CAL LAB

THE INTERNATIONAL JOURNAL OF METROLOGY

Certificate of Calibration - Accredited Versus Unaccredited Calibration

The Hidden Value of FDA 21 CFR Part 11 - Electronic Records & Electronic Signatures

Near Three Decades in the Making: The U.S. Department of Labor's Occupational Outlook Handbook Now Includes Calibration Practitioners

2023
JULY
AUGUST
SEPTEMBER

PRECISION CURRENT INSTRUMENTATION AND CURRENT CALIBRATION

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THE INTERNATIONAL JOURNAL OF METROLOGY

VOLUME 30, NUMBER 3

www.callabmag.com

FEATURES

DEPARTMENTS

ON THE COVER: A Josephson voltage standard at the 1A CAL GmbH laboratory in Kassel, Germany.

CALENDAR

UPCOMING CONFERENCES & MEETINGS

The following event dates and delivery methods are subject to change. Visit the event URL provided for the latest information.

Oct 25-27, 2023 IEEE International Conference on Metrology for eXtended Reality, Artificial Intelligence and Neural Engineering (MetroXRAINE). Milano, Italy. IEEE MetroXRAINE 2023 - will be an international event mainly aimed at creating a synergy between experts in eXtended Reality, Brain-Computer Interface, and Artificial Intelligence, with special attention to the Measurement. https://metroxraine.org/

Nov 6-8, 2023 International Workshop on Metrology for Agriculture and Forestry (MetroAgriFor). Pisa, Italy. Since the first edition, MetroAgriFor intends to create an active and stimulating forum where academics, researchers and industry experts in the field of measurement and data processing techniques for Agriculture, Forestry and Food can meet and share new advances and research results. https://www.metroagrifor.org/

Nov 6-8, 2023 Joint Biennial Cnc/Cie, Cie-Usnc & Corm Conference. Virtual. CORM. The joint research conference of the Canadian and United States CIE National Committees and the Council for Optical Radiation Measurements will be held virtually on November 6 to 8, 2023. We invite abstract submissions for oral presentations covering any topic related to optical radiation, light, lighting, and vision. https://cormusa.org/

Jan 21-24, 2024 102nd ARFTG Microwave Measurement Conference. San Antonio, TX. Event is co-located with IEEE Radio & Wireless Week 2024. https://www.arftg.org/

Jan 22-24, 2024 NCSLI Technical Exchange. New Orleans, LA. Broaden your depth and breadth of knowledge over a wide range of measurement science topics, techniques, methods, and theory for the opportunities ahead. https://ncsli.org/mpage/TE_2024

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EDITOR'S DESK

AI Buzz

I've been streaming educator podcasts lately and there is one called #EdTech that I liked so much, I went back to Episode One from 2014. Wow! It is a trip to hear familiar applications come and go, the early emergence of district-wide, online platforms and how educators struggle with implementation. I was a little overwhelmed when I first started listening to podcasts during the pandemic. I had gone back to school, became disillusioned during my classes post-pandemic and then middle-aged life got in the way. Now I'm back to my podcasts and the topic of AI is inescapable. In many of these podcasts, the host will interview author educators. Apparently, not all educators are freaking out about AI. Instead, many are already using AI as a tool to assist with lesson plans and research. They have already published papers and books on how to utilize it and talk about the legal/ethical challenges surrounding it. Obviously, it's not just in education that AI is propelling software development. Almost every day, another aspect from another flavor of AI comes through my feeds. Then I read that our current methods of AI computing eat up gobs of energy, leading to discussions of quantum computing, and then my brain just gums up completely.

I am so unprepared for integrating AI into my daily tasks and processes. Adobe added beta features into their products to generate and alter images through text prompts. Not only is the term "beta" appropriate, but the user has to learn how to use the feature. Essentially, we all have to learn how to use these tools and educators are the frontline in preparing their students for this new reality… daunting stuff. My feeds are slanted towards education, so I'm not hearing how AI is being used in testing and measuring. Maybe we'll be able to include an article or two on that subject in the near future!

This issue is heavy on documentation and traceability. Indysoft's Walter Nowocin just received the Education & Training Award at this year's NCSLI Workshop & Symposium in Orlando, Florida. Having worked reviously at Medtronic, he is very knowledgeable of regulations affecting the biomedical industry. He kindly contributed his paper on "The Hidden Value of FDA 21 CFR Part 11 Electronic Records & Electronic Signatures," where he highlights the value of software systems able to maintain and comply with specific regulations.

David Lohbeck is an ANSI National Accreditation Board Lead Assessor, with decades of knowledge in safety engineering, testing, and certification. His article, "Certificate of Calibration – Accredited Versus Unaccredited Calibration," clarifies the importance of accreditation and the meaning of certification.

And finally, Christopher Grachanen contributed a final installment on the saga of "Calibration Technologists and Technicians" making it into the annals of the U.S. Department of Labor's Occupational Outlook Handbook (OOH). This was a long time coming and very welcome as the industry is in such a need to recruit the next generation of calibration technicians and engineers. The OOH is a critical tool in reaching out to prospective technicians, as well as defining the profession and tracking statistics.

Happy Measuring,

Sita Schwartz

CALENDAR

Mar 24-28, 2024 MSC Training Symposium. Anaheim, CA. The 2024 MSC theme is: Quantum Revolution. Come explore Quantum Metrology, Quantum Engineering, and Quantum SI! The conference will offer many exceptional measurement related courses and technical sessions. https://annualconf.msc-conf.com

Apr 10-12, 2024 METROMEET. Bilbao, Spain. METROMEET is a unique event and the most important annual conference in the sector of Industrial Dimensional Metrology. https://metromeet.org/

Apr 21-24, 2024 A2LA Annual Conference (ANNCON24). Denver, CO. The A2LA Annual Conference is the ultimate opportunity for professionals to meet face-to-face, learn new skills, and collaborate on topics associated with the accreditation industry. https://a2la.org/Annual_Conference/

May 20-23, 2024 IEEE International Instrumentation and Measurement Technology Conference (I2MTC). Glasgow, UK. The flagship conference of the IEEE Instrumentation and Measurement Society, dedicated to advances in measurement methodologies, measurement systems, instrumentation and sensors in all areas of science and technology. https://i2mtc2024.ieee-ims.org/

May 27-29, 2024 24th International Conference on Metrology and Properties of Surfaces. Marrakech, Morocco. The 24th International Conference on Metrology and Properties of Surfaces (Met&Props) will contain a broad array of scientific themes including, surface characterization, measurement and instrumentation, in-process surface metrology, archaeology and anthropology and forensic science. https://metprops2024.org/

Jun 3-5, 2024 11th International Workshop on Metrology for AeroSpace. Lublin, Poland. MetroAeroSpace aims to gather people who work in developing instrumentation and measurement methods for aerospace. https://www.metroaerospace.org/

Jun 12-13, 2024 CEESI Gas Ultrasonic Meter User's Conference. Colorado Springs, CO. This conference provides

a forum for ultrasonic meter manufacturers and end users to discuss measurement challenges in the hydrocarbon measurement industry. https://www.ceesi.com/

Jun 16-21, 2024 IEEE International Microwave Symposium (IMS). Washington, DC. The IEEE International Microwave Symposium (IMS) is the world's foremost conference covering the UHF, RF, wireless, microwave, millimeter-wave, terahertz, and optical frequencies. https://www.ims-ieee.org/

Jul 6-10, 2024 NCSLI Workshop & Symposium/ Conference on Precision Electromagnetic Measurement. Denver, CO. The theme for this joint event with CPEM and NCSLI Workshop & Symposium will be "Innovation through Measurement: A Focus on Critical and Emerging Technologies." https://ncsli.org/

Jul 22-25, 2024 Coordinate Metrology Society Conference. Charlotte, NC. The Coordinate Metrology Society (CMS) is excited to unveil the grand celebration of its 40th Year Anniversary! https://www.cmsc.org/conference

SEMINARS & WEBINARS: Dimensional

Oct 24-25, 2023 Precision Gage Calibration & Repair Training. Virtual. IICT Calibration & Metrology Training. This 2-day, online precision gage and repair training offers specialized training in calibration and repair for the individual who has some knowledge of basic Metrology. https://calibrationtraining.com/

Nov 7-9, 2023 Gage Calibration Methods Class. Cincinnati, OH. QC Training. This 3-day hands-on workshop offers specialized training in calibration and repair for the individual who has some knowledge of basic Metrology. Attendees will be equipped with the knowledge to meet current and future calibration needs, be prepared to save the company money on calibrations, and grow professionally. https://qctraininginc.com/class-calendar/

Nov 14-16, 2023 Dimensional Gage Calibration. Aurora, IL. Mitutoyo America's Gage Calibration course is a unique, active, educational experience designed specifically for those who plan and perform calibrations of dimensional

measuring tools, gages, and instruments. https://www.mitutoyo.com/training-education/

Nov 15-16, 2023 Precision Gage Calibration & Repair Training. Virtual. IICT Calibration & Metrology Training. This 2-day, online precision gage and repair training offers specialized training in calibration and repair for the individual who has some knowledge of basic Metrology. https://calibrationtraining.com/

Nov 30, 2023 Introduction to Dimensional Gage Calibration. Virtual Classroom. Mitutoyo. This course is taught in the Mitutoyo Institute of Metrology's Training Lab in Aurora, IL and broadcast live in a virtual session. The course combines modern calibration and quality management ideas with best practices and "how-to" calibration methods for common calibrations of micrometers and calipers. The course is ideal for those operating in ISO/IEC 17025 accredited laboratories or in gage labs directly supporting manufacturing operations. https://www.mitutoyo.com/training-education/

Dec 5-6, 2023 Precision Gage Calibration & Repair Training. Bloomington, MN. IICT Calibration & Metrology Training. This in-person, 2-day precision gage and repair training offers specialized training in calibration and repair for the individual who has some knowledge of basic Metrology. https://calibrationtraining.com/

Dec 5-7, 2023 Dimensional Gage Calibration. Aurora, IL. Mitutoyo America's Gage Calibration course is a unique, active, educational experience designed specifically for those who plan and perform calibrations of dimensional measuring tools, gages, and instruments. https://www.mitutoyo.com/training-education/

Dec 12-13, 2023 Precision Gage Calibration & Repair Training. Virtual. IICT Calibration & Metrology Training. This 2-day online precision gage and repair training offers specialized training in calibration and repair for the individual who has some knowledge of basic Metrology. https://calibrationtraining.com/

May 1-2, 2024 Dimensional Measurement. Port Melbourne, VIC. National Measurement Institute, Australia. This two-day course (9 am to 5 pm) presents a comprehensive overview of the fundamental principles in dimensional metrology and geometric dimensioning and tolerancing. https://shop.measurement.gov.au/collections/physical-metrology-training

SEMINARS & WEBINARS: Education

Feb 1, 2024 Metric System Education Resources. Adobe Connect Pro. NIST. This 1.5 hour session will explore NIST Metric Program education publications and other resources that can be downloaded and freely reproduced by teachers, parents, and students. These resources are helpful to students as they become familiar with metric units, develop measurement quantity reference points, and learn more about SI basics. https://www.nist.gov/pml/owm/training

SEMINARS & WEBINARS: Electrical

Oct 30-Nov 2, 2023 Basic Hands-On Metrology. Everett, WA. Fluke Calibration. This Metrology 101 basic metrology training course introduces the student to basic measurement concepts, basic electronics related to measurement instruments and math used in calibration. https://us.flukecal.com/training

Mar 4-7, 2024 Basic Hands-On Metrology. Everett, WA. Fluke Calibration. This Metrology 101 basic metrology training course introduces the student to basic measurement concepts, basic electronics related to measurement instruments and math used in calibration. https://us.flukecal.com/training

Apr 8-11, 2024 Advanced Hands-On Metrology. Everett, WA. Fluke Calibration. This course introduces the student to advanced measurement concepts and math used in standards laboratories. The student will learn how to make various types of measurements using different measurement methods. We will also teach techniques for making good high precision measurements using reference standards. https://us.flukecal.com/training

May 22-23, 2024 Electrical Measurement. Lindfield, NSW, Australia. NMI. This two day (9am-5pm) course covers essential knowledge of the theory and practice of electrical measurement using digital multimeters and calibrators; special attention is given to important practical issues such as grounding, interference and thermal effects. https://shop.measurement.gov.au/collections/physical-metrology-training

Jun 10-13, 2024 Basic Hands-On Metrology. Everett, WA. Fluke Calibration. This Metrology 101 basic metrology training course introduces the student to basic measurement concepts, basic electronics related to measurement instruments and math used in calibration. https://us.flukecal.com/training

Sep 23-26, 2024 Advanced Hands-On Metrology. Everett, WA. Fluke Calibration. This course introduces the student to advanced measurement concepts and math used in standards laboratories. The student will learn how to make various types of measurements using different measurement methods. https://us.flukecal.com/training

Calibrating Sanitary Sensors Just Got Simpler!

Sanitary Sensors found in the pharmaceutical and food industries have traditionally been some of the most challenging sensors to calibrate, as they must be perfectly placed in the uniform zone of the calibrator. The new JOFRA RTC-168 Reference Temperature Calibrator provides a solution with a new well design, redesigned sensor basket, and a temperature equalizer that combine to create an extended uniformity zone resulting in improved, highly accurate liquid calibrations

The JOFRA RTC-168

- Patented DLC (Dynamic Load Compensation) system for perfect temperature uniformity in the insert.
- Redesigned liquid basket vertically extends the temperature uniformity zone.
- Industry first reverse airflow system protects the sensor under test from excess heat.
- Special sanitary sensor insert supports small sensing cables.
- Intuitive, fast, and user-friendly navigation.
- USB connector for communication.
- High profile design and well-known, long lasting JOFRA quality.

