

BOSTON



RELIABILITY CHAPTER
& NE-ESDA, IMAPS/NE
AND BOSTON SMTA

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PROF. DEV. TRAINING:
S/W DEVELOPMENT FOR
MEDICAL DEVICE MANUFACTURERS
LIVE WEBINAR

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PROF. DEV. TRAINING:
LATEST INSIGHTS IN RF AMPLIFIER
DESIGN: FUNDAMENTALS AND
APPLICATIONS - LIVE WEBINAR

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THE REFLECTOR

ISSUE #8
AUGUST 2020

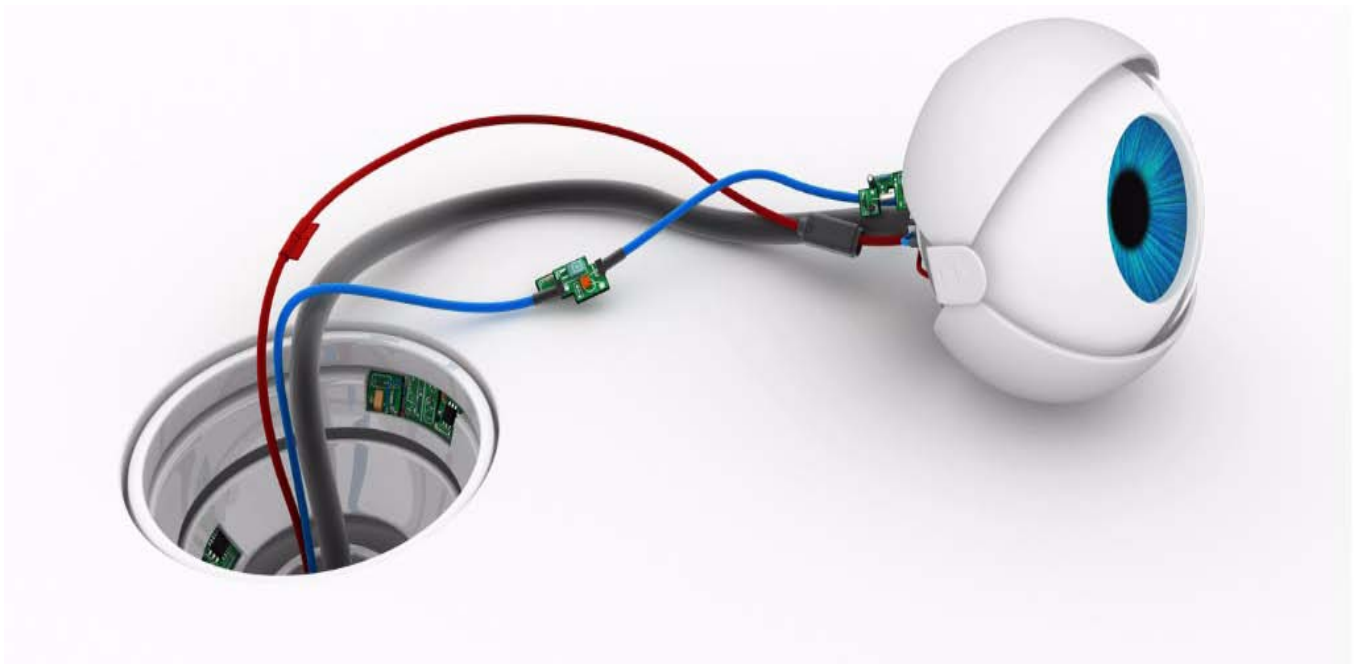


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Are Those Real?

by Karen Panetta, Reflector Editor

I recall being on an elevator when my son was two-years old. He has always loved to touch (break) everything, especially buttons. As he was pushing the elevator buttons and his Mama was busy digging out the disinfectant wipes in anticipation of all the germs on those buttons eager to jump on those little hands, the elevator began to shudder violently.

When I looked up at the elevator control panel, I noticed that my son was pushing two floor selection buttons simultaneously, while the doors were closing. The elevator controller clearly did not anticipate this sequence of events and got itself in a confused state.

When the doors opened, we saw a block wall and the floor we entered from, was looming above us. My baby looked at me as if to say, “Am I going to be in trouble for this?”

The expression on his face, threw my mind into a flashback of my early industry days as a new hire straight out of college. I was developing a diagnostic test for a new mainframe and vividly remember a puff of smoke coming from the clock module board I was testing. Recall that back in those days, hardware was jumbo sized, so our CPU spanned across many boards.

The lead engineer came over and inspected the smoking board and said, “Well, there goes 100,000 dollars”. At that moment, I envisioned my future career flipping burgers in a fast food establishment. This put me in a panic since I can’t cook. It was true then and true now that it would be cruel and unusual punishment for anyone to be subjected to eat my cooking.

