BOSTON

THE REFLECTOR

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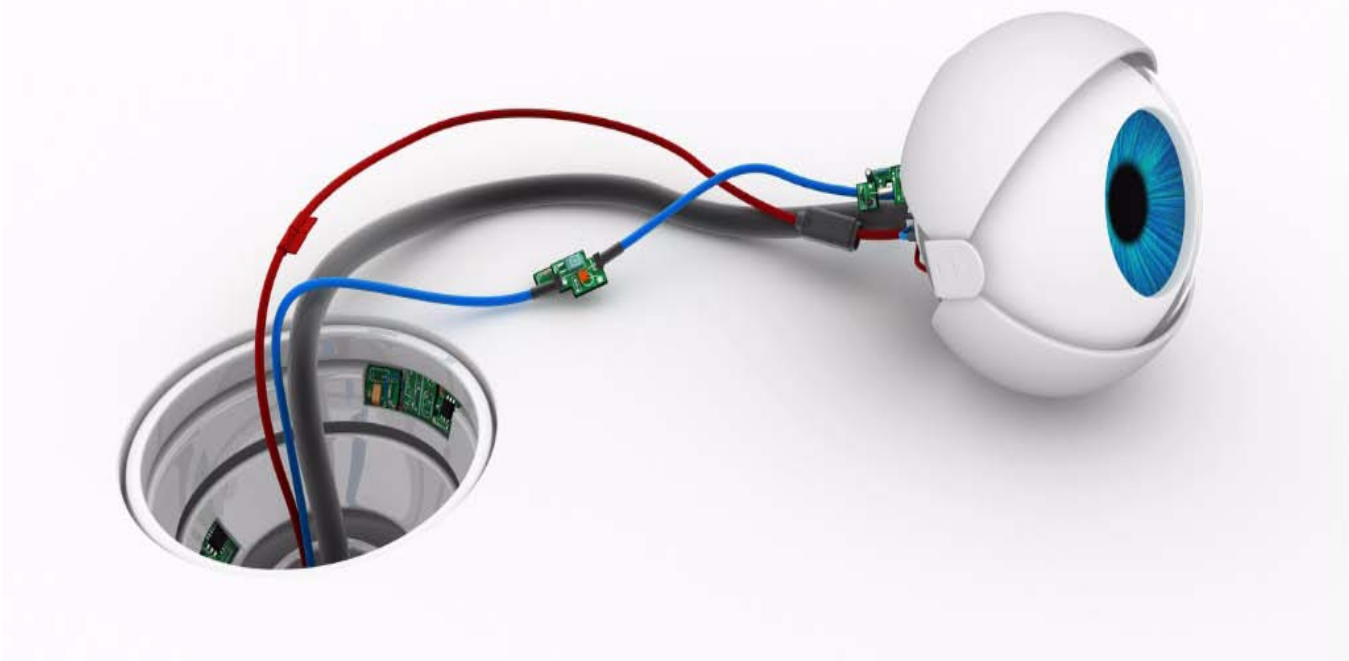

IEEE
Advancing Technology for Humanity

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The Unusual Path to Technology

Kevin Flavin, Chair, Electronic Communication Team

As a parent, my attention has slowly snapped back to school. The forms that I should have filled out in May and June are now due before Labor Day. Included in these emails are announcements sent to many parents regarding new programs to boost STEM in our schools. (STEM means Science, Technology, Engineering, and Mathematics)

STEM reaches into our lives - your smartphone, the card-swipe thing, the automated doors of the grocery store - the underpinning of most of our purchases, whether you're using distributed networking by watching Netflix or distribution tracking of your package through the mail. We don't notice it, or even realize it any more.

This summer, I've had a lot of time to think about how these things work. We've been putting some serious miles on our old vehicles trying to visit colleges for our eldest. During those long miles in Maine, I made a realization that my own family has some serious chops in STEM education and vocation. I venture to say even a solid representation in mathematics, medicine, and, of course, technology.

