USNC CURRENT

Vol. 20, No. 2 – Spring 2025

DIGITAL TRANSFORMATION AND SMART STANDARDS

IEC
United States National Committee of the IEC

Published by the U.S. National Committee of the IEC, a committee of the American National Standards Institute

DIGITAL TRANSFORMATION AND SMART STANDARDS

FEATURED STORIES

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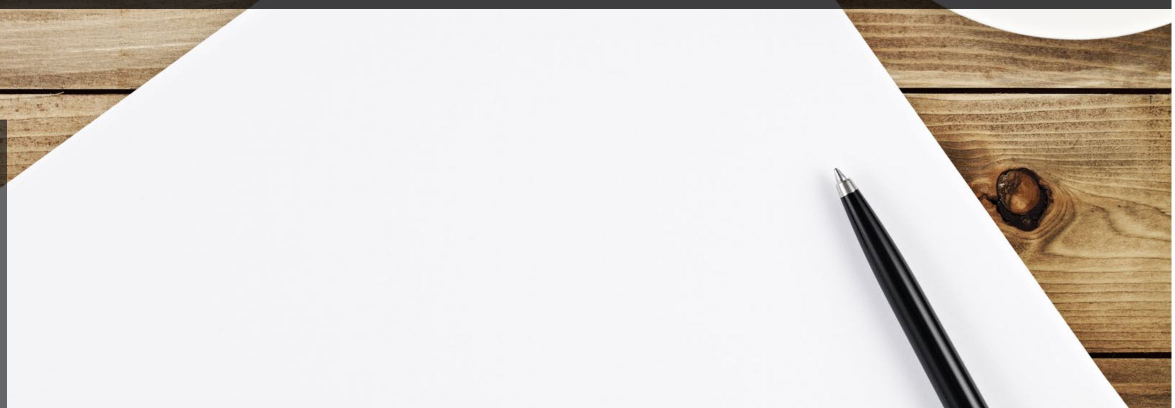
LETTER FROM THE USNC PRESIDENT: TRANSFORMING INDUSTRIES—THE IMPACT OF IEC'S DIGITAL TRANSFORMATION AND SMART STANDARDIZATION IN THE U.S.

Veronica Lancaster – USNC President; Vice President, Standards Programs at Consumer Technology Association



In recent years, the International Electrotechnical Commission (IEC) has been betting on the future of standardization being digital. This journey began in 2017 when the IEC's General Assembly approved a strategy to leverage the digital era to develop new products and services. The years 2018 through 2022 were more formative years in this digital journey. The IEC focused on developing the backbone of smart standardization in 2018 through 2020 by converting standards into XML, updating the IEC's collaboration platform, and creating an online authoring platform called "OSD," which stands for Online Standards Development. From 2021–2022, the IEC Board established a smart task force to focus on next steps in the digital transformation, including hiring a Digital Transformation Officer. The transformation really kicked into high gear in 2023 when the IEC Board approved further investment in digital transformation by expanding the digital team, setting core principles, and beginning pilots. This decision was supported due to the historical number of reserves in the IEC budget coupled with the historical revenues achieved by 2023.

This digital transformation to "smart standardization" is nothing new in the U.S.; several SDOs have been creating smart standards for some time. Let's talk about what smart standards are. Smart standards are standards that are digital, machine-readable, and adaptable for various applications, such as in areas like smart manufacturing. Smart standards refer to the integration of advanced technologies and digital tools into the process of setting, managing, and complying with standards.

Let's consider some U.S. SDOs that use smart standardization today and how they use it. Health Level-7 (HL7) was created by the SDO Health Level Seven International. HL7 has become a well-known set of standards in the healthcare industry; these standards are used to share heathcare data between various healthcare providers, as well as through different health IT applications.[1] One example of HL7's standards is

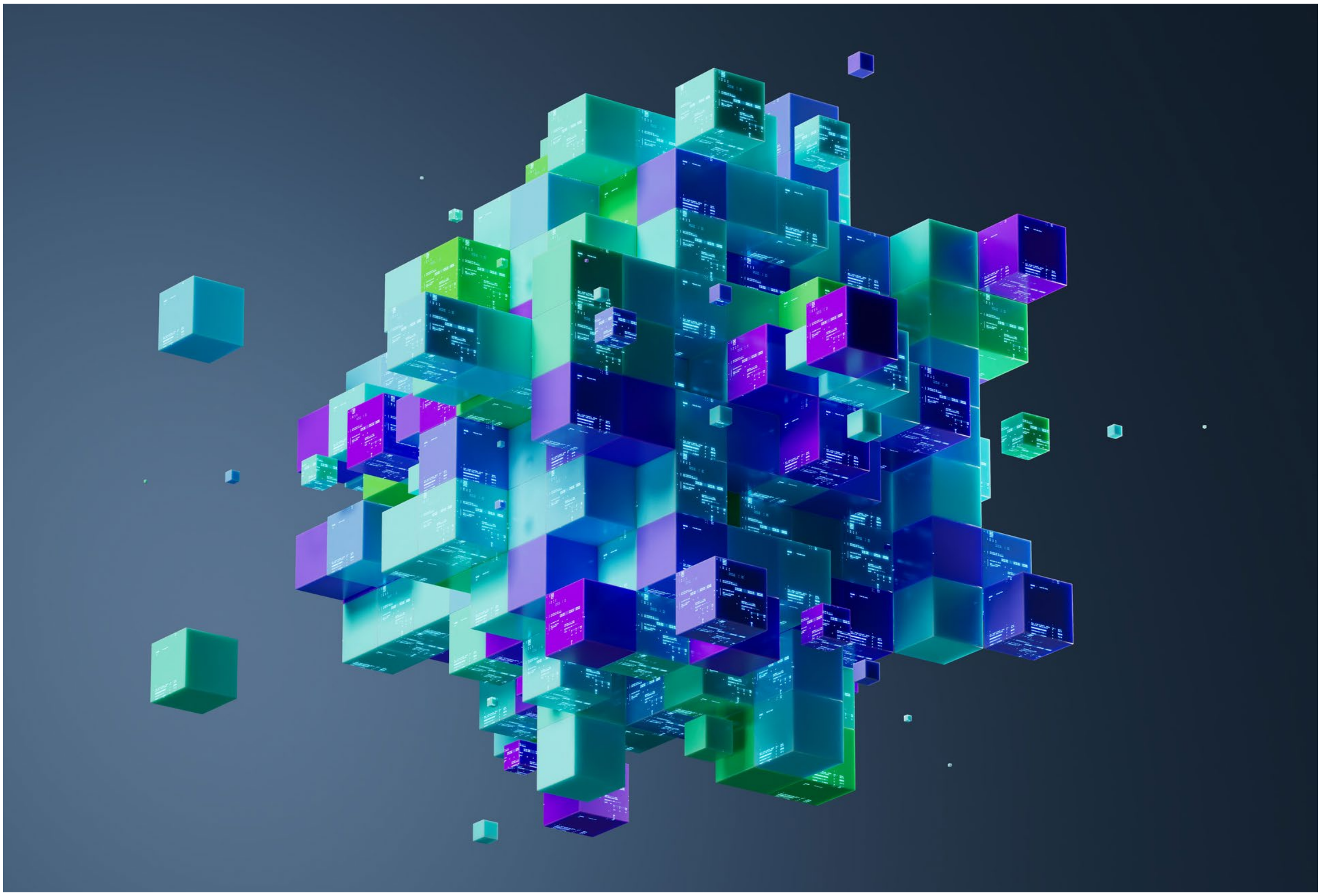
1 Rhapsody Health Solutions Team. (2025). What is HL7? – An Overview of HL7 Standard. Rhapsody. https://rhapsody.health/blog/what-is-hl7.