Anyway, I was pleasantly surprised that instead of being shown the way out the door, I received a pat on the back from my team, which followed by a \$500 check and a recognition award. Little did I know that I had just invented self-destructive circuits, which would become important for today’s homeland security applications.

The fact that my son had found a condition that made a system fail made me proud. He definitely takes after his Mama and is on track to exceed her skills at breaking everything. If he becomes a superhero, such as one of the X-men, his nickname will be “Captain Havoc”.

The experience of finding conditions that makes systems fail has intrigued me so much that it has influenced my entire research career.

Around the same time I was frying CPU modules, a radiation therapy machine called the Therac-25 was connected to the deaths of six patients, each of whom received lethal doses of radiation. It was discovered that many untested, unanticipated scenarios of conditions and incorrect design assumptions caused the deaths. These events were the motivation for my future research and eventually the topic of my Ph.D. dissertation.

It also inspired one of my mantras for teaching, which states, “Just because a program compiles, doesn’t mean it works!”

Testing for system safety has been a predominant concern since the Therac-25 incidents. However, today these undetected safety issues and design flaws are being exploited intentionally for malicious purposes. Years ago, we designed targeting at achieving desired operating features and cost. The slogan was “Good, Fast, Cheap, pick-two”. Today, it seems like the slogan should be “Good, Cheap, Authentic, pick-two”.

Today’s designers need to think about how to protect their designs from being exploited by the coo-coo heads and from the counterfeiters that are going through our manufacturing trash bins recovering our discarded junk and re-selling it as “good, cheap, authentic” components. Incorporating counterfeit avoidance techniques into new hardware designs is being met with many of the same challenges that my industry designs once faced.

I can recall trying to convince marketing teams that Built-in self-test (BIST) and other manufacturing quality assurance hardware that the customer never uses in their applications was not a waste of money. However, the counter argument from these brilliant minds was always, "If the chip doesn't work, just throw it away."

Even if companies are willing to spend the money to include counterfeiting avoidance techniques in their designs, it is very expensive and unfortunately, the counterfeiters are getting smarter. Consider the case where one component manufacturer had a design defect in their component and the counterfeiters detected it and fixed it before the company itself released the new revision. These are some very talented counterfeiters. This is now a multi-billion-dollar business and consumers and manufacturers alike are suffering the ramifications of selling and buying junk components. This is not the worst of it. These bogus components are making their way back into our military's equipment, where the components' failure could endanger lives and affect homeland security.

Back in the elevator, all these issues flashed by in my mind until my son tugged at me and brought me back into the reality of the moment. We climbed out of the elevator and popped up from beneath the second floor to a group of curious on lookers.

Statistically, I convinced myself that these kinds of events were rare and it should be a long time between failures before I was the victim of another system failure. However, upon reaching my class, I powered up my laptop and it hung showing only a screen with the name of the hard drive manufacturer displayed across

the monitor. My students thought this was cool. They had never seen such a failure. This wasn't a typical "blue screen of Death," it was the "Curse of the Counterfeit Component".

The computer manufacturer had purchased counterfeit hard drives and passed them on to their customers. The component failures went undetected until a number of drives failed once in the hands of customers. To add more insult to injury, it is more cost-effective to buy a new computer than to replace the hard drive.

As a consumer, what confidence do we have that our products are authentic? Right now, we have very little confidence and no recourse when we become a victim of counterfeiting.

Who will save us from these villains? We need a superhero who excels at testing and breaking designs to reveal design defects. We need a superhero who will help us guarantee product authenticity with robust anti-counterfeiting techniques. We need Captain Havoc!

Captain Havoc is now eight years old and we will need to wait a few years for him to learn to control and hone his powers. It will be up to his IEEE Fellow Mama and her IEEE comrades to ensure that the curriculum and training for counterfeit detection, avoidance and security is ready for his generation to use against this dastardly enemy!

If you are interested in learning more about integrated circuit counterfeiting, check out the IEEE the IEEE North Atlantic Test Workshop.

Consumer Technology Society Call for Volunteers!

We are currently looking for volunteers who would be interested in pushing forward the mission of the Consumer Technology (CT-S), Boston Chapter. The chapter is looking for volunteers to help organize chapter meetings and help meet the needs of the local CT-S member needs. The Boston Section is organizing chapters into groups of similar technical interest areas to pool their resources for easier and better chapter collaboration in planning the chapter events.

If you have interest in volunteering for a chapter leadership position or are interested in learning more about what these volunteer positions may entail, please send an email to Karen Safina in the IEEE Boston Section office at, k.safina@ieee.org.

