Contains Nonbinding Recommendations

Electromagnetic Compatibility (EMC) of Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 6, 2022.

The draft of this document was issued on November 17, 2020.

This document will supersede "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices," issued July 11, 2016, 1 year after the publication of this guidance for in vitro diagnostics and 60 days after the publication of this guidance for other device types within the scope of this guidance.

For questions about this document, contact the Office of Science and Engineering Laboratories (OSEL) at OSEL_CDRH@fda.hhs.gov or (301) 796-2530; the Division of Biomedical Physics, OSEL at (301) 796-2580; or Seth Seidman at (301) 796-2477 or by email at seth.seidman@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2015-D-3787. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1400057 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

Table of Contents

I. Introduction 4
II. Scope 5
III. Overview 5
IV. EMC Information for Premarket Submissions 6
A. EMC-Related Device Characteristics and Intended Use Environments 7
B. Assessment of Medical Device Risks 8
C. Consensus Standards 8
(1) Non-implantable Medical Devices 9
(2) Active Implantable Medical Devices (AIMDs) 10
(3) Special Environments 11
D. Essential Performance and Immunity Pass/Fail Criteria 11
(1) Essential Performance 11
(2) Immunity Pass/Fail Criteria 12
E. Medical Device Configuration and Functions Tested 13
F. Results of EMC Testing 15
G. Allowances 15
H. Deviations 15
I. Modifications 16
J. Common Electromagnetic (EM) Emitters 16
K. Labeling 17
V. EMC Information to Support Investigational Device Exemption (IDE) or Investigational New Drug (IND) Submissions 19
Appendix A – Examples of Typical Medical Device Locations within Intended Use Environments 20

Electromagnetic Compatibility (EMC) of Medical Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) has developed this guidance document to recommend information that should be provided in a premarket submission (i.e., premarket approval (PMA) application, humanitarian device exemption (HDE), premarket notification (510(k)) submission, investigational device exemption (IDE), De Novo request, and certain biologics license application (BLA) and investigational new drug (IND)[1]) to demonstrate electromagnetic compatibility (EMC) for electrically-powered medical devices and medical devices with electrical or electronic functions. Typically, the review of EMC information in a submission is based on the risk associated with malfunction or degradation of the medical device under consideration, where malfunction or degradation could be caused by inadequate EMC. The review is also based on the use of appropriate consensus standards. This guidance, when final, will replace the FDA guidance, "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices" (hereafter referred to as the 2016 EMC guidance), published July 11, 2016. This guidance provides additional technical information to address the recommendations in the 2016 EMC guidance. Throughout this guidance, the terms "FDA," "the Agency," "we," and "us" refer to the Food and Drug Administration and the terms "you" and "yours" refer to medical device manufacturers.

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information

[1] INDs and BLAs for devices that are regulated as biological products under section 351 of the Public Health Service (PHS) Act.

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[3]

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope

This guidance applies to medical devices, including in vitro diagnostic products,[4] and accessories[5] that:

- are electrically-powered; or
- have functions or sensors that are implemented using electrical or electronic circuitry.

FDA recognizes and anticipates that the Agency and industry may need up to 1 year to perform activities to operationalize the policies within the guidance, only for in vitro diagnostic products. Since this guidance generally reflects current practice for the assessment of EMC for other device types, but some activities to fully operationalize the policies are needed (e.g., updates to eSTAR[6]), FDA intends to implement this guidance 60 days after issuance for device types within the scope of this guidance, excluding in vitro diagnostic products. If new information regarding electromagnetic compatibility as outlined in this guidance is not included in a premarket submission for an in vitro diagnostic received by FDA before or up to 1 year after the publication of this guidance or for other device types within the scope of this guidance before or up to 60 days after the publication of this guidance, FDA does not generally intend to request such information during the review of the submission. FDA does, however, intend to review any such information if submitted.

III. Overview

For the purpose of this document, EMC is defined as the ability of a medical device to function safely and effectively in its intended electromagnetic (EM) environment, including immunity to

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

[4] See 21 CFR 809.3(a)

[5] For more information, see "Medical Device Accessories - Describing Accessories and Classification Pathways: Guidance for Industry and FDA Staff" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-accessories-describing-accessories-and-classification-pathways and "Medical Device Accessories" at https://www.fda.gov/medical-devices/classify-your-medical-device/medical-device-accessories

[6] Available at https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program

EM disturbances (i.e., interference)[7], without introducing excessive EM disturbances (i.e., emissions) that might interfere with other equipment. Immunity is the ability to protect against unacceptable degradation due to EM disturbances such as radio waves, power surges, radiofrequency (RF) disturbances, and electrostatic discharge (ESD). Interference can cause medical devices to not perform as intended and lead to hazardous situations, such as delays or errors in diagnosis, treatment, or monitoring that can result in serious injury or death. Emissions limits are established to protect radio services and minimize interference to other equipment, both medical and non-medical.

