

IEC 60601-1

Medical Design Standards for Power Supplies



Standards are an integral part of product design and development, and are certainly important in medical applications. While some technical standards — such as IEEE 802 for Wi-Fi — only define final performance, standards for medical design have evolved in recent years to go much deeper, covering design methodology and verification, safety and risk assessment, implementation, and much more.

In this paper we will look at the IEC 60601-1 medical standard and its impact on power supply design. IEC 60601-1 provides general requirements, in a series of standards, that address the basic safety and essential performance requirements of medical electrical equipment. We will see how the standard has evolved, through to the 4th edition that establishes new “environments” when considering electromagnetic compatibility (EMC) between medical electrical equipment and other electronic devices.

IEC 60601-1 OVERVIEW

WHAT IS IEC 60601-1?

IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment.

THE PRIMARY STANDARD

The primary standard governing medical device design is formally known as IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. More simply it is referred to as IEC 60601-1 or just “60601,” and compliance with this standard has become a de facto requirement for bringing new medical devices to market in many countries. We will look at the global adoption of the standard in more detail later, but it is worth noting that there are European (EN 60601-1) and Canadian (CSA 60601-1) versions of the standard that are identical to the IEC standard. There are also deviations from the standard that relate to country-specific requirements.

COLLATERAL STANDARDS

Within IEC 60601-1, there are “collateral” standards that are denoted as IEC 60601-1-x; for example, IEC 60601-1-2 is the EMC collateral standard mentioned above. Other collateral standards include 60601-1-3, covering radiation protection for diagnostic x-ray systems, 60601-1-9 relating to environmental design, and 60601-1-11 recently introduced for home healthcare equipment.

PARTICULAR STANDARDS

As well as collateral standards, there are also many “particular” standards, denoted as IEC 60601-2-x that define specific requirements related to particular types of products, e.g. 60601-2-16 covers blood dialysis and filtration equipment. These particular standards are largely outside the scope of this paper.

THE EVOLUTION OF IEC 60601

The IEC 60601 standard has a long history with a number of revisions. The original IEC 60601-1 for medical devices was published in 1977. The 2nd edition, published in 1988, focused on safety within the vicinity of a patient. In 2005, the IEC released the 3rd edition, which reflected a further change of perspective, looking at “means of protection” (MOP) both for patients and equipment operators. A substantial amendment to the 3rd edition, known as Edition 3.1, was introduced in 2012. This addressed numerous ambiguities arising from evolving medical equipment technology. Most recently, in 2014, a new version of collateral standard IEC 60601-1-2, “Electromagnetic disturbances – Requirements and tests,” was published. This EMC standard provides us with what is now commonly referred to as the “4th edition.”

IEC 60601-1 AND ITS RELEVANCE TO POWER SUPPLIES

The IEC 60601-1 standard has a significant impact on the product development process, going beyond performance test and verification. This is because product complexity generally yields innumerable potential test cases, permutations, and combinations in both normal and abnormal operating modes, and these cannot be assessed in the final design alone.

While power supplies by themselves are not medical devices and, are therefore, not directly covered by the IEC 60606-1 directive, they are nevertheless integral to the design and operation of medical equipment.

*FIGURE 1:
The shift to IEC
60601-1 4th edition
standards for medical
devices has significant
implications for
medical device design*



2nd EDITION - PATIENT FOCUS

The intrinsic nature of an ac-dc power supply or a dc-dc converter means the voltages and currents they provide can potentially be hazardous if not properly managed. In the context of safe operation of medical equipment, the 2nd edition of IEC 60601-1 established risk guidelines that applied when a device was within a 6-foot radius from the patient, referred to as the “patient vicinity.” Three use categories of increasing severity were defined:

- B** **Type B (body)** equipment operates within this vicinity, but without patient contact. Examples of type B equipment include x-ray machines, hospital beds, LED operating lighting, and MRI scanners.
- BF** **Type BF (body floating)** equipment makes physical contact with the patient. Examples of type BF equipment include blood pressure monitors, ultrasound equipment, and thermometers.
- CF** **Type CF (cardiac floating)** makes physical contact with the heart. Examples of type CF equipment include defibrillators and dialysis machines.

This classification determined applicable levels of isolation, insulation, creepage, clearance, and leakage as highlighted in figure 2.