All-In-One Solution

The RTC-168 is more than just a wet bath calibrator. With its revolutionary removable liquid container you can switch from wet to dry calibration in just minutes, with temperature ranges from -30° to 165°C in both wet and dry configurations.

www.ametekcalibration.com

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SEMINARS & WEBINARS: General

Dec 1, 2023 Calibration and Measurement Fundamentals. Online. National Measurement Institute, Australia. This course covers general metrological terms, definitions and explains practical concept applications involved in calibration and measurements. The course is recommended for technical officers and laboratory technicians working in all industry sectors who are involved in making measurements and calibration process. https://shop.measurement.gov.au/collections/physical-metrology-training

Jan 29-Feb 2, 2024 Fundamentals of Metrology. Gaithersburg, MD. NIST. The 5-day Fundamentals of Metrology seminar is an intensive course that introduces participants to the concepts of measurement systems, units, good laboratory practices, data integrity, measurement uncertainty, measurement assurance, traceability, basic statistics and how they fit into a laboratory Quality Management System. https://www.nist.gov/pml/owm/training

Apr 1-5, 2024 Fundamentals of Metrology. Gaithersburg, MD. NIST. The 5-day Fundamentals of Metrology seminar is an intensive course that introduces participants to the concepts of measurement systems, units, good laboratory practices, data integrity, measurement uncertainty, measurement assurance, traceability, basic statistics and how they fit into a laboratory Quality Management System. https://www.nist.gov/pml/owm/training

SEMINARS & WEBINARS: Industry Standards

Nov 1-2, 2023 Internal Auditing for all Standards. Scheduled online for the Americas. IAS. This 2-day Training Course examines auditing principles and techniques and facilitates the practice of required internal audit skills. It is based on internationally-recognized approaches to conducting conformant internal audits. The techniques learned by participants promote the involvement of all types of staff as auditors and auditees. https://www.iasonline.org/training/ias-training-schedule/

Nov 14-15, 2023 Understanding ISO/IEC 17025:2017 for Testing and Calibration Laboratories. Online. A2LA

Workplace Training. This course is a comprehensive review of the philosophies and requirements of ISO/IEC 17025:2017. The participant will gain an understanding of conformity assessment using the risks and opportunities-based approach. https://www.a2lawpt.org/events

Nov 16-17, 2023 Auditing Your Laboratory to ISO/IEC 17025:2017. Online. A2LA Workplace Training. This ISO/IEC 17025 auditor training course will introduce participants to ISO/IEC 19011, the guideline for auditing management systems as applied to ISO/IEC 17025:2017. The participant will learn about auditing principles and develop skills for performing higher-value internal audits. https://www.a2lawpt.org/events

Dec 4-7, 2023 Understanding ISO/IEC 17025:2017 for Testing and Calibration Laboratories. Online. A2LA WorkPlace Training. This course is a comprehensive review of the philosophies and requirements of ISO/IEC 17025:2017. The participant will gain an understanding of conformity assessment using the risks and opportunities-based approach. https://www.a2lawpt.org/events

Dec 5-6, 2023 Laboratories: Understanding the Requirements and Concepts of ISO/IEC 17025:2017. Online. ANAB. This introductory course is specifically designed for those individuals who want to understand the requirements of ISO/IEC 17025:2017 and how those requirements apply to laboratories. https://anab.ansi.org/training

Dec 5-6, 2023 Understanding ISO/IEC 17025 for Testing and Calibration Labs. Online. IAS. This course examines structural components of the standard. See the published syllabus. Quality system and technical requirements are grouped in a manner that makes them clear and understandable. https://www.iasonline.org/training/ias-training-schedule/

Dec 11-14, 2023 Auditing Your Laboratory to ISO/IEC 17025:2017. Online. A2LA Workplace Training. This training course will introduce participants to ISO/IEC 19011, the guideline for auditing management systems as applied to ISO/IEC 17025:2017. The participant will learn about auditing principles and develop skills for performing higher-value internal audits. https://www.a2lawpt.org/events

CALENDAR

SEMINARS & WEBINARS: Mass

Feb 26-Mar 8, 2024 Mass Metrology Seminar. Gaithersburg, MD. The Mass Metrology Seminar is a two-week, "hands-on" seminar. It incorporates approximately 30 percent lectures and 70 percent demonstrations and laboratory work in which the participant performs measurements by applying procedures and equations discussed in the classroom. https://www.nist.gov/pml/owm/training

SEMINARS & WEBINARS: Measurement Uncertainty

Dec 4, 2023 Introduction to Measurement Uncertainty. Online. A2LA WorkPlaceTraining. This course is a suitable introduction for both calibration and testing laboratory participants, focusing on the concepts and mathematics of the measurement uncertainty evaluation process. The participant will gain an understanding of the statistical techniques required to estimate measurement uncertainty, and will practice those skills to create basic uncertainty budgets. https://www.a2lawpt.org/events

Dec 4-5, 2023 Measurement Confidence: Fundamentals. Online. ANAB. This Measurement Confidence course introduces the foundational concepts of measurement traceability, measurement assurance and measurement uncertainty as well as provides a detailed review of applicable requirements from ISO/IEC 17025 and ISO/IEC 17020. https://anab.ansi.org/training

Dec 12-14, 2023 Measurement Uncertainty – Fundamentals and Applications. West Chester (Cincinnati), OH. Mitutoyo. This course will teach you how to see the application of measurement uncertainty in your organization and meet the most demanding requirements for your measuring systems. https://www.mitutoyo.com/training-education/

Dec 13-15, 2023 Measurement Uncertainty: Practical Applications. Live Online. ANAB. This course reviews the basic concepts and accreditation requirements associated with measurement traceability, measurement assurance, and measurement uncertainty as well as their interrelationships. https://anab.ansi.org/training

SEMINARS & WEBINARS: Photometry & Radiometry

Feb 21-22, 2024 Photometry and Radiometry. Lindfield NSW. NMI Australia. This two-day course covers the broad range of equipment and techniques used to measure colour and light output, the basic operating principles involved in radiometry, working techniques, potential problems and their solutions. https://shop.measurement.gov.au/collections/physical-metrology-training

SEMINARS & WEBINARS: Pressure

Nov 6, 2023 Pressure Level 1. Chelmsford, MA. Sine Calibration School. Hosted by Essco. Learn the basics of pressure calibration through a hands-on learning experience. https://www.sinecalibration.com/pressure-level-1

Feb 26-Mar 1, 2024 Principles of Pressure Calibration. Phoenix, AZ. Fluke Calibration. A five-day training course on the principles and practices of pressure calibration using digital pressure calibrators and piston gauges (pressure balances).The class is designed to focus on the practical considerations of pressure calibrations. https://us.flukecal.com/training

Apr 8-12, 2024 Principles of Pressure Calibration. Phoenix, AZ. Fluke Calibration. A five-day training course on the principles and practices of pressure calibration using digital pressure calibrators and piston gauges (pressure balances).The class is designed to focus on the practical considerations of pressure calibrations. https://us.flukecal.com/training

Jun 19-20, 2024 Pressure Measurement. Port Melbourne, VIC. Australian NMI. This two-day course (9 am to 5 pm each day) covers essential knowledge of the calibration and use of a wide range of pressure measuring instruments, their principles of operation and potential sources of error — it incorporates extensive hands-on practical exercises. https://shop.measurement.gov.au/collections/physical-metrology-training

SEMINARS & WEBINARS: RF & Microwave

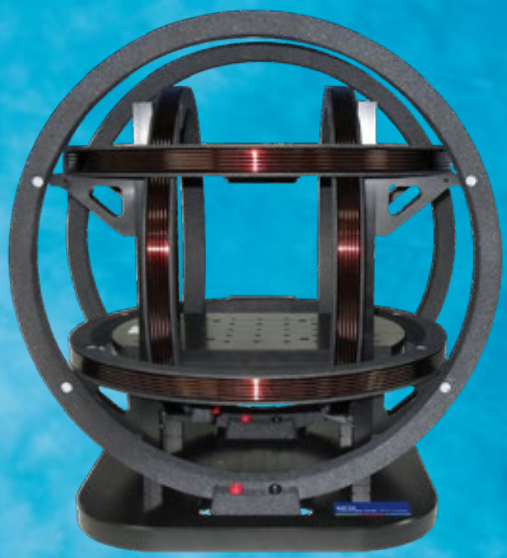
Nov 8, 2023 RF and Microwave Level 1. Chelmsford, MA. Sine Calibration. Hosted by Essco. https://www.sinecalibration.com/

SEMINARS & WEBINARS: Software

Nov 7-9, 2023 VNA Tools Training Course. Berne-Wabern, Switzerland. Federal Institute of Metrology METAS. VNA Tools is free software developed by METAS for measurements with the Vector Network Analyzer (VNA). The software facilitates the tasks of evaluating measurement uncertainty in compliance with the ISO-GUM and vindicating metrological traceability. The software is available for download at www.metas.ch/vnatools. The three day course provides a practical and hands-on lesson with this superior and versatile software. https://www.metas.ch/metas/en/home/dl/kurse---seminare.html

HELMHOLTZ COIL SYSTEMS

HC2



HC16

- 350mm, 500mm and 1m coil diameters
- Orthogonality correction using PA1
- Active compensation using CU2
- Control software available

HC1

Range of Fluxgate Magnetometers Available

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Nov 13-17, 2023 Basic MET/CAL® Procedure Writing. Everett, WA. Fluke Calibration. In this five-day Basic MET/CAL Procedure Writing course, you will learn to configure MET/CAL software to create, edit, and maintain calibration solutions, projects and procedures. https://us.flukecal.com/training

Nov 13-17, 2023 MET/TEAM® Basic Web-Based Training. Fluke Calibration. This web-based course presents an overview of how to use MET/TEAM Test Equipment and Asset Management Software in an Internet browser to develop your asset management system. https://us.flukecal.com/training

Mar 11-15, 2024 Basic MET/CAL® Procedure Writing. Everett, WA. Fluke Calibration. In this five-day Basic MET/CAL Procedure Writing course, you will learn to configure MET/CAL software to create, edit, and maintain calibration solutions, projects and procedures. https://us.flukecal.com/training

Apr 15-19, 2024 MET/TEAM® Asset Management. Everett, WA. Fluke Calibration. This five-day course presents a comprehensive overview of how to use MET/TEAM Test Equipment and Asset Management Software in an Internet browser to develop your asset management system. You will learn a systematic approach to collect the information you need to manage your lab assets routinely, consistently and completely. https://us.flukecal.com/training

Apr 23-25, 2024 VNA Tools Training Course. Beaverton, OR. Federal Institute of Metrology METAS. VNA Tools is free software developed by METAS for measurements with the Vector Network Analyzer (VNA). The software facilitates the tasks of evaluating measurement uncertainty in compliance with the ISO-GUM and vindicating metrological traceability. The software is available for download at www.metas.ch/vnatools. The three day course provides a practical and hands-on lesson with this superior and versatile software. https://www.metas.ch/metas/en/home/dl/kurse---seminare.html

May 6-10, 2024 Basic MET/CAL® Procedure Writing. Everett, WA. Fluke Calibration. In this five-day Basic MET/

CALProcedure Writing course, you will learn to configure MET/CAL software to create, edit, and maintain calibration solutions, projects and procedures. https://us.flukecal.com/training

May 28-30, 2024 VNA Tools Training Course. Berne-Wabern, Switzerland. Federal Institute of Metrology METAS. VNA Tools is free software developed by METAS for measurements with the Vector Network Analyzer (VNA). The software facilitates the tasks of evaluating measurement uncertainty in compliance with the ISO-GUM and vindicating metrological traceability. The software is available for download at www.metas.ch/vnatools. The three day course provides a practical and hands-on lesson with this superior and versatile software. https://www.metas.ch/metas/en/home/dl/kurse---seminare.html

Jul 15-19, 2024 Basic MET/CAL® Procedure Writing. Everett, WA. Fluke Calibration. In this five-day course, you will learn to configure MET/CAL software to create, edit, and maintain calibration solutions, projects and procedures. https://us.flukecal.com/training

Sep 9-13, 2024 Basic MET/CAL® Procedure Writing. Everett, WA. Fluke Calibration. In this five-day Basic MET/CAL Procedure Writing course, you will learn to configure MET/CAL software to create, edit, and maintain calibration solutions, projects and procedures. https://us.flukecal.com/training

Oct 7-11, 2024 Advanced MET/CAL® Procedure Writing. Everett, WA. Fluke Calibration. A five-day procedure writing course for advanced users of MET/CALcalibrations software. Prerequisites Note: This course covers advanced topics and requires an existing knowledge of MET/CALcalibration software. https://us.flukecal.com/training

Oct 21-25, 2024 MET/TEAM® Asset Management. Everett, WA. Fluke Calibration. This five-day course presents a comprehensive overview of how to use MET/TEAM Test Equipment and Asset Management Software in an Internet browser to develop your asset management system. You will learn a systematic approach to collect the information you need to manage your lab assets routinely, consistently and completely. https://us.flukecal.com/training

CALENDAR

SEMINARS & WEBINARS: Temperature & Humidity

Nov 7, 2023 Temperature Level 1. Chelmsford, MA. Sine Calibration. Hosted by Essco, this in-person training includes access to digital online version of this training for LIFE! https://www.sinecalibration.com/

Mar 18-20, 2024 Practical Temperature Calibration. American Fork, UT. Fluke Calibration. A three-day course loaded with valuable principles and hands-on training designed to help calibration technicians and engineers get a solid base of temperature calibration fundamentals. https://us.flukecal.com/training

Mar 21-22, 2024 Infrared Calibration. American Fork, UT. Fluke Calibration. A two-day course with plenty of hands on experience in infrared temperature metrology. This course is for calibration technicians, engineers, metrologists, and technical experts who are beginning or sustaining an infrared temperature calibration program. https://us.flukecal.com/training

May 6-8, 2024 Advanced Topics in Temperature Metrology. American Fork, UT. Fluke Calibration. A three-day course for those who need to get into the details of temperature metrology. This course is for experienced calibration technicians, metrologists, engineers, and technical experts working in primary and secondary-level temperature calibration laboratories who would like to validate, refresh, or expand their understanding of advanced topics in temperature metrology. https://us.flukecal.com/training

