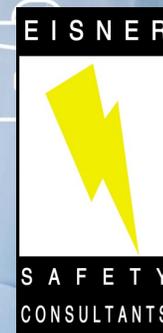


Impact of IEC 60601-1, 4th Ed



Leo Eisner – The IEC 60601 Guy

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Leo Eisner – The "IEC 60601 Guy"

Founder & Principal Consultant, Eisner Safety Consultants

30+ years in medical devices,
40+ years in product safety testing,
20+ years in standards development,
experience at 3 Notified Bodies and 2 test labs,

- Leo is a global expert in product safety, compliance, and standards development

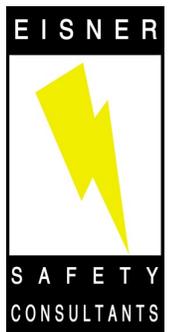
Eisner Safety Consultants, founded in 1997: Leo and his team provides comprehensive real-world support on product safety compliance, EMC, software lifecycle, risk management, labeling, DHF/technical documentation, standards strategy, and more

Leo is a recognized expert in the standards development process, with deep, long-standing leadership in evolving global medical device standards

- Co-convener IEC/TC 62/SC 62A/WG39 (User Interface for IEC 60601-1, 4th ed.),
- US co-chair of AAMI TAG 62D on electromedical equipment, and
- holds leadership roles across key AAMI and IEC committees.
- He has led or contributed to IEC 60601-1 (ed. 3.2 & 4th), ISO 15223, ISO 20417, and many more.

Leo is a guest speaker for webinars, podcasts, and written many articles

 More at [Leo's LinkedIn Profile](#)



Eisner Safety Consultants

Eisner Safety Consultants is a consulting firm that supports your company through the process of on-time product approvals via safety & regulatory agencies.

We provide consulting services for medical devices companies:



Product Safety
(60601)



