

Technical Information Report

AAMI TIR69: 2017/(R)2020

Risk management of
radio-frequency wireless
coexistence for medical
devices and systems

Risk management of radio-frequency wireless coexistence for medical devices and systems

Approved 28 February 2017 and reaffirmed 10 April 2020 by
AAMI

Abstract: This Technical Information Report (TIR) provides a process and guidance on performing a radio-frequency (RF) wireless coexistence evaluation of a medical device as part of an overall medical device risk management approach. The process includes pre-testing activities to gather information needed to determine the tier at which to perform testing, the testing and report, and post-test analysis. The TIR also provides sample reports and additional information to aid in documenting the medical device wireless coexistence evaluation and integration into risk assessment and management.

Keywords: wireless medical devices, wireless technology, wireless coexistence, risk management, interference, radio frequency (RF)

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Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

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Printed in the United States of America

ISBN 978-1-57020-656-6

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Medical Device Wireless Committee

This technical information report (TIR) was developed by the AAMI Medical Device Wireless Committee. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Medical Device Wireless Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

With the growing importance and use of radio-frequency (RF) wireless technology, spectrum is becoming increasingly crowded. The potential for RF wireless devices to affect and potentially interfere with other transmissions is growing and is a regular occurrence in some frequency bands. RF wireless technology is more than a convenience and enables a number of applications that might otherwise not be possible. Impressive improvements and innovations continue to be made increasing the already considerable appeal of the technology. RF wireless technology is being put to use in an ever expanding variety of applications. Healthcare delivery is a full participant in this trend, making it increasingly important that the hazards and associated risks related to the ability of wireless medical devices and systems to coexist are effectively and efficiently managed.

Users of a wireless medical device system come to rely on the functions and applications. Degradation of the wireless link can occur if a device's transmission conflicts with transmission from other wireless products in the vicinity, resulting in a delay or loss of communication. The potential for this is even greater when several different wireless services and devices share the same unlicensed frequency band as is the case for the most widely used wireless technologies. This document provides guidance on understanding and managing potential wireless technology communication conflicts in the drive towards coexistence. The TIR offers a process to assess, categorize, and document the risks associated with the wireless functions of the medical device or system and suggestions to help improve coexistence.

Introduction

This TIR provides guidance for assessing wireless coexistence and the risks associated with interference or degradation when using RF wireless technology to perform medical functions and/or communicate medical data. Wireless coexistence is the ability of the medical device to function properly in a shared electromagnetic environment and is important for wireless medical devices because such devices and systems can be expected to function in environments where other wireless communications products are possibly used. This document provides guidance on evaluating the ability of a wireless medical device or system to wirelessly coexist.

This TIR offers a process to assess and categorize the risks associated with the wireless functions of the medical device or system, which should be integral to the risk-management-based approach. Wireless coexistence testing can also be used to characterize relevant risk mitigations and to monitor and ensure safety, performance, and effectiveness of the wireless functions of a medical device or system.

Wireless coexistence testing exposes an RF receiver of the subject medical device to transmissions from other wireless devices to document and assess the potential impact of the other unintended transmission. The unintended signals are selected to give insight about how a subject wireless device will perform in the intended electromagnetic (wireless) environment. For example, during testing a strong unintended signal might be introduced based on the assumption that if a device can tolerate a strong unintended signal it can also tolerate that signal at lower levels. Similarly, when a wide variety of wireless signal modulations and waveforms from different wireless technologies operating in the same RF spectrum band might be used by an unintended transmitter, the modulation or waveform known to be the harshest might be used in testing. Wireless coexistence brings together an understanding of how the device being evaluated is able to use its wireless capability in the presence of other transmissions. Coexistence testing provides valuable insight about how the subject medical device will perform in its intended use environment and can identify areas requiring mitigation.

In general, the process for the assessment of wireless medical device coexistence begins with the steps in this TIR that include identifying the wireless technology and functions, assessing and categorizing the risks for these functions, and developing appropriate criteria for testing (see 6). The TIR goes on to provide details on setting up and performing the testing (see 7), assessing the findings (see 8), and providing a test report (see 9).

