Software in Metrology for the Digital Age: Addressing Compliance Challenges with MID, NAWID, and MDR

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Abstract. In the digital era, software is integral to devices regulated by European directives like MID, NAWID, and MDR, ensuring accuracy, reliability, and safety. While metrology has been crucial, software now plays an equally significant role, enabling data processing, automation, and new functionalities. Emerging technologies like AI, IoT, or cloud computing introduce compliance challenges. This article analyzes and compares software requirements in MID, NAWID, and MDR, focusing on software lifecycle, regulatory gaps, and risk assessment.

1 Introduction

In the digital age, software has become an integral part of measuring devices. Directives such as the Measuring Instruments Directive (MID) 2014/32/EU [1], the Non-Automatic Weighing Instruments Directive (NAWID) 2014/31/EU [2] and the Medical Devices Regulation (MDR) 2017/745/EU [3] sets out requirements for placing a product on the market. The development of technologies such as artificial intelligence (AI), the Internet of Things (IoT), or cloud computing (CC) brings new opportunities but also challenges in the adjustment of software requirements. This evolution has an impact on data processing and storage, cybersecurity, and the overall integrity of measurement processes. The aim of this article is to analyse and compare the software requirements set out in the MID, NAWID and MDR, identify key differences and common features. Special attention will be paid to the software life cycle, risk management methods, and the possibilities of adapting regulations to modern technological trends.

2 The impact of software on measurement systems

The implementation of software in measuring systems can retrospectively be considered an extreme advance in the field of measurement when we realize that most of the measuring systems around us are equipped with software. This has brought about a fundamental step forward in data processing, storage and analysis. It gives measurement systems flexibility, the possibility of automated evaluation and integration with remote IT systems. Before software solutions, the accuracy, reliability and safety of measurement systems were ensured primarily by high-quality material processing and mechanical modifications. However, with the advent of digitalization, software solutions have been implemented in these systems, which have fundamentally expanded their functionality and efficiency. Software now enables automated correction of measurement processes and analyzes historical data for predictive purposes. Its main benefits include flexibility, higher accuracy and reliability thanks to the elimination of measurement deviations and automation that minimizes the need for manual manipulation. On the other hand, software in measurement systems also brings new challenges, such as cybersecurity, quality assurance and software trustworthiness.

3 Relationship between directives, standards and guides

In the regulatory environment of the European Union (EU), there is a hierarchy of legislative and technical documents that affect the placing of products on the market. European directives are legally binding documents that set out essential requirements for the safety, functionality and reliability of products. Compliance with the requirements of a given directive is essential for placing a product on the market within the EU. Manufacturers can demonstrate these requirements in various ways, one of the simplest being the use of standards. Standards can be divided into harmonised and non-harmonised. Harmonised standards are officially published in the Official Journal of the European Union (OJEU) [4] for each directive and compliance with them means that they meet certain requirements of the directive with a high degree of probability. This process is explained in detail by Regulation (EU) No 1025/2012 [5], which lays down

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the rules for the development and recognition of harmonized standards within the EU. Non-harmonized standards can be used to demonstrate compliance with the directive, but in that case it must be clearly documented how the specific standard reflects the requirements of the directive. It is also necessary to mention guidance documents, which can essentially also be used similarly to non-harmonized standards. Each of the directives (MID, NAWID, MDR) has harmonized standards however there is no harmonized standard specifically addressing software (status early 2025). NAWID has a harmonized standard EN 45501:2015[6], which contains some software requirements. MID has no harmonized standards for software in legal metrology. MDR also has no harmonized standards, but there are standards specifically aimed at software in medical devices, such as IEC 62304 [7], IEC 82304 [8] and IEC 81001-5-1 [9]. For each directive, there are guideline documents that provide detailed explanations on how to implement and understand the software requirements. Although the guides are not legally binding, they are an important source of recommendations.

Table 1. Overview of software in MID, NAWID, and MDR.