Clinical Document Architecture. This standard specifies the structure and semantics of clinical documents so that it can be exchanged through a variety of systems as a complete information object. These object are encoded in XML, and they can include text, images, sounds, or other multimedia.[2]

With the IEC's digital transformation, you may wonder why this impacts the U.S. One of the primary impacts of the IEC's initiatives in the U.S. is the facilitation of technological integration. By promoting standards that harmonize digital systems across different sectors, the IEC hopes to enable seamless interoperability. This interoperability is crucial in fields such as smart grids, where various components must communicate effectively to optimize energy distribution and consumption. The future ability to digitally "pull" information from existing digital sources will be a major improvement to standards-writing.

Overall, smart standards and digital transformation aim to make standardization more efficient, adaptable, and supportive of technological innovation, thereby accelerating digital transformation across industries and ensuring sustainable development. I look forward to watching the IEC's digital transformation reshape standards, paving the way for a future where technology serves as a catalyst for sustainable growth and global connectivity.

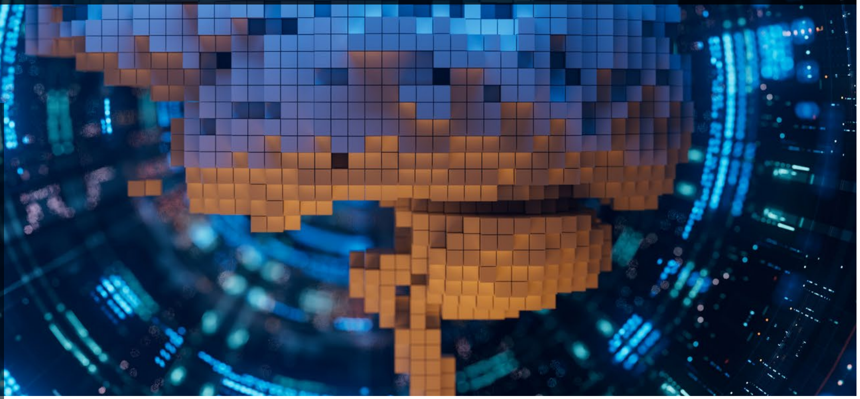
2 Dolin, R. H., Alschuler, L., Boyer, S., Beebe, C., Behlen, F. M., Biron, P. V., & Shabo Shvo, A. (2006). HL7 Clinical Document Architecture, Release 2. Journal of the American Medical Informatics Association : JAMIA, 13(1), 30–39. https://doi.org/10.1197/jamia.M1888



NAVIGATING AI RISKS IN DIGITAL TRANSFORMATION: ADVANCING SAFETY THROUGH SMART STANDARDS

Young M. Lee – Technical Leader, Artificial Intelligence, UL Solutions

Kenneth Boyce – Vice President, Engineering, UL Solutions



Digital transformation is driving unprecedented changes across industries. From manufacturing and mobility to healthcare and retail, artificial intelligence (AI) has become a cornerstone of innovation. AI systems, ranging from predictive maintenance algorithms, autonomous vehicles, medical imaging, to large language models (LLMs), are enabling automation, efficiency, innovation, and entirely new forms of digital interaction.

Yet, the rapid integration of AI also presents substantial risks. These systems, which often operate with a degree of autonomy and adaptiveness, bring new safety challenges that traditional standards are ill-equipped to address. As AI becomes embedded in safety-critical systems and societal infrastructure, ensuring that these technologies operate safely, reliably, ethically, and responsibly is a growing imperative.

There is a pressing need for a comprehensive framework to guide the safety assessment and assurance of AI-based systems. Such a framework must address not only the technical dimensions of system performance, but also the ethical and governance-related implications of deploying AI at scale. Smart safety standards that are dynamic, risk-based and interoperable with global norms offer a path forward.

THE AI SAFETY CHALLENGE IN DIGITAL TRANSFORMATION

AI systems differ fundamentally from conventional digital technologies. They are often:

- Nondeterministic, producing variable outcomes based on evolving data
- Self-learning, adapting to new training data over time
- Opaque, making decisions through complex internal logic that may not be transparent even to developers

These characteristics introduce a new class of risks. As noted in recent studies[1,2], AI systems can malfunction, propagate bias, degrade over time, or be manipulated

1 Sinha, S. and Lee, Y. (2024). "Challenges with developing and deploying AI models and applications in industrial systems." *Discover Artificial Intelligence*, 4:55.

2 Amershi, D., et al. (2019). *Software Engineering for Machine Learning: A Case Study.* ICSE.

through adversarial inputs. In high-stakes domains, such as industrial control, healthcare and autonomous systems, these failures can have serious consequences.

Additionally, the complexity of AI systems complicates efforts to achieve regulatory compliance, gain user trust and promote accountability. Governments and international bodies are responding with new guidance, including the National Institute of Science and Technology (NIST) AI Risk Management Framework (2023)[3], the European Union (EU) Artificial Intelligence Act (2024)[4] and the ISO/IEC 23894:2023[5] guidance on AI risk management. However, there remains a lack of unified methodology for evaluating AI safety in products across sectors.

THREE PILLARS OF AI SAFETY

To manage these risks systematically, a forward-looking framework for AI safety should be organized around three interdependent pillars:

- **Technical safety:** Ensuring system robustness, reliability, quality and safe integration of AI algorithms into broader systems
- **Ethical safety:** Addressing issues such as bias, fairness, transparency, and human oversight
- **Governance safety:** Managing AI system documentation, life cycle accountability, and organizational controls

These pillars should be translated into concrete safety principles and requirements that can be applied to AI systems throughout their life cycle.

ELEVEN CORE PRINCIPLES FOR AI SAFETY

Within these pillars, 11 safety principles serve as foundational elements for evaluating the safety of AI-based systems. These principles are drawn from emerging best practices, regulatory expectations, and applicable international standards.

TECHNICAL PRINCIPLES

- **Quality management:** Integration of structured software development life cycles (SDLCs), verification methodologies, and alignment with quality standards such as ISO/IEC 25059:2023[6]
- **Robustness and reliability:** Safeguarding performance under stress, error conditions, and data variation, with guidance from ISO/IEC TR 24029-1[7]
- **Risk management:** Implementing life cycle-based risk identification, assessment, mitigation and monitoring, consistent with ISO/IEC 23894:2023[8] and the NIST AI Risk Management Framework (RMF)[9]
- **Functional safety of AI:** Applying principles of IEC 61508 and ISO/IEC TR 5469:2024[10] to assess the safe integration of AI in systems where failure could result in harm

ETHICAL PRINCIPLES

- **Fairness and bias:** Identifying and mitigating discriminatory outcomes in training data, algorithms, and predictions using techniques such as fairness auditing and reweighting[11]

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3 NIST AI RMF 1.0, 2023.

