LECTURE 2

IMPORTANCE of ACCREDITATION

Why ISO?

To obtain a structured & controlled **System for Consistent** quality products / services in meeting the customers' requirements.

To provide greater **Confidence** to the market place & to gear up your business for a **Competitive** world.

To win new **Customers** & to retain **Existing Customers**
$$$

WHY Accreditation is IMPORTANT?

THE BENEFITS OF USING AN ACCREDITED LABORATORY to Government and Regulators by:

Increasing confidence in data that is used to establish baselines for key analyses and decisions.

Reducing uncertainties associated with decisions that affect the protection of human health and the environment.

Increasing public confidence, because accreditation is a recognizable mark of approval.

Eliminating redundant reviews and improving the efficiency of the assessment process (which may reduce costs).

WHY Accreditation is IMPORTANT?

Using an accredited laboratory also increases confidence that:

Decisions

- *Decisions regarding multiple facilities are based on comparable data.*

Safe & Reliable

- *Purchases received from suppliers are safe and reliable.*

Minimised Costs

- *Costs associated with laboratory problems, including re-testing, re-sampling and lost time are minimized.*

Minimised Compliance Affect

- *False positives and negatives, which can directly affect compliance with regulations are minimized.*

Facilitates trade & Growth

- *Using accredited laboratories also facilitates trade and economic growth.*

IMPLICATIONS ON TRADE

Recognition The mutual recognition of test data, reports and certificates from laboratories /certification bodies accredited by MRA (Mutual Recognition Arrangement) signatories is a major step toward the reduction of technical barriers to trade.

Reduction Reducing the need for re-testing a product or re-certification in importing countries mean significant savings of time and money for exporters. Exporters would be enjoying these benefits.

Reliable Clients of certification bodies and users of the laboratories would also receive services and tests data that are reliable.

Objectives of Laboratory Accreditation Systems

1. Ensure validity of test data by ensuring that the laboratory is operating to the best of its ability.
2. Promote the acceptance of test data by users of laboratory services so that data produced by one lab can be accepted by another without further tests.
3. Facilitate international trade through the acceptance of test data from accredited laboratories.
4. Make more efficient use of testing facilities within a country by coordinating existing capabilities.
5. Add to the credibility and give additional status to competent laboratories.
6. Promote good testing practices.
7. Improve testing methods by providing feedback to standards-producing bodies on the adequacy of test methods.
8. Provide technical and other information to accredited laboratories
9. Facilitate establishment of mutual recognition agreements.

ACCREDITATION

ñThird-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment mark ò

ISO/IEC 17011:2004

Accreditation body (AB) is the authoritative body that performs accreditation and the authority of an AB is generally derived from the government.

CERTIFICATION

ÅProcedure by which a third party (certification body) gives a written assurance that a product, process or service (of an organisation) conforms to specified requirements.

ISO/IEC Guide 2:1996

Å *Certification does not specifically evaluate technical competence.*
Å *Certification is not appropriate for laboratories or inspection bodies.*

ACCREDITATION

Accreditation to ISO/IEC 17025 ...

- **Assures the customer that the procedures are technically valid**
- **Recognizes the technical competence of laboratory staff**
- **Assures the customer that the results are technically valid**
- **Endorses the quality management system**

ACCREDITATION VERSUS CERTIFICATION

CERTIFICATION = CONFORMITY

ACCREDITATION = 

ACCREDITATION PROCESS

- Application and submission
- Adequacy audit
- Pre-assessment audit
- Compliance audit
- Surveillance audit (yearly)
- Re-assessment audit (3 years)