The IEC 60601/80601[8] series of standards applies to medical devices and systems that directly apply or transfer energy to the patient, and the IEC 61010-1 standard applies to electrical laboratory equipment. These standards are used in the majority of premarket submissions for electrically-powered medical devices to support device safety. These standards attempt to address all hazards (e.g., mechanical, electrical, radiation). Besides addressing the wide range of generic safety requirements, the IEC 60601/80601 and IEC 61010 series include close to 100 "particular standards" with safety requirements for specific types of devices, such as clinical thermometers, infusion pumps, infant incubators, laboratory centrifuges, medical device sterilizers and reprocessors, and medical washer-disinfectors. There are also consensus standards for active implantable medical devices that include information on EMC.

For electrically-powered medical devices and medical devices with electrical or electronic functions, you should provide evidence that the medical device is safe and performs as intended in the environments of use. This evidence includes risk management with regard to EM disturbances, testing, and labeling, as recommended in this guidance. To facilitate premarket submissions and reviews for EMC, we recommend you include the information listed in Section IV. Section V contains additional information specific to IDE or IND submissions.

IV. EMC Information for Premarket Submissions

To facilitate the review of EMC information in premarket submissions, we recommend you include the information listed in subsections A-K below in the EMC section of the submission, labeled with the section headings in the same order as they are listed in this guidance. If test reports or test report summaries (e.g., Accreditation Scheme for Conformity Assessment Summary Test Report[9]) or other sections of the premarket submission include any of the

[7] To harmonize with international definitions, this document will use the word "disturbance" as the cause (per IEC 60601-1-2) and "interference" as the effect (per IEC 60050). In the US, "interference" is often used interchangeably for both cause and effect.

[8] In this document, the reference to the IEC 60601/80601 series of standards includes the ANSI/AAMI ES 60601-1, the IEC and US adopted collaterals [60601-1-xx], the IEC 60601-2-xx, and the IEC or ISO 80601-2-xx particulars.

[9] For more information, see the FDA guidance: "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program and "Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and

recommended information below, the specific location within these documents should be noted in the EMC section of the submission.

A. EMC-Related Device Characteristics and Intended Use Environments

We recommend that you provide a description of all EMC-related device characteristics and intended use environments including:

- an overview of the device and its functions and modes, including block diagrams, photographs, cables, relevant accessories, and device interoperability;
- a description of the power supply (i.e., mains-powered only, internally-powered only, mains and internally-powered) including if the internally-powered medical device can be used while charging;
- a statement regarding the environments in which the medical device is intended to be used (see Appendix A);
- a description of any wireless technology (for additional considerations regarding wirelessly-enabled medical devices, refer to FDA guidance, Radio Frequency Wireless Technology in Medical Devices[10]); and
- a description of any intentional RF emitters in the medical device that could be sources of EM disturbances.

Specifying the intended use environments provides important information to determine the appropriate testing for expected EM disturbances. For the purposes of this guidance and EMC evaluation, we categorize the intended use environments into one (or more) of the following environments:

- Professional Healthcare Facility Environment: any environment where personnel with medical training are continually available to oversee or administer the use of medical devices. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, limited care facilities, emergency medical services, clinics, physicians' offices, outpatient treatment facilities, and clinical laboratories.
- Home Healthcare Environment: any environment where personnel with medical training are not continually available to oversee or administer the use of medical devices. This includes, but is not limited to, outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes.
- Special Environment: any environment with EM characteristics different from those specified in EMC consensus standards. This includes, but is not limited to, aircraft, military areas, heavy industrial areas, medical treatment areas with high-powered medical devices such as magnetic resonance imaging (MRI).

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.

See Appendix A for examples of typical medical device locations for each of the three intended use environments mentioned above.

When considering the intended use environments, we recommend addressing common EM emitters and unique medical emitters. These emitters are listed and discussed in detail in Section IV.J below.