I know that making the pitch for a STEM career is like the proverbial 'preaching to the choir' in these pages.

Whenever I bring up career choices to my kids, I get the question 'what is STEM again?' I think it's important to expand that question to the applications in our daily lives.

Here's an example, my wife received a BSBA in political science, with a history concentration. Today, her work touches on finding scientists and leaders in biotech. She can rattle off the advances in using genomics to treat diseases faster than I can say "oncology". Sometimes, the interest in a field comes later, I guess.

My own experiences could still be STEM, sort of. Starting in Electrical Engineering, working for a satellite technology company testing the dishes, was definitely on the path of hard tech. Then, I took a detour into a bank, working on modeling the emerging markets. The math fascinated me far more in that role. Now, twenty years later in the financial services industry, I can speak about multiplicative vs. additive performance measurement and attribution. Would those topics fall within the STEM definition? I'm not sure.

Does work for a software company qualify as a STEM field? How about finished carpentry? Does a STEM job require wearing a suit? My best friend has a Civil Engineering degree, most of his classmates wear boots, jeans, and a t-shirt.

Now, I have to ask, what is STEM again?

As a parent of two daughters, I struggle with guiding them toward a STEM career, maybe it's a pride thing, but I'm really not that worried about it - referencing my wife's own journey, things change.

I can, without reservation, say that I wish I had a resource to help me along in that goal. To be fair, I didn't think that I needed advice in raising scientists, but after seeing the new book by our own Karen Panetta and her colleague Katianne Williams, I regret not having this.

Count Us In, by Karen Panetta and Katianne Williams is on my Reading Now list, and I have to reiterate, I wish I had this back then. The book covers how to approach

the topic of STEM with girls, whether you're a parent or any adult with a responsibility to teach and guide children and young adults. The first section, the one I'm deep into right now, breaks out advice for elementary age, middle school age, high school age, and university age. It's a perfect vector on this topic.

I can't recommend the book enough, and with some luck, we're hoping to get an interview with them in an upcoming Digital ReflectoR.

On a more immediate topic, there's a Women in Engineering Conference coming in November, so register right away! I recommend starting at their twitter account to keep up to date on the latest : https://twitter.com/IEEEWIEForumUSA

Now, it's off to finish supply shopping; it's art supplies and an arduino on the list. Wish us luck, and I wish the same for you.

This editorial was originally publsuhed in the September 2018 issue

IEEE Boston Section Excom Member Recipient of MGA Leadership Award

This award is to recognize those individuals who have exhibited exemplary and substantive leadership of an extraordinary nature in implementing activities that support the goals of Member and Geographic Activities (MGA) at the local, regional, national, and/or international level.

The accomplishments of the candidate should be of "significant performance" and should have made a distinguishing contribution to IEEE. The focus should be on volunteering for IEEE, MGA, or its organizational units, not on professional achievement.

The 2020 MGA Leadershiop Award recipient is Karen Panetta.

IEEE MGA Leadership Award Citation
"For outstanding leadership and distinguished service to IEEE by promoting women in engineering and increasing the value of membership by engaging all populations including students, young professionals and life members"

Karen Panetta received a B.S. in Computer Engineering from Boston University, and a M.S. and Ph.D. in Electrical Engineering from Northeastern University. As the first female electrical engineer to be given tenure in the Electrical and Computer Engineering department, Panetta continues to promote the interests of women in her field. From 2007 to 2009, she was the worldwide director for IEEE Women in Engineering, the largest international professional organization dedicated to promoting women engineers and scientists, and she served as editor-in-chief of the IEEE Women in Engineering magazine. She is the faculty adviser to the Tufts student chapters of both the Society of Women Engineers and the IEEE, and is founder of the nationally acclaimed Nerd Girls program, which promotes engineering disciplines to young students.

She is a fellow of the Institute of Electrical and Electronics Engineers (IEEE) and was awarded the 2013 IEEE Award for Distinguished Ethical Practices for exemplary contributions and leadership in developing ethics and social responsibility in students. She has received several NASA and National Science Foundation research grants, including the NSF CAREER Award. In 2011, President Barack Obama awarded Panetta the Presidential Award for Science and Engineering Education and Mentoring.

