FDA U.S. FOOD & DRUG ADMINISTRATION

Information required to evaluate Risk Management requirements of ANSI/AMMI/ES 60601-1 Ed 3.1

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Agenda

- 60601-1 Scope, and application of risk management to the 60601 series
- What test reports should tell regulatory reviewers in regards to manufacturer's risk management activities?

Scope of IEC 60601

- Safety of electrical medical devices that touch the patient directly (or nearly so) or transfer energy to or from the patient But NOT
- Implantable devices (intimate contact poses unique challenges)
- Laboratory equipment (doesn't touch the patient)

Not just addressing electrical safety, but rather an "all-hazards" approach

Risk management in IEC 60601

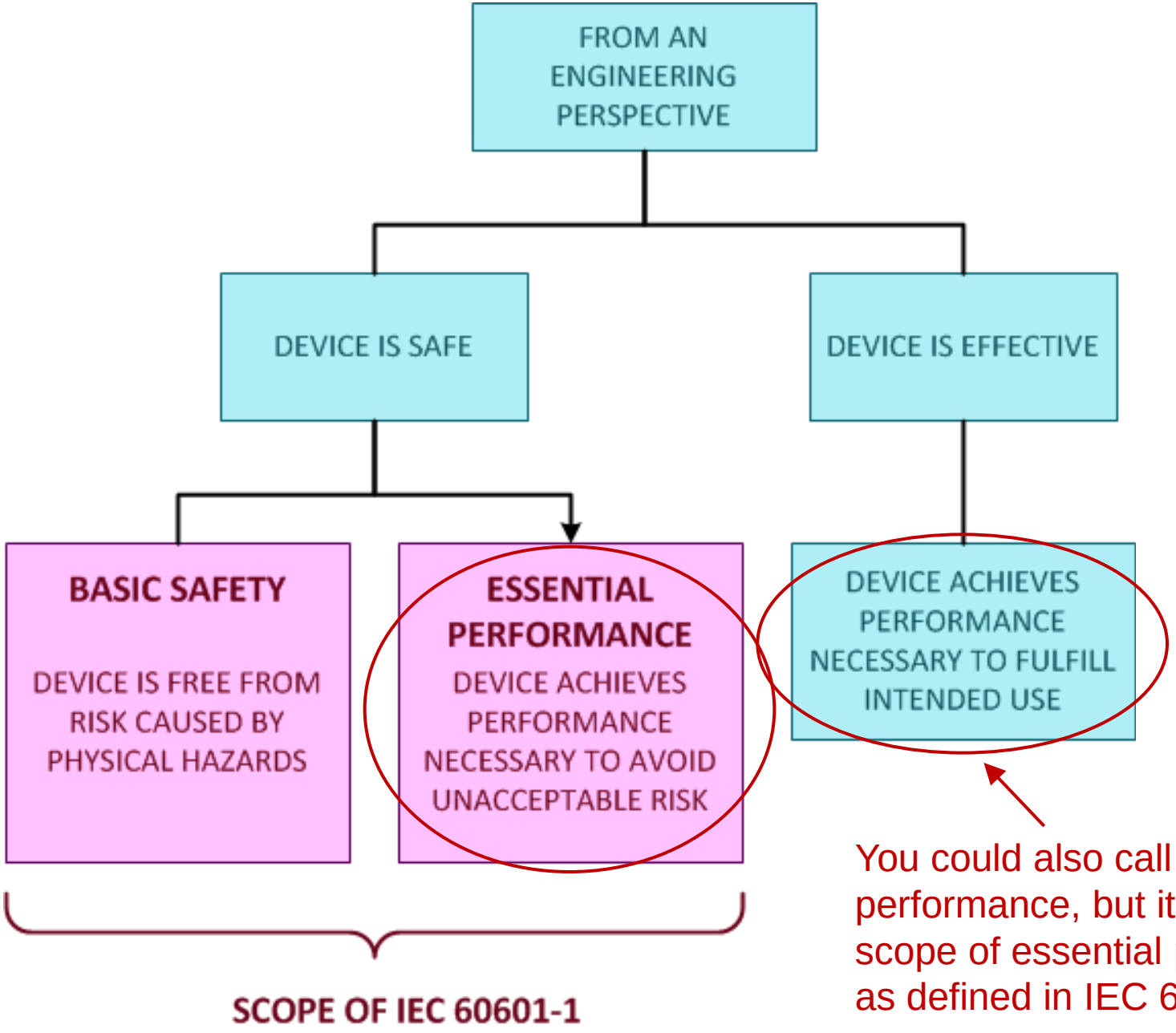
- IEC 60601 has always been about managing risk.
- Every clause in the standard is a risk mitigation.
- The FDA has always permitted a manufacturer to deviate from a requirement of the standard so long as they could justify the deviation.

Risk management in IEC 60601 (cont'd)

- The first and second editions focused on basic safety (i.e. freedom from unacceptable risk directly caused by physical hazards)
- The standard didn't address the safety implications of equipment failures so long as the as device didn't burn, shock, or injured the patient, etc.

Risk management in IEC 60601 (cont'd)

- In the third edition:
  - a formal risk assessment process within a risk management structure is introduced as a requirement. (ISO14791 as normative).
  - essential performance was introduced.
- Both basic safety and essential performance depend on the definition of "unacceptable risk."



You could also call this essential performance, but it's outside the scope of essential performance as defined in IEC 60601.

Clause 4.2

- RISK MANAGEMENT PROCESS specified in this standard is required to comply with the relevant requirements of ISO 14971.
  - What information is required for the Manufacturers and how this requirement is checked?

FDA is interested in:

- Description of the essential performance.
- Design failure modes affecting safety and EP.
- Risks that are associated with reduction of essential performance of the device.
- Mitigations of those risks.
- Verification of those mitigations.
- Teaming approaches to leverage expertise

Questions?