ITI Promoting Innovation Worldwide

ITI Position Paper: IEC 62368-1, 4th edition

Summary

The safety standard IEC 62368-1 incorporates hazard-based safety engineering (HBSE), an approach that is invaluable for evaluating a wide variety of products as new technologies are brought to market. It is the state-of-the-art standard that replaces both IEC 60950-1 (for information and communication technology (ICT) equipment) and IEC 60065 (audio-visual (AV) equipment).

Now that AV and ICT equipment technology overlap in so many products, a single harmonized standard gives a clearer framework to evaluate product safety. IEC 62368-1 intends to provide greater flexibility in the design of safety measures while requiring rigorous analyses to ensure that products are safe to use and will not cause bodily injury or fire. Incorporating HBSE principles into the standard provides flexibility in product design and evaluation and enables manufacturers to keep up with technology without requiring frequent, expensive, and time-consuming revisions traditionally required by the prescriptive approaches of IEC 60950-1 and IEC 60065.

Nearly every country has adopted (or is in the process of adopting) a version of IEC 62368-1 as optional or mandatory. Countries still referencing IEC 60950-1 and/or IEC 60065 are encouraged to transition to IEC 62368-1. As IEC moves to adopt the 4th edition of this standard, regulatory agencies and national standards development organizations (SDOs) have an opportunity to enhance the ease of doing business in their respective countries by accepting certification reports to the 4th edition.

The national adoption and transition of IEC 62368-1 from the 2nd edition (2014) and/or 3rd edition (2018) to the 4th edition (expected in 2023) should be weighed against the timing for lab accreditation and testing and the impacts to supply chains and components. As shown in the table, 24 to 36 months are typically needed for IEC, national and regional standard bodies, third-party test labs, and manufacturers to accomplish the steps associated with a new or updated standard.

IEC	Publish Standard or Amendment	24-36 Months
	Publish test report format (TRF), if applicable	
	Update national/group differences when adopted	
National / Regional Standards Body	Consider adoption of standard or amendment	
	Consider national/group differences	
	Consultation/Public Comments	
	Official publication of standard or amendment	
3rd Party Test Labs	Country accreditations for new standard or amendment	
	TRF and data sheet updates, if applicable	
	Perform testing or witness testing, if applicable	
	Issue test reports and certificates, if applicable	
Manufacturers	Redesign equipment to comply with new standard or amendment, if applicable	
	Update component certifications (and global markings)	
	Update system certifications (and global markings)	
	Update compliance documentation (DoC, TCF, etc.)	
	Global supply chain and inventory management	

Once there is global adoption of the 4th edition, companies will only need one certification report (4th edition) rather than multiple reports for different versions of the standard to comply with various countries' national regulations (see text box below for further explanation).

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Insights into IEC62368-1 Global Adoption Challenges

The 2nd edition of IEC 62368-1 was not widely accepted by the industry or national standards bodies. With changes made in the 3rd edition, adoption has become more prevalent. Unforeseen challenges in the European Union (EU) standards adoption process caused the 3rd edition to not be uniformly adopted in countries that mirror EU directives or align with EU's conformity assessment process. This lack of global adoption led to unpredictable adoption timelines and manufacturers having to design and test products to three versions of the safety standards. The 4th edition of IEC 62368-1 is expected to be published in 2023 and, with global adoption and sufficient transition time, should help resolve these issues.

Recommendations to National Standards Bodies and Regulators

To ease the transition between standards and ensure ease of doing business, ITI recommends standards bodies and regulatory authorities take the following actions:

- Adopt IEC 62368-1:2023, 4th edition nationally as soon as practicable. This state-of-the-art safety standard should be permitted as a regulatory compliance alternative to IEC 62368-1:2018, IEC 62368-1:2014, IEC 60950-1 and/or IEC 60065.
- Provide a minimum transition period of 24 months, and preferably 36 months, before any national adoption of IEC 62368-1 4th edition becomes mandatory for new products and components. During the transition period, conformance to any currently accepted standard or 4th edition should be allowed. These best practices facilitate timely lab accreditation and allow manufacturers time to update their components and supply chain.
- For established (legacy) products that are already declared or certified to prior versions of IEC 62368-1, allow certificates to remain valid until a major technical change to the product or until the certificate expiration date, if applicable. This allows products that have already been proven to be safe, according to an accepted standard, to remain on the market.

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