EMC



Risk
Management



Labeling
Review



Standards
Regulations
Laws/Guidances



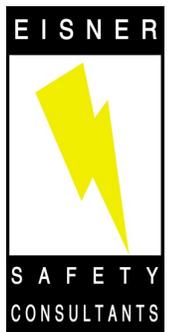
Design



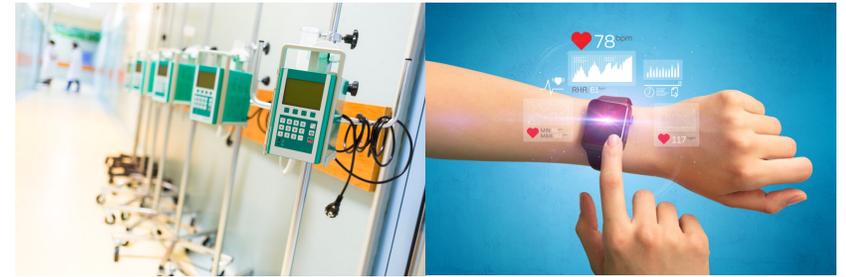
DHF/TF/TD



Training



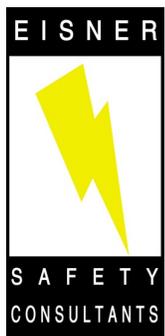
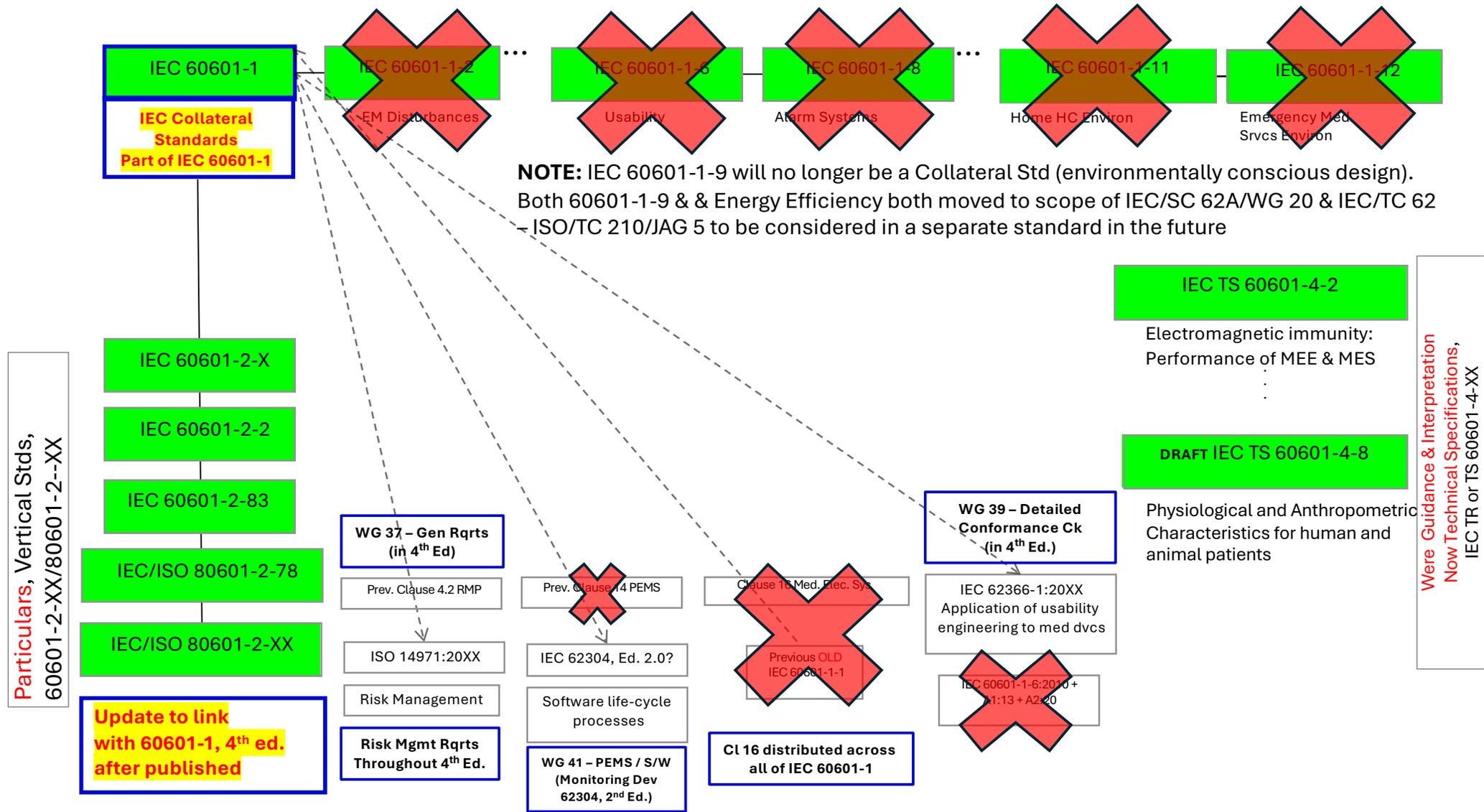
IEC 60601-1, 4th Ed. - Scope



- Scope: **(red font changes from Ed. 3.2 to 4 Ed.)**
 - Applies to Medical Electrical Equipment (MEE) and Med Elec Sys (MES)
 - Specifies the general requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEE and MES, **intended for use by the specific USERS and in the specific ENVIRONMENTS of use as specified in the IFU.**
 - **Applies to s/w integrated into an MEE (SiMD), SaMD (element of MES), when the SaMD contributes to basic safety or essential performance.**
 - **Applies to subassemblies of MEE or MES.**
 - **EXAMPLE: Power supply unit or x-ray tube assembly.**
- Does not apply to: (Same for Ed. 3.2 & 4th)
 - In-Vitro Diagnostics (IEC 61010 Series Test & Lab Equipment)
 - Implantable parts of Active Implants (but does include the external controllers) (ISO 14708 Series)
 - Medical gas pipeline systems (ISO 7396-1)