Dennis Shapiro, Chair, IEEE Boston Consumer Technology Chapter

IEEE Boston Section Online Courses:

(Students have 90 day access to all online, self-paced courses)

Verilog101:Verilog Foundations

Full course description and registration at ,
<http://ieeeeboston.org/verilog-101-verilog-foundations-online-course/>

System Verilog 101: Design Constructs

Full course description and registration at ,
<http://ieeeeboston.org/systemverilog-101-sv101-design-constructs-online-course/>

System Verilog 102: Verification Constructs

Full course description and registration at ,
<http://ieeeeboston.org/systemverilog-102-sv102-verification-constructs-online-course/>

High Performance Project Management

Full course description and registration at ,
<http://ieeeeboston.org/high-performance-project-management-online-course/>

Introduction to Embedded Linux Part I

Full course description and registration at ,
<http://ieeeeboston.org/introduction-to-embedded-linux-part-i-el201-online-course/>

Embedded Linux Optimization - Tools and Techniques

Full course description and registration at ,
<http://ieeeeboston.org/embedded-linux-optimization-tools-techniques-line-course/>

Embedded Linux Board Support Packages and Device Drivers

Full course description and registration at ,
<http://ieeeeboston.org/embedded-linux-bsps-device-drivers-line-course/>

Software Development for Medical Device Manufacturers

Full course description and registration at ,
<http://ieeeeboston.org/software-development-medical-device-manufacturers-line-course/>

Fundamental Mathematics Concepts Relating to Electromagnetics

Full course description and registration at ,
<http://ieeeeboston.org/fundamental-mathematics-concepts-relating-electromagnetics-line-course/>

Reliability Engineering for the Business World

Full course description and registration at ,
<http://ieeeeboston.org/reliability-engineering-business-world-line-course/>

Design Thinking for Today's Technical Work

<http://ieeeeboston.org/design-thinking-technical-work-line-course/>

Fundamentals of Real-Time Operating Systems

<http://ieeeeboston.org/fundamentals-of-real-time-operating-systems-rt201-on-line-course/>

Reliability Society, NE ESDA Chapter, iMAPS New England and Boston SMTA –
4:00PM, Wednesday, August 11

Near Field Emc Scanning Method Based on an E-Field Collapse - FREE Webinar w/ Q&A and Video Demonstration



NE ESDA Chapter in conjunction with the IEEE Boston Reliability Chapter, iMAPS New England and Boston SMTA offer this webinar to share a new, inexpensive method to validate EMC/ESD robustness. At registration you must provide a valid e-mail address, to receive the Webinar Session link the day before the event.

REGISTRATION

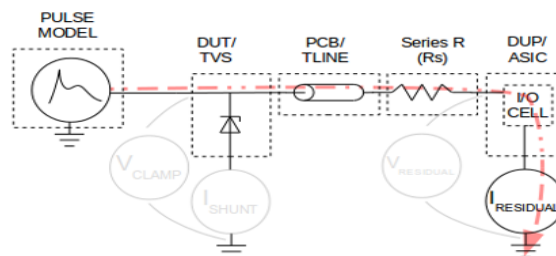
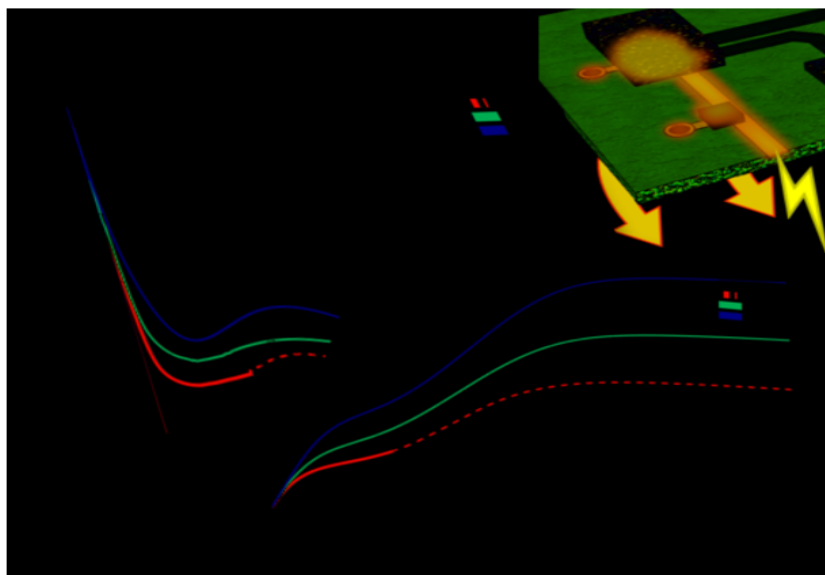
Starts 22 July 2020 12:00 PM; Ends 10 August 2020 05:00 PM; All times are US/Eastern

