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2024 JULY AUGUST SEPTEMBER **Optical Radiation Calibration**

What a Long-Term Instrument Warranty Can Mean to a Calibration Operation

The Top 10 Best Papers for Life Science Calibration and Testing Laboratories

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Volume 31, Number 3



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ON THE COVER: Technician Chancy Balk of Rothe Enterprises Inc. (a NASA Calibration Lab) uses the vernier adjustment while calibrating a high accuracy pressure gauge utilizing a Ruska 2475-610 Deadweight Pressure System.

UPCOMING CONFERENCES & MEETINGS

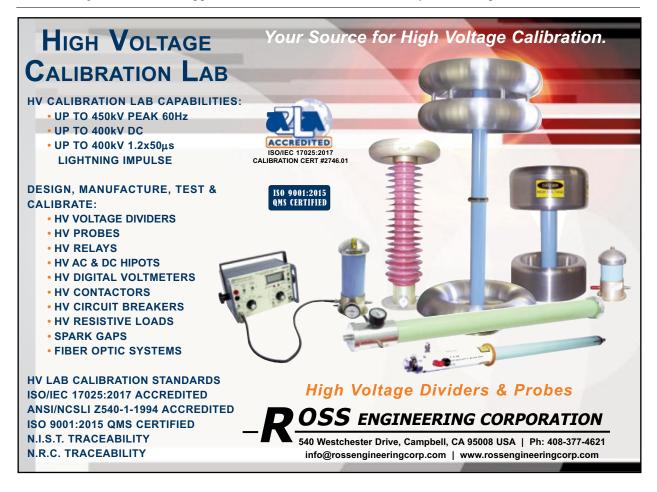
The following event dates are subject to change. Visit the event URL provided for the latest information.

Oct 9-11, 2024 IEEE Conference on Antenna Measurements and Applications. Da Nang, Vietnam. IEEE CAMA is an international conference sponsored by IEEE AP-S to provide an international and interdisciplinary forum for sharing state-of-the-art of topics covering all areas related to antenna measurements in controlled and non-controlled (in-situ) environments, Antenna testing, electromagnetic measurement techniques including systems considerations. https://2024ieeecama.org/

Oct 14-16, 2024 IEEE International Workshop on Metrology for the Sea; Learning to Measure Sea Health Parameters. Portorose, Slovenia. MetroSea conference will be broad in scope covering all areas concerning research in measurements and instrumentation field. With the breadth of topics covered, this conference seeks to attract diverse participation and collaboration from academia, industry, and government agencies that will promote marine science and technologies interests with opportunities to increase technical depth and breadth as well as networking with peers. https://www.metrosea.org/

Oct 16-17, 2024 Les Journees de la Mesure. Lyon, France. Les Journées de la Mesure 2024 auront lieu les 16 et 17 octobre au Centre de Congrès de la Cité Internationale de Lyon en partenariat avec le salon Mesures Solutions Expo (même lieu et même date). L'inscription aux JM permet de suivre les tutoriels et ateliers, d'accéder aux pauses café et buffets de midi, de découvrir les exposants du salon. https://www.cfmetrologie.com/fr/evenements/ journees-de-la-mesure-2024-lyon

Oct 21-23, 2024 IEEE International Conference on Metrology for eXtended Reality, Artificial Intelligence and Neural Engineering. St. Albans, London, United Kingdom. IEEE MetroXRAINE 2023 - will be an international event mainly aimed at creating a synergy between experts in eXtended Reality, Brain-Computer Interface, and Artificial



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^{*p*}: Lumos

I try to source material from a variety of industries. You never know when a specific article or cover photo can spark an idea or illuminate something familiar. Besides calibration, we've heard a couple times how we should reach the testing community as well. I think this might be casting the net too wide for one editor to handle, but sometimes the lines blur a little. As long as it continues to spark that need to know what we don't know when it comes to measurements.

One area of measurement I've been unable to source material about is optical. I reached out to six organizations this past year before Gigahertz-Optik pulled through with a Metrology 101 on "Optical Radiation Calibration." After a trip to NIST in Boulder, Colorado, where I got to see how lasers turn corners, and reading an article about NREL's Solar Radiation Research Laboratory, I became aware of the scope of optical radiation. Even today, I learned from a news story about ancient cheese that mass spectrometry was used to analyze DNA information. For something used to measure the scope of galaxies to the makeup of our molecules, I hope we can get more organizations to shed some "light" on such instrumentation testing and measuring in the calibration lab.

For our Features this issue, we have a gem of a reference article titled, "A Quality Review: The Top 10 Best Papers for Life Science Calibration and Testing Laboratories," by Walter Nowocin, Life Sciences Product Manager for Indysoft. But before that, we have Jesse Morse's article, "What a Long-Term Instrument Warranty Can Mean to a Calibration Operation," to help labs weigh the pros and cons when acquiring new standards.

Finally, Dan Wiswell continues "In Days of Old" with some serendipitous moments of discovery, where each vintage instrument has a story to tell, including a "Visibility Meter" and a light meter with original green photocells.

Happy Measuring,

Sita Schwartz

(\$) SI

Intelligence, with special attention to the Measurement. The conference will be a unique opportunity for discussion among scientists, technologists, and companies on very specific sectors in order to increase the visibility and the scientific impact for the participants. https://www. metroxraine.org/

Oct 29-31, 2024 IEEE International Workshop on Metrology for Agriculture and Forestry. Padova, Italy. 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 5-6, 2024 Metrologietagen. Munich, Germany. For the fifth time, the metrology network comes together for knowledge exchange and special insights into the practice of calibration. https://www.metrologietage.de/

SEMINARS & WEBINARS: Dimensional

Oct 21-25, 2024 Advanced Dimensional Metrology. Pretoria, South Africa. NMISA. The course objective is to obtain an in-depth understanding of Dimensional Metrology. The course built on the Basic dimensional metrology course explaining the key principles and techniques used in dimensional metrology. https://store. nmisa.org/collections/face-to-face-courses

Oct 22-24, 2024 Gage Calibration Methods Class. Cincinnati, OH. QC Training. This 3-day hands-on workshop offers specialized training in gage 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/course/ gage-calibration-methods/

Nov 12-14, 2024 EDU-114: Dimensional Gage Calibration and Repair (In-person). Aurora, IL. Mitutoyo America's

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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/classroom/

Dec 5-6, 2024 Fundamentals of Geometrical Dimensioning and Tolerancing (ASME) – ONLINE. Australian NMI. This course is based on ASME Y14.5-2009 standard. You will learn about the symbols, modifiers, rules and concepts of geometric dimensioning and tolerancing (GD&T). https:// shop.measurement.gov.au/

Dec 10-13, 2024 EDUB-110: Small Tool, Introduction, Calibration and Repair BUNDLE (In-person). Aurora, IL. EDUB-110 pairs together EDU-101, EDU-113, and EDU-301. Customize your training by choosing to attend a training session independently, or group together multiple training sessions for the discounted BUNDLE pricing! https://www.mitutoyo.com/training-education/classroom/

Dec 11-12, 2024 EDU-113: Dimensional Gage Calibration (In-person). 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/classroom/

Dec 18-20, 2024 Gage Calibration Methods Class. Lisle, IL. QC Training. This 3-day hands-on workshop offers specialized training in gage 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/course/gagecalibration-methods/

SEMINARS & WEBINARS: Education

Feb 13, 2025 Metric System Education Resources. Online. NIST. This 1.5-hour session will explore NIST Metric Program education publications and other resources teachers, parents, and students can download and freely reproduce. 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/owm-training-andevents

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SEMINARS & WEBINARS: Electrical

Nov 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

SEMINARS & WEBINARS: Flow

Feb 5-6, 2025 Calibration of Liquid Hydrocarbon Flow Meters. Londonderry, NSW. Australian NMI. This twoday course provides training on the calibration of liquidhydrocarbon LPG and petroleum flow meters. It is aimed at manufacturers, technicians and laboratory managers involved in the calibration and use of flowmeters. https:// shop.measurement.gov.au/

SEMINARS & WEBINARS: General

Dec 11, 2024 Calibration and Measurement Fundamentals.

Online Trainer-Delivered. Australian NMI. This course covers general metrological terms, definitions and explains practical concept applications involved in calibration and measurements. https://shop.measurement. gov.au/

Jan 27-31, 2025 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

SEMINARS & WEBINARS: Industry Standards

Oct 15-16, 2024 Understanding ISO/IEC 17025:2017 for Testing & Calibration Labs. Cinnaminson, NJ. A2LA WorkPlace Training. This course is a comprehensive review of the philosophies and requirements of ISO/IEC 17025:2017. https://a2lawpt.org/



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Oct 16-17, 2024 Understanding the Requirements and Concepts of ISO/IEC17024:2012. Live Online Event. This course is designed to introduce organizations considering accreditation by ANAB to the international standard ISO/ IEC 17024, General requirements for bodies operating certification schemes for persons. The standard is a globally accepted benchmark for bodies managing the certification of persons and is being increasingly recognized by the U.S. federal government, the certification industry, and organized labor. https://anab.ansi.org/

Nov 5-6, 2024 Laboratories: Understanding the Requirements and Concepts of ISO/IEC 17025:2017. Live Online. ANAB. Understand requirements of ISO/ IEC 17025:2017, including general, structural, resource, process, and management system requirements. Learn practical concepts, such as impartiality, documents control, ensuring validity of results and risk management. Gain an understanding of an ISO/IEC 17025:2017 laboratory management system. https://anab.ansi.org/

Nov 12-13, 2024 3004 Understanding ISO/IEC 17025 for

Testing and Calibration Labs. Online for the Middle-East & South Asia time zone. IAS. This Training Course applies to testing and calibration laboratories and regulatory agencies seeking to specify 17025 within their policies and regulations. https://www.iasonline.org/training/

Nov 13-14, 2024 Auditing Your Laboratory to ISO/IEC 17025:2017. Virtual. 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. https://a2lawpt.org/

Nov 18-19, 2024 Understanding ISO/IEC 17025:2017 for Testing & Calibration Labs. Livonia, MI. A2LA WorkPlace Training. This course is a comprehensive review of the philosophies and requirements of ISO/IEC 17025:2017. https://a2lawpt.org/

Nov 20-21, 2024 Auditing Your Laboratory to ISO/IEC 17025:2017. Livonia, MI. A2LA WorkPlace Training. This ISO/IEC 17025 auditor training course will introduce



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participants to ISO/IEC 19011, the guideline for auditing management systems as applied to ISO/IEC 17025:2017. https://a2lawpt.org/

Dec 3-4, 2024 ISO/IEC 17043:2023 and Statistical Analysis for Proficiency Testing. Frederick, MD. A2LA WorkPlace Training. This course provides the participant with a comprehensive look at Proficiency Testing (PT), including the design and operation of PT schemes, statistical methods, reporting, and interpretation. https://a2lawpt.org/

Dec 9-12, 2024 Auditing Your Laboratory to ISO/IEC 17025:2017. Virtual. 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. https://a2lawpt.org/

Dec 10-11, 2024 Laboratories: Understanding the Requirements and Concepts of ISO/IEC 17025:2017. Live Online. ANAB. Understand requirements of ISO/ IEC 17025:2017, including general, structural, resource, process, and management system requirements. Learn practical concepts, such as impartiality, documents control, ensuring validity of results and risk management. Gain an understanding of an ISO/IEC 17025:2017 laboratory management system. https://anab.ansi.org/training

Dec 10-12, 2024 Internal Training to ISO/IEC 17025:2017 (**Non-Forensic**). Live Online. ANAB. This training is designed for laboratory managers, technical staff, and others who want or need to learn better audit practices. https://anab.ansi.org/training

Dec 18-19, 2024 Understanding the Requirements and Concepts of ISO/IEC17024:2012. Live Online. This course is designed to introduce organizations considering accreditation by ANAB to the international standard ISO/ IEC 17024, General requirements for bodies operating certification schemes for persons. The standard is a globally accepted benchmark for bodies managing the certification of persons and is being increasingly recognized by the U.S. federal government, the certification industry, and organized labor. https://anab.ansi.org/

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Jan 13-16, 2025 Understanding ISO/IEC 17025:2017 for Testing & Calibration Labs. Virtual. A2LA WorkPlace Training. This course is a comprehensive review of the philosophies and requirements of ISO/IEC 17025:2017. https://a2lawpt.org/

Jan 13-16, 2025 Auditing Your Laboratory to ISO/IEC 17025:2017. Virtual. 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. https://a2lawpt.org/

