



# Essential Performance for MED 601-1 3<sup>rd</sup> ed.

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## 3.27 Essential Performance

- “Old” (3<sup>rd</sup> ed.):  
performance necessary to achieve freedom from unacceptable risk
- “New” (Amd. 1):  
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

## 3.10 Basic Safety

- And just as a reminder:

### BASIC SAFETY

freedom from unacceptable risk directly caused by physical hazards when MEE is used under normal condition and single fault condition

## 3.27 Essential Performance – Rationale\*

- It has long been recognized that MEE or an MES that does not perform properly could result in unacceptable risk for patients, operators, or others
- Hence the concept of "safety" has been broadened from the basic safety considerations in the first and second editions of this standard to include essential performance matters

## 3.27 Essential Performance – Rationale\*

- In order to achieve its intended use, the MEE or MES needs to perform within certain limits
- These limits are usually specified by the manufacturer but could be specified by this standard, a collateral standard or a particular standard in the IEC 60601 family

## 3.27 Essential Performance – Rationale\*

Examples of essential performance are:

- correct administration of a drug by a syringe pump where inaccuracy/incorrect administration would cause an unacceptable risk to the patient;
- the ability of an electrocardiograph/monitor to recover from the effects of the discharge of a defibrillator where the failure to recover could lead to an incorrect response by the medical staff that would present an unacceptable risk to the patient;

## 3.27 Essential Performance – Rationale\*

Examples of essential performance are:

- correct operation of an alarm system in an intensive care or operating room monitoring system where an incorrect/missing alarm signal could lead to an incorrect response by the medical staff that would present an unacceptable risk to the patient; or
- correct output of diagnostic information from MEE that is likely to be relied upon to determine treatment, where incorrect information could lead to an inappropriate treatment that would present an unacceptable risk to the patient

## 3.27 Essential Performance – Rationale\*

- For purposes of this standard, performance related to basic safety aspects of the MEE, such as the performance of basic insulation, is not considered to be essential performance
- Particular and collateral standards in the IEC 60601 family are expected to identify specific essential performance



## 4.3 Essential Performance – Rationale\*

- During the initial risk analysis, the manufacturer identifies the performance of the MEE or MES that is necessary to achieving the intended use
- The manufacturer also identifies other qualitative and quantitative characteristics that could affect the safety of the MEE or MES

## 4.3 Essential Performance – Rationale\*

- The performance limits specified by the manufacturer could be anywhere within the full range of intended performance in NC and SFC, to no performance
- The manufacturer then determines if the loss or failure to perform within specified limits would result in a risk to the patient

## 4.3 Essential Performance – Rationale\*

- The estimate is often made with the assumption that the performance aspect in question has been lost or degraded beyond the specified limits
- The manufacturer takes into account the probability of a hazardous situation leading to harm as well as the severity of that harm

## 4.3 Essential Performance – Rationale\*

- The manufacturer then evaluates the risk using their established risk acceptance criteria
- If the risk is unacceptable, then the identified performance is Essential Performance because risk reduction is required to achieve an acceptable level of residual risk

## 4.3 Essential Performance – Rationale\*

- Once the essential performance is identified, the manufacturer puts in place risk control measures that are appropriate to reduce the risk to an acceptable level
- When conducting the risk control option analysis, the manufacturer is to follow the priority order listed in ISO 14971, namely:
  - a) Inherent safety by design
  - b) Protective measures
  - c) Information for safety

# 62A/666/INF – Essential Performance

- Life-supporting devices should have adequate performance, perform as instructed by the operator, or signal clearly that a fault exists
- Even a total failure should alert the operator via internally powered alarms

# 62A/666/INF – Essential Performance

- Similar requirements should apply to diagnostic equipment which might be used in emergency or rescue situations where reliance could be placed solely on the information from the device to determine immediate clinical action, e.g. an ECG monitor used to determine the effect of a cardiac defibrillator discharge

# 62A/666/INF – Essential Performance

- Other non-life-supporting devices may have differing performance specifications and may fail without causing an unacceptable risk
- In many instances the failure will be obvious to the operator



# 62A/666/INF – Essential Performance

Examples of Essential Performance requirements include those characteristics where inaccuracy, inadequacy or failure could:

- directly affect the PATIENT's safety e.g. accuracy of a life-supporting function, incorrect administration of a drug by a syringe pump, etc.