B. Assessment of Medical Device Risks

We recommend that you provide a summary description of the risks associated with malfunction, disruption, or degradation of the performance of the subject medical device due to EM disturbances. This should include each potential malfunction, disruption, or degradation due to electromagnetic interference (EMI) that could cause harm to the patient, user or operator. This summary should categorize the severity of each harm into the following three levels based upon the FDA guidance, "Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions Guidance for Industry and FDA Staff"[11]:

- Medical device-related deaths and serious injuries[12] include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to a death or injury or illness that is life-threatening, results in permanent impairment or damage to the body, or requires medical or surgical intervention to prevent permanent harm to the body.
- Medical device-related non-serious adverse events include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to minor, temporary or medically reversible injuries that do not meet the criteria for classification as a medical device-related serious injury.
- Medical device-related events without reported or potential harm include medical device nonconformities that have no related harm, medical device malfunctions that have no related harm, and procedure-related complications with no related harm.

These considerations should be used in determining the immunity pass/fail criteria (see Section IV.D) and in addressing EMI caused by common EM emitters (see Section IV.J). For the 60601 series of standards, a risk analysis is used to determine the Essential Performance,[13] upon which the immunity pass/fail criteria are based, as well as other aspects of EMC testing (e.g., additional modulation frequencies).

C. Consensus Standards

We recommend that you provide a summary describing all voluntary consensus standards used to evaluate EMC. When applicable, we recommend that EMC tests be performed

[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-regarding-benefit-risk-medical-device-product-availability-compliance-and

[12] See 21 CFR 803.3(w)

[13] Essential Performance is a defined term from ANSI/AAMI/ES 60601-1:2005 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*. See Section IV.D below for more details.

using methods described in FDA-recognized consensus standards that are appropriate for the medical device. If you chose to declare conformity to a standard, we recommend providing the supporting information described in this guidance and consistent with the FDA guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[14] The extent of FDA recognition of a consensus standard is included in the Supplemental Information Sheet (SIS) published in the FDA Recognized Consensus Standards Database.[15] The "Extent of Recognition" section of the SIS can specify an acceptable deviation or non-recognized clauses from the published standard. The "Transition" section of the SIS can specify the date when recognition of one edition of a standard is superseded by the next edition. A cleared or approved device does not need to be assessed or submitted again as a result of any changes to an FDA-recognized EMC consensus standard.[16]

If the consensus standard(s) referenced in the submission are not recognized by FDA,[17] sufficient justification should be provided regarding how the EMC testing performed adequately addresses EMC, based on the medical device's functions, modes, indications for use, intended use, and intended use environments. If no consensus standard exists for a certain medical device type, we recommend specific EMC testing be performed based on foreseeable EM disturbances in the intended use environments. We recommend referencing an existing FDA-recognized consensus standard for a similar medical device type and environment and modifying the test specifications in the standard to address the subject medical device. Each change in test specification should be documented and accompanied by justification.

When using consensus standards, we recommend verifying that the intended use environments are adequately addressed by the standards. Many consensus standards only address and specify test levels for the home healthcare environment and the professional healthcare facility environment.

The medical device configuration and intended use environments can determine the applicability of FDA-recognized consensus standards for EMC. These can be generalized into one or more of the following three categories:

(1) Non-implantable Medical Devices

The ANSI/AAMI/IEC 60601-1-2 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard:*

---

[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

[15] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[16] For more information, refer to Section VIII of the FDA guidance, When Devices or Standards Change After Marketing Authorization, of the "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" guidance available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

[17] For more information on use of consensus standards that are not FDA-recognized, refer to Section IV B. General Use of the "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" guidance.

Electromagnetic disturbances – Requirements and tests is a collateral standard to the ANSI/AAMI ES 60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* standard and is recognized by FDA for testing of non-implantable medical devices that are within its scope. The 60601-1-2 consensus standard provides details about testing medical devices for safety with regard to EM disturbances based on the Basic Safety[18] and Essential Performance of the medical device, the medical device design, and the intended use environments.

When using any consensus standard, careful consideration to the scope is critical. For example, the scope of 60601 standards is limited to medical device safety. Evaluation of medical device effectiveness is generally not within the scope of 60601 standards. This is discussed in detail in subsection D(2) below.

