Medical Devices: Diagnosing the New EMC Standard

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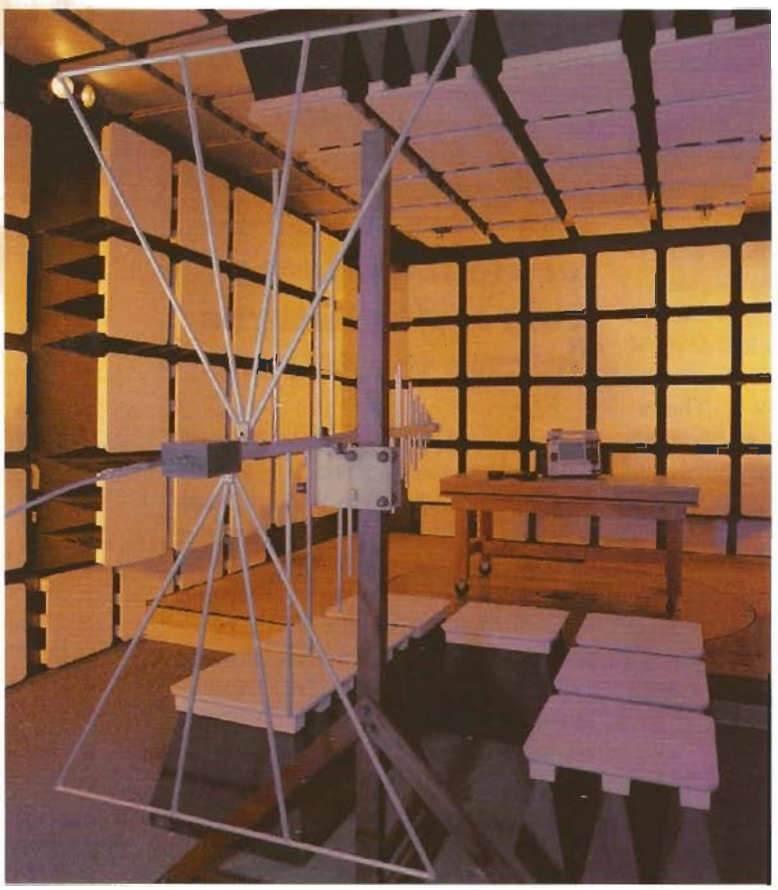
A significantly expanded electromagnetic compatibility (EMC) standard for medical devices highlights the need for risk analysis.

In September 2001, the International Electrotechnical Commission (IEC) published the second edition of IEC 60601-1-2, "General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests." This new document significantly expanded the original 15-page standard to an extensive 93-page set of electromagnetic compatibility requirements for medical devices.

In addition to being published as an IEC standard, the second edition of IEC 60601-1-2 has been adopted as a European Norm (EN 60601-1-2). Although the standard is published by two different organizations, the requirements of both the European and IEC documents are identical.



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Whether manufacturers use the IEC or the EN publication, the standard plays a crucial role in demonstrating that an electrically powered medical device complies with regulatory requirements (as did its predecessor). In the United States, the Food and Drug Administration (FDA) has officially "recognized" the new standard, and the countries of the European Union (EU) have "harmonized" it for use in demonstrating regulatory compliance. In both the United States and Europe, standards such as 60601-1-2 (harmonized or recognized standards) are specified only as "a way" of proving that a device meets regulatory requirements. Use of such standards, therefore, is not required. However, when alternative approaches are used, regulators will frequently use these standards as a benchmark.

Neither FDA nor the EU expects instantaneous upgrading of devices to the new standard. In fact, the EU will effectively allow use of the old standard until November 2004. However, the extent of the effects on products (including accompanying documents and labeling) suggests that manufacturers should begin identifying necessary changes to bring products currently in production into compliance. Manufacturers should also begin defining a strategy for implementing changes to these products as soon as possible. Manufacturers should also evaluate products currently in the development phase of the product life cycle and determine whether they should be designed to the new standard. To provide a starting point for this process, this article provides an overview of the new standard.

The requirements of IEC/EN 60601-1-2 cover three basic aspects of EMC in electrically operated medical devices. The first is the general requirements that relate to the overall device and do not directly relate to physical testing. With only four subclauses, the requirements in this category are the least extensive but were not addressed in the first edition.

