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MEDICAL OEM WIRELESS COEXISTENCE TESTING

FDA REQUIREMENTS AND EXPECTATIONS

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September 19, 2024

AGENDA

01 Introduction, History, and Motivation

02 AAMI TIR69 and IEEE/ANSI C63.27

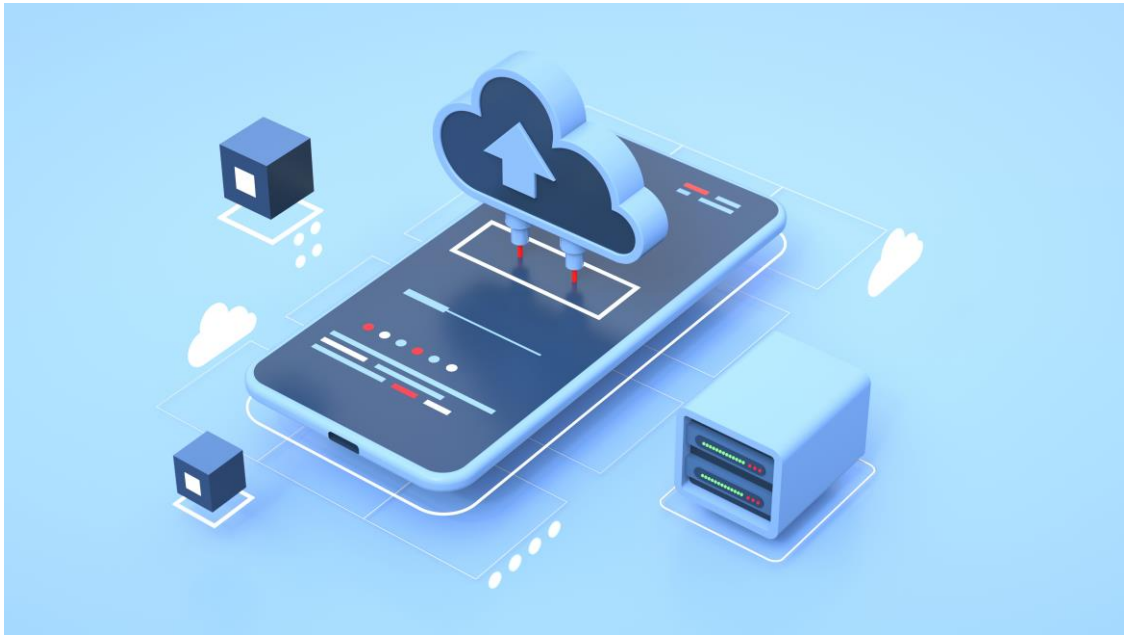
03 Test Plan Preparation

04 Test Execution

05 Interpreting the Results

01 INTRODUCTION, HISTORY, AND MOTIVATION
WHAT IS COEXISTENCE?

Wireless 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 may or may not be using the same set of rules.[4]



01 INTRODUCTION, HISTORY, AND MOTIVATION
WHAT IS COEXISTENCE?

01 INTRODUCTION, HISTORY, AND MOTIVATION
WHAT IS COEXISTENCE?

On May 3, 2011, ASC C63® Subcommittee 7 commissioned a task group to study the need for wireless coexistence evaluation methods. In response to a request from the U.S. Food and Drug Administration (FDA) the committee considered developing such evaluation methods. The FDA has observed an increasing use of wireless communication links in medical devices and, simultaneously, a growing application of home telehealth, with wireless devices going with patients into a wider variety of environments. Their concern is that these devices and their wireless interface be designed to be suitable for a range of electromagnetic environments in which they will be used, particularly in the presence of in-band and adjacent band congestion. [2]

The assignment of the task group, quoting from its PINS-C, was:

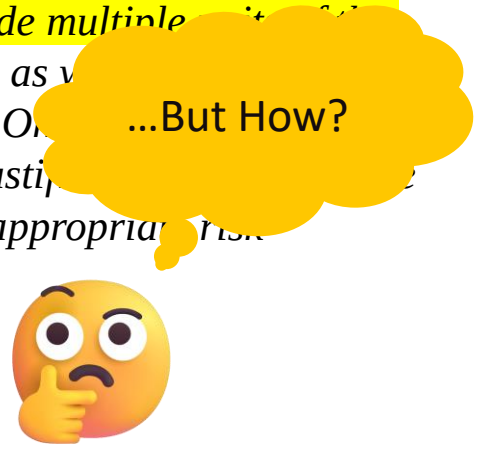
> *This committee project will study the need and approach to a set of tests and evaluation methods for wireless interference and coexistence. Regulators, IT system planners and others need tests that accurately evaluate the ability of wireless devices to operate in their intended environments, particularly in the vicinity of nearby in-band and adjacent-band transmitters.*

The task group presented its report to Subcommittee 7, recommending development of this standard. That recommendation was acted on by Subcommittee 7. As a result, ASC C63® approved this project on April 19, 2012.

