Artificial Intelligence-Enabled Medical Device Standards: A Multidisciplinary Literature Review

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Abstract. Concern has been noted at the lack of international standards available for Artificial Intelligence-enabled Medical Device (AIeMD) development, evaluation, and monitoring. This multidisciplinary literature review provides an overview of the current standards in development in support of the EU Artificial Intelligence (AI) Act. The EU AI Act requires that high-risk AI is regulated, though notably with an absence of regulatory guidance within healthcare to date. The medical device industry has already released hundreds of AIeMDs on the global market. This research is therefore necessary to provide the much-needed awareness of current and forthcoming standards. This research demonstrates that technical guidance is available to industry and requires consideration where it represents the current State of the Art (SoTA).

Keywords: Artificial Intelligence · Software as a Medical Device · Machine Learning · Artificial Intelligence-enabled Medical Device · International Standards · State-of-the-Art

1 Introduction

Concern has been noted by the lack of a regulatory framework to govern Artificial Intelligence- enabled Medical Devices (AIeMDs) in the European Union (EU) [1]. International standards are slow to emerge, though notably, many are currently under development with the aim of supporting industry in achieving the goals set out by the EU AI Act [2] and the EU Ethical Guidelines [3] in achieving Trustworthy AI, capable of harnessing the many benefits promised [4–6]. This study is designed to allay fears of a lack of harmonised standards and inform industry of the extensive work that is ongoing in building a regulatory framework, through a range of standards and guidance for AIeMD development, evaluation, and monitoring within the EU. Innovation has not waited, with hundreds of AIeMD devices available on the global market [7]. The opportunity for hazardous situations is reduced where the majority of the marketed AIeMDs are primarily intended to *support* clinical decision-making using radiological data, rather than replace it. Nevertheless, there are many risks to mitigate throughout the full lifecycle of AIeMDs and therefore, it is essential that industry is equipped to

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adequately address these in a timely manner, and not wait for harmonization of standards that is increasingly difficult to achieve.

1.1 AIeMD Devices on the Market

According to the FDA (Food and Drug Administration), as at 13 May 2024, there are 883 unique AIeMDs released to the US market, with 171 new devices added between Oct 2022 and Oct 2023 and an additional 191 added in the most recent update of 13 May 2024 [8]. The FDA AI/ML database was created for transparency purposes with EU lagging in this regard [9]. We can see from Fig.1, that the majority are from the field of Radiology (76%), with Cardiovascular (10%) a distant 2nd, followed by Neurology (4%), Hematology (2%) and other clinical specialties at $\leq$ 1%. The European EUDAMED database is not yet fully functional, resulting in difficulties determining numbers of AI/ML devices on the EU market. Although EUDAMED does not allow for an "AI/ML" search criteria to be entered, a total of 2,224 records were returned from a search of "software" as a criterion within EUAMED. Nevertheless, research reflects that Europe follows a similar pattern to the US, which is hardly surprising given the global reach of the developers of existing AIeMD devices [7–10]. Further transparency in the EU will be realised once the AI database, identified within the AI Act is implemented, whereby deployers (i.e., clinicians using the AIeMD) are required to register high-risk AI devices prior to use [2].