Figure 1 provides an overview of the process. Additional details on the overall process flow is in Section 5 of this TIR.

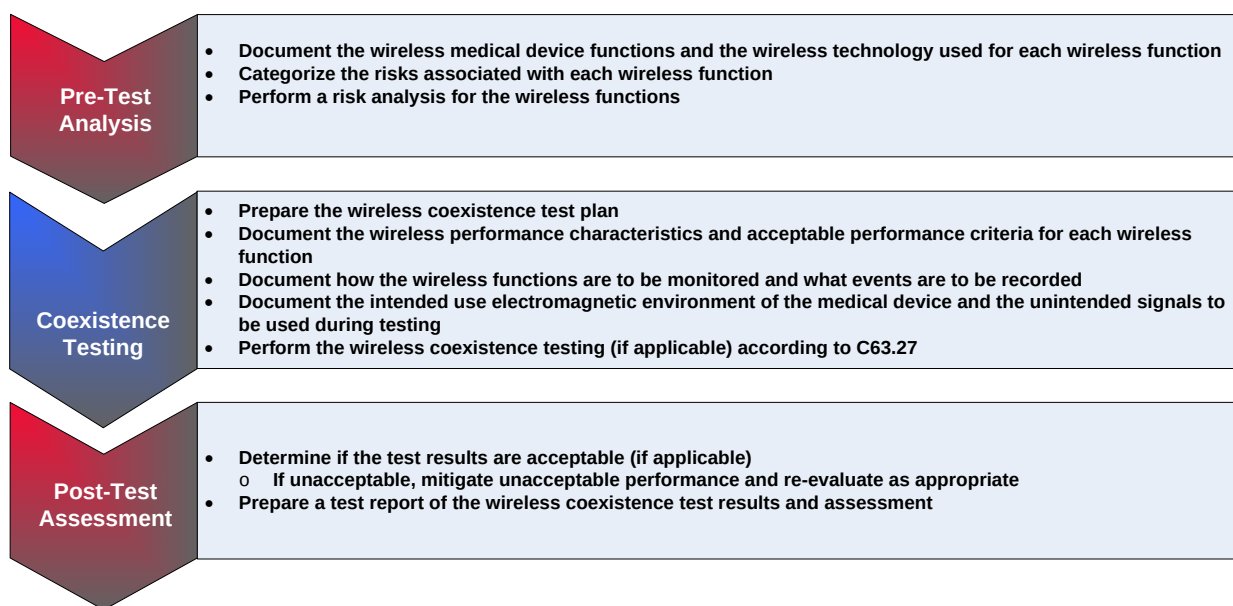


Figure 1 – Overview of the this TIR

NOTE—This introduction does not contain all detailed provisions of this TIR, which addresses wireless coexistence for medical devices and systems. It is intended to provide a general overview of the issues and process detailed in this TIR.

Addressing radio-frequency wireless coexistence for medical devices and systems

1. General

1.1 Purpose and intent

This technical information report (TIR) provides information, guidance, and best practices for supporting the risk management process as it applies to the ability of medical devices and systems that use radio-frequency (RF) wireless technology to coexist and operate within the electromagnetic environment in the area of the device's intended use.

The TIR provides a method to test for wireless coexistence and a process to document and communicate those results to designers, manufacturers, regulatory bodies and agencies, and users of wireless medical devices and systems.

Issues for wireless medical device coexistence include:

- the type of hazardous situation that might occur,
- the potential consequences,
- mitigating and managing hazards,
- and how to test those mitigations.

This document is intended to address regulated medical devices that incorporate wireless technology. The focus is on the risks related to the wireless functions of the medical device or system. The use cases presented and the risks assessed herein are intended to address such systems and aid device manufacturers and others in applying mitigating or compensating controls. Moreover, the principles and procedures mentioned here can be applicable to other portions of the wireless systems to which the medical device is connected.