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://ieeeboston.org/verilog-101-verilog-foundations-online-course/

System Verilog 101: Design Constructs
Full course description and registration at ,
http://ieeeboston.org/systemverilog-101-sv101-design-constructs-online-course/

System Verilog 102: Verification Constructs
Full course description and registration at ,
http://ieeeboston.org/systemverilog-102-sv102-verification-constructs-online-course/

High Performance Project Management
Full course description and registration at ,
http://ieeeboston.org/high-performance-project-management-online-course/

Introduction to Embedded Linux Part I
Full course description and registration at ,
http://ieeeboston.org/introduction-to-embedded-linux-part-i-el201-online-course/

Embedded Linux Optimization - Tools and Techniques
Full course description and registration at ,
http://ieeeboston.org/embedded-linux-optimization-tools-techniques-line-course/

Embedded Linux Board Support Packages and Device Drivers
Full course description and registration at ,
http://ieeeboston.org/embedded-linux-bsps-device-drivers-line-course/

Software Development for Medical Device Manufacturers
Full course description and registration at ,
http://ieeeboston.org/software-development-medical-device-manufacturers-line-course/

Fundamental Mathematics Concepts Relating to Electromagnetics
Full course description and registration at ,
http://ieeeboston.org/fundamental-mathematics-concepts-relating-electromagnetics-line-course/

Reliability Engineering for the Business World
Full course description and registration at ,
http://ieeeboston.org/reliability-engineering-business-world-line-course/

Design Thinking for Today's Technical Work
http://ieeeboston.org/design-thinking-technical-work-line-course/

Fundamentals of Real-Time Operating Systems
http://ieeeboston.org/fundamentals-of-real-time-operating-systems-rt201-on-line-course/

The goal of this monthly webinar series is to provide a pulpit to experts in the Artificial Intelligence field to present their expertise and knowledge to other technologists, engineers and scientists.

Confirmed Speakers Include:

Vinton G. Cerf
President & Chief Internet Evangelist of Google

Alton D. Romig, Jr.
Executive Officer of the National Academy of Engineering

David Cox, IBM
Director of the MIT-IBM Watson AI Lab

Manuela M. Veloso,
Head of J.P. Morgan AI Research

Steve Wozniack, Co-Founder, Apple Computer

Helen Greiner, Co-Founder, iRobot

Dates:

Monthly Webinar Series beginning January 21, 2021 with Session 1:

Does AI Mean Artificial Intelligence or Artificial Idiocy?

and

Birds vs. Drones: Real vs. Artificial Intelligence

Time:

12:00PM – 1:30PM (ET)

Cost:

IEEE Members: $25.
Non-members: $35.

For more info and to register, please visit:
http://ieeeboston.org/artificial-intelligence-webinar-series/

Life Members, 7:00PM, Wednesday, December 2

Confront Covid-19 and Climate Change Now

By Paul H. Carr, PhD, IEEE Life Fellow

Both COVID-19 and climate change are global and involve temperature increases.
If we wait for a crisis, it will be too late. The "stay in place" crisis response to the increase in COVID cases in March brought about reductions within months.

The response time for a climate crisis could take a century, which is the lifetime of the greenhouse gas CO 2 in our atmosphere. A climate crisis could be a 2 to 10-foot rise in sea level, should an Antarctic ice sheet break off. We need to reduce CO 2 emissions now or swim later. "A stitch in time saves nine." The COVID "stay in place" restriction with reduced travel also lowered greenhouse gas emissions as much as 17%. Wearing masks and physical distancing is critical to saving lives and our economy.

Government funding to deal with COVID unemployment could reduce climate change. Grants for more energy efficient residences and businesses would create jobs for contractors. Similar funding could expedite the deployment of next generation small modular nuclear reactors. They are safer with half the construction cost. A MIT study showed that a reactor buildup could decarbonize electricity generation in 30 years. A carbon fee plus dividend could reduce carbon emissions without increasing the US national debt.