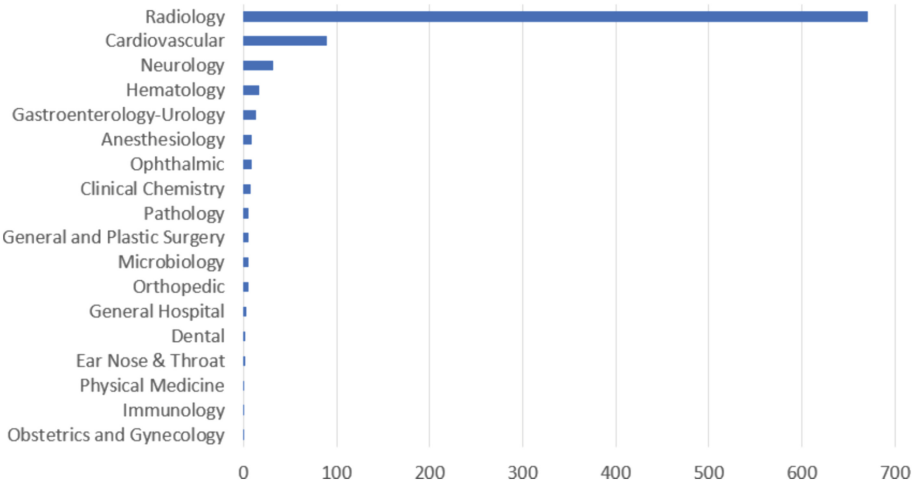

Fig. 1. FDA Accepted AI/ML Devices on US Market - last update 13 May 2024

Another source of data is ClinicalTrials.gov online database, which was created in 2000 arising from the Federal Food Drug and Cosmetic Act 1997[11], intended to provide information on clinical studies and includes studies that take place in over 50 US states and 200 countries following expansion to other markets, with the inclusion of the EU. This database supports the preposition that AI is a growing industry within

healthcare. A search of the Clinical Trials database resulted in 1,886 global studies when the search term "*Artificial Intelligence*" is used from a total of 489,887 studies (0.4%) and when adding "*Machine Learning*" as a search term and removing duplicates between the two searches, the total amounts to 3,401 studies (0.7%). We can see the recent rise in AIeMD clinical observation and interventional studies with most active AI/ML studies expecting to be completed in 2024–2027. We know from previous research that the EU has already released numerous AIeMDs to the market [7, 12], and this growth is continuing as we see from industry research and clinical testing. Therefore, the urgency to formulate guidelines and harmonised international standards is increasing.

1.2 AIeMDs Reviewed Under Existing Regulatory Framework

Of the 883 AIeMDs released to US market, earlier AI/ML models were reported to be *locked* algorithms, i.e., AI algorithms that are non-changing when released to market, as opposed to *adaptive* algorithms, that continue to learn from the data presented to it when placed on the market [13]. In the Oct 2023 update of the FDA AI/ML database, the claim that all AIeMDs were locked was withdrawn and replaced by a statement indicating that the AI/ML algorithms currently approved take a hybrid approach for best results. There is no clear definition reported as to which AIeMDs are considered locked, adaptive or hybrid and the algorithms or learning models (supervised, unsupervised, or reinforced) are not readily identifiable from research or databases [7].

To differentiate between such models, may in any case, be a moot point, given research demonstrates that degradation can occur [14, 15] and data quality, in the first instance, is vitally important [16]. In the meantime, considering the recent surge in AIeMDs being placed on the global market including the EU, the existing regulatory framework has been flexed, in so far as traditional compliance requirements have been used to review AIeMDs, primarily identified as AI/ML algorithms within Software as a Medical Device (SaMD) or Software in a Medical Device (SiMD).

Health Software of all categories (e.g., SaMD, SiMD, AIeMD) require application of standards such as IEC 62304 [17], IEC 82304–1 [18] for Software Development Lifecycle, ISO 14971[19] for Risk Management, and IEC 81001–5-1 [20] for a Secure Lifecycle. These standards are process standards that require significantly more guidance to consistently deliver robust trustworthy AI devices capable of meeting the legislation and ethical values required of them. This research presents a multidisciplinary review of standards available under the existing regulatory framework and reviews technical committees (TCs) from leading standards organizations in development.

2 Method

2.1 Research Methodology

A multidisciplinary literature review was used to identify the current standards released to support industry in development of AIeMD and identify those in development with specific focus on the EU or international standards intended for global use. The search terms used were "*Artificial Intelligence*" and "*Machine Learning*". All standards organizations considered relevant for application to healthcare or AIeMD development within

the EU were reviewed and are listed in Table 1**:** Multidisciplinary Literature Review Sources.

Table 1. Multidisciplinary Literature Review Sources

Source	Titles Returned (Quantity)
AAMI – Association for the Advancement of Medical Instrumentation	1
ANSI – American National Standards Institute	2
BSOI/BSI - British Standards Organisation	75
CSA – Canada Standards Group	4
DIN – German Standards	5
DS – Danish Standards	25
FDA Consensus Standards	3
IEC – International Electrotechnical Commission	4
IEEE – Institute of Electrical and Electronics Engineers	14
ISO – International Standards Organisation	25
SIS – Swedish Standards Institute	12

3 Results

A total of 170 standards were identified when a search of various relevant standards organizations was performed using the search term "*Artificial Intelligence*" or "*Machine Learning*", as presented in Table 1**:** Multidisciplinary Literature Review Sources. AI Standards from China (n = 8) were excluded from the literature review due to language restrictions of English only. Of the 75 AI/ML standards returned from BSOI only 52 were accessible. Any duplicate standards across organizations were also removed from the results.