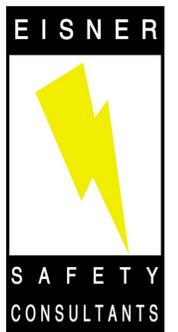


60601 Series of Standards – Format, 4th ed.



Drivers Behind the Next Edition

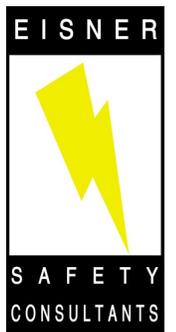
- **New Technologies / Changes to Technology**
 - AI/ML, SaMD/SiMD, Robotics
 - Defibrillation & User Interfaces
 - **New Requirements**
 - Wireless Coexistence, EMF, Battery Management, Reduction in Spacings using IEC 60664, AI, Cybersecurity, Thermal Phantom requirements, **More validation reports...**
 - **Address safety gaps** – close them
 - **Standards evolved** since 3rd ed.
 - ISO 20417, ISO 18562 Series, Battery stds, Robotics,
 - Existing normative standards updated → impacts requirements in IEC 60601-1, 4th Ed.
 - **More International Regulatory Interest** (FDA, PMDA, TGA, SFDA, EU NB's...)
 - **Regulators are signaling adoption**
- Your impact: planning now avoids re-design & QMS **FIRE DRILLS** 



Drivers Behind the Next Edition

Architecture Specification V3.0 (2020)

- **Sharpen focus on Basic Safety & Essential Performance**
 - Clarify Concepts and include rationale for each requirement
- **Clarify Scope:**
 - Patients types - Neonates to Geriatric, size (TBD), human & animal
- **Medical environments**
 - Inside & Outside Hospital (EMS, Home Healthcare, Dental Offices, etc.)
 - Basic, Intermediate & Critical Care Environments
- **Consistent terminology for *medical device industry*: [IEV 60050-880](#) (1/2634/CDV)**
- **Atomic requirements:** Each requirement **distinct** & ***design-ready***
- **Align IEC 60601 with IMDRF Essential Principles N47 (Safety & Performance) & N52 (labeling) → *Regulatory Ready***
- Online Standards Development (OSD) tool – **goal DB standard** approx 5 to 10 years away



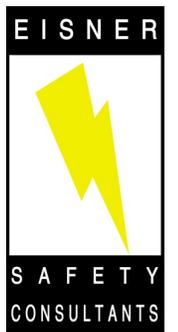
Drivers Behind the Next Edition

Design Specification

- **Hazard-centric layout (12 hazard Working Groups - WGs)**
 - WG 37 – WG 48 (Detail WG Names Next Slide)
 - + Editing Team **AG 50 – Leadership of all 12 WGs**
- **Road Map**   for WGs to develop IEC 60601-1, 4th ed
 - **How implement Architecture Spec.**
 - **Areas taken from IEC 60601-1, 3rd Ed., other standards, new requirements**
 - **Deleted requirements**
 - Cross ref's: Single Faults (Cl. 13), Mech Haz's Cl. 16.7 → Cl. 9
 - Cathode ray tubes 9.5.2 – Technology no longer used
 - IEC 60601-1-9 - environmentally conscious design → Collateral going away, separate std under future work via IEC/SC 62A/WG 20 & IEC/TC 62 – ISO/TC 210/JAG 5

Hazard Based – Working Groups (Cheat Sheet)

Working Group (WG) #	WG (Hazard Based) Title	Additional Notes	Fragment #
37	General Requirements		1
38	Physical Environment Hazards		2
39	User-Interface aspects (including all labelling and information to be provided)	Includes Usability, & Alarms	3
40	Materials Hazards	(Biocompatibility, Processing, Cleaning, etc.)	4
41	PEMS (e.g., SaMD, SiMD, firmware, software, apps, OS, drivers) related hazards		5
42	Electrical Hazards		6
43	Mechanical Hazards		7
44	Thermal and Fire Hazards		8
45	Optical Radiation (visible, UV and IR) Hazards		9
46	Ionizing Radiation Hazards	(X-ray)	10
47	Electromagnetic Exposure (not optical or ionizing but including SAR) Hazards	Electro Magnetic Fields (EMF)	11
48	Electromagnetic Disturbances (including coexistence) Hazards		12





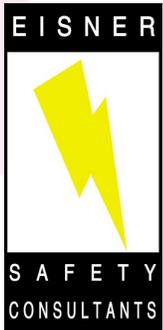
Project Timeline

4th Ed. General development schedule updated June 2025



Project start
Apr '24

Fragment Info
Group 1 →
Frag 1- 4, 11
Group 2 →
Frag 5 - 8, 10 & 12
Frag 9 not issued yet