There are over 80 particular consensus standards (e.g., IEC 60601-2-X, ISO 80601-2-X) that cover a wide variety of medical devices. These particular consensus standards augment or supersede the specifications in 60601-1-2 and can provide more detailed or alternative EM test specifications. However, not all particular consensus standards are FDA recognized at the time of this guidance publication, and the EMC specifications in these particular standards should be assessed to ensure that they are appropriate for the medical device's functions, modes, indications for use, intended use, and intended use environments.

Most laboratory equipment and in vitro diagnostic devices (IVDs) are outside the scope of 60601-1-2. At the time of the issuance of this guidance, we partially recognize IEC 61326-1:2020 and IEC 61326-2-6:2020 and recommend using the test methods from these standards. However, we recommend using acceptance criteria specific to the device's functions and intended use. Additionally, we recommend using test levels specified by 60601-1-2 or, alternatively, determining the reasonably foreseeable maximum levels of the electromagnetic phenomena in the device intended use environments (e.g., through study of published literature or environmental measurements).

(2) Active Implantable Medical Devices (AIMDs)

AIMDs are outside the scope of 60601-1-2. However, for AIMD systems, we recommend that the non-implantable subsystems (e.g., pacemaker programmer) be tested to consensus standards appropriate for non-implantable devices (e.g., 60601-1-2). Consensus standards such as ISO 14117 *Active implantable medical devices -- Electromagnetic compatibility -- EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices* and the ISO 14708 series are often referenced to address EMC for AIMDs.

EMC consensus standards for AIMDs focus on EM phenomena to address the immunity of the medical device. The ISO 14708 Series and ISO 14117 standards assess AIMD

[18] Basic Safety is defined in ANSI/AAMI/ES 60601-1:2005 as "freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION."

performance when exposed to commonly encountered EM sources as well as particular sources that an implantable device is likely to encounter. For example, cardiac implantable electronic device consensus standards (e.g., ISO 14117) include immunity testing for exposure to defibrillation devices, which inject high-energy electrical signals into the heart for life-saving functions.

(3) Special Environments

It is important to understand the scope and limitations of each standard. For example, 60601-1-2 is generally applicable to both the home healthcare environment and the professional healthcare facility environment. However, if a medical device is intended to be used in a special environment, we recommend that you provide additional EMC information and perform testing for the given special environment. This could be achieved by referencing appropriate standards for each special environment. For example, we recommend immunity testing to RTCA DO-160 *Environmental Conditions and Test Procedures for Airborne Equipment* for non-implantable medical devices that are intended or expected to be used in an aircraft environment. Note that some AIMD consensus standards do not specify EMC test parameters for use in a magnetic resonance imaging (MRI) environment (e.g., exposure within the bore of an MRI system). Where an applicable AIMD standard does not specify such requirements, we recommend test methods specific to this potentially high-risk environment, such as those described in ISO/TS 10974 *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*.

D. Essential Performance and Immunity Pass/Fail Criteria

We recommend that you provide clear immunity pass/fail criteria, and, if applicable, a clear statement of the device's Essential Performance. The Essential Performance and immunity pass/fail criteria are fundamental to performing and assessing the adequacy of EMC testing to demonstrate that the medical device is safe and performs as intended.

(1) Essential Performance

Essential Performance is defined in ANSI/AAMI/ES 60601-1:2005 as "performance of a clinical function, other than that related to Basic Safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk. Note: Essential Performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk." If you reference 60601-1-2, 60601-2-X, or 80601-2-X, you should specify the Essential Performance of the medical device. Essential Performance should be specific to each medical device and be determined by you by assessing the risk to the patient. The Essential Performance should be determined by:

- identifying the performance of the clinical functions,
- specifying performance limits for fully functional performance versus loss or degradation of the identified performance, and

- evaluating the risk from the loss, disruption, deviation, degradation, or over-delivery of the identified performance.

If the resulting risk is determined to be unacceptable, then the identified performance is Essential Performance.

It is also possible for a medical device to have no Essential Performance. A determination of no Essential Performance should be accompanied by scientific justification and risk analysis. Even for medical devices that have no Essential Performance, appropriate immunity pass/fail criteria should be used to demonstrate that the device is safe and performs as intended.

See informative annex "General guidance and rationale" of ANSI/AAMI ES 60601-1 and Clause 2.3.4 of AAMI CR500:2019 *Basic Introduction to the IEC 60601 Series* for additional information regarding Essential Performance.