FIGURE 2:
The IEC 60601-1
2nd edition “means
of protection”
classifications

2 nd EDITION REQUIREMENTS BY CLASSIFICATION			
Classification	Isolation	Creepage	Insulation
Type B	1500 Vac	2.5 mm	Basic
Type BF	3000 Vac	5 mm	Double
Type CF	4000 Vac	8 mm	Double

3rd EDITION - MEANS OF PROTECTION

The 3rd edition of IEC 60601-1 extends the patient focus to require an overall means of protection (MOP) that combines one or more “means of operator protection” (MOOP) and “means of patient protection” (MOPP). So, while the basic provisions of the 2nd and 3rd editions to guard against failure remain, the 3rd edition recognizes that the potential hazards seen by each user can be quite different; an operator has access to a control panel, for example, while the patient may be “connected” via probes.

For 2nd edition Type B use, the standard requires a device to have two isolation barriers to meet MOP requirements. However, a non-medical rated supply may be satisfactory as long as it has reduced leakage currents below 500 μ A – this meets what the 3rd edition refers to as “one MOPP” protection. 2nd edition Type BF applications need to meet the 3rd edition’s “two MOOP” and “one MOPP” requirements, and 2nd edition Type CF not only requires an IEC 60601-1 qualified supply, but must ensure an additional isolation barrier between the supply and the part that touches the patient. The latter mandate is typically met with an isolation transformer or a dc-dc converter with 8 mm creepage and double insulation - per the “two MOPP” classification shown in figure 3.

FIGURE 3:
The IEC 60601-1
3rd edition “means
of protection”
classifications

3 rd EDITION REQUIREMENTS BY CLASSIFICATION			
Classification	Isolation	Creepage	Insulation
One MOOP	1500 Vac	2.5 mm	Basic
Two MOOP	3000 Vac	5 mm	Double
One MOPP	1500 Vac	4 mm	Basic
Two MOPP	4000 Vac	8 mm	Double

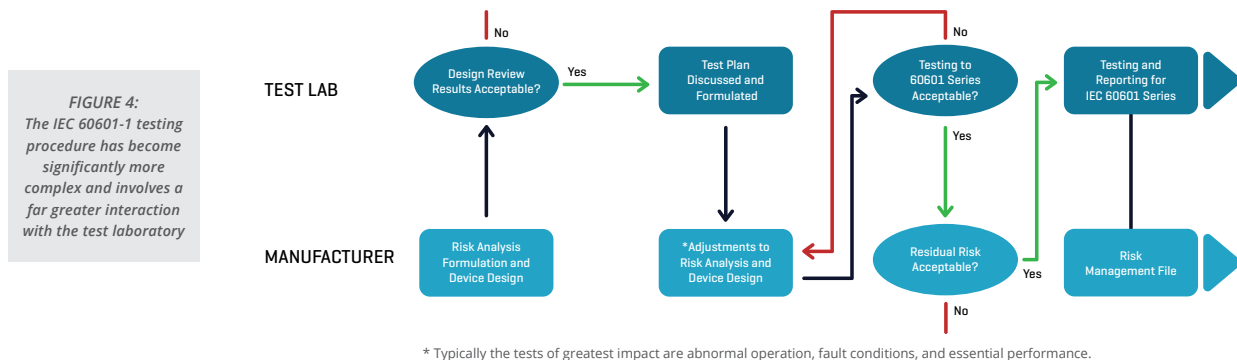
It is important to note that the changes from 2nd to 3rd edition are more a matter of definition than performance. Although determining whether a particular circuit or function falls under MOOP or MOPP categories can be difficult, a power supply that only incorporates MOOP is generally less expensive than one that also includes MOPP. However, adding MOPP later would be costly, often making it best to go with a supply that meets both criteria.

3rd EDITION – ANALYZING RISK

The above distinctions are quite specific, but the broader principle underlying revisions to the standard is one of understanding safety and managing risk. This is why the title of the 3rd edition uses the phrase “basic safety and essential performance” in place of “basic safety,” as used by the 2nd edition. Avoiding unacceptable risk in the event of failure or degraded performance or functionality is a prime objective of the 3rd edition. Hence, it requires equipment developers to establish a risk management process, determine acceptable levels of risk, and show that the remaining risk is acceptable.

The 3rd edition standard specifically calls out the Risk Management Process described in ISO 14971 that includes a risk management file where identifiable fault conditions are identified and assessed.

It also demands greater interaction between the equipment manufacturer and the test laboratory, as illustrated in figure 4. This distinguishes between the criteria established by the risk analysis and the test processes used to demonstrate compliance.