01 INTRODUCTION, HISTORY, AND MOTIVATION
WHAT IS COEXISTENCE?

On August 14, 2013, the FDA issued its Radio Frequency Wireless Technology in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, with the following regarding coexistence:

If the RF wireless medical device is expected to be used in proximity to other RF wireless in-band (i.e., the same or nearby RF frequency) sources, FDA recommends addressing such risks through testing for coexistence of the device wireless system in the presence of the number and type of in-band sources expected to be in proximity to the device. Depending upon the wireless medical device, this should also include multiple [illegible] subject device operating in the same vicinity, such as [illegible] sitting adjacent to one another in a waiting room. O[illegible] associated risks are identified, we recommend a justi[illegible] risk, or testing or other measures to demonstrate appropria[illegible] mitigation.[4]



Radio Frequency Wireless Technology in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: August 14, 2013

The draft of this document was issued on January 3, 2007.

For questions regarding this document, contact Donald Witters (CDRH) at 301-796-2483 or by electronic mail at donald.witters@fda.hhs.gov or CBER's Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 301-827-1800.

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

Office of Science and Engineering Laboratories

Center for Biologics Evaluation and Research

01 INTRODUCTION, HISTORY, AND MOTIVATION
WHAT IS COEXISTENCE?

On February 28, 2017, AAMI TIR69:2017 was published. On May 11, 2017, IEEE/ANSI C63.27-2017 was published.

On August 21, 2017, the FDA officially recognized AAMI TIR69:2017 and IEEE/ANSI C63.27-2017 for Electrical Safety/Electromagnetic Compatibility[3]

F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
19–22	Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.	AAMI TIR69: 2017.
19–23	Primary batteries—Part 4: Safety of lithium batteries	IEC 60086–4 Edition 4.0 2014–09.
19–24	Primary batteries—Part 5: Safety of batteries with aqueous electrolyte	IEC 60086–5 Edition 4.0 2016–07.
19–25	Safety requirements for secondary batteries and battery installations—Part 1: General safety information.	IEC 62485–1 Edition 1.0 2015–04.
19–26	Safety requirements for secondary batteries and battery installations—Part 2: Stationary batteries.	IEC 62485–2 Edition 1.0 2010–06.
19–27	Safety requirements for secondary batteries and battery installations—Part 3: Traction batteries.	IEC 62485–3 Edition 2.0 2014–07.
19–28	Safety requirements for secondary batteries and battery installations—Part 4: Valve-regulated lead-acid batteries for use in portable appliances.	IEC 62485–4 Edition 1.0 2015–01.
19–29	American National Standard for Evaluation of Wireless Coexistence	IEEE/ANSI C63.27–2017.

02 AAMI TIR69 AND IEEE/ANSI C63.27 OVERVIEW

AAMI TIR69

- Technical Information Report (TIR), not a standard or recommended practice
- Provides "… information, guidance, and best practice for supporting the risk management process" for wireless medical equipment[6]
- Colorful table in Annex B gives guidance to determine risk category for each wireless function
- Pre-Test Analysis, Coexistence Testing, Post-Test Assessment
- Measurand is Signal-to-Interference (SIR) ratio in dB
- A lot of identical coverage to ANSI C63.27.

IEEE/ANSI C63.27

- Collection of test methods for assessing coexistence
- No specific or generic pass/fail criteria
  - Estimation of "Likelihood of Coexistence"
- Guidance for preparation of a test plan and test report
- Examples of interferers for common radio types
- One-way and two-way* coexistence
- Tiers of evaluation based on risk
  - Considerations for adjacent and co-channel interferers
- Measurand is Intentional-to-Unintentional (I/U) ratio in dB, or correlated to separation distance in some* instances

