

WHITE PAPER | 2026

# Demystifying IEC 60601: A Practical Guide for Understanding the IEC 60601 Family Standards

Understanding Collateral and Particular  
Standards, Global Regulations, and Compliance  
Requirements

BOB BUREK

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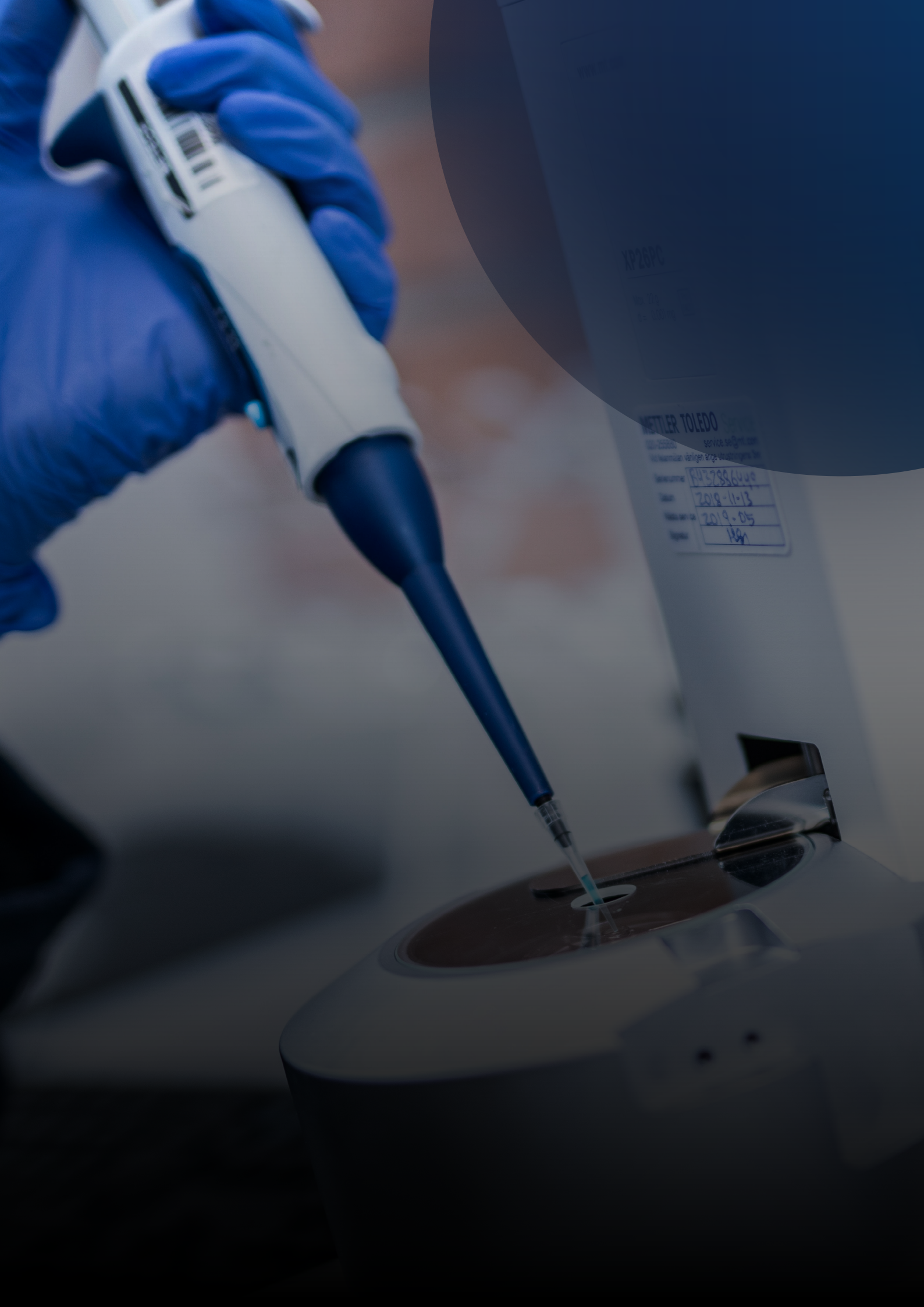
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# INTRODUCTION

The IEC 60601 standard series represents the global benchmark for safety and essential performance in medical electrical devices.

