METROLOGY AND ITS IMPACT TO THE CLINICAL LABORATORY COMMUNITY

WEBINAR BY

Asia Pacific Metrology Programme
Technical Committee for Amount of Substance

DATE
20 September 2024

TIME
UTC 4:00 TO 7:00

PLATFORM
ZOOM

REGISTRATION LINK
https://go.gov.sg/apmpwebinar2024
Please register your interest by 16 August 2024

PROGRAMME

Introduction and Opening Address
Dr Byungjoo Kim, Chair, APMP TCQM, KRISS, Republic of Korea

Importance of Metrological Traceability and CRMs for Laboratory Medicine
Dr Tony Badrick, President, Asia Pacific Federation for Clinical Biochemistry and Laboratory Medicine / CEO, Royal College of Pathologists of Australasia

Certified Reference Material for Clinical Measurement (connecting with requirements of ISO 17034 and guidelines in ISO 33405:2024)
Dr Mark Lewin, NMIA, Australia

Importance of Commutability of Clinical Certified Reference Materials
Dr Liqing Wu, NIM, China

Beyond Measurements: Development of the National Standard Reference Data – Korean Health Index
Dr Ji-Seon Jeong, KRISS, Republic of Korea

Organising Accuracy-Based EQA Programmes and its Impact on Regulation
Dr Qinde Liu, HSA, Singapore

Ensuring Accurate Diagnosis: How NIMT Standardises Clinical Measurements in Thailand
Dr Jintana Nammoonnoy, NIMT, Thailand

About

Asia Pacific Metrology Programme (APMP)

The APMP is a grouping of metrology institutes (national metrology institutes and designated institutes) from the Asia-Pacific region engaged in improving regional metrological capability through the sharing of expertise and exchange of technical services among member institutes.

The APMP is one of the six Regional Metrology Organisations (RMOs) to implement the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA) for the worldwide mutual recognition of measurement standards and of calibration and measurement certificates.

It is also one of the Specialist Regional Bodies (SRBs) working with the Asia Pacific Economic Cooperation (APEC) to facilitate the development and implementation of standards and conformance infrastructures that addresses APEC goals.

Technical Committee for Amount of Substance (TCQM)

The TCQM is one of the 12 technical committees within APMP. It is responsible for developing and improving the equivalence of national reference systems for chemical and biological measurements. The TCQM is also responsible for initiating and monitoring the TCQM comparison programmes and ensuring that these link to the international comparison programmes conducted through the CIPM Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM).

For more information about APMP, please visit: https://apmpweb.org/

APMP TCQM CHAIR

DR BYUNGJOO KIM

PRINCIPAL RESEARCH SCIENTIST, KOREA RESEARCH INSTITUTE OF STANDARDS AND SCIENCE (KRISS), REPUBLIC OF KOREA / PROFESSOR, UNIVERSITY OF SCIENCE AND TECHNOLOGY (UST) / CHAIR, APMP TCQM

Dr Byungjoo Kim is currently a principal research scientist in KRISS, Daejon, Korea. He received his B.Sc. (1988), M.Sc. (1990) degrees in Chemistry from Seoul National University, and Ph.D. (1995) in Chemistry from Brown University, Rhode Island, USA. He held the position of Post-Doctoral Research Associate at the Department of Chemistry, University of California, Santa Barbara from January 1995 to December 1996. He joined KRISS in 1997 and has worked there since then. In KRISS, Dr Kim's research has been focused on establishing national standard system in organic analysis area, including developing methodologies for purity assay of primary reference materials, preparation/verification of primary standard solutions, and isotope dilution mass spectrometry (IDMS) based on GC/MS and LC/MS. His current research is focused on the development of IDMS methods and certified reference materials in food safety area, especially for the measurement of mycotoxins and veterinary drug residues.

Dr Kim served as the President of the Korean Society for Mass Spectrometry (KSMS) in 2022 & 2023. He is the current Chair of APMP's Technical Committe for Amount of Substance (TCQM).

