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MS ISO/IEC 17025:2017 MANAGEMENT SYSTEM – UNDERSTANDING THE ELEMENTS

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Institut Biosains

Zufliha Zakaria
6 February 2020

COURSE OUTLINE

TIME	TOPIC
9.00 – 10.15	• Introduction and course objectives • Related Acts and Regulations • The 8 management principles and its application to the management of the laboratory • Accreditation process
10.15-10.30	Morning break
10.30-12.30	• Interpreting and understanding the ISO/IEC standard • Structure of quality system documentation • The requirements – general, resource, process and management system

INTRODUCTION

"**accreditation**" means a procedure by which the Department gives attestation that a conformity assessment body is competent to carry out specific conformity assessment activity;

"**Department**" means the Department of Standards, Malaysia which is responsible for national standardization and accreditation;

- Act 549, Laws of Malaysia

INTRODUCTION

Accreditation – formal recognition that an organization is competent to perform specific processes, activities or tasks (which are detailed in a scope of accreditation). It follows that:

- Accreditation must be objective, transparent and effective
- AB must be highly professional competent assessors and technical experts in all relevant fields
- AB employees (and subcontractors) must be reliable, ethical and competent in both accreditation processes and the relevant technical fields

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)

Administration : Department of Standards Malaysia, Ministry of International Trade and Industry

Objective: to provide a credible accreditation service to testing and calibration laboratories including medical testing laboratories such that ultimately SAMM endorsed test reports and calibration certificates are accepted internationally (ILAC, APLAC= APAC).

COMBINED ILAC-MRA LOGO

License agreement JSM-ILAC : labs are entitled to use the ILAC MRA mark, provided:

- SAMM Policy 3 (SP3) - POLICY ON THE USE OF SAMM ACCREDITATION SYMBOL AND COMBINED ILAC MRA MARK OR REFERENCE TO SAMM ACCREDITATION
- Rules for the use of the ILAC MRA Mark ILAC-R7: 05/2015

VITAR-SEGATEC SDN. BHD.
Calibration & Measurement Centre

CERTIFICATE OF CALIBRATION

CERTIFICATE NO. : STT 19 03 - S0205 - 7 Page 1 of 3

Submitted By : INSTITUT BIOSAINS
UNIVERSITI PUTRA MALAYSIA,
43400 SERDANG, SELANGOR DARUL EHSAN.

Date Issued : 27 March, 2019

Date Received : -

Date Calibrated : 27 March, 2019 Recalibration date specified by client : 26 March, 2020

Instrument Description

Description : Freezer
Make : THERMO SCIENTIFIC
Model : FORMA 88000 SERIES
Serial No : [illegible]
Location : MAKMAL TEKNOLOGI ENZIM, LABORATORI BIOUBATAN MOLEKUL

The result of calibration shown relates only to the instrument being calibrated as described above.

Environmental Condition

Temperature : (25.2 ± 2.0)°C
Relative Humidity : (56 ± 10) %r.h.

The instrument has been calibrated on site at the address as shown in above under the environmental condition as stated above.

Reference Method : The calibration was based upon Calibration Procedure CP-K

The temperature scale used is International Temperature Scale of 1990 (ITS-90).

The reference standards used are traceable to either the national standards maintained at the National Metrology Institute of Malaysia, SIRIM Bhd or other recognised International Standard Laboratories.

Reference Standard	ID. No.	Serial No.	Traceable	Cert. No.	Due Date
Temperature Calibrator	ST-MC7	2002Z B40 0021 A	NMIM & NPL	ST-MC7-1905	17-May-19
Reference Thermocouple Wires	ST-TLA1 – ST-TLA8	-	NIST & SST	SST/SA/R/2018D/941	11-Apr-19

K Factor = 2

Calibrated by
Muhammad Syukri Bin Ahmad

Approved Signatory
Mohamad [illegible] Bin Asari

SIRIM SST

CERTIFICATE OF CALIBRATION

DATE OF ISSUE : 09 October 2019
CERTIFICATE NUMBER : SST/SA/R/2019/497

ISSUED BY : SIRIM Standards Technology Sdn. Bhd.
(Co.No. 292201-P)
Lot 12, 18 & 20, Jalan Bersatu 13/12,
Seksyen 13,
40200 Shah Alam,
Selangor Darul Ehsan.
Tel. : 03-55109066 Fax. : 03-55109077

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APPROVED SIGNATORIES
Mohamad Najib Kamaruddin ✓

Submitted by : Universiti Putra Malaysia (Institut Biosains)
Institut Biosains,
Universiti Putra Malaysia,
43400 Serdang, Selangor.

(Attn. : Mrs. Norhasazalina)

Job No. : SA2019-6364-13
Date Received : 09/10/2019

Instrument : Analytical Balance
Manufacturer : Mettler Toledo
Model No. : AB265-S/FACT
Serial No. : 390008021

Instrument Condition When Received :
Physically in good condition

Instrument Condition When Returned :
1. Calibrated and readings tabulated as obtained at the time of calibration.