02 AAMI TIR69 AND IEEE/ANSI C63.27 OVERVIEW

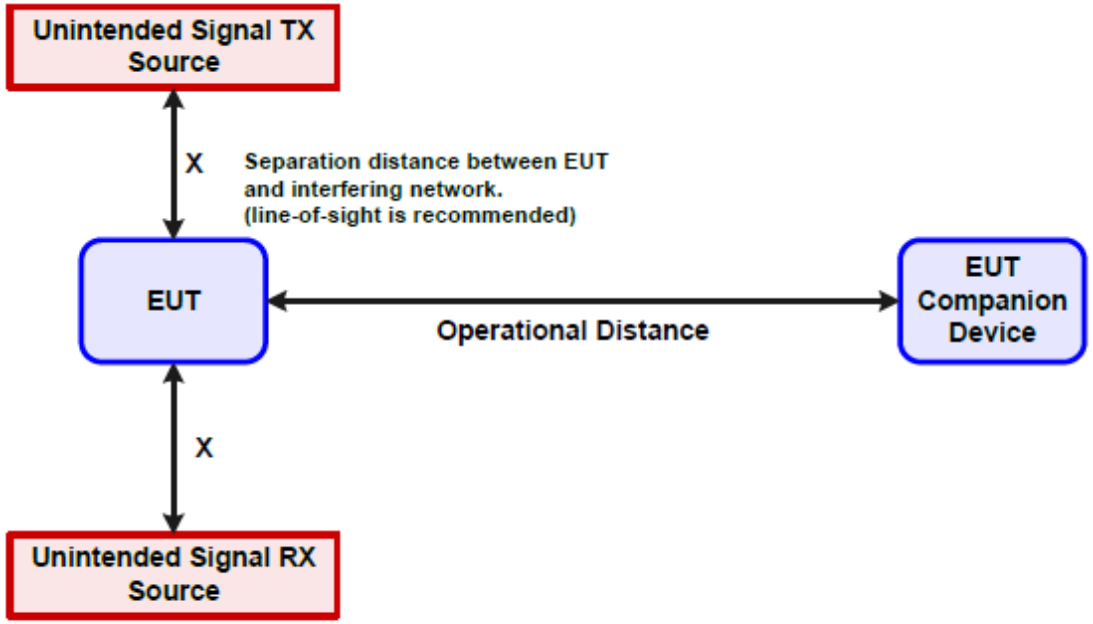


Figure 3—Test setup where primarily the EUT is exposed to the unintended signal

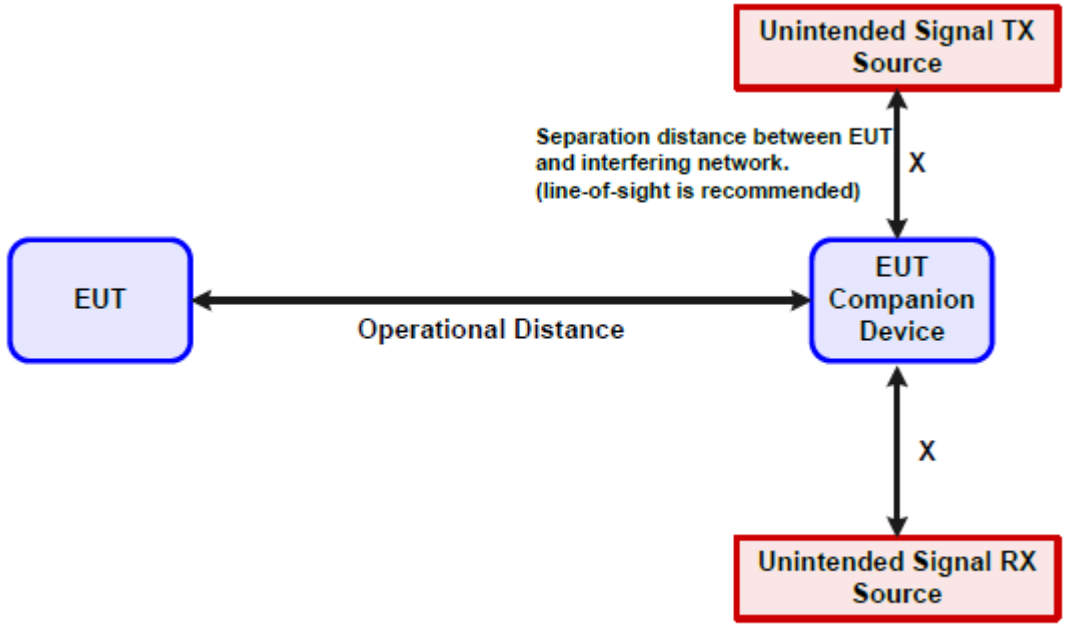


Figure 4—Test setup where primarily the EUT companion device is exposed to the unintended signal

02 AAMI TIR69 AND IEEE/ANSI C63.27 COMPARISON OF TEST METHODS

Conducted (Annex B)	Multiple Chamber (Annex C)	Radiated Anechoic Chamber (RAC) (Annex D)	Radiated Open Environment (ROE) (Annex E)
+ Lowest MU	+ Good repeatability	+ Good repeatability	+ Simplest setup
+ Highest repeatability	+ Standard samples	+ Standard samples	+ No chambers required
	+ Good correlation from I/U to distance	+ Good correlation from I/U to distance	+ Standard samples
- Requires specially prepared samples	- Requires multiple chambers	- Limited physical arrangement	- Highest MU
- Not a great correlation from I/U to distance	- Higher MU with multiple radiated paths	- MU limited by site validation	- Lowest repeatability
		- Multipath interference	- Environmental interferers
			- Harder to determine I/U ratio
			- Multipath interference