• No Admission Charge

Click here to register: <https://events.vtools.ieee.org/event/register/235882>

This Webinar will be delivered through WebEx. Ensure your device has WebEx installed in advance

Biography: Jeffrey Dunnihoo is the founder of Pragma Design specializing in interface design architecture and ESD, EOS, and other transient analysis, and he also collaborates with Dangelmayr Associates for system and factory consulting issues. These engineering services are based on decades of experience in I/O ASIC and serial bus interface protection and design. Pragma Design's current PESTO online ESD simulation tool implements the Industry Council's system efficient ESD design methodology which is used in Littelfuse's iDesign simulation tool. Jeff has presented at IEEE EMC, ESDA, ISTFA, and has co-authored a new textbook with other ESD experts on ESD co-design fundamentals, as well as a series of children's books about engineering. Email: jeffhoo@pragma-design.com



Since the introduction of the Field Collapse Event (FCE: Dunnihoo, Tamminen, Viheriäkoski 2015) testing improvements over Charged Board Events (CBE), Pragma Design has continued to apply and adapt this methodology to other ESD/EOS/EMC domains. While high-voltage referenced CBE is a real and distinct ESD aggressor in manufacturing and in the field, FCE methods allow functional and powered testing with similar real-world pulses while the system under test remains at a safe ground potential. Combining this new method together with fully automated near field scanning equipment to construct *E*- and *H*-field information of a system during transient ESD events is described. This inexpensive method provides an alternative way for system designers to validate and analyze the EMC/ESD robustness of electronic systems without TLP pulsers, IEC61000-4-2 guns, or precision inductive current probes.

Aerospace and Electronic Systems Society – 7:00PM, Wednesday, August 26

Family Talk on How Radar Helped Win WW II

Dr. Eli Brookner (Raytheon, retired)



This talk is intended for the general public of all ages. An easy to understand explanation of how radar works will be given. Radar was in its infancy at the start of World War II. The British were using radar effectively along their coastline with a network of antennas on 300-foot-tall towers to warn of approaching enemy aircraft and missiles but they needed an

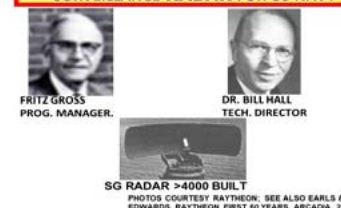
invention that would allow radars to be small enough to fit on ships and aircraft. They came up with the cavity magnetron invention. They looked to American manufacturing know-how and resources to mass produce this device in a hurry. After turndowns by all the major US firms, a small Boston newcomer, Raytheon Company, came up with a solution and ended up making 85% of all magnetrons used by the allies in the war, and changed the course of the war. By the end of WW II Raytheon's shipborne radars were on all allied ships military and civilian. Radar can see at night, through clouds, in and fog. Radar can be used to land aircraft in zero visibility. Radar can be used to identify targets to prevent fratricide, deploy forces optimally, for navigation, for collision avoidance.

Eli Brookner, who worked at Raytheon Company from 1962 to 2014, will show just how dramatically the use of radar on aircraft and ships helped to destroy enemy aircraft, ships, missiles and submarines. How the use of miniature radars on the tops of artillery shells immensely increased their effectiveness against aircraft, missiles, infantry men and their equipment. These miniature TOP SECRET radars, called proximity fuzes, used miniature glass tubes which had to withstand 20,000 g when blasted from the artillery guns. Raytheon was one of the suppliers of these tubes. 22,000,000 proximity fuzes with 140,000,000 tubes were produced during WW II. Radar was used with the atomic bombs. Eli holds a bachelor's degree in Electrical Engineering from The City College of New York and a Master's and D.Sc. degree from Columbia University. He is the author of four books on radar, antennas and tracking, has published more than 230 papers, and has taught courses on Radar, Phased Arrays and Tracking in 26 countries to over 10,000.

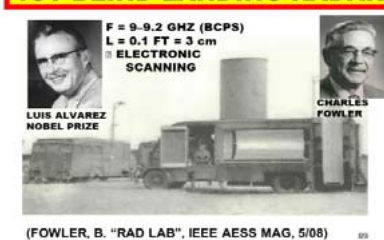
MIT RAD LAB SCR-584



WW-2 SG RAYTHEON SHIPBOARD SURVEILLANCE RADAR FOR US NAVY



1ST BLIND LANDING RADAR



BRITISH BREAKTHROUGH CAVITY MAGNETRON INVENTION



PROXIMITY FUZE – TOP SECRET ONE OF 3 INVENTIONS CREDITED WITH WINNING WW-2



NORM KRIM WITH
SUBMINATURE TUBE USED
IN PROXIMITY FUZE,
WITHSTOOD 20,000 G.
LATER USED IN HEARING AIDS, POCKET RADIOS.

