



AIDE-MEMOIRE

CAPABILITY BUILDING OF RESEARCH TECHNOLOGY ORGANIZATIONS (RTOs) IN ISO/IEC17025

PHASE I: -

Workshop and Training in ISO/IEC 17025
Shah Alam, Selangor, MALAYSIA
October 12-30, 2009

PHASE II: -

Documentation Review of Quality System of Five Selected
WAITRO-ISESCO Organizations Member Laboratories

PHASE III: -

Technical Assistance to One Chosen Organization
Laboratory to Develop Laboratory Quality System
Compliance to ISO/IEC 17025

1. INTRODUCTION

In today's competitive market climate, good business demands that products and services be designed, produced, delivered, installed and serviced under controlled, consistent and safe conditions. Many national and international regulations and standards are available to ensure that the conditions are met. Among those are the ISO 9000 and the ISO/IEC 17025.

While ISO 9000 focuses on the competence in the general service and manufacturing environment, ISO/IEC 17025, focuses on the laboratory competence.

2. THE NEED FOR COMPETENT LABORATORIES

The lack of acceptance of laboratory test data across national borders has been identified as a significant barrier to trade. The World Trade Organization has adopted two major new agreements to ensure that technical requirements do not restrict trade: the Agreement on Technical Barriers to Trade (TBT); and the Agreement on Sanitary and Phytosanitary Measures (SPS).

Asia Pacific Economic Cooperation (APEC) has given priority to conformity assessment issues. The Declaration on APEC Standards and Conformance Framework and Osaka Action Agenda confirm the intention of members to achieve mutual recognition of conformity assessment among the eighteen APEC economies in both the regulated and voluntary sectors. Activities are being coordinated through the APEC sub-committee on Standards and Conformance with direct involvement from the "specialist regional bodies", including the Asia Pacific Laboratory Accreditation Cooperation (APLAC). Other regional trade groupings are also enhancing cooperation in standards and conforming in order to facilitate trade.

Regional and international mutual recognition agreements are in place to facilitate acceptance of conformity assessment results, which include test results. These

include the International Laboratory Accreditation Cooperation (ILAC) and the Asia-Pacific Laboratory Accreditation Cooperation (APLAC).

These agreements and policies aim to avoid expensive testing. If they are to be effective, regulators and customers must be able to rely on test conducted in other countries. They need to know the status and competence of the testing laboratories supplying the data and to have independent assurance that the test results are valid.

When testing laboratory implements an internationally accepted standards such as the ISO/IEC 17025 standard, the laboratory demonstrates that it has the competence to perform the tests and the test results produced are valid. Test reports/data generated by these laboratories provide Government bodies and regulators with the confidence in order to make their decisions based on sound technical judgments. These decisions relate to industry efficiency and technological development, enforcement of regulations for safety, health, environment protection and assure consumer interests are protected.

There has also been a dramatic change in product liability litigation. The validity of product testing may be subject to legal challenge. This too has prompted interest in independent evidence of the competence of testing laboratories.

3. OBJECTIVE OF PROGRAMME

The objectives of the programme are: -

- i. To equip RTOs with the knowledge on the international standards ISO/IEC 17025;
- ii. To develop the capability of the laboratory personals of RTO's in implementing ISO/IEC 17025 systems;
- iii. To enhance the quality of testing in RTO laboratories through the implementation of technical components of proficiency testing and measurement uncertainty;
- iv. To initiate the implementation of a quality management system in **five** selected RTOs, through the development of a quality manual and the review of the quality system documentation of each RTO;
- v. To implement the quality system complying with ISO/IEC 17025 in **one** RTO laboratory as a test case.

4. SCOPE OF THE PROGRAM

The scope of the program is as follows: -

Phase One: -

Training on ISO/IEC 17025 will be schedule to be held in Shah Alam, Selangor Darul Ehsan, Malaysia on **October 12 – 30, 2009**.

Phase Two: -

Review of Quality Manual and Quality System Documentation is schedule to be held on March 2010.