**Whether you're launching a new infusion pump in the United States, an ECG monitor in Europe, or a surgical device destined for markets across Asia, you'll need to demonstrate compliance with these standards. They're not just regulatory checkboxes; they're a comprehensive framework of requirements designed to protect patients, operators, and anyone else who might come into contact with your device.**

This whitepaper breaks down the IEC 60601 framework into digestible pieces. We'll walk through the structure of the standards, explain how they connect to regulatory requirements in major markets like the US, Canada, and Europe, and share practical insights for integrating compliance into your engineering workflow. Think of this as your field guide to making sense of IEC 60601, written by Element's Product Safety Technical Manager, Bob Burek, who has extensive industry experience and knows what actually matters when you're trying to bring an electrical medical device to market.



# UNDERSTANDING THE STRUCTURE: GENERAL, COLLATERAL, AND PARTICULAR STANDARDS

The IEC 60601 family isn't a single monolithic document; instead, it's organized into three distinct tiers that work together to define what "safe" looks like for medical electrical equipment. Understanding how these tiers interact is essential because your device will likely need to comply with standards from all three categories simultaneously.

## THE GENERAL STANDARD: IEC 60601-1

At the foundation sits IEC 60601-1, the general standard that applies to virtually all medical electrical equipment.

This is your starting point, and it's comprehensive. IEC 60601-1 covers basic safety and essential performance requirements across multiple hazard categories:

- Electrical shock
- Mechanical hazards
- Fire and explosion risks
- Excessive temperatures
- Radiation exposure (for certain devices)
- And more

One concept that often trips up design teams is "essential performance." Essential performance refers to any performance characteristic or function of your device that, if absent or degraded beyond certain limits, would result in unacceptable risk. Identifying and documenting your device's essential performance isn't optional; it's a core requirement that feeds directly into your risk management process, your test protocols, and ultimately your regulatory submissions.

The general standard also mandates that manufacturers follow ISO 14971 for risk management. In practice, this means you can't treat safety as an afterthought. From the earliest design sketches through final production, you need to identify hazards, estimate and evaluate risks, implement controls, and verify their effectiveness. IEC 60601-1 and ISO 14971 are deeply intertwined, and regulators expect to see evidence of this integration throughout your technical documentation. Below are two tables showcasing the structure of the IEC 60601 and IEC 61010 family of standards.



## STRUCTURE OF THE IEC 60601 FAMILY OF STANDARDS

1.	<b>IEC 60601-1 MEDICAL ELECTRICAL EQUIPMENT</b>	
	<b>PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE</b>	
	2.	-1-2: Electromagnetic Compatibility
		-1-3: Radiation Protection in Diagnostic X-ray Equipment
		-1-6: Usability
		-1-8: Alarm Systems
		-1-9: Environmentally Conscious Design
		-1-10: Physiological Closed-Loop Controllers
		-1-11: Home Healthcare Environment
		-1-12: Emergency Medical Services Environment
+	IEC 60601-1-X Collateral Standards (for classes of products)	
3.	IEC 60601-2-X Particular Standards (for specific products)	
Part 2: Particular requirements for basic safety and essential performance ... of about 80 product types e.g. endoscopes, ultrasound, vital signs, imaging		

