Active Medical Devices

Navigating the technical requirements enabling regulatory compliance for Medical Electrical Equipment and Medical Electrical Systems

RØMER
CONSULTING

60601-1-2 4th edition and RMP

Requirement Overview

Detailed Requirements

Proposed solution

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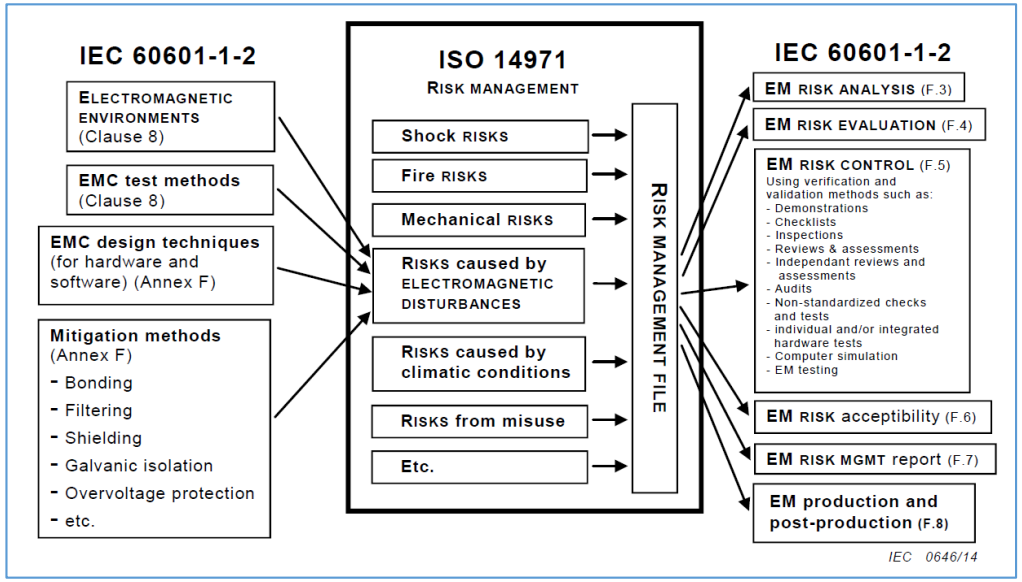
EMC and Risk Management (-1-2 4th ed.)

- Test configurations
- EMC environment / EMC phenomena
- Immunity acceptance criteria
- Immunity test levels
- Degradation over expected service life
- Simultaneous events and phenomena
- False signals
- Reset, latch-up and looping

EMC and Risk Management (-1-2 4th ed.)

- RISKS resulting from **reasonably foreseeable ELECTROMAGNETIC DISTURBANCES** shall be taken into account in the RISK MANAGEMENT PROCESS.
- This collateral standard requires the MANUFACTURER to perform a number of activities with regard to EM DISTURBANCES during the **design and realization** of their ME EQUIPMENT or ME SYSTEM, and to document them in the RISK MANAGEMENT FILE.



- **non-ME EQUIPMENT** used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT shall be tested according to the requirements of this collateral standard.
- Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.
- **IFU:** the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed.

Test configurations

- ME EQUIPMENT and ME SYSTEMS shall be tested in **representative configurations**, consistent with INTENDED USE, that are **most likely to result in unacceptable RISK**.

- During IMMUNITY testing, the BASIC SAFETY and ESSENTIAL PERFORMANCE shall be tested in the **modes and settings** (e.g. gain) that are **most likely to result in an unacceptable RISK**, as determined by the MANUFACTURER.

Immunity Acceptance Criteria

- **Before IMMUNITY testing begins**, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES.

- IMMUNITY pass/fail criteria **may specify degradations that are acceptable** because they do not result in unacceptable RISK.
- **Following the tests**, any effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES should be considered in the **on-going RISK MANAGEMENT PROCESS**.

IMMUNITY TEST LEVELS

- When a MANUFACTURER knows from experience, published data, or representative measurements that the **environment of INTENDED USE** has unique characteristics that would alter EM DISTURBANCE levels that form the basis of IMMUNITY TEST LEVELS specified in Table 4 through Table 9, the MANUFACTURER shall take this into consideration in the RISK MANAGEMENT PROCESS.
- The MANUFACTURER should consider reducing the **minimum separation distance**, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance.
- Testing may be performed at other **modulation frequencies** identified by the RISK MANAGEMENT PROCESS.
- The frequencies and services listed in Table 9 are representative examples that are based on **RF communications equipment** in use at the time of publication of this collateral standard. The test specification does not attempt to cover every frequency and service used in every country. The RISK MANAGEMENT PROCESS should take current communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table 9.

