



2-Day Training Workshop

**Implementing Risk-Based Thinking
and Decision Rule as per
MS ISO/IEC 17025:2017 Requirements**

29 – 30 April 2019

KSL Hotel & Resorts,
Johor Bahru, Johor

HRDF CLAIMABLE

Organized by
Institut Kimia Malaysia Cawangan Selatan

Introduction

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 participants 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.

Who should attend

This training workshop will benefit :

- Laboratory Director, Laboratory Manager, Quality Manager who are responsible for migrating the ISO/IEC 17025:2015 version to the new standard, and in the daily implementation of laboratory quality management system.

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 BSc(Hons) and MSc (Chemistry) degree from University of Malaya, is the senior partner of GLP Consulting (<http://consultqlp.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 post in November 2016.

Mr Yeoh is a trainer, appointed External Lead Assessor & 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.

Course Contents

Part 1

Review the basic statistical knowledge relevant to risk assessment and decision rule :

- Basic statistical and probability concepts
- Hypothesis testing : Type 1 & Type 2 errors : Consumer's & producer's risks
- Relationship between significance level and Typr 1 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 Course 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

Fees and Payment

IKM Member	Non-IKM Member
RM 650	RM 850

Payment (cheque / internet banking) shall be made to:

Payee: **Institut Kimia Malaysia Cawangan Selatan**

Bank: **Alliance Bank**, Pelangi Branch

Account: **01130-001-001 3950**

Kindly WhatsApp Proof of Payment to: 017-716 2244 or 016-979 9858

Accommodations

Hotel Room Rate at KSL Resort Hotel Johor Bahru :

Superior Single: RM 205 nett per night with buffet breakfast

Superior Twin: RM 235 nett per night with buffet breakfast

Enquiry and Registration

All enquiries and registration should be addressed to:

Associate Prof Dr Jafariah Jaafar

Mobile : 017- 716 2244

Ms. Poo Sher Lin

Mobile: 019-979 9858

You may use the Registration Form provided or email your registration to:

ijaafar@gmail.com, or sherlin@alliedchemists.com.my,

Closing date for registration : 22nd April 2019

Registration Form

2-Day Training Workshop Implementing Risk-Based Thinking and Decision Rule as per MS ISO/IEC 17025 : 2017 Requirements

Name: _____

Organization: _____

Address: _____

Contact No (Company): _____ Mobile: _____

Email: _____

Category: IKM Member Non-IKM Member

Hotel Booking (if applicable)

Please book on my behalf hotel accommodation at KSL Resort Johor Bahru for ____ night(s).

Stay in: Superior Single / Superior Twin*

Check-In Date : Check-Out Date :

Total Registration Fees: RM

Hotel Deposit RM
(One night deposit for hotel confirmation)

Total Amount: RM

Signature: _____

Date: _____

Payment (cheque / internet banking) shall be made to:

Payee: **Institut Kimia Malaysia Cawangan Selatan**

Bank: Alliance Bank, Pelangi Branch

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