Paul H. Carr, BS, MIT, 1957; MS, MIT; PhD Brandeis; IEEE Life Fellow; led the Component Technology Branch of the Air Force Research Laboratory, Bedford, MA. It developed surface acoustic wave (SAW) filters used in cell phones and radar. After retiring in 1995, Paul was awarded Templeton Foundation grants for the philosophy courses he taught at U Mass Lowell. This inspired his book "Beauty in Science and Spirit." In 2005, after hurricane Katrina forced his relatives to migrate north of New Orleans, he became more interested in climate change. He has participated in IEEE climate change debates, championed The Wicked Problem of Climate Change 2017 conference on Star Island off Portsmouth, NH, and published over 80 scientific papers. In 2002, he moved from Bedford, MA to Bedford, NH to marry Ginny. His web page is
www.MirrorOfNature.org

Registration:
https://events.vtools.ieee.org/m/247629

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

Reliability Society - Boston/Providence/New Hampshire – 11:00AM – Tuesday, December 8

Covariate Software Reliability Models and Applications

Please visit our website at www.ieee.org/bostonrel

FREE Webinar

Traditional software reliability growth models enable quantitative assessment of the software testing process by characterizing defect detection in terms of testing time or effort. However, the majority of these parametric models do not identify specific testing activities underlying defect discovery and thus can only provide general guidance on how to incrementally allocate effort. This talk presents a non-homogeneous Poisson process software reliability growth model incorporating covariates based on the discrete Cox proportional hazards model, which explicitly links test activities to defect discovery. Efficient and stable expectation conditional maximization algorithms are derived to estimate the numerical parameters of a model that best characterize the failure data collected during testing. An optimal test activity allocation problem is formulated to maximize defects discovered, so that they can be corrected prior to release. An overview of the Covariate Software Failure and Reliability Assessment Tool (C-SFRAT) will also be provided.

Location:
This Webinar is to be delivered via Webex.
At registration, you must provide a valid e-mail address to receive the Webinar Session link approximately 16 hours before the event.

If you don't see it in your inbox, please remember to check your spam folder for the e-mail with the link.

Contact:
• michael.bannan@ieee.org
• Michael W. Bannan, Chair

• Boston/Providence/New Hampshire Reliability Chapter
Registration:
- Starts 1 October 2020 9:00 PM
- Ends 7 December 2020 6:00 PM
- All times are US/Eastern
- No Admission Charge
- Register https://events.vtools.ieee.org/m/247948

Distinguished Lecturer
Lance Fiondella of University of Massachusetts Dartmouth
Lance is an associate professor in the Department of Electrical & Computer Engineering at the University of Massachusetts Dartmouth. He received his PhD (2012) in Computer Science & Engineering from the University of Connecticut. Dr. Fiondella has published over 130 peer-reviewed journal articles and conference papers, twelve of which have been recognized with awards, including seven with his students. His research has been funded by the United States Department of Homeland Security, U.S. Army Research Laboratory, Naval Air Systems Command, Naval Sea Systems Command, National Aeronautics and Space Administration, and National Science Foundation, including a CAREER award.

Agenda:
11:00 AM Technical Presentation
12:00 PM Adjournment

The meeting is open to all. You do not need to belong to the IEEE to attend this event; however, we welcome your consideration of IEEE membership as a career enhancing technical affiliation. There is no cost to register or attend, but registration is required.