RM Process requirements

Subclause 3.1 and Figure 1 of ISO 14971:2007 summarize the main steps of the RISK MANAGEMENT PROCESS. Other subclauses in that standard cover:

- management responsibilities;
- qualification of personnel;
- RISK MANAGEMENT plan;
- RISK MANAGEMENT.

All of these requirements apply fully to issues related to the effects of EM DISTURBANCES on both the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS.

Risk Analysis – additional standards and tests

When applying any RISK ANALYSIS methods to comply with this collateral standard, these methods should take into account the possible **effects of the EM ENVIRONMENT** to which the ME EQUIPMENT or ME SYSTEM could reasonably foreseeably be exposed over its **EXPECTED SERVICE LIFE**. While this collateral standard specifies a set of tests for IMMUNITY to ELECTROMAGNETIC DISTURBANCES, the RISK ANALYSIS should consider additional electromagnetic phenomena, tests and standards than might be applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM over its EXPECTED SERVICE LIFE in its EM ENVIRONMENTS of INTENDED USE.

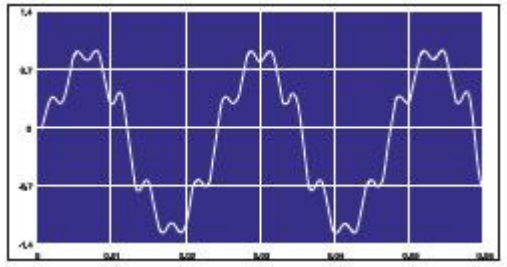
Additional standards and tests to take into consideration:

- IEC 61000-3-11 [10];
- IEC 61000-3-12 [11];
- IEC 61000-4-13 [12];
- MIL_STD-461G [38];
- EUROCAE ED-14G [39] or RTCA DO-160G [40];
- PATIENT-COUPLED cables EMISSIONS, as specified in Annex H;
- low-frequency magnetic field EMISSIONS;
- proximity magnetic field IMMUNITY, e.g. ISO 11452-8 [21];
- proximity electromagnetic field IMMUNITY, e.g. ISO 11452-9.2 [22];
- frequency bands of new RF communications equipment technologies that are not listed in Table 9.

Risk Analysis – Additional EM phenomena

Conducted low frequency

- Harmonics, interharmonics
- Signalling voltages
- Voltage fluctuations
- Voltage dips and interruptions
- Voltage unbalance
- Power frequency variations
- Induced low frequency voltages
- d.c. in a.c. networks



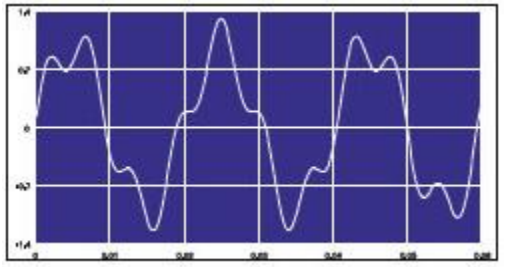
Radiated low frequency

- Magnetic fields
- Electric fields

Intentional EMI

Conducted high frequency

- Directly coupled or induced continuous voltages or
- currents
- Unidirectional transients
- Oscillatory transients



Radiated high frequency

- Magnetic fields
- Electric fields
- Electromagnetic fields
  - continuous waves
  - transients

ESD

- Human and machine

HF SURGICAL EQUIPMENT

For ME EQUIPMENT and ME SYSTEMS intended to be **used near active HF SURGICAL EQUIPMENT**, it is particularly important to consider conducted and radiated EMISSIONS from HF SURGICAL EQUIPMENT, specifically:

- energy conducted through the PATIENT, and
- radiated EMISSIONS from HF SURGICAL ACCESSORY cables.

In general these EMISSIONS have high field strength and are broadband. As a result, IEC 61000-4-3 is not adequate for assuring IMMUNITY to these EMISSIONS.

EXPECTED SERVICE LIFE and Risk Analysis

Take into account

- Physical, climatic and use environments
- Ageing
  - Condensation
  - Liquid spillages and sprays
  - Mould growth
  - Particulate matter
  - Dust
  - Cleaning
  - Maintenance
  - Wear and tear
- Effects of reasonably foreseeable faults and use/misuse

Degradation of the ability of an ME EQUIPMENT or ME SYSTEM to function as intended in the presence of ELECTROMAGNETIC DISTURBANCES

Risk Analysis – additional considerations

- Reasonably foreseeable **simultaneous events** and phenomena including ELECTROMAGNETIC DISTURBANCES, physical and climatic phenomena, faults and OPERATOR actions.
- ELECTROMAGNETIC DISTURBANCES can cause degraded, **distorted or false signals** that could affect BASIC SAFETY or ESSENTIAL PERFORMANCE

- **Reset, latch-up and looping**, including:
  - reset of programmable devices;
  - 'latch-up' of semiconductor hardware devices (transistors, ICs, etc.);
  - 'looping' or 'crashing' of software and firmware in programmable devices.