## STRUCTURE OF THE IEC 61010 FAMILY OF STANDARDS

1.	<b>IEC 61010-1 SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 1 GENERAL REQUIREMENTS</b>	
	2.	-010, 011, 012: Heating & cooling, chambers
		-020: Centrifuges
		-030, 031, 032, 033, 034: Electrical measurements
		-040: Sterilizers and autoclaves
		-051, 061: Stirrers, mass spectrometers, automatic cycling
		-091: Cabinet x-ray systems (industrial)
		-101: in vitro diagnostic (IVD) medical equipment
		-201, 202: Industrial applications
	+	IEC 61010-2-X Collateral Standards (for classes of products)
3.	EMC IEC 61326 & IEC 60601-1-2	
IEC 61326-1 (general EMC) IEC 61326-2-6 (IVD medical) IEC 60601-1-2 (supplement as needed, FDA & other regulatory bodies)		

# COLLATERAL STANDARDS: EXPANDING THE SAFETY NET

While IEC 60601-1 provides the baseline, the collateral standards (designated as IEC 60601-1-x) address topics that cut across most or all types of medical electrical equipment. These aren't optional add-ons; many of them are mandatory depending on your device's characteristics and intended use. Let's explore the major collaterals.

## IEC 60601-1-2: ELECTROMAGNETIC COMPATIBILITY

**IEC 60601-1-2 covers electromagnetic compatibility, or EMC.**

EMC measures the impact your device has on other electronics in its environment. It must not emit excessive electromagnetic interference that could disrupt nearby equipment, and it must be immune to electromagnetic disturbances (EMI) that could compromise its safety or essential performance. EMC failures are among the most common reasons devices fail testing, so early attention to shielding, grounding, filtering, and PCB layout can save you significant headaches down the road.

## IEC 60601-1-6: USABILITY

**IEC 60601-1-6 deals with usability engineering, integrating human factors analysis into the medical device design process.**

This standard recognizes that even the safest device on paper can become dangerous if clinicians or patients can't use it correctly. You'll need to conduct use-related risk analyses, develop user interface specifications, perform formative and summative evaluations, and document everything meticulously. Usability isn't just about making things user-friendly, it's about preventing use errors that could harm patients.

## IEC 60601-1-8: ALARM SYSTEMS

**For devices that incorporate alarm systems, IEC 60601-1-8 sets requirements to ensure alarms are effective and don't create new hazards.**

Missed alarms, alarm fatigue, and confusing alert signals have all contributed to patient harm in real-world settings. The standard addresses alarm priority, signal characteristics, alarm limits, and how alarms integrate with overall risk management.

## IEC 60601-1-10: PHYSIOLOGIC CLOSED LOOP CONTROLLERS

**IEC 60601-1-10 applies to physiologic closed-loop controllers, devices that automatically adjust therapy based on physiologic feedback (think insulin pumps with continuous glucose monitoring, or ventilators that adjust based on patient breathing patterns).**

These systems introduce unique risks around software control logic, sensor accuracy, and fail-safe behaviour, all of which this collateral standard addresses in detail.

## IEC 60601-1-11: HOME HEALTHCARE ENVIRONMENT

**IEC 60601-1-11 defines the additional safety and performance requirements for medical electrical equipment used outside professional healthcare facilities, specifically in home environments, where users may be untrained, environmental controls are minimal, and conditions are more variable.**

The standard ensures your device remains safe and effective when operated by lay users and exposed to everyday household risks. The key takeaway? Collateral standards aren't isolated requirements. They overlap and interact with both the general standard and each other. Your usability analysis (60601-1-6) might reveal alarm-related risks that need to be addressed under 60601-1-8. Your essential performance definition influences how you test EMC immunity under 60601-1-2. Successful compliance requires seeing these connections and addressing them holistically.

# PARTICULAR STANDARDS: DEVICE-SPECIFIC REQUIREMENTS

**Particular standards, designated IEC 60601-2-xx, IEC 80601-2-xx, and ISO 80601-2-xx, take the general and collateral requirements and tailor them to specific device types.**

For instance, IEC 60601-2-2 covers high-frequency surgical equipment, with additional requirements for things like neutral electrode monitoring and insulation integrity at higher frequencies. IEC 60601-2-24 addresses infusion pumps and controllers, specifying requirements for flow accuracy, occlusion detection, and air-in-line detection.