Feb 11-12, 2025 Understanding the Requirements and Concepts of ISO/IEC17024:2012. Live Online Event. This course is designed to introduce organizations considering accreditation by ANAB to the international standard ISO/ IEC 17024, General requirements for bodies operating certification schemes for persons. The standard is a globally accepted benchmark for bodies managing the certification of persons and is being increasingly recognized by the U.S. federal government, the certification industry, and organized labor. https://anab.ansi.org/

Feb 18-19, 2025 Understanding ISO/IEC 17025:2017 for Testing & Calibration Labs. Virtual. A2LA WorkPlace Training. This course is a comprehensive review of the philosophies and requirements of ISO/IEC 17025:2017. https://a2lawpt.org/

Feb 25-26, 2025 Understanding the Requirements and Concepts of ISO/IEC 17025:2017. Live Online. Understand requirements of ISO/IEC 17025:2017, including general, structural, resource, process, and management system requirements. Learn practical concepts, such as impartiality, documents control, ensuring validity of results and risk management. Gain an understanding of an ISO/ IEC 17025:2017 laboratory management system. https:// anab.ansi.org/find-training/

Mar 10-13, 2025 Understanding ISO/IEC 17025:2017 for Testing & Calibration Labs. Virtual. A2LA WorkPlace Training. This course is a comprehensive review of the philosophies and requirements of ISO/IEC 17025:2017. https://a2lawpt.org/

Mar 11-12, 2025 ISO/IEC 17043:2023 and Statistical Analysis for Proficiency Testing. Virtual. A2LA WorkPlace Training. This course provides the participant with a comprehensive look at Proficiency Testing (PT), including the design and operation of PT schemes, statistical methods, reporting, and interpretation. https://a2lawpt.org/

Mar 11-12, 2025 Auditing Your Laboratory to ISO/IEC 17025:2017. Virtual. 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. https://a2lawpt.org/

SEMINARS & WEBINARS: Mass

Oct 21-Nov 1, 2024 Mass Metrology Seminar. Gaithersburg, MD. NIST. 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/owm-training-and-events

Mar 3-14, 2025 Mass Metrology Seminar. Gaithersburg, MD. NIST. 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/owm-training-and-events

SEMINARS & WEBINARS: Measurement Uncertainty

Oct 23 & 25, 2024 Introduction to Estimating Measurement Uncertainty (Online Trainer Delivery). Australian NMI. This course will give you a clear step-by-step approach to uncertainty estimation with practical examples; you will learn techniques covering the whole process from identifying the sources of uncertainty in your measurements right through to completing the uncertainty budget. https://shop.measurement.gov.au/

Oct 28-30, 2024 Uncertainty of Measurement for Testing Laboratories. Pretoria, South Africa. NMISA. The objective of this course is to introduce analysts to the basic concepts of the estimation of uncertainty of measurement. During the evaluation of the measurement uncertainty, the focus will be on the identification and quantification of individual uncertainty sources according to the principles of the Guide to the Expression of Uncertainty of Measurement (GUM) (Type A and B evaluations). To combine these uncertainties into the final expanded measurement uncertainty, participants will be taught simplified approaches such as the use of relative uncertainties and method validation data. https://store.nmisa.org/collections/face-to-face-courses

Oct 29-31, 2024 Measurement Uncertainty – Fundamentals and Application. Aurora, IL. Mitutoyo. EDU-210 is firmly rooted in national and international standards in terminology and uncertainty. The course

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follows the concepts from ISO/IEC Guide 98-3 (GUM), which is the required standard for almost all uncertainty evaluations, including labs accredited to ISO/IEC 17025. This course also introduces the powerful concepts of test uncertainty (ISO 14253-5) for the evaluation of measurement uncertainty in the calibration of measuring instruments. https://www.mitutoyo.com/training-education/classroom/

Nov 18, 2024 Introduction to Measurement Uncertainty. Livonia, MI. A2LA WorkPlace Training. 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. https://a2lawpt.org/

Nov 19-20, 2024 Applied Measurement Uncertainty for Testing Laboratories. Livonia, MI. A2LA WorkPlace Training. During this course, students will be introduced to several tools and techniques to develop accurate measurement uncertainty budgets that comply with ISO 17025 requirements and increase confidence in your measurement results. Hands-on exercises provide a practical approach so you can apply these methods in a variety of testing laboratories. https://a2lawpt.org/courses/training/

Nov 27 & 29, 2024 Introduction to Estimating Measurement Uncertainty (Online Trainer Delivery). Australian NMI. This course will give you a clear step-by-step approach to uncertainty estimation with practical examples; you will learn techniques covering the whole process from identifying the sources of uncertainty in your measurements right through to completing the uncertainty budget. https://shop. measurement.gov.au/

Dec 3-4, 2024 Introduction to Measurement Uncertainty. Virtual. A2LA WorkPlace Training. 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. https:// a2lawpt.org/

Dec 9-10, 2024 Measurement Confidence: Fundamentals. Live Online. ANAB. This Measurement Confidence course introduces the foundational concepts of measurement



traceability, measurement assurance, and measurement uncertainty and details ISO/IEC 17025 and ISO/IEC 17020 requirements. https://anab.ansi.org/

Dec 11-12, 2024 Measurement Uncertainty: Practical Applications. Live Online. ANAB. This class covers concepts and accreditation requirements associated with measurement traceability, measurement assurance, and measurement uncertainty. https://anab.ansi.org/

Jan 7-8, 2025 Uncertainty, Sampling and Data Analysis: Understanding Statistical Calculations. Live Online. ANAB. This course provides an introduction to statistical concepts and techniques used for the collection, organization, analysis, and presentation of various types of data. The course touches on both descriptive statistics and inferential statistics, including how to compute measures of central tendency and dispersion, and how to assess the relationship between two variables. https://anab.ansi.org/

Jan 22-23, 2025 Introduction to Measurement Uncertainty. Virtual. A2LA WorkPlace Training. 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. https:// a2lawpt.org/

Feb 20-21, 2025 Measurement Uncertainty: Practical Applications. Live Online. ANAB. This class covers concepts and accreditation requirements associated with measurement traceability, measurement assurance, and measurement uncertainty. https://anab.ansi.org/

Mar 4-5, 2025 Introduction to Measurement Uncertainty. Virtual. A2LA WorkPlace Training. 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. https:// a2lawpt.org/

Apr 15, 2025 Introduction to Estimating Measurement Uncertainty. Lindfield, NSW. Australian NMI. This course will give you a clear step-by-step approach to uncertainty estimation with practical examples; you will learn



techniques covering the whole process from identifying the sources of uncertainty in your measurements right through to completing the uncertainty budget. https://shop. measurement.gov.au/

SEMINARS & WEBINARS: Photometry & Radiometry

Feb 26-27, 2025 Photometry and Radiometry. Lindfield, NSW. NMI of Australia. This two-day course (9 am to 5 pm) 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/

SEMINARS & WEBINARS: Software

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

Oct 29-31, 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

Nov 18-22, 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

SEMINARS & WEBINARS: Temperature & Humidity

Apr 3, 2025 Humidity Measurement. Lindfield NSW. National Measurement Institute, Australia. This one-day course provides information about the main concepts and practical techniques involved in measuring humidity in air and explains how to make such measurements accurately and consistently. https://shop.measurement.gov.au/

SEMINARS & WEBINARS: Time & Frequency

Mar 5-6, 2025 Time and Frequency Measurement. Lindfield, NSW. NMI of 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/

SEMINARS & WEBINARS: Validation & Verification

Oct 14-16, 2024 Method Validation. Pretoria, South Africa. NMISA. The objective of this course is to introduce analysts to the basic concepts of method validation and quality control. https://store.nmisa.org/collections/face-to-face-courses

Nov 19, 2024 Validation and Verification of Analytical Methods. Live Online. ANAB. This course provides an introduction to validation and verification of analytical methods and ISO/IEC 17025 & ISO/IEC 17020 requirements. https://anab.ansi.org/

Feb 6, 2025 Validation and Verification of Analytical Methods. Live Online. ANAB. This course provides an introduction to validation and verification of analytical methods and ISO/IEC 17025 & ISO/IEC 17020 requirements. https://anab.ansi.org/

SEMINARS & WEBINARS: Volume

Feb 3-7, 2025 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/owm/owm-training-and-events

SEMINARS & WEBINARS: Weight

Nov 4-7, 2024 5853 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/pml/owm/ training



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- Intrinsic DC Voltage traceability via an inhouse Josephson
- Voltage Standard (JVS), one of the few independently operated labs in Europe with that capability
- Competitive, aggressive CMCs, exceeding those of many manufacturers. See our full Scope and Quality Documents at https://1acal.de/#/nachweise
- For US customers, a domestic shipping address is available so there's no worry about import/export licensing, making shipping simple and easy
- Upon receipt, our US based Service Partner places all instruments from US customers in special, worry-free transit cases that we provide for safe, secure shipment to the lab
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1A CAL is an independent metrology company where high quality calibration and service is our only business. Give us a try today and discover real service and support at an affordable cost!

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INDUSTRY AND RESEARCH NEWS

NIST Rebuilds World-Class UV Calibration System

July 22, 2024, NIST News – Ultraviolet (UV) light may seem like an invisible hero, quietly disinfecting our hospitals, curing our nail polish, and killing pathogens in our water. But how can we be sure it's being used in ways that are safe and effective? To help ensure that every UV beam serves its purpose with accuracy and precision, the National Institute of Standards and Technology (NIST) has rebuilt its specialized calibration laboratory, called the Ultraviolet Spectral Comparator Facility (UVSCF), where industry customers send their UV detection equipment to be precisely measured and calibrated.

UV light serves a wide variety of applications. The germicidal properties of UV light make it a valuable tool for sanitization and disinfection, especially in health-care settings. It also is an effective way to combat microbial contamination in water and is used for drinking water, wastewater and surface water disinfection. Homeowners use UV-cured epoxy to put new kitchen countertops in place. In the nail salon industry, UV light boxes cure gel nail products. And, in recent years, a proliferation of new consumer products, such as UV-protective clothing, prevent unwanted exposure to UV light. Carefully calibrated UV light sources are needed to ensure that these products work as intended.

Understanding the UV Spectrum

Ultraviolet light is invisible, having shorter wavelengths than the light we can see with our eyes. There are three different categories of UV light based on the wavelength: UVA, UVB and UVC. Wavelength refers to the distance between the peaks of a light wave and, when visible, different colors of light. While NIST's new calibration system caters to all three, its unique forte lies in accurately measuring UVC light, which falls into the 200-300 nanometer range.

UVC light has shorter, higher-energy wavelengths compared with UVA and UVB. This makes UVC very effective at killing germs and viruses.

"Approximately 100,000 people a year die from health care-associated infections in the U.S. They go into a hospital to be treated for one thing, but then end up with an infection from inadequate sanitization," said NIST research chemist Cameron Miller. "Using UV light to disinfect rooms and



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equipment offers a potential solution."

However, UVC light can also harm human skin and eyes, so it needs to be used carefully.

Organizations that use UV light, from the military and research institutions to universities and industrial manufacturers, can check that UV light sources are emitting the right amount and intensity of light with a compact, hand-held device called a UV detector. Like any other measurement instrument, these detectors need to be calibrated, so users periodically pack them up and send them to NIST's Ultraviolet Spectral Comparator Facility.

Just as one might calibrate a scale by putting an object of known weight on it, NIST experts calibrate the detectors by exposing them to specific UV wavelengths and comparing their readings to a precisely calibrated standard detector. They then assign the calibration values for each detector.

"We are able to measure UV light at very short wavelengths with extremely high accuracy and precision," said NIST physicist Jeanne Houston. "The UVC range of the UV spectrum is the most challenging part to measure, so achieving this level of precision is something we don't typically see in this field." NIST then returns the detector to the customer, who can have confidence in using it to ensure the safety and effectiveness of their UV systems and products.

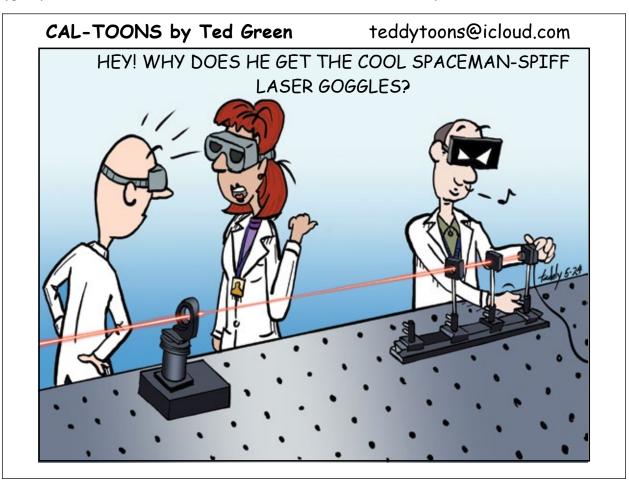
Serving the Needs of Emerging Technologies

NIST has maintained a UV calibration facility since the late 1980s. However, by the mid-2010s, the facility could no longer meet the needs of emerging technologies such as UV disinfection because it was not optimized for the critical wavelength range needed for disinfection. The COVID-19 pandemic brought a new interest in improving and rebuilding the system.