	MID	**NAWID**	**MDR**
Year of issue	2015	2014	2020
Number of requirements	3	0	17+
The word "software"	12	0	48
Harmonized standards	0	1	0
Non-harmonized standards	0	0	25+
Guides	7+	1	100+

4 Software requirements analysis

Directives set out the essential requirements that products must meet, but do not usually contain detailed technical specifications. It is therefore appropriate to link these requirements to relevant standards and guidance documents in a reasonable way. In the case of MID, it is possible to base it on WELMEC Guide 7.2 Software Guide [10]. Requirements are categorized based on common functions of software for measuring instruments, such as user and communication interface, software integrity, parameter protection, software protection and security, and data display trustworthiness. Furthermore, there are optional additional requirements such as data transfer, long-term data storage, software separation, software updates, or special requirements for operating systems in the case of more complex software. The following are requirements that are specific to measuring instruments under MID, such as data erasure prevention, fault recovery, back up, or requirements related to power failure. The checking of the fulfillment of these requirements is primarily based on technical documentation and performance of functional tests on the device that contains the software. The tests should be performed by a person who is not part of the software design. A total of 48 requirements are identified, with each requirement explained in detail. It explains what should be included in the submitted technical documentation, as well as instructions for the tester on what to check in the documentation and how to proceed with functional tests. Another interesting guidance document is OIML D31[11]. The number of requirements according to the final checklist is 31. In terms of the interpretation of the requirements, both documents are quite similar, with the difference that OIML D31 does not have requirements for specific measuring instruments. After reading both documents, the idea of fulfilling the requirements is clearer.

In the case of NAWID we can base ourselves on WELMEC Guide 7.5 Software in NAWIs [12]. The aim of this Guide is to bridge the requirements in EN 45501:2015 with WELMEC Guide 7.2, given that the standard has 20 requirements.

In the case of MDR, the software requirements are more specific than in MID. It is directly linked to risk, life cycle and also takes into account mobile computing platforms. An important standard is IEC 62304 Medical device software — Software life cycle processes. The standard briefly outlines four general requirements such as quality system, risk management, security, and legacy software. However, it primarily focuses on software design, leaving the identification of specific requirements to manufacturers within individual chapters of the standard. The IEC 82304 Health software standard Part 1: General requirements for product safety directly refers to the IEC 62304 standard but also includes more specific requirements such as interoperability and language support. Norme IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security. As the name suggests, it is focused directly on security. The specific wording of the requirements is also left to the manufacturer, but there are specified areas that need to be addressed, such as testing, maintenance, or response to incidents reported from the real field. There are a number of guidance documents for MDR that are freely available, and sources such as MDCG [13], IMDR [14] or FDA[15] are certainly worth highlighting, where they are available for free.

Table 2. Overview of standards and guides related to MID, NAWID and MDR.

MID	
Standards	-
Guides	WELMEC Guide 7.2, OIML D31
NAWID	
Standards (harm.)	EN 45501:2015
Guides	
MDR	
Standards	IEC 62304, IEC 82304, IEC 81001-5-1
Guides	MDCG, IMDRF, FDA

5 Software lifecycle

Software lifecycle refers to every stage of software development, release and support. But only MDR works with software lifecycle and addresses all its stages, for MID and NAWID it is foreign term. This is shame because these two could easily benefit from this approach if it would be addressed properly.

It is important to realize what stages are in software lifecycle to correctly handle requirements of each stage. When it comes to medical device software, the most comprehensive and widely recognized standard for managing the software lifecycle is IEC 62304. This standard provides a structured framework for software development and maintenance, ensuring that all necessary safety and risk management processes are integrated throughout the software lifecycle.

Table 3. Software life cycle phases

Phase	Description
Planning	Defining project scope, objectives, regulatory requirements, and resources.
Development	Designing, implementing, testing, and integrating software components to meet defined requirements.
Maintenance	Managing software updates, bug fixes, performance improvements, and compliance adjustments.
Risk management	Identifying, analysing, and mitigating software-related risks.
Problem resolution	Detecting, documenting, and resolving software issues.
Decommissioning	Ensuring that the software is safely retired, data is properly handled.

6 Risk assessment

Risk assessment is mentioned in all three directives, but only MDR explicitly classifies medical devices into classes I, IIa, IIb, and III, where each classification reflects risk. Furthermore, MDR establishes additional requirements where risk is directly linked to software, ensuring that safety considerations are integrated throughout the software lifecycle. For MDR, the harmonized standard ISO 14971:2019 Medical devices — Application of risk management to medical devices [16] but the standard does not explicitly address software. However, a previous version of ISO 14971 is cross-referenced with IEC 62304. The idea is that manufacturers propose their own risk assessment, considering all relevant aspects, evaluating severity and probability, and proposing mitigation measures to reduce risks to an acceptable level.