Other commonly referenced particular standards include IEC 60601-2-25 and 60601-2-27 for ECG and monitoring equipment, IEC 60601-2-40 for evoked response equipment, and IEC 60601-2-66 for hearing instruments. Each particular standard refines essential performance definitions, specifies device-specific test methods, and may add unique safety requirements that aren't covered in the general or collateral standards.

Here's the crucial point: regulators in major markets expect concurrent compliance with the general standard, applicable collateral standards, and the relevant particular standard for your device. You can't pick and choose. If your device is an infusion pump, you need 60601-1, the applicable collaterals (certainly 60601-1-2 for EMC, likely 60601-1-6 for usability and 60601-1-8 for alarms), and 60601-2-24. Thinking about these as separate silos will set you up for failure. They need to be addressed as an integrated whole from the beginning of your design process.

# GLOBAL REGULATORY PATHWAYS: WHERE IEC 60601 MEETS MARKET ACCESS

Compliance with IEC 60601 standards is necessary, but it's not sufficient on its own to get your device into the hands of patients.

Each market has its own regulatory framework, and understanding how 60601 fits into those frameworks is critical. Let's walk through the major markets most manufacturers target.

## UNITED STATES: THE FDA AND NRTL

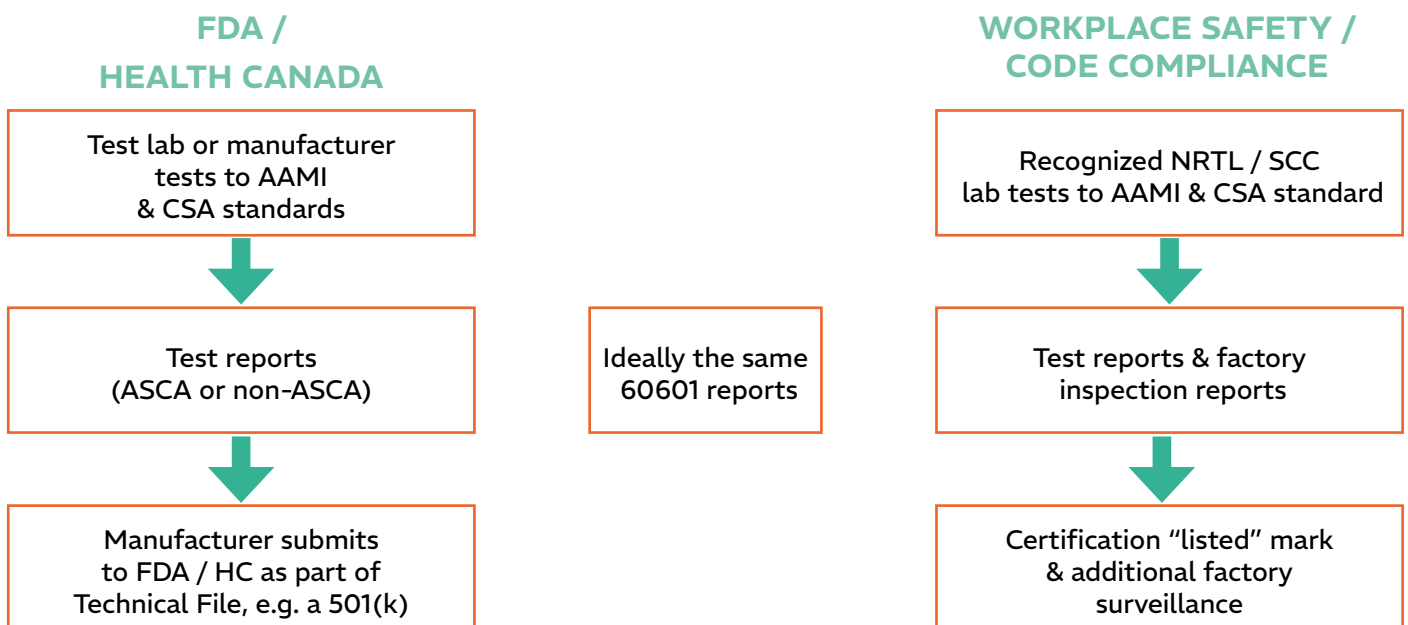


In the United States, you're dealing with two parallel requirements.