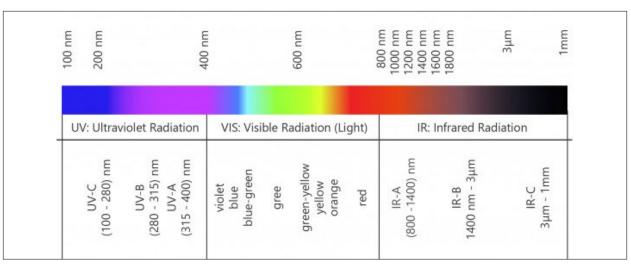
"Once COVID struck, UV disinfection was hitting the big time and we were able to totally rebuild the system," said Houston. "We have implemented massive improvements, and it is my opinion that our new facility is the best in the world."

For more information, visit the NIST website: https:// www.nist.gov/programs-projects/spectral-responsivitymeasurement

Source: https://www.nist.gov/news-events/ news/2024/07/pandemics-pedicures-nist-rebuilds-worldclass-uv-calibration-system



Optical Radiation Calibration



Bob Angelo Gigahertz-Optik Inc.

Figure 1. Electromagnetic Spectra

Introduction

As this readership is well aware, calibration is a prerequisite for maintaining accuracy in any type of measurement instrument. It is the foundation upon which subsequent measurements are based upon. This is especially true for radiometric and photometric devices, where in some applications, they are exposed to intense ultraviolet radiation and hot or dirty environments. Short wave UV is highly energetic and will degrade components in its path over time. Heat, moisture or contamination can cause changes in sensitivity that need to be corrected.

As a quick review, optical radiation is that part of the electromagnetic spectrum which spans from 100 nm to 1 mm in wavelength (Figure 1). Within this total radiometric range, optical radiation visible to the human eye (light), spans from 360 nm to 830 nm per CIE International Standard S 026/E:2018 [1], the photometric range. There are many radiometric SI units derived from the watt (W) and many photometric SI units derived from the basic lumen (lm) (refer to Table 1).

Measurement of optical radiation is challenging with uncertainties much higher than found in

electrical or mechanical fields. This is because optical radiation follows the laws of geometrical optics –distributed over wavelength, position, direction, time and polarization. So, optical calibration and measurement uncertainties are much higher than the readout part of the system that can measure currents within <0.2% over most ranges, since there is no distribution of signal, except for time.

Rather than a step by step how to guide, the goal of this article is to provide a broad overview of the terms, instrumentation, applicable SI units, methods and just a few pitfalls to be aware of in the science of light measurement and calibration.

Radiometric & Photometric SI Units			
Radiometric Quantity	Radiometric Unit	Photometric Quantity	Photometric Unit
Irradiance	W/m²	Illuminance	lm/m² (lux)
Radiance	W/(sr⋅m²)	Luminance	cd/m²
Radiant Intensity	W/sr	Luminance Intensity	candela (cd)
Radiance Flux	Watts (W)	Luminous Flux	lumens (lm)

Table 1.

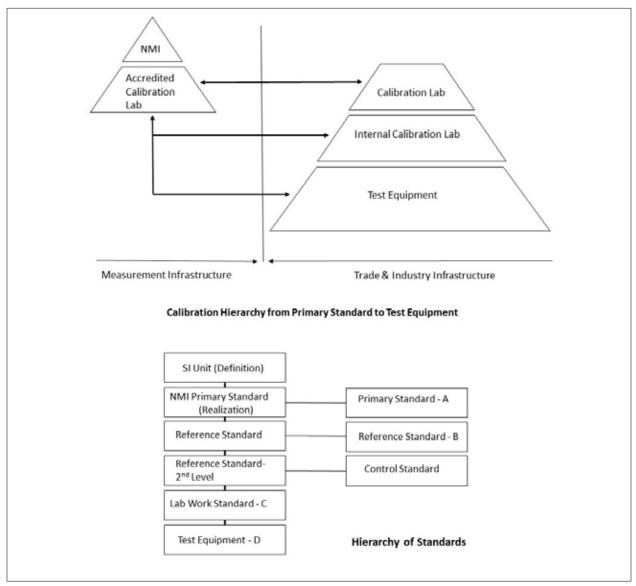


Figure 2. Calibration Hierarchy

Calibration Traceability – An Unbroken Chain of Transfer Comparisons

Calibration is typically done using the transfer method where the relationship between the reading of a device under test and that of a calibration standard is compared under defined environmental conditions. The test device reading is then adjusted to that of the standard as needed, recorded and certified.

Following accredited level calibration procedures, the deviation of the measured variable of a test

device is determined. The result and associated measurement uncertainty are recorded on a calibration certificate.

Since this is a direct comparison, qualification of this transfer standard is of the highest importance. A qualified standard should display an unbroken chain of transfer comparisons originating at a national metrology institute. The US National Institute of Standards and Technology (NIST) and the German Physikalisch-Technische Bundesanstalt (PTB) are NMIs.



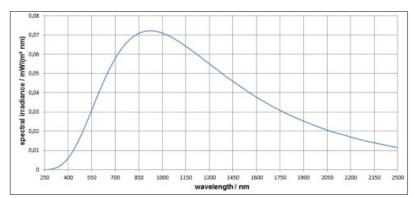


Figure 3. FEL Lamp with Spectra

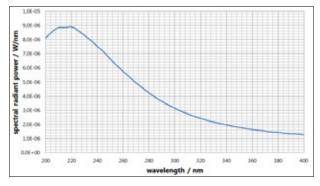


Figure 4. Deuterium Lamp Spectra

A primary standard transfer standard obtained from a national metrological laboratory (A) is used to calibrate a reference standard (B) at a qualified calibration laboratory. This reference standard is used to calibrate the laboratory work standard (C) to be used daily by the calibration laboratory. More than one transfer standard is recommended. This working or transfer standard is then used to calibrate the final product (D) or device under test. Accordingly, the calibration path is A-B-C-D. This path is called the chain of traceability. Each transfer device in the chain should be subjected to periodic examination to ensure its long term stability. The time span between examinations is typically set by the lab performing the calibration and is selfaudited.

Accredited calibration laboratories guarantee recalibration cycle times for their standards plus a review of their calibration procedures since they are subject to annual review by an official accreditation authority (Figure 2).

A common reference standard used throughout industry is the 1000W FEL-type quartz-halogen

lamp that has been carefully selected after a burn-in procedure of about 80 to 100 hours. The useful spectral range of these sources is 250 to 2500 nm (Figure 3).

The FEL lamp is normally calibrated in spectral irradiance W/(m² nm). This type of calibration, which offers the lowest available calibration uncertainty, is normally requested by high level industrial calibration laboratories or institutions who may in turn use the calibrated device as their own reference standard. Also, $E(\lambda)$ is the most basic radiometric measurement quantity that can be used to calculate many other light measurement quantities like integral irradiance (Effective W/m²) over set spectral ranges or action spectra, illuminance (lux) and color quantities. Deuterium lamp standards calibrated from 200 to 400nm are employed for UV calibrations (Figure 4). Just as important as the lamp qualifications, a constant current, high quality lamp power supply is required since any minute changes in current to the lamp results in changes to the lamp light output.

Calibrations are performed in a dark room or a light-tight enclosure.

Each optical radiation quantity requires its own calibration set-up as shown in Figure 5. The light source standard is mounted onto an optical rail system, first with the transfer standard, then the device under test (DUT) at a set distance. The detectors are overfilled with signal in turn and measured. Baffles are placed between the source and detector to block any stray room light from reaching the detector. In practice, measurement of total radiant/luminous flux is typically performed using an integrating sphere or a goniometer as shown in Figure 6. The hollow sphere with mounted light detector collects all emitted light from the source, whether narrow beam (2π) directed into port or

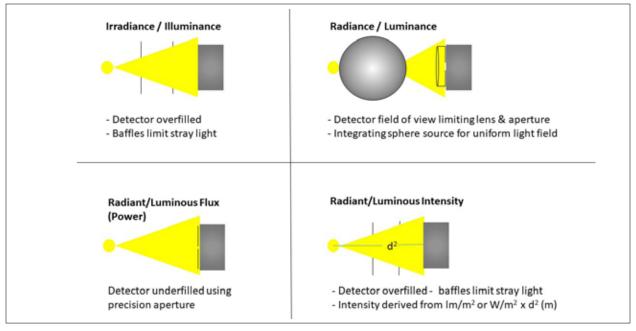


Figure 5. Calibration Set-ups

omnidirectional (4π) with source inside the sphere. Including all of the light signal in the measurement is the basic criteria for total power measurement. The tutorial "Theory and Applications of Integrating Spheres" provides much more detailed information on this subject [2].

More advanced labs have automated motor driven rail systems to precisely position the calibration process. NIST has recently renovated its lab with two automated equipment tables, one for the light sources and the other for the detectors. The tables travel on a rail system that positions the detectors anywhere between 0 to 5 meters away from the lamps. The distances can be controlled to within 50 μ m, and the tables can be programmed to move without requiring continuous human intervention [3].

Recently, LED based calibration standard lamps have been introduced (Figure 7). The LED standard pictured follows CIE reference spectrum L41 (CIE 251) lamp for luminous flux or irradiance calibration.

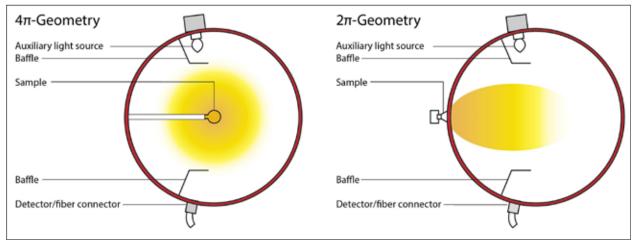


Figure 6.



Figure 7. LED Standard

Figure 8. Detector Standard

Also, detector based standards, which are much more stable than lamp standards, are employed. Silicon photodiode solid state detectors can maintain stability for many years when properly cared for (Figure 8). Research and development of laser based sources are in progress.

Different calibration set-ups are required for each type of radiometric/photometric quantity.

Filter Radiometers and Photometers

A typical filter radiometer/photometer consists of a meter/display unit accompanied by a photodetector as shown (Figure 9). The input optic on the front end of the detector determines the SI optical unit of calibration. For example, an irradiance calibration (W/m²) requires, by definition, a diffuser input optic which gives the detector a cosine field-of-view. This way the detector emulates the way a flat surface would receive light impinging upon it. The next element in the detector stack is typically an optical bandpass filter keyed in on a particular wavelength

range. Together, the detector/filter/input device covers a tailored spectral bandpass to fulfill a particular application. For example, a detector stack that ranges from 315-400 nm covers the UV-A specific action spectra.

The readout part of the radiometer/photometer receives the light signal from the detector in voltage or current and typically amplified. Note that light signals, detectable by a silicon photodiode, can range in the tens of femto ampere range. Most meters will display the raw current reading, but to arrive at the optical unit of choice, calibration of the detector is needed. For the photometer to measure and display illuminance (lux), a calibration factor describing the detector sensitivity in A/lx is done. The meter divides the current measured by the calibration factor to arrive and display the optical unit lux. The same process is used for all radiometric/photometric quantities.

In the now distant past, basic filter radiometers and photometers were adjusted into calibration by means of a simple potentiometer setting. Currently, an eeprom mounted on the detector or detector connector is programmed with the detector calibration and other information stored on it. Once connected to the meter, the data is transferred and used by the radiometer/photometer in the measurement.