4 European Union Artificial Intelligence Act, 2024.

5 ISO/IEC 23894:2023, *Information Technology – Artificial Intelligence – Guidance on Risk Management.*

6 ISO/IEC 25059:2023, *Software Engineering – Systems and Software Quality Requirements and Evaluation (SQuaRE) – Quality Model for AI Systems.*

7 ISO/IEC TR 24029-1:2021, *Artificial Intelligence – Assessment of the Robustness of Neural Networks – Part 1: Overview.*

8 ISO/IEC 23894:2023, *Information Technology – Artificial Intelligence – Guidance on Risk Management.*

9 NIST AI RMF 1.0, 2023.

10 ISO/IEC TR 5469:2024, *Artificial Intelligence – Functional Safety and AI Systems.*

11 Barocas, S., Hardt, M. and Narayanan, A. (2023). *Fairness and Machine Learning: Limitation and Opportunities.*

- **Data privacy:** Ensuring responsible collection, processing, and protection of personal and sensitive data, aligned with regulations such as the EU General Data Protection Regulation (GDPR)[12]
- **Control and oversight:** Preserving meaningful human oversight, including the ability to monitor, intervene with, or override automated decisions when necessary
- **Transparency and explainability:** Enhancing the intelligibility of AI models and their decisions, with techniques such as SHapley Additive exPlanations (SHAP) and local interpretable model-agnostic explanations (LIME)[13], and aligning with emerging legal rights to explanation[14]

GOVERNANCE PRINCIPLES

- **Data management:** Establishing robust policies for data sourcing, labeling, quality assurance, and traceability
- **Documentation and reporting:** Maintaining comprehensive records of AI model development, testing, deployment, and monitoring activities to support audits and conformity assessments
- **Life cycle management:** Applying a full-life-cycle approach that accounts for model evolution, performance monitoring, periodic review, and decommissioning aligned with ISO/IEC 5338[15]

SMART STANDARDS FOR AI ASSURANCE

What distinguishes this safety framework is its alignment with the concept of smart standards that are:

- **Modular:** Not all principles apply to all systems equally; requirements are tailored based on use case and risk profile.
- **Scalable:** Applicable to both small-scale consumer products and complex industrial systems
- **Dynamic:** Capable of evolving with advancements in AI methods, threat vectors, and societal expectations
- **Interoperable:** Designed to complement sector-specific standards such as ISO 26262[16] (road vehicles) or IEC 60601[17] (medical devices)

A smart standard approach enables a risk-based evaluation process where AI systems are assessed based on the expected risks, their potential impact and requirements for mitigating the risks. A quantitative safety score can be derived from a system's conformance to relevant principles. AI safety certification then may be granted to the AI system when the score exceeds a defined threshold appropriate to the product's risk classification.

This approach promotes both accountability and innovation, providing assurance to regulators and users while allowing AI developers to innovate within a known safety envelope.

EMBEDDING SAFETY INTO INNOVATION

Embedding safety into AI systems is not a barrier to innovation, but a prerequisite for responsible and scalable deployment. In safety-critical sectors, a lack of trust in AI can delay adoption and increase liability. Conversely, robust safety standards create a shared language for assessment, encourage cross-sector collaboration, and accelerate time to market by reducing regulatory uncertainty.

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12 European General Data Protection Regulation (GDPR), 2018.

13 Ribeiro, M. T., et al. (2016). "'Why Should I Trust You?': Explaining the Predictions of Any Classifier." *KDD*.

14 ISO/IEC 5338, *Information Technology – Artificial Intelligence – AI System Life Cycle Processes.*

15 ISO/IEC 5338, *Information Technology – Artificial Intelligence – AI System Life Cycle Processes.*

16 IEC 60601-1-11:2015, *Medical Electrical Equipment, Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.*

17 ISO 26262-1:2018, *Road Vehicles – Functional Safety, Part 1: Vocabulary.*

International organizations such as ISO/IEC JTC 1/SC 42 on AI, the Institute of Electrical and Electronics Engineers Standards Association (IEEE SA), and the International Electrotechnical Commission (IEC) are actively developing standards in this space, contributing to a global ecosystem of AI assurance.

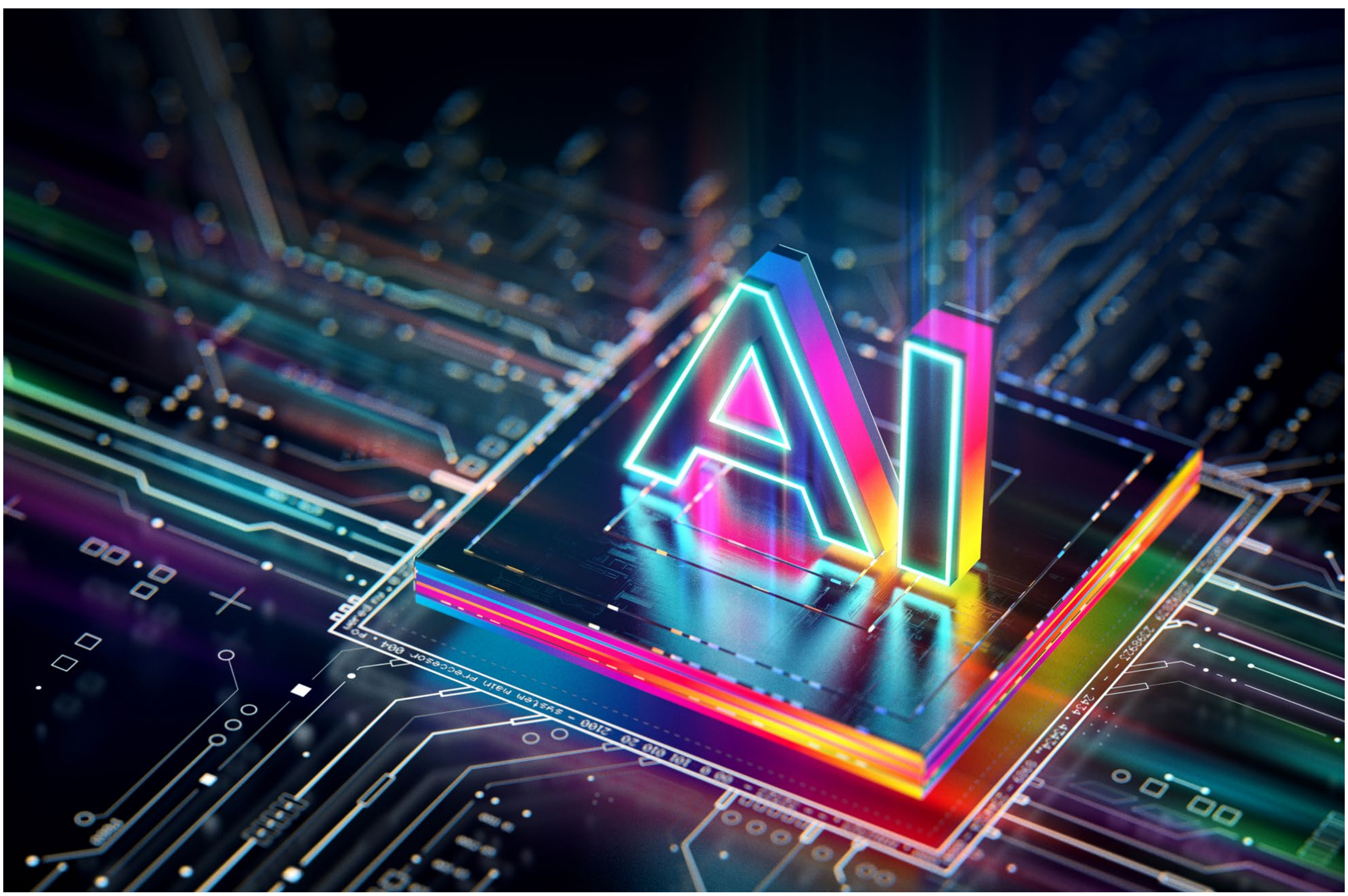
By aligning with emerging global standards, regulations and best practices, the proposed framework contributes to a safer, more trustworthy digital transformation.

