

# 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

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*FMFM*. United States. Marine Corps, **Command and Staff Action** United States. Marine Corps, 1979 *Public Relations Writing* Valerie Fields, 2024-09-17 With a focus on storytelling social media and socially conscious content Public Relations Writing Essential Skills for Effective Storytelling is a step by step how to guide that helps students develop and hone the skills they need to become strong writers and versatile storytellers within the Public Relations field The Political Science Student Writer's Manual and Reader's Guide Gregory M. Scott, Stephen M. Garrison, 2016-09-22 The Political Science Student Writer's Manual and Reader's Guide is a practical guide to research reading and writing in political science The Political Science Student Writer's Manual and Reader's Guide Eighth Edition is a set of instructions and exercises that sequentially develop citizenship academic and professional skills while providing students with knowledge about a wide range of political and governmental concepts phenomena and information sources It begins by teaching beginning students to engage newspapers and other political media sources critically and analytically It focuses on the crafts of writing and scholarship by providing the basics of grammar style formats and source citation and then introduces students to a variety of rich information resources including the Congressional Record Federal Register and the Library of Congress Students actively apply their knowledge and skills by corresponding with their representatives and commenting on pending government regulations Part 1 concludes with campaign management policy analysis legislation assessment and similar exercises that develop student skilled observation proficiency Part 2 prepares students to research read write review and critique political science scholarship Finally Part 3 teaches advanced students how to investigate public opinion analyze domestic and international public policies author amicus briefs and participate in the universal community that deliberates the continuing rich tradition of political philosophy The Sociology Student Writer's Manual and Reader's Guide William A. Johnson Jr., Gregory M. Scott, Stephen M. Garrison, 2016-09-22 The Sociology Student Writer's Manual and Reader's Guide Seventh Edition is a practical guide to research reading and writing in sociology The Sociology Student Writer's Manual and Reader's Guide Seventh Edition is a set of instructions and exercises that sequentially develop citizenship academic and professional skills while providing students with knowledge about a wide range of sociological concepts phenomena and information sources Part 1 begins by teaching students to read newspapers and other sociological media sources critically and analytically It focuses on the crafts of writing and scholarship by providing the basics of grammar style formats and source citation and then introduces students to a variety of rich information resources including the sociological journals and the Library of Congress Part 2 prepares students to research read write review and critique sociology scholarship Finally Part 3 provides advanced exercises in observing culture socialization inequality and ethnicity and race *Diplomacy and Negotiation for Humanitarian NGOs* Larry Winter Roeder, Jr., Albert Simard, 2013-05-25 Diplomacy and Funding for Humanitarian Non Profits is a practical guide to best practices in diplomacy and negotiation for non profits NGOs who work

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

**The Philosophy Student Writer's Manual and Reader's Guide** Anthony J. Graybosch, Gregory M. Scott, Stephen M. Garrison, 2017-06-29 The Philosophy Student Writer s Manual and Reader s Guide Fourth Edition is a set of instructions and exercises that sequentially develop citizenship academic and professional skills while providing students with knowledge about a wide range of philosophical concepts phenomena and information sources Part 1 begins by teaching students to read newspapers and other media sources critically and analytically It focuses on the crafts of writing and scholarship by providing the basics of grammar style formats and source citation and then introduces students to a variety of rich information resources Part 2 provides advanced exercises in ethics metaphysics philosophy of the mind philosophy of religion and political philosophy *HQMC Supplement to the Department of the Navy (DON) Correspondence Manual* United States. Marine Corps, 1992

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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 **The Model**

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