Here are some different types of light detector sensitivity calibrations (Figure 10):

Integral Calibration: A broadband light source is used to irradiate the detector under test. The irradiation intensity of the light source is calibrated

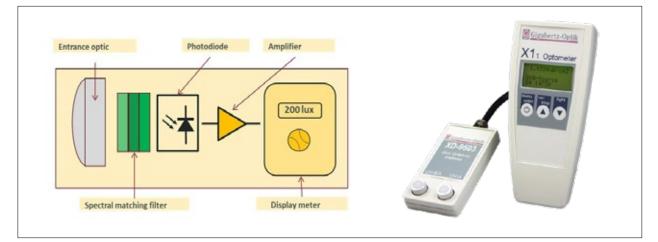


Figure 9. Radiometer Schematic and Radiometer

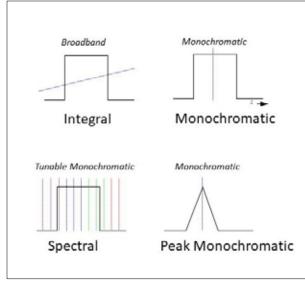


Figure 10. Calibration Types

within the sample detector's spectral sensitivity range in the appropriate units of measurement.

By comparing the detector's signal current to the given light intensity, the test detector's sensitivity is calibrated.

Typical examples where integral calibration are employed:

- Photometric light detectors where calibration is done with a standard Illuminant A light source at 2856 K.
- Integral radiometric detectors such as UV-A, VISIBLE, Erythema & PAR used in applications with broadband light sources.

Spectral Calibration: A monochromatic light source is used to irradiate the test detector at a specified wavelength in the appropriate units of measurement. By comparing the detector's signal current to the given light intensity, the test detector's sensitivity can be calibrated.

Typical examples where monochromatic calibrations are employed:

- Light detectors used to measure lasers or quasi monochromatic light sources. Calibration is performed at the laser wavelength or the peak wavelength of the quasi monochromatic light.
- Light detectors with narrow band pass filters. Calibration is done at the peak wavelength of sensitivity.

Spectral Calibration Dataset: This calibration is identical to the spectral calibration except a tunable monochromatic light source is used. This allows multipoint calibration of detector sensitivity over a series of different wavelengths. Typically, the calibration is done in nm steps within the spectral sensitivity range of the detector assembly.

Typical examples for the selection of spectral calibrations are:

- Light detectors used to measure lasers or quasi monochromatic light sources at different wavelengths.
- Light detectors used for the calibration of tunable monochromatic light sources.
- In addition to integral calibrations of broadband detectors when used to measure light sources with different spectra than the lamp calibration standard. A calibration correction can be calculated to correct for spectral mismatch error.

Note that calibration of spectral measurement devices or spectroradiometers that measure wavelength, as well as absolute values, require specialized line sources (monochromatic) for their wavelength calibration. This type of calibration is beyond the scope of this article.

Relative Spectral Calibration: This spectral sensitivity data allows computation of estimated measurement uncertainty, as well as calculation of spectral mismatch calibration correction factor.

To confirm traceability, every calibration is documented by a calibration certificate, which lists the calibrated device's identification data, calibration procedure, calibration uncertainty, and environmental conditions, as well as the traceability data back to the national standards laboratory. The certificate is signed by the calibration engineer and stamped by the calibration laboratory manager.

Meter Current (Ampere) Calibration

Radiometers and Photometers employ precision, multi-gain range current amplifiers to process the light detector signal. Meters are calibrated and certified using a variable current source which itself is calibrated by an outside accredited calibration laboratory.

Correction factors are calculated based on the calibration values and used to adjust the display

readings at each gain range. Calibration uncertainty and traceability information is supplied on the calibration certificate.

Calibration Uncertainty

Finally, any optical radiation calibration laboratory worth its salt will include calibration uncertainties for any optical radiation quantity within their scope in their certifications. Accreditation to ISO/IEC 17025 for testing and calibration laboratories requires this in its guidelines to guarantee traceability [4].

For calculating uncertainty, refer to ISO/IEC Guide 98-3:2008, a reissue of the 1995 version of the Guide to the Expression of Uncertainty in Measurement (GUM), with minor corrections. This Guide establishes general rules for evaluating and expressing uncertainty in measurement [5].

Setting up an optical radiation calibration laboratory takes a lot of research, effort, technical know-how and expense. Establishing and maintaining accreditation increases these efforts tremendously since a key stone of accreditation is to ensure the lab's stated uncertainties are real and maintained through yearly audits and interlaboratory comparison. Beforehand, one must weigh these costs and efforts against those of simply returning the instrumentation to the manufacturer for recalibration on a scheduled interval.

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What a Long-Term Instrument Warranty Can Mean to a Calibration Operation

Jesse Morse Morse Metrology

Most all test and measurement equipment (TME) come with some amount of warranty: 90 days, one year, etc. From the manufacturer's perspective, it is simply to protect the buyer from having to pay for a repair should it occur within the warranty period. However, from the buyer's perspective it can mean a lot more than just a "free" repair. This article is meant to outline the advantages of having an instrument (i.e. precision calibrator) under manufacturer's warranty for as long as possible – even when that warranty must be purchased separately.

Let's set the stage...

The cost to repair a modern sophisticated instrument, such as a precision calibrator, can be substantial if its warranty period has expired. But whether the instrument is covered by a warranty or not, the cost of it being out of service for some period of time, in the event of a malfunction, can be significant due to downtime. And, if it is out of warranty, that downtime can be extensive.

Here are two scenarios that compare the possible amount of downtime if the instrument is out of warranty versus if it is in-warranty.

Scenario 1 – Out of Warranty Repair Based on Typical Manufacturer Practice

Here is a rather typical process for getting an instrument repaired <u>out of warranty</u> by a manufacturer's repair facility: (The flow diagram shown in Figure 1 includes the estimated time each step in the process might take.)

- 1. The repair facility receives the instrument with the owner's *Request for Quote* (RFQ) paperwork.
- 2. The instrument is placed on a shelf probably named *Awaiting Quote* (AWQ).
- 3. The instrument is logged into the repair facility's Order Processing System.
- 4. The instrument sits until a technician is

assigned to determine the actual repair costs or determine if it qualifies for an available "Flat-Rate Charge."

- 5. When assigned, the technician brings the instrument to their workbench where they do the evaluation.
- 6. When the evaluation is complete, the technician informs the administrator of the cost to repair the instrument.
- 7. The admin communicates the cost to the instrument's owner (accounting department) for approval and issuance of a *Purchase Order* (PO).
- 8. The technician places the instrument on a shelf identified as *Awaiting Quote Approval* where it will sit until the owner's accounting department approves the quoted amount and issues a PO. The cost may be approved immediately, or it may be delayed by the owner's accounting department while they contact an internal manager for budgetary approval.
- 9. Once approved, the owner's accounting department contacts the repair facility and gives them the go-ahead to proceed with the repair.
- 10. The repair facility administrator notifies the technician that the instrument may now be repaired.
- 11. Now that accounting has given the go ahead, your instrument gets placed in the *Awaiting Work* queue where it will be moved up at a rate determined by the repair facility, which is determined by their internal cycle time.

So far, your instrument has been just sitting idle on a shelf at the repair facility for several days. During this time, any other similar instrument coming in for repair, <u>that is under a warranty or pre-approved</u>, will be put into the queue ahead of yours. What a Long-Term Instrument Warranty Can Mean to a Calibration Operation Jesse Morse

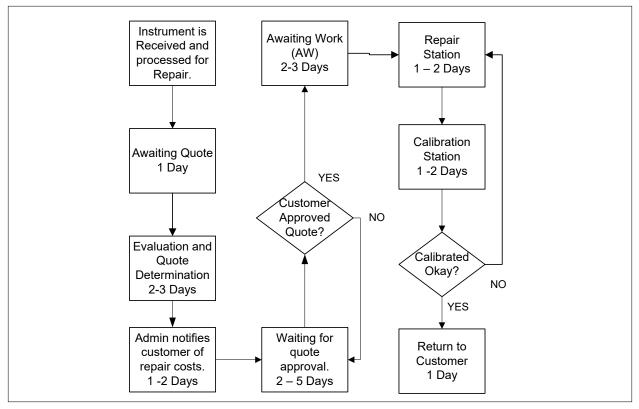


Figure 1. Out-of-Warranty Process

If there are no further complications, your instrument should finally be on its way back to you soon.

But what if, after repair, the instrument fails in calibration?

- a. If the instrument fails in calibration, it might go on a "Next On Bench" shelf where it will wait, again, for a technician to determine why it failed calibration and correct the problem. Note that this might also require another call by the repair facility to the owner's accounting department for more money.
- b. The process then most likely gets repeated from (4) above. This whole process might take one to several weeks to complete.

Now, while the instrument is out for repair for upwards of a month, the workload it supports is still arriving for calibration and backlog is increasing, which affects your turnaround time (TAT) for your customers.

The problem you face is, "How to burn off that backlog and get back to meeting your TAT goal."

To do that you may have to pay your technician overtime to clear the backlog, or just decide to carry a larger backlog. Note that the latter could impact your customer's future production goals or cause them to ask the company for spare instruments to cover for your longer turnaround time. Neither case is ideal, but <u>without a warranty</u> you can't do much to change this process because it is mostly out of your control.

Scenario 2 – In-Warranty Repair Based on Typical Manufacturer Practice

In comparison to Scenario 1, here is a typical process for getting an instrument repaired at a manufacturer's repair facility when it is <u>covered by a warranty</u>. Note that the instrument owners accounting department is not <u>usually</u> involved in this process, thus saving significant downtime in some cases (refer to process flow diagram shown in Figure 2).

1. The instrument arrives at the repair facility with a request for repair under warranty.

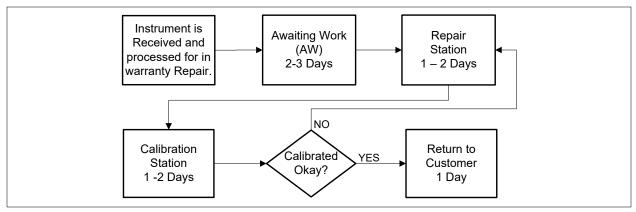


Figure 2. In-Warranty or Pre-Approved Process

- 2. The instrument is most likely recorded in the system the same day, workorder is produced and the instrument is placed immediately on the *Awaiting Work Shelf*. Some manufacturers prioritize in-warranty repairs ahead of out-of-warranty.
- 3. Depending on the repair facility's *Throughput Rate* (their TAT) your instrument is put on a bench in due time, repaired, calibrated and prepared for return to you.

Comparing Scenario 1 and 2, Scenario 1 can be very long, as much as a month, while Scenario 2 is as quick as the repair facility's normal TAT – probably on the order of 5 to 10 days.

Other Considerations Having to do With Lab Instrument Management

Within a lab operation, it is not uncommon for the operating budget to include a line item for the cost to repair its own equipment. In as much as an equipment failure is very random, it is difficult to budget for the repair costs involved should a failure occur. Think about what would happen if you had an unexpected repair invoice for several thousand dollars over what you had budgeted that year. Especially when requesting a PO that far exceeds budget.

To avoid unplanned budgetary impact and a lengthy downtime getting an out of warranty instrument repaired, one should look at more than the specifications and price of an instrument when making a buying decision. The length of the manufacturer's warranty should be considered if comparing competing brands. For example, if one instrument has a 1-year warranty and another has a 5-year warranty, the price of the one with a 1-year warranty must be increased by price of that manufacturer's "5-year Extended Warranty" in order to get an accurate price comparison of the two.

In summary, the overall advantages of a warranty are:

- a. It will save you <u>significant downtime</u> if the instrument fails while it is covered.
- b. It prevents an unexpected/unplanned high repair cost.
- c. An instrument with a built-in 5-year warranty might have a noteworthy price advantage over a competing product with only a 1- or 2-year warranty.
- d. It also might mean that the instrument with a 5-year warranty included is simply much more reliable than the other.

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A Quality Review: The Top 10 Best Papers for Life Science Calibration and Testing Laboratories

Walter Nowocin, MEM IndySoft Corporation

In the past fifteen years, there have been many exceptional technical papers presented at the annual NCSL International Workshop and Symposium and the Measurement Science Conference. At Medtronic, we benefited from many of these papers to improve our calibration program supporting high-volume medical device manufacturing operations using high quality inspection, measuring, and test equipment. However, many life science calibration and testing laboratories may not have benefited from these papers due to high lab management turnover, lack of support in attending industry conferences, or lack of visibility to these valuable presentations and how they can be used to improve laboratory operations.

In this paper, we will review the top ten best papers and how they can be used to improve the quality of calibration laboratory operations. At the end of the paper, we will discuss a bonus resource which along with the technical papers can be considered an essential part of a life science's knowledge retention toolbox.

Introduction

One of the key tenants of an effective knowledge retention program is the ability to store critical information, but also to be able to easily retrieve the information by knowing that it exists and where it is. The NCSL International organization has done an excellent job of storing and making accessible all of the published technical papers presented at the annual workshops and symposiums going all the way back to 1990! But you have to know what you are looking for. And for many lab managers, they just do not know that these exceptional papers exist and how they can help them improve their lab operations.