CONCLUSION

AI is no longer an experimental technology; it is a defining element of the digital future, but for AI to deliver on its promise, industries must adopt a proactive and structured approach to managing risk. Traditional safety standards are no longer adequate for systems that learn, adapt and interact autonomously with people and environments.

A new generation of smart safety standards is needed—standards that are holistic, risk-informed and rooted in technical, ethical and governance principles. The proposed 11-principle framework offers such an approach—flexible enough to support innovation, yet rigorous enough to protect people, property, and the public good.

As industries continue to digitize and automate, the call to action is clear: Build AI that is not only powerful and intelligent, but also safe, responsible, and trustworthy.



IEC TC 114, MARINE ENERGY, REACHES CRITICAL OSD MILESTONE

Jonathan Colby – Founder & President, Streamwise Development, LLC; IEC TC 114 Chair

Philip Beauchamp – AG 2 Co-convener, PB Mechanical Consulting Service, LLC; IEC TC 114, AG 2 Co-Convener

In December of 2024, IEC TC 114 *Marine energy - Wave, tidal and other water current converters*, reached a critical milestone regarding the IEC Online Standards Development (OSD) platform: 100% of the active Work Programme within the TC is being conducted using the OSD! It is the intention of TC 114 to ensure all future work is conducted within the OSD platform as well.

TC 114 has been an active participant within the OSD platform since volunteering for an initial pilot program in late 2019. As Chair, I made it a critical priority for our TC to embrace the OSD platform, engage with its development, and migrate all our technical work to the platform as quickly as possible. To facilitate this transition, our Advisory Group 2 (Publication alignment support) was asked to support the TC 114 experts using the OSD and to act as the liaison to the OSD support team, among other roles, to ensure as smooth of a transition as possible.

While TC 114 experts have identified many bugs during the past ~6 years, the OSD support team have been incredibly responsive to the emails and suggested improvements to the platform and our experts have noticed the significant improvement in the platform over time.

The reasons for the rapid adoption of the OSD platform by our TC are many, and I share a few here:

- IEC TC 114 is a relatively new Technical Committee, with experts that are nearly all new to standards development and our membership is constantly changing. As such, our experts do not have a long history of developing standards using the former methodology.
- The technical content of the standards developed by TC 114 relate to a rapidly evolving portfolio of renewable energy technologies and the experts involved utilize a broad suite of digital tools to enable real-time collaboration within their organizations. As such, the transition away from emailing version-controlled Word documents to working within a real-time collaborative platform was intuitive and welcome.

» The TC discussed this IEC initiative at the very earliest stages of its inception, actively participated within the pilot program, and established a group to support the transition, Advisory Group 2, which has maintained an OSD agenda item on its regularly scheduled meetings since 2022. As such, training began early and the TC had many years to discuss, consider and understand the OSD platform and to contribute to its development.

Ultimately, the experts and leadership of TC 114 are very excited to have reached this critical milestone, and we are eager to continue championing the use of the OSD platform moving forward. While we certainly recognize that the tool still has room for improvement, we commend the OSD team for their work to date and for the development of this platform.

JUST PUBLISHED

Check out the latest and greatest recently published standards by the IEC. A complete list of recently published documents can be found here. Here's just one (of many!) we think you'll find interesting:

IEC 60092-376:2025- ELECTRICAL INSTALLATIONS IN SHIPS - PART 376: CABLES FOR CONTROL AND INSTRUMENTATION CIRCUITS 150/250 V (300 V)

IEC 60092-376:2025 applies to screened and unscreened cables for control and instrumentation circuits on ships and offshore units. The cables have an extruded solid insulation with a voltage rating of 150/250 V (300 V) (see Clause 4) and are intended for fixed installations. The various types of cables are given in Clause 5. The construction requirements and test methods are aligned with those indicated in IEC 60092-350, unless otherwise specified in this document. This fourth edition cancels and replaces the third edition published in 2017. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- Addition of a colour code for wires and tapes for unit identification;
- addition of the core numbering for multicore cables;
- Addition of design and test requirements for cables to be installed in explosive atmosphere areas;
- Addition of the design and test requirements for cables to be installed between areas with and without explosive atmospheres.

Developed by IEC TC 18 Electrical installations of ships and of mobile and fixed offshore units

PILOTING IEC'S ONLINE STANDARDS DEVELOPMENT TOOL: A PRACTICAL PERSPECTIVE

Valera Davis – International Standards Manager, ULSE, IEC TC 108 Secretary

As the Secretary of IEC Technical Committee 108, Safety of Electronic Equipment within the Field of Audio/Video, Information Technology and Communication Technology, and Chair of the USNC Subcommittee on Operating Procedures (SCOOP), I've had the unique opportunity to work with IEC's Online Standards Development (OSD) platform from multiple angles: as an author, a commenter, and a contributor to the development of the OSD Supplement that helps guide its use. I'd like to share some insights from this experience as an informational snapshot from someone who's been deeply involved in early adoption and implementation.

TC 108 was among the first technical committees invited to pilot the OSD platform for authoring. At the time, we had two new project teams (PT 63315 and PT 63316) beginning development on international standards. This presented an ideal opportunity to test the platform's capabilities in a real-world scenario.

Our first step was to input the structured outlines of each standard into the OSD tool. Our editorial group, composed of TC officers, divided the document into sections so that each person could work within the platform and provide feedback. This distributed approach allowed us to generate a broad base of user experience, which we then shared with IEC staff to support the tool's refinement.

At the inaugural meetings of each project team, we demonstrated how to use the OSD system for commenting and collaboration. We also provided members with a practical "cheat sheet" for first-time users. After some initial trial and error, we received positive feedback — most members found the tool intuitive and easy to navigate once they became familiar with the interface.

One of the key benefits from a TC Secretary's perspective was that the authoring function closely mirrors the user experience of Microsoft Word, but with added advantages. The platform streamlines formatting and editing tasks, minimizing the burden on the Secretariat and reducing time spent on document management.

Another feature we found especially useful was the commenting tool. By using it between project team meetings, members were able to review drafts, provide suggestions, and engage in discussions directly within the platform. This improved the efficiency of our drafting process and helped us maintain momentum between formal sessions.

While our overall experience with the OSD platform was positive, we did encounter some challenges, particularly in the early stages of use. As with any new digital tool, there was a learning curve — not only for authors, but also for project team members unfamiliar with the platform. Initial feedback included some frustration with navigation, document structuring, and unfamiliar terminology within the tool's interface. For users accustomed to traditional document editing software, adapting to a web-based environment took time.

Additionally, during the comment resolution process for IEC 62911, we encountered a significant issue when a batch of comments appeared to be missing from the system. This understandably created some confusion and required close coordination with IEC staff to identify and recover the missing input. The incident reinforced the importance of maintaining backup records of submissions and underscored the need for enhanced safeguards and visibility within the tool — particularly when managing comment resolution across multiple contributors.

There were also occasional technical hiccups, such as slow loading times or version control confusion when multiple contributors were working simultaneously. These issues were mitigated through training and shared resources, such as our customized cheat sheet, but they did highlight the importance of support and onboarding for new users.

Crucially, whenever we raised these issues, IEC staff were responsive and willing to work with us directly to find solutions. Their openness to feedback and collaborative approach to improvement made a significant difference in overcoming these early obstacles.