First, you need FDA clearance or approval, typically a 510(k) premarket

notification for Class II devices or a Premarket Approval (PMA) for Class III devices. The FDA relies heavily on consensus standards, including IEC 60601, as a means of demonstrating safety and effectiveness. When you reference a recognized consensus standard in your FDA submission and declare conformity to it, you're essentially telling the FDA, "We followed the established best practices for safety."

But here's where it gets interesting. FDA recognition of IEC 60601 isn't enough for workplace safety. Under OSHA regulations, medical electrical equipment used in healthcare facilities must be evaluated by a Nationally Recognized Testing Laboratory (NRTL) for safety. This dual requirement is often a common source of confusion. You might have your FDA 510(k) clearance, but without NRTL certification, hospitals and clinics legally cannot use your device. The below flow chart shows the processes required by both the FDA and Health Canada, as well as the NRTL processes.





Element is one of the accredited NRTL laboratories in the US and UK. Element helps manufacturers perform third-party testing and certification to verify compliance with applicable standards, including IEC 60601. The Element NRTL mark on your device provides assurance to healthcare facilities that your product meets workplace safety requirements.

The same dual requirement applies to EMC. We've already highlighted that all medical electrical equipment needs to be assessed against IEC 60601-1-2, but given that these devices very often include wireless, intentional transmitters, they

also require Federal Communications Commission (FCC) certification through a Telecommunication Certification Body (TCB), such as Element. For more technical and compliance information regarding implementing wireless technologies into a medical device, [download our Medical Radio Module Integration guide here](#).

So in practical terms, for the US market, you need FDA submission materials demonstrating compliance with applicable standards and NRTL and FCC certification from a recognized lab or certification body. Plan for all of these paths early, and ideally work with an NRTL/FCC TCB that has deep experience with FDA-regulated medical devices, they can help you navigate these processes more efficiently.

## CANADA: HEALTH CANADA AND NRTL



**Health Canada**

**Canada's approach closely mirrors the United States in many respects.**

Health Canada requires compliance with the Canadian adoption of IEC 60601 standards (published as CAN/CSA-C22.2 No. 60601 series). Fortunately, Canadian and US requirements are similar, and Health Canada generally accepts evaluations from US-recognized laboratories, particularly when those labs also have accreditation from the Standards Council of Canada (SCC) for compliance to the Canadian Electrical Code and Provincial electrical safety requirements.

This means if you've already engaged with an NRTL for the US market, extending that work to cover Canadian requirements is usually straightforward. The key is ensuring your test lab has the appropriate accreditations for both markets and understands any minor differences between the US and Canadian versions of the standards.

The same is largely true for the wireless approval of medical devices for Canada. The Canadian regulator (ISED) follows very similar processes; however, approving a device in Canada requires different accreditations from both the test lab and certification body. Element is able to issue certification against ISED and FCC requirements.

risk devices (Class IIa, IIb, and III). Your technical file must demonstrate conformity to applicable IEC 60601 general, collateral, and particular standards. The conformity assessment process is rigorous and requires detailed documentation of design, risk management, clinical evaluation, and post-market surveillance plans.

One important consideration: the EU's harmonized standards list can lag behind the latest IEC editions. You may find yourself referencing an older edition of 60601-1 or a collateral standard because that's the version that's been officially harmonized. Stay current with the EU Official Journal to know which versions are recognized. Testing to newer versions of the IEC standards is always best practice since they represent 'state of the art' – these won't provide a presumption of conformity, but is expected from Notified Bodies.