Register, https://events.vtools.ieee.org/m/247948

Python Applications for Digital Design and Signal Processing

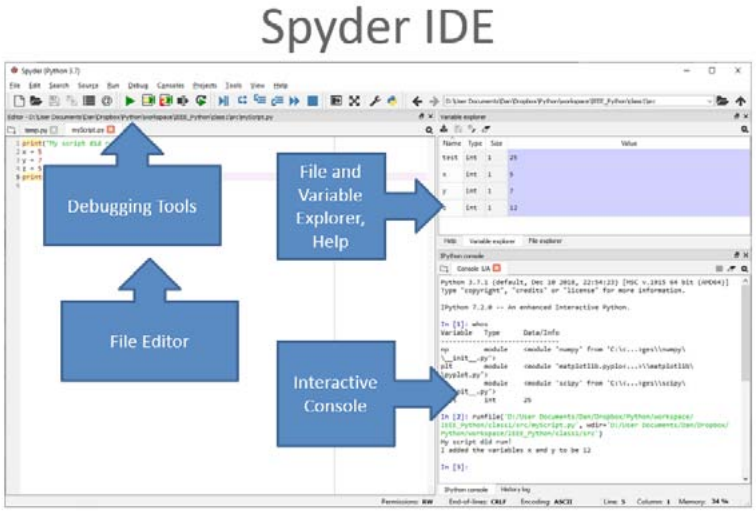
Times and Dates (for live Q&A sessions) : 7 - 8PM ET, February 4, 11, 18, 25, 2021

Speaker: Dan Boschen

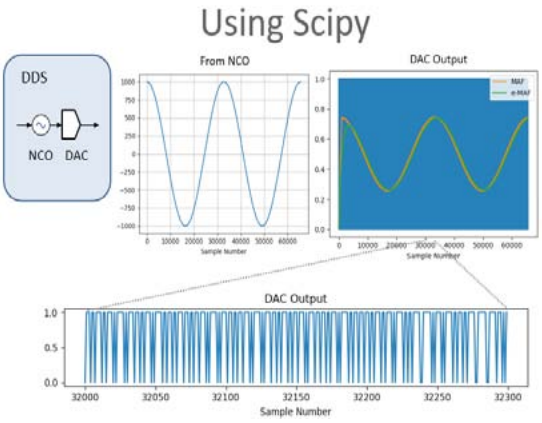
This is a hands-on course combining pre-recorded lectures with live Q&A and workshop sessions in the popular and powerful open source Python programming language.

New Format with Pre-Recorded Videos: The course format has been updated to release pre-recorded video lectures that students can watch on their own schedule, and an unlimited number of times, prior to live Q&A workshop sessions on Zoom with the instructor. The videos will also be available to the students for viewing for up to two months after the conclusion of the course.

Overview: Dan provides simple, straight-forward navigation through the multiple configurations and options, providing a best-practices approach for quickly getting up to speed using Python for modelling and analysis for applications in signal processing and digital design verification. Students will be using the Anaconda distribution, which combines Python with the most popular data science applications, and Jupyter Notebooks for a rich, interactive experience.

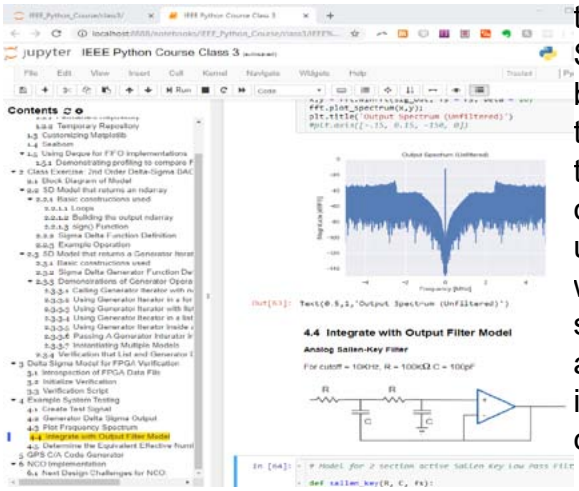


The course begins with basic Python data structures and constructs, including key "Pythonic" concepts, followed by an overview and use of popular packages for scientific computing enabling rapid prototyping for system design.



