COCIR Position paper on the interpretation of potential essential performance in the IEC 60601 series

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This position paper concerns the interpretation of "potential essential performance" as used in IEC 60601-1 (*Medical electrical equipment – Part 1: Requirements for basic safety and essential performance*) and its collateral and particular standards. The purpose of this position paper is to clarify:

- how to manage "potential essential performance" defined in particular standards,
- how particular standards can assist the manufacturer in determining actual essential performance, and
- how the test requirements against electromagnetic disturbances in collateral standard IEC 60601-1-2 must be applied to basic safety and essential performance.

IEC 60601 series

The IEC 60601 series of safety standards consists of:

- **the general standard IEC 60601-1**, which provides general requirements for basic safety and essential performance, applicable to all types of medical electrical equipment (MEE) and medical electrical systems (MES);
- **collateral standards IEC 60601-1-xx**, which provide general requirements for Basic Safety and Essential Performance applicable to a specific characteristic of all MEE and MES (such as electromagnetic compatibility and usability) or to a specific subgroup of MEE and MES (such as alarm systems, radiation protection, home healthcare and emergency environment);
- **particular standards IEC 60601-2-yy**, which provide specific requirements applicable to particular MEE and MES (e.g., X-ray/MRI/CT imaging equipment, radiotherapy equipment, ventilators, incubators, infusion pumps).

Particular standards can modify, replace or delete requirements from the general and collateral standards and can add new requirements, as appropriate for the particular type of MEE and MES. Particular standards take precedence over the general and collateral standards. When no particular standard exists for a given type of MEE or MES, then the general and collateral standards apply without modification.

Basic safety and essential performance

Basic safety is defined as "*freedom from unacceptable risk directly caused by physical hazards when medical electrical equipment is used under normal condition and single fault condition*" (see 3.10 of IEC 60601-1:2005).

Essential performance is defined as the "*performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk*" (see 3.27 of IEC 60601-1:2005/AMD1:2012). The concept of essential performance is most easily understood by considering whether

loss of the clinical function or degradation of its performance would result in unacceptable risk to the patient (or the operator).

Both, basic safety and essential performance must be maintained during the expected service life of MEE and MES.

Particular standards and "potential" essential performance

Subclause 4.3 of IEC 60601-1:2005/AMD1:2012 requires the manufacturer to determine the essential performance of MEE and MES. To assist the manufacturer in this determination, several particular standards IEC 60601-2-yy provide in their subclause 201.4.3 a list or a table of clinical functions that are indicated as "potential essential performance". This list or table is intended to be used by the manufacturer in the risk management process and provides examples of "potential" essential performance aspects. It is not a mandatory list of essential performance for all products in scope of this particular standard.

The manufacturer must determine the "actual" essential performance for every product in scope of such a standard. Actual essential performance is given, if loss or degradation of the performance of the listed clinical functions leads to an unacceptable risk to the patient or the operator. The manufacturer also needs to determine, if loss or degradation of other clinical functions leads to unacceptable risk which would make them additional actual essential performance. If the risk remains acceptable, the clinical function is not essential performance. These determinations must follow the steps of the process described in subclause 4.3 of IEC 60601-1:2005/AMD1:2012 and the necessary steps are clarified in further detail in the Interpretation Sheet IEC 60601-1:2005/AMD1:2012/ ISH1:2021.

It is incorrect to consider all clinical functions listed as "potential essential performance" in a particular standard IEC 60601-2-yy as actual essential performance, i.e., essential performance of a specific MEE or MES. It is the manufacturer's responsibility to determine all essential performance individually in the risk management process. The "potential essential performance" as listed in a particular standard aims to assist the manufacturer in this determination.

The (actual) essential performance must be documented by the manufacturer in the risk management file for the MEE and MES. Additionally, the manufacturer must implement risk control measures to reduce the identified risks to an acceptable level, assess which of those risk control measures need verification of effectiveness, and specify methods for such verification. The relevant results must be documented in the risk management file to serve as objective evidence that the required activities have been performed.

Essential performance and Electromagnetic Compatibility (EMC) testing

MEE and MES must conform to the requirements in collateral standard IEC 60601-1-2 (*Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*). This standard provides requirements for the basic safety and essential performance of MEE and MES in the presence of electromagnetic disturbances (immunity) and for the emission of electromagnetic disturbances by the MEE and MES itself.

The third edition IEC 60601-1-2:2007 specifies tests to ensure that no unacceptable risk occurs in the presence of a single electromagnetic disturbance phenomenon. The tests are performed for one electromagnetic disturbance at a time in a controlled test environment, an Electromagnetic Compatibility (EMC) laboratory.

While the third edition has limited requirements for risk management, the fourth edition IEC 60601-1-2:2014 (and its amendment IEC 60601-1-2:2014/AMD1:2020) requires the manufacturer to perform risk management in relation to electromagnetic disturbances. This risk management includes the determination of performance criteria against which the

MEE or MES was evaluated before, during and after applying the electromagnetic disturbances. The EMC performance criteria are based on manufacturer's analysis of basic safety and essential performance. Derivation of the EMC performance criteria must be documented in manufacturer's risk management file.

The test methods must be tailored and specified by the manufacturer to the specific design of the MEE or MES. This may include special tools to be used during the tests. The test methods and performance criteria must be disclosed in the EMC test plan. In this way, qualified EMC laboratories can perform those tests using the specified methods and evaluate the results against the specified performance criteria.

Conclusion

The clinical functions listed as "potential essential performance" in a particular standard IEC 60601-2-yy are provided to assist the manufacturer in the determination of essential performance. They are just candidates of actual essential performance. Finally, the manufacturer can and shall determine all essential performance in the risk management process and documents it in the risk management file for the MEE or MES under consideration.