



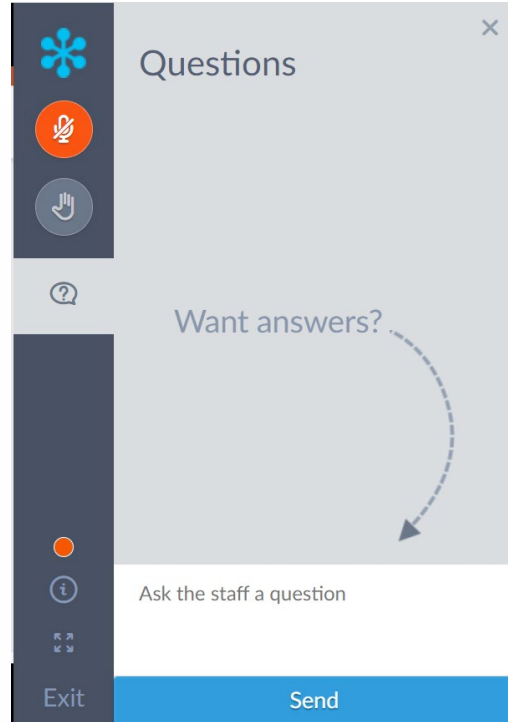
Compliance without Complexity

Design for Compliance & Laboratory Preparations

June 17, 2021



Housekeeping



- All attendees are muted to reduce background noise.
- If you have any questions, please type them into the chat box in your GoToWebinar control panel.
- We will be distributing the on-demand webinar link and copy of presentation.

Meet Our Presenters

Jandrew Gonzales



Jandrew Gonzales is a Key Account Manager with Nemko Canada. He began his career in the Testing, Inspection and Certification industry as an EMC Test Engineer for 4 years. Since then, Jandrew has moved into Business Development and enjoys educating and supporting device manufacturers who want to get their products to market.