Increasing repeatability / Decreasing practicality

Decreasing repeatability / Increasing practicality

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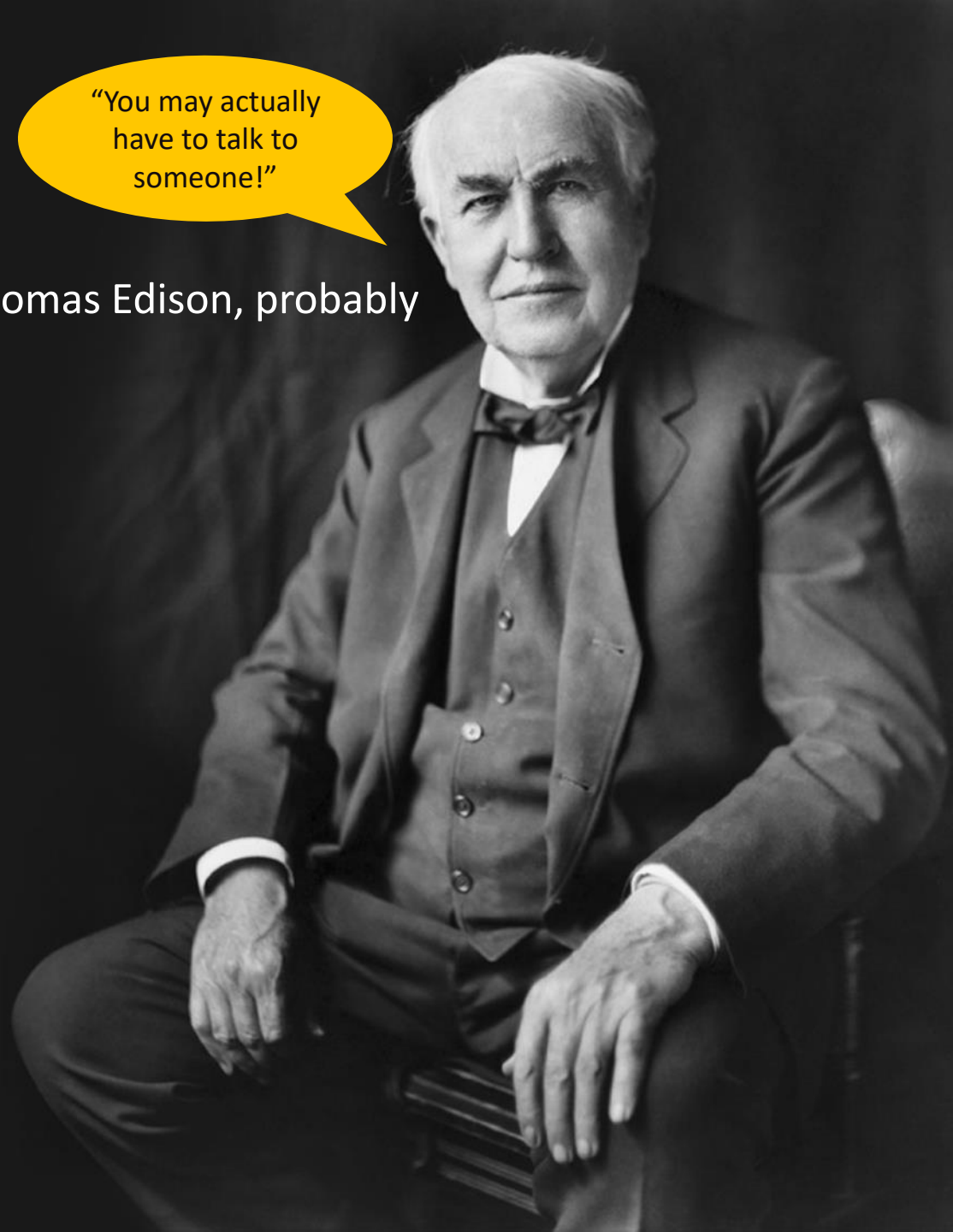


- Thomas Edison, probably

03 TEST PLAN PREPARATION

NEGOTIATION WITH YOUR TEST LAB

September 19, 2024

03 TEST PLAN PREPARATION
NEGOTIATION WITH YOUR TEST LAB

OEM

"Why are you quoting wireless coexistence testing? Doesn't IEC 60601-1-2 include immunity to proximity RF?"