## THE CB SCHEME: YOUR PASSPORT TO GLOBAL MARKETS



**Here's where things get really interesting for manufacturers targeting multiple markets.**

The IECEE CB Scheme (Certification Body Scheme) enables mutual recognition of test reports across more than 50 member countries. For many manufacturers, this is one of the most efficient pathways for global market access.

Here's how it works: You engage with a CB Testing Laboratory (CBTL) that's part of the scheme, for example, Element. They test your device to IEC 60601 standards and issue a CB Test Report and CB Certificate. You can then submit these documents to National Certification Bodies in other CB Scheme member countries, who will accept them as evidence of compliance. This eliminates the need to repeat full compliance testing in every market.

Of course, there are caveats. Some countries may still require review of the CB documentation by their national authorities, and some have additional national deviations or requirements beyond the base IEC standards. But even with those qualifications, the CB Scheme dramatically reduces duplicate testing, saves money, and accelerates market entry timelines. If you're planning to sell globally, engaging with the CB Scheme should be part of your strategy from the outset.

## EUROPE: EU MDR AND HARMONIZED STANDARDS



**The European market operates under the Medical Device Regulation (EU MDR 2017/745), which replaced the previous Medical Device Directive.**

Under the MDR, manufacturers must demonstrate compliance with essential safety and performance requirements. IEC 60601 standards, when harmonized under EU law, provide a "presumption of conformity", meaning that if you comply with the harmonized standard, you can presume you've met the corresponding essential (legal) requirements.

The process typically involves technical documentation review and assessment by a Notified Body for higher-



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# PRACTICAL DESIGN STRATEGIES: BUILDING COMPLIANCE INTO YOUR DNA

Knowing the standards and regulatory pathways is one thing. Actually designing a compliant device is another. Based on lessons learned from thousands of product evaluations, here are the key strategies that separate successful projects from those that hit expensive roadblocks late in development.

## START RISK MANAGEMENT ON DAY ONE

We've mentioned ISO 14971 and risk management several times already, and there's a reason for that: risk management isn't something you tack on at the end of your design process.

It needs to be woven into every decision you make. Define your essential performance early. What functions absolutely must work for your device to be safe? Document potential hazards, estimate their risks, implement controls, and verify that those controls actually reduce risk to acceptable levels.

This early risk work feeds directly into your IEC 60601 testing strategy. Your essential performance definition determines which tests need to be conducted under fault conditions. Your hazard analysis informs which alarm functions need validation under 60601-1-8. Your usability risk analysis shapes the scope of your human factors validation under 60601-1-6. When risk management is truly integrated, everything else flows more smoothly.

## PAY ATTENTION TO POWER SUPPLIES AND BATTERIES

Power supply integration is a common source of compliance failures.

Many design teams underestimate the complexity of integrating off-the-shelf or custom power supplies and battery packs. There are critical considerations around leakage current, creepage and clearance distances, temperature rise under normal and fault conditions, and protection against electric shock.

For battery-powered devices, you also need to address risks related to charging circuits, battery chemistry (especially lithium-ion), thermal runaway scenarios, and energy storage hazards. IEC 60601-1 has specific requirements for separation of circuits, protective earth connections, and enclosure design that all interact with your power architecture. Get your electrical engineers and mechanical engineers in the same room early to address these issues, rather than discovering them during formal testing.

## DESIGN ARCHITECTURE WITH COMPLIANCE IN MIND

Component selection, grounding strategies, connector choices, PCB layout, and enclosure materials all need to align with IEC 60601 requirements.

For example, if your device will have patient-applied parts, you need to ensure proper isolation and limit leakage currents. If you're designing for a wet environment or require decontamination, your enclosure and sealing strategy must meet ingress protection (IP) ratings specified in the standards.