The second category addresses labeling and accompanying documents. Although the first edition did contain some requirements applicable to these items, the second edition has significantly expanded the amount of documentation required, as well as the level of detail that must be provided to equipment users.

The third category addresses the technical and performance requirements to which devices will be tested. As in the first edition, this category has two subcategories: limitations on the emissions of the device and immunity of the device to electromagnetic interference (EMI). The significance of the changes in this area varies greatly, depending on the specific device in question.

In all cases, the information in this article is intended only as an overview. To identify actions required for a specific device, manufacturers must do so based on the standard itself.

General Requirements (Clause 3)

Before addressing the new requirements, it is critical to understand a fundamental principle that applies to both the first and second editions of 60601-1-2. This principle is crucial in properly evaluating equipment, especially in terms of the technical requirements for a device to be immune to the effects of electromagnetic radiation.

Although IEC/EN 60601-1-2 is an extensive document, it is not intended to be used by itself. It is, in fact, part of an entire family of standards (covering general safety, specific technologies implemented in the equipment, and specific issues related to particular devices). When used in combination, these standards are intended to ensure the overall safety of electrically operated medical equipment. The parent document (IEC/EN 60601-1) of the entire family (including 60601-1-2) establishes the baseline for applying the requirements of all standards within the family.

The current (second) edition of the 60601-1 parent document (or general standard) establishes the scope of application of all standards within the 60601 family by stating that it applies to the safety of medical equipment. This scope is reiterated in the general requirements of the standard, which states that equipment that does not comply with the letter of the standard is considered to be acceptable if "an equivalent level of safety is provided." The general standard is currently being revised, but this principle remains crucial when applying the general standard or other documents in the family.

The principle of equivalent safety has only minimal application in terms of the emission of electromagnetic energy. This is because the basis of the emission requirements is to prevent interference with the safe operation of other medical equipment and to meet internationally accepted legal requirements not to interfere with broadcast as described in Clause 3.201.1 of the EMC standard. However, the concept of equivalent safety is fundamental in determining which functions of the equipment being tested are subject to immunity requirements. Only equipment failures that present an unacceptable risk to persons, animals, or the environment are considered a violation of the requirements in the 60601 family of standards.

Closely related to this basic principle of safety is the concept of essential performance in Clause 3.201.2 of IEC 60601-1-2. Essential performance is any functional aspect of a device that, if not performed as intended, would result in an unacceptable risk (a concept introduced in the first draft of the third edition of the general standard). Some of the more obvious examples

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of essential performance include operation of a ventilator or defibrillator. Failure of a ventilator could result in suffocation of the patient. Because a defibrillator is used only in emergency situations, failure to operate could easily result in death as well. Less-obvious examples include the failure of some types of diagnostic equipment in which a failure to provide the appropriate treatment (due to incorrect information) could result in injury.

It is, therefore, critical that the first step in determining compliance with the EMC standard (or any standard in the 60601 family) is to perform a thorough risk analysis. Ideally, such an analysis should be done as part of an overall risk management process as defined in IEC/ISO 14971. It is important to note that compliance with IEC/ISO 14971 will be a requirement of the third edition of the IEC 60601-1 general standard scheduled for publication in 2005.

In testing equipment to the second edition of 60601-1-2, certification bodies will now need to make sure that the manufacturer has performed a risk analysis to (at minimum) identify the safety-related aspects of the device; otherwise, the certifier will assume that all characteristics of the equipment are safety related. Although the wording of IEC 60601-1-2 implies a responsibility on the part of certifiers to ensure that a safety-related risk analysis was performed, certifiers are not to determine the validity of the judgments made in evaluating those risks. The manufacturer remains the authority on their device and its safe use.

In Clause 3.201.4, the new EMC standard also introduces (in terms of electromagnetic compatibility) the concept of medical systems that utilize or connect to other medical devices or other nonmedical equipment, such as personal computers, during operation. Such configurations have become increasingly common in recent years. The IEC 60601-1-2 standard states that such equipment does not need to be tested for EMC compliance if it is unlikely that the nonmedical equipment will affect the essential performance of the medical equipment, or is unlikely to cause the system to exceed acceptable emissions limits.

