9 Things RA/QA Leaders Must Know About IEC 60601-1 4th Edition

The 4th Edition introduces significant changes to safety, software, EMC, and compliance documentation. These nine points help RA/QA leaders prepare for the April 2030 publication and transition.

Friday In-Focus — August 15, 2025 | Leo Eisner ("The IEC 60601 Guy")

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1 Scope & Essential Performance (01:05–02:09)

"It specifies general requirements for basic safety and essential performance. That's the core of the standard."

Defines the boundaries for design, testing, and compliance. Serves as the backbone of design control.

2 Use Environments & Users in Scope (02:09)

The manufacturer gets to define the users and the specific environments of use… now having it defined in the scope is great."

Specifies user profiles and environments directly in the scope. Usability files and IFUs must match.

3 Software Requirements Expanded (02:09–03:10)

Software is a huge addition… there's a huge, big area on software and PEMS."

Adds detailed requirements for PEMS, SAMD, and SIMD. Requires additional documentation and validation.

4 Collaterals Integrated into One Standard (05:15, 07:24)

You get rid of all the collaterals being updated, so you're saving three years in the cycle."

Combines multiple documents into a consolidated 1,000+ page standard.

5 Regulator Participation & Timeline (10:36–11:50, 17:17)

"We… hope to have it published April 2030."

Strong involvement from regulators. Publication targeted for April 2030 with a 2–3 year transition.

6 QMS Impact Areas (18:20–21:21)

"A buzzer doesn't meet 60601-1-8 alarm system requirements…but if notifying a hazardous situation shall include an alarm system"

Includes updates to usability, alarms, labeling, and verification and validation processes.

7 Hardware & Documentation Updates (29:11, 30:29)

Ingress protection minimum changes to IP22. Increases reliance on ISO 20417

8 EMC & Wireless Coexistence (49:54, 52:04)

"Wireless coexistence… is going to be an international requirement."

Increases RF field limits and introduces new coexistence requirements that may require redesigns.

9 Immediate Actions (53:14–53:57)

"Spot disruptive changes… prevent costly redesigns."

Create a 4th Edition impact register, begin EMC testing, and update labeling and risk management files.

Next Steps:
- **Download** Leo's Slide Deck
- **Contact Leo** — Book a 60601-1 4th Edition team briefing

Watch the Replay on YouTube

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