Titu Botos

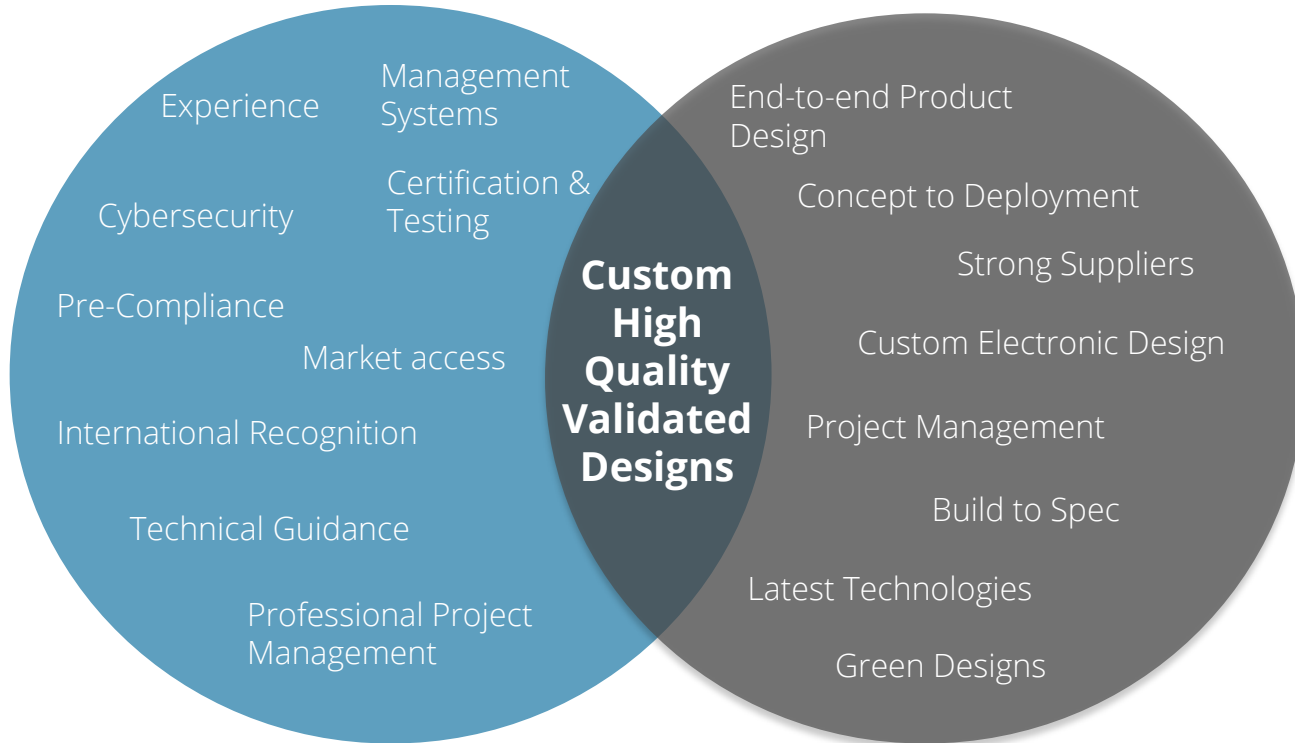


Titu Botos is the CEO of NeuronixWorks and has held various positions in leading organizations like Exploranium, MDA (formerly SPAR Aerospace), Vishay Precision Group (formerly KELK) and has also held teaching positions at University of Timisoara. He has over 30 years of experience in analysis, design, testing and debugging of both analog and digital systems and has a strong background in engineering research and training.



REVIEW OF SEMINAR I

- What is Regulatory Compliance?
- Why is it necessary to be compliant?
- Who needs to abide by compliance regulations?
- How to abide by the regulations while designing?



NeuronicWorks Inc.

CUSTOM ELECTRONIC PRODUCT DEVELOPMENT

400+

years of combined
experience

200+

successfully completed
projects

50+

highly skilled engineers
and designers

16

industries disrupted
with innovative
technology

6

months - average
project completion

Customer owns
the IP

Customer has
full control of
the design
process

Total
transparency of
the work
process

Total
confidentiality is
guaranteed

Support during
all stages and
post-delivery
process



Hardware Design



Firmware Design



Software Design



Web and App
Design



UX/UI Design



FPGA Design



Mechanical
Design



Industrial Design



Prototyping



Testing Support



Certification
Support



Manufacturing
Support



OUR CAPABILITIES

NeuronicWorks provides turnkey, end-to-end, custom electronics and embedded systems product development services.



Scientific &
Medical



Transportation



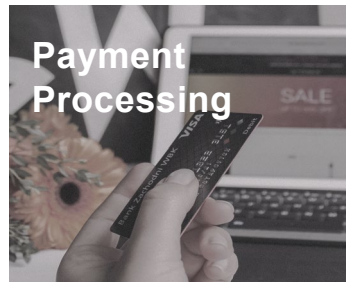
Industrial
Control



Tele-
communication
IOT



Payment
Processing



Edge
Computing &
Wearables



Gaming



Consumer
Electronics

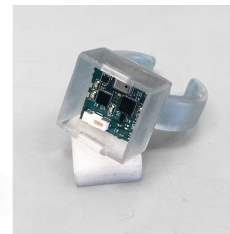


Agriculture



INDUSTRIES SERVED

Our breadth of expertise has strengthened our presence in key industries, which today represent 85% of our portfolio.