Oct 7-9, 2024 Advanced Topics in Temperature Metrology. American Fork, UT. Fluke Calibration. A three-day course for those who need to get into the details of temperature metrology. This course is for experienced calibration technicians, metrologists, engineers, and technical experts working in primary and secondary-level temperature calibration laboratories who would like to validate, refresh, or expand their understanding of advanced topics in temperature metrology. https://us.flukecal.com/training

SEMINARS & WEBINARS: Time & Frequency

May 8-9, 2024 Time and Frequency Measurement. Lindfield, NSW. National Measurement Institute, Australia. This two-day course covers the broad range of equipment and techniques used to measure time and frequency and to calibrate time and frequency instruments. https://shop.measurement.gov.au/collections/physical-metrology-training

SEMINARS & WEBINARS: Vibration

Nov 7-9, 2023 Fundamentals of Random Vibration and Shock Testing. Newark, CA. This three-day Training in Fundamentals of Random Vibration and Shock Testing covers all the information required to plan, perform, and interpret the results of all types of dynamic testing. Some of the additional areas covered are fixture design, field data measurement and interpretation, evolution of test standards and HALT/HASS processes. https://equipment-reliability.com/open-courses/

SEMINARS & WEBINARS: Volume

Apr 8-12, 2024 Volume Metrology Seminar. Gaithersburg, MD. NIST. The 5-day OWM Volume Metrology Seminar is designed to enable metrologists to apply fundamental measurement concepts to volume calibrations. A large percentage of time is spent on hands-on measurements, applying procedures and equations discussed in the classroom. https://www.nist.gov/pml/weights-and-measures/training

SEMINARS & WEBINARS: Weight

Feb 5-8, 2024 Balance and Scale Calibration and Uncertainties. NIST. Gaithersburg, MD. This 4-day seminar will cover the calibration and use of analytical weighing instruments (balances and laboratory/bench-top scales), including sources of weighing errors in analytical environments, methodologies for quantifying the errors, and computation of balance calibration uncertainty and global (user) uncertainty. https://www.nist.gov/news-events/upcoming-events

Mar 21, 2024 Calibration of Weights and Balances. Lindfield NSW. National Measurement Institute (NMI), Australia. This course covers the theory and practice of the calibration of weights and balances. It incorporates hands-on practical exercises to demonstrate adjustment features and the effects of static, magnetism, vibration and draughts on balance performance. https://shop.measurement.gov.au/collections/physical-metrology-training

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NIST Demonstrates a New 'Primary Standard' for Measuring Ultralow Pressures

August 10, 2023, NIST News – A vacuum chamber is never perfectly empty. A small number of atoms or molecules always remain, and measuring the tiny pressures they exert is critical. For instance, semiconductor manufacturers create microchips in vacuum chambers that must be almost entirely devoid of atomic and molecular contaminants, and so they need to monitor the gas pressure in the chamber to ensure that the contaminant levels are acceptably low.

Now, scientists at the National Institute of Standards and Technology (NIST) have validated a new approach to measuring extremely low gas pressures called CAVS, for cold atom vacuum standard. They have established that their technique can serve as a "primary standard" — in other words, it can make intrinsically accurate measurements without first needing to be calibrated to reference pressure readings.

Having developed CAVS over the last seven years, NIST researchers recently put their technique through its most rigorous tests to date. Their new study, in the journal *AVS Quantum Science* [https://doi.org/10.1116/5.0147686], shows that CAVS results agreed with the traditional "gold standard" method for measuring low pressures, demonstrating that this new technique can make measurements with the same degree of accuracy and reliability.

Not only can CAVS make measurements as good as those in traditional pressure gauges, but it can also reliably measure the much lower vacuum pressures — a trillionth of the Earth's sea-level atmospheric pressure and below — that will be required for future chip manufacturing and next-generation science. And its operation, based on well-understood quantum physics principles, means that it can make accurate readings "right out of the box," without requiring any adjustments or calibration to other reference pressure sources or techniques.

"This is the culminating result," said NIST physicist Julia Scherschligt. "We have had numerous positive developments before. But this validates the fact that our cold atom standard is truly a standard."

In addition to semiconductor manufacturing, the new

method can be useful for other applications that require high-vacuum environments, such as quantum computers, gravitational wave detectors, particle accelerators and many more.

CAVS technology measures vacuum pressures using a cold gas of about a hundred thousand lithium or rubidium atoms trapped in a magnetic field. These atoms fluoresce when illuminated by a laser tuned to just the right frequency. Researchers can count the number of trapped atoms precisely by measuring the intensity of this glow.

When the CAVS sensor is connected to a vacuum chamber, the leftover atoms or molecules in the chamber collide with the trapped atoms. Each collision knocks an atom out of the trap, reducing the number of atoms and the intensity of light emitted. That intensity, easily measured by light sensors, serves as a sensitive measure of pressure. This relationship between the rate of dimming and the number of molecules is predicted exactly by quantum mechanics.

In the new work, the NIST researchers attached their CAVS sensors to the classical gold-standard reference standard for gas pressure, known as a dynamic expansion system.

Dynamic expansion systems work by injecting a known amount of gas, measured in molecules per second, into a vacuum chamber, then slowly removing the gas from the other end of the chamber at a known rate. The researchers then calculate the resulting pressure in the chamber.

In this experiment, the researchers built a high-performance dynamic expansion system that allowed for extremely small flows of gas — in the range of 10 billion to 100 billion atoms or molecules per second — and included a custom-built flowmeter to measure flows that low. The hole they built to remove atoms slowly from the chamber was machined to submicrometer precision.

"The heavy lifting needed to stand up one of these classical standard devices is monumental," Scherschligt said. "Going through the effort of doing that really drove home the point of this whole experiment, which is that CAVS provides high accuracy in a much simpler form."

The NIST researchers tested two types of CAVS sensors in their work. One is a laboratory version; the second is a mobile version that can easily be used in advanced chip manufacturing settings.

"Indeed, the portable version is so simple, we eventually

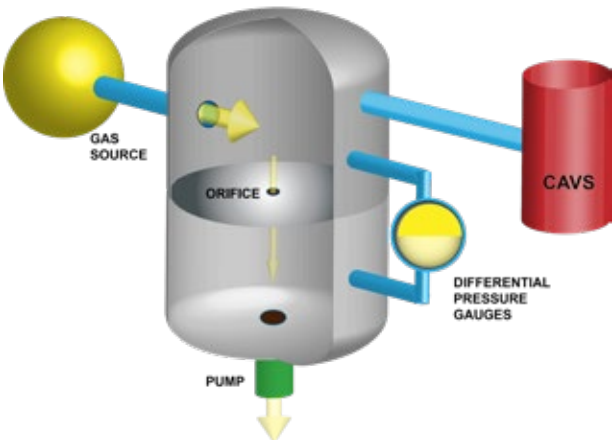
decided to automate it such that we very rarely had to intervene in its operation. In fact, most of the data from the portable CAVS for this study was taken while we were comfortably asleep at home," said NIST physicist Dan Barker.

"The gases we measured — including nitrogen, helium, argon and even neon — are all inert semiconductor process gases," said NIST physicist Steve Eckel. "But in the future, we hope to measure more reactive gases like hydrogen, carbon dioxide, carbon monoxide and oxygen, which are all both common residual gases found in vacuum chambers and useful gases for semiconductor manufacturing."

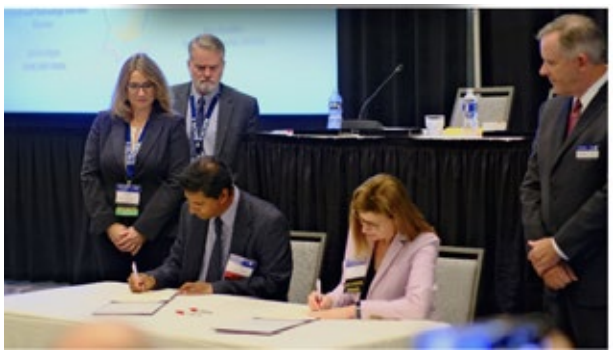
Together, these CAVS systems promise to help researchers working with ultralow pressures reach new highs in both science and technology.

Paper: Daniel S. Barker, James A. Fedchak, Jacek Kłos, Julia Scherschligt, Abrar A. Sheikh, Eite Tiesinga and Stephen P. Eckel. Accurate measurement of the loss rate of cold atoms due to background gas collisions for the quantum-based cold atom vacuum standard. *AVS Quantum Science*. Published online Aug. 1, 2023. DOI: 10.1116/5.0147686

Source: https://www.nist.gov/news-events/news/2023/08/nist-demonstrates-new-primary-standard-measuring-ultralow-pressures



To verify the accuracy of their cold atom vacuum standard (CAVS) for measuring ultralow vacuum pressures, NIST researchers built a high-performance version of a traditional pressure metrology setup known as a dynamic expansion system. In this system, they injected gas at a flow rate of roughly 10 billion to 100 billion molecules per second into the top chamber. The gas moved from the upper chamber to the lower chamber, which is evacuated by a large pump at a known rate through a precisely dimensioned orifice. A set of gauges measured the pressure ratio between the top and bottom chambers to correct for imperfections. Using the gas inflow rate and the rate that gas moves between the two chambers, the researchers calculated the pressure in the top chamber, which the CAVS independently measures. The researchers found agreement between this known pressure value and the readings from the CAVS sensors, thereby validating their new method. Credit: NIST



NCWM and NIST Enter Agreement Defining Roles for the Future

September 29, 2023 – The two national organizations responsible for how every product in the economy is weighed and measured have forged a historic agreement outlining how they will work together to serve manufacturers and customers alike, as the world gets ever more technologically complex.

The National Conference on Weights and Measures (NCWM) and the National Institute of Standards and Technology (NIST) trace their shared history back 118 years, to a 1905 meeting of the states to discuss the lack of uniformity in the way products in the marketplace were weighed and measured. NIST, then known as the National Bureau of Standards, coordinated state support around uniform national standards to ensure products sold in every state were weighed and measured the same. The move guaranteed accuracy and fairness for product makers as well as consumers throughout the nation and led to the creation of the NCWM. The two organizations have evolved in their respective roles through the years since.

"The NCWM, a nonprofit corporation, and NIST, a nonregulatory agency understand the importance of their relationship," said Immediate Past NCWM Chairman Mahesh Albuquerque. "We share common goals and recognize that by working together we are more successful. It is important that we clearly define our respective roles toward that success. For this reason, we have entered into a Memorandum of Understanding."

The NCWM today is the forum where regulators and industry come together to develop the model weights and measures standards for commerce for the United States. Staff of the NIST Office of Weights and Measures participate in that process, serving on the various committees and task groups in an advisory role, while regulators and industry collaborate on developing the standards. NIST promotes uniformity by publishing those model standards for voluntary adoption and enforcement by the states.

NIST Director Dr. Laurie Locascio and NIST Chief of the Office of Weights and Measures Dr. Katrice Lippa joined the NCWM Chairman Albuquerque and Executive

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Typical Shunt	10	0.1	140	> 10 minutes	0.01%	No spec	10	4	4
Typical Shunt	300	0.001	100	> 10 minutes	0.01%	No spec	10	4	4
6311A	10	0	N/A	< 10 seconds	< 0.0005%	< 20	0.05	0	0
6311A	300	0	N/A	< 10 seconds	< 0.0005%	< 20	0.05	0	0

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Director Don Onwiler in a signing ceremony of the MOU at the 108th NCWM Annual Meeting in Virginia in July. At that meeting, Dr. Locascio pointed to the challenges of the future with technological advances, stating, "In line with this, the new MOU that we will sign today provides a new framework for NIST and the NCWM to work together more effectively to meet such challenges."

"I am so grateful that Laurie Loccasio was able to join us to sign the new Memorandum of Understanding between NIST and the NCWM, which strengthens our relationships with each other and the mutual stakeholders we serve," Albuquerque said.

The National Conference on Weights and Measures is a professional nonprofit association of state and local weights and measures officials, federal agencies, manufacturers, retailers and consumers, which has served as a forum for developing the national weights and measures standards since 1905. The NCWM focuses on creating new standards to accommodate innovation in the marketplace and to promote uniformity in net content regulation.

Source: https://www.linkedin.com/pulse/ncwm-nist-enter-agreement-defining-roles-future-national-conference

NPL Makes History with First UK Optical Clock to Contribute to Determining International Atomic Time

September 4, 2023, NPL News – A major milestone towards the redefinition of the second has been achieved by scientists at the National Physical Laboratory (NPL) with the first inclusion of a UK optical frequency standard (NPL-Sr1) in the determination of International Atomic Time (TAI).

Calculating TAI is a major resource for determining Coordinated Universal Time (UTC), the shared international reference time scale that countries worldwide use to synchronize clocks. Without UTC in place as the world's agreed consistent time-base, global navigation, financial and telecommunications systems would not function properly.

The definition of the SI second is the foundation upon which all timing applications are built, and any improvement in its precision directly translates to knock-on improvements along the measurement chain. Currently, the best optical atomic clocks are approximately 100 times more

precise than the best caesium atomic clocks – however, without redefining the second, this improved precision cannot as yet be harnessed.

International Atomic Time is calculated monthly by the International Bureau of Weights and Measures (BIPM) by first taking the weighted average of more than 400 atomic clocks located at approximately 80 metrology laboratories around the world – including NPL in the UK. This average is then 'steered' by frequency standards from a pre-approved list. Most are caesium microwave standards, but recent years have seen optical standards contributing more and more.

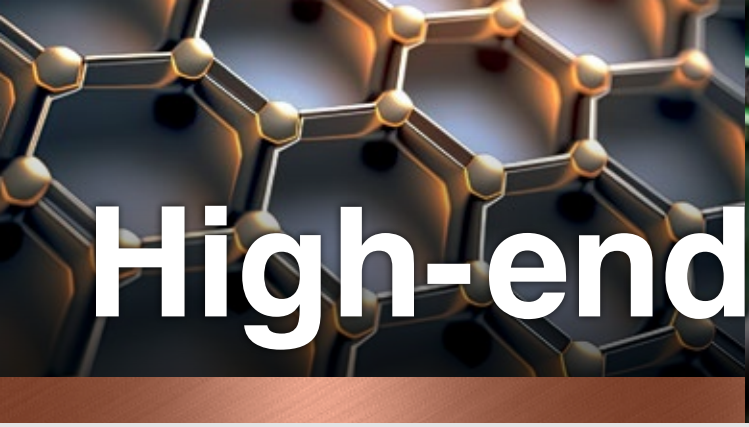
This regular contribution to International Atomic Time by optical secondary frequency standards is one of the mandatory criteria that must be met before a redefinition of the second can take place. The target date for redefining the SI second is set for 2030.