Table 4. Example of a risk assessment for a medical device. (A-acceptable risk, N-unacceptable risk, Probability:1-Improbable, 5-Frequent, Severity:1-Negligible, 5-Criticial).

	Severity				
Probability	**1**	**2**	**3**	**4**	**5**
1	*A*	*A*	*A*	*A*	*N*
2	*A*	*A*	*A*	*N*	*N*
3	*A*	*A*	*N*	*N*	*N*
4	*A*	*A*	*N*	*N*	*N*

In contrast, for MID and NAWID, risk assessment follows guidance from WELMEC Guide 7.2, which categorizes risk into classes A–F, each with specific criteria determining when a particular risk class should be considered, based on level software protection, examination, and conformity.

Table 5. Definition of risk classes according to WELMEC Guide 7.2[10].

Risk Class	Software protection	Software Examination	Software Conformity
A	*LOW*	*LOW*	*LOW*
B	*MIDDLE*	*MIDDLE*	*LOW*
C	*MIDDLE*	*MIDDLE*	*MIDDLE*
D	*HIGH*	*MIDDLE*	*MIDDLE*
E	*HIGH*	*HIGH*	*MIDDLE*
F	*HIGH*	*HIGH*	*HIGH*

Another approach for MID/NAWID is outlined in WELMEC Guide 7.6, which introduces a quantitative risk assessment methodology. This methodology is based on a structured evaluation of assets, attack vectors, and attacker motivation, drawing upon principles from the ISO/IEC 27005:2011[17] standard, which is widely used for information security risk management.

7 Discussion

The analysis of directives from a software perspective has shown that not every directive has clearly defined software requirements. The most comprehensive approach is found in MDR, which is likely due to it being the most recent directive. Although there are ways to address software requirements in each directive, the approaches vary significantly. One key strength of MDR is that it leaves the definition of specific software requirements to manufacturers. This makes sense, as software is best understood by the manufacturer itself, and defining broad requirement categories rather than rigid specifications allows for greater flexibility. When it comes to risk assessment, the situation remains diverse. Since all three directives can apply to measurement systems, there could be a methodology that is applicable independently of the specific directive.

One major gap in MID and NAWID is missing requirements for the software lifecycle. Given the increasing reliance on software across all industries, this omission can be seen as a missing piece in these directives. MDR, on the other hand, fully incorporates the concept of a software lifecycle, providing a structured approach to software development, validation, and maintenance. Addressing this gap in MID and NAWID would be a significant improvement,

helping manufacturers manage software updates, security patches, and long-term compliance more effectively. Looking ahead, one of the biggest challenges remains the creation of a harmonized standard for software in legal metrology. While MDR has at least software-related standards like IEC 62304. There is currently no harmonized standard specifically addressing software within MID and NAWID. Establishing such a standard would bring comprehensibility and consistency to software conformity in legal metrology. It is also essential to consider how directives are set to adopt the new technologies. As technology continuously evolves, applications such as Virtual Reality, AI tools, Cloud Computing, Arbitrary Devices, and IoT present new challenges. However, not all directives can integrate technologies into existing products.

Table 6. Adoption of new technologies from the perspective of directives. (* AI tools that continuously learn and adapt in real-time based on new data and interactions)

	MID	NAWID	MDR
Virtual Reality	+	+	+
AI tools*	-	-	-
Cloud Computing	-	-	+
Arbitrary device	-	+	+
IoT	+	+	+

8 Conclusion

The selection of MID, NAWID, and MDR for this analysis was intentional, as measurement systems play a crucial role in each of these directives. However, when a measurement system integrates software, the processes for market entry differ significantly across these directives. While MDR provides a more robust and structured framework, MID and NAWID lag behind in defining clear software-related requirements. One of the critical challenges across all three directives is the lack of harmonized standards for software. Despite this, numerous guidelines and non-harmonized standards exist that manufacturers can utilize. However, despite the availability of numerous approaches, their inconsistency leads to unnecessary complexity. Given that measurement systems are relatively stable, the lack of a unified framework results in regulatory fragmentation, making compliance more challenging than necessary.

It is important to recognize that measurement processes remain relatively stable, meaning that technological advancements, rather than fundamental measurement principles, will drive product attractiveness in the future. The most effective way to integrate new technologies into regulated measurement systems is to incorporate a structured software lifecycle and standardized risk management into directives where they are currently missing. Establishing such a more unified approach would enhance regulatory clarity, support technological innovation, and ensure consistent safety and compliance across all three directives.

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