ORGANISER AND HOST

DR TANG LIN TEO

DIVISION DIRECTOR, HEALTH SCIENCES AUTHORITY (HSA), SINGAPORE / CHAIR-ELECT, APMP TCQM

Dr Teo obtained their Ph.D. in Chemistry from the National University of Singapore in 2007. After a short period of teaching, she joined HSA in 2008, initially as a forensic scientist for six months before joining the pioneering team which established the chemical metrology programme in HSA. Dr Teo leads the chemical metrology division in HSA since 2021.

Dr Teo served as APMP Executive Committee member between 2019-2023 and as Peer Reviewer/Leader of Peer Review Team on 5 occasions. Dr Teo is currently the Co-Convenor of the joint Proficiency Testing Working Group formed as a result of a long-standing MOU between APMP and the Asia Pacific Accreditation Cooperation (APAC). She is also a member of the CCQM Key Comparison & CMC Quality Working Group and member of the Executive Committee of Cooperation on International Traceability in Analytical Chemistry (CITAC). In Singapore, she is actively involved in standards and conformity activities, serving as Council Member of the Singapore Accreditation Council (SAC), Deputy Chair of Technical Committee on Conformity Assessment (CASCO), Co-Convenor/Singapore's head of delegation for the national mirror working group on ISO TC 334, and Technical Assessor for SAC.

SPEAKER

DR TONY BADRICK

CHIEF EXECUTIVE, THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA (RCPA), AUSTRALIA

AM, BAppSc, BSc, BA, M Lit St (Math), MBA, PhD (QUT), PhD (UQ), FAIMS, FAACB, FACB, FAIM, Member Aust Maths Soc, FRCPA (Hon), FFSc(RCPA), GAICD.

Dr Badrick is the CEO of the RCPA Quality Assurance Programs; Adjunct Professor at the School of Pharmacy and Pharmacology, Griffith University, Honorary Associate Professor at the National Centre for Epidemiology and Public Health ANU College of Health and Medicine and ANU College of Science, Honorary Associate Professor, Faculty of Medicine, Bond University, Gold Coast, Visiting Fellow, Australian Institute for Health Innovation, Macquarie University. He is president of the Asian Pacific Federation of Clinical Biochemistry and Laboratory Medicine, a member of the Executive Board of the International Federation of Clinical Chemistry, and the Chief Examiner of the Faculty of Science of the Royal College of Pathologists of Australasia.

ABSTRACT

IMPORTANCE OF METROLOGICAL TRACEABILITY AND CRMS FOR LABORATORY MEDICINE

Clinical laboratory results are required for the diagnosis and treatment monitoring of many diseases. These processes involve either comparing a patient's result against a clinical decision level for diagnosis, comparing the result against a reference interval from a ‘non-diseased’ population, monitoring changes in a patient’s results over time with treatment, or relying on clinical experience of biomarker results and other clinical signs and symptoms. In every case, the result interpretation depends on consistency and, therefore, the traceability of the results. However, because of the problems with the definition of some measurands and, consequently, because of the lack of CRMs or RMs, traceability has not been achieved for a significant number of analytes in laboratory medicine.

The presentation will highlight the successes and problems in applying traceability in laboratory medicine.

SPEAKER

DR MARK LEWIN

TECHINICAL AND DEVELOPMENT MANAGER, NATIONAL MEASUREMENT INSTITUTE, AUSTRALIA (NMIA)

Dr Lewin has over ten years' experience in a commercial contract laboratory as a research and development chemist performing analyses of priority pollutants, pesticides, veterinary drugs, and client specific analytes under ISO 17025 accreditation and OECD GLP recognition. Since starting at NMIA in 2017, Dr Lewin has been responsible for the provision of reference values for proficiency testing programs and the certification of reference materials for small molecule organic analytes in environmental, food, and clinical matrices.

ABSTRACT

CERTIFIED REFERENCE MATERIAL FOR CLINICAL MEASUREMENT (CONNECTING WITH REQUIREMENTS OF ISO 17034 AND GUIDELINES IN ISO 33405:2024)

Certified reference materials (CRMs) in the clinical sector are vital to ensure that results from laboratories are reliable, comparable, and metrologically traceable. Requirements for certification are defined in international standards including ISO 17034 and ISO 15194, and adherence to these standards is important to produce high quality, fit-for-purpose materials.