ELECTROMAGNETIC DISTURBANCES should be fully taken into account in the following subclauses in Clause 4 of ISO 14971:2007:

- **INTENDED USE** and identification of characteristics related to the safety of the medical device (in Subclause 4.2);
- **Identification of HAZARDS** (in Subclause 4.3);
- **Estimation of the RISK(s)** for each HAZARDOUS SITUATION (in Subclause 4.4).

The challenge is …

- Most risk analysis documents (e.g. FMEA tables) have a **single line** to manage electrical safety and for EMC.
- Expanding these lines to the required level
  - adds complexity and a high level of detail to the overall product/process risk analysis.
  - causes confusion.
  - may not add value.

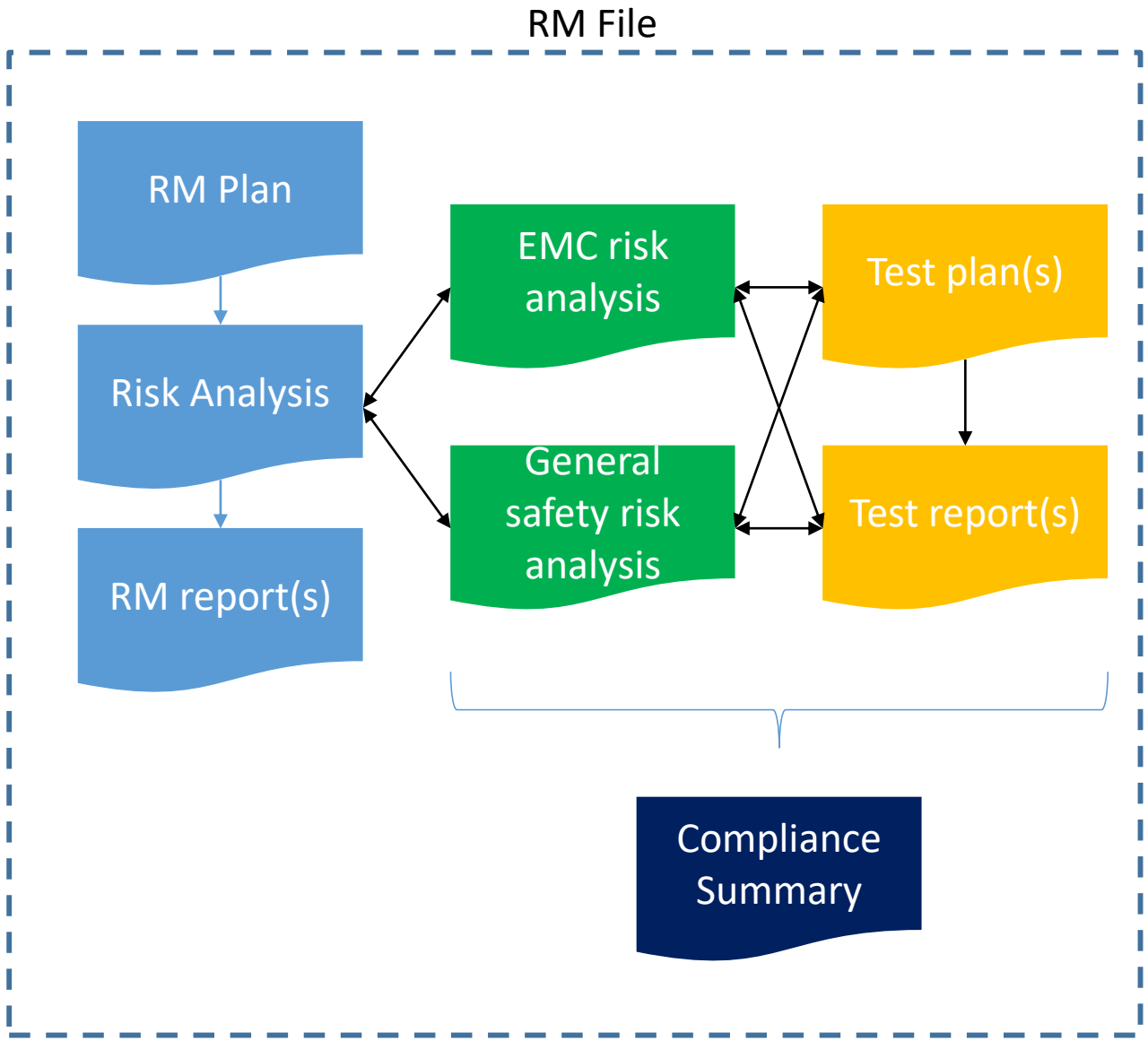
Proposed solution

Create a separate risk analysis document for general safety and for EMC.