Phase Three: -

Assisting in the consultation of one selected RTO to develop laboratory quality system for ISO/IEC 17025 compliance, schedule to be held on May 2010.

5. PARTICIPANTS

Phase One: Training on ISO/IEC 17025

Five RTOs shall be invited to attend the workshop and training. Each RTO shall nominate two participants making a total number of ten participants.

Phase Two: Review of Quality Manual and Quality System Documentation

Five RTOs from Phase I shall have their quality system documentation reviewed by an independent reviewer.

Phase Three: Technical Assistance to an RTO

One RTO shall be selected from Phase Two to participate in Phase III.

Criteria for Participation

The criteria for acceptance of participants for all the phases of the project are as follows: -

a) General

Participation is only open to WAITRO and ISESCO's member organizations.

b) For the Participants

Technical Manager / Quality Manager/ Key personnel of an RTO laboratory, which is already in operation. The person should have a technical or scientific background.

Each applicant is required to complete the Application Form, WGLP/F/ App.

c) For the Laboratory

- The Laboratory shall be testing laboratory.
- The Laboratory is in operation and undertakes to implement and maintain ISO/IEC 17025.
- It undertakes product testing or evaluation activities for external clients, especially for small and medium scale enterprises (SMEs).
- The majority of the testing or evaluation is carried out using standard methods;
- The laboratory management demonstrates their commitment by providing adequate resources and designating key personnel and a quality representative with the authority to implement the project.
- Quality Representative and key personnel have a good command of **English**.
- The Organization is not currently assisted or receiving any grants/funding from other funding agencies (national or international).

Each Laboratory is required to complete the questionnaire, WGLP/F/Que.

In addition, for Phase III, the selected RTO must agree to: -

- Provide accommodation and local hospitality to resource persons
- Provide office space, telecommunications and computer facilities
- Operate the laboratory according to the quality system that will be established during the project.
- Pursue efforts in getting the laboratory accredited to ISO IEC 17025.

Expenses in pursuing the accreditation will be borne by the selected RTO.

6. PROGRAMME STRUCTURE

Phase 1 – Training on ISO/IEC 17025

- Introduction on ISO/IEC 17025
- Documenting and implementing a Laboratory Quality System.

- Laboratory Internal Audit
- Measurement of Uncertainty
- Development of Quality Manual

Phase 2 – Review of Quality Manual and Quality System Documentation

- Reviewing of Quality Manual, Procedures and Test Methods
- Evaluation of documentation and recommendation for Phase 3.

Phase 3 – Technical Assistance to an RTO

- Pre- Assessment and Gap Analysis
- Laboratory Quality System Planning
- Development of documentation for accreditation
- Internal Quality Control Review
- Internal Audit
- Management Review
- Pre-audit to ensure effective implementation of laboratory quality system
- Corrective and Preventive Action

7. RESOURCE PERSONS

Resource persons will be identified by WAITRO and ISESCO.

8. SPONSORSHIP

Phase 1 – Training on ISO/IEC 17025

WAITRO and ISESCO will provide sponsorship of economy airfare, accommodation, and reasonable subsistence allowance to ten participants from WAITRO and ISESCO member organizations.

➤ TERMS AND CONDITIONS OF SPONSORSHIP:

- i. As part of this training programme, each participant is required to prepare a Country report on the application and development of ISO/IEC 17025 in his/her respective country.

To facilitate the preparation of the country paper to ensure consistency, please follow the guidelines as indicated below: -

- **Objective**
To provide an opportunity for participants to exchange, sharing of knowledge and experiences in the area of ISO/IEC 17025 of all participating administrations/countries.
- **Subject Area**
The subject area for the country paper should reflect the experiences, challenges and problems encountered in planning, implementing or evaluating performance-oriented policies and practices in ISO/IEC 17025 in the participating administrations/countries. Participants may add to/or expand on any of the above-mentioned topics or describe any special development project in their respective countries.