In addition to adequate planning and production control, the certification process requires that the material be characterised for each property value assigned. Characterisation may use one or more reference measurement procedures or other methods of demonstratable accuracy and involve a single laboratory or a network of competent laboratories. Each CRM must also demonstrate adequate homogeneity and must be assessed for transport and long term stabilities, and the extent of commutability. The uncertainty associated with each property value of a CRM must be evaluated and appropriate for the intended use of the material.

CRMs are accompanied by a certificate of analysis informing the user of each property value and associated uncertainty, intended use, handling and storage requirements, and an expiry date. The use of CRMs as either calibrators, as part of validation, or as ongoing quality control, contribute to the reliability of laboratory results and therefore to better decision making and improved clinical outcomes.

SPEAKER

DR LIQING WU

RESEARCH FELLOW, NATIONAL INSTITUTE OF METROLOGY (NIM), CHINA

Dr Wu received his Ph.D. degree in bio-analytical chemistry from Peking University in China in 2005. He came to National Institute of Metrology after he graduated and became the group leader of protein measurement team in 2012. His research interests include developing higher order measurement procedures for protein quantitation and protein activity measurement, and developing protein CRMs used in in-vitro diagnostics. He has published over 60 scientific papers, obtained 12 national invention patents, and developed over 10 CRMs. He served as the Convenor of Biological Working Group of the Asian Collaboration on Reference Materials (ACRM) since 2015 to 2017, and has been appointed as Vice-Chair of the Protein Analysis Working Group of CCQM since 2024.

ABSTRACT

IMPORTANCE OF COMMUTABILITY OF CLINICAL CERTIFIED REFERENCE MATERIALS

This presentation explores the concept of commutability of certified reference materials (CRMs), which is essential for ensuring consistent responses across different measurement procedures. It discusses the challenges associated with achieving commutability and outlines the criteria set by the Joint Committee for Traceability in Laboratory Medicine (JCTLM) and ISO 17511 for evaluating CRMs. Also, the presentation emphasizes the significance of commutability in the development and application of CRMs in clinical area. With practical examples, it reviews various methods for assessing commutability, highlighting their respective advantage and weaknesses. Finally, it presents ongoing efforts to improve the commutability of CRMs, and underscoring its critical role in clinical diagnostics.

SPEAKER

DR JI-SEON JEONG

PRINCIPLE RESEARCH SCIENTIST, KOREA RESEARCH INSTITUTE OF STANDARDS AND SCIENCE (KRISS), REPUBLIC OF KOREA

Dr Jeong pursued her undergraduate major in Oriental Pharmaceutical Science at the College of Pharmacy, Kyung Hee University, Republic of Korea. Additionally, she obtained her PhD and PharmD at the same university, specializing in Natural Products Chemistry. Dr Jeong's research primarily focused on developing analytical methods for polar and small molecules of physiological and nutritional biomarkers in both clinical samples and natural products. In 2012, Dr Jeong joined KRISS, specifically the Bio-metrology Group, where she contributed to the development of reference measurement procedures and CRMs for the quantification of proteins and clinical diagnostic markers. She transitioned to the Organic Metrology Group from 2023, where her work centers on developing measurement standards for small molecules in clinical samples. This includes not only clinical biomarkers but also environmental hazardous substances.

ABSTRACT

BEYOND MEASUREMENTS: DEVELOPMENT OF THE NATIONAL STANDARD REFERENCE DATA – KOREAN HEALTH INDEX

Korea is one of the welfare-fortified countries with a well-established national healthcare system throughout life, from pre-birth. Particularly, nationwide general health checkups have been promoted for active health management at the prevention level, at least every two years, for all citizens over 20 years old. These checkups contain not only general health assessments but also cancer screenings. Consequently, a tremendous amount of measurement data has been gathered as national resources. To utilize the value of this collected data, KRISS designated a Big Data team within the National Health Insurance Services to establish the Standard Reference Data (SRD) center for developing the National SRD, named the Korean Health Index, in 2015. Thus far, ten SRD sets have been developed with representative clinical biomarkers such as glucose, creatinine, total cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, total hemoglobin, aspartate aminotransferase, alanine aminotransferase, and gamma glutamyl transpeptidase. Among them, five SRD sets have been qualified for traceability to SI, with certified reference materials provided by KRISS.