It is important to note that much of the clinical functionality of current and future wireless medical devices can be, and are being, enhanced and replaced by wireless connections to networks external to the devices and systems designed and tested by the medical device manufacturer. In these circumstances, the data extracted from the medical device is transmitted through, and in some cases post-processed by, systems outside the direct control of the medical device in question. Consequently, transfer of the data through these peripheral systems can present additional risks not considered in this document but should be considered in a comprehensive risk management process or communicated to the customer if outside of the manufacturer's control. Such additional risks are outside the scope of this document and generally outside the control of the medical device manufacturer and in some cases outside the control of the user facility. Therefore, it is recommended that any third party integrating wireless medical devices into larger systems assess the risks outlined in this document and utilize this understanding in planning a deployment. By applying appropriate regulatory guidelines or consensus standards to integrate mitigation and compensating controls, the level of operational coexistence and reliability demonstrated through testing can be provided in actual use.

1.2 Scope

This TIR applies to medical devices and systems (also known as medical electrical equipment) that incorporate RF wireless technology used to perform or control a medical function or to communicate medical data. This includes wireless technology whose operation and function directly support the medical device's intended use, as it relates to the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

When evaluating the intended use environment for a wireless medical device the emissions from both intentional and unintentional radiators (medical and non-medical equipment) should be considered, depending on the frequency band of the medical device wireless operation. For example, a medical device that operates below 300 kHz should

consider emissions from an intentional radiator (emitter) like radio frequency identification (RFID) and localized spurious (unintentional) emissions from switch mode power supplies embedded in medical and non-medical equipment.

1.3 Intended audience

The intended audience for this TIR includes the following:

- Medical device designers and manufacturers
- Wireless test engineers and test laboratories
- Healthcare organizations
- Agencies and organizations responsible for overseeing the safety and effectiveness of medical devices

2. Reference standards and documents

This TIR refers to the following existing standards, regulations, and guidance:

- AAMI TIR18:2010, *Guidance on electromagnetic compatibility of medical devices in healthcare facilities*
- ANSI/AAMI/IEC 60601-1-2:2014, *Medical Electrical Equipment – Part 1-2: General requirement for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances- Requirements and tests*
- ANSI C63.27, *Standard for the Evaluation of Wireless Coexistence*, expected publication 2017.
- FDA *Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration (final August 13, 2013)*
- FDA *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices: Guidance for Industry and Food and Drug Administration Staff (Final July 11, 2016)*
- IEC/TR 60601-4-2:2016, *Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: Performance of medical electrical equipment and medical electrical systems*
- ANSI/AAMI/IEC/TR 80001-1:2010, *Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities*
- ANSI/AAMI/IEC/TR 80001-2-2:2012, *Application of risk management for IT-networks incorporating medical devices -- Part 2-2: Guidance for the communication of medical device security needs, risks and controls*
- ANSI/AAMI/IEC/TR 80001-2-3 Edition 1.0 2012-07, *Application of risk management for IT networks incorporating medical devices—Part 2-3: Guidance for wireless networks*
- ANSI/AAMI/IEC/TR 80002-1:2009, *Guidance on the application of ISO 14971 for medical device software*
- IEEE 1900.1:2008, *IEEE Standard Definitions and Concepts for Dynamic Spectrum Access: Terminology Relating to Emerging Wireless Networks, System Functionality, and Spectrum Management*
- IEEE 1900.2:2008, *IEEE Recommended Practice for the Analysis of In-Band and Adjacent Band Interference and Coexistence Between Radio Systems*
- ANSI/AAMIISO 14971:2007, *Medical devices-Application of risk management to medical devices*
- ISO TR 21730: 2007, *Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities - Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices*

3. Definitions

For the purposes of this document, the following terms and definitions apply:

ADJACENT BAND

An adjacent radio frequency band is one that is either above or below the frequency band of interest. Typically different radio technology transmitters use different frequency bands for transmission. However, in the ISM bands multiple technologies can use adjacent frequency bands. For example, an IEEE 802.11b/g/n network operating in the 2.4 GHz ISM band on channel 1 (2.412 GHz) and a LTE network operating in LTE band 40 (2.3-2.4 GHz) are operating on adjacent bands.

ADJACENT CHANNEL

An adjacent radio frequency channel is one that is either above or below the channel of interest. Radio transmitters in the ISM bands can use the same frequency band though typically not the same channel at the same time. For example, two IEEE 802.11b/g/n networks are considered adjacent channel if one network is operating on channel 1 (2.412 GHz), and the other network is operating on channel 6 (2.437 GHz).