Major Changes

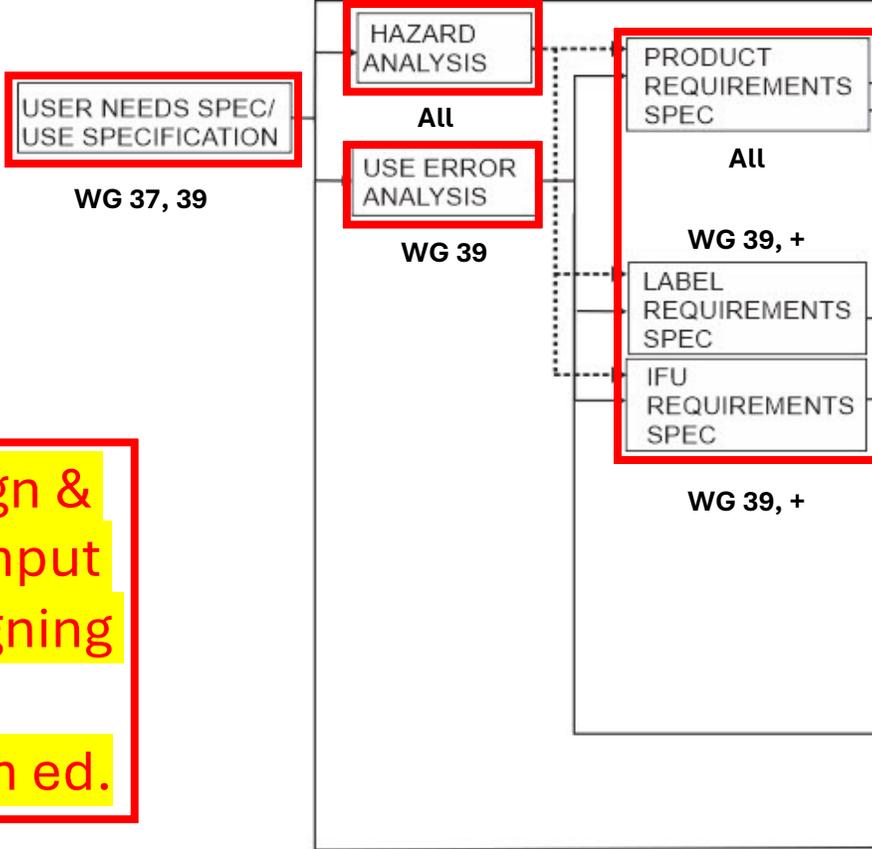
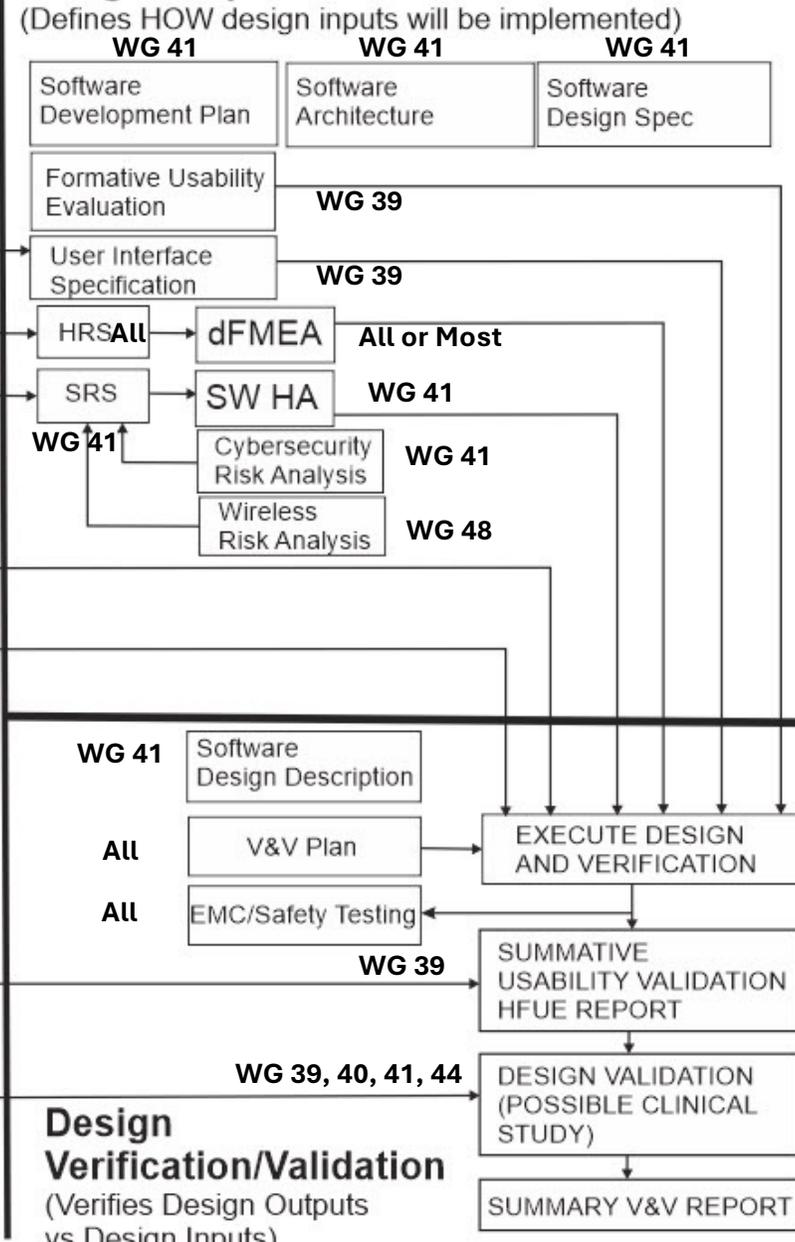