At Medtronic, a trip report was written after each conference (from 2004 to 2018) which described the conference and its details including an executive summary of each presentation and paper. The typical trip report was six to eight pages long with web links to each paper. The trip report was shared with all Medtronic calibration lab members, leaders, and peer groups and saved to a global knowledge retention website. For this paper, the trip reports were reviewed to identify the most valuable technical papers for life science lab managers. We will share how the contents of the technical papers were used to improve our laboratory operations and highlight other valuable recommendations.

Number 10

"So, What's in a Range," Dennis Dubro, PhD., Metrology Consultant, 2015

This is a good paper to start off with as it does a very nice job of explaining calibration terms from the perspective of the manufacturing process. One of the most challenging roles for life science calibration and testing laboratories is to provide calibration recommendations to process engineers. An understanding of the key terms in Dr. Dubro's paper will help in these discussions.

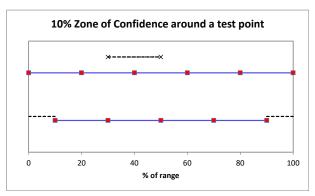


Figure 1. Six-point test point calibration across a range versus five-point. [Dubro, 2015]

The author starts off with describing the various terms for "range" as it pertains to instruments; e.g. manufacturer, calibrated, process, validated, and uncertainty. Validated and process ranges are a key focus of the paper to illustrate the difference between the two terms as they are often interchanged. Another aspect within the range discussion is that measurement uncertainty can be considered another type of range which Dr. Dubro describes as "a range within a range within a range."

The next key term in the paper is "tolerance" which carries with it the concept of range. Tolerance is described as having three meanings:

- 1. An acceptable range.
- 2. The maximum permissible variation or limits allowed a quantity/parameter from a specified value.
- 3. A number agreed upon by interested parties (e.g., a buyer and a seller) as a medium of exchange—a parameter of acceptability. [Dubro, 2015]

Another valuable discussion is highlighting the four common calibration scenarios as explained in NCSLI Recommended Practice 12 *Determining and Reporting Measurement Uncertainty.* The paper does a nice job of using graphics to describe each of these four scenarios:

- Scenario 1: A Calibration Standard Measures a Unit Under Test Attribute Value.
- Scenario 2: A UUT Measures a Calibration Standard Attribute Value.
- Scenario 3: Both a Calibration Standard and a UUT are Measured by a Comparator Device.
- Scenario 4: Both a Calibration Standard and a UUT Measure a Common Artifact.

The concept of "process guard-banding" is introduced as a way to ensure that a validated process is rarely out of specification. By "process guard-banding" to the calibration tolerance of the measuring device at minimum, the process parameter will operate within the validated range to a high confidence level. The use of graphics to display the various terms of validated range, process range, calibration tolerance, uncertainty, and process guardbanding will be useful in collaborating with process engineers.

The author concludes by introducing another key concept of selection of calibration test points.

Dr. Dubro does an excellent job of describing the difference between the terms of "interpolation" and "extrapolation" as it applies to the basic understanding of what goes into making calibration test point selection decisions. This discussion then supports his conclusion that a six-point across-a-range calibration, where possible, is better than a more typical five-point calibration that would require an explanation of "extrapolation" to an external auditor; see Figure 1.

If you are new to leading a life science calibration or testing lab or if you are new to the life science industry, this paper should be included in your "toolbox" of important and valuable quality resources.

Number 9

"Best Practices for Pipette Calibration Uncertainty Budgets and CMC Determination," George Rodrigues, Artel and Mark Ruefenacht, Heusser Neweigh, 2015

Pipettes are critical instruments used in life science calibration and testing laboratories in a variety of nonquantitative and quantitative purposes. Additionally, the effective use and calibration of pipettes is highly dependent on repeatable and reproduceable technique and skill. Therefore, internal calibration of pipettes and the assessment of third-party pipette calibration service providers is one of the most important activities for life science calibration and testing laboratories. This paper provides valuable information to identify the critical quality parameters, processes, and methods for evaluating high quality pipette calibrations.

The authors start by identifying the three most important measurement uncertainty sources for pipettes: (1) weighing of water, (2) operator influences, and (3) variability of the pipette under test. The weighing of water has several error contributors and can be associated into three uncertainty categories: uncertainties associated with the balance and balance calibration (*weighing*), *evaporation* of water, and conversion of indicated weight to volume by accounting for the density of water and air buoyancy forces (*Z factor*). Figure 2 shows the importance of understanding the uncertainty contributors and how they increase over the range of pipette volumes. A Quality Review: The Top 10 Best Papers for Life Science Calibration and Testing Laboratories Walter Nowocin

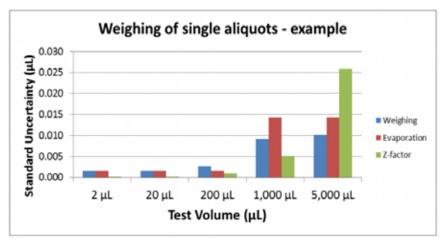


Figure 2. Example weighing uncertainty components. [Rodrigues, 2013]

The most valuable aspect of the paper is the recommendation of the authors in the areas of calibration practices, measurement uncertainties, scopes of accreditation, certificates of calibration, statements of compliance, etc. These recommendations are useful from the internal calibration perspective and when reviewing third-party calibration services. Some examples:

Calibration Practices

- Accurately document standard practices and train technicians to follow them to attain acceptable repeatability and reproducibility results.
- Pipettes should be calibrated using the same tips that the equipment owner will use. This will minimize systemic measurement errors.
- Users should send in tips with pipettes for calibration.

Scopes of Accreditation

- Scopes which contain nearly constant Calibration Measurement Capability (CMC) across volume ranges should be carefully reviewed for correct UUT Repeatability and Z Factor Uncertainty data.
- Carefully examine CMCs that decrease with increasing test volumes for any inaccuracies.

Number 8

"Traceability Considerations for the Characterization and Use of Measuring Systems," Charles D. Ehrlich, NIST, 2015 Life science calibration and testing labs perform characterizations on equipment used in manufacturing operations under FDA regulatory requirements. Though not required, there is a desire to follow best practices provided by ISO 17025 *General Requirements for the Competence of Testing and Calibration Laboratories*. This is a challenge to life science calibration and testing labs as the FDA and ISO do not use the same terms and definitions; e.g., calibration and verification. In fact, there have been several high-profile FDA Warning Letters related to the application of these two terms with much controversy.

Dr. Ehrlich's paper does an excellent job of describing the three characterization methods identified within the VIM: *calibration, adjustment, and verification*. His paper goes into great detail on the basic considerations of measuring system characterizations in the areas of input quantity, indication, and conversion factor along with influence quantities, operating conditions, and typical properties of a measuring system (resolution, repeatability, reproducibility, and variation of indication.) These descriptions are well supported by detailed diagrams of the different characterizations.

One area in particular will be of value to life science calibration and testing labs. His description of the verification characterization without explicit measurement uncertainty is the best that I have seen published, see Figure 3. This is critical because the vast majority of life science calibration and testing labs will use this approach. Dr. Ehrlich does an A Quality Review: The Top 10 Best Papers for Life Science Calibration and Testing Laboratories Walter Nowocin

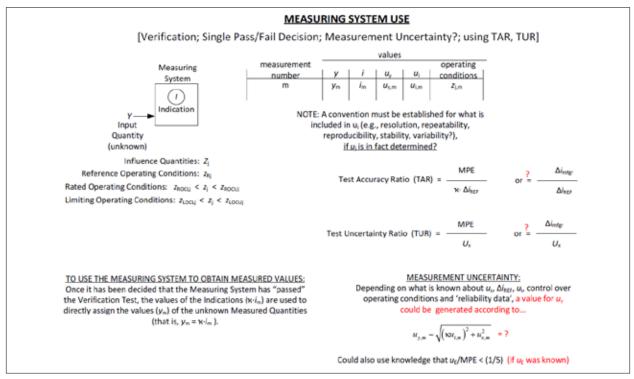


Figure 3. Measuring system use - verification without uncertainty recorded. [Ehrlich, 2015]

excellent job of explaining this process and how it uses either *test accuracy ratios* or *test uncertainty ratios* as a main aspect of the characterization. His paper concludes that the use of this verification characterization method, using TAR or TUR, to construct a bound on the measurement uncertainty can provide evidence of measurement traceability. Though he acknowledges that more work needs to be performed in this analysis.

Number 7

"Strategies for Dealing with Low Test Uncertainty Ratios," Dennis Jackson, PhD., Ed Trovato, NSWC Corona Division, 2017

Managing risk is a critical activity in life science organizations and therefore for calibration and testing laboratories. One of the critical areas for labs is in determining the outcome of a calibration or test such as a pass or fail result for each test parameter. The important aspect is to minimize the probability of a false accept decision. One way that labs do this is by anchoring calibrations and tests to a test uncertainty ratio target of 4:1 or better. But what should calibration and testing labs do if the TUR target is not met? The authors describe an effective four-step process for managing low TUR risk: validate, eliminate, mitigate, and document. The validate step is pretty straight-forward. At a high level the process engineers should verify that the inspection, measuring, and test equipment require calibration and that the calibration tolerances are correct. The authors describe a very detailed eliminate process which will be very useful to life science calibration and testing laboratories:

Change the calibration requirement if appropriate

Validate

- Change the tolerances if appropriate
- Use a Special Calibration label
- Change the calibration methodology
- Use a report of calibration instead of a calibration test
- Use a higher-level calibration lab
- Obtain a different Standard or Unit Under Test
- Use an R&D process to develop a Standard or Calibration Method

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These steps are very similar to the steps we used at Medtronic as part of our calibration procedure development process. We used these steps for any situation not meeting our measurement target:

- Identify a replacement reference standard that will meet the measurement target
- Identify a calibration supplier that can meet the measurement target
- Limit (remove) the test range not meeting the measurement target
- De-rate (widen tolerance/decrease accuracy) the test parameter to achieve the measurement target
- Apply a guard-band to achieve the equivalent measurement target decision

The authors described two mitigation steps with nice detail: guard-banding and shortening the calibration intervals. Another valuable recommendation from the authors is in the document process. They provide a "Risk Matrix," see Figure 4, that helps document the consequence of the calibration or testing at each TUR level. This approach is a very useful example for life science calibration and testing laboratories to help them both document and assess the appropriate level of risk and consequences.

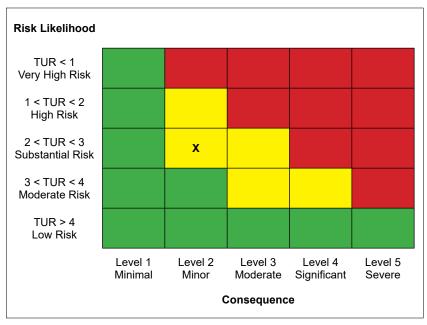


Figure 4. Risk matrix. [Jackson, 2017]

Number 6

"To Optimize or Not to Optimize: Black Swans and Metrology," Mark Kuster, Pantex Metrology, 2012

This paper was arguably the best paper at the 2012 Measurement Science Conference. The author did a nice job of using a New York Times Best Seller List book "The Black Swan: The Impact of the Highly Improbable" by N. H. Taleb and applying themes to metrology methods. It was truly original thinking with innovative application of optimization and detailed explanation of mediocristan and extremistan environments. One of the key concepts of a Black Swan's extremely high-impact, low-probability event is the idea that we tend to over simplify the event in hindsight and believe that we could have and should have predicted the event. What we should be doing is continuing to build robustness into our daily activities to minimize the black swan possibilities in the first place.

As I was attentively listening to Mr. Kuster and taking detailed notes, I felt inspired to go back to our calibration lab at Medtronic and put more focus into our annual business continuity plan template that we are asked to fill out each year. Like many managers,

> I did not put too much effort into these plans and just performed cursory reviews. However, now I felt that this was the ideal tool to implement the black swan concept of building in robustness into critical activities with high-impact if they fail. Here are some of the activities we put into place, with some corporate and local business financial support:

> • Focused on procuring laptops and smart pads for technicians to be more mobile

• Divested our single-site critical equipment spare parts inventory to multi-site parts storage

• Divested our single-site spare equipment storage to multisite equipment storage locations

- Implemented a paperless out-of-tolerance reporting and investigation documentation process
- Converted hundreds of hard-copy equipment manuals into electronic format with global access
- Reached out to third-party suppliers and asked them how much added work could they do for us in a critical, short-term situation
- Identified a critical, one-of-a-kind, custom-built calibration reference standard and put in a priority order for engineering to build a second standard which was then stored at another lab site as a spare

These activities were prioritized and implemented over the next several years. Then the global pandemic happened (black swan event) and everyone was significantly impacted by depleted supply chains and severely isolated, quarantined work environments. Our lab was able to migrate through these challenges due to the many robust processes we had put into place over the past several years. We had become a more mobile and nimble work team and we had a strong core of local and remote third-party suppliers to leverage. So, despite many challenges our team was providing effective calibration support to our customers during the early parts of the pandemic.