PHOTOS COURTESY RAYTHEON; SEE ALSO EARLS & EDWARDS, RAYTHEON FIRST 60 YEARS, ARCADIA



CHAIN HOME RADAR



YEAR 1938
FREQUENCY 20-55 MCPS
WAVELENGTH 18-50 FT

SIR
WATSON
WATT



FORCE
ENHANCER.

To register for this family talk, please click the url:

<https://events.vtools.ieee.org/m/236596>

Inventorship Determinations May Get Muddier: Should Naming an Inventor in a Patent Application be Required for AI-Developed Inventions?

By: Greg K. Gerstenzang



Under current US law, there is no provision for determining inventorship or ownership to otherwise inventive solutions developed by artificial intelligence (AI) systems. AI systems are used in industry and academia to develop solutions to problems in areas such as drug discovery, materials science, and nanotechnology. The inability to determine inventorship of inventive solutions developed by AI systems in these and other fields makes it nearly impossible to apply for patents or properly assign ownership to these solutions. Without guidance, this inability to apply for patents for AI-developed inventions or assign ownership may, potentially, stifle innovation and impair one of the objects of the patent system itself – to disseminate knowledge regarding new inventions to the public by describing these inventions in patents. To incentivize this type of innovation, a solution is needed that allows for AI-developed inventions to be protected, enforced, and assigned.

Under US case law “[t]he threshold question in determining inventorship is who conceived of the invention.” One who reduces a conceived invention to practice or who performs optimization of a conceived invention, without contributing to the conception of the invention itself, is not considered an inventor. For example, if a chemist invented a method of synthesizing a novel chemical compound and instructed a lab assistant to run experiments to determine an optimal temperature at which the method should be performed, the chemist, but not the lab assistant, would be considered the inventor of the method.

Under US case law “[t]he threshold question in determining inventorship is who conceived of the invention.” One who reduces a conceived invention to practice or who performs optimization of a conceived invention, without contributing to the conception of the invention itself, is not considered an inventor. For example, if a chemist invented a method of synthesizing a novel chemical compound and instructed a lab assistant to run experiments to determine an optimal temperature at which the method should be performed, the chemist, but not the lab assistant, would be considered the inventor of the method.

For inventions that are developed utilizing an AI system, who, if anyone, is the inventor? Where a person conceives of an inventive solution to a problem and then instructs an AI system to optimize certain features of the inventive solution, the answer is clearer. Performance of routine optimization by the AI system will not call into question whether the AI system is an inven-

tor. Things get murkier, however, if a person presents a problem to be solved by an AI system, and the system develops an otherwise inventive solution that the person had not conceived of. Now who is the inventor of the solution? The person did not conceive of the solution, so in accordance with current patent law, the person is not the inventor. But what if the person programmed the algorithm that the AI system utilized to arrive at the solution? Again, according to US law, if the person did not conceive of the particular solution arrived at by the AI system, he/she is not the inventor. The question of who may be properly named as the inventor of an otherwise inventive solution developed by an AI system is not just for academics. To apply for a patent on an invention, one must list the inventor(s).

Declaring an AI system as an inventor because it develops an otherwise inventive solution is inconsistent with current patent statutes and case law. The patent statutes utilize pronouns (e.g. “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter ... may obtain a patent therefore”) that strongly suggest, but do not explicitly state, that an inventor must be a natural person. In 2019 a group of patent attorneys known as the “Artificial Inventor Project,” applied for a patent listing an AI system as the inventor and listed the developer of the AI system, Stephen L. Thaler, as the applicant. The United States Patent and Trademark Office (USPTO) rejected the application for not listing a human inventor, finding that the language of the patent statutes should be interpreted to limit inventors to natural persons, and citing court precedent holding that only natural persons can be “inventors.”

Therefore, if neither the person who instructs an AI system or an AI system itself can be considered the inventor of a solution, could anyone apply for a patent on the solution? According to current patent law, it would seem the answer is “no.” This may impact innovation, because the promise by the USPTO, and indeed the Constitution, to grant the right to exclude others from

practicing a patented invention provides an incentive for individuals and companies to fund research and development for new inventions. Without the possibility of being able to file patent applications on inventions created by an AI system, there is little protection for the perceived inventors, e.g. the companies or persons who own the AI.

A patent provides its named inventor(s) with rights to the invention defined by the claims of the patent. However, there is nothing in the law, statute or case law, that holds that an AI system -- any other object that may itself be considered property, can own property. If an AI system cannot "own" any intellectual property rights to an inventive solution it produces, and the operator of the system cannot claim to be the inventor of the solution, then there is no reasonable solution for patenting the solution. Without the patent, there is no defined owner of the intellectual property, e.g. the solution.