EDITION 3.1 – ADDRESSING 3rd EDITION AMBIGUITIES

60601-1 Edition 3.1 was introduced in 2012 by the IEC to address many issues identified as unclear or ambiguous in the original 3.0 standard that was released in 2005. Formally referred to as IEC 60601-1: 2005+AMD1: 2012, this updated standard includes almost 500 changes and clarifications across a spectrum of subjects, including essential performance, risk management, mechanical testing, temperature testing, and humidity testing. The amended standard also defines several new specifications for mechanical and electrical hazards.

4th EDITION – ADDRESSING EMC CONCERNS

The 4th edition expands on the risk analysis approach developed previously by delving more deeply into what we might simply call “EMC concerns.” The new IEC 60601-1-2 collateral standard describes this as, “The basic safety and essential performance of medical equipment and systems in the presence of electromagnetic disturbances and electromagnetic disturbances emitted by that equipment and systems.”

In other words, the 4th edition addresses a reciprocal concern about EMC affecting both the medical device in question and other devices in the vicinity. The purpose of this additional risk analysis is to determine appropriate levels of electromagnetic immunity, taking account of the equipment’s intended operating environment and anticipated levels of disturbances.

Part of the reason for introducing this requirement lies in the growing use of devices like smart phones, laptops, tablets, etc. that communicate wirelessly using a cellular network, Wi-Fi, Bluetooth and other wireless protocols.

In the past, it may have been possible to exclude these sources of interference from sensitive medical environments, such as hospitals, but with more and more medical equipment now intended to operate in home and other environments, that approach is no longer viable.

4th EDITION – INTENDED USE ENVIRONMENTS

Instead, the 4th edition considers immunity in terms of “intended use environments” and no longer includes the “life-supporting” equipment category, a definition which led to uncertainty about whether a particular piece of equipment needed to comply with those requirements or not. Specifically, the intended use environments are:



Professional healthcare facilities with attending medical staff, e.g. hospitals, intensive care units, and dental offices.



Home healthcare as defined in collateral standard IEC 60601-1-11, as dwelling places where patients live or are present (excluding professional healthcare facilities mentioned above). Here equipment will be used by non-specialist users and equipment must also be tolerant of poor electrical supplies.



“Special” environments that could include somewhere with high levels of electromagnetic disturbance (e.g. due to industrial machinery), or where particularly high-power medical equipment might be used (e.g. radio-therapy equipment).

Complying with the EMC requirements detailed in the 4th edition requires a number of tests as defined by other standards, including more rigorously defined ac supply conditions. The differences between the 3rd and 4th edition of the IEC 60601 standard are quite extensive, and hence, are detailed in appendix A of this white paper.

THE GLOBAL ADOPTION OF IEC 60601-1

Figure 5 on the following page illustrates the adoption timeline of 60601-1 as it relates to various territories around the globe. The following sections provide further detail.

Broadly, it is expected that manufacturers will adopt newer standards well before mandatory transition dates. Indeed, in the United States, the FDA has already accepted the 4th edition and prefers products to be tested to that standard. This includes an explicit recommendation to do so for devices intended for home use. Consequently, manufacturers intending to ship products to the US have an additional incentive to comply early. However, the same is equally true for territories that have yet to transition from previous editions of the standard.