Design Control Process

Design Inputs (Defines WHAT the device must do)

Design/Development Plan	All or Most
Risk Management Plan	All
HFUE Usability Plan	All

Design Outputs (Defines HOW design inputs will be implemented)



Essential Design & Development Input Documents Aligning with IEC 60601-1, 4th ed.

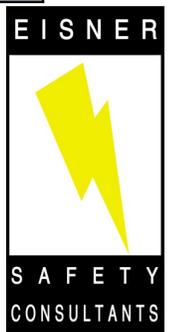
High Level Changes

- **WG 37 – General Requirements**

- **Expanded “Use Specification”**: now requires defining intended environments, user profiles, patient populations, and medical indications up front; *impacts design controls, risk management, labeling, and usability documentation*
- **Categorization (previously classification)**: Partial listing

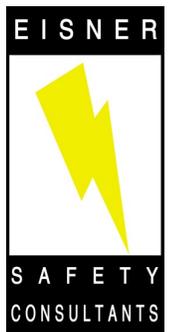
Expanded significantly – <i>Tag ID applicable db std requirements, tests, etc.</i>		
Environment of Use (6.8)	Single & Multiple Use (6.7)	Type of Mobility (6.9) – MEE (6.9.1); MEE parts & acc’s (6.9.2)
Methods of Processing (6.3) - Cleaning, Disinfection, & Sterilization (ISO 17664)		Level of Autonomy (6.13 – WG41)
External pressurized fluid input (6.12) pressurized or not	Size & Mass (6.10 - TBD)	MR environment 6.15)
Functional connections – btwn MEE & MES (6.11)		Emission of radiation (6.14)

- **Alarm Systems**: If risk control involves **notifying the user of a hazardous situation**, MEE/MES **shall include an alarm system** (60601-1-8); *impacts design, RMF*
- **Conformity evaluation file**: Plan & results (rprts, etc.) of evaluation for MEE, MES their parts & acc’s, with proposed flexible structure; *Mfr to provide the planning doc’s up front*



High Level Changes

- **WG 38 – Physical environment hazards**
 - **Environmental Conditions & tests:** expanded requirements for temperature, humidity, pressure, shock, vibration, and corrosive pollutants (IEC 62368-1 Annex N & Y.3); *impacts labeling, IFUs, designs, and test plans*
 - **Environmental condition symbols (ISO 20417, 2nd ed. draft):** Transport, Storage, Operation, Transient Conditions; *must appear in packaging and documentation, as applicable*
 - **Ingress Protection (→ dust & liquids) & MRI Safety Marking:** Min IP22 for professional HC environ's (controlled/partially temp controlled); MRI safe/MRI conditional/MRI unsafe marking per IEC 62570; *impacts design, labeling & testing*
 - **Battery Management Systems:** new chemistries, transport compliance (UN 38.3, IEC 62133), enclosure fire/temp limits, charge/discharge control, protective ckts, inductive charging ports, storage/conditioning, venting, impact on EP, Reese's Law ...; *requires design, test, and compliance updates*