3.1 Current AIeMD Standards

The standards currently released and available for use by AIeMD developing organizations are presented in Table 2. This list cannot be accepted as complete, where alternative AI standards exist, albeit not explicitly noted by medical device regulatory bodies or databases as being adopted for AIeMD application. Nevertheless, this review demonstrates the validity of alternative AI standards to be considered for achieving trustworthy and safe AIeMD to the current State of the Art (SoTA).

Table 2. Standards adopted for AIeMD Development or Healthcare

Title	Document No
Assessing Credibility of Computational Modelling Through Verification and Validation: Application to Medical Devices	ASME V&V 40–2018
Definitions/Characteristics of AI in Healthcare	CTA-2089.1
Guidance on the application of ISO 14971 to AI and ML	AAMI TIR 34971:2023
Health Informatics - Applications of Machine Learning Technologies in Im- aging and Other Medical Applications	DS/ISO/TR 24291:2021
IEEE Recommended Practice for The Quality Management of Datasets for Medical Artificial Intelligence	IEEE 2801–2022
IEEE Standard for Performance and Safety Evaluation of Artificial Intelli- gence Based Medical Devices: Terminology	IEEE 2802–2022
The use of AI in Healthcare: Trustworthiness	CTA-2090
Validation framework for the use of artificial intelligence (AI) within healthcare. Specification	BS 30440:2023

3.2 Current AI Standards (Non-Industry Specific)

AI standards and guidance documents, with inclusion of Technical Reports (TR) and Technical Specifications (TS), are listed under Table 3. The intention for many AI standards is trustworthy and safe AI development and application. Therefore, the standards listed are not specific to healthcare or AIeMD development though are considered the current SoTA [21]. Standards with- out any clear relationship to AIeMD were removed (e.g., Chinese medicine, estate management, nuclear facilities, etc.)

3.3 Standards Under Development

This research identifies AI standards relevant for healthcare that are under development at time of review and presented in Table 4 These include standards reviewed from ISO/IEC Technical Committees (TCs) to which individual country-specific standards organizations contribute by membership. To avoid duplication of work the standards organizations (IEC/CENELEC/ISO) act in parallel and share content. The individual country-specific standards organization contributes through TC membership, with the opportunity to comment and provide input to these standards with extensive review and voting systems.

It should be noted that documents listed as *TRs* are *technical reports* that are intended as guidance and *TSs* are *specifications,* which are also considered guidance, though are a higher order than the TR and may be referred to in a standard or required by relevant Notified Body as being best practice. A *standard* is considered the highest order of guidance and once adopted by individual countries or recommended for use, would be considered SoTA (e.g., I.S. for Ireland or B.S. for British Standard demonstrates Irish or British adoption of a standard).

Table 3. **S**tandards Released for AI (not specifically for AIeMD)

Title	Document Number
Artificial Intelligence – Assessment of the robustness of neural networks. Overview	PD ISO/IEC TR 24029- 1:2021
Artificial Intelligence – Functional Safety and AI Systems	DS/ISO/IEC TR 5469:2024
Artificial Intelligence - Life Cycle Processes and Quality Requirements - Part 1: Quality Meta Model	DIN SPEC 92001-1:2019
Artificial Intelligence – Life Cycle Processes and Quality Requirements - Part 3: Explainability	DIN SPEC 92001-3:2023
Artificial Intelligence – Part 3: Bias	DS/PAS 2500–3:2023
Artificial Intelligence – Uncertainty Quantification in Machine Learning	DIN SPEC 92005:2024
Framework For Artificial Intelligence (AI) Systems Using Machine Learning (ML) (Adopted ISO/IEC 23053:2022, 1st Edition, 2022–06)	ISO/IEC 23053–2023
Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms	AAMI TIR66: 2017(R)2020
IEEE Standard for Robustness Testing and Evaluation of Artificial Intelligence (AI)-Based Image Recognition Service	IEEE 3129–2023
Information Technology - Artificial Intelligence - Artificial Intelligence Concepts and Terminology (Adopted ISO/IEC 22989:2022, 1st Edition, 2022–07)	ISO/IEC 22989–2023
Information technology. Artificial intelligence (AI). Bias in AI systems and AI aided decision making	PD ISO/IEC TR 24027:2021
Information technology. Artificial intelligence (AI). Overview of computational approaches for AI systems	PD ISO/IEC TR 24372:2021
Information Technology. Artificial Intelligence (AI). Use Cases	ISO/IEC TR 24030:2024
Information technology. Artificial intelligence. AI system life cycle processes	ISO/IEC 5338:2023
Information technology. Artificial Intelligence. Assessment of machine learning classification performance	PD ISO/IEC/TS 4213:2022
Information technology. Artificial Intelligence. Controllability of automated artificial intelligence systems	ISO/IEC TS 8200:2024
Information Technology. Artificial Intelligence. Data Life Cycle Framework	ISO/IEC 8183:2023

