



Pancyprian Union of Chemists
Division of Quality Assurance
Eurachem Cyprus Committee

Laboratory Accreditation

A TWO-DAY TRAINING COURSE ON THE NEW STANDARD, ISO 15189:2022 *Medical laboratories – Requirements for quality and competence*

16-17 March 2023

Cleopatra Hotel, Nicosia, Cyprus

Day 1 – Thursday 16 March 2023

09.00 - 09.30	<ul style="list-style-type: none">- Welcome addresses by Eurachem ETWG, Association of Clinical Laboratory Directors, Biomedical and Clinical Laboratory Scientists and PUC (Division of Quality Assurance)- Presentation of the tutors and the participants- Introduction – Scope and expectations of the training- <i>Short video</i>
09.30 - 10.15	<ul style="list-style-type: none">- The new standard; what is changing- Comparison with the 2012 version (in brief)- The structure of the standard - Terminology- The new provisions - An introduction – POCT requirements- Transition to the new standard- Laboratory activities - Scope of accreditation
10.15 - 11.00	<ul style="list-style-type: none">- General requirements- Structural and governance requirements
11.00 - 11.30	Coffee break
11.30 - 12.30	- Resource requirements – Personnel – Facilities – Equipment
12.30 - 13.00	- Process requirements
13.00 - 14.00	Lunch break
14.00 - 14.45	- Metrological traceability - ISO 17511 (<i>Elvar Theodorsson</i>)*
14.45 - 15.15	- Regulation <i>in vitro</i> diagnostics (<i>Elvar Theodorsson</i>)*
15.15 - 15.30	Coffee break
15.30 - 16.15	- Technical requirements: Steps to be followed by laboratories (<i>Irini Leimoni</i>)
16.15 - 16.45	- Exercise 1
16.45 - 17.15	- Discussion on Exercise 1
17.15	End of Day 1
20.00	Dinner

Day 2 – Friday 17 March 2023

09.00 - 09.30	- Discussion on Exercise 1
09.30 - 10.00	- Control of data and information management
10.00 - 10.30	- The management system - Options A and B
10.30 - 11.00	- Risks and opportunities
11.00 - 11.30	Coffee break
11.30 - 12.00	- Measurement uncertainty (Mike Ramsey)*
12.00 - 12.30	- Uncertainty arising from sampling (Mike Ramsey)*
12.30 - 13.00	- Exercise 2
13.00 - 14.00	Lunch break
14.00 - 15.00	- Discussion on Exercise 2
15.00 - 15.30	Coffee break
15.30 - 16.00	- Management requirements: Steps to be followed by laboratories (Irini Leimoni)
16.00 - 16.30	- Genetic Epidemiology of SARS-CoV-2 Infection in Cyprus (Leontios Kostrikis)
16.30 - 17.00	Discussion - Concluding remarks - Handing over of certificates
17.00	End of the training course

Notes:

**To be presented virtually*

Kyriacos Tsimillis and Despina Charalambous will be the two tutors to present the requirements of the new Standard

The trainers...

Irini Leimoni

Irini studied Biology in the University of Athens and received a PhD in Biology (Biochemistry) from the same University. The main topic of her thesis was the purification and study of a specific for poly (U) and poly (C) Ribonuclease from human tissues. She worked as Biochemical Analyst and member of Technical Management Group and Quality Manager in the Central Clinical Laboratory of Euromedica S.A, Athens, Greece (2002-2009). From April 2009, she joined AFFIDEA as Director of Laboratories Development and Quality Assurance Officer. In the frame of this position she worked for the development of Clinical Laboratories in several towns of Greece. Since 2016, she is working as Country Quality Manager, Country Data Protection Officer and Member of the Clinical Governance Committee in AFFIDEA Greece. As from 2008, after special training and evaluation, she joined the Hellenic National Accreditation Body (ESYD), as an Assessor and later (2011) as a Lead Assessor for Clinical Laboratories (ISO 15189). In the frame of this role, she



participated in the assessment of more than 350 clinical laboratories in Greece, Albania and Cyprus. She is also Assessor of ESYD for ISO/IEC 17043 and ISO/IEC 17025. Since 2017 she is elected member of the executive council of the Hellenic Society of Clinical Chemistry-Clinical Biochemistry. She is also a corresponding member of the Working Group of EFCC for the Biological Variation.