Similarly, EMC compliance (60601-1-2) isn't something you can "fix" with a few ferrite beads after your PCB is finalized. It requires careful attention to grounding, shielding, filtering, and signal routing from the very first schematic. Engage with an EMC specialist early in your design cycle, conduct pre-compliance testing on early prototypes, and iterate your design based on those results. Catching EMC issues after your hardware is locked down is painful and expensive.

Another area of early consideration is software. IEC 62304 defines the lifecycle processes required to develop safe, reliable medical device software, establishing a structured framework for planning, development, risk management, verification, maintenance, and problem resolution, ensuring that the software's essential performance is controlled and traceable throughout its entire lifecycle. Compliance isn't something you can "bolt on" at the end. It requires disciplined processes from day one: clear requirements, risk-driven architecture, rigorous documentation, version control, and continuous verification aligned with your software safety class (A, B, or C). Engage your software, quality, and regulatory teams early, build traceability as you go, and integrate risk management directly into design decisions. Trying to retrofit IEC 62304 compliance after the codebase is finished is just as painful and expensive as discovering EMC issues after your hardware is locked down.

## DOCUMENT EVERYTHING - YES, EVERYTHING

Regulators and test labs will ask for comprehensive technical documentation that ties together your essential performance definitions, risk management activities, design decisions, test results, usability evaluations, and clinical evidence.

If it's not documented, it didn't happen. Maintain design history files, risk management files, verification and validation protocols and reports, and traceability matrices that map requirements to design inputs to test results.

This documentation serves multiple purposes. It supports regulatory submissions (FDA 510(k), EU MDR technical file), provides evidence of due diligence to NRTL evaluators, and creates a knowledge base for future design iterations and troubleshooting. Treat documentation as a core engineering deliverable, not an afterthought.

# THE COMPLIANCE WORKFLOW: A STEP-BY-STEP ROADMAP

With all of this context in place, let's outline a practical workflow for navigating IEC 60601 compliance from concept to market launch. This isn't the only way to structure your process, but it represents a proven approach that minimizes risk and avoids costly surprises.

## 1. First, determine which standards apply to your device.

This means identifying the applicable general standard (IEC 60601-1), all relevant collateral standards (at minimum 60601-1-2 for EMC, and likely 60601-1-6 for usability), and the particular standard that matches your device type. Don't guess, engage with regulatory consultants or experienced test labs early to confirm your standard applicability. Element's RegNav team supports manufacturers with early regulatory framework mapping.

## 2. Second, create a detailed essential performance map.

Identify every function and characteristic that, if lost or degraded, could lead to unacceptable risk. Link these to your risk management file and define the conditions under which essential performance must be maintained (e.g., under single fault conditions, during electromagnetic disturbances, after transport and storage stress testing). This becomes your blueprint for what needs to be verified during formal testing.

## 3. Third, conduct pre-compliance activities.

Perform design reviews focused on electrical safety, run EMC pre-scans in a screening environment, conduct formative usability studies, and review your design against common failure modes seen in your device category. Pre-compliance testing is dramatically cheaper than formal testing, and catching issues here saves enormous time and money.

## 4. Fourth, select an accredited test house or NRTL and engage them early, ideally before your design is finalized.

Organizations like Element have extensive experience with IEC 60601 testing and can provide valuable guidance on test planning, sample requirements, and documentation expectations. If you're targeting global markets, confirm whether the lab participates in the CB Scheme and can issue CB Test Reports. Element can support with Global Market Access services to streamline multiple market access simultaneously.

## 5. Fifth, conduct formal compliance testing.

This includes functional safety evaluations, EMC immunity and emissions testing, mechanical and environmental stress tests, thermal safety assessments, usability validation studies per 60601-1-6, and alarm system evaluations per 60601-1-8. The test lab will follow the applicable standards methodically, and you'll need to provide samples, documentation, and technical support throughout the process.

