



IEC 60601-1, 4th Edition: Strategic Changes and Preparation Strategy

Companion one-pager distilling Leo Eisner's IEC 60601-14th ed. insights into practical strategy for cross-functional teams



Your 4-Part Survival Kit

[Listen to Podcast Episode](#)

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[EMD Magazine #2 Feature](#)

[4th ed. Survival Guide](#)

What's changing in 4th Edition

Across the Working Groups, changes are focused on:

- Scope and Essential Performance
- User environments and intended use
- Software and PEMS
- International wireless coexistence expectations
- EMF exposure concepts
- Hazard-based structure

How to use this kit

1. Brief leadership using the podcast as the shared baseline.
2. Revisit your intended use, user environments, and understand the changing scope of the standard now.
3. Assign owners to track the Working Groups most relevant to your product.
4. Track areas likely to affect: QMS documentation, labeling and IFUs, test strategy and planning, design impacts, and your impact register.

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