(*continued*)

Table 3. (*continued*)

Title	Document Number
Information Technology. Artificial Intelligence. Guidance For AI Applications	ISO/IEC 5339:2024
Information technology. Artificial intelligence. Guidance on risk management	ISO/IEC 23894:2023
Information Technology. Artificial intelligence. Management system	ISO/IEC 42001:2022
Information technology. Artificial intelligence. Overview of ethical and socie- tal concerns	PD ISO/IEC TR 24368:2022
Information technology. Artificial intelligence. Overview of trustworthiness in artificial intelligence	ISO/IEC TR 24028:2023
Information technology. Artificial intelligence. Process management frame- work for big data analytics	ISO/IEC 24668:2022
Information Technology. Artificial Intelligence. Reference Architecture of Knowledge Engineering	ISO/IEC 5392:2024
Information technology. Governance of IT. Governance implications of the use of artificial intelligence by organizations	ISO/IEC 38507:2022
Information technology. Vocabulary. Part 28: Artificial intelligence. Basic concepts and expert systems	ISO/IEC 2382–28:1995
Information technology. Vocabulary. Part 29: Artificial Intelligence. Speech recognition and synthesis	ISO/IEC 2382–29:1999
Information technology. Vocabulary. Part 31: Artificial intelligence. Machine learning	ISO/IEC 2382–31:1997 (R11)
Information technology. Vocabulary. Part 34: Artificial Intelligence. Neural Networks	ISO/IEC 2382–34:1999
Safety of machinery. Relationship with ISO 12100. Implications of artificial intelligence machine learning	PD CEN ISO/TR 22100–5:2022
Security And Privacy in Artificial Intelligence Use Cases. Best Practices	PD ISO/IEC TR 27563:2023
Software and systems engineering. Software testing. Guidelines on the testing of AI-based systems	PD ISO/IEC TR 29119- 11:2020
Systems And Software Engineering. Systems And Software Quality Requirements and Evaluation (SQuaRE). Guidance For Quality Evaluation of Artificial Intelligence (AI) Systems (British Standard)	PD ISO/IEC TS 25058:2024

Once proposed and approved for adoption by all member states within the EU, a standard can be listed as an EN. The *EN* document can be put forward for harmonization by publishing in the *Official Journal of the European Union* and if agreed, once published,

is then considered harmonised within the EU and hence, available for presumption of conformity to the relevant regulations under which it is published.

Although there is considerable work continuing to achieve a full harmonised listing in Europe, including those standards necessary to meet the updated Medical Device MDR 2017/745 and IVDR 2017/746 requirements, there is delay in achieving agreement across member states for standardisation adoption. This applies to all standards, not least AI or AIeMD standards and guidance. Nevertheless, this research presents the SoTA of both generic AI and AIeMD standards with extensive guidance that should be considered by manufacturers and healthcare organizations when developing or distributing AIeMDs.