Throughout the process, the IEC staff provided consistent support. They responded quickly to questions, helped troubleshoot challenges, and welcomed our input for future enhancements. This constructive dialogue with IEC made it clear that the OSD platform is a living tool — one that will continue to evolve with feedback from its users.

I have also been able to use my early onboarding experience to help with the development of an OSD Supplement to the Model Operating Procedures in my role as Chair of SCOOP. The OSD Supplement for USNC Technical Advisory Groups (TAGs) provides practical guidance on how to engage with IEC's platform while maintaining compliance with U.S. procedures. It outlines how USNC TAGs can navigate using OSD for National Committee commenting, emphasizes that official U.S. positions must still be developed through the USNC TAG consensus process, and offers best practices for recordkeeping and coordination between USNC TAG members. It also highlights the importance of training and offers pathways for providing feedback to support ongoing improvement of the tool.

The OSD platform is still evolving, and that's a good thing. Innovation in standards development tools is necessary to keep pace with the increasing complexity and global nature of our work. Based on my experience, I believe the OSD platform offers real potential to enhance collaboration, streamline document development, and make it easier for experts to participate meaningfully in the standards process — no matter where they are in the world.

As more committees begin to use OSD, I encourage my colleagues to approach it with curiosity and patience. Like any new system, there's a learning curve — but with strong support from IEC staff and a commitment to continuous improvement, the journey is well worth it.

For those preparing to get started, IEC provides user guides and live training, and many committees — like TC 108 — have also developed internal resources to help members familiarize themselves with the platform. These tools, combined with open communication and constructive feedback, will be key to helping the OSD platform reach its full potential.

PROTECT YOUR LEGACY: IEC 61850-80-5 MAPPING MODBUS DEVICES INTO AN IEC 61850 SYSTEM

Keith Gray – POWER Engineers, IEC Co-Convener; USNC TAG IEC TC 57

Joel Greene – Vice President, SISCO; USNC TAG IEC TC 57

Despite (or perhaps due to) the simplicity of the Modbus protocol, it has been deployed widely over many decades. Despite its many shortcomings, like not having any defined data model and not having native support for data quality and timestamping, it continues to be implemented in a wide range of devices, especially those produced in high volumes. For example, solar inverters almost exclusively use Modbus. Many sensors that only support Modbus are selected for their simplicity.

The advantages of IEC 61850, primarily the well-defined data model, have been accepted widely in the power utility industry for many years. The benefits of the 61850 data model and engineering process allow rigorous validation because the configuration is machine processable. While there are some competing wireline protocols, the DER industry has largely harmonized on the 61850 datamodels (61850-7-420)

Building on one of the tenants of 61850—reducing labor costs and errors by using machine processable configurations that enable tooling and reuse—part 80-5 creates a System Configuration Language (SCL) extension that enables encoding of the Modbus device information to facilitate configuration of gateway devices.

Because of the proliferation of Modbus, many users have significant investments in legacy devices. In many cases this legacy investment is a significant hinderance to adoption of IEC 61850. Providing a standardized method of mapping these devices into an IEC 61850 environment allows realization of the benefits of the data model and engineering process without stranding these assets. This process can also lower the barrier to adoption of IEC 61850 due to the perception of stranded assets.

As Modbus provides no guidance on how to model the data of a device, there are many unique interpretations in the field. No assumptions can be made as to how data is presented in the Modbus interface. Therefore, the approach of this work is to provide a syntax and set of functions capable of describing most access and conversions necessary to retrieve data from the Modbus device and convert it into to appropriate datatype for the IEC 61850 Data Attribute.

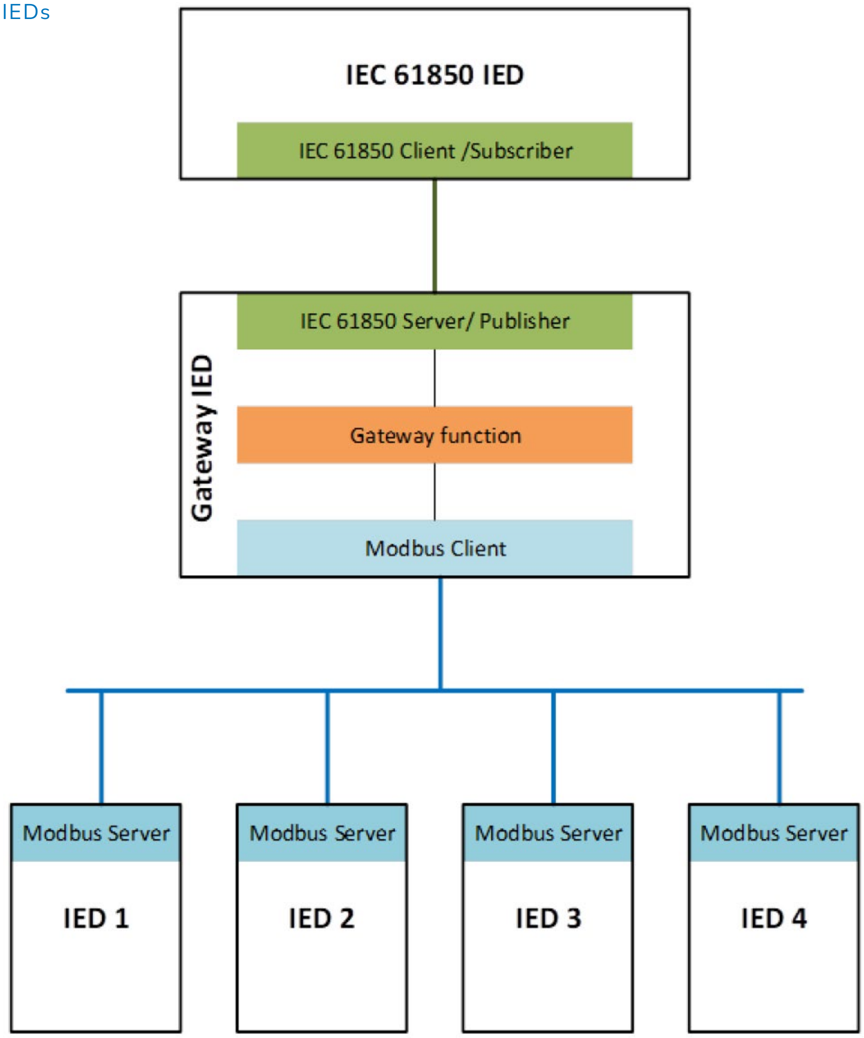
As the 61850 data model sematic provides the data-type and range for each Data Attribute, the conversion functions use this information implicitly, simplifying the syntax.

IEC has recognized the need for use of the standard by vendors building tools in order to meet the objectives of the standard. In order to accomplish these goals, the IEC publishes "code components" along with the standards documents. These components include schemas and namespace definitions that are licensed for vendors to incorporate in products to limit copyright liability questions and errors from manually interpreting PDF documents. Code components take priority over PDF standards for implementation.

80-5 introduces a new SCL filetype, the Modbus Configuration Description (MCD), and related Modbus Configuration Tool. The code component that comes with part 80-5 includes the schema for the MCD, as well as some example files.

Part 80-5 focuses on the use case of mapping Modbus servers into a gateway implementing the IEC 61850 server, as seen in Figure 1. Because of the wide variety of data structures in Modbus devices and the engineering

Figure 1 – Mapping Modbus IEDs into an IEC 61850 Gateway



creativity involved in many of them, the Task Force concluded that the best approach to modelling Modbus data is to define a set of conversion functions that can be stacked as needed. Because we cannot control, or even predict, the data model in Modbus devices—some of which have been in the field for decades—the job here is to define a set of functions that will allow us to map arbitrary data into 61850 data types and semantics.