- Length

The country paper should be at least 5 pages, covering the following topics:

- The country's general information and background
- Country report on experiences, challenges and problem encountered in planning, implementing or evaluating performance-oriented policies and practices in ISO/IEC 17025.
- Conclusion

- Instruction

Participants are required to submit the completed country paper to WAITRO Secretariat two (2) weeks before the course as a prerequisite to issuing the air-tickets.

- The country paper should be typewritten, 1 ½ spacing, font 12 Arial in a Microsoft Word and send via email to nesrul@sirim.my / info@waitro.sirim.my or fax to **+603 5544 6735**
- Participants will be required to give 15 minutes presentation of the country paper/report to their fellow participants and also to be prepared for a “question and answer session”.
- For presentation during the Workshop, participants are very much encouraged to use Power Point. Presentation may be supported by videos tapes, slides or multi-media presentation.

ii. Participants shall conduct themselves at all times in a manner compatible with their responsibilities as WAITRO and ISESCO sponsored participant and abide by the laws, rules and regulations of the land and institution.

iii. For lectures, participants are required to dress in long-sleeved shirts with ties, tailored pants and blazer or uniform and ladies should be appropriately dressed in office attire. For formal occasions – lounge suit, national costume or smart casual is required.

- iv. Participants are not allowed to participate in any political and/or commercial activities in any capacity whatsoever. Participants shall not take up paid employment during the tenure of their scholarship or serve on the staff of their Official Representatives in the country where the programme is held.
- v. Participants are **NOT** allowed to bring along their spouses or families for the duration of the course. Participants will be required to return to their own countries upon completion of the course or at the end of the tenure of the sponsorship, whichever is earlier.
- vi. WAITRO, ISESCO and its resource provider, may terminate the award at any time due to unsatisfactory conduct, breach of the conditions of the award, failure to make satisfactory progress or as deemed necessary.
- vii. Participants who are found to be medically unfit during the course of the programme will be required to return to their country.
- viii. To carry out such instructions and abide by such conditions as stipulated by WAITRO and ISESCO.
- ix. To observe those rules and regulations at the place of accommodation and not to change accommodation designated by WAITRO - ISESCO.

10. RESPONSIBILITY REGARDING EXPENDITURES:

Neither the host Government nor WAITRO will assume responsibility for the following expenditures:

- Costs incurred by participants with respect to travel insurance, accident insurance, medical bills, and hospitalization fees in connection with his/her attendance at the training program;
- Compensation in the event of death, disability or illness of the participant in connection with the attendance at the training program;

- Incidental costs incurred in connection with travel abroad, e.g. passport, visas, vaccinations, stop-over, travel to and from the airport;
- Loss or damage to personal property of the participant attending the training program;
- Purchase of personal goods or compensation in the event of damage caused to such goods by climatic or other conditions; and
- Other unforeseen expenditures.

11. HOW TO APPLY

The application form and questionnaire must be submitted to WAITRO Secretariat by **September 4, 2009**. It must also be accompanied with the applicant's medical report and a copy of his/her passport. A copy of the application form should be mailed, fax or email directly to:

**WAITRO Secretariat
c/o SIRIM Berhad,
1 Persiaran Dato' Menteri, Section 2
P. O. Box 7035, 40911 Shah Alam, MALAYSIA
(Attn: Secretary General)
Tel: 603-55446730 Fax: +603-55446735
E-mail: nesrul@sirim.my / info@waitro.sirim.my**

The selected applicants will be notified of their acceptance to the training offered by WAITRO Secretariat through a letter of acceptance by mail, fax and e-mail.

Decisions by the Selection Committee are final and no appeals will be entertained.



QUESTIONNAIRE ON READINESS/ COMMITMENT OF RTO LABORATORY

The objective of this questionnaire is to gauge the readiness/commitment of RTO laboratory in implementing a laboratory quality system. There are eight (8) parts to this questionnaire and the RTO laboratory is required to answer all questions.

Name of RTOs :

Name of Laboratory :

A. LABORATORY

1. Please identify type of laboratory (please tick)

Chemical	Mechanical	Electrical	Others, please specify:

2. Please briefly describe activities of the laboratory. Please attach corporate profile/brochure (*including type of products tested, laboratory customers etc*).