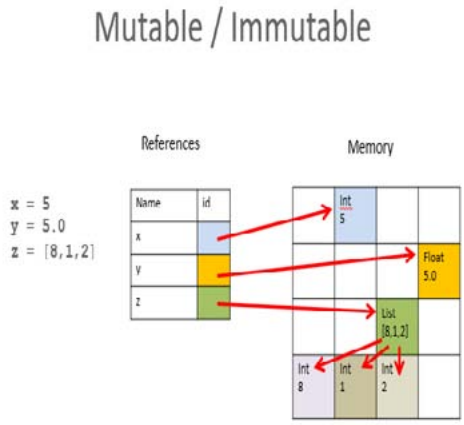
During the course students will create example designs including a sigma delta converter and direct digital synthesizer both in floating point and fixed point. This will include considerations for cycle and bit accurate models useful for digital design verification (FPGA/ASIC), while bringing forward the signal processing tools for frequency and time domain analysis.

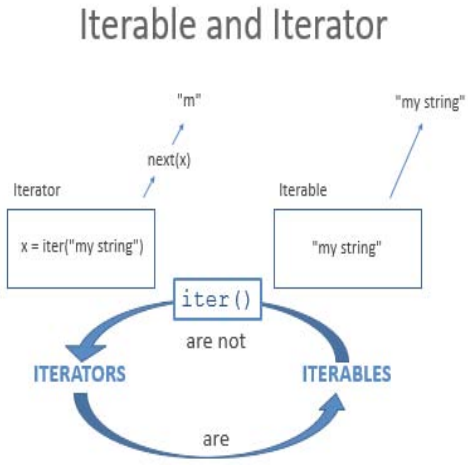
Jupyter Notebooks: This course makes extensive use of Jupyter Notebooks which combines running Python code with interactive plots and graphics for a rich user experience. Jupyter Notebooks is an open-source web-based application (that can be run locally) that allows users to create and share visually appealing documents containing code, graphics, visualizations and in-



teractive plots. Students will be able to interact with the notebook contents and use "take-it-with-you" results for future applications in signal processing.

Target Audience: This course is targeted toward users with little to no prior experience in Python, however familiarity with other modern programming languages and an exposure to object-oriented constructs is very helpful. Students should be comfortable with basic signal processing concepts in the frequency and time domain. Familiarity with Matlab or Octave is not required, but the equivalent operations in Python using the NumPy package will be provided for those students that do currently use Matlab and/or Octave for signal processing applications.





Benefits of Attending / Goals of Course: Attendees will gain an overall appreciation of using Python and quickly get up to speed in best practice use of Python and related tools specific to modeling and simulation for signal processing analysis and design.

A laptop (Mac or PC) preconfigured with Anaconda is required; the specific installation instructions will be emailed to students prior to the start of class.

Pre-recorded lectures (3 hours each) will be distributed Friday prior to all Workshop dates. Workshop/ Q&A Sessions are 7pm-8pm on the dates listed below:

OUTLINE

Thursday, February 4

Topic 1: Intro to Jupyter Notebooks, the Spyder IDE and the course design examples. Core Python constructs.

Thursday, February 11

Topic 2: Core Python constructs; iterators, functions, reading writing data files.

Thursday, February 18

Topic 3: Signal processing simulation with popular packages including NumPy, SciPy, and Matplotlib.

Thursday, February 25

Topic 4: Bit/cycle accurate modelling and analysis using the design examples and simulation packages

Biography:

Dan Boschen has a MS in Communications and Signal Processing from Northeastern University, with over 25 years of experience in system and hardware design for radio transceivers and modems. He has held various positions at Signal Technologies, MITRE, Airvana and Hittite Microwave designing and developing transceiver hardware from baseband to antenna for wireless communications systems. Dan is currently at Microchip (formerly Microsemi and Symmetricom) leading design efforts for advanced frequency and time solutions.
For more background information, please view Dan's Linked-In page

Decision (Run/Cancel) Date for this Course is Thursday, January 28, 2021

IEEE Members	**$190**
Non-members	**$210**

http://ieeeboston.org/python-for-signal-processing/

Modern Applications of RISC-C CPU Design

Access Period: March 1 - 31, 2021

Speaker: Steve Hoover, Redwood, EDA

Type of Course: Self-paced, on-demand Course. Lab format

Course Overview: CPUs are a fundamental building block of complex SoCs, and RISC-V is taking hold as the ISA of choice. In this workshop, you will create a Verilog RISC-V CPU from scratch, and you will modify this CPU to be suitable for different applications.