In this context, IEC 61850 protocol features, such as Behavior and Health, are functions of the IEC 61850 server in the gateway and may not represent Modbus data.

USING PART 80-5

The configuration of the Modbus to IEC 61850 Gateway involves two main tasks. Each of these tasks can be split up into several steps.

MODBUS DEVICE DEFINITION

The first major step is to create a semantically defined IEC 61850 data object model, using the Modbus Configuration Tool (MCT). This step produces a Modbus Configuration Description (.mcd) file (See part 80-5 Annex B [1]), for each Modbus device (based on 7-3, 7-4, etc.) which includes:

- Find the semantically matching IEC 61850 data object for the Modbus information
- Identify the required data attributes of the CDC for the selected IEC 61850 information
- Define the links between the data attributes and the respective Modbus information
- Define the required conversion functions between the Modbus information and the IEC 61850 data attributes
- Define Semantic Data Model

Part 80-5 describes how to define the semantic data model for a Modbus IED. The following example uses that definition to show how to map A-Phase current from Modbus register 320 into a MMXU Logical Node (LN).

As defined in Part 80-5, a Private element of type “eIEC61850-80-5” contains all of the Modbus mapping.

```
<LN lnType="MMXU_TYPE" lnClass="MMXU" inst="1" prefix="FloatEx">
 <DOI name="A">
  <SDI name="phsA">
   <SDI name="instCVal">
    <SDI name=”mag”>
     <DAI name="f">
      <Private type="eIEC61850-80-5">
       <eIEC61850-80-5:RegisterRef addr="320" type="HoldingRegister" variableName="P1" dataType="INT16"/>
       <eIEC61850-80-5:ConvFunctRef>
        <eIEC61850-80-5:ApplicableConversion conversion="ConvertToFloat" inputVariable="P1" />
       </eIEC61850-80-5:ConvFunctRef>
      </Private>
     </DAI>
    </SDI>
   </SDI>
  </SDI>
  <SDI name="units">
   <DAI name="SIUnit">
    <Val>A</Val>
   </DAI>
   <DAI name="multiplier">
    <Val></Val>
   </DAI>
  </SDI>
 </DOI>
</LN>
```

Source Code Listing 1 – Mapping A-Phase Current from Modbus Register 320

Inside that Private element, a RegisterRef element is a reference to a Modbus register. Line 6 of Source Code Listing 1 references Modbus Holding Register 320 and uses a variable named “P1” to contain the value of that register. Next, in lines 8-11, the ConvFunctRef element contains conversion functions applied to the Modbus values. Source Code Listing 1 provides a simple example of converting the value stored in variable “P1” to a float. Finally, because the result of the “ConvertToFloat” conversion function is not stored in a variable, the value resulting from that conversion is taken as the value for the MMXU.A.phsA.instCVal.mag.f data attribute. This example demonstrates steps 1–4 as described above.

The Modbus communications parameters are also described in the *.mcd file.

```
<Communication>
 <SubNetwork name="SubNetworkName" type="MODBUS-IP">
  <ConnectedAP apName="AP" iedName="TEMPLATE">
   <Address>
    <P type="IP" xsi:type="eIEC61850-80-5:tP_IPModbus">192.168.0.2</P>
    <P type="ADDRESS" xsi:type="eIEC61850-80-5:tP_ADDR">2</P>
    <P type="PORT" xsi:type="eIEC61850-80-5:tP_PORT">502</P>
   </Address>
  </ConnectedAP>
 </SubNetwork>
</Communication>
```

Source Code Listing 2 – Modbus IED Communications Parameters

Source Code Listing 2 shows how the Modbus IED’s IP Address, Modbus Address, and TCP port are defined in the communications section.

Part 80-5 contains descriptions of all the SCL elements used in this section. It also provides examples showing the usage of the elements.

GATEWAY CONFIGURATION

When the IEC 61850 data models for all Modbus devices have been created, the Modbus to IEC 61850 Gateway can be configured using the IED Configuration Description (.icd) file format (See part 80-5 Annex B [1]).

- » Create the object model of the IEC 61850 server out of the data models for the Modbus devices
- » Define the supported IEC 61850 communication services and the communication parameters of the server

The following examples show portions of the gateway’s *.icd file using the Modbus IED from Source Code Listing 1. The ellipsis in the examples denote portions of the file left out of the code for brevity.

```
<IED name="TEMPLATE" manufacturer="IEC" configVersion="1.0" originalSclRelease="4"
  originalSclRevision="B" originalSclVersion="2007">
  <AccessPoint name="AP">
   <Server>
    <Authentication/>
    <LDevice inst="GTW_LD1">
     <LN0 lnType="LLN0_2007" lnClass="LLN0" inst="">
      <DOI name="NamPlt">
       <DAI name="vendor">
        <Val>Example Vendor</Val>
       </DAI>
      </DOI>
     </LN0>
     <LN lnType="LPHD_TYPE" lnClass="LPHD" inst="1" prefix="">
```

```
        <DOI name="PhyNam">
          <DAI name="vendor">
            <Val>Example Vendor</Val>
          </DAI>
          <DAI name="name">
            <Val>Gateway</Val>
          </DAI>
        </DOI>
        <DOI name="Proxy">
          <DAI name="stVal">
            <Val>false</Val>
          </DAI>
        </DOI>
      </LN>
    </LDevice>
...
</IED>
```

Source Code Listing 3 – Gateway Data Model

The *.icd file snippet shown in Source Code Listing 3 demonstrates that the Gateway IED will contain a Logical Device describing the gateway itself.

```
<LDevice inst="LD_MB1">
 <LN0 lnType="LLN0_2007" lnClass="LLN0" inst="">
...
 </LN0>
 <LN lnType="MMXU_TYPE" lnClass="MMXU" inst="1" prefix="FloatEx">
   <DOI name="A">
     <SDI name="phsA">
       <SDI name="instCVal">
         <SDI name=”mag”>
           <DAI name="f">
             <Private type="eIEC61850-80-5">
               <eIEC61850-80-5:RegisterRef addr="320" type="HoldingRegister" variableName="P1" dataType="INT16"/>
               <eIEC61850-80-5:ConvFunctRef>
                 <eIEC61850-80-5:ApplicableConversion conversion="ConvertToFloat" inputVariable="P1" />
               </eIEC61850-80-5:ConvFunctRef>
             </Private>
           </DAI>
         </SDI>
       </SDI>
     </SDI>
     <SDI name="units">
       <DAI name="SIUnit">
         <Val>A</Val>
       </DAI>
       <DAI name="multiplier">
         <Val></Val>
       </DAI>
     </SDI>
   </DOI>
 </LN>
...
</LDevice>
```

The *.icd file snippet shown in Source Code Listing 3 demonstrates that the Gateway IED will contain one Logical Device for each Modbus device. Part 80-5 defines a guideline for naming the Logical Devices. Source Code Listing 3 also shows the Modbus mapping for A-Phase current for the device imported from Source Code Listing 1.