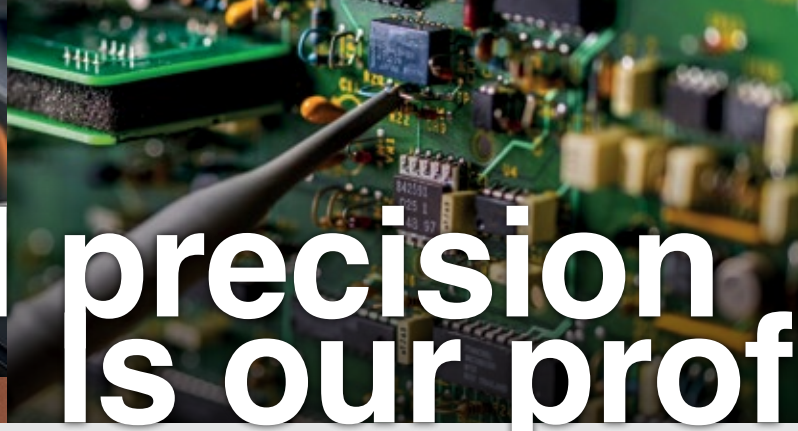
The NPL team submitted their historic optical frequency data comparing NPL-Sr1 with the UK's own UTC(k) time scale over several periods, the longest of which was one month. After a rigorous assessment by the CIPM's Consultative for Time and Frequency Working Group, NPL-Sr1 was accepted as the first UK optical clock to contribute to International Atomic Time.

The next steps are to make on-time data submissions which enable NPL-Sr1 to have a much greater significance in steering TAI. The first of these was made at the end of April 2023 in which NPL-Sr1 was the third highest contributor (9.63%) of the 14 primary and secondary frequency standards that contributed that month. A second submission was made at the end of May 2023 benefitting from the momentum of the first. Expect to continue to see more contributions from NPL-Sr1 in the years leading up to redefinition.

Dr. Ian Hill, Principal Scientist and lead for the optical lattice clock project in NPL's Optical Frequency Metrology group, said: "This is a significant achievement for NPL and the wider time & frequency community with well over a decade of invested hard work coming to bear fruit. We now join a select group of optical clocks from around the world that have a say on TAI and support the transition to a possible new SI second."

Dr. Jacob Tunesi, Senior Scientist at NPL, said: "An optical representation of the SI second requires that we





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For technical support or other questions regarding 1A CAL service, US customers can contact David Martson directly at david.martson.ext@1acal.de.

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demonstrate that optical clocks can be a benefit to the real world and there's no better way than by contributions to the international time scale which underpins modern life. It has been a pleasure to have played a part in bringing NPL's Sr lattice optical clock onto this stage and I look forward to contributing more in the future."

Prof. Helen Margolis, Head of Science (Time and Frequency) and Senior NPL Fellow said: "Reaching this milestone represents a significant achievement for the team and stems from a huge effort from many people over many years. I am delighted that we are now able to use our strontium optical lattice clock to contribute to global timekeeping and make progress towards a redefinition of the second."

The chair of the CCTF Working Group on Primary and Secondary Frequency Standards, Stefan Weyers said: "Ensuring correct world time is accomplished using a relatively small ensemble of a good dozen caesium atomic clocks and optical atomic clocks. Since, in the context of a future redefinition of the second, optical atomic clocks will have a much greater importance in this process, the contributions of the new clock NPL-Sr1 are an important step into the future of national and international timekeeping."

The Director of the BIPM Time Department, Patrizia Tavella said: "The BIPM welcomes all the activities leading to new optical frequency standards that can contribute to UTC and the recent achievements of NPL are greatly appreciated. The development of the NPL Sr1 frequency standard and its capacity to measure the accuracy of Coordinated Universal Time provide an added value to the entire UTC community. The NPL Sr1 measurement has been taken into account by the BIPM in the most recent UTC computations, together with all the other measurements of primary and secondary standards operated all over the world, including the cesium fountain NPL-CsF2. The availability and the great accuracy of the measurements are allowing a relative accuracy of UTC at the level of 2 parts in 10^{16} which means a possible error of half a nanosecond (half of a billionth of a second) over one month.

Source: https://www.npl.co.uk/news/npl-makes-history-with-first-uk-optical-clock

Confidence in Virtual Flowmeters

PTBnews 2.2023 – A method for calculating the simulation uncertainty of a virtual ultrasonic flowmeter has been developed in PTB's VirtMet Competence Center. This method allows calibration factors relevant to fluid mechanics to be calculated for real measuring devices. The method is based on the comparison of real and virtual measurements and allows the continuous determination of calibration factors with their corresponding expanded uncertainty and confidence interval.

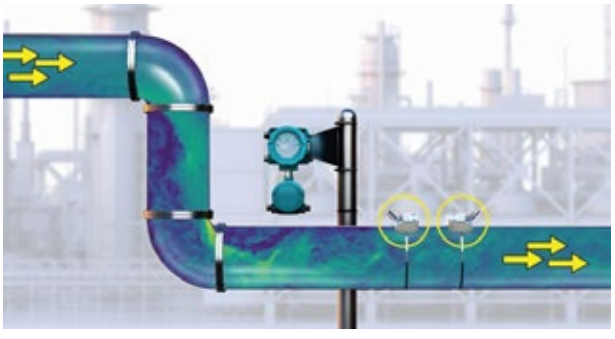
When a real measurement procedure is reproduced by simulations, it may be referred to as a "virtual measurement". From a metrological point of view, the question is how to ensure confidence in such virtual measurements. While methods to estimate diverse sources of error in simulations have been developed over the past decades, there has to date been no accepted strategy for meeting the metrological requirements for virtual measuring devices. Now, researchers at PTB have developed a method for calculating the simulation uncertainty of a virtual ultrasonic clamp-on meter for flow rate measurements.

Ultrasonic clamp-on meters have become an established technology for flow rate measurements. Under real, non-ideal flow conditions downstream of bends, valves, etc., the measurement values of flowmeters must be corrected by means of fluid mechanical calibration factors. Because of the variety of relevant flow configurations and installation positions, the experimental determination of these factors is supplemented by simulations. As in the case of real uncertainties, the approach to determining the simulation uncertainty is based on the use of an expanded uncertainty with the associated confidence interval. The simulation errors are determined at discrete measurement positions, and a continuous simulation uncertainty is derived from this, i.e., simulation uncertainties that are applicable to all installation positions of the meter. The newly developed method allows experimental data to be replaced by virtual measurements – a metrologically justifiable approach. This method is not limited only to certain devices and flow configurations in flow rate measurements but is generally also applicable to other areas of metrology to improve confidence in virtual measurement devices.

Contact: Martin Straka, Department 7.5, Heat and Vacuum, Phone: +49 30 3481-7769, martin.straka@ptb.de.

Scientific publication: M. Straka, A. Weissenbrunner, C. Koglin, C. Höhne, S. Schmelter: Simulation uncertainty for a virtual ultrasonic flow meter. Metrology 2, 335–359 (2022)

Source: https://www.ptb.de/cms/en/presseaktuelles/journals-magazines/ptb-news.html



Two ultrasonic clamp-on flowmeters (yellow circles) downstream of a bend configuration. The flow development in the pipe and the fluid mechanical calibration factors of the device are modeled on the basis of a "virtual measurement." Credit: PTB

Establishment of a CCTF Task Group to Address Progress Towards a Continuous UTC

The 27th meeting of the CGPM (2022) adopted Resolution 4 *On the use and further development of UTC*. Subsequently, the CCTF Working Group on Strategic Planning established a task group (TG) in May 2023 to address the progress towards a continuous UTC.

The TG shall work together with the CCTF, laboratories that contribute to UTC, GNSS providers, International Organizations - such as the International Astronomical Union, the International Telecommunication Union (ITU), the International Earth Rotation and Reference Systems Service (IERS) - and other stakeholders to prepare a draft resolution for the 28th meeting of the CGPM (2026) including:

- the extended tolerance value of UT1-UTC*
- the procedure to align UTC to UT1 when the new tolerance is reached
- the revision periodicity of this decision by the CGPM
- the exact implementation date.

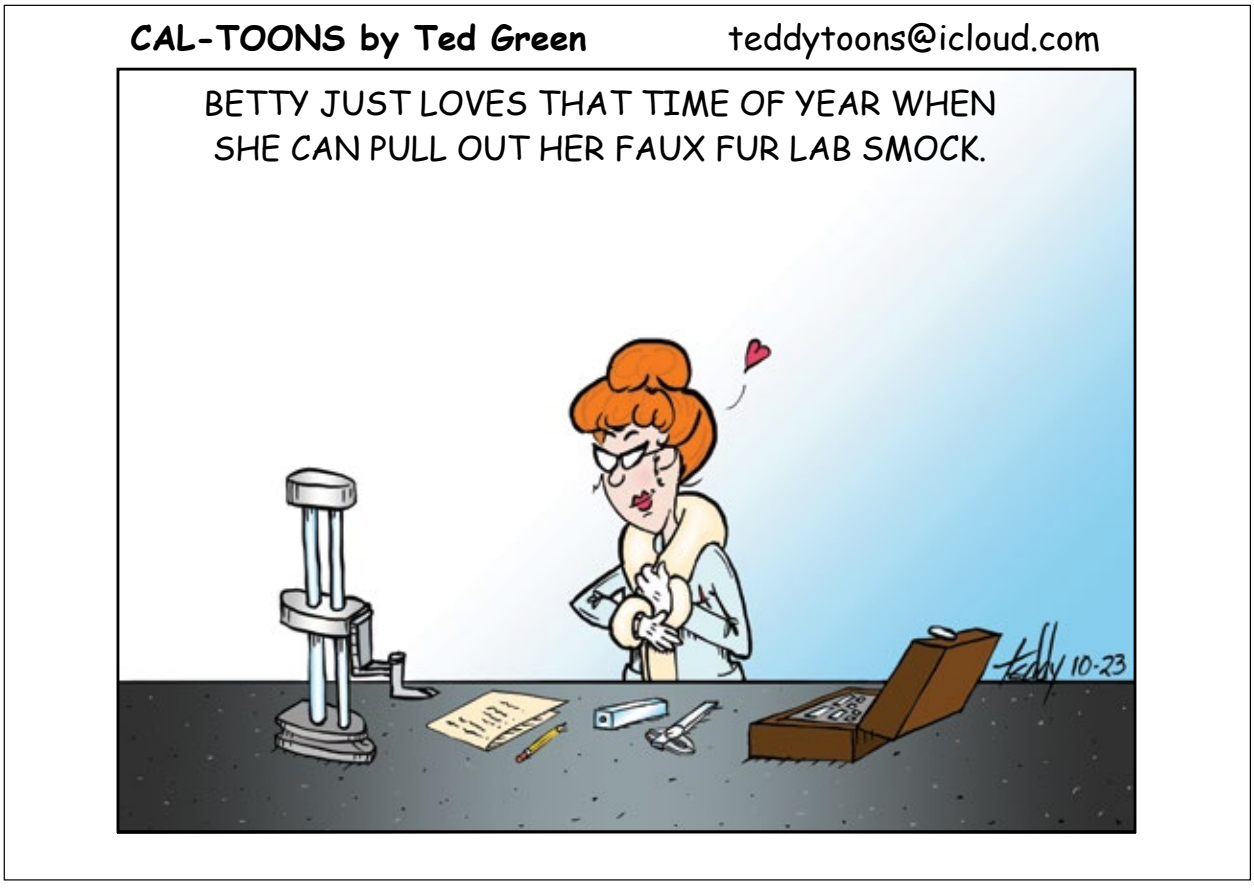
The TG aims to provide support to ITU delegations so that they are well prepared for the 2023 ITU World Radiocommunication Conference (https://www.itu.int/wrc-23/), where the update on UTC will be considered. Finally, the TG will foster communication efforts to increase awareness about this initiative, which will have profound implications for the future of reference time scales. Educational materials and promotional initiatives will be developed and shared over the coming years.

The TG looks forward to submitting a proposal to the 28th meeting of the CGPM that takes into account the requests and constraints of the different communities, while enabling UTC to be universally accepted, robust and useful.

* UTC - Coordinated Universal Time - is a time scale produced by the International Bureau of Weights and Measures (BIPM) with the same rate as International Atomic Time (TAI). It differs from TAI only by an integral number of seconds.

UT1 is the time scale describing the angular rotation of the Earth.

Source: https://www.bipm.org/en/-/2023-07-28-cctf-tg. BIPM content is licensed under the terms of the Creative Commons Attribution 3.0 IGO (https://creativecommons.org/licenses/by/3.0/igo/). Some content was left out for the sake of space. Visit Source URL for the complete news story.



Certificate of Calibration – Accredited Versus Unaccredited Calibration

David Lohbeck
ANSI National Accreditation Board (ANAB)

Introduction

As an assessor, I am often asked the following question: "Is a calibration certificate issued from an ISO/IEC 17025-accredited laboratory always acceptable?" My answer: "No, it may not be." Read on to find out why.

Calibration certificates can be confusing—especially if you aren't a metrologist. Calibration certificates document the quality and accuracy of test equipment measurement results, so it's important to understand the terminology and what the seemingly random numbers mean. More than a few test laboratories are receiving calibration certificates that are not accredited and, therefore, questionable.

Is the calibration certificate you are considering suited for its intended purpose? Decision makers can be influenced by many factors, such as comprehension of technical and industry standards, cost/benefit, and the all-important company timeline.