Table 4. Standards Under Development

Source TC	Title	Standard No
IEC SC 62A ISO/TC 210	Health software and health IT systems safety, effectiveness, and security - Part 2–2: Guidance for the implementation, disclosure and communication of security needs, risks, and controls	IEC TS 81001–2-2
IEC SC 62A ISO/TC 210	Revise IEC 62304 - Medical device software - Software life cycle processes - Edition 2 (Ed2)	IEC 62304 Ed2
IEC SC 62B	AI-enabled MD - computer assisted analysis software for pulmonary images - algorithm performance test methods	IEC 63524
IEC/TC62/ TC 210	Machine Learning-enabled MD – Performance Evaluation Process	IEC 63521
IEC/TC62/ TC 210	Medical devices—Guidance on the application of ISO 14971—Part 2: Machine learning in artificial intelligence	ISO 24971–2
IEC/TC62/ TC 210	Testing of AI / ML-enabled MD (MLMD): Methods for Verification and Validation	IEC 63450
ISO/IEC JTC1/SC 42	Artificial intelligence—Application of AI technologies in health informatics	ISO/IEC AWI TR 18988

(*continued*)

Table 4. (*continued*)

Source TC	Title	Standard No
ISO/IEC JTC1/SC 42	Artificial intelligence—Data quality for analytics and machine learning (ML) —Part 1: Overview, terminology, and examples	ISO/IEC DIS 5259-1
ISO/IEC JTC1/SC 42	Artificial intelligence—Data quality for analytics and machine learning (ML) —Part 2: Data quality measures	ISO/IEC DIS 5259-2
ISO/IEC JTC1/SC 42	Artificial intelligence—Data quality for analytics and machine learning (ML) —Part 3: Data quality management requirements and guidelines	ISO/IEC DIS 5259-3
ISO/IEC JTC1/SC 42	Artificial intelligence—Data quality for analytics and machine learning (ML) —Part 4: Data quality process framework	ISO/IEC DIS 5259-4
ISO/IEC JTC1/SC 42	Artificial intelligence—Data quality for analytics and machine learning (ML) —Part 5: Data quality governance framework	ISO/IEC DIS 5259-5
ISO/IEC JTC1/SC 42	Artificial intelligence—Data quality for analytics and machine learning (ML) —Part 6: Visualization framework for data quality	ISO/IEC CD TR 5259–6
ISO/IEC JTC1/SC 42	Artificial Intelligence—Evaluation methods for accurate natural language processing systems	ISO/IEC AWI 23282
ISO/IEC JTC1/SC 42	Artificial intelligence—Functional safety and AI systems — Requirements (Part 1); Guidance (Part 2); Examples (Part 3)	ISO/IEC AWI TS 22440–1, -2, -3
ISO/IEC JTC1/SC 42	Artificial intelligence—Overview of AI tasks and functionalities related to natural language processing	ISO/IEC AWI TR 23281

(*continued*)

Table 4. (*continued*)

Source TC	Title	Standard No
ISO/IEC JTC1/SC 42	Artificial intelligence (AI)—Assessment of the robustness of neural networks. Part 2: Methodology for the use of for-mal methods 22/30444391DC	EN ISO/IEC 24029-2:2023
ISO/IEC JTC1/SC 42	Artificial intelligence (AI)—Assessment of the robustness of neural networks —Part 3: Methodology for the use of statistical methods	ISO/IEC AWI 24029–3
ISO/IEC JTC1/SC 42	Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML) —Amendment 1	ISO/IEC 23053:2022/AWI Amd1
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—AI system impact assessment	ISO/IEC DIS 42005
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Artificial intelligence concepts and terminology—Amendment 1	ISO/IEC 22989:2022 / AWI Amd1
ISO/IEC JTC1/SC 42	Information technology – Artificial intelligence – Beneficial AI systems	ISO/IEC AWI TR 21221
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Environmental sustainability aspects of AI systems	ISO/IEC CD/TR 20226
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Guidance for human oversight of AI systems	ISO/IEC AWI 42105
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Guidance on addressing societal concerns and ethical considera-tions	ISO/IEC AWI TS 22443

(*continued*)

Table 4. (*continued*)

Source TC	Title	Standard No
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Overview of differentiated benchmarking of AI system quality characteristics	ISO/IEC AWI TR 42106
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Overview of machine learning computing devices	ISO/IEC TR 17903
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Overview of synthetic data in the context of AI systems	ISO/IEC AWI TR 42103
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Requirements for bodies providing audit and certification of artificial intelligence management systems	ISO/IEC DIS 42006
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Taxonomy of AI system methods and capabilities	ISO/IEC AWK 42102
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Transparency taxonomy of AI systems	ISO/IEC DIS 12792
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence—Verification and validation analysis of AI systems	ISO/IEC AWI TS 17847
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence (AI)—Use cases of human-machine teaming	ISO/IEC AWI 42109