You will learn and use modern techniques, using Transaction-Level Verilog to generate and modify your Verilog code more reliably, in far less time. You will discover how concepts like pipelining and hazards can be incorporated easily using timing-abstract design principles. All labs will be completed online in the Makerchip.com IDE for open-source circuit design. The skills you learn will be applicable far beyond CPU design.

Outline of Topics to be Covered:
Digital logic using TL-Verilog and Makerchip
– combinational logic
– sequential logic
– pipelined logic
– validity
– a calculator circuit
Basic RISC-V CPU microarchitecture
– single-cycle CPU microarchitecture
– testbench, test program, and lab setup for your CPU
– fetch, decode, and execute logic for RISC-V subset
– control flow logic
Pipelined RISC-V subset CPU microarchitecture
– simple pipelining of the CPU
– hazards and PC redirects
Completing the RISC-V CPU
– data memory and load/store
– remaining RISC-V (RV32I) instructions

Course Format:
– self paced, on demand course, providing attendees a flexible schedule
– access to content for 30 days
– pre-scheduled live Zoom and chat sessions with the instructors during the 30 day access period
– offline chat available with instructors during the entire 30 day access period (reply within 24 hours).

Target Audience: Engineers interested in a career in digital logic design or adjacent disciplines, including experienced engineers looking to modernize their skill set.

Prerequisites: An engineering education and basic understanding of digital logic. (Verilog knowledge is not a prerequisite.)

Benefits of Attending:
– Develop a solidified understanding of pipelined CPU design through hands-on labs.
– Acquire knowledge of advanced digital circuit design methodology.
– Gain exposure to an open-source design ecosystem.

Speaker Bio: Steve Hoover is the founder of Redwood EDA, an early-stage startup focused on advanced silicon design methodology and tools. Steve is a former logic design lead for DEC, Compaq, and Intel and has extensive experience designing high-performance server CPUs and network switches.

System Requirements: All resources are free and online; no download or installation required. We will use Slack, Zoom, GitHub Classroom, and Makerchip.com.

Decision (Run/Cancel) Date for this Course is Thursday, February, 25, 2021

IEEE Members	**$350**
Non-members	**$395**

http://ieeeboston.org/event/modern-applications-of-risc-v-cpu-design-course/?instance_id=2955

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

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 divers 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.

Polar Codes - Encoding and Decoding Aspects

Web-based Course with live Instructor!

Times & Dates: 10AM ET, Tuesdays, March 2, 9, 16, 23, Thursdays, March 4, 11, 18, 25, 2021

Speaker: Orhan Gazi, Cankaya University, Ankara-Turkey

Course Format: Live Webinar, 8 one hour, sessions

Overview: Forward error correction is a vital process in communication systems. **The last channel codes discovered in the research world are the "polar codes" which are adapted to be used in 5G standard.** The construction and decoding of polar codes are quite different from the construction and decoding of classical channel nodes. Polar codes are the only codes constructed in a non-trivial manner. The discovery of polar codes can be considered as a breakthrough in coding society. It is clear that future channel codes will follow the logic of polar codes. For this reason, it is critical to learn the encoding and decoding philosophy of the polar codes which is the state of art of the coding world.