A questionable calibration certificate could mean invalid calibrations that can jeopardize a test laboratory's own ISO/IEC 17025 accreditation when nonconformities (NC) are identified during an audit. No one wants to hear, "Go back and do it again," which means a loss of time and money.

The purpose of this article is to explain the meaning and importance of accredited calibrations and the meaning of certification. Common misconceptions about calibration certificates will be covered with guidance about how to quickly spot accredited and unaccredited certificates.

This article covers:

- Purpose of a calibration certification
- Accredited versus unaccredited calibration certificates
- Chain of custody of calibration reports
- Declaration versus certification
- The five key elements of a calibration certificate
- The Accreditation Body (AB) Accreditation Status (known as the *AB Symbol*)

> *"The primary significance of calibration is that it maintains accuracy, standardization and repeatability in measurements, assuring reliable benchmarks and results. Without regular calibration, equipment can fall out of spec, provide inaccurate measurements, and threaten quality, safety . . .* [1]*"*
>
> *"Accredited calibrations provide a certificate of calibration with the accrediting body's [AB] logo [symbol] on the document. The calibration date is on the certificate and the calibration due date is only placed on the document when specified by the customer or contractually agreed. A traceability statement is provided* [2]*."*

Standards

Understanding normative (requirements) standards ISO/IEC 17025 and 17065, and informative (guidance) standard ISO/IEC 17000 helps us to understand the world of accreditation and calibration. Important standards are as follows:

- ISO/IEC 17025—Requirements for the competence of testing and calibration laboratories.
- ISO/IEC 17065—Requirements for Certification Bodies (CB) [3].
  Note: ISO/IEC 17065 refers to ISO/IEC 17025 for calibration, testing, reports, and certificates.
- ISO/IEC 17011—Requirements for Accreditation Bodies (AB) accrediting conformity assessment bodies (CAB/CB).
- ISO/IEC 17000—Conformity assessment vocabulary and general principles.

ISO/IEC 17025 is the most important standard for testing and calibration laboratories. Independent, third-party Accreditation Bodies, such as ANAB, use 17025 for assessment and accreditation of calibration laboratories. Once a calibration lab has successfully passed an Accreditation Body (AB) assessment they are accredited and can affix the AB Symbol (Logo) to their calibration certificates and reports, thereby indicating conformity with ISO/IEC 17025 and the AB requirements.

The term AB Symbol is used by the CAB and AB Logo is used by the Accreditation Body and are not used interchangeable. Refer to Table I for a summary of the key standards.

Accreditation Status and Certification Process

The Accreditation Body Symbol is displayed to identify the Conformity Assessment Body's (CAB)

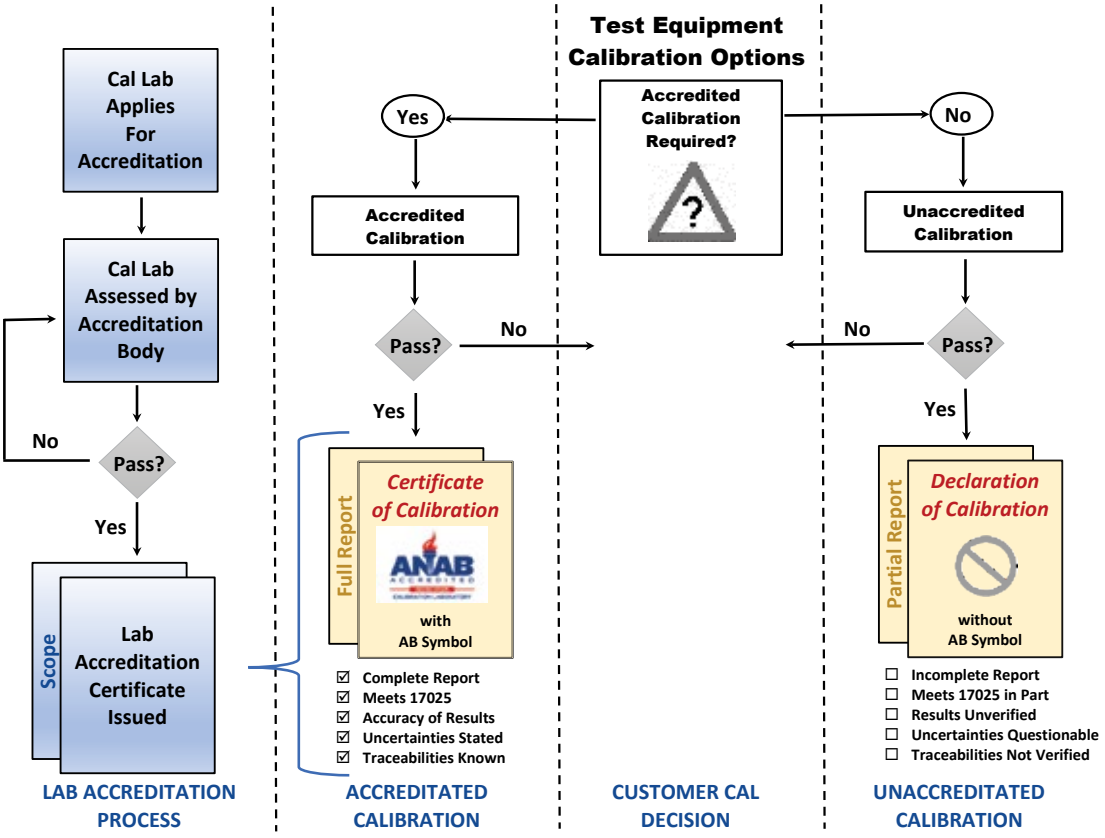


Figure 1. Process for Accredited and Unaccredited Calibration

accreditation status of the service provided within the calibration certificate. Without an AB symbol, the calibration results and certificate, and 17025 conformity can be held in doubt. AB Accreditation Symbol make it crystal clear.

Accreditation Bodies (AB) [4] are authoritative bodies that perform assessments and accreditations of testing and calibration labs. The authority of an AB can be derived from government, authorities, contracts, market acceptance or scheme owners. Accreditation is a *third-party attestation* related to a conformity assessment body, conveying formal demonstration of its competence, consistent operation, and impartiality in performing specific conformity assessment activities. ABs assess and accredit calibration laboratories allowing them to issue attestations (certificates) with the AB's Symbol which proves that ISO/IEC 17025 as well as that the AB's requirements are met, as shown in Figure 1.

When the calibration lab is accredited, a Certificate [5] is issued with an AB Symbol, as described in the Accredited versus Unaccredited Certificates section. ABs that perform lab assessments and audits, such as ANAB and others, often require accredited calibrations with AB Symbols on calibration certificates as evidence of accreditation.

The Chain of Custody of Calibration Reports

The calibration certificate is the tell-all report on the equipment's calibration. Most calibration labs issue certificates and reports as one document. For simple calibrations, the certificate and report can be one page. More complex certificates have additional pages, with key information starting on page one, and calibration data and results on subsequent pages. If all pages are one continuous document, the AB Symbol on the first page covers the entire document.

If the report and certificate are separate, there is no assurance that the report is connected to the certificate, even when the certificate number is listed on both documents. Additionally, a separated report is often missing critical information, such as the identity of the person who performed the calibration, calibration date, revision history, AB Symbol, and so on. Separate reports may also mean that they were issued/revised at different times and by different persons, which breaks the Chain of Custody [7].

There should be one continuous certificate and report document to ensure that the Chain of Custody is preserved, and that the AB Symbol covers both the certificate and report. If you receive a certificate and report as separate documents, demand AB Symbol on both the certificate and report from the calibration provider.

ANAB AR 2250 – ACCREDITATION REQUIREMENTS: ISO/IEC 17025 TESTING LABORATORIES (NON-FORENSICS) [6]

2.1.2. Traceability from an ISO/IEC 17025 Accredited Calibration Laboratory: Applicant and accredited laboratories should use ISO/IEC 17025 accredited calibration laboratory services whenever available. Acceptable ISO/IEC 17025 accredited calibration laboratories are those accredited by ANAB or another accreditation body that is a signatory of the International Laboratory Accreditation Cooperation (ILAC) MRA with the appropriate calibration services listed in the scope of accreditation. . .

When using accredited calibration laboratory services, ***the calibration certificates shall be accompanied by a recognized accreditation body symbol*** **[AB Symbol]*** or otherwise refer to accredited status to be considered satisfactory for traceability purposes.

ANAB FM 2807 Traceability Tracking form is used to list calibrated test equipment with the equipment's accredited calibration providers and accreditation certificate numbers.

* Bold italics added for emphasis

When Accredited Calibration is Required and Not Required

A key element in determining compliance with ISO/IEC 17025 calibration requirements is the validity and accuracy of the equipment's measurements and calibration results. Equipment used to perform testing and measurements should provide the necessary level of confidence in the results of the measurements and tests performed. Accredited calibration is essential when accuracy is paramount. Industries such as aerospace, medical, and aviation require measurement accuracy. Out-of-tolerance instruments may give false information leading to unreliable products and customer dissatisfaction. Questionable or out-of-tolerance conditions may cause products to fail tests, which ultimately results in unnecessary rework costs and production delays.

Let's consider a few examples where accredited and unaccredited calibration may be justified.

Example 1—Accredited Calibration is Not Required:

Unaccredited calibration, or no calibration, may be justified if measurement results are not critical, or when approximations will suffice. Some examples are as follows:

- The equipment and tests not used to evaluate a product's design
- There is no product safety risk or impact from unverified measurement results
- The test results does not impact a product's electromagnetic compatibility (EMC)
- The measurements are not critical or allow for large tolerances for manufacturing test equipment, such as certain gauges, instruments, scales, timers, tape measures, and so on.

Remember that accredited calibration is required for most test equipment; rare exceptions are made for testing a product that will *not* be used to evaluate a product's design, safety performance, or other situations where measurement results are not critical.

Example 2—Accredited Calibration is Not Practical:

Some original equipment manufacturers (OEMs) sell complex equipment that only the OEM can calibrate, and the OEM's lab is not an ISO/IEC 17025 accredited lab. In this special case, OEM equipment receives a conditional unaccredited calibration by the OEM and is then re-checked internally using reference standards/devices by the testing lab as a verification process. The standards/devices used for the calibration verification must have accredited calibrations with traceability to NIST. ABs may require that the testing lab, not the calibration lab, apply for a traceability waiver for unaccredited calibrations.

Example 3—Accredited Calibration Required:

Accredited calibration is required for the test equipment when measurement results and accuracy are important. Some examples include dielectric withstand and ground continuity tests (shock and fire tests) that are performed on some products during the manufacturing process to confirm a product's safety insulation and grounding. Production safety tests (known as routine tests) are performed on all products being produced. An accredited calibration is required for the test equipment because the tests are critical to user safety and are typically specified by the Certification Body (CB) that certified the product, as shown in Figure 1.

Accredited calibration is required in many cases, especially when measurement results are critical or if your company must meet regulatory requirements as specified by an accreditation body audit.

NOTE: When purchasing or renting new test equipment be sure to obtain a calibration certificate; otherwise, you will need to get the equipment calibrated prior to its use.

Accredited versus Unaccredited Certificates

Calibration laboratories often offer both accredited and unaccredited calibrations. Unaccredited certificates are *non-credentialed* and accreditors will consider them as *Declarations*, known as Declaration of Conformity or DoC.

Unaccredited calibration certificates do not certify calibration results.

Unaccredited calibration certificates may or may not contain a data report, traceability verification, and/or measurement uncertainties (MU), and, therefore, may not fully comply with ISO/IEC 17025.

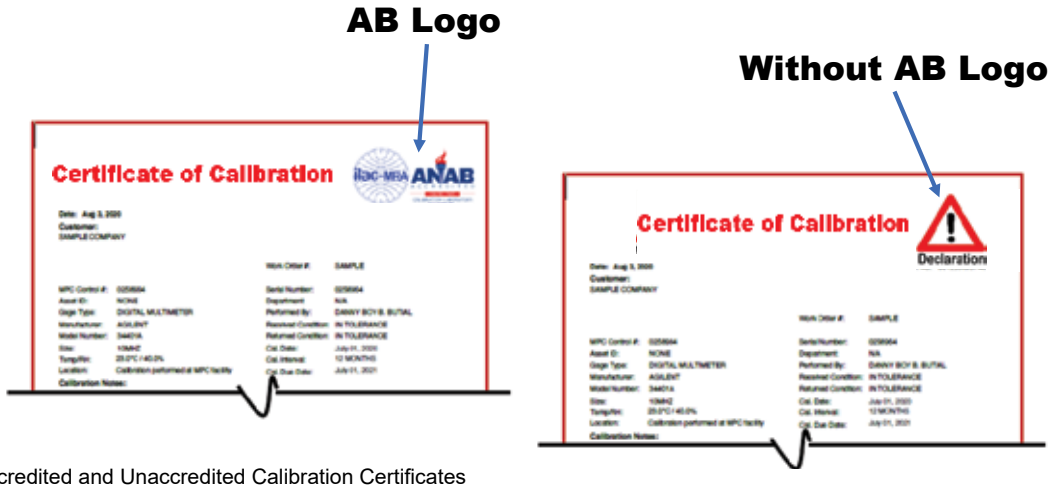


Figure 2. Accredited and Unaccredited Calibration Certificates

Unaccredited calibration certificates may cost less but be aware that they may not be independently verified by an AB to meet ISO/IEC 17025.