# 62A/666/INF – Essential Performance

continued ..... (are EP)

- lead to an incorrect response by the medical staff which might be hazardous for the patient, e.g. inability of an electrocardiograph/monitor to recover from the effects of the discharge of a defibrillator, incorrect operation of an alarm in an intensive care or operating room monitoring system, etc.

# 62A/666/INF – Essential Performance

continued ..... (are EP)

- lead to an incorrect diagnosis where the device is likely to be the only source of evidence, e.g. devices used in accident and emergency situation outside the hospital environment, diagnostic devices prescribed for use by a patient to determine self treatment,
- results in repetition of a procedure associated with a known risk to the patient.

# 62A/666/INF – Essential Performance

Examples of requirements that are **NOT** essential performance requirements but may be suitable for inclusion in other standards or technical reports:

- accuracy of measuring systems where other evidence is available e.g. pulse rate in an ECG monitor, unless part of an intensive care system with high and low rate alarms,

# 62A/666/INF – Essential Performance

continued ..... (not EP)

- accuracy of presentation of parameters of non vital physiological functions e.g. EEG, EMG, ENG, Audiometry, Kinesiology, Optometry, etc.
- format of records, displays, communication protocols, etc.,

# 62A/666/INF – Essential Performance

continued ..... (not EP)

- limits of performance e.g. frequency response, electrical noise levels, cross talk, data processing capabilities, etc.,
- output power 2, flow rates, etc.

# 62A/666/INF – Essential Performance

continued ..... (not EP)

- accuracy of a diagnostic advisory function (e.g., ECG rhythm classification or interpretation of ECG morphology) where: medical staff have access to original patient data on which the advice is based, and the advisory function does not automatically initiate patient treatment
- In this case, the accompanying documentation must explain the limitations of the accuracy and use of the function

# 62A/666/INF – Essential Performance

- It is unnecessary and sometimes even difficult to differentiate between basic safety and other essential performance requirements, for example: ....



# 62A/666/INF – Essential Performance

- Specific limits on electrical output might be necessary in order to achieve acceptable risk levels for equipment such as defibrillators, electrosurgical units and therapeutic stimulators
- The performance necessary to ensure the output does not exceed these limits might be seen as a basic safety requirement if excessive output can result in tissue damage, while the performance necessary to ensure at least adequate output might be seen as essential performance too little output would result in failure to achieve the intended purpose.

# 62A/666/INF – Essential Performance

- Specific thermal requirements may be necessary in equipment such as dialysis machines, blood warmers and heart-lung machines
- The performance necessary to ensure the extracorporeal circulation is not over-heated might be seen as a basic safety requirement if excessive heating could result in physical damage (haemolysis) while the performance necessary to ensure at least adequate heating might be seen as essential performance.

# 62A/666/INF – Essential Performance

- In some cases one user of the 3rd edition of IEC 60601-1 may even treat a particular requirement as a basic safety issue while another user may treat it as essential performance .....

# 62A/666/INF – Essential Performance

- For example, specific accuracy requirements may be necessary for the high voltage generator in diagnostic X-ray equipment.
- Some might see the performance necessary to achieve this as a basic safety requirement because an inadequate image might result in the need for additional films with an inherent increase in radiation dose and an increased risk of physical damage to the patient (cancer).
- Others might see this as an essential performance requirement because an inadequate image might result in an incorrect diagnosis and inappropriate treatment.

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- While ISO 14971 clearly requires the manufacturer of a particular product to differentiate between the performance necessary to achieve freedom from unacceptable risk and other non-essential performance
- ..... it is usually a waste of time differentiating between basic safety and essential performance requirements .....