For equipment in which this is asserted to be the case, manufacturers must provide supporting documentation. Such

documentation can include the manufacturer's risk analysis or proof that the nonmedical equipment complies with the appropriate international EMC standards. Whether medical or nonmedical, equipment intended to be connected to another medical device by supplying power, interchange of data, or even functional mechanical connections constitutes a medical system when applying the standards in the IEC 60601 family. Whether a single device or a medical system, equipment must remain safe. In the case of the EMC standard, equipment must also remain compliant with emissions limits during normal use and under any reasonably foreseeable single-fault condition.

Identification, Marking, and Documentation (Clause 6)

Increasing the amount of information to be provided to users of medical equipment presents no technical challenges to manufacturers. It does, however, place additional burdens on the design process and adds costs to the development and maintenance of a device. It is important to note that when applying the EMC standard, disclosing information on the electromagnetic characteristics of a device or system can allow significant flexibility in the physical design. Such flexibility is possible when the characteristics of a device make literal compliance with the requirements physically impossible or financially unfeasible.

Clause 6 of IEC 60601-1-2 identifies the information that must be disclosed. It addresses both information requirements for users or operators, and for installation and maintenance personnel. It covers information that must be provided through labeling (marking on the outside of the equipment) or by placement in a device's accompanying documents (instructions for use or technical description).

When equipment does not provide an option to manually adjust for gain, the instructions must specify minimum input levels.

The requirement to use the appropriate symbol on equipment incorporating intentional radiators (transmitters or equipment intended to radiate to achieve clinical results) has been retained (in Clause 6.1.201.1) from the first edition. In addition, the standard now requires (in Clause 6.1.201.3) that a warning label be placed on equipment when operation in an electromagnetically shielded location is necessary to meet the requirements of the standard. In the technical requirements of Clause 36.2.202.2, the standard has added the possibility of a technical exemption from requirements to perform electrostatic discharge (ESD) testing on input and output ports. When this exemption is exercised, a "no touch" symbol must be placed in proximity to the connector in question (per Clause 6.1.201.2).

Information provided in instructions, which is targeted to clinicians or even patients (for home-use equipment), is generally not highly technical. Clause 6.8.2.201 requires that manufacturers provide the following information in the instructions for use:

- Electrically operated medical devices require special care (in terms of EMC) when being installed. (A reference to the location of such information must be included in the technical description.)
- A warning that portable and mobile radio-frequency (RF) communications equipment can interfere with the equipment's operation.

The standard also requires that when equipment does not provide an option to manually adjust for sensitivity (or gain) of physiological signals, the instructions must specify minimum input levels and warn that failure to provide the minimum level could result in inaccurate results. The wording of this requirement can be misleading. It is important to remember that this standard addresses only EMC and is, therefore, applicable only to equipment using electromagnetic energy, such as RF, for transmission of such physiological data from the patient to the equipment. Although the scope of IEC 60601-1-2 effectively limits the application of this requirement to wireless telemetry, it would be wise to apply the principle to wired systems where appropriate.

The EMC standard (or any other IEC 60601 standard) requires manufacturers to provide a technical description that includes a significant amount of information related to installing and maintaining the equipment. The information can be provided in one of four ways:

- In a service manual.
- As a part of the instructions for use (when no service manual is provided).
- As part of the setup, installation, and maintenance documentation.
- In an appropriate combination of such documents.

It is important to keep in mind that the target audience for the technical description is the installation, service, and maintenance personnel. This includes technicians who install, maintain, and in many cases repair the equipment, and those who need the information throughout the product life cycle to maintain compliance.

To ensure ongoing compliance in terms of equipment EMC, technical personnel may require information such as identification of all cables and their lengths (where incorrect replacement could change the emissions characteristics or sensitivity to electromagnetic energy). They may also need to know specific technical characteristics of system components, accessories, or transducers that could affect EMC compliance. The extent of the information provided may be greatly reduced when specific written instructions indicate that only the manufacturer can service the equipment or provide replacement components and accessories. When determining what information will need to be provided and where it will be presented, it is imperative to focus on the purpose of the requirement (the audience, what do they need to know, and when do they need to know it).