(2) Immunity Pass/Fail Criteria

Immunity pass/fail criteria should address the degradation of the medical device's functions caused by the test disturbance. Your EMC test plan should specify which degradations are considered acceptable. Acceptance criteria should be documented in the EMC test plan prior to testing. We recommend that you specify detailed immunity pass/fail criteria that are (1) quantitative, (2) specific to the medical device and functions, and (3) observable. These criteria should be determined based on the medical device's functions, modes, indications for use, intended use, and Essential Performance (if applicable). If a medical device has multiple medical device subsystems (e.g., an AIMD with active external parts) or more than one function (e.g., a ventilator with physiological monitoring), then each medical device subsystem or function can have specific immunity pass/fail criteria. We recommend that you specify how the immunity pass/fail criteria were derived, quantified, and monitored, and justify how they demonstrate that the medical device remains safe and performs as intended.

Immunity pass/fail criteria can be different for transient EM phenomena and for continuous EM phenomena. Transient phenomena include ESD, electrical fast transients/bursts, surges, and voltage dips and interruptions. Continuous phenomena include conducted and radiated RF disturbances and power-frequency magnetic fields. For transient phenomena, it might be acceptable that the medical device provides the specified performance after application of the test disturbance. A recovery time can be acceptable and should be specified based on the risk analysis. For continuous phenomena, the medical device should provide the specified performance during and after application of the test disturbance.

Some EMC test standards list general examples of immunity pass/fail criteria for a medical device or general descriptions of immunity pass/fail criteria (e.g., Performance Criterion A, Operates as Intended). However, these general immunity pass/fail criteria are not sufficiently specific to the medical device's functions, modes, indications for use, intended use, and Essential Performance (if applicable). Even devices with the same

hardware could have different immunity pass/fail criteria. For example, immunity pass/fail criteria for a ventilator for adult patients would be expected to be different from that for neonatal patients because of the different physiological characteristics of the intended use populations.

If a submission references a standard in the 60601 family of standards, then the immunity pass/fail criteria should address both Basic Safety and Essential Performance. Many particular standards (e.g., 60601-2-X) specify the Essential Performance and some specify immunity pass/fail criteria. As noted in subsection C(1) above, the scope of 60601 standards is limited to safety (i.e., Basic Safety and Essential Performance). Therefore, we recommend that the immunity pass/fail criteria include considerations to demonstrate that the device performs as intended. We recommend conforming to IEC TR 60601-4-2 *Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems* to assess the immunity of the performance associated with the intended use because the test methods are similar to 60601-1-2 and can be tested at the same time.

See IEC 60601-1-2 informative annex "Identification of IMMUNITY pass/fail criteria" for additional information and examples on determination of specific immunity pass/fail criteria.

E. Medical Device Configuration and Functions Tested

We recommend that you provide a detailed description of the medical device under test, including the configuration, functions, modes, and settings that were tested. We recommend testing functions and modes that include a feature or control such that the failure or malfunction would most likely result in an unacceptable risk or to not achieve its intended use. The description of the device under test should include the medical device name, model number, manufacturer, and an indication of whether the device is the final production-ready medical device currently under review.

We recommend you perform testing on the final finished device. If the device tested is not the final finished device, the description of the device under test should include an explanation and a scientific justification of how test results are applicable to the final finished device. When leveraging EMC test results from a prior or different medical device model/version to another model/version, we recommend that you:

- identify and summarize all modifications or changes from the previously tested medical device and include any changes in the medical device's indications, intended use, and intended use environments,
- provide an analysis of whether each modification could affect EMC of the medical device, and
- assess whether the consensus standard used for the prior EMC testing has been superseded/replaced by a revised version.

New EMC testing should be performed if any of the analyses of the device differences indicate that the prior testing might not support the EMC of the updated medical device

model/version. We also recommend applying these considerations when you perform EMC testing on only a subset of models within a product family.