ADJACENT-CHANNEL INTERFERENCE

Adjacent channel interference is caused when extraneous power from a signal in the adjacent channel is in the intended channel of communication. Adjacent channel interference can be caused by inadequate filtering, such as incomplete filtering of unwanted modulation products in frequency modulation (FM) systems, improper tuning, or poor frequency control, in either the reference channel or the interfering channel or both. Adjacent-channel interference is distinguished from crosstalk.

[Source: Federal Standard 1037C Telecommunications: Glossary of Telecommunications Terms]

CO-CHANNEL

Co-channel transmissions can exist when two or more transmitters use the same channel or an overlapping frequency for transmission.

CO-CHANNEL INTERFERENCE

Interference resulting from two or more simultaneous transmissions on the same channel.

[Source: Federal Standard 1037C Telecommunications: Glossary of Telecommunications Terms]

COEXISTENCE

The ability of one wireless system to perform a task in a given shared environment where other systems (in that environment) have an ability to perform their tasks and might or might not be using the same set of rules.

[SOURCE: Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff]

DEVICE UNDER TEST (DUT)

Device under test is a term used to refer to a medical device or system undergoing testing.

DEVICE UNDER TEST (DUT) COMPANION DEVICE

The corresponding wireless node that is wirelessly communicating with the DUT (e.g., an IEEE 802.11b/g/n access point).

EFFECTIVENESS

The ability to produce the intended result for the PATIENT and the RESPONSIBLE ORGANIZATION

[SOURCE: IEC/TR 80001-1:2010, definition 2.6]

INTENDED USE

The use for which a product, PROCESS or service is intended, according to the specifications, instructions and information provided by the MANUFACTURER

[SOURCE: IEC/TR 80001-1:2010, definition 2.10]

INTEROPERABILITY

The property permitting diverse systems or components to work together for a specified purpose.

[SOURCE: IEC/TR 80001-1:2010, definition 2.11]

INDUSTRIAL, SCIENTIFIC, and MEDICAL (ISM) FREQUENCY BANDS

The industrial, scientific and medical (ISM) radio bands are radio bands reserved for the use of radio frequency (RF) energy for industrial, scientific and medical purposes other than telecommunications. There are multiple ISM band allocations that in recent years have seen rapid growth for uses of these bands for short-range, low power communications systems.

RADIO FREQUENCY (RF) WIRELESS MEDICAL DEVICE

A medical device that includes at least one function that is implemented using RF wireless communications; examples of functions that might be implemented wirelessly include data transfer, device control, programming, power transmission, remote sensing and monitoring, and identification.

[SOURCE: Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff]

4. Risk management

4.1 Overview

This TIR provides a process for risk management of the risks related to wireless coexistence for a medical device equipped with wireless capability. It is aligned with the principles outlined in the ISO 14971 standard on risk management. For guidance on test methods, this TIR references ANSI C63.27.

The objective of this TIR is to understand the probability of occurrence and severity of the risks related to the wireless capability of the medical device and then to mitigate those risks to acceptable levels. The result is an assessment and management of the risks from the wireless functions of the medical device. This TIR provides context for making assessments of the category of risks when the device is used according to manufacturer guidance and mitigations are enabled. The result is an understanding of the ability of a wireless medical device to coexist in its intended use environment.

Developers of medical devices should integrate risk management early in the process of requirement development and continue this throughout the design process and into post market surveillance. Managers of hospital and healthcare delivery systems and their users share the concerns of developers but have different options available for managing risk. The wireless coexistence risk-management process begins with questions that should be asked early in the development of the wirelessly enabled medical device to help focus attention on key areas. These questions include:

1. What hazards and hazardous situations can occur related to the wireless technology incorporated into the medical device or device system?
2. How often might these happen? (What is the likelihood of occurrence?)
3. What are the potential harms to the patient if the wireless functions are impaired?
4. What can be done about these? (What kind of risk controls or mitigations are appropriate?)

Different options are available at different stages of the process. Developers have the greatest freedom to modify the design. Facility managers cannot modify the design but can make changes in the use environment.