CONFORMITY ASSESSMENT

Accreditation Body

Competence *(accreditation)*

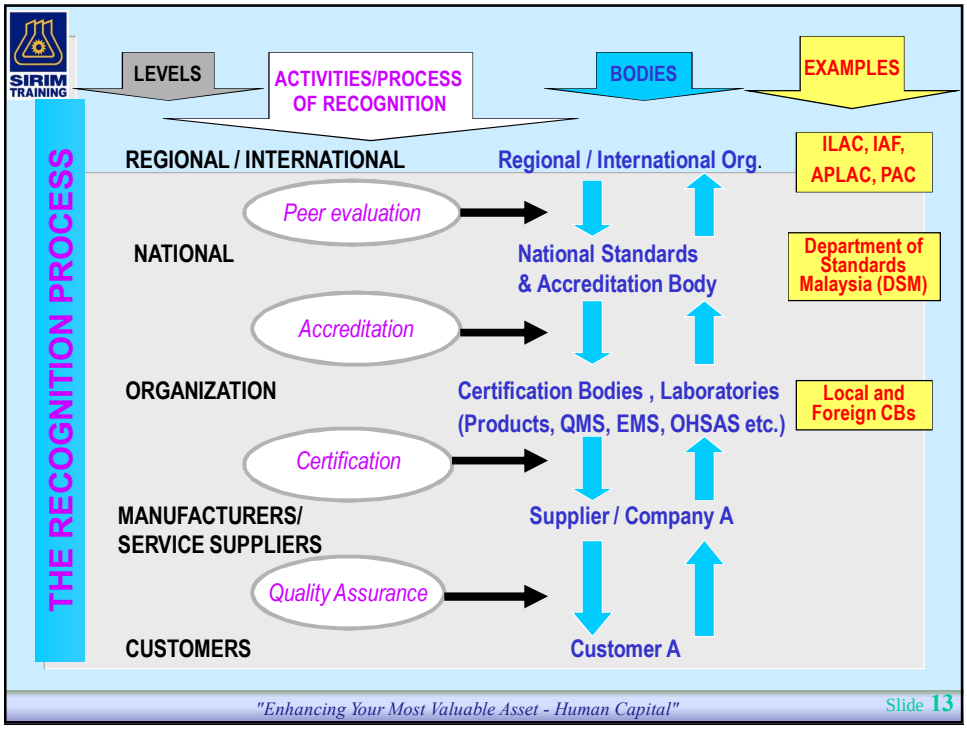
Conformity Assessment Bodies

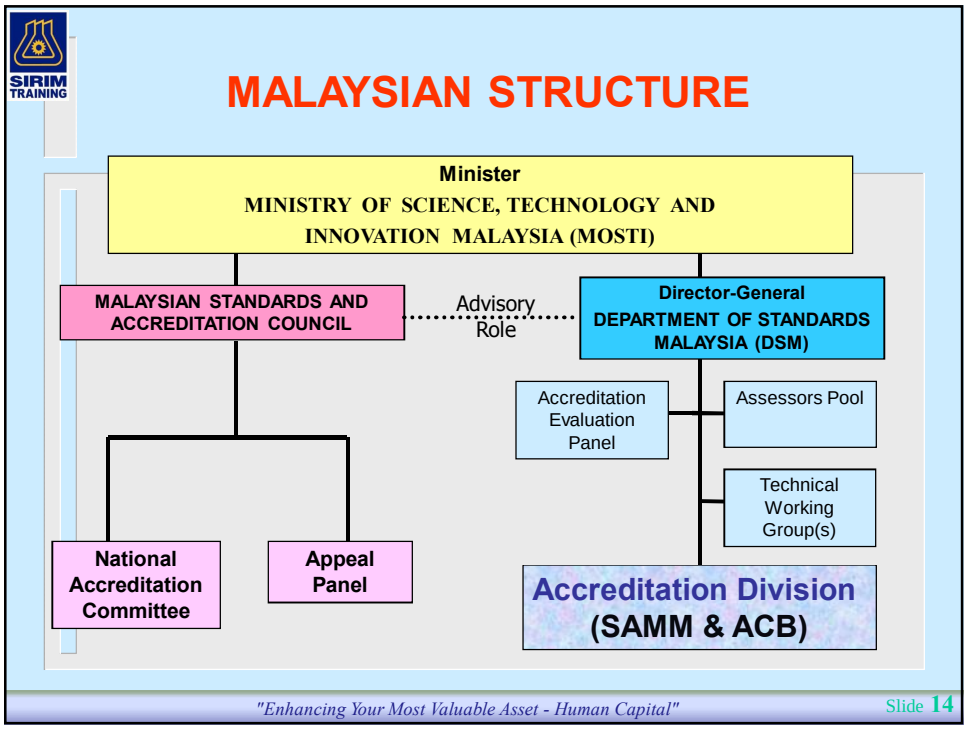
Certification Bodies	Testing/Calibration Laboratories	Inspection Bodies

Compliance *(certification)*

Products/Services

Suppliers/Manufacturers


SIRIM TRAINING
LEVELS
ACTIVITIES/PROCESS OF RECOGNITION
BODIES
EXAMPLES
THE RECOGNITION PROCESS
REGIONAL / INTERNATIONAL
Regional / International Org.
ILAC, IAF, APLAC, PAC
Peer evaluation
NATIONAL
National Standards & Accreditation Body
Department of Standards Malaysia (DSM)
Accreditation
ORGANIZATION
Certification Bodies , Laboratories (Products, QMS, EMS, OHSAS etc.)
Local and Foreign CBs
Certification
MANUFACTURERS/ SERVICE SUPPLIERS
Supplier / Company A
Quality Assurance
CUSTOMERS
Customer A
"Enhancing Your Most Valuable Asset - Human Capital"
Slide 13