Perhaps the concept of "inventor" may need to be expanded to include AI systems operating under the control or direction of a human or to include the human(s) operating the AI systems, regardless of the extent to

which they conceived of the inventive solution. Or perhaps the requirement to name a particular inventor in a patent application may be eliminated, and patents may be applied for naming only applicants or assignees. Presumably, AI systems will continue to advance and will be used more extensively in developing solutions to problems that people may have difficulty otherwise solving. For example, developing or identifying promising drug candidates for different diseases, or new algorithms to identify valuable stocks. The possibilities of what AI might find are limitless. Therefore, finding the answer to the questions: "how to address the requirements for identification of an inventor in a patent application?" and, "how to assign ownership of AI-developed inventions?" will become imperative as the present absence of possibility to file for and obtain a patent will likely correlate with the reduction of new inventions being shared and protected.

Gregory Gerstenzang is an intellectual property attorney and partner at Boston, MA law firm, Lando & Anastasi, LLP. He can be reached at 617-395-7048 or GGerstenzang@LaLaw.com

Consumer Technology Society Call for Volunteers!

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Dennis Shapiro, Chair, IEEE Boston Consumer Technology Chapter

Call for Articles

Now that the Reflector is all electronic, we are expanding the content of the publication. One of the new features we will be adding are technical, professional development, and general interest articles to our members and the local technology community. These will supplement the existing material already in our publication.

Technical submissions should be of reasonable technical depth and include graphics and, if needed, any supporting files. The length is flexible; however, a four to five page limit should be used as a guide. An appropriate guide may be a technical paper in a conference proceeding rather than one in an IEEE journal or transaction.

Professional development or general interest articles should have broad applicability to the engineering community and should not explicitly promote services for which a fee or payment is

required. A maximum length of two to three pages would be best.

To ensure quality, technical submissions will be reviewed by the appropriate technical area(s). Professional/interest articles will be reviewed by the Publications Committee for suitability. The author will be notified of the reviewers' decision.

The Reflector is published the first of each month. The target submission deadline for the articles should be five weeks before the issue date (e.g., June 1st issue date; article submission is April 27). This will allow sufficient time for a thorough review and notification to the author.

We are excited about this new feature and hope you are eager to participate!

Submissions should be sent to;
ieeebostonsection@gmail.com

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IEEE Boston Section is the largest, most active, and technically diverse section in the U.S. Comprised of Engineers, scientists and professionals in the electrical and computer sciences and engineering industry

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Contact Kevin Flavin or 978-733-0003 for more information on rates for Print and Online Advertising

Call for Course Speakers/Organizers

IEEE's core purpose is to foster technological innovation and excellence for the benefit of humanity. The IEEE Boston Section, its dedicated volunteers, and over 8,500 members are committed to fulfilling this core purpose to the local technology community through chapter meetings, conferences, continuing education short courses, and professional and educational activities.

Twice each year a committee of local IEEE volunteers meet to consider course topics for its continuing education program. This committee is comprised of practicing engineers in various technical disciplines. In an effort to expand these course topics for our members and the local technical community at large, the committee is publicizing this CALL FOR COURSE SPEAKERS AND ORGANIZERS.

The Boston Section is one of the largest and most technically diverse sections of the IEEE. We have over 20 active chapters and affinity groups.

If you have an expertise that you feel might be of interest to our members, please submit that to our online course proposal form on the section's website (www.ieeeboston.org) and click on the course proposal link (direct course proposal form link is

<http://ieeeboston.org/course-proposals/> . Alternatively, you may contact the IEEE Boston Section office at ieeebostonsection@gmail.com or 781 245 5405.

- **Honoraria can be considered for course lecturers**
- Applications oriented, practical focused courses are best (all courses should help attendees expand their knowledge based and help them do their job better after completing a course)
- Courses should be no more than 2 full days, or 18 hours for a multi-evening course
- Your course will be publicized to over 10,000 local engineers
- You will be providing a valuable service to your profession
- Previous lecturers include: Dr. Eli Brookner, Dr. Steven Best, Colin Brench, to name a few.

IEEE Boston Section Social Media Links:

Twitter: <https://twitter.com/ieeeboston>

Facebook: <https://www.facebook.com/IEEEBoston>

YouTube: <https://www.youtube.com/user/IEEEBostonSection>

LinkedIn: <https://www.linkedin.com/groups/IEEE-Boston-Section-3763694/about>



The IEEE High Performance Extreme Computing Conference (HPEC 2020) will be held in the Greater Boston Area, Massachusetts, USA on 22 – 24 September 2020. IEEE HPEC will have virtual conference options that allow safe participation and full publication in the IEEE Digital Xplore Library!