(*continued*)

Table 4. (*continued*)

Source TC	Title	Standard No
ISO/IEC JTC1/SC 42	Information technology—Artificial intelligence (AI)—Use cases	ISO/IEC TR 24030
ISO/IEC JTC1/SC 42	Information technology. Artificial intelligence. Data life cycle framework 22/30452608 DC	BS EN ISO/IEC 8183:2023 + Amd
ISO/IEC JTC1/SC 42	IT – AI – Objectives and approaches for Explainability and interpretability of ML models and AI systems	ISO/IEC CDTS 6254
ISO/IEC JTC1/SC 42	IT – AI – Treatment of unwanted bias in classification and regression ML tasks	ISO/IEC DTS 12791.2
ISO/IEC JTC1/SC 42	Software and systems engineering—Software testing—Part 11: Testing of AI systems (will replace 2020)	ISO/IEC TS 29119-11
ISO/IEC JTC1/SC 42	Software Engineering – Systems and software quality requirements and evaluation (SQuaRE) – quality model for AI systems (will replace 2023)	ISO/IEC AWI 25059
ISO/IEC/JTC1/ SC27	Cybersecurity and privacy in AI - Medical imaging diagnosis	ISO/IEC WD 27091.2

3.4 Literature Review Summary

According to the IEC Technical Committee List [22], ISO/IEC JTC 1/SC42 Artificial Intelligence have accounted for 26 publications since their inception in January 2019 to 2024, however, these are not solely related to healthcare (ref. Table 4). IEC TC 62 with sub-committees A-D have specific application to medical device development and AI, accounting for 9 publications in work at time of this review, when including mirror groups TC5 and TC210. These can be seen in Table 4: Standards Under Development.

According to IEC, two new foundational standards for AI are suggested to provide important building blocks for digital transformation. ISO/IEC 22989 [23] that covers AI concepts and terminology and ISO/IEC 23053 [24] that describes a generic framework for using machine learning (ML) technologies [25]. The IEC's White Paper discuss the need for standards' development and present a 5–10-year plan for driving AI development practices and mitigating risks to safety, security, privacy, trust, and ethical considerations and ensuring AI systems are developed in line with societies values and individual rights. To that end, IEC have promoted the significant role of Joint Technical

Committee (JTC) 1/SC 42[1] in developing horizonal AI standards that are presented in this research. The medical device technical committees consequently can harness these and refer to these standards as necessary for AIeMD specific application.

4 Discussion

4.1 Regulatory Driver for AI Standards

The need for standards is multifaceted and one only needs to review the current regulations to provide a case in point. For example, the EU Cybersecurity Regulation stipulates that AI needs cybersecurity to be trustworthy and address high-performance computing capabilities to support AI learning. One objective of the Cybersecurity Regulation states that, although the regulation is distinct in its own right, it is interdependent to other regulations for achievement of goals. The same can be said for medical device regulations, and indeed standards, where they either directly or indirectly reference other regulatory requirements and guidance that must be assessed to appropriately consider the SoTA.

For instance, the recently updated Machinery Regulation of June 2023 provides a clear case of a direct relationship. *Machinery* is called out within the Medical Device Regulation (MDR) (EU) 2017/745, where it is stated that, in the event of a *hazard to safety* arising from machinery, the Essential Requirements of the Machinery Directive 2006/42/EC shall apply, where there are more specific requirements documented in it than those identified in the General Safety and Performance Requirements (GSPR) of the MDR. The Machinery Regulation (EU) 2023/1230 repeals and replaces the Directive from 20 Jan 2027. The medical device industry is well versed in the IEC 60601 family of standards that deals with safety of medical electrical equipment and machinery. However, the relevance to AIeMD is not yet well understood from the perspective of the Machinery Regulation, particularly, in the absence of standards. That said, we can expect to see the adoption of AAMI TIR 34971:2023[26] by ISO soon, which provides guidance on risk management for AI within the ISO 14971[19] framework and which addresses autonomous machinery such as surgical robots and more.

Another example comes from the Interoperability Europe Act that entered into force in April 2024[27] and addresses enabling central digital infrastructure for connecting services and applications, including AI models to achieve interoperability solutions. Data sharing is a prerequisite for all AIeMD data modelling and effectiveness, required to avoid biased training data sets and reduce errors that could lead to safety and ethical issues, such as inaccurate diagnosis [28, 29]. Notable interdependent regulations related to medical devices within the EU are therefore shown in Table 5**:** Interdependent Regulations.