The Five Key Elements of a Calibration Certificate

You may assume a calibration certificate is acceptable because the term *Certificate* is on the document, but be aware of five key elements of a calibration certificate:

1. **The AB Symbol–Accreditation Body (AB) Accreditation Status**—An accredited calibration lab means that the lab has been assessed by an AB according to the ISO/IEC 17025 standard and can demonstrate the lab's competence, impartiality, and performance capability. Accredited calibration provides the highest quality assurance and is generally accepted by accreditation (auditing) bodies. An AB Symbol affixed to a calibration certificate displays the CAB's accreditation status and ensures that the certificate and report are complete and accurate. However, just because a lab is accredited, it does not mean that the calibration and certificate is accredited. When the AB Symbol is affixed to calibration certificates, it ensures an accredited calibration (refer to Figures 1 and 2).
2. **As Received/As Returned Conditions**—As Received (as found) and As Returned (as left) conditions are commonly stated as In- or Out-of-Tolerance results on certificates. If the As Received condition is In-Tolerance then the measurement device was within tolerance and yielded correct measurement values when the equipment/device was received by the calibration lab. On the other hand, if the As Received condition of a device was Out-of-Tolerance, then the equipment was measuring incorrectly when delivered to the lab for calibration. Therefore, Out-of-Tolerance readings may have been occurring since the last calibration, yielding incorrect measurements for a year or more. In this case, you need to perform an investigation of the tests and measurements performed since the previous calibration to determine potential impact.
3. **Traceability**—Metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty." In other words, traceability is a comparison between standards of known accuracy with an unbroken chain of calibrations that may involve several steps along the way including the calibration lab's process, uncertainties, instruments used, and reference and primary standards, until traceability can be established through the NIST, or another National Metrology Institute, to the SI unit. It is important to note that a traceability statement may only be a declaration, and therefore unsubstantiated,

unless verified by an AB Symbol displayed on the calibration certificate [8].

4. **Measurement Uncertainty (MU)**—MU quantifies and validates possible effects of uncertainties including variations in the measurement device. The values associated with the uncertainty indicates how reliable the measurement is. Labs must identify and analyze contributions to Measurement Uncertainty for all calibrations. MU is reflected in a calibration labs uncertainty budget with MU often denoted as +/– values that must be considered throughout the entire calibration process. MU statements are typically indicated on certificates in two ways:
   - Calculated MU values, from the labs MU budget, are listed alongside the calibration results
   - A generic MU statement usually found in the fine print or footnote such as, *uncertainty of 95% confidence level using coverage factor k=2*, or similar wording.

   Calculated MU values may not be listed on unaccredited calibration certificates; or if MU values are present, they may only be estimated values. Accredited calibration certificates require listing calculated MUs.
5. **Scope of Accreditation**—In addition to verifying the previously-listed elements on a calibration certificate, ensure that you review a copy of the calibration lab's Scope of Accreditation. Scopes are part of the lab's AB certificate of accreditation, which require different documents than the calibration certificate (see Figure 3). The test equipment's measurement parameters e.g., voltage, current, and the measurement ranges and +/– tolerances, are listed on the Scope. Review the calibration lab's Scope of Accreditation and ensure that the measurements/tests and parameters you need are listed. For example, if you need to measure 600 V AC and the range on the Scope of Accreditation is 0 V DC to 600 V DC, the equipment was not calibrated for ACvoltage (V AC) and the calibration will not be acceptable for your needs.

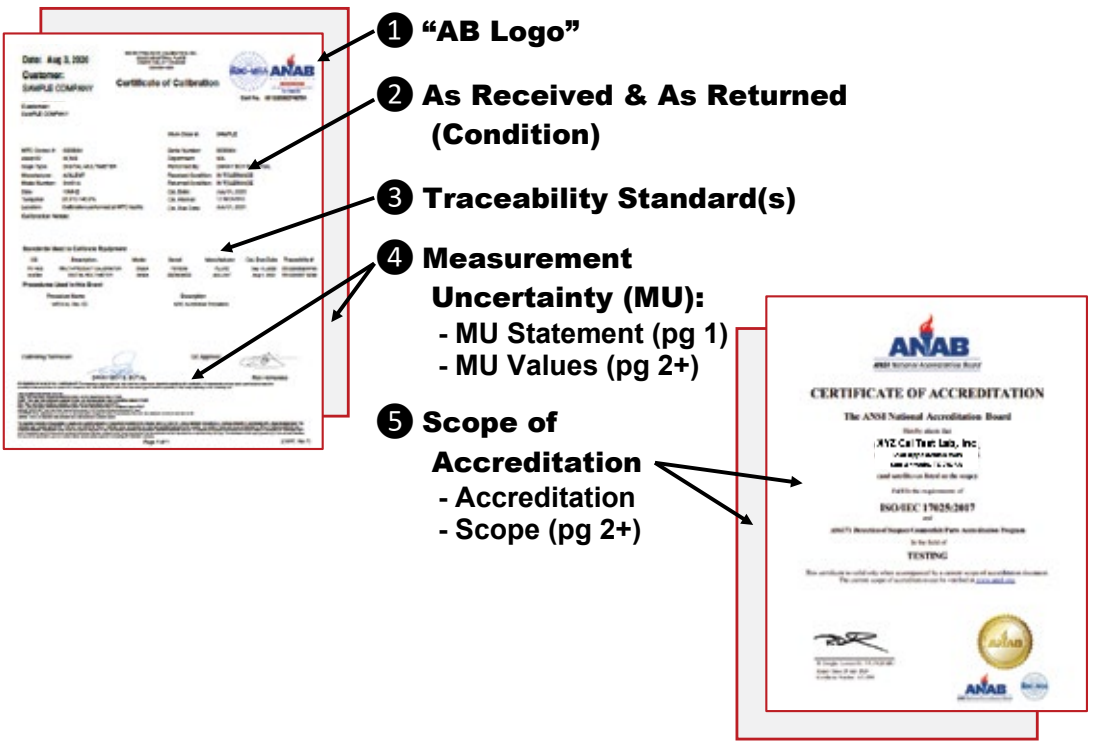


Figure 3. The Five Key Elements of a Calibration Certificate

Conclusion

Accredited calibration laboratories can offer both accredited and unaccredited calibrations. Accredited calibrations provided by the cal lab are identified with an Accreditation Body (AB) Symbol on the calibration certificate. Accredited calibrations assure the integrity and quality of the calibration including results, accuracy, traceability, uncertainties, and—most importantly—compliance with ISO/IEC 17025. Unaccredited calibration certificates—while economically attractive—may not be accepted by customers, authorities, or auditors.

There is more to a calibration certificate than just the term "Certificate" on a document. When we understand a few simple rules, we can quickly review calibration certificates to ensure they meet the high levels of calibration quality. Don't be misled and receive a "Declaration of Calibration" when you want an accredited "Certificate of Calibration" (Figures 1 and 2).

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[6] ANAB ACCREDITATION REQUIREMENTS: ISO/IEC 17025 TESTING LABORATORIES (NON-FORENSICS): https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=8160
[7] NIST Chain of Custody Definition: https://csrc.nist.gov/glossary/term/chain_of_custody
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TABLE I – STANDARDS and SCOPE

ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories.[1]

Intro: "This document has been developed with the objective of promoting confidence in the operation of laboratories. This document contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results."

Scope: "This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories. This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel. Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies [AB's], and others use this document in confirming or recognizing the competence of laboratories."

Authors Note: *Accreditation Bodies (AB's) assess calibration labs according to this standard plus the AB's requirements. If a calibration lab successfully passes an audit, it then is accredited and can issue accredited calibration certificates which ensure that the calibration lab, and calibration results, meet 17025.*

TABLE I – STANDARDS and SCOPE (continued)

ISO/IEC 17065 - Conformity Assessment – Requirements for bodies [CB's] certifying products, processes and services [e.g., cal labs].[1]

Intro: "The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party . . . Certification of products, processes or services is a means of providing assurance that they comply with specified requirements in standards and other normative documents."

Scope: "This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies [CB's] . . . Certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000)."

Authors Note: *Calibration labs are first-parties when they issue unaccredited calibration certificates (no AB Symbol) and they are viewed as third-parties when they issue accredited calibration certificates which bear an AB Symbol.*

ISO/IEC 17011 - Conformity assessment — Requirements for accreditation bodies [AB's] accrediting conformity assessment bodies [CB's & Labs].[1]

Intro: "The ISO [International Standards Organization] Committee on conformity assessment (CASCO) develops International Standards relating to conformity assessment activities such as testing, inspection and various forms of certification."

Scope: "This document specifies requirements for the competence, consistent operation and impartiality of accreditation bodies [AB's] assessing and accrediting conformity assessment bodies (CAB's/CBs)."

Authors Note: *Accreditation Bodies (AB's) are authoritative bodies that perform assessments and accreditation of calibration and testing laboratories according to ISO/IEC 17025. The AB's must follow 17011 during the calibration laboratory assessment process.*

Note: The words "certification body" have been replaced by "accreditation body."

ISO/IEC 17000 - Conformity Assessment – Vocabulary and general principles[1]

Intro: "The ISO [International Standards Organization] Committee on conformity assessment (CASCO) develops International Standards relating to conformity assessment activities such as testing, inspection and various forms of certification."

Scope: This document specifies general terms and definitions relating to conformity assessment (including the accreditation of conformity assessment bodies) and to the use of conformity assessment to facilitate trade.

Authors Note: *Vocabulary and terms are in 17000 and related standards mentioned in this table.*

1 IEC Standards Webstore: https://webstore.iec.ch/

The Hidden Value of FDA 21 CFR Part 11 Electronic Records & Electronic Signatures

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There are many regulatory requirements that bio-medical companies need to follow; however, *FDA 21 CFR Part 11 – Electronic Records; Electronic Signatures* is one of the more obscure and misunderstood of the compliance regulations. In this article, we will review the background and content of FDA 21 CFR Part 11. We will highlight the three most important aspects of the document and then reveal the hidden value of FDA 21 CFR Part 11 for computer software applications.

Background

FDA 21 CFR Part 11 is a section in the Code of Federal Regulations (CFR) that creates the United States Food and Drug Administration's (FDA) rules on using electronic records and electronic signatures. Each title of the CFR targets a different regulated area, 21 CFR relates to Pharmaceuticals and Medical Devices and Part 11 being related to electronic records and electronic signatures. 21 CFR Part 11 is therefore decoded as [1]:

21: Short for *Title* 21 which denotes the section of the CFR that applies to food and drugs. The CFR comprises 50 "titles."

CFR: Stands for *Code of Federal Regulations* which is a coded (numbers and letters) set of laws issued by the federal government of the United States.

Part 11: Scope is specific to electronic records and electronic signatures which contains electronic submissions to the FDA.

At a high level, Part 11 is a law that ensures that life science companies initiate good business practices by defining the conditions under which electronic records and signatures are considered to be accurate, reliable, truthful, authentic, available, and equivalent to paper records and handwritten signatures on paper. Part 11 fundamentally allows any paper records to be replaced by an electronic record, and allows any handwritten signature to be replaced by an electronic one.

Content

Part 11 has three main sections; see Figure 1: (1) Subpart A - General Provisions, (2) Subpart B - Electronic Records, and (3) Subpart C - Electronic Signatures.

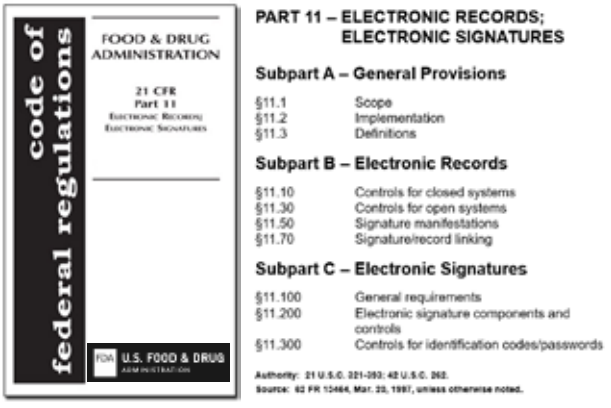

Figure 1. FDA 21 CFR Part 11, Electronic Records; Electronic Signatures.

Subpart A - General Provisions

The General Provisions of Part 11 describe the scope, implementation, and definitions of the regulation.

The scope of Part 11 applies to all electronic records that fall under the oversight of the FDA. If an organization can prove to an auditor that their electronic records/signatures are as trustworthy as paper records/ink signatures, the FDA will accept electronic instead of paper.

There are three primary areas of focus when implementing Part 11: (1) Standard Operating Procedures, (2) Validation, and (3) System Features [2].

Many people may not realize that half of the requirements of Part 11 deal with the expectation that there will be standard operating procedures in place to govern and describe how organizations are to implement and control Part 11 features. Some of the high-level SOPs deal with System Validation, Record Processing and Protection, System Access Rights, Audit Trails, Personnel Qualification, Document Control, and Electronic Signatures.

One of the most important aspects of implementing Part 11 is to validate. The FDA expects organizations to ensure that they document that the electronic system is fit for its intended use, that is, demonstrate that the system does what it is supposed to do. Validation also needs to ensure that the system has the necessary system features to properly manage electronic records and electronic signature processes to be compliant to Part 11.

There are several key definitions within Part 11 [3]:

Electronic Record: Any combination of text, graphics, data, audio, or pictorial information represented in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer.

Electronic Signature: A combination of any symbol(s) executed to be the legally binding equivalent of an individual's handwritten signature.

Handwritten Signature: The scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form.

Subpart B - Electronic Records

Organizations using Part 11 need to ensure that electronic records have documented procedures and controls in these areas:

- Able to create accurate and complete copies in both human readable and electronic form for inspection, review, and copying.
- Protection of records for accurate and ready retrieval throughout the records retention period.
- Use of secure audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.
- Electronic signatures and handwritten signatures in electronic records need to be linked to their respective electronic records to deter falsifying an electronic record by normal means.

Subpart C - Electronic Signatures

Part 11 has the following additional control expectations for electronic signatures:

- Each electronic signature has to be unique to one individual and will not be used by anyone else.
- Electronic signatures will be used only by the authorized owner.
- Identification codes and passwords need to be periodically checked.
- Detect and report any attempts for unauthorized access to the system.

Three Core Aspects

Part 11 has over 30 individual procedure and control requirements; however, there are three core aspects that define the regulation for computer system usage: Identification Components, Signature Components, and Audit Trails.

Identification Components

Part 11 requires two distinct user identification components. First, there is the expectation that there is a unique Identification Code assigned to the individual such as an abbreviated name or identification number. Second, Part 11 expects that the Identification Code has an associated user password so that there is a two-part coded access.

Signature Components

For each signed off electronic record, Part 11 requires that there be **four** electronic signature components: (1) Printed Name of the Signer, (2) Date of the Signature, (3) Time of the Signature, and (4) **Meaning** of the Signature.