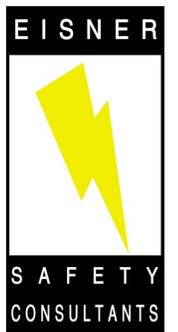
High Level Changes

- **WG 39 – User interface aspects hazards (→ Includes Info Supplied by Mfr (labeling), Usability, & Alarms)**
 - **Information provided by the manufacturer & Installation/Site Planning:** 1) Follow **ISO 20417** (2nd ed. draft) for labeling, packaging, symbols, safety signs, IFU, and technical documentation 2) **unless 60601-1 specifies otherwise for particular hazards;** include proper installation & site planning guidance (where applicable/TBD); *may impact labeling, packaging, symbols, safety signs, IFU, & technical documentation*
 - **Legibility Requirements:** markings/**displays** must remain clear in expected use; includes **visual** alarm signals & **visual** information signals (**60601-1-8**), including **with PPE**
 - **Usability Engineering (IEC 62366-1):** Detailed Conformity Check; IEC 60601-1-6 deleted
 - **User Interface Clause:** Covers intended user/environment; includes indications such as **graphical displays**, indicator lights, **textual displays**, **auditory outputs** (tones, speech); also covers **controls**, connections, advanced inputs (**voice, gesture**), **autonomy**, and **distributed interfaces...**; *impacts usability design, design, test protocols, and labeling updates*
 - **Indication & Control Requirements:** Covers alarm visibility/audibility, power status, and control responsiveness (latency); *impacts usability design, test protocols, and labeling updates*

High Level Changes

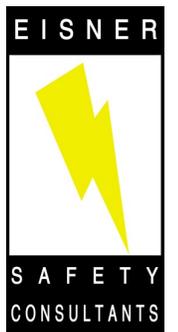
- **WG 40 – Material hazards**

- **Biocompatibility & Processing Requirements:** Aligns w/ **ISO 10993 series, ISO 18562 series, ISO 7405** and document conformity via **biocompatibility assessment reports**; processing of MEE/MES must follow **ISO 17664** series or **applicable sterilization standards** based on device type (reusable/single-use, home/clinical, etc.), with **validation reports inspected**
- **Compatibility With Substances:** Covers substances intended to be delivered to the patient, exposed during normal use, used prior to patient use, or used to achieve intended use but not intended for patient delivery
- **Conductive Surface Coatings:** Adds **IEC 62368-1:2023, Annex P.4** as a test standard
- **Adhesives Applied to Intact Skin:** Must attach securely & be removed without skin damage



High Level Changes

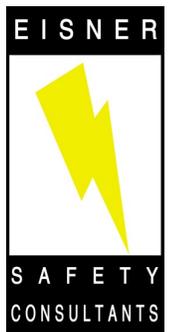
- **WG 41 – PEMS (e.g., SaMD, SiMD, f/w, s/w, apps, OS, drivers) related hazards**
 - **PEMS Development Process:** expanded requirements for software lifecycle, verification, and validation
 - **Electronic Data Interface (EDI):** manufacturer responsibility for connected device design, documentation, & validation; includes network integration & interoperability requirements
 - **Physiologic Closed-Loop Controller (PCLC):** based on IEC 60601-1-10; requires defined attributes, fallback modes, and robust validation strategies
 - **Cybersecurity:** threat modeling, vulnerability/malware/penetration testing, source code analysis, SBOM, & legacy PEMS; *will require specialized internal teams or external services, adding significant cost & expertise needs*
 - **Artificial Intelligence (AI/ML):** draft rqrts for data quality, validation, transparency, bias, & human-AI interaction; ***clinical & pre-clinical data must include explicit demographic labels (age, gender, ethnicity, ...) & be sized to power each subgroup for statistical fairness checks***
 - **Remote Control:** covers control authority, cybersecurity, and usability; overlaps with WG 39 distributed user interface work