Although all AIeMD standards and guidance are not yet in place, the AI Act is pending imminent adoption, based on the accepted version presented to the European Parliament and 27 member states in Dec 2023 and since then has been approved in plenary by the European Council [2]. The AI Act clearly stipulates that more than one legislation can apply to one product in line with the Blue Guide of EU product rules [38]. To that end, the regulatory requirements for AI devices including AIeMD, which are considered

[1] JTC 1: Information Technology with Special Committee SC42 responsible for AI.

Table 5. Interdependent Regulations

The EU AI Act (2024) [2]
The Machinery Regulation 2023/1230 [30]
Interoperability Europe Act Regulation (EU) 2024/903 [27]
Cybersecurity Regulation (EU) 2019/881 [31]
Fair Access and Use of Data Regulation 2023/2854 [32] General Data Protection Regulation 2016/679 [33]
Digital Services Regulation [34]
Medical Device Regulation [35] / In Vitro Diagnostic Regulation 2017/746 [36, 37]

in the high-risk AI category having potential for adverse impact on safety, wellbeing, and human rights, must therefore, regardless of standards availability, ensure the safety and performance of devices are assured to the current SoTA. It is no longer acceptable for industry to limit the standards budget to those that are harmonised, when harmonization is increasingly difficult to realize, and extensive guidance already exists as SoTA. In the interests of the Code of Conduct for Technical Work [39] in which confidentiality and protection of committee documents is upheld, this paper is not intended to provide a critique of the yet to be published standards, but instead allay fears that further guidance is forthcoming.

In any event, the *AI Office* recently established within the *European Commission*, is designed to strengthen *safe* and *trustworthy* AI, and intends to regulate and ensure compliance with enforcement, capable of administering infringements and sanctions. Although medical devices are already certified by Notified Bodies, who are designated by Competent Authorities and answerable to the EU Commission, the AI Office also has authority over safety of AI and intends to include areas such as robotics, health, biotech, manufacturing, and more. It is not yet clear how these two regulatory frameworks will collaborate, though they have indicated they will act to ensure efficiency and ensure a unilateral approach is applied across union member states, whilst competent authorities will continue their responsibilities within their member states.

4.1.1 AIeMD Development Lifecycle

The TC's project list of draft standards demonstrates considerable expertise aimed at shaping the future of AIeMD. IEC 62304 Ed2 [40] intends to expand its scope to *Health Software* to include new technologies, including AI. IEC 62304 [17] remains the accepted foundational process for medical device software development [21]. It would be challenging to fit an AI development lifecycle into a traditional software development framework. Hence, we can expect rationality to prevail with reference to existing standards such as ISO/IEC 5338 [41] which provides AI system life cycle processes and the ISO/IEC 5259 family of standards (in draft) which covers governance through to data quality processes [39, 40].

4.1.2 Data Quality

Data quality is a critical factor in any AI system with model learning dependent on the data quantity and quality [44]. It is not surprising there is commonality between existing standards such as ISO/IEC 25024 for *Measurement of Data Quality* [45] and draft AI standards listed in this research [39, 40, 43–45]. For instance, requirements are necessary for a set of data quality measures for each characteristic applied during the AI data-lifecycle, together with an explanation of how to apply data quality measures and test methods throughout the lifecycle [49].

Another example is the definition of *accuracy* in ISO/IEC 5259–4 [42] having both *syntactic* and *semantic* components, which is adopted from ISO/IEC 25012 [50]. As the name suggests, *syntactic accuracy* is ensuring the formation of data is accurate, such as the measured variable, unit of measure, etc., whereas *sematic accuracy* assesses the meaningfulness of the measured variable in context [42, 48].

ISO/IEC 8183[51] and ISO 5259–3 [46] are also comparable. These examples of commonality between released standards and those in development are presented to demonstrate that where possible, TC's aim to be consistent across standards to avoid ambiguity and build on best-practice. Therefore, industry can benefit from considering the existing standards [50] already published and any drafts available for public comment [42, 43, 46, 48, 49] to address current regulations.