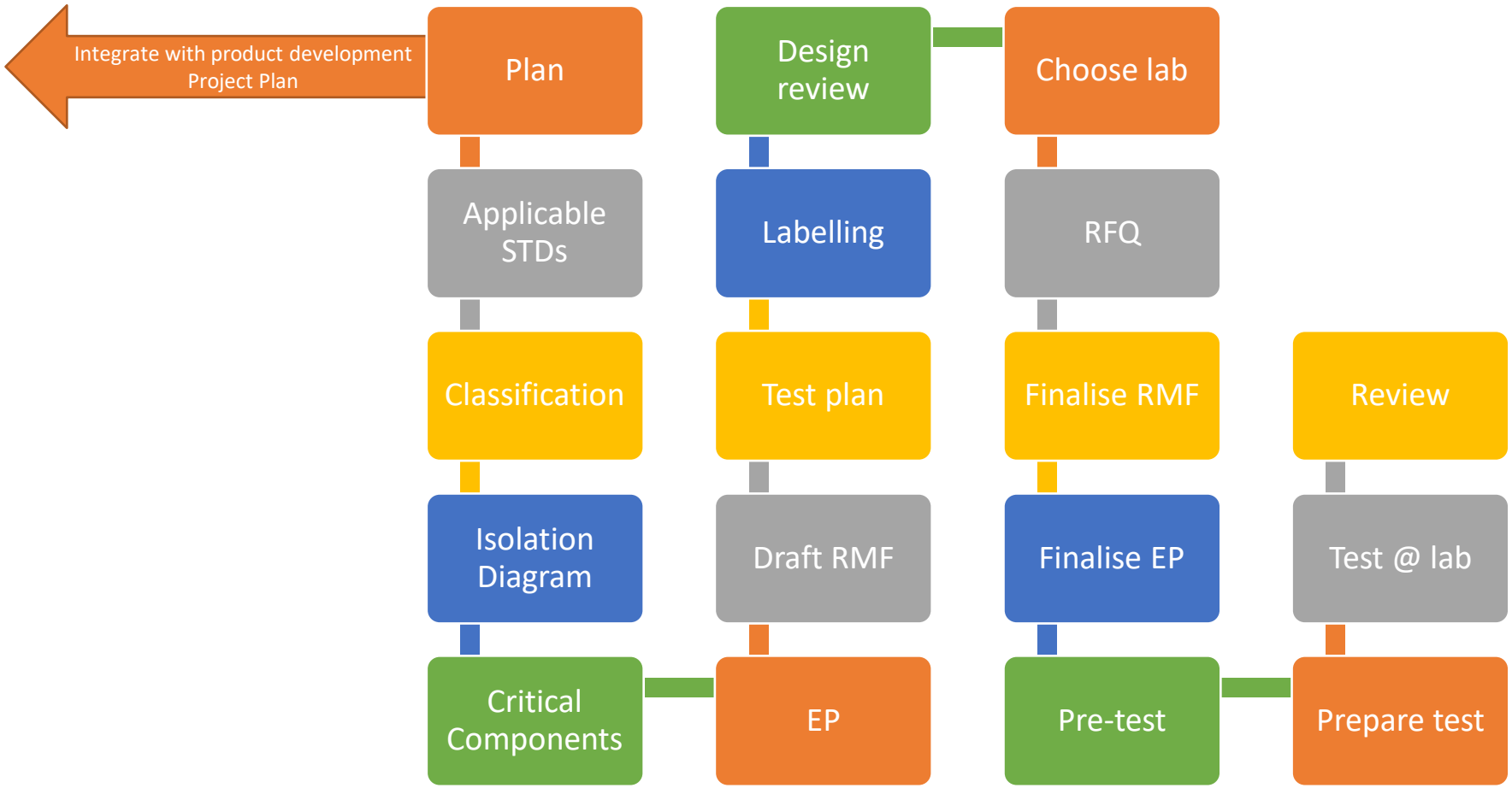
Link to these documents from the ‘main risk analysis’.

Link to test plan(s) and test report(s).

Consider a compliance summary document for general safety and for EMC.



The route to a successful type test



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