We recommend that you consider the following to help determine the appropriate device configuration(s) for testing:

- The device should be tested as a system with all medical device accessories, components, and subsystems connected and functioning as intended. If non-medical equipment is used in a medical system and could affect the ability of the medical device to meet the immunity pass/fail criteria, the non-medical equipment should also be tested as part of the medical device system. Examples of non-medical equipment include mobile phones, tablets, and computers. Any non-medical equipment, medical device accessories, or subsystems not included in the EMC test should be listed with a rationale for why they were not tested. You should provide a scientific justification for how the test configuration demonstrates EMC of the entire medical device system.
- If a medical device has multiple subsystems or accessories (e.g., a left ventricular assist device (LVAD) that includes an implantable blood pump and external controller), or more than one function (e.g., a ventilator with physiological monitoring), then the medical device system test specifications should consider all EMC-related consensus standards applicable to those subsystems, accessories, and functions. This can be used to formulate an appropriate superset of test specifications.
- If EMC testing is performed on a subsystem basis, each subsystem not included in the testing should be simulated, including any potential third-party medical devices or connections.
- Medical device and test or ancillary equipment should be configured in the modes and with settings considered to be representative of the medical device's intended use. For example, a medical device that can operate in battery power mode and in mains power mode should be tested in both modes. Additionally, batteries with embedded electronic circuitry (i.e., smart batteries) that are intended to be handled by the user should be removed from the medical device and tested separately for immunity to ESD due to the potential of ESD damaging the circuitry of the battery.
- Patient simulators should be used where specified by the referenced EMC consensus standards or as appropriate for the medical device. For example, certain EMC test methods for AIMDs specify that the medical device be submerged in a saline phantom with specific conductivity. Other consensus standards such as 60601-1-2 specify that patient coupled medical devices be electrically loaded in a way that simulates a patient and be provided with electrical or mechanical signals that simulate a patient.
- If wireless technology is used in the medical device to achieve its intended use, the wireless technology should be "on" and communicating with other medical device subsystems or ancillary equipment during EMC testing. This is important because having active connections at each antenna could affect whether the subject medical device operates as intended when exposed to EM disturbances.

You should also include a description of how the medical device was monitored during EMC testing. Monitoring methods should include a means to quantitatively observe performance associated with the immunity pass/fail criteria without significant perturbation or effect on the test being performed or to the device under test.

F. Results of EMC Testing

We recommend that you provide a summary of EMC testing. This information should summarize the medical device emissions and the immunity to EM disturbances at test levels appropriate for the medical device's intended use environments. If neither the test methods nor the acceptance criteria are well-defined in the EMC consensus standard(s), we recommend that information requested in this guidance be supported by the inclusion of EMC test reports.[19] We recommend that the summary of EMC testing include the following:

- Name and location of the test facility, the date of the testing.
- Results for each emissions test. Pass/Fail criteria should be expressed in terms of limits, against which the medical device's measured emissions are compared and should not exceed.
- Results for each immunity test performed (e.g., ESD, voltage dips, radiated immunity). This should include any degradations that were observed during and after each immunity test for continuous phenomena and after each immunity test for transient phenomena. For all degradations, you should detail how the medical device continued to meet the immunity pass/fail criteria and if any additional mitigations will be implemented.

G. Allowances

Allowances are specifications within a consensus standard that permit well-defined or conditional variations of, or exemptions from, certain requirements of the standard. In general, an allowance of a standard can include the test setup, test methodology, immunity test levels, or immunity test modulations. For example, a consensus standard might provide an exemption from certain immunity and emissions tests that are applicable for permanently installed large medical electrical equipment or medical electrical systems with a rated input current more than 16 A per phase. We recommend that you provide a description of all allowances used, with a justification to support the use of each allowance. The allowance should only be used if all the specified conditions of the allowance are satisfied. The use of allowances should not increase risks to patients or operators. If the conditions for use of an allowance cannot be justified, then the allowance should not be used.

H. Deviations

A deviation from a consensus standard is when a requirement of the consensus standard is intentionally not satisfied, or testing is performed in an alternative way other than that

[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

specified and allowed in the standard. The difference between a deviation and an allowance is that an allowance is specified in a standard, whereas a deviation is not. We recommend that you provide a description of all deviations used along with a justification to support the use of each deviation. Deviations from a referenced consensus standard should be supported with a justification that explains how the deviation would not adversely impact the safety or performance of the medical device.

I. Modifications

If the device was modified or altered to pass the EMC testing, such as after initial EMC test failure, then we recommend that you include a description and analysis of those medical device modifications. Many types of modifications can alter medical device EMC, including hardware, software, firmware, and even cosmetic changes (e.g., use of a metallic material for labeling where the prior labeling was non-conductive). Some common device modifications made to pass EMC testing include incorporating ferrite beads, adding filters or EMC shielding materials, and changes or updates to firmware or software. When a medical device is modified to pass EMC testing, we recommend the following information be provided:

- A description of all changes or modifications that were made to the medical device in order to pass EMC testing.
- A statement whether the provided EMC test results occurred before or after the modifications were incorporated into the medical device. If EMC testing was not performed after the modifications were made to the medical device, a risk analysis and scientific justification should be provided that the modified medical device does not adversely impact the safety or performance of the medical device.
- A statement indicating that the changes will be incorporated into the final finished medical device prior to marketing; the changes must be documented in the design history file in accordance with design controls.[20]
- An analysis as to whether these modifications might impact other aspects of the medical device safety or performance, such as whether they increase risks to patients or operators, alter the biocompatibility or sterility, affect electrical safety, or introduce software anomalies/defects.