High Level Changes

- **WG 42 – Electrical hazards**

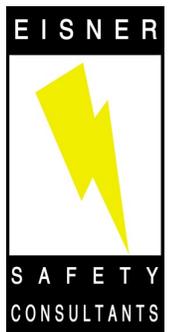
- **Insulation & Spacing:** proposal to align w/ IEC 60664; reduced spacings (creepage & clearance) rqrts for both patient & user (same); *impacts design of insulation systems & component selection – Industry game-changer 🏆💥👍 could shrink device size*
- **Colours of Conductors:** new “in some countries” cl. for conductor colors; *May affect supply chains, IFU cord specs, and testing – impacts still unclear*
- **Earthing:** updated rqrts for protective, functional earthing & potential equalization; 4th Ed. keeps technical earthing limits of Ed. 3.2 but *tightens documentation & testing*; allows parts to meet IEC 62368-1 if meet rqrts & tests for protective earthing & serve as MOOP
- **Production Line Testing:** includes protective earth continuity, leakage current, patient auxiliary current, and dielectric strength per IEC TR 62354 (non-destructive testing) – *Impact purchase production line equipment, QMS documentation for & conducting production line testing*



High Level Changes

- **WG 43 – Mechanical hazards**

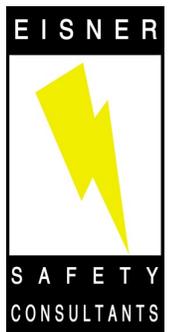
- **Edges and Corners:** expanded to include accessible sharp edges/corners during assembly, use, and maintenance; functional sharp edges allowed with ISO 7010-W022 safety sign; *may require design changes or new labeling*
- **Stability and Tip Resistance:** centralized test planning in 4.3.1; **weight-based stability (overbalance)/tip criteria with braking/retention** verification; *could trigger re-testing and redesign for heavier or mobile equipment*
- **Force of Propulsion:** propulsion force = initial force; defines which mobile MEE to test; improved test method; safety sign if force limit (200 N) exceeded; *may require drive system or labeling updates*
- **Support Systems:** updated requirements for **attachment methods** and **strength of patient/user supports**; *could require redesign or requalification of beds, tables, support arms, lifting devices, etc.*



High Level Changes

- **WG 44 – Thermal & fire hazards**

- **Temperature limits:** clarified for accessible parts in normal and single fault; applies to all body contact types, **non-skin contact APs & delivered gas, infused liquids** (?); the **infused liquids limit is still under NC review**; *could require redesign, insulation, or material changes for affected accessible parts*
- **Phantom testing:** use of phantoms introduced for thermal evaluation; partially based on FDA draft guidance on evaluation of thermal effects of medical devices that produce tissue heating and/or cooling; *impact your test protocols, QMS & design controls*
- **Means of fire protection:** easy-to-follow flowchart for each circuit of MEE/MES acceptable fire protection options; *simplifies design decisions and conformity checks*
- **Fire protection:** fire enclosure rules + material flame tests added; new top enclosure requirements; single fault limits now clearly separated from normal use; *could require material upgrades or redesign for compliance*



High Level Changes

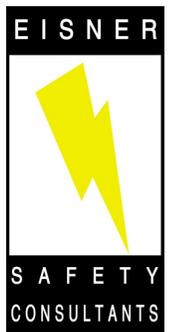
- **WG 45 – Optical radiation (Visible, UV & IR) hazards**
 - **Release delayed:** WG 45 CD release delayed due to TC 76 disagreement; *clause details and timing remain unknown*
 - **Wavelength range:** 180 nm – 1 mm (60601-1: 10.4 – 10.7 → lasers; other visible EM, infrared, and ultraviolet radiation); same wavelength scope as existing
 - **Non-visual photobiological effects:** non-laser sources of **200 nm – 3 000 nm**, other than risk class 1C, to **meet IEC 62471**; *may require testing to this standard for applicable devices → costly testing*
 - **New Exemption (to IEC 62471):** individual indicator lights, IR remotes, IR devices for data transmission within MES, LCD/computer displays, similar low optical power devices (6.2.1 b))
 - **Therapy/diagnosis equipment:** IEC 62471; IEC 60601-2-75 applies for relevant equipment types