However, our global colleagues were struggling with an insufficient third-party supplier pipeline and with significantly reduced internal calibration resources. They were quickly experiencing a growing backlog of overdue calibrated instruments with no short-term solution. As the leader of the global calibration forum group, the Quality VP reached out to me to see how we could quickly help solve the problem. We presented to the VP a risk-based approach to calibration schedule extensions as many European calibration labs did not have this as part of their standard operating procedures. Using our standard process as a model, we were able to quickly put into place a risk-based calibration schedule extension process as an emergency global policy.

Life science calibration and testing labs should use a business continuity plan as it can be a very effective way to reduce the risk of extremely highimpact, low probability situations (black swans) from developing into real, everyday problems. Will your lab be ready for the next black swan event?

Number 5

"Instrument Adjustment Policies," Paul Reese, Baxter Healthcare Corporation, 2015

Life science calibration and testing labs operate under unique circumstances. Unlike NMIs and thirdparty calibration laboratories, life science calibration and testing labs must follow FDA regulatory requirements. As part of this expectation, the FDA will perform on-site inspections of manufacturing operations to include inspection and review of equipment records used to perform calibration and maintenance actions.

There is one area in particular where the FDA inspections have created controversy. The FDA has written inspection findings from the expectation that instruments require *adjustment* of all test parameters in order to meet the definition of a calibration. A fundamental misunderstanding of calibration. However, it is very intimidating to challenge FDA inspectors despite what we know to be true.

Paul Reese does an excellent job in his paper to provide a detailed explanation of this situation. His paper has valuable information that can be used to support a rebuttal to any FDA inspection where a misapplied calibration definition is cited regarding calibrations and an *adjustment* expectation.

His paper is organized into nine sections:

- Background
- NCSLI RP-1 Establishment and Adjustment of Calibration Intervals
- Empirical Examples: Systemic Drift Superimposed Over Random Fluctuations
- Assumptions of the Drift Model
- Modeling and Selection of Magnitude for Drift and Random Variation
- Results
- EOPR Reliability Targets
- Non-adjustable Instruments
- Conclusions

One conclusion of the paper is that statistical data supports the concept that the best practice regarding adjustments is to not make any adjustment to allow for an instrument to be the most stable. Figure 5 shows the detailed Monte Carlo analysis used in the paper. A QUALITY REVIEW: THE TOP 10 BEST PAPERS FOR LIFE SCIENCE CALIBRATION AND TESTING LABORATORIES WALTER NOWOCIN

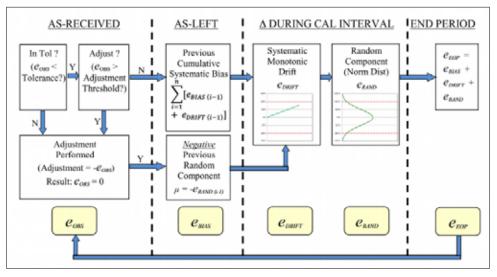


Figure 5. Monte carlo simulation model. [Reese, 2015]

As with many of Mr. Reese's papers, his bibliography section and appendixes are themselves worthy of review and use. This paper is no different. The bibliography is six pages long and essentially a historical record of the *adjustment* topic.

Additionally, Appendix B is worth a read in itself as it documents in great detail the current state of Excel 2010 as a statistical tool and the comparisons to the previous inadequate versions of Excel.

Number 4

"Calibration Point Selection – Who Makes the Call?" Joseph Petersen, Abbott Laboratories, 2012

One important metrology measurement area that does not get much discussion or guidance is on how to select the quantity of calibration test points across a range of test parameters. For life science calibration and testing labs, calibration and test point selection are critical to ensuring adequate reliability of measurements for inspection, measuring, and test equipment used in manufacturing operations. Mr. Petersen's award-winning paper does an excellent job of addressing many of the important factors that go into this complex decision. The author starts off with a list of general principles for test point selection:

• Consider hysteresis testing for mechanical instruments.

- Single point calibrations are adequate for instruments that operate at a fixed point such as body temp ovens. [NOTE: The FDA will focus in on any single-point calibration for appropriate rationale.]
- A minimum of three test points are used to verify linearity, span (sensitivity), and zero. With five or ten test points as the secondary choices. Two-point calibrations are not commonly seen; however, the FDA does expect that any usage range is "bracketed" for calibration test points at a minimum.
- Avoid over-ranging or pegging instruments by choosing 10% and 90% of full-scale readings. Equipment manufacturers may suggest 100% of readings when the instrument is capable.
- Follow recommendations from the equipment manufacturer and from regulatory standards and guidance documents before defaulting to general test point selection rules. These default general test point rules should be described in your standard operating procedures.

Though the concept of calibration test point selection would appear to be a simple process, as we have seen, there are many different and conflicting general principles. There are even different recommendations from equipment manufacturers and from regulatory bodies. See Figure 6, for the author's example for a fairly common and simple instrument in the life science environment—a balance.

The author next discusses another important aspect

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Publication	Minimum # of Accuracy/Linearity Test Points (excluding zero)		
OIML R76-1, sec. 3.6.2, 8.3.3 & A.4 [12]	5		
UKAS LAB14 [13]	10, evenly spaced		
Code of Practice for Industrial Weighing Machines,	5, evenly spaced		
United Kingdom Weighing Federation, (5.7.3.6) [14]			
SANAS R15-03, South African National	5, evenly spaced		
Accreditation System [15]			
Mettler Balance Tolerances [16]	typically 4, evenly spaced		
Sartorius Tolerances for Testing Metrological	typically 4, evenly spaced		
Specifications [17]			
ASTM E898 [18]	10, evenly spaced		
EURAMET cg-18, Guidelines on the calibration of	5 or more, evenly spaced		
non-automatic weighing instruments [19]	(for verification of whole range)		

Figure 6. Balance calibration point guidelines. [Petersen, 2012]

and that is "who is in the best position to select calibration test points?" The equipment manufacturer, the calibration service provider, and the process owner all have limited information of the total aspect of instrument calibration and testing. Therefore, Mr. Petersen recommends a "team approach" should be used for critical process calibrations.

The author ends the paper with adding a very interesting discussion on the topic of test point selection and suggests that this process could be considered a "quality sampling." Mr. Petersen brings up a very good point in that by describing the process as a sampling, many quality principles could be used to help quantify and rationalize the test point selection methods being selected.

Number 3

"Guardbanding With Confidence," David Deaver, Fluke Corporation, 1994

There are many published papers regarding the concept of guardbanding to make a measurement decision when the TUR target of 4:1 has not been met. In reviewing many of these papers one paper started to emerge as the best paper due to its simplicity and also due to its coverage of a good list of guardbanding strategies. Though Mr. Deaver's paper was published in 1994 it is amazing to see that four of the six strategies discussed in the paper

GUARDBANDING METHOD	TUR 4:1	TUR 3:1	TUR 2:1
CR4:1 (or RP-10 Statistical Z, Deaver Method 1)			
Probability of False Accept (PFA) [Consumer Risk CR]	0.80	0.80	0.80
Probability of False Reject (PFR) [Producer Risk PR]	1.50	2.80	6.60
Fluke RSS (or M3003 M3, Deaver Method 4)			
PFA	0.60	0.64	0.63
PFR	2.00	3.40	8.20
NCSLI RP-10 Linear Z			
PFA	0.80	0.59	0.42
PFR	1.50	3.70	11.10
Deaver Method 3 (or Original RP-10 Method)			
PFA	0.80	0.50	0.30
PFR	1.50	4.10	14.00
ANSI Z540 Method 6 (or Dobbert's Method, 1.04) *			
PFA	1.95	1.92	1.89
PFR	2.97	5.15	10.61
NCSLI RP-10 Constant Z (80% Rule)			
PFA	0.05	0.07	0.09
PFR	7.60	11.90	23.90
ANSI Z540 Method 5 (ILAC G8, U95, Deaver Method 2, ISO 14523-1)			
PFA	0.02	0.02	0.03
PFR	10.00	24.00	33.00

Figure 7. Guardband methods with PFA and PFR comparisons. [Hogan 2022, Deaver 1994, *Greg Cenker 2024]

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are still being reviewed and recommended today.

The author does a very nice job of explaining a very complex topic regarding the trade-offs between managing consumer risk (false accept risk) and producer risk (false reject risk). The probability of false accept and the probability of false reject are quality metrics for calibration and testing processes and provide a measure of confidence that the calibrated instrument meets the specified requirements. Life science calibration and testing labs need to understand these risk trade-offs and select a guardbanding strategy that best meets the organizational goal of reducing consumer risk without adding significant producer risk. The paper has a nice table comparing these risks at various TUR levels in the various guardbanding methods.

There is another excellent resource that describes Mr. Deaver's methods along with several additional guardbanding methods. Richard Hogan, CEO of ISO Budgets, has a wonderful website exploring all areas of metrology to include an in-depth guardbanding web page (https://www.isobudgets.com/guardbanding-how-to-take-uncertainty-into-account/). Mr. Hogan describes thirteen guardbanding strategies including four of Mr. Deaver's six methods. I used information from both sources to create a table, see Figure 7, that compares the best seven methods Number 2

"Using Reliability to Meet Z540.3's 2% Rule," Scott Mimbs, NASA Metrology and Calibration Program, 2011

Mr. Mimbs ground-breaking paper on the Z540.3 2% rule came along at a critical time when we were deciding on how to proceed with our continuous improvement journey related to transitioning from the basic use of test accuracy ratios to incorporating more measurement uncertainty into our calibration methods. We were struggling with how to prioritize our limited resources to this enormous change. Mr. Mimbs' paper provided excellent insight on how we could proceed with balancing our limited resources and improve our quality measurements as we had a high EOPR metric. This paper needs to be part of every life science calibration and testing laboratory toolbox of technical guidance resources.

The paper describes the results from NASA's engineering review to examine ways to mitigate the costs related with attaining compliance to the Z540.32% rule. The ultimate outcome of this technical review was identification of the use of End-of-Period Reliability metric as a quality measure to determine compliance.

with comparisons of PFA and PFR to TUR levels. The methods are in order of the best fit in both PFA and PFR over the three TUR levels of 4:1, 3:1, and 2:1.

Interestingly, at Medtronic we decided over ten years ago to use the Fluke RSS method for establishing our lab measurement decision rule. We found the Fluke RSS method to be a good combination of ease of use and a nice trade-off between PFA and PFR. It was exciting to see how well the Fluke RSS model compared to the other six guardband methods.

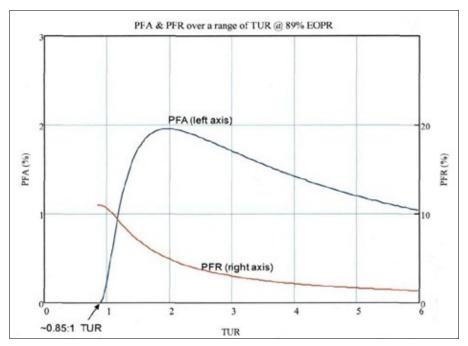


Figure 8. PFA and PFR graphed over a range of TUR values for 89% EOPR. [Mimbs, 2011]

The NASA engineers determined that by achieving an EOPR of 89% or better would equate to meeting the Z540.3 2% PFA Rule at all TUR levels, see Figure 8. This was an impressive conclusion. Another conclusion was that a high EOPR meant that "the calibration process is reliable and that all of the uncertainty sources are either insignificant or have been addressed through the design, implementation, and control of the calibration process." Another valuable take-away.

The reliability of EOPR empirical data is essential to being able to use this metric to meet the Z540.3 2% Rule. Therefore, NASA identified several factors supporting the validity of using EOPR to meet Z540.3 2% Rule:

- Calibration processes need to be consistent and stable.
- Calibration processes need to be documented and validated.
- EOPR Data Capture Policy should include: proper identification of as-received conditions and in-tolerance and out-of-tolerance criteria.
- True EOPR will always be higher than Observed (Metric) EOPR. For example: at TUR 4:1, an Observed EOPR of 89% will equate to a True EOPR of 89.7%.
- Using EOPR at the equipment model or high level than the test-point level is valid for achieving the Z540.3 PFA 2% requirement as the reported PFA will be greater than at any lower test point level (therefore, if PFA of 2% or less is met at the Model level, it will be met at the test point level).

