead the some 170 standardization bodies in the world (the IEC being dedicated to electrotechnologies).

# High-risk AI players, the first to be affected

The European AI Act sets proportionate requirements, following a risk-based approach. This approach makes it possible to adapt the type and content of requirements,

to the intensity and scope of risks that AI systems can generate. Four levels of AI risk are defined. Artificial intelligence presenting an unacceptable risk is prohibited. High risk systems are identified in Annexes II and III of the Regulation. We find among others:

- Medical devices
- Machines
- · Biometric identification systems,
- AI systems for school guidance
- AI systems used for recruitment
- AI systems intended to be used to assess people's creditworthiness

"The AI Act is one of the European regulations responsible for ensuring the free movement of products in the single market, with harmonized requirements, with the aim of limiting risks to the health and safety of people. These texts provide for CE marking of products, proving that they comply, as for medical devices for example, with requirements applicable to each link in the value chain. The ISO/IEC 42001 standard will be useful to products incorporating AI when they undergo a conformity assessment in this regard"explains Thomas Lommatzsch, in charge of the medical sector at AFNOR Certification.

Complying with the ISO/IEC 42001 standard is therefore a good way to prepare for the arrival of the AI Act, whatever your sector of activity. With possibly a dose of training: AFNOR Compétences offers one over two days to understand the requirements. "Companies that wish to go further and obtain certification will need to be vigilant on several points, which the auditor will specifically examine during the audit. They are specified in appendix A of the standard", explains Virginie Desbordes, head of the digital trust division at AFNOR Certification. This concerns policy relating to artificial intelligence, internal organization, AI system resources, identification of impacts, understanding of AI life cycles, quality data, information to stakeholders, AI users and communication to third parties and customers. Appendix B is also valuable.

#### Concrete case A – biases

For skin cancer diagnostic software, AI training data could generate bias if it only included clinical data from Caucasian, white-skinned patients, to the detriment of white-skinned patients. black skin. In this case, the auditor will question the company: "How have you qualified your data so that it is representative of all the patients on whom your device is likely to intervene?"

# Concrete case B - the risk of excessive confidence

In the case of a radiology department, the practitioner trusts artificial intelligence to identify pathologies. The automation, autonomy and good results of AI lead the practitioner to adopt excessive confidence in the algorithm and to automatically validate the images submitted at the risk of missing a decisive element. The auditor will be able to question the designer of this system about the means implemented to avoid this risk.

# To consult the voluntary standard ISO/IEC 42001, available in English for the moment, you can send an email to the AFNOR Group press service presse@afnor.org

# About the AFNOR Group

For almost a century, AFNOR has led private and public actors to collectively imagine a more responsible world guided by trust and quality. An international and associative group, serving the general interest and sustainable development, it has 1,250 employees and 60,000 customers worldwide and is present in 36 countries. AFNOR helps economic players to write a common language, make their solutions interoperable and promote good practices through voluntary standards with an international scope. The Group, through its wide range of expertise, also trains professionals, employees or independents, to improve their skills, delivers robust certifications and signs of recognition which bring confidence to the market, and facilitates the deciphering of normative and regulatory developments. The AFNOR group is managed by Olivier Peyrat and chaired by Guy Maugis.

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