J. Common Electromagnetic (EM) Emitters

Certain emitters commonly found in some use environments might not be adequately addressed by FDA-recognized consensus standards. This could be because a consensus standard specifies a range of frequencies that omits some bands, such as emitters in the kHz range, or it could be because a technology is adopted so quickly that consensus standards cannot keep up with the rapidly changing EM environment. You should be familiar with their intended use environments and reasonably foresee the potential for interference from emitters commonly found in those environments.

At the time of publication of this guidance, some examples of common EM emitters not adequately addressed by FDA-recognized consensus standards are radiofrequency

[20] 21 CFR 820.30

identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment. The EM disturbances caused by these emitters should be taken into account during the risk management process.

We recommend mitigating the risks associated with these common EM emitters and unique medical emitters based on the intended use environments and the potential severity of harm the medical device could cause (see Section IV.B above). For medical devices in the risk category "Medical device-related events without reported or potential harm," we recommend that the medical device labeling (e.g., user manual, instructions for use) mention the potential for EMI from emitters expected to be nearby. If you make specific claims or specify a specific intended use regarding any particular emitter, we recommend that those claims be supported with additional testing, engineering analysis, or computer modeling. For medical devices in the risk category "Medical device-related deaths and serious injuries" or "Medical device-related non-serious adverse events" we recommend that:

- testing be performed according to FDA-recognized consensus standards (e.g., FDA-recognized AIM 7351731 *Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard* or IEC 60601-1-2:2020 Clause 8.11 for RFID emitters), or equivalent EMC test methods, with justification. If no consensus standards exist, specific immunity testing should be performed to demonstrate that the medical device is safe with regard to each identified emitter that is foreseeable in the intended use environment; and

- labeling be specific to the risks to patients and operators and include any mitigations and warnings needed, based on the test results.

K. Labeling

It is important to include EMC-related information in the labeling because EMC testing alone may be insufficient to mitigate the risk associated with use in all environments. For example, EMC specifications in the labeling can help end users select equipment with electromagnetic immunity that is compatible with the environments in which the device is intended to be used, or to compare EMC characteristics of candidate equipment prior to purchase. Providing EMC information in the labeling (e.g., instructions for use) can help make users aware of the degradations that can be caused by EMI and to understand the circumstances to avoid. We recommend that the submission include EMC information to be included in the labeling to enable safe and effective installation and use of the medical device in the intended EM environments over the expected service life. EMC-related information can be presented as physical markings on the medical device related to EMC, or in accompanying documents, such as instructions for use, user manual, and/or technical and service manuals. The EMC-information included in the labeling should meet the specifications of the referenced medical device consensus standards (e.g.,

60601-1-2, 60601-4-2).[21] We recommend that the medical device labeling include the following information related to EMC:

- The environments of use for which the medical device is suitable to be used/exposed.
- Accessories and other equipment with which the device has been determined to be compatible.
- The medical device's functions/performance and a description of what the operator can expect if the functions/performance are lost or degraded due to EM disturbances. For 60601-4-2, these are the functions/performance needed to demonstrate the medical device performs as intended, and for all other 60601 standards this is Basic Safety and Essential Performance.
- The compliance level for each emissions and immunity test.
- The use of any deviations from, or allowances specified by, the referenced standards.
- Precautions regarding sources of EM energy that:
  - emit levels of EM energy that exceed the immunity test levels of the referenced EMC standards used, or
  - have other emission characteristics to which the medical device has not been tested for immunity.
- Specifications of the wireless communication for medical devices with RF wireless functions.
- Any maintenance instructions needed to ensure that the medical device remains safe and performs as intended with regard to EM disturbances throughout the expected service life.
- Markings affixed to the medical device and warnings for certain types of known EM environments, such as in or near an MRI scanner. Medical devices intended for use in the MR environment that have not been shown to be MR Safe or MR Conditional should be marked with the ASTM F2503 symbol for MR Unsafe. (See ASTM F2503-13 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*.)
- The FCC term "harmful interference" has a meaning that is different from that of the term "harm" as used in medical device risk management and ANSI/AAMI/ISO 14971 *Medical devices - Application of risk management to medical devices*. To avoid confusion and concern regarding the FCC term, we recommend adding the note specified below after the FCC warning in the labeling:
  - NOTE: "Harmful interference" is defined in 47 CFR §2.1[22] by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