## 6. Finally, compile your regulatory submissions.

For the US, this means your FDA 510(k) or PMA package, along with NRTL certification documentation. For Europe, it's your EU MDR technical file and Notified Body assessment materials. For Canada, it's Health Canada submissions with supporting NRTL or SCC-accredited test reports. For other markets, leverage CB Scheme certificates and reports to streamline national approvals.

Throughout this workflow, maintain close communication between your engineering, quality, regulatory, and clinical teams. IEC 60601 compliance is a cross-functional effort, and breaking down silos ensures everyone understands how their work contributes to the overall compliance story.

# BRINGING IT ALL TOGETHER

**The IEC 60601 family of standards can seem overwhelming at first glance, but when you understand the underlying structure, see how the standards interconnect, and recognize how they map to regulatory requirements in major markets, the path forward becomes much clearer.**

**The insights shared in this whitepaper underscore a fundamental truth: IEC 60601 compliance isn't a barrier to innovation.**

When approached thoughtfully and integrated early into the design process, it becomes a framework that guides you toward building safer, more reliable devices. The standards represent decades of accumulated knowledge about what can go wrong with medical electrical equipment and how to prevent those failures.

- Start with a clear understanding of your device's essential performance.
- Build risk management into your design from day one.
- Pay attention to the interactions between general, collateral, and particular standards.
- Engage with experienced test labs early.
- Conduct pre-compliance testing to catch issues before they become expensive problems.
- Document everything meticulously.
- And approach the process with the mindset that compliance is about building quality in, not bolting it on at the end.

**Done right, IEC 60601 compliance becomes more than just a regulatory checkbox. It's a powerful tool for risk reduction, design excellence, and global market access. It's how you demonstrate to regulators, clinicians, patients, and healthcare facilities that your device is safe, effective, and ready to make a positive impact on patient care.**



# WHY ELEMENT

**Element is a global leader in medical device testing, providing manufacturers with the confidence, expertise, and end-to-end support needed to bring safe, compliant electrical medical devices to market quickly and efficiently.**

With deep technical capabilities across IEC 60601 safety, EMC performance, and full lifecycle medical device testing, Element streamlines complex regulatory pathways and accelerates time-to-market.

Element offers comprehensive IEC 60601 medical electrical testing services, covering everything from early design consultation, clinical validation, to final certification. Our global network of local labs help manufacturers to simplify compliance, reduce complexity, and ensure devices meet rigorous international requirements across the complete lifecycle—from concept to clinical trial and beyond.

**Element can help in three main ways:**

- 1. Accelerated Regulatory Compliance**  
End-to-end guidance across IEC 60601, EMC, FDA 510(k), CE marking, ISO 14971, and other global standards ensures faster routes to approval and reduced certification effort.
- 2. Integrated Testing Across the Full Product Lifecycle**  
Element supports every stage, from design reviews and gap assessments to prototype testing, formal verification, and production quality control, enabling predictable, efficient development and validation.
- 3. Single-Source Expertize for All Electrical Medical Device Testing**  
With combined capabilities in safety, EMC, software, wireless, usability, risk management, and clinical validation, Element provides a unified testing experience that reduces complexity, cost, and time-to-market.

## RELATED SERVICES

- Advisory services
- Pre-compliance testing
- Safety testing (IEC 60601 & 61010)
- Wireless medical testing
- EMC testing
- Battery testing
- Medical software testing
- Clinical Validation
- Certification (FDA ASCA, FCC, Health Canada, ISED, MDR)
- NRTL accredited laboratories (US and UK)
- Global Market Access



Scan to find out more.

## WHY CHOOSE ELEMENT?

Element Connected Technologies & Mobility, is a leading provider of testing, inspection, and certification services for connected devices and mobility solutions.

**We provide comprehensive testing and certification services that ensure products meet international standards for connectivity, interoperability, and safety.**

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