These questions are considered in the following paragraphs:

1. What hazards and hazardous situations can occur?

This is answered through risk analysis¹ and assessed by understanding how the device uses its wireless capabilities and its intended use. At the functional level, the potential consequences of delayed, disrupted, or failed wireless communication are assessed.

2. How often might it happen?

A fundamental part of risk management is understanding how often a hazardous situation might occur. This can be related to the intended use environment and what other wireless technology or products might be expected in that environment.

3. What are the potential harms to the patient if the wireless functions are delayed, disrupted, or impaired?

The potential consequences of delayed, disrupted, or failed wireless communications are determined during risk analysis. The actual harms to a patient are specific to the intended use of the device so these typically are not fully described in a technical document. As part of risk management, the design teams should evaluate different types of risk controls necessary to avoid unacceptable risk, and understanding the consequences of such risk also helps to evaluate whether wireless coexistence testing is necessary to assure patient safety.

4.2 Risk management of medical device wireless functions

4.2.1 Overview

An overall risk assessment is performed by using an ISO 14971 compliant risk management process (or equivalent) to understand potential hazards and risks associated with a particular medical device. This section provides additional insight when evaluating the wireless functions through risk management.

¹ This TIR is written to be used in the context of a risk assessment following the guidance of ISO 14971. It provides additional guidance for evaluating the risk related to wireless coexistence.

The associated risk of the wireless functions should be assessed based on the risk of delayed, disrupted, or failed communication and include consideration of the intended use environment. Because there are numerous medical device functions that can be enabled by wireless technology, device manufactures should consider the importance and priority of the particular functions and the potential impact of unintended signals before deciding to implement a function wirelessly.

When evaluating the wireless coexistence of a medical device in its intended use environment, it is important to consider other wireless medical devices and non-medical wireless products (e.g., wireless computers, microwave ovens) that could operate in the same vicinity and in the same or adjacent radio frequency (RF) spectrum. These environments could vary, but efforts should be made to understand as many likely scenarios as possible.

When evaluating the intended use environment for a wireless medical device, it might be necessary to consider emissions from both intentional and unintentional radiators (medical and non-medical equipment), depending on the frequency band of operation. For example, a medical device which operates below 300 kHz should consider emissions from an intentional radiator like radio frequency identification (RFID) and localized spurious (unintentional) emissions from switch mode power supplies embedded in medical and non-medical equipment.

There are special considerations to be made when assessing specific wireless functions of a medical device. These should include whether these wireless-dependent functions of the device have failure mitigation features in the event of delayed, disrupted, or failed communication. Helpful questions to consider include:

- What mitigations are available?
- Does the mitigation rely on a wireless connection?
- Do all functions use the same wireless link in the same frequency band?
- Do some functions operate at different or multiple portions of the spectrum?
- Are different wireless technologies used?

4.2.2 Alignment with relevant standards

Appropriate risk management of a medical device should be done throughout the life-cycle of the medical device. During the design phase, a good design process should include an ISO 14971 risk assessment (or equivalent) on the planned wireless functions to provide an opportunity to introduce design-level risk mitigations for critical wireless functions. The assumptions for these risk mitigations should be examined throughout the design process and post-market surveillance, with follow-up risk assessments, verification activities, and monitoring.

The IEC 60601-1 standard, which is applicable to medical electrical equipment and systems, requires a manufacturer to specify the essential performance of the medical device. Therefore, any wireless function that is used in support of an essential performance function should be monitored during coexistence testing and the results evaluated in the succeeding risk analysis. Coexistence testing is done for reasons in addition to evaluating essential performance. It is appropriate to include testing to evaluate anticipated user experience and other purposes. When such testing is performed in combination with an essential performance evaluation, the categories of functions should be clearly identified in the test plan and test report.

In addition, see the IEC/TR 80001-1 risk management process and the wireless-specific document IEC/TR 80001-2-3 for the use and maintenance of medical devices on a healthcare facility wireless network and sharing of responsibility for continued risk management of medical devices on the medical IT network. The wireless requirements for supporting the critical functions of the medical device should be clearly outlined for the healthcare provider so that the network architecture can support those requirements.