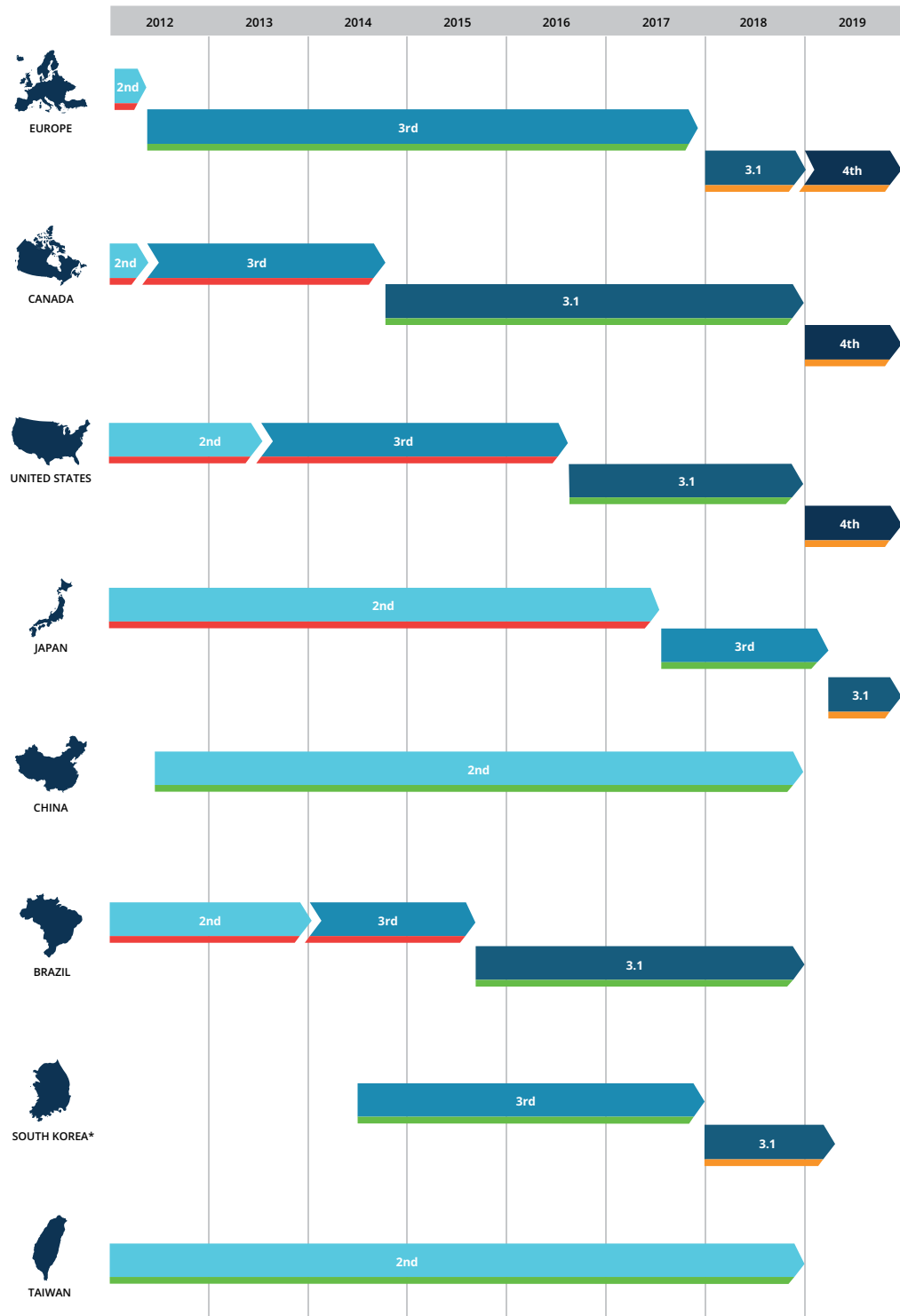
FIGURE 5:
Regional compliance
requirements. See
appendix B for
additional details

Standard:

-  2nd Edition
-  3rd Edition
-  3.1 Edition
-  4th Edition

Compliance Status:

-  Withdrawn/Superseded
-  Effective Now
-  Optional



* Implementation - date depends on product class



EUROPE

Member countries of the European Union and many other countries in Europe currently comply with the 3rd edition of the standard, known in Europe as EN60601-1:2006. This has been in force since the 2nd edition was withdrawn on June 1, 2012. However, it is set to be superseded by edition 3.1 (EN 60601-1 A1:2013) from December 31, 2017, with the adoption of the 4th edition EMC standard (EN 60601-1-2:2015) beginning on December 31, 2018.



NORTH AMERICA

The US and Canada currently require compliance with Edition 3.1 and originally targeted April 1, 2017 for compliance with the changes required by IEC 60601-1-2. This was subsequently amended to December 31, 2018 to harmonize with the EU timeline for its adoption of the 4th edition. Both new products and pre-existing products that are subject to a design change must comply with the 4th edition standard after the transition date. However, as noted above, the FDA acceptance and recommendations for testing to the 4th edition make it likely that domestic manufacturers will transition earlier than this.



THE REST OF THE WORLD

Adoption of the various revisions of IEC 60601-1 in other parts of the world is a mixed picture, with transition to the 4th edition being unclear:



Japan compliance to the 2nd edition standard was withdrawn from May 31, 2017 at which time 3rd edition became effective, although from March 1, 2019 this must be to IEC 60601-1:2005 with Amendment 1 (also referred to as edition 3.1).



China is currently aligned to 2nd edition as endorsed by its GB 9706.1-2007 standard, along with a collateral EMC standard YY 0505-2012 that became effective from January 1, 2014. Adoption of the 3.0, 3.1, and 4th edition standards has yet to be determined with no clear timeframe available for implementation.