# 62A/666/INF – Essential Performance

- The risk management file required under IEC 60601-1 and ISO 14971 will already identify all the equipment performance necessary to achieve freedom from unacceptable risk and there will be no need to differentiate between basic safety and essential performance

# 62A/666/INF – Essential Performance

- Standards in the IEC 60601 series provide tried-and-true requirements by which some risks can be reduced to acceptable levels in some particular MEE
- The general standard and the collateral standards clearly do not include an adequate range of tried-and-true requirements for every type of MEE

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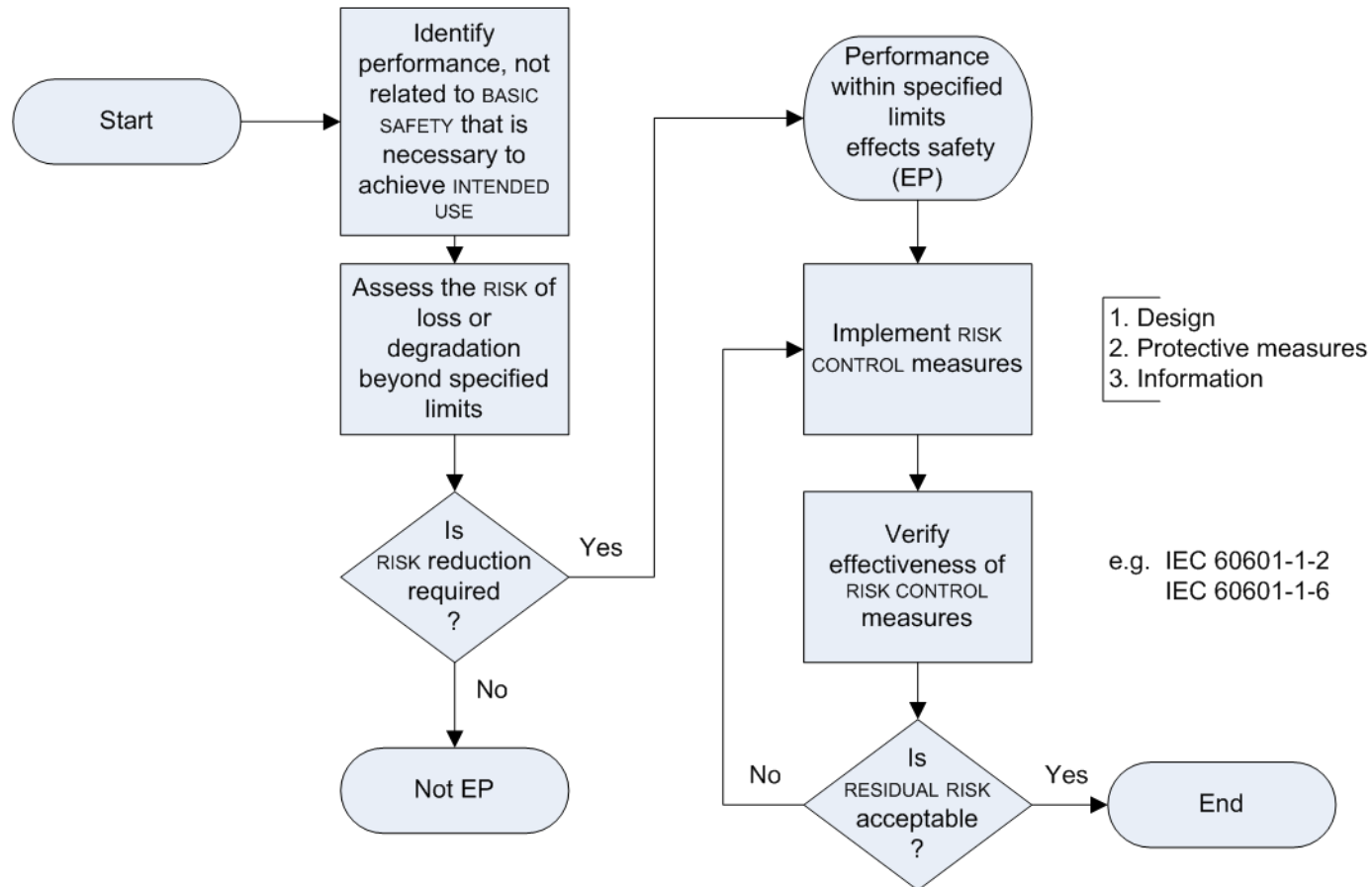
- The role of a particular standard is to modify the general requirements and specify additional requirements where appropriate for a particular type of MEE
- all of the additional requirements set out in a particular standard address either basic safety or essential performance



# 62A/666/INF – Essential Performance

- as IEC 60601-1 and its associated collateral standards provide adequate basic safety requirements for most MEE,
- the additional requirements set out in most particular standards are about the essential performance required for the particular type of equipment.

# 4.3 Essential Performance – Frank O’Brien



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