

Modular Structure of IEC 60601-Series

Part 1: Generic

IEC 60601-1: General requirements

Collateral Standards

IEC 60601-1-2: Electromagnetic Compatibility

IEC 60601-1-3: Radiation Protection

IEC 60601-1-6: Usability

IEC 60601-1-8: Alarms

IEC 60601-1-9: Environment

IEC 60601-1-10: Physiological Closed-Loop Controllers

IEC 60601-1-11: Home Healthcare Environment

IEC 60601-1-12: Emergency Services Environment**

ISO 14971 Risk management

Part 2: Particular

IEC 60601-2-x standards rule

- Within its scope a part 2 takes priority over all part 1 standards.
- 70 in IEC, many more in ISO
- Specific to a category of products.
- Modifications to requirements in part 1
 - Addition,
 - Replacement or
 - Exemption
- Dated references to part 1 standards.

En 60601 1 2012

Judd E. Hollander



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