"Functional Wireless Performance is assessed separately from Basic Safety and Essential Performance."

Test Lab

OEM

"Why do we need to do a separate risk analysis if wireless performance is already included as part of our RMF?"

"AAMI TIR69 risk management includes identification of Functional Wireless Performance and Key Performance Indicators."

Test Lab

03 TEST PLAN PREPARATION NEGOTIATION WITH YOUR TEST LAB

OEM

"We need a test plan for wireless coexistence!"

"We can't write a test plan for you."

Test Lab

OEM

"Well why not?"

"ISO 17025 Clause 4.1, Impartiality. We can provide a limited sample test plan and requirements, but specific details must come from you."

Test Lab

03 TEST PLAN PREPARATION NEGOTIATION WITH YOUR TEST LAB

OEM

"What samples do you need for coexistence testing?"

"Whatever equipment or software is required to assess the Functional Wireless Performance and measure Key Performance Indicators during testing."

Test Lab

OEM

"What if our device can connect to a variety of devices?"

"A representative sample or samples of companion devices can be included as part of the test plan."

Test Lab

03 TEST PLAN PREPARATION
NEGOTIATION WITH YOUR TEST LAB

OEM

"What if we can't measure things like latency or throughput?"

"Key Performance Indicators can also be specified on the application layer, such as completing a task."[2]

Test Lab

OEM

"What is the pass or fail criteria for coexistence testing?"

"There is no generic pass or fail criteria. The purpose is to determine at what distance or level your device no longer maintains its Functional Wireless Performance."

Test Lab

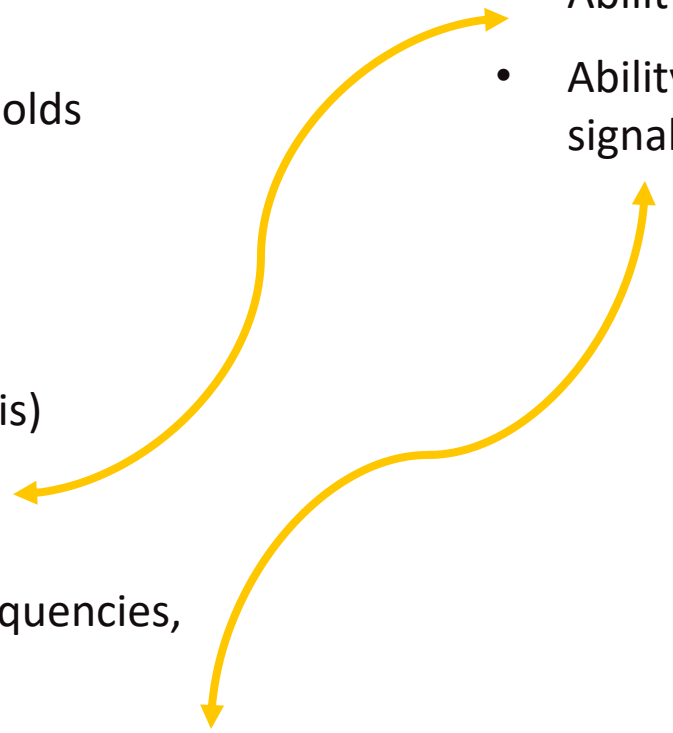
03 TEST PLAN PREPARATION
WHAT GOES INTO AN IEEE/ANSI C63.27 TEST PLAN?

From the Manufacturer

- Intended EM environment
- FWP and associated KPIs and thresholds
- Method to verify the FWP
- Companion Device(s)
- Evaluation tier (based on risk analysis)
- Test method and EUT configuration
- Intended signal(s) and operating frequencies, bandwidth, level, and signal quality
- Unintended signal(s), optionally including band specific guidance from Annex A

From the Test Lab

- Ability to do chosen test method
- Ability to generate and verify chosen unintended signals



These may require some back-and-forth with the test lab!

03 TEST PLAN PREPARATION
WHAT UNINTENTIONAL SIGNALS SHOULD YOU USE?

IEEE/ANSI C63.27 Annex A gives examples of interferers for certain radio types, including:

- 2.4GHz Bluetooth
- 2.4GHz and 5GHz Wi-Fi
- DECT

Interferers are considered for both adjacent channel and co-channel interference!

FDA: “What about 5G?”

