

The movement toward an IEC 62368-1:2018-based standard in Europe

Manufacturers of Audio/Video and Information and Communication Technology (AV/ICT) equipment around the world have a heightened interest in the European adoption of an IEC 62368-1:2018-based standard, especially with EN IEC 62368-1:2020/A11:2020 having been published by CENELEC on March 06, 2020.

Of particular interest is how the latest EN 62368-1 standard will be used for establishing conformity of AV/ICT equipment and components with the essential provisions of relevant European Directives that cover product safety, including the Low-Voltage Directive (LVD)(2014/35/EU) and Radio Equipment Directive (RED) (2014/53/EU). This communication provides a perspective on related activity in Europe as of March 2020.

Background

Historically, when European standards such as EN 60950-1 were published and proposed to meet the essential requirements of the European Directives, New Approach Consultants would review the standards on behalf of the European Commission and make a recommendation for suitability as a harmonized standard demonstrating compliance with the essential requirements. If recommended, the standards would be published in the Official Journal (OJ) of the European Union; as a result, the harmonized standards then could be used to establish principal compliance with the essential requirements of the applicable Directive(s), which, as of 2016, also has required additional risk assessment.

In 2018, a new system of Harmonized Standards (HAS) Consultants was launched with the aim of improving the quality and timely availability of safety standards for products being placed on the EU Single Market. The HAS Consultants act as intermediaries between Technical Committees and the relevant Commission's services. More specifically, they assess to what extent documents drafted by the European Standardization Organizations (ESOs), such as CENELEC, comply with and support relevant essential or other requirements set out by the related EU harmonization legislation.

The new process has introduced challenges. The HAS Consultants are reviewing the proposed standards more closely, concentrating on the legal certainty that the EN standards demonstrate compliance with the essential provisions of the Directives. These reviews are more focused and have caused difficulties in gaining HAS Consultant support for the inclusion of these standards in multiple Directives, including the Low Voltage Directive (LVD), Radio Equipment Directive (RED) and Electromagnetic Compatibility (EMC) Directive.

Present situation with EN IEC 62368-1:2020

The recent HAS Consultant review of the latest EN IEC 62368-1:2020—including its European Common Modifications and Special National Conditions—has encountered such challenges. The latest EN IEC 62368-1 standard, based on IEC 62368-1:2018 (Ed. No. 3), originally was submitted to the European Commission for proposed inclusion in the LVD and RED, thus requiring a review by the HAS Consultants.

That review prompted more than 100 comments to the CENELEC 108X Technical Committee that will require additional work on the Standard to satisfy the HAS Consultants' concerns. The comments ranged from relatively simple editorial comments, which likely will be able to be addressed via eventual modification of the IEC standard, to complex, technical that challenged basic principles in IEC 62368-1. Additionally, some comments were simply questions. A similar situation is the case for EN IEC 62368-3.

The CENELEC 108X Technical Committee is studying how to best address the concerns of the HAS Consultants, while also resolving how to position this next edition of EN 62368-1 (and -3) in Europe as a useful standard. In 2019, as part of a consultation between 108X committee management and members, two questionnaires (three questions total) were circulated to voting member countries as part of the effort to consider options. The questions asked opinions on potentially decoupling from the LVD and RED the latest EN IEC 62368-1 and EN

IEC 62368-3 due to the difficulties reaching resolution with the HAS Consultants, in addition to delisting EN 62368-1:2014 from the same Directives. If the latest EN standards were decoupled they would not be listed in the OJ of the EU even though published as European Norms.

Note, if the standards are not referenced in the OJ, this means that they are not designated as standards allowed to demonstrate compliance with the essential provisions of the Directives, e.g., Annex I of 2014/35/EU, using harmonized standards as the principal method. As such, manufacturers need to demonstrate compliance with the essential provisions of the directives other than by relying principally on harmonized standards, such as by use of standards other than listed in the OJ (including an EN version of IEC 62368-1:2018), direct application of the Directive, unique test methods, a more comprehensive risk assessment than typical, or other strategies, either alone or in combination. This additional detail on compliance needs to be contained in a more robust Technical File for each product that demonstrates how the manufacturer meets the essential provisions of the Directives other than by a harmonized standard listed in the OJ as the principal method.

The CENELEC 108X questionnaires yielded mixed results, requiring CENELEC TC108X management to further consult with 108X member countries on a plan to move solutions forward. In fact, the subsequent vote resulted in favorable support for EN IEC 62368-1 and EN IEC 62368-3 continuing to be pursued for publication in their present state, without significant modification. Additionally, it was decided EN 62368-1: 2014 will continue to be listed in the OJ as an EU harmonized standard.

In parallel, CENELEC 108X issued a new work proposal with an objective to develop, propose and implement changes to the relevant standards to satisfy the concerns of the HAS Consultants, thus allowing for a future version of EN 62368-1 (and -3) to be listed in the OJ as a harmonized standard that could be used to demonstrate conformity with the essential provisions of the Directives. In response, numerous national committees within CENELEC expressed interest in assisting with this development work.

Moving forward

As mentioned earlier, EN IEC 62368-1:2020/A11:2020, based on IEC 62368-1:2018, was published by CENELEC on 2020-03-06.

The IEC-harmonized content is contained in EN IEC 62368-1:2020 and European Common Modifications and Special National Conditions are contained in its Amendment No. 11 (A11).

The Date of Withdrawal (DOW) associated with EN IEC 62368-1:2020/A11:2020 is 2023-01-06, which is the date that EN IEC 62368-1:2020/A11:2020 will succeed the prior version of the standard as EN 62368-1:2014 will be withdrawn on that date.

As mentioned earlier, this latest EN 62368-1 Standard is not listed in the OJ, and thus will not be able to be used alone to establish presumption of conformity with the LVD. As a result, more substantiation will be required in addition to the EN standard to demonstrate compliance with the Directive, such as direct application of the Directive's provisions, unique test methods, a more comprehensive risk assessment than typical, or other strategies, alone or in combination.

At the same time, and today, EN 62368-1:2014 continues to be available and listed in the EU OJ as a harmonized standard providing presumption of conformity of compliance with the essential provisions of the LVD. For constructions that can be shown to comply with it, EN 62368-1:2014 continues to be able to be used as the principal method to demonstrate conformity with the LVD by using a

harmonized standard (although both the LVD (2014/35/EU) and RED (2014/53/EU) additionally have included a Risk Assessment provision since 2016).

As a result, for market entry into Europe, manufacturers of AV/ICT equipment will be able to use either EN 62368-1:2014, as it is used today, or EN IEC 62368-1:2020/A11:2020, but supplemented with additional justification in their technical file on how they establish presumption of conformity with the essential provisions of the Directive.

This situation will remain the status quo until, as mentioned earlier, CENELEC 108X eventually develops, proposes and gets accepted changes to the relevant standards to satisfy the concerns of the HAS Consultants, thus allowing for a future version of EN 62368-1 to be listed in the OJ as a harmonized standard that once again could be used to demonstrate conformity with the essential provisions of the Directives.

As the current situation is fluid, AV/ICT equipment/component manufacturers should continue to monitor the European situation, in addition to the wider global transition to 62368-1, and be prepared to act accordingly. Since China, Korea, Taiwan, and several other countries all are preparing to have published IEC 62368-1 Ed. No. 3-based standards available for product certification within the next year, it is critical that manufacturers continue to monitor developments and factor them into their strategic business and certification plans for global market access.