Outline of the topics to be covered:
- Entropy and Mutual Information
- Philosophy of Polar Codes
- Generator Matrices of Polar Codes
- Polar Encoder Structures
- Recursive Structures for Polar Encoders
- Channel Splitting and Concept of Channel Polarization
- Split Channels
- Calculation of Splitted Channel Capacities
- Polar Decoding
- Polar Decoding for Noiseless Transmission
- Polar Decoding Formulas for Kernel Structure for noisy Transmission
- Successive Cancelation Decoding of Polar Codes
- Polar Encoders and Decoders in 5G New Radio (NR) and Future Channel Codes

Target Audience: Electronic and Communication Engineers, electronic engineers, computer engineers, engineers working in communication industry

Benefits of Attending Course:
1) The participant will have an idea about the state of art polar codes.
2) Polar codes are used in 5G standard; the participant can comprehend the polar code used in 5G standard.
3) The participant will learn successive cancelation decoding of polar codes.

Speaker Bio: Prof. Orhan Gazi is the author of the book "Polar Codes. A Non-Trivial Approach to Channel Coding" which can be reached from https://www.springer.com/gp/book/9789811307362 The book is selected by IEEE COMSOC as one of the best readings in polar codes, https://www.comsoc.org/publications/best-readings/polar-coding

Prof. Orhan Gazi is the sole author of 10 books written in electrical engineering subjects. Apart from the polar code book, he is the single author of the books "Information Theory for Electrical Engineers" https://www.springer.com/gp/book/9789811084317 and "Forward Error Correction via Channel Coding" https://www.springer.com/gp/book/9783030333799. The research area of Prof. Orhan Gazi involves "channel coding", and "digital communication subjects". Recently, he focuses on over capacity data transmission using polar codes. He is also interested in practical applications of communication systems involving FPGA devices. He is delivering courses with titles "VHDL circuit design", "interface design using VHDL for FPGA devices" and "system on chip design".

Materials to be included: Lecture slides will be provided.

Decision (Run/Cancel) Date for this Course is Tuesday, February, 23, 2021

IEEE Members	**$250**
Non-members	**$300**

http://ieeeboston.org/event/polar-codes-encoding-and-decoding-aspects-live-webinar/?instance_id=2965

Software Development for Medical Device Manufacturers

Web-based Course with live Instructor!

(11 hours of instructions!)

Times & Dates: **1:00 - 4:00PM ET, May 3, 4, 5, 6, 2021**

Speaker: **Steve Rakitin, Software Qualtiy Consulting**

Course Format: Live Webinar, four, 3 hour sessions

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 notes, access to an extensive collection of reference documents and a training certificate are 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.

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:
- Guidance for Content of Pre-market Submissions for Medical Devices Containing Software
- Off-the-Shelf Software Use in Medical Devices
- General Principles of Software Validation
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Policy for Software Device Functions and Mobile Medical Applications
- Applying Human Factors and Usability Engineering to Medical Devices

International Standards:

- ISO 13485:2016 Medical Devices – Quality Management Systems
- IEC 62304: 2015 Medical Device Software – Software Lifecycle Processes
- ISO 14971: 2019 Application of Risk Management to Medical Devices

• 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
    • How does Agile Development fit?
    • Medical Device Software Lifecycle Processes
• Risk Management
    • FDA Levels of Concern
    • IEC 62304 Software Safety Classification
• Software Requirements
    • 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
    • Technical Reviews
    • Static Analysis
    • 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
    • Deciding which tools need to be validated
    • Validation approach for software tools
• Validation of Manufacturing Software and Quality System Software
• Risk Management Using Fault Tree Analysis (FTA)
    • Review of ISO/EN 14971:2019 Requirements
    • Example of Fault Tree Analysis and Failure Modes Effect Criticality Analysis (FMECA)

About the instructor: Steven R. Rakitin has over 45 years experience as a software engineer. He has over 30 years of experience in the medical device industry and has been a medical device consultant for over 20 years. He has worked with over 100 medical device manufacturers and biotech companies worldwide, from startups to Fortune 100 corporations. He has published papers on medical device software risk management 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 IEEE.

Steve works collaboratively with medical device companies to help them 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, April 26, 2021

IEEE Members	**$285**
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http://ieeeboston.org/event/live-course-software-development-for-medical-device-manufacturers/

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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.

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