The gateway's IEC 61850 communications parameters are defined in the *.icd file as they typically are for any IEC 61850 project. In addition to the IEC 61850 communications parameters, the gateway's Modbus communications parameters are also defined.

```
1   <Communication>
2    <SubNetwork name="SubNetworkName">
3     <ConnectedAP apName="AP" iedName="TEMPLATE">
4      <Address>
5       <P type="OSI-AP-Title">1,1,9999,1</P>
6       <P type="OSI-AE-Qualifier">12</P>
7       <P type="OSI-PSEL">00000001</P>
8       <P type="OSI-SSEL">0001</P>
9       <P type="OSI-TSEL">0001</P>
10     </Address>
11    </ConnectedAP>
12   </SubNetwork>
13   <SubNetwork type="MODBUS-IP" name="W1">
14    <ConnectedAP apName="Modbus" iedName="TEMPLATE">
15     <Address>
16      <P type="IP" xsi:type="eIEC61850-80-5:tP_IPModbus">192.168.0.1</P>
17      <P type="ADDRESS" xsi:type="eIEC61850-80-5:tP_ADDR">1</P>
18      <P type="PORT" xsi:type="eIEC61850-80-5:tP_PORT">502</P>
19     </Address>
20    </ConnectedAP>
21   </SubNetwork>
22  </Communication>
```

Source Code Listing 4 – Gateway Communications Parameters

Source Code Listing 4 shows both the gateway's IEC 61850 (lines 2-12) and Modbus communications parameters (lines 13-21).

CONTROL DIRECTION

The examples in the previous sections show how to integrate data read from Modbus devices into a gateway. This section shows the control direction. Source Code Listing 5 shows an example of mapping CSWI.Pos.Oper.ctlVal to a Modbus coil. Note the use of the "@" symbol, which is used to indicate the value coming from the IEC 61850 side is to be used as the value sent to the Modbus IED. Further examples of the control direction can be found in part 80-5.

```
<LN lnType="CSWI_TYPE" lnClass="CSWI" inst="1" prefix="">
 <DOI name="Pos">
  <SDI name="Oper">
   <DAI name="ctlVal">
    <Private type="eIEC61850-80-5">
     <eIEC61850-80-5:RegisterRef addr="119" type="Coil" dataType="Boolean" inputVariable="@"/>
    </Private>
   </DAI>
  </SDI>
 </DOI>
</LN>
```

Source Code Listing 5 – Control Direction

PROPOSED FUTURE WORK

As mentioned in the introduction, the solar inverter industry has adopted Modbus as their standard protocol. The SunSpec Alliance has put significant work into defining a register map for solar inverters, energy storage devices, trackers, meters, and other devices. It would be valuable to the industry if an 80-5 mapping were developed for the SunSpec Modbus standards. The potential benefit is a simplified engineering process making it more efficient and less error prone.

CONCLUSION

IEC 61850-80-5 defines a standard language for integrating Modbus IEDs into an IED 61850 substation. This Technical Report provides valuable information to help you realize an overall IEC 61850 strategy without stranding existing assets.. Once the industry adopts this technical report, and starts creating tools around it, engineering Modbus IEDs into modern power systems should become part of a robust process.

REFERENCE

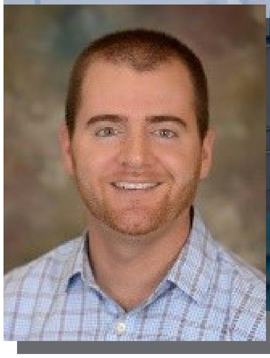
[1] IEC Technical Report 61850-80-5, "Part 80-5: Guideline for Mapping Information between IEC 61850 and IEC 61158-15"

THANK YOU TO OUR MAY 2025 USNC MANAGEMENT MEETING HOST, UL STANDARDS & ENGAGEMENT!

On May 19-21, the three USNC policy committees (USNC Council, Technical Management Committee (TMC) and the Conformity Assessment Policy Coordinating Committee (CAPCC) met in Evanston, IL at UL Standards & Engagement for three days of productive meetings. Thank you to ULSE for hosting us!

SMART STANDARDS IN MEDICAL DEVICE DEVELOPMENT

Rich Davidson, M. Eng. ASQ CMQ/OE, CMDA & CQE – Sr. Principal Engineer



A "Smart Standard" for the medical device industry can be defined as a set of guidelines, protocols, and best practices that integrate advanced technologies, data analytics, and adaptive methodologies to enhance the design, manufacturing, and regulatory processes of medical devices. These standards aim to improve patient safety, product quality, and compliance while fostering innovation and efficiency within the industry. Smart Standards in the medical device industry address the evolving complexities of standards and regulations in a digitally advancing environment. These standards and regulations aim to enhance the evaluation of data for the development of compliant medical devices. Essentially, the need for faster data evaluation across multiple complex standards, while recognizing data interconnections, drives the adoption of Smart Standards.

The medical device industry is governed by stringent standards and regulations to ensure the safety and effectiveness of products and services. Two pivotal frameworks underpinning this regulatory landscape are ISO 14971, which addresses risk management for medical devices, and the FDA Quality Management System Regulation (QMSR). QMSR is intended to harmonize U.S. regulations with global standards, particularly ISO 13485:2016, facilitating global compliance. This article explores how smart standards enhance the review of these regulations and optimize the integration of innovative technologies into the product development process for medical devices.

CURRENT STATE

Reviewing medical device standards and regulations is an intense task that demands extensive hours of careful examination and interpretation. This process involves meticulously analyzing the intricacies of various regulatory frameworks, ensuring compliance with both existing standards and emerging guidelines. For example, my team undertook a comprehensive review of the new Quality Management System Regulation (QMSR), dedicating significant time to assess not only the new requirements but also the myriad comments presented in the preamble. This involved interpreting complex language, comparing it with previous regulations, and discussing implications for our processes, underscoring the critical nature of our work in maintaining high safety and efficacy standards in medical devices.

UNDERSTANDING SMART STANDARDS

Smart standards migrate beyond traditional static frameworks. They leverage technology, data, and continuous feedback to ensure compliance with evolving regulations while fostering innovation. The notion of smart standards in the context of ISO 14971 and QMSR entails enhanced mechanisms for managing risk and quality, crucial for medical device manufacturers aiming to deliver safe and effective healthcare solutions.

Key Features of Smart Standards:

- **Real-Time Data Utilization:** Smart standards harness real-time data analytics to assess compliance and product efficacy continuously.
- **Adaptive Frameworks:** They can adjust to new evidence, regulatory updates, and market demands, providing a flexible pathway for compliance.
- **Enhanced Stakeholder Engagement:** Facilitating communication and feedback among stakeholders improves the overall quality management processes.

ISO 14971: RISK MANAGEMENT IN MEDICAL DEVICES

ISO 14971 provides a systematic approach to identifying and managing risks associated with medical devices throughout their life cycle. Risk management is vital for ensuring that medical devices are safe for users and meet regulatory requirements.

The following key aspects in assessing risk are instrumental in the integration of Smart Standards with ISO 14971:

- **Health & Safety Risk Assessments:** Smart standards facilitate real-time risk assessment by integrating data from various sources, including clinical trials, post-market surveillance, and user feedback.

- **Predictive Analytics:** Advanced analytics can predict potential risks before they materialize, allowing manufacturers to implement mitigations proactively.
- **Automated Documentation:** Smart standards are a component of a smart system that automates the documentation processes required by ISO 14971, significantly reducing manual errors and improving efficiency.

FDA QUALITY MANAGEMENT SYSTEM REGULATION (QMSR)

The FDA QMSR provides a regulatory framework that ensures quality in the design, manufacturing, and distribution of medical devices in which risk management is an integral part of the product development process. Compliance with QMSR is imperative for obtaining FDA approval and maintaining market access.