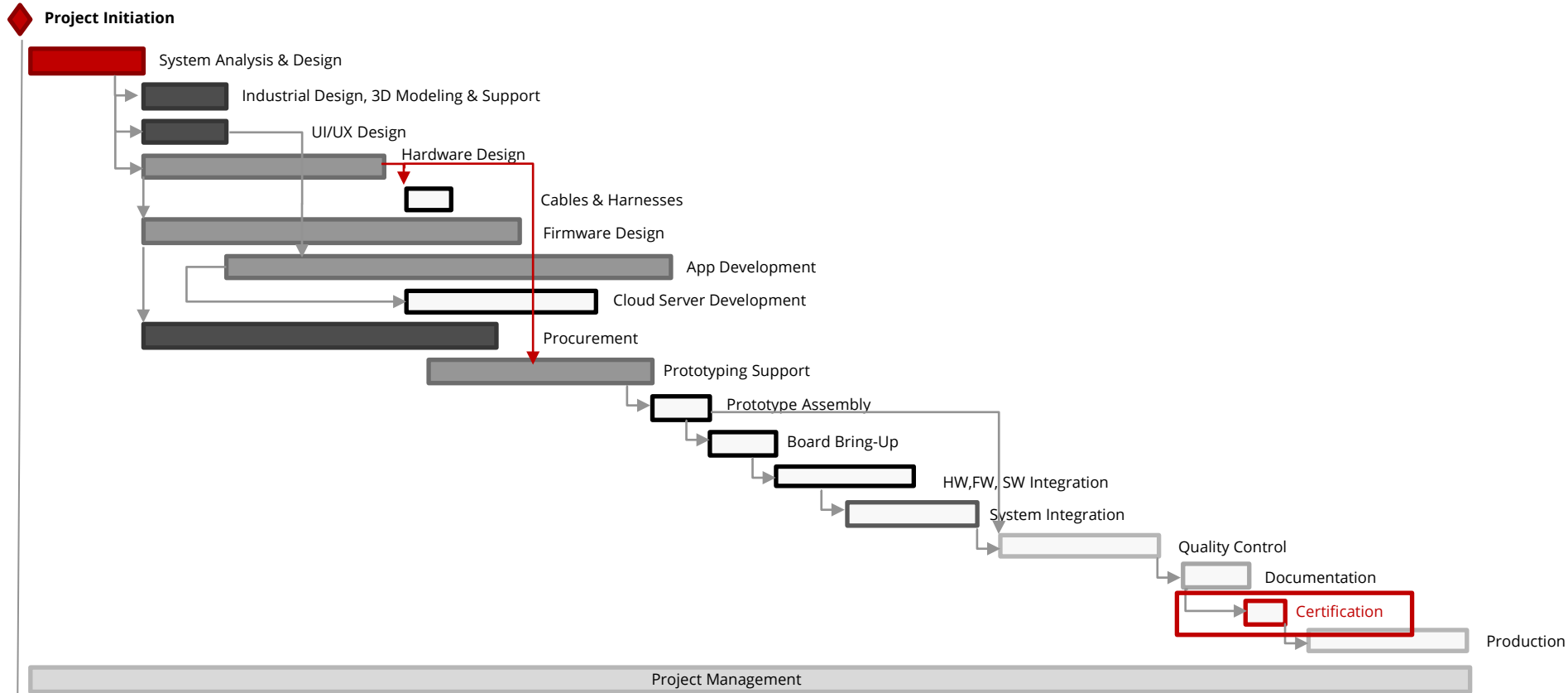


**OUR DESIGN,
YOUR SUCCESS!**

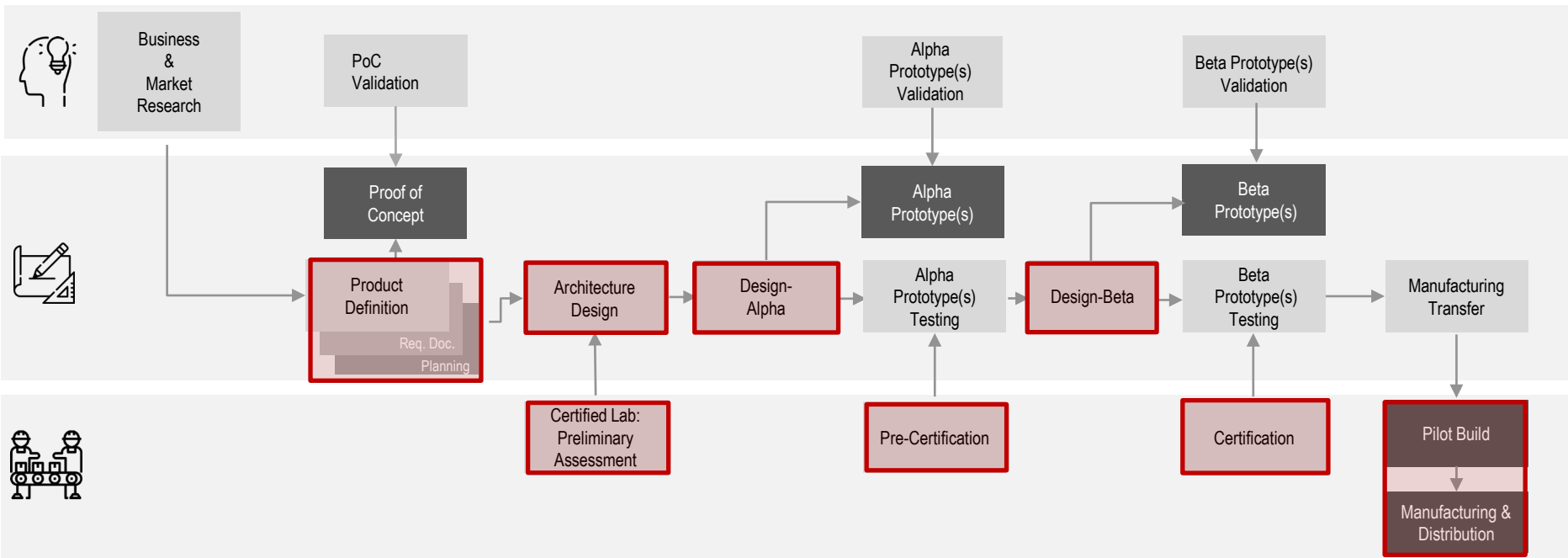
Typical Project Timeline



THE “TYPICAL” PROJECT TIMELINE



PRODUCT DEVELOPMENT PROCESS

IDEATION**PRODUCT
DEFINITION****ARCHITECTURE****DESIGN - PROTOTYPING - VALIDATION****NEW PRODUCT
INTRODUCTION**



BENEFITS: DESIGNING FOR COMPLIANCE

1

REDUCE THE DESIGN TIME

2

REDUCE DEVELOPMENT COST

3

GET PRODUCTS TO MARKET FASTER

Who is Nemko?

- **Our Vision**

- Nemko makes the world a safer place.

- **Mission Statement**

- Nemko safeguards products and systems, by supplying efficient third-party compliance and market access solutions.

- **At Nemko, our values are clear, we:**

- **Are** passionate about providing a great customer experience
- **Believe** in continuous learning and competence development
- **Care** for our customers, colleagues and the environment
- **Demonstrate** our integrity in everything we do

Advantages of using Nemko

Experience – Nemko has a great experience in **certification** projects and **market access**, that was built thanks to contacts with more than 160 countries in the world.

- **Recognition** – Nemko test reports and certificates are worldwide recognized.

- **Expertise** – Nemko offers experienced technical guidance for telecom and radio technologies.

- **Professional project management** – Our aim is to lead your product into the market in a faster and safer way. By using this service, you can get the product to the market in a timely manner ahead of the competition.



Our focus is your market access!

Our worldwide presence

Europe

- Nemko Group, Norway
- Nemko Norway
- Nemko Sweden
- Nemk Denmark
- Nemko Germany
- Nemko Italy
- Nemko Ltd., UK

North America

- Nemko San Diego
- Nemko Salt Lake
- Nemko Dallas
- Nemko Montreal
- Nemko Ottawa
- Nemko Toronto

Asia

- Nemko Beijing
- Nemko Shanghai
- Nemko Shenzhen
- Nemko Hong Kong
- Nemko Taiwan
- Nemko Korea
- Nemko Japan
- Nemko India

Middle East & Africa

- Nemko representation, Jordan
- Nemko representation, Saudi Arabia
- Nemko certification representation, Uganda

Nemko Cambridge Waterloo Laboratory



EMC Chamber



Compliance without Complexity

Pre-Compliance and Formal Testing: “How to be best prepared for a day at the lab”.