Brazil has required compliance to Edition 3.1 of the standard since September 25, 2015 but additionally to collateral standard IEC 60601-1-9 (environmental considerations) since December 1, 2016.



South Korea has required 3rd edition compliance since June 1, 2014 for Class 3 & 4 devices, since June 1, 2015 for Class 2, and since June 1, 2016 for Class 1. It will transition to Edition 3.1 from January 1, 2018.



Taiwan requires 2nd edition compliance with 3.0 and 3.1 editions being optional.

Because of this unclear picture, equipment intended to ship internationally may require designs that can either meet more than one revision of the standard or multiple versions of the same design, all of which entails additional effort.

SUMMARY

The IEC 60601-1 standard is complex, and has become ever more complicated based on its many regional variations. The related collateral and particular standards often present additional requirements while some simply provide guidance. Knowing which you need to follow and be formally certified as complying with can be challenging, as there are many areas of conflict, confusion, and ambiguity. The lengthy timelines associated with rolling out revisions further complicates matters.

Simply shipping a medical device with basic documentation to a certification lab is no longer adequate. Comprehensive, carefully structured documentation is needed for the design analysis, the design process, and the design rationale with explanations for why certain elements were or were not included or undertaken. The increasing emphasis on risk assessment and considerations about use environments adds to this burden.

In order to help ease the compliance process for medical device designers, CUI offers a comprehensive line of external and embedded medical power supplies ranging from 6 watts to 550 watts that have been certified to IEC 60601 edition 3.1 two MOPP safety standards and 4th edition EMC standards.



View our entire line of internal and external medical power supplies

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APPENDIX A

COMPARISON BETWEEN 3rd AND 4th EDITION IMMUNITY TEST REQUIREMENTS

AC TEST VOLTAGE AND POWER FREQUENCY		
Test	3rd Edition	4th Edition
CISPR 11: AC Emissions	Nominal	Any voltage or frequency
CISPR 11: Radiated Emissions	Nominal	Any voltage or frequency
IEC 61000-3-2: Harmonics	230 Vac/50 Hz (sometimes 100 Vac/50 Hz and 100 V 60 Hz) or rated voltage	Rated single voltage or 230 Vac for single-phase 400 Vac for 3-phase, 50 or 60 Hz
IEC 6100-3-3: Voltage Fluctuations and Flicker	230 Vac/50 Hz or rated voltage	Rated single voltage or 230 Vac for single-phase 400 Vac for 3-phase, 50 or 60 Hz
IEC 61000-4-2: Electrostatic Discharge	Any voltage or frequency	Any voltage or frequency
IEC 61000-4-3: Radiated RF Immunity	Any voltage or frequency	Any voltage or frequency
IEC 61000-4-4: Electrical Fast Transients/Burst	Lowest and highest rated voltage, any frequency	Any voltage or frequency
IEC 61000-4-5: Surge	Lowest and highest rated voltage, any frequency	Any voltage or frequency
IEC 61000-4-6: Conducted RF Immunity	Any voltage or frequency	Any voltage or frequency
IEC 61000-4-8: Power Frequency Magnetics	Any voltage, 50 and 60 Hz	Any voltage, 50 and 60 Hz
IEC 61000-4-11: Voltage Dips, Dropouts & Interruptions:	Min and max rated voltage, min power frequency	If rated voltage range <25% of lowest rated voltage, any one voltage. Otherwise, lowest and highest rated voltage.

IEC 61000-4-2: ELECTROSTATIC DISCHARGE		
Test	3rd Edition	4th Edition
Contact Discharges	±2, 4, 6 kV	±2, 4, 8 kV
Air Discharges	±2, 4, 8 kV	±2, 4, 8, 15 kV