4.1.3 Performance Evaluation

A critical facet of the AIeMD lifecycle is how continuous validation will be performed and *performance*[2] measured in the maintenance (post-market) phase. We can expect the forthcoming AI Verification and Validation Test Methods (IEC 63450 in work) and Performance Evaluation (PE) (IEC 63521 in work) standards to provide guidance on test methods for measuring AI models and ensure performance characteristics are adequately defined and documented in a PE Plan and Report. However, the method for *continuous monitoring* of *adaptive* (or continuous learning) algorithms cannot be left to *calibration* control checks alone, where AIeMDs continue to autonomously modify internal algorithms and outputs in response to new data [44]. Article 72 of the AI Act has indicated that a template for a performance monitoring plan will be provided by the EU Commission and this can be integrated with elements already in place by other legislation, where available, provided it delivers the same level of protection [2].

It is neither logical nor acceptable to limit AI to locked algorithms only, as the potential for beneficial healthcare would be inhibited. We also cannot limit the intended use to *support-only* roles for clinical decision-making in the long-term, without anticipating clinical over-trust in AIeMD performance. Whilst avoiding over-hype, sufficient quality data for continuous learning of adaptive models have the potential to out-perform clinicians and the AI-system itself following initial release, due to its ability to process an extensive data set. Therefore, clearly defined and implemented controls are necessary for monitoring and oversight by developers.

[2] Performance: the ability of a medical device to achieve its intended purpose as stated by the manufacturer.Performance may include both clinical and technical aspects[21].

A risk-based post-market (PM) monitoring plan is therefore a necessary element of the device's Technical Documentation to be reviewed by Notified Bodies (NB) prior to AIeMD release to market, and preferably, using automated real-time monitoring and notification processes of changes to critical performance characteristics such as error, accuracy, recall, and precision to name a few [2]. The PM monitoring plan is required to ensure the requirements of Chapter III of the AI Act are complied with throughout the lifetime of the AIeMD, which includes classification, identification of requirements and risks, identifying obligations and reporting to authorities and NBs, transparency, human-oversight, technical documentation maintenance and more. The seven (7) principles of the 2019 Ethics guideline are also fundamental to the AI Act for trustworthy AI and should serve as a guide to considerations for inclusion; human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being and accountability [3]. The Singapore's 'Model Framework' on Generative AI provides some level of guidance, advising continuous auditing, following input from the EC's High-Level Expert Group and the OECD Expert Group on AI [52]. To date, the only standard's organization identified as dealing with clinical post-market monitoring of healthcare AI is that proposed by IEEE with a target date for draft of Feb 2025 [53]. Nevertheless, the AI Act states that the Risk Management System employed must be continuous, iterative and run throughout the entire life of the AI system and aimed at "*identifying and mitigating the relevant risks of AI systems on health, safety and fundamental rights*" [2, p. 64] . The inclusion of *fundamental rights* goes somewhat beyond the existing Risk Management File contents under ISO 14971, which will require upgrade by developers.

4.2 Conclusion

AI standardisation is still considered in early-stage development. The results of the research presented here demonstrate that considerable ground has already been covered and this work continues. It is essential that non-industry specific AI standards are reviewed for application to AIeMD development. Also, it is unwise to limit the standards budget to harmonised or AIeMD only standards, where cross-pollination of AI best practice is to be expected in forth-coming standards and regulations clearly call for safe and trustworthy AI devices within healthcare that go well beyond the medical device MDR 2017/745 or invitro diagnostic regulation IVDR 2017/746 to achieve.

Companies with financial restrictions or those largely reliant on harmonization standards risk not understanding best practices or the complete SoTA. Whilst it can be confusing to understand which standards are relevant to the SoTA, there exists an extensive amount of research, including guidance presented freely through IMDRF and other interested groups to support identifying the starting point [43, 51, 52], including this research.

A proactive approach is necessary if the industry is to embrace innovation with safety and effective performance whilst reducing defects and recalls. All standards must be considered for relevance and adopted for compliance where the standards support the regulations for improved outcomes. The prospect of an AI-performed review of technical documentation may not be inconceivable in the future and would not be limited to a

harmonised list of standards, but instead would incorporate the entire SoTA in the interests of trustworthy AI. Regardless, what is clear is that standards development is well underway, and although not yet complete, the industry must move forward with innovation and ensure ethical values, safety and performance requirements of their devices are achieved to the current SoTA.

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