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3. Laboratory facilities (please tick).

Permanent	Mobile	At Site

4. Special arrangements for use of facilities, if any. Please describe

B. PERSONNEL

1. Please attach organization structure of laboratory.

2. Please list the technical staff of the laboratory and indicate their qualifications

Job Designation	No. (s)	Qualification

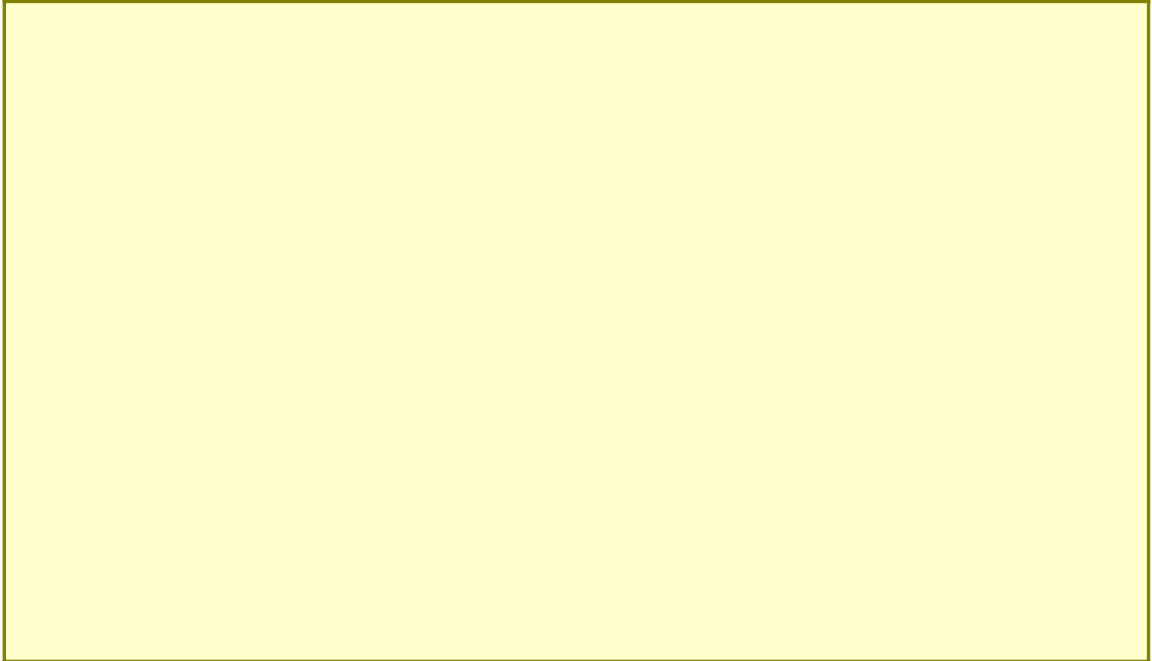
C. EQUIPMENT

1. Kindly furnish information on major equipment that the laboratory uses.

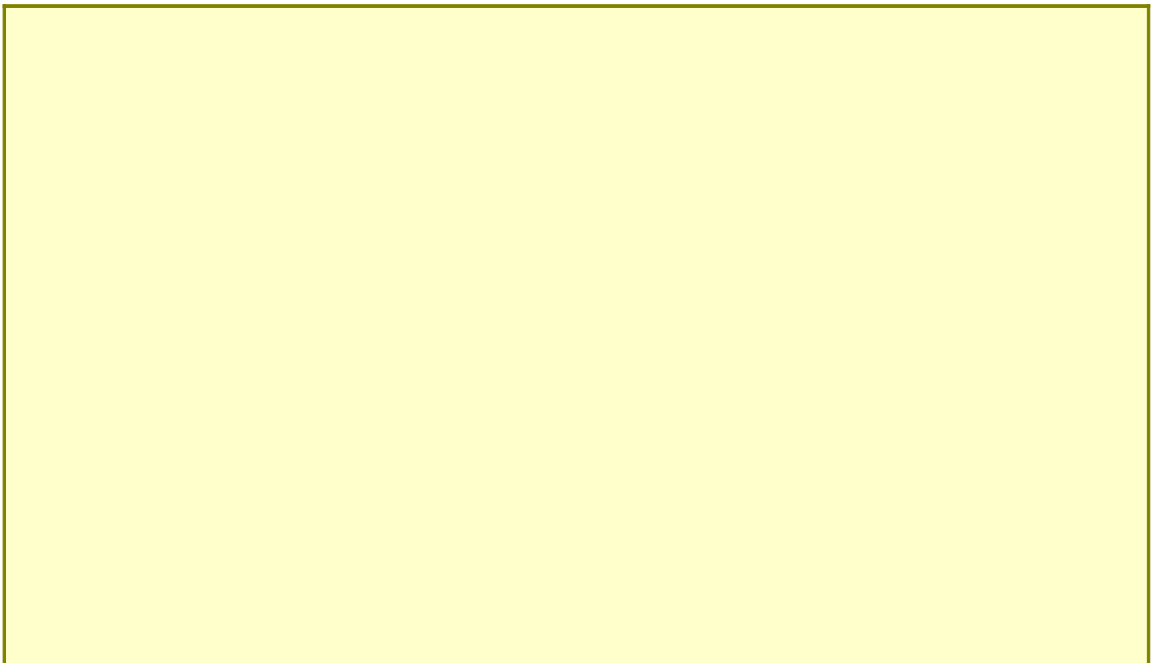
No.	Equipment Name	Calibration Programme Available (Please Tick)		Maintenance Programme Available (Please Tick)	
		Yes	No	Yes	No.

D. ACOMMODATION AND ENVIRONMENT

1. Are contamination and interferences that can affect the quality of tests managed and controlled? If yes please provide brief description of controlled measures/management employed and for which tests.



2. Are storage facilities available for samples, chemicals, solvents and waste? If yes, please provide brief description of storage facilities.



E. TEST METHODS AND PROCEDURES

1. Please list National/International test methods used

2. Please identify quality control methods currently used in the laboratory.
(eg control chart, spiking, standard reference materials, inter-lab comparison)

F. DOCUMENTATION

1. List all laboratory documentation available (e.g. test manual, test requisition form, test report, worksheets, etc)

2. Are you able to bring your laboratory operating manual? * Please tick

YES	NO
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G.SUPPLEMENTARY INFORMATION

1. Does your organization currently implement a quality management system such as ISO9001:2000? Please tick.

YES	NO
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2. Is there any intention by your laboratory to obtain accreditation? If so, why?

Note:

Participants are encouraged to have readily available soft copies of the laboratory operating manual as basis for the workshop on quality manual development



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APPLICATION FORM (Typewritten or block letters)

TITLE OF COURSE : <u>CAPABILITY BUILDING OF RESEARCH TECHNOLOGY ORGANIZATIONS (RTOs) IN ISO/IEC 17025</u>	Duration: Phase I : October 12 – 30, 2009 SIRIM Berhad, Selangor Darul Ehsan, Malaysia
NAME OF RTO :	

1. PERSONAL DATA

Family name (surname)	Date of birth Day Month Year
First Name	Nationality (citizenship) :
Other names	Gender: Male / Female #
City and country of birth	Marital status: Single / Married / Divorced / Widowed #
Passport No:	Religion:

Delete accordingly

2. COMMUNICATION AND MAILING ADDRESS

Applicant's Office Address:	Applicant's Postal / Home Address:
	Home telephone Country Area Number
Office telephone Country Area Number	Telefax Country Area Number
Email	
Person to be contacted in case of emergency, name, telephone and address:	

3. EDUCATION (list in order of time, starting with last institution attended)

Name of institution and place of study	Major field of study	Years of study: from - to -	Degree

4. EMPLOYMENT RECORD

A. Present or most recent post	B. Previous post
Employer:	Employer:
Years of service (from – to):	Years of service (from – to):
Title of your post/position :	Title of your post/position :
Name of supervisor and title:	Name of supervisor and title:
Type of organization: Government / Semi Government / Private / NGO #	Type of organization Government / Semi Government / Private / NGO #
Main functions of organization:	Main functions of organization:
Total number of employees:	Total number of employees:

Delete accordingly

Description of your work including your responsibility:

Please continue on supplementary pages if necessary

5. REASONS FOR APPLYING THIS COURSE

Please state briefly the reasons for applying to this course and how you hope to benefit from the programme.