Examples of interferers for Bluetooth devices:

Tier 3:

- One 802.11n 64-QAM 20MHz BW 20dBm EIRP @ 2437MHz

Tier 2:

- Two 802.11n 64-QAM 20MHz BW 20dBm EIRP @ 2412MHz and 2462MHz
- Dual LTE OFDM 1.4MHz BW 17dBm EIRP@ 2395MHz and 2501MHz

Tier 1:

- Three 802.11n 64-QAM 20MHz BW 20dBm EIRP@ 2412MHz, 2437MHz, and 2462MHz
- Dual LTE OFDM 10MHz BW 23dBm EIRP @ 2395MHz and 2501MHz

03 TEST PLAN PREPARATION
4G VERSUS 5G INTERFERERS

4G Interferers

- Up to 20MHz bandwidth
- Sub-6GHz bands only
- 0.5ms time slot (2 slots per subframe, 10 subframes per 10ms)

5G Interferers

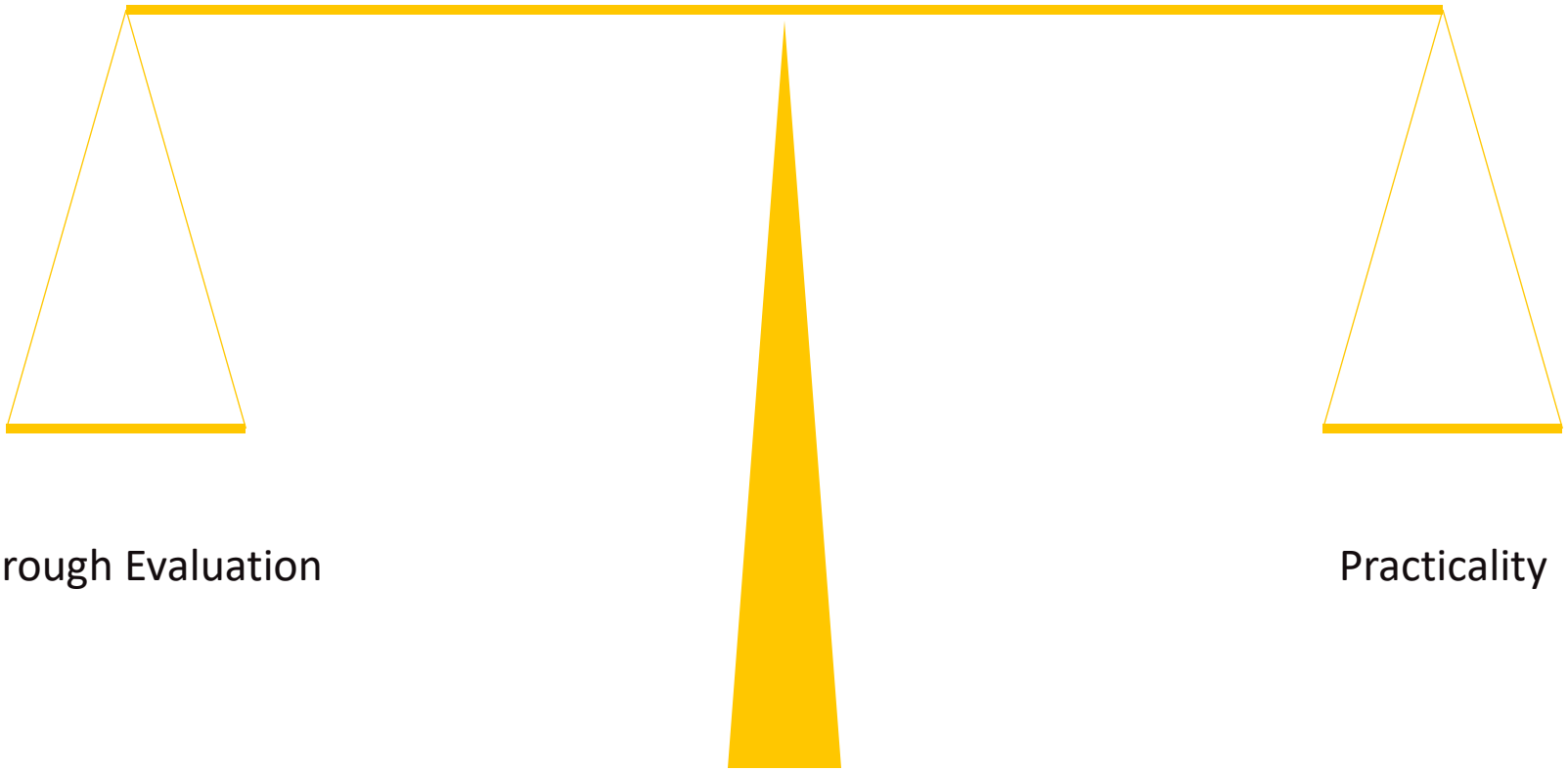
- Up to 100MHz bandwidth
- Sub-6GHz and mmWave (~24-48GHz) bands
- 62.5µs – 1 ms time slot (depending on subcarrier spacing, SCS)
- Different physical layer channels and signals for uplink and downlink
- Different data encoding scheme (LDPC)

If you are not decoding the data, they both tend to "look" the same as white noise from an interference standpoint!