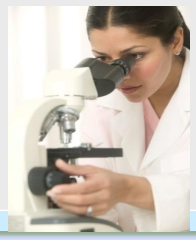

SIRIM TRAINING
MALAYSIAN STRUCTURE
Minister
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION MALAYSIA (MOSTI)
MALAYSIAN STANDARDS AND ACCREDITATION COUNCIL
Advisory Role
Director-General
DEPARTMENT OF STANDARDS MALAYSIA (DSM)
Accreditation Evaluation Panel
Assessors Pool
Technical Working Group(s)
National Accreditation Committee
Appeal Panel
Accreditation Division
(SAMM & ACB)
"Enhancing Your Most Valuable Asset - Human Capital"
Slide 14

MS ISO/IEC 17025 : 2005

GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

Accreditation Requirements:

- Standards MS ISO/IEC 17025:2005
  AND/OR MS ISO 15189:2007
- SAMM Policies (SP)
- Specific Technical Requirements (STR)
- Specific Criteria (SC)
- Measurement Uncertainty (MU)



SAMM SCHEME FIELDS AND PROGRAMS
Accreditation Standard:
ISO/IEC 17025:2005

Fields of testing:

- Chemical testing
- Microbiological testing
- Electrical testing
- Mechanical / physical testing
- Non-destructive testing
- Radioactivity testing
- Household pesticide
- Toxicity
- Electromagnetic Compatibility (EMC)
- Veterinary
- Genetically Modified Organisms (GMO)
- Nucleic Acid
- DNA Profiling for Forensic Science
- Analysis of accelerant in Fire Debris for Forensic Science

Fields of calibration:

- Heat and temperature measurements
- Mass and Mass-Related Quantities
- Electrical measurements
- Optical and Photometric measurements
- Acoustic & Vibration Measurements
- Length and dimensional measurements
- Radioactivity measurement

SAMM SCHEME FIELDS AND PROGRAMS
Accreditation standard:
ISO 15189:2003

Medical Testing :

- **Anatomical pathology *(cytopathology)***
- **Anatomical pathology *(histopathology)***
- **Chemical pathology**
- **Haematology**
- **Medical microbiology**
- **Medical microbiology *(virology)***

STR -

Specific Technical Requirements

STR : Specific Technical Requirements

Provide technical requirements **specific** for particular issues in certain areas of each **discipline.**

Specific for each field in **testing and calibration** as below:

STR 1.1	● Bio-efficacy of Household Pesticide
STR 1.2	● Toxicity Testing
STR 1.3	● EMC Testing (Electromagnetic Compatibility)
STR 1.4	● Veterinary Testing
STR 1.5	● GMO Testing (Genetically Modified Organisms)

STR : Specific Technical Requirements

Specific for each field in **testing and calibration** as below:

STR 1.6	● Nucleic Acid Testing
STR 1.7	● DNA Profiling for Forensic Science
STR 1.8	● Accelerant in Fire Debris for Forensic Science
STR 1.9	● Document Examination for Forensic Science
STR 1.10	● Information Technology Security Evaluation and Testing (common criteria)

STR : Specific Technical Requirements

Specific for each field in **testing and calibration** as below:

STR 1.11	● Dangerous Drugs & Other Controlled Substances for Forensic Science
STR 1.12	● Trace Evidence Analysis For Forensic Science Testing Laboratories
STR 1.13	● Accreditation Of Software Testing Laboratories

STR : Specific Technical Requirements

Specific for each field in **medical testing** as below:

- STR 2.1 ● Anatomical Pathology (Cytopathology)
- STR 2.2 ● Anatomical Pathology (Histopathology)
- STR 2.3 ● Chemical Pathology
- STR 2.4 ● Haematology
- STR 2.5 ● Medical Microbiology
- STR 2.6 ● Medical Microbiology (Virology)
- STR 2.7 ● Assisted Reproductive Technology (ART)
- STR 2.8 ● Cytogenetic Testing

