



Workshop on Implementing Risk-based Thinking and Decision Rule as per MS ISO/IEC 17025:2017 Requirements

22 & 23 July 2019
(2 days workshop, 9am to 5pm)

Novotel Kuala Lumpur City Centre Hotel
2, Jalan Kia Peng, 50450 Kuala Lumpur

OBJECTIVES

The newly revised MS ISO/IEC 17025:2017 accreditation standard has introduced the requirements of (1) risk-based thinking in the routine laboratory operation and (2) decision rule for making a statement of conformance to a specification or compliance to a regulatory limit.

The “risk-based thinking” which requires the accredited laboratory to plan and implement actions to identify and address potential risks and opportunities associated with the laboratory activities. Also, in making a statement of specification conformity or regulatory compliance, one has to evaluate the risk of “false accept” or “false reject” in making such statement which has to take the uncertainty of measurement into account, and make decision rules which are to be discussed and agreed by the clients concerned.

To implement the above requirements effectively, an accredited laboratory operator needs to acquire some basic knowledge of probability and inferential statistics, and how to apply them.

This training workshop is specially designed to help the participant to gain an understanding of using the risks and opportunities-based approach to evaluate the routine laboratory operational risks in areas of concern such as impartiality, confidentiality, personnel, technical nature in contract review, test method deviation and validity of test results, and to make valid interpretations in specification conformity or regulatory compliance assessments.

PREREQUISITES

Familiarity with ISO/IEC 17025:2017 might prove beneficial. This workshop intends to teach participants with no previous conformity assessment experience.

PRESENTATION STYLE

The course materials are to be delivered using a combination of interactive discussions and lectures supplemented with individual and group exercises and role-playing scenarios.



THE TRAINER – MR YEOH GUAN HUAH

Mr Yeoh, a Fellow of IKM and holder of B.Sc.(Hons) and M.Sc. (Chemistry) degrees from the University of Malaya is the senior partner

of GLP Consulting (<http://consultglp.com>), a laboratory quality management consultancy and training firm incorporated in Singapore. He was the General Manager of ALS Group of Laboratories (Life Sciences Division) since 1993 and retired from the posts in November 2016.

Mr Yeoh is a trainer, appointed External Lead Assessor and TA of SAC-SINGLAS in its Chemical & Biological and Environmental fields. He has been conducting regular short courses and workshops in this region on Measurement Uncertainty (MU) Evaluation, Method Validation (MV) Techniques, Internal Audits, etc.

Mr Yeoh has represented SIRIM/DSM in the ISO Technical Committee TC69 (Application of statistical methods) in 2005-2016 involved in the working group for the development of ISO 21748, 5725 series and 13528, and, was a Convenor of its ad hoc Group AHG1 in 2007-2016.

TARGET AUDIENCE

Laboratory director, laboratory manager, quality manager who are responsible for migrating the ISO/IEC 17025:2005 version to the new standard, and in the daily implementation of laboratory quality management system.



* SUBJECT TO APPROVAL

COURSE CONTENTS

Part 1

Review the basic statistical knowledge relevant to risk assessment and decision rules

- ◆ Basic statistical and probability concepts
- ◆ Hypothesis testing; Type I and Type II errors; Consumer's and producer's risks
- ◆ Relationship between significance level and Type I error

Part 2

- ◆ Related clauses in ISO/IEC 17025:2017 standard on risks and opportunities
- ◆ Conformance testing and risks – what and why
- ◆ Identifying the risks and opportunities to a laboratory operation
- ◆ Risk assessment methods – qualitative and quantitative
- ◆ Developing a quality control plan (QCP) as a risk control tool in testing

Part 3

- ◆ Related clauses in ISO/IEC 17025:2017 standard on decision rule
- ◆ Decision rule – what, why and how
- ◆ Issues of making a statement of conformance
- ◆ Deciding on acceptable risk levels by applying the guidance of ILAC, JCGM and Eurachem

TRAINING OUTCOMES

- ◆ To appreciate that there are risks in laboratory operations
- ◆ To know the requirements of ISO/IEC 17025:2017 on risk-based thinking
- ◆ To understand the basic approaches for risk assessment and develop decision rules that mitigate the risks identified
- ◆ To apply decision rules based on the knowledge of hypothesis testing for making statements of conformity or compliance

PAYMENT METHOD

- a) Online transfer to **PUBLIC BANK ACCOUNT**

Account number: **3127731017**
OR

- b) Cheque payable to
INSTITUT KIMIA MALAYSIA

TERMS & CONDITIONS

All fees must be paid in advance after receiving our conformation letter. Letter of Undertaking is required for payment delay. No refunds will be given for cancellation received less than 07 days before the course. Substitutions will be accepted at any time.

REGISTRATION FEE:

IKM MEMBER - RM650.00 per person

NON IKM MEMBER - RM850.00 per person

Kindly contact **Ms Nurul Idayu** for further information.

Tel : **03 – 7728 3272 or 7728 3858**

Email : **ayu@ikm.org.my**

REGISTRATION DETAILS

Please register at the links below:

Single participant: **<https://ikm.org.my/single-training.php>**

Multiple participant: **<https://ikm.org.my/multiple-training.php>**



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