This talk introduces the entire process of developing SRDs from various laboratory testing data sources, including defining measurand definitions, establishing data acquisition criteria, outlining measurement procedures, evaluating uncertainty, and assessing reliability of each SRD. It emphasized the importance and priority of measurement traceability in modern laboratory testing for enhancing data quality and unlocking new value from them as novel social resources beyond mere measurements.

SPEAKER

DR QINDE LIU

CONSULTANT SCIENTIST, HEALTH SCIENCES AUTHORITY (HSA), SINGAPORE

Dr Liu is a Consultant Scientist and leader of the Organic (Clinical) Section of the Chemical Metrology Division of the Health Sciences Authority, Singapore. Dr Liu's team focuses on developing high-accuracy reference methods for health status markers in human samples. Other interests of Dr Liu's team are purity assessment of amino acids, peptides, and proteins as primary calibration standards and development of clinical certified reference materials. Dr Liu is also one of the coordinators for the HSA External Quality Assessment Programme (EQAP) in Clinical Chemistry and the Singapore National EQAP on HbA1c Testing. Dr Liu is highly involved in the Joint Committee for Traceability in Laboratory Medicine (JCTLM), serving as the Vice Chair (Analyte Group 1) of JCTLM Database Working Group, as well as the leader of the JCTLM Non-Peptide Hormones review team and a member of the JCTLM Metabolites & Substrates review team.

ABSTRACT

ORGANISING ACCURACY-BASED EQA PROGRAMMES AND ITS IMPACT ON REGULATION

Accurate clinical measurement is essential for effective disease diagnosis and patient treatment monitoring. Participation in External Quality Assessment (EQA) programmes is crucial to ensuring this accuracy. In contrast to EQA programmes based on consensus assigned values, accuracy-based programmes make use of assigned values which are typically determined by high-accuracy reference methods. The latter are particularly vital when labs' results are used to make clinical decisions based on cut-offs.

The Health Sciences Authority (HSA) in Singapore has over 14 years' experience in organizing annual accuracy based EQA programmes for local clinical laboratories. All assigned values in these programmes were determined using high-accuracy reference methods, primarily based on isotope dilution mass spectrometry techniques. Covering 19 clinical markers associated mainly with chronic diseases (including lipid disorders, diabetes, renal failure/damage, and others), affecting majority of Singapore population, the HSA's EQA programmes play a role in ensuring measurement accuracy of the local clinical laboratories.

Notably, the HSA EQA Programme on Haemoglobin (Hb) A1c Testing has evolved into a national EQA Programme to assist Singapore's health ministry in the licencing of clinical laboratories or medical clinics reporting HbA1c for the diagnosis of diabetes mellitus as the country continues its "war against diabetes". This presentation will share insights from HSA's experience in engaging its health regulator in their journey to regularise this programme.

SPEAKER

DR JINTANA NAMMOONNOY

SENIOR METROLOGIST, NATIONAL INSTITUTE OF METROLOGY, THAILAND (NIMT)

Dr Nammoonnoy is an analytical chemist with a Ph.D. in the field from Oregon State University. Since joining the National Institute of Metrology (Thailand) in late 2011, Dr. Jintana has focused on method development for organic analysis, particularly within the field of clinical chemistry. Key areas of expertise include microfluidics, LC-MS/MS, and IDMS (Isotope Dilution Mass Spectrometry).

ABSTRACT

ENSURING ACCURATE DIAGNOSIS: HOW NIMT STANDARDISES CLINICAL MEASUREMENTS IN THAILAND

Accurate and standardised clinical measurements are essential for proper diagnosis and treatment. NIMT plays a critical role in ensuring these standards are met throughout the country. This talk will explore NIMT's contributions to Thailand's clinical measurement landscape. NIMT actively participates in key comparisons, fostering robust measurement infrastructure and ensuring the accuracy and reliability of clinical chemistry tests. They further serve as the national traceability provider for external quality assurance (EQA) programs, safeguarding the integrity of measurements across Thailand. Additionally, NIMT collaborates with reference material producers to guarantee measurement quality throughout the chain. These initiatives demonstrate NIMT's significant role in establishing standardised and accurate clinical measurements. Ultimately, these efforts empower healthcare professionals with reliable data for informed patient care decisions, potentially leading to improved healthcare outcomes.