Other information and warnings required in the technical description include:

- A warning should state that stacking or placing equipment adjacent to other devices is not recommended, and that where such configurations are necessary, all equipment in question should be carefully observed to ensure that EMI does not degrade performance.
- When manufacturers intend other equipment they provide (but which is not part of a system) to be stacked or placed in proximity to the equipment (being certified to the standard), manufacturers should describe all testing that purchasers must perform to ensure that no risks are associated with the anticipated configuration.
- If test levels lower than those specified by the standard for immunity are used (which is allowed under certain conditions), manufacturers must indicate the levels used and an explanation as to why such reduced levels were necessary.
- For equipment intended for use in shielded locations, manufacturers must list other equipment allowed and prohibited from use within the shielded area.
- If the equipment generates RF energy to produce clinical effects (diagnosis or treatment), instructions for avoiding or alleviating disturbances to other medical equipment must be provided.
- Where the equipment receives electromagnetic energy in order to perform its intended function (such as wireless telemetry), each frequency or reception band used and, where applicable, the preferred frequency or band must be identified. A warning must indicate that emissions from other equipment may prevent correct operation of the device.
- For devices that incorporate RF transmitters, the frequency or frequencies and band or bands of transmission must be identified. In addition, the characteristics of the modulation and effective radiated power must be given.
- For equipment or systems in which the risk analysis has determined that the failure to perform any intended function or the degradation of such a function does not constitute an unacceptable risk (i.e., there are no essential performance characteristics) and in which possible failure modes (caused by electromagnetic disturbances) will not result in an unacceptable risk, a statement must be included indicating that testing for immunity has not been performed. This statement will replace Tables 202 through 208 described below.

Most standards in the IEC 60601 family generally avoid defining the format of information. The EMC standard, however, does specify the format of tables that are to be included (where appropriate) in the technical description. These tables define:

- Emissions characteristics of the equipment or system (Table 201).
- Equipment or system sensitivity to ESD (Table 202).
- RF immunity of life-support equipment or system (Table 203).
- RF immunity of non-life-support equipment or system (Table 204).
- Recommended separation distances between life-support equipment or system and portable or mobile RF communications equipment (Table 205).
- Recommended separation distances between non-life-support equipment or system and portable or mobile RF communications equipment (Table 206).
- RF immunity of life-support equipment or system that is specified for use in shielded locations (Table 207).
- RF immunity of non-life-support equipment or system that is specified for use in shielded locations (Table 208).

In each case, the standard provides both text and flowcharts that define how the information required in the tables is determined. For equipment or systems that do not provide essential performance and where no unacceptable risk is associated with possible failure modes, Tables 202–208 need not be provided.

Technical Requirements (Clause 36)

The technical requirements category includes two subcategories. The first addresses limits on the emissions (for electromagnetic energy radiated through the air or conducted through the power or mains connection) of electromagnetic energy by the equipment or system. The second subcategory sets requirements related to how the equipment or system reacts to the electromagnetic environment (immunity).

Simple medical equipment that includes no circuitry operating at greater than 9 kHz may be tested under CISPR 14.

Emissions (36.201). For the most part, the allowable emissions levels under the second edition of IEC 60601-1-2 have been left unchanged from those of the first edition. This is because the emissions limitations are primarily based on requirements written by the International Special Committee on Radio Interference (CISPR). The requirements are implemented in the national law of participating countries based on international treaty.

Under both editions of the medical device EMC standard, most medical device emissions are required to be in compliance with CISPR 11 (emissions limits for industrial, scientific, and medical equipment). However, under the second edition, simple medical equipment (not systems) that includes no circuitry operating at greater than 9 kHz may be tested under CISPR 14 (emissions limits for household appliances and tools).

Medical lighting equipment may be classified and tested according to CISPR 15 (lighting), and information technology equipment (ITE) that is either intended to be connected to the device or is part of a system may be classified and tested to CISPR 22 (ITE emission requirements). For equipment or systems specified for use in electromagnetically shielded environments, the appropriate limits of CISPR 11 may be increased

(made less stringent), but when this is done, the levels used must be disclosed in the technical description (as described previously).

For equipment being classified and tested to CISPR 11 or 22, the most important determination is whether the equipment falls under Class A (industrial environments) or Class B (domestic environments). The higher (less stringent) limits of Class A are intended to be used for equipment that will be operated in environments such as hospitals, where the likelihood of negative effects to public broadcasts are unlikely and where the mains supply (ac wall voltage) is likely to be isolated from the public distribution network. Class B limits are more restrictive because the levels of electromagnetic isolation in such areas are unreliable.

