



## **Perspective: Movement toward an IEC 62368-1:2018-based standard in Europe – Update!**

Manufacturers of Audio/Video and Information & 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 will the latest EN 62368-1 standard will be able to 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 happening 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 more recently, as of 2016, also has required additional risk assessment.

Since 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.



While originally it was expected the transition would be relatively straightforward, the new process in practice has introduced challenges since the HAS Consultants are reviewing the proposed standards closer than in the past, concentrating on 'legal certainty' that the EN standards demonstrate compliance with the essential provisions of the Directives. These more onerous and focused reviews have resulted in difficulties gaining HAS Consultant support for 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**

Encountering such challenges as described above is the case with the recent HAS Consultant review of latest EN IEC 62368-1:2020, including its European Common Modifications and Special National Conditions. 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 & RED, thus requiring a review by the HAS Consultants.

As a result of the subsequent HAS Consultant review, well over 100 comments were provided to the CENELEC 108X Technical Committee that will require additional work on the Standard to satisfy the HAS Consultant's concerns. The comments ranged in content from relatively simple editorial comments, which likely will be able to be addressed via eventual modification of the IEC standard, to complex, technical comments that challenge some of the basic principles in IEC 62368-1. Additionally, some of the comments were simply questions. A similar situation is the case for EN IEC 62368-3.

Currently, 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 specifically asked opinions on potentially 'decoupling' from the LVD & 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 also '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 these standards 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, manufactures 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.

When the results of the CENELEC 108X questionnaires were tallied, there were some mixed results, requiring CENELEC TC108X management to further consult with 108X member countries with a new formal voting 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 eventually get accepted 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. A working group, as CENELEC 108X Working



Group 06, recently has commenced activity and will continue their activity for the next year or so.

### **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.

This is the Date of availability (dav) date when the definitive text in the official language versions of an approved CEN/CENELEC publication is distributed by the Central Secretariat. Publication of identical national standards, or by endorsement is expected to follow relatively soon after.

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 will not be 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 as it is 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.