Enhancements through Smart Standards provides the ability of the manufacturer to continuously develop quality driven products that align with international standards through the following:

- **Streamlined Quality Processes:** Smart standards automate processes mandated by QMSR, resulting in faster production cycles and reduced time-to-market.
- **Integrated Feedback Loops:** Continuous monitoring and feedback mechanisms contribute to ongoing improvements in product quality and compliance driving product improvements without compromising product quality.
- **Traceability and Transparency:** Smart technologies ensure comprehensive traceability of materials and processes, aiding compliance documentation for audits and inspections ensuring products design integrity is maintained for the life of the product in market.

IMPROVING THE REVIEW OF NEW STANDARDS AND REGULATIONS

Smart standards significantly impact how organizations review and adapt to new regulations and standards. The continuous need to review new/updated standards and regulations ensures that the products continue to be developed and/or meet the industry standards for medical device products. This provides the ability for manufacturers to facilitate the development and marketing of products based on the following:

- **Faster Implementation of Changes:** With an adaptive framework, organizations can quickly integrate updates from regulatory bodies, ensuring compliance and product quality is maintained.
- **Improved Stakeholder Collaboration:** Enhanced communication between regulatory bodies, manufacturers, and healthcare providers fosters a collaborative approach to compliance and innovation.
- **Higher Regulatory Confidence:** The use of smart standards in conjunction with ISO 14971 and QMSR enhances transparency, leading to increased confidence from regulatory authorities and stakeholders alike.

CONCLUSION

The integration of smart standards presents a comprehensive strategy for managing risk and ensuring product quality in the development of products in the medical device industry. By embracing and utilizing digital and technological advancements and adaptive methodologies, organizations can improve their compliance processes while facilitating innovation in product development. As the regulatory landscape continues to evolve, smart standards will play a pivotal role in the development of complex devices while navigating compliance challenges and delivering safer, more effective medical devices to the market.

IN MEMORY OF JOSEPH L. KOEPFINGER, PE, ACTIVE MEMBER OF USNC

The U.S. National Committee to the IEC mourns the loss of Joseph L. Koepfinger, PE, who dedicated his career to global electrotechnology standardization. Koepfinger, who passed away earlier this year, was recognized as an Honorary Life Member in the U.S. National Committee in 2005 for his work advancing the interests of the U.S. electric utility industry.

Koepfinger's work primarily focused in the areas of electricity transmission and distribution, where he made outstanding contributions in the areas of electrical energy supply and surge arresters. He served as USNC technical advisor for the IEC technical committees on systems aspects for electrical energy supply (TC 8) and surge arresters (TC 37); he also represented the U.S. on IEC Sector Board 1, Electricity Transmission and Distribution.

Earlier in his career, Koepfinger was director of system studies and research for Duquesne Light Company, where he was responsible for managing the research programs and for the conduct of special investigations of technical problems, insulation coordination, surge protection and, in particular, the studies of electrical transient conditions in power systems. He was also responsible for the implementation of first ever automated distribution system at Duquesne Light Company in 1967.

His professional activities included various chairmanships and membership at the Institute of Electrical Engineering Committee and the IEEE Standards Association. He was Member Emeritus of the IEEE Standard Association, a past member of the IEEE Board of Directors, and an IEEE Distinguished lecturer in surge protection and distributed resources.

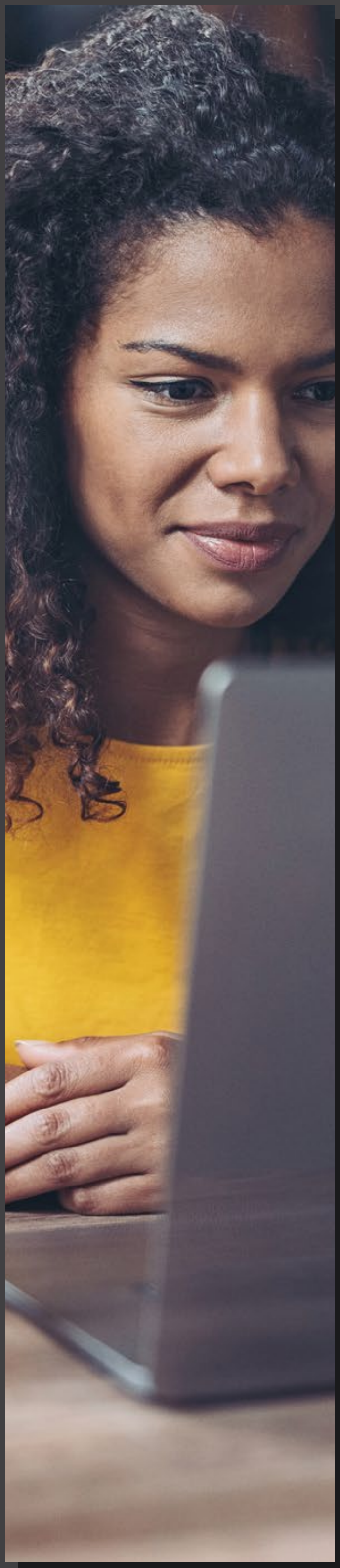
Koepfinger was honored with the IEEE Steinmetz Award in 1989 for significant influence in the development of standards and for contribution to protection system technology and the IEEE Excellence in Power Distribution Engineering Award in 1998 for engineering contributions that have enhanced the quality and economy of electric power distribution.

ANSI awarded him with the Elihu Thomson Electrotechnology Medal in 2008 in recognition of his exceptional contributions to the field of electrotechnology standards, conformity assessment, and related activities at the national and international levels.

Joseph's obituary can be read here.

IEEE's tribute to Joseph can be read here.

USNC/IEC TRAINING & EDUCATION



New to USNC? The USNC provides education and training resources for electrotechnical standardization and conformity assessment.

We encourage you to take advantage of our training opportunities available now on the USNC webpage!

- USNC Constituent Training Modules
- USNC Effective IEC Participation Webinar
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- Why IEC Standards Work Is Important to My Company
- Benefits of Standards Work for Emerging Professionals

Upcoming Webinar: The Role of Positive Energy Districts in City Transformation

Join us on Tuesday, June 10 from 7am–10am ET to learn about how cities around the world are tackling the climate crisis.

The workshop will cover Positive Energy Districts (PED) projects from around the world and some key standards committees, help identify the key characteristics of PEDs and use this to help develop a clear definition of the topic. It will also identify the key challenges cities face in implementing PEDs and what standards exist or could be developed to help.

The workshop will be of value to:

- Participants in existing PED projects and those considering the development of such projects
- Solution providers that could provide products and services to help
- Standards development committees that are working in areas of relevance to PEDs

Register here to attend or to receive the webinar recording.

Stay Tuned: The USNC will be hosting an Online Standards Development (OSD) hybrid training session in the fall. Location and date TBD.

ICYMI: The USNC hosted a webinar on Effective Participation in the IEC. View the webinar recording here.

Looking for more? IEC Academy & Capacity Building hosts frequent webinars. You can access past webinar recordings and register for upcoming webinars here.

United States National Committee of the IEC

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ABOUT THIS PUBLICATION

The USNC *Current* newsletter is distributed to the constituency of the U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC). It provides updates on technical activities and other information of interest to members of the electrotechnical community. Some articles are reprinted with permission from the IEC News log.

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Contributions are gladly accepted for review and possible publication, subject to revision by the editors. Submit proposed news items to: Catherine Pilishvili (cpilishvili@ansi.org).