The fourth signature component is one of the most overlooked requirements within Part 11. The *meaning* of the signature needs to represent the individual's role in the sign-off such as the *approver, reviewer, verifier, or performed by*. An example of the record sign-off:

Signer's Name:	Walter Nowocin
Signed Date:	26 July 2023
Signed Time:	9:30AM CST
Signed Meaning:	Approver

Another over-looked aspect to the signature components is that the four signature components not only need to be visible and part of the electronic record, but furthermore the four signature components need to be part of any **printed** record. Part 11 paragraph 11.50(b) requires that the electronic signature components will be "included as part of any human readable form of the electronic record (such as electronic display or printout)."

Audit Trails

One of the most important aspects of Part 11 is audit trails, specifically for database entries and actions. There are several specific expectations from the FDA regarding audit trails:

- Use of secure, computer-generated, time-stamped audit trails.
- Record the date and time of operator entries.
- Record operator actions that create, modify, or delete electronic records during normal operation.
- Record changes shall not obscure previously recorded information.
- Audit trail documentation shall be retained for as long as that required for the electronic record.
- Audit trails shall be available for FDA viewing and copying.

One important misconception regarding audit trails and Part 11 is that audit trails are required to be periodically reviewed. Part 11 does not make periodic review of audit trails a documented requirement. Audit trails provide data to focus on electronic record changes for traceability of the history of the record. Furthermore, Part 11 does not even require that electronic records are required to be periodically reviewed.

Guidance Document

One point of confusion is that there are two FDA documents related to 21 CFR Part 11. There is the regulation document released in 1997 titled: *21 CFR Part 11, Electronic Records; Electronic Signatures*. This is the document that is the primary focus of this article. See Figure 1.

Then there is a guidance document released in 2003 titled: *Guidance for Industry Part 11, Scope and Application*. This document provides additional clarification and guidance for the implementation of 21 CFR Part 11 requirements; but without any new stated requirements [4]. See Figure 2.

Another misconception is that the Part 11 *Guidance for Industry* document has superseded or replaced Part 11 and that Part 11 is obsolete. This is not the case, both Part 11 and the *Guidance for Industry* document for Part 11 are both still active documents. One has regulatory requirements and the other provides recommendations on how to implement and maintain Part 11.

Guidance for Industry explains that the FDA intends to interpret Part 11 very narrowly in scope only to records that are required under FDA regulations and when organizations chose to use those records in electronic format in place of paper format.

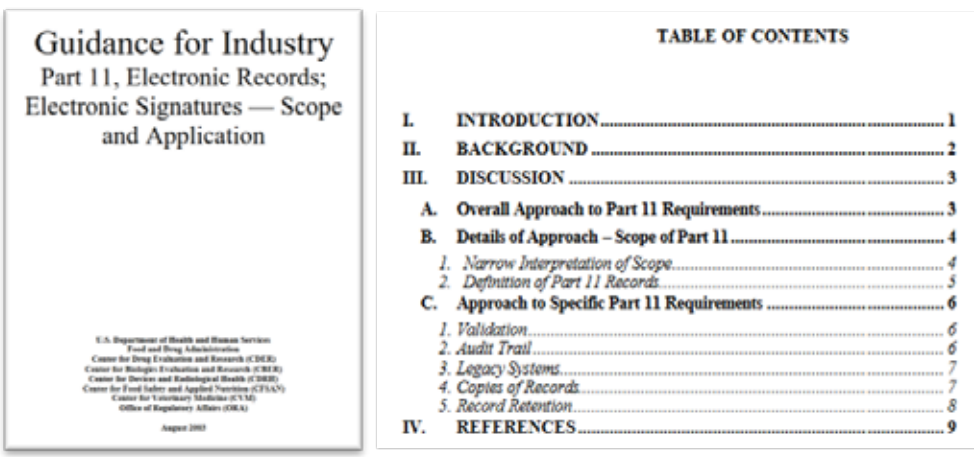
Guidance for Industry
Part 11, Electronic Records; Electronic Signatures — Scope and Application

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Figure 2. Guidance for Industry Part 11, Electronic Records; Electronic Signatures—Scope and Application.

	PART 11 #	PART 11 DESCRIPTION
PROCEDURES	11.10(a)	System Validation - Procedures
	11.10(b)	Generate and Process Records - Procedures
	11.10(c)	Protecting Records - Procedures
	11.10(d)	Limiting System Access - Procedures
	11.10(e)	Audit Trails - Procedures
	11.10(f)	Sequencing of Steps and Events - Procedures
	11.10(g)	Authority Checks - Procedures
	11.10(h)	Source Verification - Procedures
	11.10(i)	Personnel Qualification - Procedures
	11.10(j)	Individual Accountability and Responsibility - Procedures
	11.10(k1)	Database SOP Control and Access - Procedures
	11.10(k2)	Database SOP Change Control - Procedures
CONTROLS	11.10(a)	System Validation
	11.10(b)	Generate and Process Records
	11.10(c)	Protecting Records
	11.10(d)	Limiting System Access
	11.10(e)	Audit Trails
	11.10(f)	Sequencing of Steps and Events
	11.10(g)	Authority Checks
	11.10(h)	Source Verification

	PART 11 #	PART 11 DESCRIPTION
C	11.50(a)	Electronic Records Signing Information
	11.50(b)	Signed Electronic Signature Displayed and Printed
	11.70	Electronic Signatures Linked to Electronic Records
P	11.100(a)	Electronic Signature Unique to One Individual - Procedures
	11.100(b)	Verifying the Identity of the Individual - Procedures
	11.100(c)	Electronic Signature are Legally Binding (FDA) Equivalent to Handwritten Signature - Procedures
C	11.200(a1)	Two Distinct Identification Components: Identification Code and Password
	11.200(a1ii)	Not a Single, Continuous Period Electronic Signing
	11.200(a2)	Genuine Owners of Electronic Signatures
P	11.200(a3)	Electronic Signature Authorized Collaboration - Procedure
C	11.300(a)	Uniqueness of Identification Code and Password
	11.300(b)	Password Aging
	11.300(d)	Prevent and Detect Unauthorized Use of Identification Codes or Passwords

Figure 3. Electronic Records and Electronic Signature Requirements List.

And finally, the *Guidance for Industry* document does a nice job of detailing expectations for how to implement Part 11 in the areas of validation, audit trails, legacy systems, copies of records, and record retention.

The Hidden Value

As we have learned, 21 CFR Part 11 is an FDA regulation directed at companies selling bio-medical products within the United States. It is very detailed in the procedural and controls of electronic records and electronic signatures for computer software systems. The hidden value is that Part 11 is a well-written document that provides a solid foundation for any company in any industry that uses a computer software system to manage their organizations assets.

The requirements of Part 11 can be converted to a robust checklist for companies to use for determining how to select, implement, and maintain equipment asset management computerized systems in the complicated and critical areas of electronic records and electronic signatures. See Figure 3. Part 11 requirements can be used in two particular areas: (1) Selecting a Computer Software System and (2) Maintaining a Computer Software System.

Selecting Computer Software System

Part 11 can be converted to a requirement check list as in Figure 3 and then be used as part of the Technical Requirements List for software selection. One way to analyze how well Part 11 requirements are met by the evaluated software is to evaluate the check list in an attribute analysis of "Yes" or "No" to each requirement and then determine a percentage of "Yes" results for the overall checklist. Then assign a grade to the percentage, such as 90% or greater would achieve an "A" grade; 80% or greater a "B" grade and so on. Now you can compare like software systems to determine which ones are acceptable to be considered further.

Maintaining Computer Software System

Likewise, a similar process can be used to perform a gap analysis of an organization's current computer software system to meet Part 11 electronic records and electronic signature requirements. Use the checklist to compare the Part 11 requirements to the system being used and then evaluate the resulting letter grade to determine how much of a gap the system has to Part 11 electronic records and electronic signature compliance. This can also be part of a risk assessment to determine how well the computer software system is able to control electronic records.

Summary

21 CFR Part 11 is an FDA regulated document targeted at bio-medical companies selling product within the United States. It provides bio-medical companies an opportunity to gain the benefits of paperless record-keeping systems [5]. It is focused on the procedural and controls for electronic records and electronic signatures of computer software systems. Electronic records are demonstrated better than paper-based record keeping in terms of traceability, accountability, and record recovery. However, even within the bio-medical community, Part 11 is obscure and misunderstood.

Part of the misunderstanding is that the FDA has two documents related to Part 11. One is the regulatory document *21 CFR Part 11, Electronic Records; Electronic Signatures* and the other is a guidance document, *Guidance for Industry Part 11, Scope and Application* providing more details on how to implement Part 11.

We also learned that there are two misunderstandings related to Part 11 in the areas of the meaning of an electronic signature and that audit trails do not require any periodic review, just as electronic records do not require any periodic review.

And finally, we learned that even though Part 11 is directed at bio-medical companies, Part 11 has a hidden value to any organization in any industry as it contains an effective list of requirements to ensure that electronic records and electronic signatures are properly applied and controlled in computer software systems.

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Near Three Decades in the Making: The U.S. Department of Labor's Occupational Outlook Handbook Now Includes Calibration Practitioners

Christopher L. Grachanen

It is most gratifying to see a grass roots initiative spanning many years come to full fruition. Such is the case for U.S. Department of Labor's formal recognition of calibration practitioners. Some may recall this initiative and the most excellent collaboration between the National Conference of Standards Laboratories International (NCSL International), the American Society for Quality (ASQ) Measurement Science Division (MQD) and the Measurement Science Conference (MSC) to solicit inclusion of calibration practitioners to the U.S. Department of Labor's Standard Occupational Classification (SOC) system which was successfully added to the SOC system in 2018. SOC updates are typically only performed once every ten years.

> The 2018 Standard Occupational Classification (SOC) system is a federal statistical standard used by federal agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data. All workers are classified into one of 867 detailed occupations according to their occupational definition. To facilitate classification, detailed occupations are combined to form 459 broad occupations, 98 minor groups, and 23 major groups. Detailed occupations in the SOC with similar job duties, and in some cases skills, education, and / or training, are grouped together.[1]

Inclusion of calibration practitioners in the SOC is a prerequisite for calibration practitioners to be included in the U.S. Department of Labor's Occupational Outlook Handbook (OOH). The OOH is the definitive guide used by academic counselors, job placement personnel, and the general public inquiring about occupational information collected by the U.S. Department of Labor. This valuable resource provides essential information regarding occupational requirements, typical tasks performed, and future job growth projections, just to name a few. Potential candidates contemplating a technical career can be made aware of the calibration profession via the OOH helping to encourage interest in the profession and hopefully spark that interest into a career. Most calibration folks will agree that one of the most critical challenges faced by calibration employers is recruiting qualified candidates into the calibration profession, especially in regard to recent high school/trade school/college graduates.

> The Occupational Outlook Handbook from the U.S. Bureau of Labor Statistics (BLS) provides information on what workers do; the work environment; education, training, and other qualifications; pay; the job outlook; information on state and area data; similar occupations; and sources of additional information, for 324 occupational profiles, covering about 4 out of 5 jobs in the economy.[2]

Recently, I was elated to learn that on September 6, 2023 the OOH was updated with Calibration Technologists and Technicians occupations which can be found at https://www.bls.gov/ooh/installation-maintenance-and-repair/calibration-technologists-and-technicians.htm.

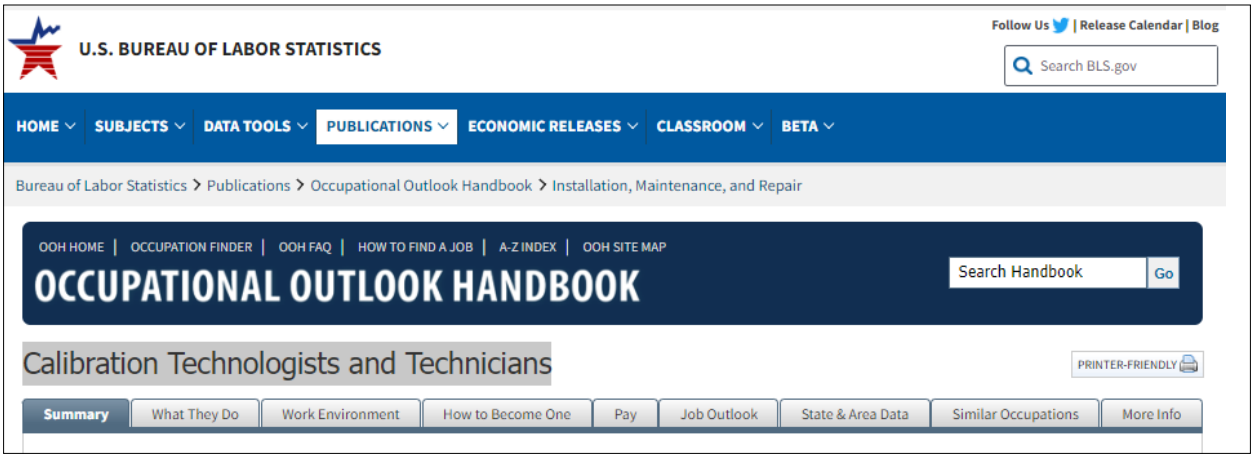


Figure. 1 OOH Website Intro

The following summary information (Figure 2) from the OOH website for Calibration Technologists and Technicians provides a cornucopia of occupational related information contained within.

Additional occupational information regarding geographic employment locations by state, as well as information about similar occupations, can be data mined from the OOH website. I thought the following OOH job outlook projection most interesting:

> Employment of calibration technologists and technicians is projected to grow 4 percent from 2022 to 2032, about as fast as the average for all occupations.
>
> About 1,100 openings for calibration technologists and technicians are projected each year, on average, over the decade. Many of those openings are expected to result from the need to replace workers who transfer to different occupations or exit the labor force, such as to retire.[2]

I encourage anybody who knows of a potential calibration practitioner candidate to have them visit the OOH Calibration Technologists and Technicians website. In closing, my work is done and with that, a big shout out to all my calibration compadres who helped make this landmark achievement possible... you know who you are ☺.