Mike Ramsey

Mike Ramsey is a Fellow of the Royal Society of Chemistry and has been a Professor at University of Sussex for 20 years, now in an Emeritus capacity. After a PhD in Analytical Geochemistry, he conducted research and lectured at Imperial College, London for 20 years. He's published over 170 scientific papers, including many on uncertainty of measurement arising from primary sampling, and its effects on decision making. Mike is Chair of the Eurachem/Eurolab/CITAC/Nordtest/AMC Working Group on Uncertainty from Sampling, which has published International Guidance on this subject. Broader research included UK-NERC-funded project on Multiple Links Towards Integrating Teams for Understanding of Disease and Environment - MULTITUDE. He was also chair of the European Section of Society for Environmental Geochemistry & Health 2005-2008. e-mail : m.h.ramsey@sussex.ac.uk



Elvar Theodorsson

Elvar Theodorsson was born in 1953 in Reykjavik, Iceland and received his M.D. degree in 1978 from the University of Iceland and license as a specialist in clinical pathology (Clinical Chemistry) in 1985. He gained his Ph.D. degree from the Department of Pharmacology, Karolinska Institute, Stockholm in 1983 and became an associate professor at the Karolinska Institute in 1986 and Professor of Neurochemistry at the University of Linköping in 1995. His main research interests include the neuroendocrinology of regulatory peptides and neurosteroids and applied metrology in Clinical chemistry. <http://orcid.org/0000-0003-0756-7723>



Leondios Kostrikis

Leondios Kostrikis is a Professor of Biological Sciences at the University of Cyprus and Head of the Laboratory of Biotechnology and Molecular Virology. He received his *B.Sc.* (1987), *M.Sc.* (1989), *M.Ph.* (1990) and *Ph.D.* (1993) degrees from New York University (NYU), United States (USA). This was followed by post-doctoral research at the Aaron Diamond AIDS Research Center of Rockefeller University (New York) on the molecular virology of Human Immunodeficiency Virus. He joined the faculty of the Aaron Diamond AIDS Research Center (ADARC) as a Staff Investigator in 1998 and the Rockefeller University as an Assistant Professor in 1999. He returned to Cyprus in 2003, joining the University of Cyprus. He was a Fulbright Scholar for his undergraduate studies in the US and received scholar awards from the Elizabeth Glazer Pediatric AIDS Foundation, the Aaron Diamond Foundation and the Patti Cadby Birch Trust in the USA. In 2005 he received an Honorary Distinction from the J. William Fulbright Foreign Scholarship Board, USA for his accomplishments which have contributed to the betterment of the world. He was among the forty



Fulbright scholars selected from 250,000 Fulbright alumni from 140 countries since 1946. He is an Editorial Board member for thirteen international journals, and has served on numerous study sections and committees for European and international grant agencies and charities. He is a cofounder of the European Society for Translational Antiviral Research (ESAR), the founder of the Cyprus HIV-1 Transmission Cohort Study (CHICS) and a scientific member of the global WHO-UNAIDS Network for HIV Isolation and Characterisation. In 2019, he was elected as a Founding Member (Biological Sciences) of The Cyprus Academy of Sciences, Letters and Arts and in 2020, he was elected as Member of the Biosciences Steering Panel of the European Academies Science Advisory Council (EASAC) and as a Distinguished Fellow of the International Engineering and Technology Institute (IETI).

Despina Charalambous

Dr. Despina Charalambous studied Chemistry at the University of Cyprus and she continued her studies with MSc Molecular Medicine at Imperial College London. She was accepted at the University of Cyprus at the Department of Biological Sciences for her PhD in Molecular Biology. She worked as a Lab Manager in private accredited laboratories in Nicosia. Since 2013, Dr. Charalambous is working as a Lecturer in the Department of Pharmacy at Frederick University. She teaches the undergraduate courses of Food Chemistry and Nutritional Analysis, Molecular Biology and Pharmaceutical Biotechnology as well as the lab courses Molecular Biology, Microbiology, Food Chemistry and Nutritional Analysis, Pharmaceutical Biotechnology and Biochemistry. Dr. Charalambous's research interests focuses on neurodegenerative diseases and the role of pharmaceutical agents in the progress of the diseases, including natural products. She is a member of the Pancyprian Union of Chemists and the Society of Biological Sciences. Since 2016, she is an external collaborator of CYS (Lead Assessor for ISO 15189:2012 and ISO/IEC 17025:2017).



Kyriacos Tsimillis

Kyriacos holds a BSc and a PhD in Chemistry (University of Athens - 1971, 1977). Postgraduate studies at the Nuclear Research Center "Demokritos" (1972-1975). Lecturer at the Physical Chemistry Department of the University of Athens (1975-1980), he was involved in standardization and certification activities in Cyprus for twenty years followed by twelve years in accreditation until his retirement (December 2013). He was the Coordinator (2005) and as from 2009 the Director of the Cyprus Accreditation Body (CYS-CYSAB). He represented CYS-CYSAB in EA and was a member of peer evaluation teams of EA (2013-2014). Since 1997 he represents the Pancyprian Union of Chemists in Eurachem, including a two-year period as its Chair (2008-2010) and for many years as a member of the Executive Committee; he also represented Cyprus in Eurolab and the Euromed Quality Programme. He is the author of research papers and a co-author in books on Quality. He was an invited speaker in seminars, workshops and conferences. He organized a lot of training activities and awareness events. Since 2014 he is a member of the Division of Quality Assurance of the PUC.