Presentations that describe advances in high performance extreme computing technologies will be presented at this conference which is to be the premier conference in the world on the confluence of HPC and Embedded Computing.

Confirmed Distinguished Speakers include:

- [Dr. Yudong Cao](#) ([Zapata Computing](#)) - *Advances in Algorithms for Near-Term Quantum Computer*
- [Dr. Jeffrey Chou and Dr. Suraj Bramhavar](#) ([Sync Computing](#)) - *The Need for Hardware-Accelerated Combinatorial Optimization*
- [Dr. John Feo](#) (PNNL) - *The Need for Integrated Analytic Platforms and Multithreaded Runtime Systems*
- [Prof. Sigal Gottlieb](#) (UMass Dartmouth Mathematics) - *High Order Efficient Methods for Black Hole Simulations*
- *More to come!*



Challenges such as [YOHO](#), [MNIST](#), [HPC Challenge](#), [ImageNet](#), and [VAST](#) have played important roles in driving progress in fields as diverse as machine learning, high performance computing, and visual analytics.

GraphChallenge encourages community approaches to developing new solutions for analyzing graphs and sparse data derived from social media, sensor feeds, and scientific data to enable relationships between events to be discovered as they unfold in the field.

IEEE-HPEC.ORG

Software Development for Medical Device Manufacturers

Web-based Course with live Instructor!

(12.5 hours of instruction!)

Times & Dates: 1:00 - 4:PM EDT; October 19, 20, 21, 22

Speaker: Steve Rakitin

This course will be presented with a live instructor using web-meeting software. The course content will be covered in 4 sessions presented over four days.

COURSE SUMMARY

Developing software in compliance with the FDA Design Control regulation, changing FDA guidance documents and latest international standards is challenging. This intensive course provides practical solutions and suggestions for developing software in a manner that meets applicable FDA regulations, guidance documents and international standards, such as IEC-62304:2015. The focus is on interpreting Design Controls for software. Each section of the Design Controls regulation (820.30) is discussed from the perspective of software development. Discussions on key topics such as Software Requirements, Traceability, Design Reviews, Software Verification & Validation and Risk Management (including recently updated standards ISO-14971:2019 and EN-14971:2019) are included. Also discussed are FDA requirements for validation of software development tools and software used in Manufacturing and Quality Systems. Also discussed are recent FDA Guidance Documents on Cybersecurity, Mobile Apps, and Usability.

THIS COURSE IS INTENDED FOR...

Software engineers, project managers, quality managers, software quality professionals, RA/QA staff, and anyone who needs to develop cost-effective processes and procedures that will enable their organizations to deliver high quality software-based medical devices that comply with FDA regulations and international standards. This course is also appropriate for people who are new to the medical device industry.

COURSE MATERIAL

Course notes, access to an extensive collection of reference documents and a training certificate will be provided.

COURSE OUTLINE

This course will be presented with a live instructor using web-meeting software. The course content will be covered in 4 sessions as described below. Please note that duration of each session may slightly change depending on the number of questions posed to the instructor.

AGENDA

SESSION 1 – Regulatory Context

Duration ~3 hours with one 15 min break

This session will cover key regulatory requirements for medical device software in the US and EU.

Regulations and Guidance:

- FDA Medical Device Regulation (21 CFR Part 820 – specifically, design controls)
- EU Medical Device Regulation
- FDA Guidance Documents:
 - o Guidance for Content of Pre-market Submissions for Medical Devices Containing Software
 - o Off-the-Shelf Software Use in Medical Devices
 - o General Principles of Software Validation
 - o Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
 - o Policy for Software Device Functions and Mobile Medical Applications
 - o Applying Human Factors and Usability Engineering to Medical Devices
- International Standards:
 - o ISO 13485:2016 Medical Devices – Quality Management Systems

- o IEC 62304: 2015 Medical Device Software – Software Lifecycle Processes
- o ISO 14971: 2019 Application of Risk Management to Medical Devices
- o EN 14971: 2019 Application of Risk Management to Medical Devices
- Off-the-Shelf (OTS) Software and Open Source software (SOUP)
- Discussion: All Software Is Defective...

SESSION 2 – FDA Design Controls and IEC 62304 – Part 1 Duration ~2.5 hours with one 15 min break

This session will cover FDA Design Controls and IEC 62304 requirements for medical device software.