The following presentation is an outline to ensure your time and the engineering time is fully utilized and your product is ready for testing.

This overview is how to prepare for testing at the Nemko laboratory for:

- Pre-Compliance (EMC and/or Safety)
- Formal testing and certification Program



WITHOUT



Anecdotes – If I had a nickel every time someone said....

Top Three Things Conversations that re-occurred while being a test engineer:

1. I was told to come here – no other details were given.
2. My device has pre-approved components; 'Insert argument for not to test here'
3. Could you fix my device if it fails? What will it take for you to pass it?

Anecdotes – If I had a nickel every time someone said....

Top Three Things Conversations that re-occurred while being a test engineer:

1. I was told to come here – no one gave me details what to expect:
 - If this is your first time going into a lab environment where testing is performed; feel free to ask questions! 😊
 - It's also important to do your own due diligence and find out what's required
 - During your first contact with the sales person – ask for a meeting with the engineers

Anecdotes – If I had a nickel every time someone said....

Top Three Things Conversations that re-occurred while being a test engineer:

2. My device has pre-approved components; 'Insert argument for not to test here'
 - Integrators or integration of components into a system changes everything, can't take it for granted
 - False assumption; a lot of the EMC / Safety standards if you dig deep mention that integrated pre-certified or pre-tested components making up a system must be tested

Anecdotes – If I had a nickel every time someone said....

Top Three Things Conversations that re-occurred while being a test engineer:

3. Could you fix my device if it fails? What will it take for you to pass it?

- A lab doesn't have to pass you. Most labs aren't 'pay to pass' so anticipate worst case with troubleshooting efforts on your end and possibly re-testing
- ISO 17025, the standard accredited labs are certified to, must take an impartial stance and not favour clients or devices that would be considered a 'conflict of interest'
- No bribes 😊

Typical Project Flow

1. Engaging with Account Managers / Lab Directly / Compliance Team at the office
2. EMC Prescan / EMC Testing / Radio Testing
3. Safety Documentation / Construction Review
4. Testing Phase & Report Phase
5. Certificate Phase; if applicable

How to Plan – EMC Testing

- Review and complete the “Check List of Samples and Documents” provided by Nemko prior to your scheduled testing date.
- Arrive at the Laboratory 15 minutes before your scheduled lab time to prepare the test specimen
- Preparing your test specimen (pre-compliance or formal testing)
- What accessories to bring for your test specimen that are required for setup and testing (including hardware, software, manuals)
- Critical listed component or sub assembly certification requirements for your intended markets
- Are you designing your product to the correct standards? Have you reviewed the standards?

What Checklist(s) to Provide before Entering the Lab

EMC Checklist and Information Packet

- Provides to Nemko the modes of operation
- Indicate power inputs, battery operated components
- Indicates the wireless frequencies, certified and uncertified
- Instructions of operation – we need to know how to run the device
- Product intended use
- Intended markets

Safety Checklist and Information Packet

- Provides the power ratings and the power sources (AC, DC, PoE, Battery)
- Components list and their approvals
- Instructions of operation – we need to know how to run the device
- Product intended use
- Intended markets



What Checklist(s) to Provide before Entering the Lab

Section 1 Summary of ME EQUIPMENT and ME SYSTEMS identification, marking and documents requirements

1.1 Summary of ME EQUIPMENT and ME SYSTEMS identification, marking and documents requirements

Table 1.1-1: General Requirements

Clause (IEC 60601-1-2)	Requirement	Notes (including where evidence can be found)
4.1	RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES taken into account in the RISK MANAGEMENT PROCESS.	