POLICIES DOCUMENTS

SAMM Policy 1	● Terms and Condition Governing the Laboratory Accreditation Scheme of Malaysia
SAMM Policy 2	● Policy on Traceability of Measurement Results
SAMM Policy 3	● Conditions for the Use of SAMM Accreditation Symbol or Reference to SAMM Accreditation
SAMM Policy 4	● Policy on Proficiency Testing Requirements for SAMM Laboratories
SAMM Policy 5	● Policy on Measurement Uncertainty Requirements for SAMM Testing Labs

POLICIES DOCUMENTS

SAMM Policy 6	● Requirements for Approved Signatory
SAMM Policy 7	● Specific Requirements on the Issue of SAMM Endorsed Calibration Certificates
SAMM Policy 8	● Requirements & Procedures for the Accreditation of Site Calibration &Testing Laboratories
SAMM Policy 9	● Specific Requirements for Measurement and Calibration System
SAMM Policy 10	● Grading of Non-Conformities

TYPE OF ASSESSMENT

- Application for accreditation
  - Initial assessment (Adequacy Audit, Pre-assessment & compliance)
- Scheduled assessment
  - Surveillance / Reassessment
- Variation of accreditation
  - New signatories, additional tests, field facilities / relocation
- Follow-up assessments
- Extra ordinary / unscheduled assessments
  - following identification of problems
  - following poor results in proficiency testing
  - following major changes in laboratory organization
  - investigation of complaints.

FLOWCHART OF ACCREDITATION PROCESS

APPLICATION BY LABORATORY

APPOINT LEAD ASSESSOR

ADEQUACY AUDIT

PRE-ASSESSMENT

COMPLIANCE

LABORATORY ACCREDITATION EVALUATION PANEL (LAEP)

DIRECTOR GENERAL APPROVAL

AWARD ACCREDITATION

SURVEILLANCE 1 (± 9 MONTHS)

SURVEILLANCE 2 (± 11 MONTHS)

REASSESSMENT & RENEWAL (3 MONTHS BEFORE EXPIRY DATE)

NOTE: Information on accreditation processes, refer to Document SI 1 (Available in STANDARDS MALAYSIA website).

ACCREDITATION SCHEMES

- *Skim Akreditasi Makmal Malaysia* (SAMM) - Laboratory Accreditation Scheme of Malaysia,

Old

New

INTERNATIONAL & REGIONAL RECOGNITION (SIGNATORY) OF DEPARTMENT STANDARD MALAYSIA

1. Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement (MRA)

Testing Field : 14th November 2002

Calibration Field : 13th November 2003

2. International Laboratory Accreditation Co-operation (ILAC) Mutual Recognition Arrangement (MRA)

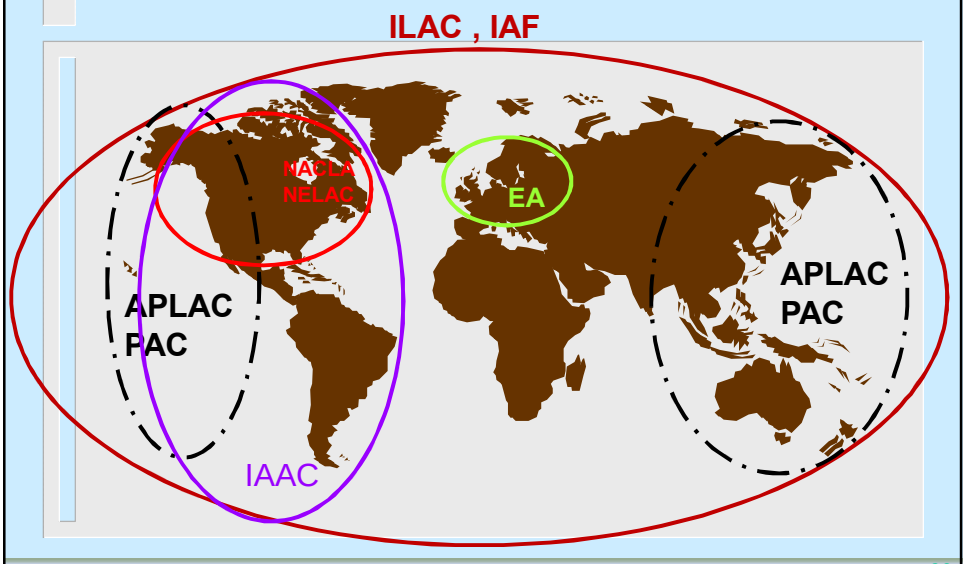
Testing Field : 16th January 2003

Calibration Field : 19th November 2003

APLAC & ILAC MRAs FOR ACCREDITATION OF TESTING/CALIBRATION LABs: ITS IMPLICATIONS

- Accredited test reports recognised by signatories:
  - 14 countries (20 organisations) for APLAC
  - 35 countries (43 organisations) for ILAC
- Avoids re-test in importing countries provided test conducted to requirements/standards required by importing countries;
- Does not mean automatic acceptance of products