IEC 61000-4-3: RADIATED RF IMMUNITY		
Test	3rd Edition	4th Edition
Enclosures	3 V/m, Life Support: 10 V/m 80% AM at 1 kHz or 2 Hz, 80 ~ 2500 MHz	3 V/m, Home: 10 V/m 80% AM AT 1 kHz or risk frequency 80 ~ 2700 MHz
IEC 61000-4-4: ELECTRICAL FAST TRANSIENTS		
Test	3rd Edition	4th Edition
Ac Mains or Dc input	±2 kV, 5 kHz PRF	±2 kV, 100 kHz PRF
Input/Output Ports	± 1 kV, 5 kHz PRF	±1 kV, 100 kHz PRF
IEC 61000-4-5: SURGES		
Test	3rd Edition	4th Edition
Ac Mains, Line to Ground	±0.5, 1, 2 kV	±0.5, 1, 2 kV
Ac Mains, Line to Line	±0.5, 1 kV	±0.5, 1 kV
Dc Input (>3m), Line to Ground	N/A	±0.5, 1,2 kV
Dc Input (>3m), Line to Line	N/A	±0.5, 1 kV
Input/Output, Line to Ground	N/A	±2 kV [outdoor lines only]
IEC 61000-4-6: CONDUCTED RF IMMUNITY		
Test	3rd Edition	4th Edition
Ac Mains	3 V, Life Support: 10 V ISM 1 kHz or 2 Hz 80% AM 150 kHz ~ 80 MHz	3 V with 6 V ISM, Home: 6 V Amateur 80% AM at 1 kHz or risk frequency 150 kHz ~ 80 MHz
Dc & I/O & Patient Couples (>3m)	3 V, Life Support: 10 V ISM 1 kHz or 2 Hz 80% AM 150 kHz ~ 80 MHz	3 V with 6 V ISM, Home: 6 V Amateur 80% AM at 1 kHz or risk frequency 150 kHz ~ 80 MHz

IEC 61000-4-8: POWER FREQUENCY MAGNETICS

Test	3rd Edition	4th Edition
Enclosure	3 A/m, 50 and 60 Hz	30 A/m, 50 and 60 Hz

IEC 61000-4-11: VOLTAGE DIPS, DROPOUTS AND INTERRUPTIONS

Test	3rd Edition	4th Edition
Voltage Dips (16 A)	>95% dip, 0.5 periods 0° and 180° 60% dip, 5 periods 30% dip, 25 periods	100% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods
Voltage Interruptions (all input current)	>95% drop, 5 sec	100% drop, 5 sec

IEC 61000-4-3: RADIATED RF IMMUNITY, RF WIRELESS COMMUNICATIONS EQUIPMENT

Test [MHz]	Band [MHz]	Service	Modulation	Max Power [W]	Test Level [V/m]
385	380-390	TETRA 400	18 Hz pulse	1.8	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz 1 kHz sine	2	28
710	704-787	LTE Band 13, 17	217 Hz pulse	0.2	9
745					
780					
810	800-960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE BAND 5	18 Hz pulse	2	28
870					
930					
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4, 25; UMTS	217 Hz pulse	2	28
1845					
1970					
2450	2400-2570	Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7	217 Hz pulse	2	28
5240	5100-5800	WLAN 802.11 a/n	217 Hz pulse	0.2	9
5500					
5785					

APPENDIX B

REGIONAL COMPLIANCE BY COUNTRY			
Region/Country	Standard	Revision Timeline	Compliance Status
Europe	2nd Edition	prior to June 1st, 2012	Withdrawn
	3rd Edition	since June 1st, 2012	Effective now
	Edition 3.1	from January 1st, 2018	Optional
	4th Edition	from January 1st, 2019	Optional
Canada	2nd Edition	prior to June 1st, 2012	Withdrawn
	3rd Edition	since June 1st, 2012	Superseded
	Edition 3.1	since August 31st, 2014	Effective now
	4th Edition	from January 1st, 2019	Optional
United States	2nd Edition	prior July 1st, 2013	Withdrawn
	3rd Edition	since July 1st, 2013	Superseded
	Edition 3.1	since August 1st, 2016	Effective now
	4th Edition	from January 1st, 2019	Optional
Japan	2nd Edition	prior to June 1st, 2017	Withdrawn
	3rd Edition	since June 1st, 2017	Effective now
	Edition 3.1	from March 1st, 2019	Optional
	4th Edition	To be determined	Optional
China	2nd Edition	since June 1st, 2012	Effective now
	3rd Edition	To be determined	Optional
	3.1 Edition	To be determined	Optional
	4th Edition	To be determined	Optional
Brazil	2nd Edition	prior to January 1st, 2014	Withdrawn
	3rd Edition	since January 1st, 2014	Superseded
	Edition 3.1	since September 25th, 2015	Effective now
	4th Edition	To be determined	Optional
South Korea*	3rd Edition	since June 1st, 2014	Effective now
	Edition 3.1	from January 1st, 2018	Optional
	4th Edition	To be determined	Optional
Taiwan	2nd Edition	-	Effective now
	3rd Edition	To be determined	Optional
	Edition 3.1	To be determined	Optional

* Implementation - date depends on product class