Table 1.1-2: General Requirements – Non-ME EQUIPMENT used in an ME SYSTEM

Clause (IEC 60601-1-2)	Requirement	Notes (including where evidence can be found)
4.2	Check 16.1 of general standard, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard non-ME EQUIPMENT used in an ME SYSTEM complies with IEC and ISO EMC standards applicable to that EQUIPMENT, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard non-ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT tested according to the requirements of this collateral standard, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard	

Table 1.1-3: General Requirements – Configurations

Clause (IEC 60601-1-2)	Requirement	Notes (including where evidence can be found)
4.3	ME EQUIPMENT and ME SYSTEMS tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK as determined by the MANUFACTURER (This was determined using RISK ANALYSIS, experience, engineering analysis, or pretesting). Compliance checked by inspection of the test report and the RISK MANAGEMENT FILE. Power input and frequencies	



ONE WORLD • OUR APPROVAL

Applicant:

[Enter applicant name](#)

Product name:

[Enter product name](#)

Model:

[Enter model](#)

Model variants:

[Enter model variants](#)

Specifications:



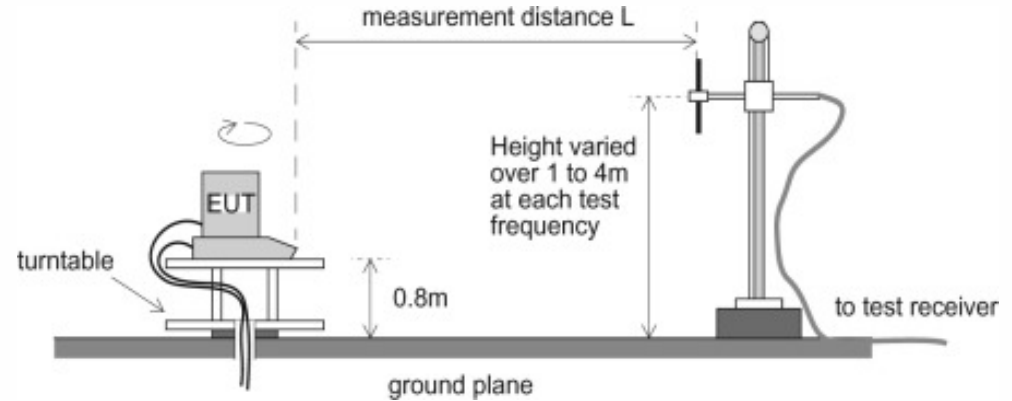
Cables & Peripherals

- All cables provided as shipped with final EUT
- All cables that could potentially be connected to ports
- Connector types
- Any cables connecting to peripheral equipment not part of the EUT must be at least 5m long



EUT Exercised to its Fullest Potential

- Special firmware to have the EUT exercised to its fullest potential
- Any peripheral equipment needs to be connected
- Generating a 'worst case scenario' for emissions on your device
- KDB 996369 D04 – RF Module Integration



Benefits of Pre-Compliance

- Reduce Product Development Time



- Possible reduction of testing costs vs possible delays during formal testing and certification



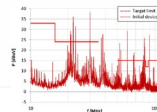
- Increase Profitability by getting your products to market faster and meeting your production timelines.



- To ensure reliability of the product and meeting safety and EMC standards related to your products.



- Generally, most issues with EMC testing is Emissions and Safety is Design to the Standard



Common Mistakes

- Not being prepared for your lab compliance date
- Coming to the laboratory late
- Not planning for possible design changes during evaluations
- Having the right company representative attending the lab testing for redesign changes
- Not starting early enough in the process to define intended use and regulatory requirements
- Not having product documentation ready and available (ie installation/user manuals)



THANK YOU!

QUESTION PERIOD



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www.neuronicworks.com

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COMING NEXT: COMPLIANCE WITHOUT COMPLEXITY III

- **Testing and Certification Process**
- Date: September 16, 2021
- Topics:
 - Different certification standards
 - Type of products that need or need not be certified
 - Documentations and forms required
 - How your design house can help prepare for certification
 - Pre and Post certification support