In addition to the requirements of the identified CISPR standards, IEC 60601-1-2 adds two requirements addressing issues related to conducted emissions for devices that are rated to draw ≤16 A per phase and are intended to be connected to the public mains power distribution network. Neither of these requirements was included in the first edition.

The requirements in question address harmonic distortion, voltage fluctuations, and flicker generated by the device on the mains power connection (power cord). These requirements can be of particular concern for manufacturers incorporating switch-mode power supplies and some types of ac motors. Such systems can cause distortion in the ac waveform or very-short-term voltage drops that are reflected back into the power lines. These reflections can cause interference in some radios and televisions that are also connected to the same mains network. Addressing harmonics in medical equipment used outside of hospitals and similar locations where isolation from the public distribution network does not exist requires a delicate balancing of harmonics and leakage current limits (established in the IEC 60601-1 general standard) if filter capacitors (to earth) are used to reduce the distortion.

The first edition included requirements for ESD testing, but the second edition has raised the bar quite a bit.

Immunity (36.202). The most important question related to immunity testing relates to determining which aspects of the medical device or system are subject to the requirements. As explained in the discussion of the general requirements, this determination is made by evaluating the equipment to identify which functions and aspects of the design could give rise to hazards that could result in unacceptable risks. Only risk-related aspects of the device or system identified during the risk analysis are required to be immune from the EMI identified in Clause 36.202.

Another aspect of the IEC 60601-1-2 standard that should be carefully considered is that the levels of interference to which it requires immunity are based on a typical healthcare environment. This condition means that when the equipment is intended for use in other environments, it may be appropriate to increase or decrease the levels of interference used to test immunity. Annex EEE of the standard attempts to provide insight into levels found in some of these other environments. Additionally, Clause 36.202.1 provides guidance on many aspects of performing testing for immunity.

During immunity testing, equipment is exposed to several types and levels of EMI, including ESD; RF; electrical fast transients (EFTs) and bursts; power-line surges; conducted RF disturbances; voltage dips, interruptions, and variations on power input lines; and power-frequency magnetic fields.

ESD. The first edition of the standard included requirements for ESD testing, but the second edition has raised the bar quite a bit. Where the old standard required that the equipment be exposed to air discharges of 8000 V and contact discharges of 3000 V (both positive and negative polarity), the new version requires air discharges of 2000, 4000, and 8000 V (both polarities) and contact discharges of 2000, 4000, and 6000 V (both polarities). As mentioned during the review of Clause 6, it is possible for some connectors to be exempted from ESD testing if appropriate labeling and disclosure requirements are met.

RF. The second edition expands RF immunity requirements in three areas. First, the highest frequencies used are increased from 1.0 to 2.5 GHz. The second important change is the modulation of the signal to which the equipment is exposed. The first edition required that the signal be amplitude modulated at 1000 Hz. The second edition requires equipment that controls or monitors physiological parameters (e.g., heart rate) be modulated at 2 Hz (closer to the frequencies of such biological parameters). Equipment that does not fall into this category is tested at a modulation frequency of 1000 Hz. The first edition did not specify the modulation level; however, the new standard sets it at 80%. Finally, equipment such as ventilators or other life-support equipment must now be tested for immunity to RF at a field strength of 10 V/m; all other equipment is still tested at 3 V/m. As with ESD, the second edition allows the RF field-strength levels used for testing to be eased under certain conditions (e.g., when the device is to be used only in shielded locations).

EFTs and Bursts. The second edition of the standard has increased the test levels for EFTs and bursts from 1 kV for equipment with power cords and plugs, and 2 kV for permanently installed equipment, to 2 kV for all mains connections (including power cord–connected equipment). Test levels for interconnecting cables greater than 3 m in length have also increased from 0.5 to 1 kV.

The new standard has also added significant detail in terms of test configurations for equipment with patient connections, that is, any conductive connection to the patient, although they are now specifically exempted from the application of EFT either conductively or through the capacitive clamp. Although EFT has not been a significant source of failures for most equipment, the doubling of the interference for all but power connections of permanently installed equipment may cause problems for sensitive equipment that has many functions deemed as essential performance.