INTERNATIONAL MUTUAL RECOGNITION



The following are the signatories of the APLAC MRA:

1. National Association of Testing Authorities (NATA), Australia
2. Standards Council of Canada (SCC), Canada
3. China National Accreditation Board for Laboratories (CNAL), People's Republic of China
4. Hong Kong Accreditation Service, Hong Kong, China

The following are the signatories of the APLAC MRA:

5. National Accreditation Board for Testing and Calibration Laboratories (NABL), **India**
6. **Komite Akreditasi Nasional (KAN), Indonesia**
7. The Japan Accreditation Board for Conformity Asessment (JAB), **Japan**
8. International Accreditation Japan (IAJapan), **Japan**

The following are the signatories of the APLAC MRA:

9. Voluntary EMC Laboratory Accreditation Center Inc (VLAC), **Japan**

10. Korea Laboratory Accreditation Scheme (KOLAS), Republic of Korea

11. Department of Standards Malaysia (DSM), **Malaysia**

12. International Accreditation New Zealand (IANZ), New Zealand

The following are the signatories of the APLAC MRA:

13. Singapore Accreditation Council (SAC-SINGLAS), **Singapore**

14. Chinese National laboratory Accreditation (CNLA), **Chinese Taipei**

15. TLAS, Office of the National Accreditation Council, Thai Industrial Standards Institute, **Thailand**

16. Department of Medical Sciences, **Thailand**

The following are the signatories of the APLAC MRA:

17. American Association for Laboratory Accreditation (A2LA), **USA**

18. International Accreditation Service Inc, **USA**

19. National Voluntary Laboratory Accreditation Program (NVLAP), **USA**

20. Vietnam Laboratory Accreditation Scheme (VILAS), **Vietnam**

3 years

Issue date: 23 June 2008
Valid until: 23 June 2011

NO: SAMM 075

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LABORATORY LOCATION:
(PERMANENT LABORATORY)

HOVID BHD.
121, JALAN TUNKU ABDUL RAHMAN
30010 IPOH, PERAK

The standard used for assessment of this laboratory is MS ISO/IEC 17025:2005

FIELD OF TESTING: CHEMICAL

SCOPE OF ACCREDITATION:

Materials/ Products tested	Type of test/ Properties Measured/ Range of Measurement	Standard test method/ Equipment/Techniques
Pharmaceutical Products : (on Finished Products)	Assay of active ingredient:	
Capsules	Piroxicam	USP 28
	Chloramphenicol	BP 2007
	Mefenamic Acid	BP 2007
	[illegible]	[illegible]
Tablets	[illegible]	[illegible]
	[illegible]	[illegible]
	Griseofulvin	*IH-HPLC-036
	Ibuprofen	*IH-HPLC-044
	Metoclorpramide HCl	*IH-HPLC-054
	Salbutamol	*IH-HPLC-080
	Terbutaline Sulfate	*IH-HPLC-085
	Mefenamic Acid	BP 2007
	Cephalexin	*IH-HPLC-136
	Dextromethorphan HBr	USP28
	Pyrantel Pamoate	*IH-HPLC-147
	Sulphamethoxazole	*IH-HPLC-079
	Trimethoprim	*IH-HPLC-083
	Loratadine	*IH-HPLC-125
	Ketoconazole	*IH-HPLC-108
	Bromhexine HCl	*IH-HPLC-195

Notes : *IH = In-house methods
BP 2007 = British Pharmacopoeia 2007
USP 28 = United States Pharmacopoeia 28

Issue date: 23 June 2008
Valid until: 23 June 2011

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FIELD OF TESTING: CHEMICAL

SCOPE OF ACCREDITATION:

Materials/ Products tested	Type of test/ Properties Measured/ Range of Measurement	Standard test method/ Equipment/Techniques
Pharmaceutical Products : (on Finished Products)	Assay of active ingredient:	
Soft Capsules	Vitamin E Tocotrienols	*IH-HPLC-091 *IH-HPLC-186
Oral Liquids	Chlorpheniramine Maleate Ketotifen Fumarate Methyl Paraben & Propyl Paraben Sodium Citrate Dihydrate Salbutamol	*IH-HPLC-133 *IH-HPLC-135 *IH-HPLC-056 *IH-HPLC-117 *IH-HPLC-237
Creams	Hydrocortisone Methyl Salicylate Menthol [illegible]	*IH-HPLC-141 *IH-GC-061 *IH-GC-062 *IH-HPLC-194
Tablets/Caps[illegible]	D[illegible]integration Test U[illegible]iformity [illegible]	BP 2007 BP 2007
Chemical Products : (on Finished Products)	Assay of active ingredient:	
Tablets	Available Chlorine in Sodium Dichloroisocyanurate	*IH-TIT-184

Notes : *IH = In-house methods
BP 2007 = British Pharmacopoeia 2007

Signatories:

1. Ng Choon Heng — IKM No. A 2587/95
2. See Lee Lan — IKM No. L 2717/96
3. Mah Huey Jiuan — IKM No. A 5255/2008
4. Yuen Yen Le — IKM No. A5253/2008

Issue date: 23 June 2008
Valid until: 23 June 2011

NO: SAMM 075

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FIELD OF TESTING: MICROBIOLOGICAL

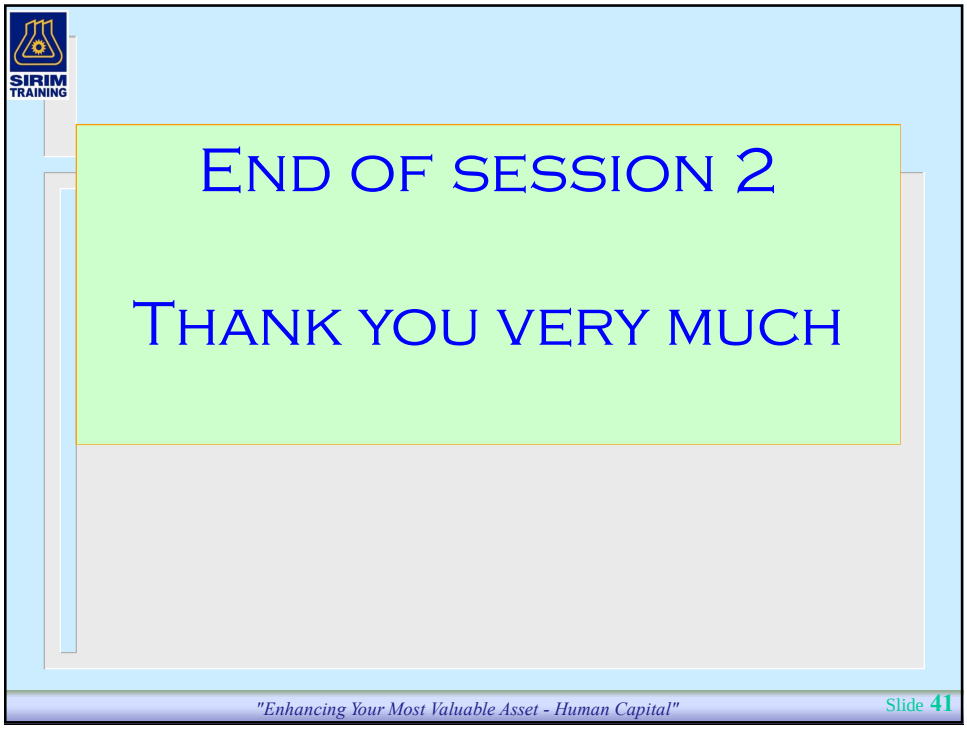
SCOPE OF ACCREDITATION:

Materials/ Products tested	Type of test/ Properties Measured/ Range of Measurement	Standard test method/ Equipment/Techniques
Pharmaceutical Products : (on Finished Products)	Microbiological assay of active ingredient :	
Tablets	Erythromycin Stearate	*IH-MICRO-030
Granules	Erythromycin Ethylsuccinate	*IH-MICRO-043
Cream	[illegible]	[illegible]
Injections	Bacterial Endotoxin Test (LAL)	USP 28
Sterile products	Sterility Test	BP 2007

Notes : *IH = In-house methods
BP 2007 = British Pharmacopoeia 2007
USP 28 = United States Pharmacopoeia 28

Signatory:

1. See Lee Lan — IKM No. L 2717/96


SIRIM
TRAINING
END OF SESSION 2
THANK YOU VERY MUCH
"Enhancing Your Most Valuable Asset - Human Capital"
Slide 41