[21] The labeling specifications of IEC 60601-1-2:2020 and IEC TR 60601-4-2:2016 are in Clause 5 and summarized in Annex B.

[22] Available at https://www.govinfo.gov/content/pkg/CFR-2018-title47-vol1/xml/CFR-2018-title47-vol1-sec2-1.xml

V. EMC Information to Support Investigational Device Exemption (IDE) or Investigational New Drug (IND) Submissions

When evaluating EMC of a medical device in an IDE or IND submission, we recommend that you consider all applicable points detailed in Section IV of this guidance that are applicable to patient and operator safety. We recognize that there are often iterations to the design of the medical device during a clinical study, and thus comprehensive EMC testing to consensus standards might not be the least burdensome approach to demonstrate EMC. Other appropriate EMC mitigations can be used to support a favorable benefit/risk determination.[23] If immunity testing has not been performed using appropriate consensus standards (see Section IV.C) for the medical device under study, you should provide in the IDE or IND submission, a description of alternative mitigations, such as ad-hoc testing and a list of labeling mitigations (e.g., continuous oversight from medical professionals, procedures to prevent harm to operators, ESD mitigation precautions) along with an explanation of how the mitigations protect the safety of patients and operators. If emissions testing has not been performed for the medical device under study per appropriate consensus standards, then you should provide in the IDE or IND submission a description of potential risks to patients and operators in case the subject medical device introduces excessive emissions that might interfere with other medical or non-medical equipment. This should include a justification about how each risk will be mitigated.

[23] For more information see the FDA guidance "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-investigational-device

Appendix A – Examples of Typical Medical Device Locations within Intended Use Environments[24]

Professional Healthcare Facility Environment	Home Healthcare Environment	Special Environment
• Physician offices • Outpatient facilities [a)] • Dental offices • Clinics • Nursing homes [b)] • Hospital facilities including emergency rooms, patient rooms, intensive care, surgery rooms, etc., (except areas with high-powered medical equipment) • Limited care facilities • Surgical centers • Birthing centers • Laboratories [c)]	• Personal residences • Dormitories • Independent living retirement homes • Restaurants and cafes • Shops, stores, markets • Cars, buses, trains, boats, ambulances [d)] • Office buildings • Schools • Churches • Libraries • Theaters and stadiums • Outdoor environments (e.g., streets, sidewalks, parks)	• Medical treatment areas with high-powered medical equipment ○ (e.g., high-frequency surgical equipment, short-wave therapy equipment, inside the RF shielded room of an MRI system) • Military areas (e.g., submarines, radar installations, weapons control systems) • Heavy industrial areas (e.g., power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries) • Aircraft environments (e.g., planes, helicopters) [e)]

a) Facilities where outpatient services, i.e., medical procedures or tests that can be performed without an overnight stay, can be performed (e.g., medical center, rehabilitation center).
b) Refer to the SIS for the scope of FDA's recognition of IEC 60601-1-11 *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*. The FDA considers nursing homes in the United States to be Professional Healthcare Facilities because professionals with medical training are available when patients are present.[25]
c) Laboratories have operators with medical training or operators without medical training. For the purpose of this guidance, we include laboratories under the Professional Healthcare Facility Environment in either case. This is because, in the latter case, there are generally no patients. According to IEC 60601-1-11, a patient is necessary to be included in the Home Healthcare Environment.
d) Although healthcare professionals are present in an ambulance, the EM environment is similar to that of the Home Healthcare Environment.
e) IEC 60601-1-2 includes aircraft in the Home Healthcare Environment while referencing RTCA DO-160G for higher immunity test levels. Since the test levels are potentially different than the Home Healthcare Environment, aircraft is included in the Special Environment (see Section IV.C(3)for more details).

[24] Adapted from IEC 60601-1-2 with modification
[25] See definitions from FDA Guidance, "Design Considerations for Devices Intended for Home Use," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use.