Power-Line Surges. The most notable change related to surge testing in the new revision of IEC 60601-1-2 was to actually make a common practice for EMC certification bodies under the old standard a requirement in the second edition. That practice was to test not only at 2000 V between power (input) lines and the equipment's ground connection but also at intervals of 500 and 1000 V as now specified in the second edition. Surge tests between power (input) conductors are now also conducted (as was previously practiced, but not strictly required) at 500 and 1000 V.

Conducted RF Disturbances. The second edition introduces requirements and tests for these conditions, which were identified only as "under consideration" in the first edition. As with radiated RF fields, the conducted RF immunity tests require a signal strength of 10 V/m for life-support equipment and 3 V/m for all other categories. The test signal is swept from 150 kHz (for all but some types of battery-powered equipment) through 80 MHz.

Voltage Dips, Interruptions, and Variations on Power Input Lines. As is the case for many other types of interference, the second edition adds these requirements where the first only referred to them as "under consideration." This section requires that equipment remain safe during and after voltage dips (in mains voltage) of 95% (dropping mains down to only 5% of nominal) for a duration of ½ cycle, 60% (mains at 40% of nominal) for 5 cycles, and 30% (mains at 70% of nominal) for 25 cycles. Equipment is also expected to remain safe when mains voltage is dropped to 5% of nominal and then restored after 5 seconds.

The second edition also requires that systems with battery backup return to operation from mains after the tests. However, if this last requirement is viewed in light of risk, it is clear that the requirement is valid only if 1) the user were not made aware of the fact that the system was operating on battery power and 2) the available charge might not allow clinicians to take reasonable actions to prevent any unacceptable risk.

Power-Frequency Magnetic Fields. The first edition of IEC 60601-1-2 contained no specific requirements for magnetic-field immunity. The second edition, however, requires that the equipment remain safe when exposed to magnetic field strengths of 3 A/m at both 50 and 60 Hz (even if powered internally) unless the equipment is intended for use only where one of the two power frequencies is available (e.g., equipment intended only for sale in Europe would be tested only at 50 Hz.). The standard specifically allows testing to be performed with the equipment powered at any allowable mains voltage level.

Conclusion

Although the second edition of the IEC 60601-1-2 standard undoubtedly provides significantly more information (both in the normative text and annexes) than its predecessor, the way the information is presented can easily become confusing. The new standard correctly points out that only safety-related failures of the equipment are of interest in some of the immunity clauses. Other clauses, however, seem to indicate that any deviation (regardless of the relation to safety) from normal operation is a failure. This complexity and lack of clarity increases the possibility that those testing a product could incorrectly identify failures if adequate documentation is not provided before testing.

The importance of the risk analysis in defining the acceptance criteria for the testing cannot be overstated. In preparing to have a product tested, the first step should be to identify which aspects of the equipment's operation qualify as essential (safety-related) performance and which EMC-initiated failures could result in unacceptable risk. Stated succinctly, manufacturers must determine which equipment operations must be maintained and which cannot self-actuate in order to ensure safety.

It is also crucial—both in terms of efficient testing and safety of the equipment—for a manufacturer to understand the electromagnetic environment in which the equipment or system will be used. Annex EEE provides some insight into this issue and can prove quite helpful in understanding it. In fact, the standard provides a great deal of background information that is helpful in applying it to equipment. Annex AAA attempts to explain the rationale for nearly every requirement in the standard. Annex BBB contains examples of the tables that

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are required in the technical description. The intended audience of Annex DDD is actually the writers of device-specific standards (called "particular" standards); however, where no such standard exists, this section may provide some help to manufacturers in applying the EMC standard.

It is now more critical than ever that medical device manufacturers thoroughly think through and document their strategies for EMC compliance. In particular, it is essential that they bring the test house and certification body into the loop early. Failing to do so will almost certainly mean that EMC testing and certification will be far more costly and time-consuming than it needs to be. Taking the time to document the information needed before contacting an EMC test house will prove to be a valuable investment. Such information includes essential performance characteristics, electromagnetic environment, typical configurations of the equipment, and block diagrams identifying the operating frequencies of subsystems. Providing this information to the test house as early as possible in the design process will prove equally valuable. (Many test houses even provide EMC design review services.) This documentation process has always been important, but the second edition of IEC 60601-1-2 makes it critical.

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