03 TEST PLAN PREPARATION
HOW MUCH IS TOO MUCH?

- KPIs
- No. of samples
- No. of Interferers
- No. of configs
- No. of positions

… etc.

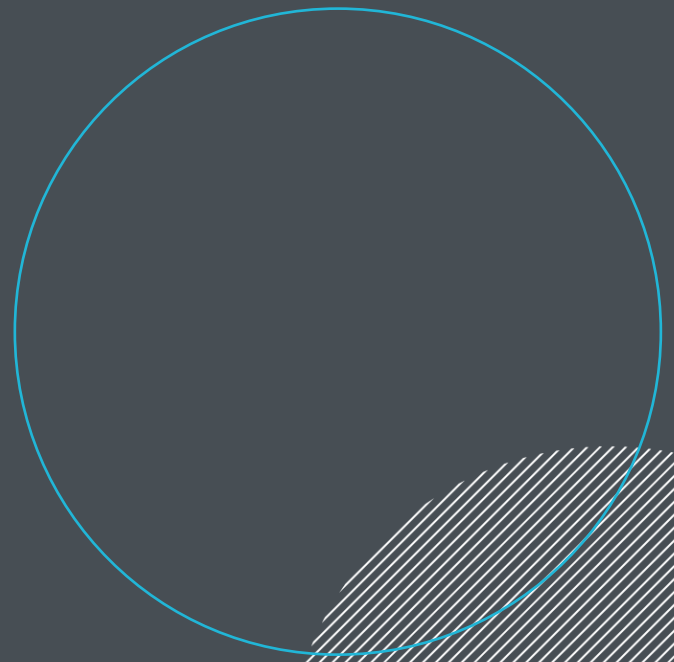


Thorough Evaluation

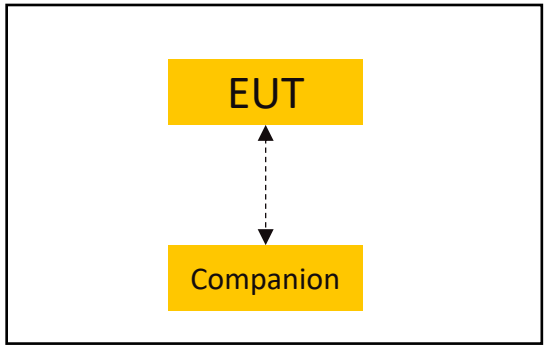
Practicality

- Time
- Money

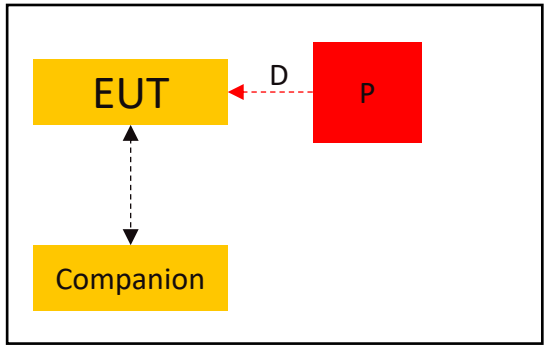
04 Test Execution



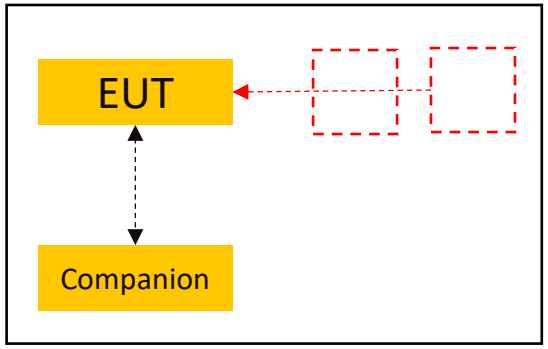
04 TEST EXECUTION
FOR MULTIPLE CHAMBER, RAC, AND ROE METHODS



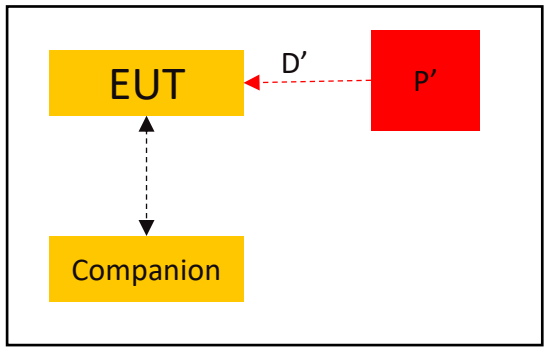
1. The Functional Wireless Performance (FWP) is baselined in the test environment with the EUT and companion device separated by their operating distance



