

Position Paper

Background

The European Commission has published their proposal for a regulation that covers many aspects of AI (Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS COM/2021/206 final) in April 2021. The draft Artificial Intelligence Act (AIA) is a horizontal regulation implementing a risk-based approach to identify the level of control on AI Systems being placed on the European market. The members of the Team NB, the EU association for Notified Bodies for medical devices and IVDs publish this position-paper with the intention to express their opinion and concerns regarding the upcoming regulations, with a focus on the interface and overlap between the upcoming regulations and the Medical Device Regulation (MDR) and IVD Regulation (IVDR).

Definitions

Article 3(1): ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with

Annex I:

- (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;
- (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;
- (c) Statistical approaches, Bayesian estimation, search and optimization methods.

Team NB Opinion:

The definition used includes terms related to logic and knowledge-based systems. This is an overly broad definition such that it could potentially include non-AI systems leading to confusion for the regulators, manufacturers and notified bodies. Since the goal of standardization is to provide harmonized definitions of technologies for the purpose of exchanges between relevant stakeholders, we recommend to use the definition found in the international standard “*ISO/IEC 2382:2015, Information technology – Vocabulary*”.

Position Paper Sample Format

**Joan Gratto Liebler, Charles R.
McConnell**



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to convince governments and international institutions to effectively protect humans through disaster assistance sustainable development and the protection of cultures The volume proposes a holistic approach to humanitarian assistance by integrating non traditional and traditional humanitarian partners Users of the book will be prepared to speak to diplomats and government officials in any setting including war zones The book mainly focuses on approaching local and national governments the United Nations system the international Red Cross movement and other international organizations The reader will learn the rules of diplomatic protocol and much about the rules and procedures of major international bodies as well as how to leverage media and knowledge management for planning establishing and managing a humanitarian initiative To provide balance and real world relevance the guide draws on a compilation of the extensive activities of both authors across a range of development emergency management knowledge management and climate issues in government and in the NGO world as well as interviews with a broad range of scholars and officials from NGOs diplomatic missions the media the United Nations the Red Cross governments and corporations

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Navy Management Review , 1967

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research knowledge and theoretical base which can support the testing of bilingual individuals By reviewing and discussing both the nature of bilingualism and the nature of standardized testing and by presenting a detailed agenda of the questions that must be answered the authors hope to influence existing and future policies which govern the use of tests and test results This area is of increasing importance to American education and the policy implications are evident

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