High Level Changes

- **WG 46 – Ionizing radiation hazards (→ X-ray equipment)**
 - **Integration of Ionizing-Radiation Hazards;** folded into IEC 60601-1 **replaces IEC 60601-1-3;** may require QMS updates and design reviews for affected products
 - **Expanded Terminology;** ≈140 draft radiology-specific definitions under Clause 3.22, IEC 60050-881 (62/553/CD → CD1 published 2025-07-04; closes 2025-09-26)
 - **Connect ALARA & Risk-Management;** “As low as reasonably achievable” requirement tied to ISO 14971:2019 risk-management policies; *may affect design decisions and RM files*
 - **Enhanced Equipment Marking & Identification;** mandatory marking of all radiation-relevant sub-assemblies for ID and compliance traceability; *could require supplier coordination and part marking changes*
 - **Operational Controls & User Indications;** detailed requirements for initiation/termination controls, audible/visible irradiation indicators, source-selection, mode-display, dose-monitoring; *may require redesign of user indications and controls*
 - **Dose-Output Performance Metrics;** reproducibility limits $\leq 5\%$ diagnostic; $\leq 2\%$ radiotherapy; leakage ≤ 1 mGy/h @ 1 m; residual ≤ 150 μ Gy/h; *could require re-testing and recalibration of existing systems*
 - **Proposed Removal – Leakage Radiation when not in Loading State;** per IEC 60601-1-3

High Level Changes

- **WG 47 – Electromagnetic exposure hazards (→ EMF)**
 - **Integration of Electromagnetic-Exposure Hazards;** EMF safety now consolidated into 60601-1 as dedicated Clause 4 replacing limited Ed 3.2 coverage; *may require QMS updates and design reviews for affected devices*
 - **EMF Exposure Assessment Report;** no structure or title required; must be provided as evidence of compliance for intentional radiators; *early wireless tech choices can influence assessment complexity, QMS & Design documentation impact*
 - **Inherently in Conformity Criteria = Exemption;** meet all 7 items (unintentional radiators) for exemption consideration
 - **Expanded Frequency & Scope;** **widened** from 1 GHz–100 GHz to **0 Hz–300 GHz** including static fields; applies to **intentional and unintentional radiators**; *antenna design and shielding strategy can shape compliance path and project timelines*
 - **Streamlined Compliance Path for Low-Risk Devices;** new low-power exemption via IEC 62479 “Pmax” method; *power management strategy early in design can avoid later delays*
 - **Tiered EMF Exposure Assessment;** **multi-level methodology** referencing IEC 62479, IEC 62311, IEC/IEEE 62209-1528, ISO 14971; *must be documented in RM file*; **consider patients with active implants**; *early planning can minimize budget impacts & impacts QMS & Design documents*

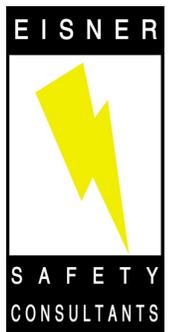


High Level Changes

- **WG 48 – Electromagnetic disturbances (including wireless coexistence) hazards**
 - **CISPR 11:2024: Major technical changes** vs. IEC 60601-1-2 Ed 4.1 normative reference; *will drive new emission testing, design changes, and RM file updates*
 - **IEC 61000-3-2 (Harmonics):** New ed. alters limits/requirements; *may affect power-supply design & compliance*
 - **Radiated RF EM Fields:** Health Care Environ (HCE) home-use remains 10 V/m (80 MHz–2.7 GHz) + new 3 V/m (2.7–6 GHz); Prof HCE now 3 V/m up to 6 GHz. *Pre-scans advised; could require antenna design & shielding changes*
 - **RF Wireless Fields (Table 3):** AIM 7351731 **levels increased** (e.g., 28 → 54 V/m; new Ham Radio freq. 45 V/m); higher failure risk for integrated-radio devices; *early design mitigation key*
 - **Wireless Coexistence:** AAMI TIR69:2020 & ANSI C63.27:2021 **now international;** *design may need to account for varying country frequency rules*
 - **Other Updates:** Flicker IEC 61000-3-3 removal under discussion; Operating modes battery-powered under consideration under IEC 61000-4-11; ESD updates – ceiling-mounted equipment added, connector method and air-discharge levels under review; All other EMC tests not listed above: no significant changes at this time – subject to change

Unlock Your **IEC 60601-1** Insider Advantage

- **Mitigate Risks:** Spot disruptive changes early, prevent costly redesigns, and align documentation ahead of competitors
- **Accelerated Compliance:** Integrate evolving requirements seamlessly into your development pipeline
- **Leadership Insight:** As part of the standards leadership, The “601 Guy” & the support of his team of experts can track areas of interest for your group based on the documents (e.g. CDs, CDVs, FDIS & others) of interest to your organization
- **Behind Closed Doors:** Access to knowledge that is being developed
- **Ready to Leap Ahead?** Let’s turn this insider pipeline into your 4th Edition fast-track





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