Number 1

"Calibration in Regulated Industries: Federal Agency Use of ANSI Z540.3 and ISO 17025," Paul Reese, Baxter Healthcare Corp., 2016

I would place Mr. Reese's paper on my life science "Mount Rushmore" of the top five most important resources for life science calibration and testing labs alongside the *ASQ Metrology Handbook, GAMP 5, NCSLI RP-6,* and *Fluke's Calibration in Practice* book. It is truly astounding how valuable his paper is at over 130 pages covering the full history of metrology requirements from a life science perspective.

Mr. Reese's monumental paper is organized into these sections with my bullet notes added:

- 1. Background (pages 2-7)
 - Table of Chronology of Calibration System Standards and Guidelines
 - Figure 1 Simplified Evolution of International and National Calibration Standards and Guidelines, see this paper Figure 9.
 - Figure 2 Divergent ISO Quality and Calibration System Standards
- 2. Historical Perspective (pages 8-10)
- 3. 1990s: ISO Guide 25, MIL-STD 45662A, and ANSI/NCSLI Z540.1 (pages 11-14)
 - Excellent Test Accuracy History Summary on page 11.
- 4. 2000s: ISO 17025, ANSI/NCSLI Z540.3 (pages 14-17)
 - List of 27 Publications on Measurement and Calibration Decision Risk. Superb resource.
- 5. Calibration in the Healthcare Industry (pages 18-32)
 - Table 2 on page 19 Review of Historical FDA GMP/QSR Calibration Requirements.
- 6. Calibration in Other Government/Regulated Industries (pages 32-45)
 - NASA, DOE, DOD, Automotive, and FAA
- 7. The National Technology Transfer and Advancement Act of 1995 (NTTAA) (pages 45-57)
- 8. Summary and Conclusions (pages 58-59)
- 9. Acknowledgements (page 60)
- 10. Bibliography (pages 61-76)
- Appendix A Additional Resources on Probability/Risk of Incorrect Decisions Due to Measurement Uncertainty (in year order) (pages 77-93)
- Appendix B Chronological Summary of Some Accuracy or Uncertainty Requirements (pages 94-110)
- Appendix C NCSLI FDA Proposal Letter (pages 111-114)
- 14. Appendix D FDA Good Practices (21 CFR Part 10.115) (page 115)
- Appendix E Silver Sheet Article: FDA Former Official Interview for Inspection Recommendations (pages 116-125)
 - An article interviewing former FDA officials on various inspection preparedness recommendations. Personal note: this document was initially circulated within

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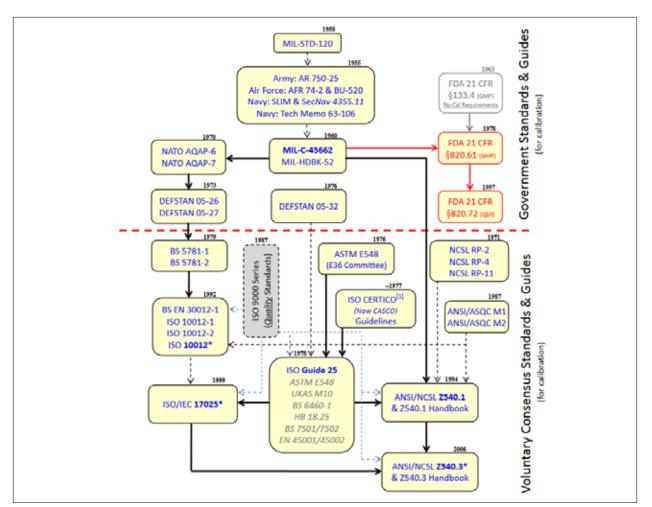


Figure 9. Simplified evolution of international and national calibration standards and guidelines. [Reese, 2016]

Medtronic with high-level quality leaders incorrectly connecting this document with actual FDA officials not recommending but actually requiring all aspects of this document. I had to review the mile long forwarded e-mail to find the original article and determine that (1) it was an FDA consultant not an FDA inspector and (2) it was an article of recommendations and not a requirements document. As one peer responded: "Thanks Walter for walking us off the ledge."

- Appendix F Medical Device Quality Systems Manual – A Small Entity Compliance Guide (pages 126-133)
 - A superb resource for all life science calibration and testing laboratories.

Bonus Resource

"NCSL International Recommended Practice Six – Calibration Quality Systems for the Healthcare Industries," Fifth Edition, NCSLI, 2022

Life science calibration and testing laboratories operate under unique regulatory requirements. The FDA regulates life science organizations that sell medical products within the United States under the Code of Federal Regulations (CFRs). Unfortunately for life science calibration and testing labs, the regulations only provide a basic set of laboratory requirements; e.g., scheduling, labelling, procedures, etc. NCSLI recognized this challenge and released the first edition of RP-6 in 1986. NCSLI has released five editions of RP-6: *Recommended Practice—Calibration Quality Systems for the Healthcare Industries,* with the fifth edition released in 2022.

The NCSLI Healthcare Metrology Committee maintains this RP on behalf of NCSLI with the philosophy that RP-6 be a resource for lab managers new to the life science industry to understand what are essential elements of a calibration quality system. The committee wanted the RP to be a "one-stop shop" resource for life science lab managers. These include elements that are beyond the FDA CFRs and are deemed important by a peer group of life science laboratory leaders.

RP-6 has the following quality system content:

- Definitions
- Instrument classification
- Adequacy of Measurement and Test Equipment (M&TE)
- Adequacy of Calibration Equipment and Standards
- Equipment Handling and Storage
- Measurement Quality
- Calibration Procedures
- Environmental Controls
- Personnel Requirements
- Computer Software Validation
- Calibration Scheduling
- Calibration Intervals
- Records
- Quality Assurance and Reliability
- Supplier Control
- Audit Requirements

New to the fifth edition and the most valuable updated elements of RP-6 are:

- CAPA
- Validation
- Computer Software Validation (in four areas: calibration management software, instrumentation software, automated calibration procedure software, and spreadsheets)
- Appendix B Adequacy of M&TE for Intended Use Decision Guideline (use of process accuracy ratios, test method uncertainty (TMU), and Z% guardband with a decision tree)

• Appendix C – Bibliography (an extensive reference and resource listing to include a special section for measurement uncertainty)

Summary

Life science calibration and testing laboratories operate under unique requirements and challenging regulatory conditions. They support high-volume medical device manufacturing operations utilizing high quality inspection, measuring, and test equipment which must deliver the highest quality and the most accurate and precise measurement output.

Lab managers are constantly challenged with being able to provide the most reliable inspection, measuring, and test equipment using a best in practice calibration and testing quality system program. One way to do this is for lab managers to stay connected with the latest industry best practices by participating in various industry organizations such as NCSLI, MSC, ASQ, A2LA, etc. These organizations provide a wealth of technical and leading industry information during presentations at various annual conferences throughout the United States and internationally.

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- Greg Cenker, IndySoft
- Stan Flores, Alcon

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You never know, you know...?

Dan Wiswell Amblyonix Industrial Instrument Company

As a collector of antique test equipment, I have visited many antique shops over the years with the hope of stumbling upon something good. A few decades ago, there were plenty of examples of highquality antique instruments for sale in a variety of after markets. Today it is fairly unusual for me to find something that I'd like to own. I've been reminded at home recently that I really don't need more than twenty-seven megohmmeters. But, every so often...

Kellogg Model 1917

Years ago, I was on Cape Cod and decided to stop at an antiques and collectables shop. My eyes were immediately drawn to the device pictured below. It is a WWI era field telephone/telegraph, made by the Kellogg Switchboard and Supply Company in Chicago, Illinois. The person behind the counter would not negotiate on price in spite of showing him that the hand-crank assembly needed repair. I left the store without it. Three years later I returned and found it again, but this time it was tucked away and on display backwards in a corner of the showroom. The proprietor gave it to me for almost half off the asking price.

It didn't take much to reseat the hand-crank

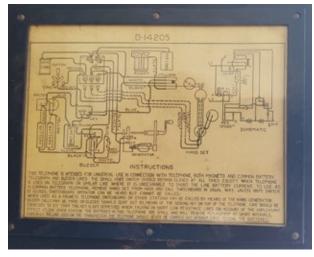
assembly. Now, if you happen to be holding onto the output while the crank is turning, you'll receive a quick lesson on the meaning of ringing out a circuit. In the pictures you can see that besides the telephone handset there is also a telegraph key. A schematic and a screwdriver are housed inside the top cover. The schematic shows auxiliary condensers (capacitors) used to integrate this unit into a larger telecommunications network. There are many references and pictures online that show equipment like this being used in various wars during the nineteenth and early twentieth centuries. Finding this device in such good condition was an absolute bonus to me. Not only was its original leather strap in place, its conveniently placed screwdriver was there too. These accessories are typically the first bits of ephemera that get separated from kit of this sort. While researching this piece prior to writing about it, I was surprised to find that the next serial number down from this specific unit is currently for sale on Ebay, minus its own screwdriver. I'm tempted to buy it so that I can give myself a call.

The Kellogg Switchboard and Supply Company was founded in 1897 by Milo Kellogg. In 1897, Alexander Graham Bell's patent for the telephone expired, which allowed Mr. Kellogg to expand his



Kellogg Model 1917 Field Telephone, 1918.

IN DAYS OF OLD



Instructions and schematics of auxiliary condensers (capacitors) used to integrate the Kellogg 1917 Field Telephone into a telecommunications network.

product line to include a variety of wall-mount and portable telephones. Prior to this, the company offered telephone switchboards designed to handle large amounts of incoming and outgoing telegraphic signal traffic. As a supplier of equipment to the U.S. military, many thousands of Models 1917 were manufactured during WWI. A poling of serial numbers for surviving units listed on various websites show that more than thirty-six hundred units were manufactured between March and June of 1918. ITT Corporation purchased controlling interests in the company in 1952, after which Kellogg ITT morphed into a number of modern telecommunications entities. The company now exists as Cortelco, based in Corinth Mississippi.

Troemner Apothecary Balance

As I've said, sometimes you just never know when you'll happen upon something that will catch your eye. In 2006 I was cruising up the coast of New England with a group of boaters from our home port of Salem, Massachusetts. On the first leg of our journey we went from Salem, passed Cape Ann, and stopped for the night in Portsmouth, New Hampshire. The next morning there was a flea market within walking distance of the place we had docked for the night, so my wife and I stopped in to take a look around. I could not believe the improbability of finding a working Troemner apothecary balance, possibly made before the beginning of the twentieth century.

Henry Troemner and his products were well regarded in his time. The discovery of gold in California during 1848 was a tremendous boon to his company. Along with many thousands of commercial balances and scales, the Troemner company also made gold bullion balances and scales for the United States mint in Philadelphia, the San Francisco mint, and the Department of Treasury. The unit pictured below is an example of a high-quality instrument that has maintained its accuracy for more than one hundred years after it was made. I can't actually ascribe a date to this particular unit. The only internal clues I can find are recorded in pencil under the top panel. Inside, the inscription reads: "F. Greiss, Maker, Phila. PA." Company history files show that Henry Troemner began making scales and balances with a partner in



Troemner Apothecary Balance, date unknown.



IN DAYS OF OLD

Philadelphia, PA in 1840. He began making them under his own name in 1844. What have I actually uncovered here? The label on the outside of the case says "Henry Troemner, Marker, Philadelphia, PA." Was F. Greiss an original partner in what became the modern Troemner company? If so, that would push my estimates of the age of this balance by a few decades.

I have seen similar beam and armature assemblies inside much older Troemner balances than what my first estimates of the age of this specimen was. My best guess before I opened it up had been somewhere between 1895 and 1905. But now? It may be significantly older. By 1910 the company was using labels that show model and serial numbers on their products. I will have to keep searching for clues to put a finer point on a date for this piece. Any help from the outside world would be greatly appreciated.

Visibility and Light Meters

There was another time when knowing a bit more about what a seller had than they did, paid off well for me. The person that I bought the instrument depicted below from thought it was some kind of picture viewing device that no longer worked.