- Design and Development Planning
 - o How does Agile Development fit?
 - o Medical Device Software Lifecycle Processes
- Risk Management
 - o FDA Levels of Concern
 - o IEC 62304 Software Safety Classification
- Software Requirements
 - o Techniques for Removing Ambiguity from Requirements
- Software Architecture and Design
- Software Design Changes

SESSION 3 – FDA Design Controls and IEC 62304 – Part 2 Duration ~2.5 hours with one 15 min break

This session will cover Software Verification and Validation requirements.

- Software Implementation
- Software Verification
 - o Technical Reviews
 - o Static Analysis
 - o Unit and Integration Testing
- System Testing
- Software Validation Testing

SESSION 4 – Software Tool Validation and Risk Management Duration ~2.5 hours with one 15 min break

This session will cover Software Tool Validation and Risk Management requirements.

- Software Tool Validation

- o Deciding which tools need to be validated
- o Validation approach for software tools
- Validation of Manufacturing Software and Quality System Software
- Risk Management Using Fault Tree Analysis (FTA)
 - o Review of ISO/EN 14971:2019 Requirements
- o Example of Fault Tree Analysis and Failure Modes Effect Criticality Analysis (FMECA)

Course Cancellation and Refund Policy: Requests for online course cancellations must be received 3 business days prior to the course date for a full refund. Once course materials have been shared with a participant, a cancellation request cannot be accommodated.

About the instructor...

Steven R. Rakitin has over 40 years experience as a software engineer and software quality manager. He helped write the first IEEE Software Engineering Standard (IEEE-STD-730 Standard for Software Quality Assurance Plans) and worked on revisions to both IEEE Standard 1012-2012 (Software Verification & Validation) and IEEE 730-2014 (Software Quality Assurance). He has written several papers on software quality as well as a book titled: Software Verification & Validation for Practitioners and Managers. He received a BSEE from Northeastern University and an MSCS from Rensselaer Polytechnic Institute. He earned certifications from the American Society for Quality (ASQ) as a Software Quality Engineer (CSQE) and Quality Auditor (CQA). He is a Senior Life Member of the IEEE. As President of Software Quality Consulting, he helps medical device companies comply with FDA regulations, guidance documents, and international standards in an efficient and cost-effective manner.

Decision (Run/Cancel) Date for this Course is Monday, October 12, 2020

IEEE Members	\$285
Non-members	\$345

Latest Insights in RF Amplifier Design from World's Leading Experts – Fundamentals and Applications

(10 hours of instruction!)

Time & Date: 6 – 8PM EDT, Tuesdays, September 29, October 6, 13, 20, 27, November 3

Live Interactive Webinar!

Course summary/overview:

This six week lecture series is intended to give a broad overview of state-of-the-art RF PA techniques with practical aspects for working professionals together with students for future RF PA designers, from fundamentals to applications. It begins with a review of RF power amplifier concepts then teaches handset PA design techniques, issues and solutions faced with designing RF PAs for mobile applications. It also discusses high efficiency amplifier structures with different classes of operation, and other architectures. A high linearity techniques lecture with behavioral modelling will follow. GaAs/GaN MMIC level millimeter-wave amplifier design tutorials and techniques will be lectured including foundry/technology selection, loadpull, loadline analysis and simulations with EDA tools. Lastly, digital perspective transmitters will be presented using GaN technology together with FPGA and ASICs.

The platforms currently being considered for the course are MS Teams and Zoom and attendees should be prepared to access the course by both platforms.

Benefits of attending:

This course will give a broad overview of state-of-the-art RF PA techniques with practical aspects to help sharpen current skill sets as well as initiate the RF PA design with better confidence.

Target Audience/who should attend:

RF engineer professionals and prospective RF amplifiers / RFIC design students

Outline

RF Amplifier Basics – (9/29/2020)

by Dr. Nestor Lopez at MIT Lincoln Laboratory

RF Power Amplifier Design for Mobile Applications – (10/06/2020) - by Dr. Douglas Teeter at Qorvo

Digital Transmitter – (10/13/2020)

by Dr. Rui Ma at Mitsubishi Electric Research Labs

High-Efficiency RF Power Amplifiers Architecture – (10/20/2020)

by Dr. Nestor Lopez at MIT Lincoln Laboratory

High Frequency RF Amplifiers MMIC Design with GaAs/GaN pHEMT with EDA tools - (10/27/2020)

by Dr. Youngho Suh at MIT Lincoln Laboratory

Behavioral Modeling and Linearization of RF Power Amplifiers – (11/03/2020)

by Dr. Kevin Chuang at NanoSemi, Inc.

Decision (Run/Cancel) Date for this Courses is Monday, September 21

IEEE Members	\$195
Non-members	\$235
Full Time Students (members)	\$75
Full Time Students (non- members)	\$95

http://ieeeboston.org/event/latest-insights-in-rf-amplifier-design/?instance_id=2845



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