4.2.3 Quality of Service

Medical devices using wirelessly enabled functions should be designed in consideration of the Quality of Service (QoS) necessary for those functions. The QoS of wireless functions is defined as the necessary level of performance in a data communications system or other service. This typically encompasses multiple performance parameters, such as reliability of data transmission, transfer rate, error rate, and mechanisms and priority levels for time-critical signals². Thus, when considering the risks associated with a particular wireless function, it is important to evaluate the overall needs of the medical device to ensure that the wireless network requirements are satisfactory.

² Guidance for Industry and Food and Drug Administration Staff: Radio Frequency Wireless Technology in Medical Devices. Final guidance issued on August 14, 2013.

4.3 Risk categories

Wireless medical functionality can serve a wide variety of uses. Different wireless functions can be associated with varying levels of risk to the patient and user. To help those responsible for wireless medical devices rank the significance of the wireless functions of their wireless devices, the TIR creates four risk categories based on the potential hazards due to delay, disruption, or failure of the wireless communication. The determination of the risk categories is aided by information gathered during normal risk management activities such as those described in ISO 14971.

The example wireless functions presented here are for illustration and guidance purposes only and should not be considered representative of all possible medical device wireless functions. Each wireless function should be considered separately and could span a range of risk categories, and there could be multiple risk categories for the same device. Annex E provides additional examples of wireless functions.

The categories described are as follows:

1. **Category A: MAJOR (High Risk Level):** medical functionality implemented via wireless technology is associated with hazards that could result in death or serious injury due to failure, disruption, or delay of wireless communication. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.
 - Critical therapy
For example:
 - o Remote programming of an infusion pump dosage.
 - o A glucometer's ability to transfer blood sugar results to pathology data systems for a hospitalized patient in a diabetic coma or insulin shock, where glucometer readings are relied on to indicate a need for intervention.
 - High priority alarms
For example:
 - o Patient physiological monitoring and vital sign monitoring to recognize a patient event.
 - o Alarms (e.g. ventilator, IV pumps) transmitted through e.g. the Nurse Call system to VOIP phones or a mobile medical app.
 - Real-Time Tracking System to locate a patient in distress
2. **Category B: MODERATE (Medium Risk Level):** medical functionality implemented via wireless technology that is associated with hazards that could result in injury or impairment requiring professional medical intervention due to failure, disruption, or delay of wireless communication. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.
For example:
 - o Defibrillator issues where there might be failure to deliver data assessing effectiveness of treatment.
3. **Category C: MINOR (Low Risk Level):** medical functionality implemented via wireless technology that is associated with hazards that could result in temporary injury or impairment not requiring professional medical intervention due to failure, disruption, or delay of wireless communication. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.
For example:
 - o Delivery of an updated drug library to an IV pump.
4. **Category D: NEGLIGIBLE (No Significant Risk Level):** medical functionality implemented via wireless technology that is associated with hazards that could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

For example:

- o CQI (Continuous Quality Information) sent from an IV pump to a server and used to determine the number of times the clinicians choose to ignore the drug library and program the pump with an out-of-limit value
- o Patient requesting a glass of water from a VOIP Phone Nurse Call system
- o Patient and device monitoring systems that send data to a central database for tracking, trending, and historical purposes, but is not used for immediate patient care.

Note: Even though testing might not be indicated for safety reasons, there might still be reasons to test wireless coexistence for other business purposes. These recommendations do not preclude the considerations for wireless coexistence for other, non-safety related reasons.

Table 1 - Risk Categories

Category	Wireless Risk	Level of Risk	Test Tiers
A	Major	High	Tier 1
B	Moderate	Medium	Tier 2
C	Minor	Low	Tier 3
D	Negligible	No Significant	No testing required ³

Each wireless function should be assigned a risk category from those listed in Table 1. The risk categories table is used to map to the corresponding testing tiers in C63.27. The tier of testing is proportionate with the risk associated with a wireless function.

For the application of risk management of wireless medical devices according to ANSI/AAMI/IEC TIR80001-2-1:2012, refer to the Clause 8 examples.

³ While testing is not required because patient risk is minimal, a manufacturer or user might choose to perform testing to assess performance or for other considerations.