It is actually a Visibility Meter designed by Matthew Luckiesh and Frank Moss, both of whom worked together in the 1930s when Mr. Luckiesh was the director of General Electric's Lighting Research Laboratory located in East Cleveland, Ohio. This device uses Neutral Density (ND) filters that are manually adjusted until an image or task is no longer visible. The observer then looks at the adjustable scale on the side of the instrument to determine the approximate light level recommended to properly illuminate a particular scene. This specific unit was manufactured in one of the first production runs, as its case has PAT.APPL.FOR. embossed on the lower left, front side of the instrument. That would put an approximate date of manufacture for this device at about 1935-1936. While we are on the subject of light measurement, let's dive a little deeper.

Illumination as a field of study has been with us for centuries. In ancient times, strategically placed light houses positioned along the world's coastlines have saved countless lives and the fortunes of many. The foot-candle is a parameter that was originally powered by whale oil. Measuring light with any degree of repeatable accuracy is a much more recent innovation. In the 1870s, the light sensitive properties of selenium were discovered, which paved the way for the development of modern photocells. This discovery happened at a very fortuitous time as the world was on the edge of electrical illumination. Light meters using selenium-based photocells became available to the general public in the 1930s with the development of products like the Weston Model 603.

Notice that the photocells of this unit are green (photo on the following page). They were designed to have their best frequency response at 550 nm (nano-meters). This coincides with the typical frequency response of the human eye which is centered in the green region of the visible light



Visibility Meter, 1935-1936.

IN DAYS OF OLD



Weston Model 603 Light Meter with originally colored photocells, circa the1930s.

spectrum. Unfortunately, these photocells were very fragile and often small amounts of air entering into the photocell's structure will cause them to oxidize and lose their original color. They also generally deteriorate with age. Of the Weston Model 603s in



Weston Direct-Reading Ohmmeter

my collection, all of them still measure light, but those with non-oxidized, green photocells exhibit the best frequency response and sensitivity.

Many people ask how old a piece of equipment is when I show them something of particular interest. Often, people also want to know how different parameters were measured prior to the advent of the various display technologies in use today, or before software became ubiquitous for that matter. This is a subject that has always fascinated me. My opinion on which of my instruments is my "favorite" has changed many times over the years. A strong contender has always been this Weston directreading Ohmmeter made in 1921 (photo to the left).

I think what draws me to this unit is that its range-changing brass peg is still with the unit. By connecting it to an old-fashioned dry-cell battery, it still measures resistance across all three of its ranges accurately. When I open a piece of equipment for the first time, whether for repair, restoration, or for research, I am continuously surprised and often humbled by the innovations that were created in what we now refer to as "the days of old." The people designing and using these instruments back then were truly advancing the state of our art.

Dan Wiswell (dcwiswell@aol.com), is a selfdescribed Philosopher of Metrology and President/ CEO of Amblyonix Industrial Instrument Company in North Billerica, Massachusetts.

NEW PRODUCTS AND SERVICES



New Low-Frequency Waveguide Standard Gain Horns Are Tailored for Test and Measurement

IRVINE, Calif. –Fairview Microwave, an Infinite Electronics brand and a leading provider of RF, microwave and millimeter-wave products, has announced the launch of its new low-frequency waveguide standard gain horns, designed specifically for test and measurement applications.

The new line is well suited for characterizing antennas and wireless systems. Models are available in WR-510, WR-650 and WR-770 sizes, both 10 dBi and 15 dBi gain options, and type-N female connectors.

The waveguide standard gain horns support frequency ranges down to 320 MHz, addressing a significant gap in the market for low-frequency testing solutions. With frequency options extending up to 2.20 GHz, the product line offers exceptional versatility, allowing users to select the right configuration for their specific needs.

The horns are built for durability and long-lasting performance, even in challenging environments. They are constructed from high-grade aluminum and finished with a corrosion-resistant powder coating. They provide consistent gain versus frequency, making them reliable tools for engineers and technicians seeking accurate and repeatable measurements.

"Our new waveguide standard gain horns deliver exceptional low-frequency performance and consistent gain, giving engineers the precision and reliability they need for accurate test and measurement applications," said Senior Product Line Manager Kevin Hietpas.

The new low-frequency waveguide standard gain horns are in stock and available for same-day shipping. For inquiries, please call +1 (972) 649-6678.

Mahr Introduces New MarSurf CD 140 AF Contour Measuring Machine

PROVIDENCE, RI – August 13, 2024 – Mahr Inc., a leading provider of dimensional metrology solutions, announced a new solution for contour measurement. A space-optimized measuring station for the production environment, the MarSurf CD 140 AF contour measuring machine features a user-friendly design and advanced capabilities that allow for simple measurement routines and reliable results for quality assurance.

Key features of the MarSurf CD 140 AF contour measuring machine include its unique probe system with a functional arm length of 350 mm (13.78 in). This probe system enables quick changes of stylus tips that don't require any tools or recalibration. Automatic measuring force selection guarantees that the correct force is selected for enhanced accuracy. Additionally, MarWin software allows for simple and repeatable program creation or just one-off measurements. The base is equipped with carrying handles for easy transport and handling.

The MarSurf CD 140 AF also includes a long 140mm measuring X-axis and boasts a positioning speed of up to 200 mm/s (7.87 in/s). This high-accuracy axis ensures reliable measurements, saving time and increasing efficiency.

With its flexible, height-adjustable clamping stand, the MarSurf CD 140 AF can measure many different kinds of workpieces, making it suitable for a wide range of measurement tasks. The stand also offers a flexible mounting plate with a 25 mm hole pattern grid for standard fixturing components, removing the need for an additional staging area and enabling a short measuring loop to positively impact cycle time. The machine also optionally offers the capability for roughness measurements (Ra >2 μ m).

"The MarSurf CD 140 AF sets a new standard for comprehensive contour measurement, providing unparalleled speed and simplicity in the production environment," said Pat Nugent, Vice President, Product Management at Mahr. "It is designed to streamline the contour measuring process, offering fast and precise measurements along with incredible versatility."

For more information, visit www.mahr.com



NEW PRODUCTS AND SERVICES

DCP Test Station for UV LED Radiant Power Measurement

Amesbury, MA, September 2024 — The DCP-Differential Continuous Pulse test station includes Gigahertz-Optik's TV-UV10 (https://www.gigahertz-optik.com/en-us/product/ dcp-led-test-station/) fluorescence-free Integrating Sphere Spectroradiometer, Vektrex's pulsed SMU Source/Measure Unit with the DCP method of measurement implemented in supplied application software or as a Python tool.

The test station meets the requirement for testing UV-A, UV-B, and UV-C LEDs with short pulses. In fact, the Vektrex SMU was used extensively in research that led to the development of the ANSI/IES UV-LED Measurement standard, LM-92-22 and currently ongoing CIE TC2-91.

LM-92-22 specifies pulses of 10 μ s and 20 μ s, and the DCP test method. The fast μ s pulse currents are produced by the SMU, captured by the TVUV10's100 mm fluorescence-free integrating sphere (25.4mm aperture) and measured by its fast UV optimized spectroradiometer BTS2048. Despite its compact size, the BTS2048 features a BiTec Sensor with back-thinned TE cooled CCD (2048 pixels, 0.8 nm optical resolution, electronic shutter) and SiC photodiode.

The current is swept automatically within the desired range and the full scan done within seconds to minutes, either run with a Python script or in the S-BTS2048 application software.

The DCP method's minimal heating keeps the LED junction close to the external ambient temperature, eliminating the need to calculate temperature shift, making DCP a natural choice for UV LEDs. IES LM-92 presents the DCP technique in detail, including tables that provide specific requirements for the pulse widths to be used for various current levels. The standard also details techniques for determining the correct forward voltage (necessary when plotting I-V curves) when the transient voltage effect is present.

Note that a peculiarity of quasi monochromatic LED optical radiation must be considered when designing integrating sphere spectroradiometers for UV LEDs. The monochromatic UV radiation of the LED causes fluorescence of the integrating sphere coating which leads to significant measurement errors that cannot be compensated by conventional correction methods. This DCP test system is based on the know-how of our fluorescence-free TVUV10 UV LED measurement system.

Gigahertz-Optik's ISO/IEC/EN 17025 optical radiation calibration and test laboratory provides traceable calibration of the TFUV10-V01 system. Unaccredited factory level calibrations are handled in the calibration laboratory using the same quality management procedure which applies to NMI accredited test measurements. NMI accredited testing measurements with an ISO/IEC/EN 17025 testing certificate are optionally available. Optional calibration standards for the DCP test station for recalibration by the user are also available.

Contact us today to discuss your standard or specialized light measurement application at 978-462-1818 - **info-us@** gigahertz-optik.com

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Brea, Calif. – Additel Corporation introduces a new and unique line of pressure gauges specifically designed to replace traditional analog dial gauges in an affordable digital format. These cutting-edge pressure gauges provide users with the latest in digital pressure measurement technology packaged in a durable stainless-steel housing at an extraordinary value. This new addition to Additel's gauge lineup utilizes years of Additel's home-grown pressure measurement expertise and customers feedback to improve on the traditional way many industries measure, record and monitor pressures. The ADT601Ex has been designed with ease of use, durability, and simplified maintenance in mind.

The new ADT601Ex is Intrinsically safe and comes ATEX certified from our headquarters in Brea, CA. These gauges also comply with IP67 standards ensuring that they are up to the task in the most demanding environments. With ranges from vacuum to 15,000 psi (1,000 bar) and configurations for a wide range of thread types, customers will find that these new gauges versatile and affordable. Each gauge comes standard with a certificate of conformity to an accuracy of 0.5% FS (full span). Bluetooth communications and compatibility with Additel Software as well as Additel's Link app coupled with a large easy-to-read and backlit display and extended battery life will keep end users informed and confident in the measurement captured by these new and improved gauges.

Product Availability

These new lines of Additel Pressure Gauges are available now. For more information visit: https://additel.com/ product-detail.html/601Ex-digital-pressure-gauge/ 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



Don't Run Your Calibration Lab Like Blockbuster

Michael L. Schwartz Cal Lab Solutions, Inc.

One of the quotes I love is by Henry Ford: "If I asked my customers what they wanted, they would have said faster horses." Another quote is from Neil deGrasse Tyson: "In the 1900s, horses were everywhere; by 1920, you couldn't give a horse away."

These two quotes, with the title "Don't run your calibration lab like Blockbuster," highlight the coming changes to the calibration industry. Digitization is coming, and these changes will change how we do business. Most importantly, these changes will happen fast, and any calibration that is slow to adapt will be left in the past.

There has been a lot of talk about "digital transformation." This is more than simply going paperless or giving your customers a thumb drive with all their calibration certificates on it.

The digitization of the metrology market will fundamentally change a calibration lab's business operations. Labs that don't keep up with technology will be left behind.

I use Blockbuster as an example because Blockbuster's failure serves as a cautionary tale for businesses that fail to adapt to changing market conditions. Despite being a dominant force in the home video rental industry for decades, Blockbuster failed to recognize the potential of streaming services like Netflix. The company's downfall highlights the importance of staying ahead of technological advancements and meeting customers' evolving needs.

Just like horses in the 1900s, you can't find a Redbox and I haven't watched a DVD from Netflix in years. In under 20 years, the market shifted from renting DVDs to streaming.

We are going to see the same kind of shift in the calibration lab. Getting an item calibrated is expensive, and the expense can be tied directly to the equipment used and labor. Changing the required hardware is difficult. The reference standards required for a calibration are expensive, and replacement hardware is not often available at a lower cost. This leaves labor as the only remaining area a lab can focus on to cut costs. But the only way to reduce those costs is to automate the calibration or simply test fewer test points with every calibration-that is if you are still running your lab in the older, Blockbuster-type paradigm.

What if you could get out of the Blockbuster-style lab operations and think new and differently.

Technology is now becoming available that would allow customers to select what they want tested on a UUT. This would allow them to select the test points they need for traceability based on how they use the equipment. This could reduce the calibration cost by as much as 90% because very few pieces of test equipment get used to 100% of their functions and range.

Then, what if those customselected test points could be automated without a programmer writing a custom calibration script for every customer's unique selection of test points?

If you told me in 1990 that I would be streaming all my TV shows and movies over the internet, I would have said, "Yeah, right."

On-demand streaming in 1990 wasn't yet available, so Blockbuster was king while we still needed a physical cassette or DVD. But technology changed, which is precisely what is happening now with the digitization of metrology.

When I told one of my customers we could increase his lab's throughput by not testing what the customer doesn't need tested. He replied, "Yeah, Right. How would you manage that?" I replied that technology is changing; this is just one of the things possible with digitization.

Digital transformation is not a luxury but a necessity for calibration labs to survive in the future. By embracing technology, labs can enhance their efficiency, provide superior customer service, and secure their place in the everevolving metrology landscape. It is time to get involved in the Digital Revolution!



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