Please continue on supplementary pages if necessary

Have you participated in any training programme in Malaysia before : YES / NO #

Name of programme Organizer Year

Have you participated in any Good Laboratory Practice training programme before : YES / NO #

Name of courses Name of Training Institute Year

Delete accordingly

6. CERTIFICATION OF ENGLISH LANGUAGE PROFICIENCY

	Excellent	Good	Fair	Basic	Remarks
Listening					
Speaking					
Writing					
Reading					

Mother tongue : _____

Language test administered by : _____

Title : _____

Address : _____

Tel. Number : _____

E mail : _____

Date and signature _____

7. MEDICAL REPORT (to be completed by an authorized physician)

Name of Applicant: _____

Age: _____	Sex: _____	Height: _____ cm	Weight: _____ kg.
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Blood Group: A B AB O Other ()

Blood Pressure: _____

Is the person examined at present in good health?	Is the person examined physically and mentally able to carry out intensive training away from home?
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Is the person free of infectious diseases (AIDS, tuberculosis, trachoma, skin diseases etc.)?	Does the person examined have any condition or defect (including teeth) which might require treatment during the course?
List any abnormalities indicated in the chest X ray.	Pregnancy Test (for women):
I certify that the applicant is medically fit to undertake a course in Malaysia.	
Name of Physician	: _____
Address of Clinic (<i>printed</i>)	: _____ _____
Telephone (<i>printed</i>)	: _____
E-mail	: _____ Date : _____
Signature of Physician	: _____ Seal of Clinic :

8. DECLARATION

Have you ever been convicted by a Court of Law of any country ? <i>If yes, please give brief details:</i>	Yes / No #
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I certify that my statements in answer to the foregoing questions are true, complete and correct to the best of my knowledge and belief.

If accepted for a training award, I undertake to:-

- (a) Carry out such instructions and abide by such conditions as may be stipulated by both the nominating organization and the host organization in respect of this course of training;
- (b) Follow the course of study or training, and abide by the rules of the institution in which I undertake to study or train;
- (c) Refrain from engaging in political activities, or any form of employment for profit or gain;
- (d) Submit any progress reports which may be prescribed; and

Return to my home country promptly upon the completion of my course of study or training.

I also fully understand that if I am granted an award it may be subsequently withdrawn if I fail to make adequate progress or for other sufficient cause determined by the host organization.	
Signature of applicant :	_____
Name :	_____
Date :	_____

Delete accordingly

9. OFFICIAL DECLARATION (to be completed by the nominating RTO)

(Name of RTO)

nominates _____

(name of applicant)

For the course under the WAITRO Training Programme on Capability Building of Research Technology Organizations (RTOs) in ISO/IEC 17025 and certifies that:

(a) all information supplied by the nominee is complete and correct;

(b) the nominee had adequate knowledge and was appropriately tested for English Language proficiency.

Remarks: _____

_____ (Name) _____ (Signature of Organization Head of RTO)

_____ Address of RTO

(Designation) _____

Official Seal / Stamp:

Office Telephone number: _____

Office Fax number : _____

E mail: _____

Date: _____

Note:

All applications must be submitted to the WAITRO Secretariat at the following address:

WAITRO Secretariat
c/o SIRIM Berhad
No. 1, Persiaran Dato' Menteri
9th Floor, Building 5
Section 2, P.O. Box 7035
40911 Shah Alam
Selangor Darul Ehsan, Malaysia
(Attn: The Secretary General)

Telephone : +(603) 5544 6635
Facsimile : +(603) 5544 6735
E-mail : nesrul@sirim.my / info@waitro.sirim.my