2. The unintended signal is introduced at a distance **D** from the EUT and EIRP[1] **P**



3. The power of the interfering signal is adjusted up or down (simulating moving closer or further) to determine the threshold at which FWP is no longer maintained



4. The adjusted EIRP **P'** is converted to a distance **D'** and reported as the calculated minimum separation distance

[1] Equivalent Isotropic Radiated Power

04 TEST EXECUTION
MEASUREMENT UNCERTAINTY

- Uncertainty in level setting procedure
  - Signal generator level
  - Power meter or receiver uncertainty
  - Antenna gain and VSWR
- Uncertainty in test procedure
  - Table effects
  - sVSWR or NSA (site imperfections)
  - Moving the antenna

Uncertainty can be upwards of ±3dB or (-50%, +100%) in distance!

How to reduce uncertainty?

- Conducted test methods
- Use wideband, frequency-selective, time-gated power sensor measurements (e.g. Rohde & Schwarz NRQ6) over spectrum analyzer
- Test site validation in the bands of interest
- Low loss dielectric materials (e.g. expanded polystyrene) over wood or metal for support structures
- **Don’t move the antenna!**

05 Interpreting the Results
What does it all mean?

05 INTERPRETING THE RESULTS LIKELIHOOD OF COEXISTENCE (LOC)

Annex F of IEEE/ANSI C63.27 gives example methods for estimating the Likelihood of Coexistence (LoC) using measurement-based or model-based calculations.

Common problems:

- Overdetermination of parameters
- Underdetermination of parameters
- Miscalculated or misattributed uncertainty
- Valid only within the chosen parameter space
- Very involved statistical calculations with limited practical application

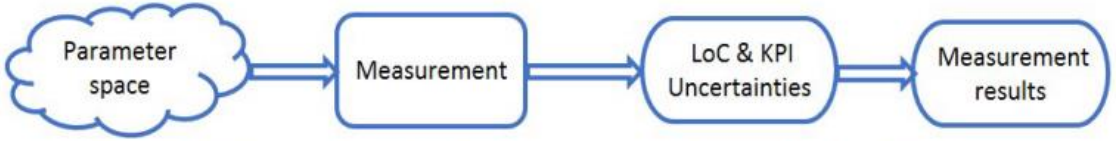


Figure F.1—Process flow of a direct-measurement (non-model-based) method for LoC and uncertainty estimation

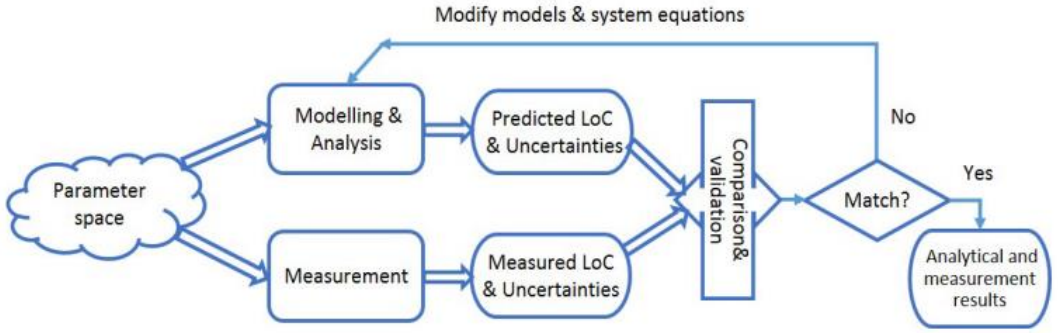


Figure F.2—Process flow of a model-based method for LoC and uncertainty estimation

05 INTERPRETING THE RESULTS LIKELIHOOD OF COEXISTENCE (LOC)

What is the probability that:

- An interfering signal comprising a particular:
  - polarization,
    - modulation,
      - amplitude,
      - frequency,
      - bandwidth, and
      - time domain component
  - Is received by the EUT,
    - And interferes with the FWP of the EUT

For <u>all</u> possible interferers??

- Consider splitting it with an independent Bayesian approach:

$$P(\text{failure}) = P(\text{failure} \mid \text{received signal}) \cdot P(\text{received signal} \mid \text{incident signal}) \cdot P(\text{incident signal}) \ldots \text{etc.}$$

- Total received signal is the energy present from a certain direction and angle, less the receive antenna gain in that direction integrated over the <u>entire</u> receive antenna pattern
- Consider an Additive White Gaussian Noise (AWGN) interferer as representative of many modern signal types

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