Endnotes

1 https://www.bls.gov/soc/
2 https://capd.mit.edu/resources/bureau-of-labor-statistics-bls-occupational-outlook-handbook/

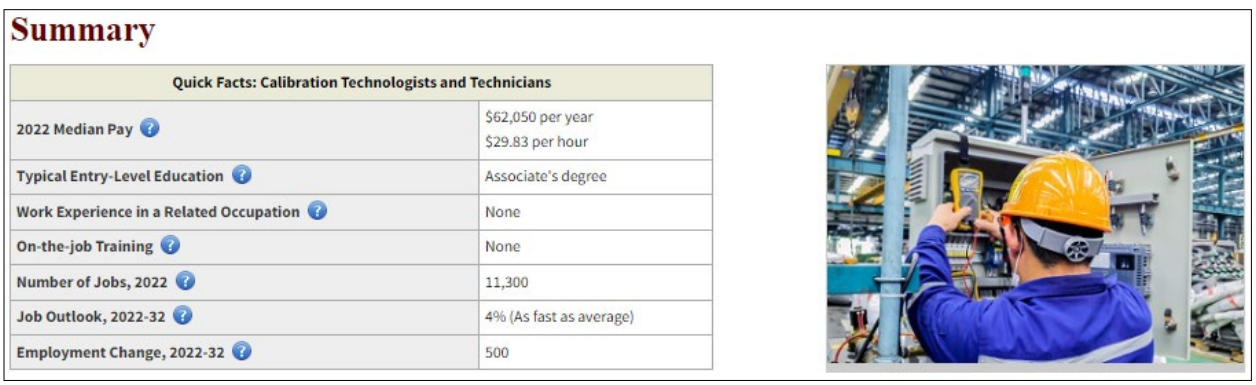
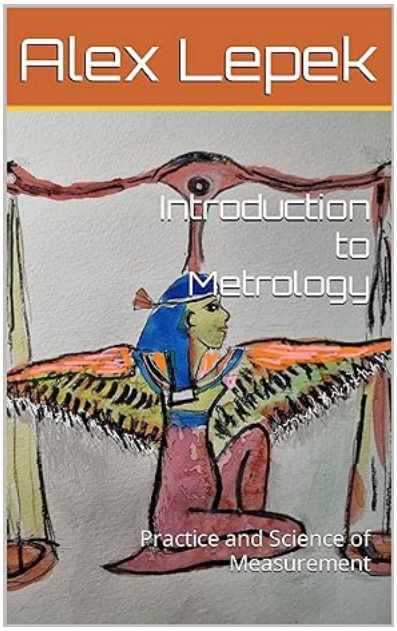


Figure. 2 OOH Website Summary

NEW PRODUCTS AND SERVICES



New Book on Metrology

Introduction to Metrology: Practice and Science of Measurement is a new book by Alex Lepek, available through Amazon (https://a.co/d/bkrJDYD) on Kindle or paperback.

Author Description: "This book is a brief introduction to metrology, which is the practice and science of measurement. The book addresses measurement, test, calibration, methods to estimate measurement uncertainties, quality assurance of these subjects and issues related to them at an introductory level.

The book was written considering readers who are new to the field and need a fast overview, but experienced practitioners can also benefit from the theoretical background. It does not focus on a specific type of measurement technology or measurement discipline but only on the general concepts and principles common to all measurements.

This book is modest. It is not intended to be a handbook and it does not have pretension to address every issue in metrology. The book shares with the reader my point of view on metrology learned during a period of over 35 years of consulting."

Keysight Next-Generation Vector Signal Generator

World's first vector signal generator with an embedded reflectometer delivers extremely accurate signals

SANTA ROSA, Calif. September 18, 2023—Keysight Technologies, Inc. (NYSE: KEYS) introduces a new compact, four-channel vector signal generator (VSG) capable of signal generation up to 8.5 GHz with 960 MHz of modulation bandwidth per channel. The N5186A MXG is the next-generation high-performance VSG in Keysight's X-Series signal generator portfolio, offering the multiple, individually complex signals needed for dense wideband multichannel applications.

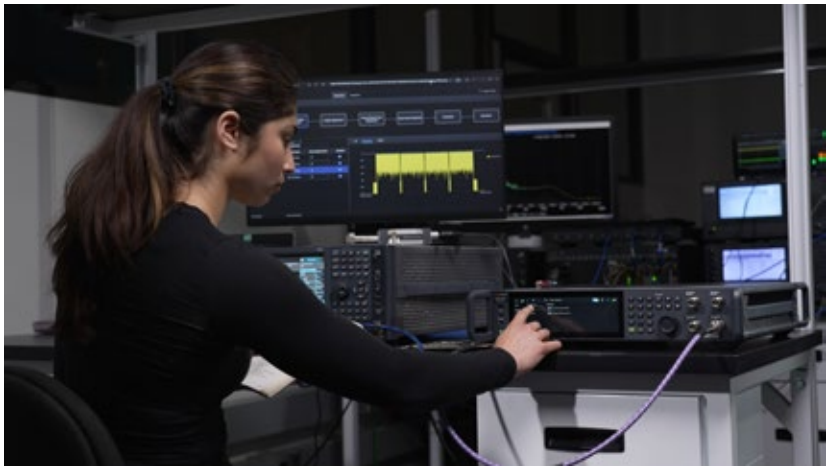
Evolving technologies in wireless communications and radar applications demand higher frequency coverage using complex modulation schemes like MIMO, beamforming, and multiplexing to maximize data throughput. Testing these applications requires signal generation instruments that maintain excellent modulation quality when working with greater bandwidths. To achieve higher frequencies, greater bandwidths, and more complex modulation schemes, network and design engineers typically need more bench space for additional test equipment and fixtures.

The Keysight N5186A MXG addresses this challenge by simplifying complex setups with reduced external connections and up to four channels in a compact 2U form factor. As the world's first signal generator to feature an embedded reflectometer, the N5186A MXG delivers extremely accurate signals to the device under test (DUT).

The N5186A MXG offers the following benefits:

- Compact design – Delivers multichannel capabilities in a 2U size that saves up to 75% of rack height.
- High-performance capabilities – Employs direct digital synthesis (DDS) digital-to-analog converter (DAC) proprietary technology for bandwidth coverage up to 960 MHz with best-in-class error vector magnitude (EVM) and adjacent channel power ratio (ACPR) performance for lower signal distortion.
- Testing convenience – Features an embedded reflectometer delivering accurate signals while enabling faster time-to-test and simplifying test setups.
- Exceptionally low phase noise – Produces pure signals enabling high resolution radar system designs and high-throughput, next-generation communications systems.

By providing consistent and repeatable results, the N5186A MXG vector signal generator is an ideal solution for a broad range of commercial and aerospace defense applications. The MXG's custom DAC



application-specific integrated circuits (ASICs) use DDS to deliver precise signals to minimize distortion and meet the evolving standards for component and module design. In addition, the embedded reflectometer expedites the setup process to correct for the match of the DUT, enabling a faster time-to-test.

Learn more at Keysight Newsroom and www.keysight.com.

Fairview Microwave Launches New Electromechanical Relay Switches

Ruggedized Electromechanical Switches Offer Robust, Reliable RF Signal Routing

IRVINE, Calif. – Fairview Microwave, an Infinite Electronics brand and a leading provider of on-demand RF, microwave and millimeter-wave components, has launched a new series of ruggedized electromechanical relay switches for reliable RF signal routing in critical applications across various market bands, from DC up to 40 GHz.

The newly launched series includes 40 different switch models and configurations, all in stock and ready to ship with no minimum order quantities. They are suitable for multiple market bands, including L, S, C, X, Ku and K, enabling versatile application possibilities and broad frequency coverage.

Notably, the switches are IP64 compliant with a Level 1 moisture seal, making them ideal for customers who face outdoor environments or moisture exposure in testing. This rugged design ensures durability and reliability in various environments.

The series also boasts exceptional performance with insertion loss as low as 0.15 dB (typical) and isolation levels as high as 90 dB, providing outstanding signal integrity and minimizing signal degradation. They are also equipped with versatile actuator options, including latching, failsafe or normally open actuators, and are compatible with TTL logic.

The high-power capability of these switches is another standout feature. They can handle power up to 160 watts continuous wave (CW) at 1 MHz, delivering reliable performance even under demanding conditions.

The ruggedized electromechanical relay switches come in compact, military-grade, coaxial package designs with SMA, 2.92 mm, TNC or N-Type connectors, depending on the frequency band.

Fairview's new ruggedized electromechanical relay switches are in stock and available for same-day shipping. For inquiries, contact Fairview Microwave at +1-949-261-1920.

Additel's new Modular Pressure Controller Line

Automatically Controls Pressure from low inH20 (mbar) to 15,000 psi (1000 bar) in a Sleek Rack Mountable package

Brea, Calif., July 12, 2023 – Additel Corporation introduces a new line of pressure controllers. As Additel continues to strive to meet the needs of their customers through innovation and automation, these new controllers expand Additel's automatic pressure controller offering with high-speed and performance in a modular configuration. Customers can choose between various accuracies and pressure ranges at the time of ordering, but as needs change, the modular design provides customers with options through the easy to swap pressure models. The all-new controllers can be fitted with an optional contamination prevention system (CPS) and barometric pressure module. The large 7" touchscreen makes the icon driven interface easy to use and communication is supported by Wi-Fi, USB & Ethernet.

These modular pressure controllers combine cutting-edge control/measurement technology, modular design, user-friendly features into a high-speed calibration solution. The controllers achieve a high control stability and high-speed control rate at a wide range of pressures. With multiple base models, ADT773 (LLP model, -0.95 bar1 bar with built-in pump), ADT783 (pneumatic model, -0.99bar250bar), and ADT793 (hydraulic model, 0-1000 bar with built-in pump), sensor manufacturers, calibration managers and technicians will find the perfect controller for their needs. For users who require automated production, test, and calibration, these new pressure controllers get the job done.

This new line of Additel Pressure Controller available now. For more information visit: https://additel.com/products/Pressure-Calibrators-and-Controllers/.

For information on Additel products and applications, or to find the location of your nearest distributor, contact Additel corporation, 2900 Saturn Street, #B, Brea, CA 92821, call 1-714-998-6899, Fax 714-998-6999, email sales@additel.com or visit the Additel website at www.additel.com.

Thinking Outside the Box with Modular Design

Michael L. Schwartz
Cal Lab Solutions, Inc.

We have all heard this before: Think outside the box! But this is easier said than done. It is especially difficult to notice your own blinders because we all see things from our point of view.

For example, I was in a meeting last week when the subject of standardizing measurement uncertainty equations came up, and I found myself arguing the difference between interface and implementation. It was then that I discovered many people don't see things out of their box.

In-the-Box Thinking: As it applies to measurement uncertainty calculations, they are thinking about the specifics of how their software currently implements uncertainty calculations. There is a single point of view on how their software calculates uncertainties, how their business does business, and what their auditors want to see in their calculations.

Problem: The problem with In-the-Box thinking is the assumption the box will always stay the same, that the software will always stay the same, the auditors will always look for the same thing, or uncertainty calculation models will always remain the same.

But this is not true... change is inevitable! Requirements will change, standards will change, models will change, and the software will change.

Outside-the-Box Thinking: Calibration labs don't all use the same software. Requirements change from lab to lab, country to country, and from one auditing body to the other; they are all different. It's hard to standardize everything by putting it in a single box, so let's accept and manage variation with Outside-the-Box thinking.

If we change the paradigm from a "How can my software do something?" to "How can my software interface with other software using an industry-standard model?" we are thinking outside of the "Our Software Box" and looking at the problem from a more extensive scope. This changes the focus from the specific implementation to the interface.

Modular Design: Modular software systems focus more on the interface used between different systems. It allows for different systems to employ vastly different implementations, as long as they adhere to the specified interface.

This changes the singular focus of "my software" into two parts: One, how can my software implement the interface? And, how can my software interface with different software solutions?

At first, it feels like double the work. But it's not! These changes will make your software more flexible and potentially even future-proof.

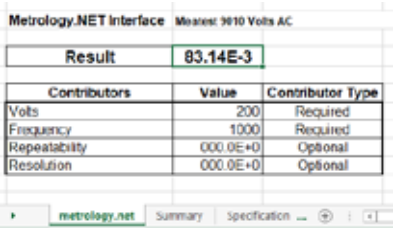
Interface: Next, we need an interface that works for ALL uncertainty calculations. Working with the NCSLI 141-MII Committee, I think we have created the perfect abstract interface. It is simple, intuitive, and easily implemented.

It starts with a Metrology Taxon definition where the required parameters are defined. The taxon will list a set of required values, but the interface allows for an unlimited list of additional values, all passed in a name-value format.

Implementation: This example is just one implementation, and it is easy to follow. When we look up Source.Voltage.AC.Sinewave (https://www.metrology.net/wiki/source-voltage-ac-sinewave/) it shows there are two required parameters: Volts and frequency with other optional parameters.

We can send the implementation "Volts= 200, Frequency= 1E3" and the implementation either returns an uncertainty based on the inputs or returns "39E39," indicating the calculation failed.

An Excel implementation can be downloaded here: https://wp.me/a6oqHz-3sW. A Metrology.NET tab can be added to an existing uncertainty budget where the input values are set by name, and the Excel sheet calculates the uncertainty.[1]



In the spreadsheet, there is a bit of Excel-ology, but most metrologist can create any uncertainty calculation in Excel. The difference with this model-driven approach is the interface is simple; all we need to do is match the name-value pairs and read the result.

In conclusion, by thinking outside the current software box and how the software specifically implements measurement uncertainties, we can see there is a simpler model that works for all uncertainties by allowing modular implementation of the uncertainty calculation. We are not just limited to Excel files; we can interface with other systems using Taxon and name-value pairs.

1 For further explanation of this example, look up "Verifying Measurement Uncertainties for Every Test Point Against Your Lab's ISO/IEC 17025 Scope of Accreditation" at https://www.metrology.net/papers/.

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