Environmental Condition(In-Situ Calibration) :-
Average Temperature : 22 ± 1 °C
Average Relative Humidity : 59 ± 2 %
Calibration Date : 09 October 2019

Calibration Method :
This instrument was calibrated using the Calibration Procedure No. MSM/0017 Rev 8.0

Calibration Standard(s) Used :

Instrument Type :	Serial No. :	Cal. Due Date :	Cal. Cert. No.	Traceability :
Mettler Toledo Std. Weights	MSM 067	28/02/2020	NMIM-0656-M-18	NMIM
Hygro-Thermometer	811479(TS177/A2/4)	21/01/2020	SST/SA/R/2018A/28	NMIM

The standard instruments used in this calibration are traceable to either the National Standards maintained at the National Metrology Institute of Malaysia or other recognised International Standard Laboratories.

Calibration Sticker No. : SA-10-497
Measurement Uncertainty : ± 0.0002 g
The uncertainty calculation is based on the ISO Guide to the Expression of Uncertainty in Measurement.
Coverage factor : $k = 2$

Approved Signatory

The uncertainties are for a confidence probability of approximately 95%

RELATED ACTS AND REGULATIONS

- Standards of Malaysia Act 1996 (Act 549)
- Chemist Act 1975 (Act 158)
- Food Analyst Act 2011 (Act 727)
- Food Act 1983 (Act 281)

CHEMIST ACT 1975 (ACT 158)

Grades of membership

Criteria	Fellow (FMIC)	Member (MMIC)	Licentiate (LMIC)
Degree	Degree or any equivalent academic qualification, in chemistry or any specialized discipline associated with chemistry from one of the examinations listed in the Second Schedule		
Practical experience in chemistry	>10 years	>3 years (degree), or >1 year for a masters or higher degree	>1 year
Age	33 or less, as allowed by the Council	21	21
Others	Made a substantial contribution to chemistry	-	-

FOOD ANALYST ACT 2011 (ACT 727)

- Degree - food science/food technology/food science and technology/any degree in science from any higher educational institution as may approved by the Council or
- Evidence that he has been selected for employment under the supervision of any registered food analyst/registered chemist; or
- 2 years working experience in food analysis (food sc./food tech./food sc. & tech. degree) or 4 years working experience in food analysis (any other degree in science)
- >18 years old

FOOD ANALYST ACT 2011 (ACT 727)

Registered food analysts may issue food analysis report (Part V, Food Analysis)

- Registered food analyst and has valid annual practising certificate
- 1st offence: <RM50,000 or imprisonment <3 years or both.
- Subsequent: <RM100,000 or imprisonment <5 years or both

FOOD ANALYST ACT 2011 (ACT 727)

Practising without annual practising certificate (Part V, Food Analysis)

- Registered food analyst practises without annual practising certificate
- 1st offence: <RM20,000 or imprisonment <2 years or both.
- Subsequent: <RM40,000 or imprisonment <4 years or both


Discussion

THE STANDARD

GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

- Proof of a laboratory's accuracy, sound management system and global recognition
- Efficient management system
- Guarantee customers, stakeholders, auditors and authorities about lab's technical competence to perform testing/calibration
- Reduce customer complaints
- Accreditation certificate for marketing and advertising

THE MANAGEMENT PRINCIPLES

MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS

Interdependent, relationship enhances the ability if both to create value

FACTUAL APPROACH TO DECISION MAKING

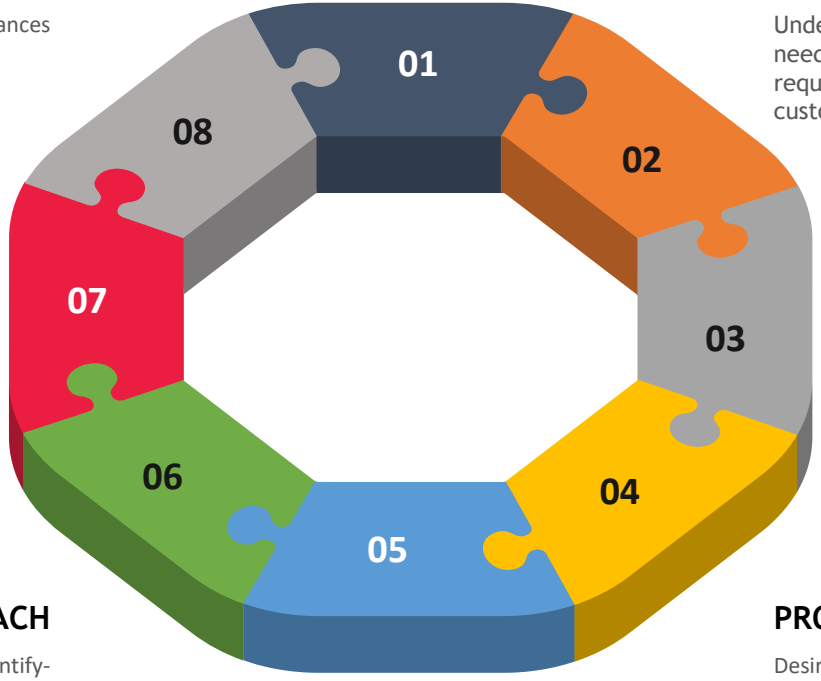
Effective decisions based on the analysis of data and information.

CONTINUOUS IMPROVEMENT

Permanent objective of the organization.

SYSTEM APPROACH

Interrelated processes (identify-understand-manage) improves the organization's effectiveness and efficiency.



CUSTOMER FOCUSED

Understand current and future needs, meet customer requirements and strive to exceed customer expectations.

LEADERSHIP

Leaders establish unity of purpose and direction of the organization.

INVOLVEMENT OF PEOPLE

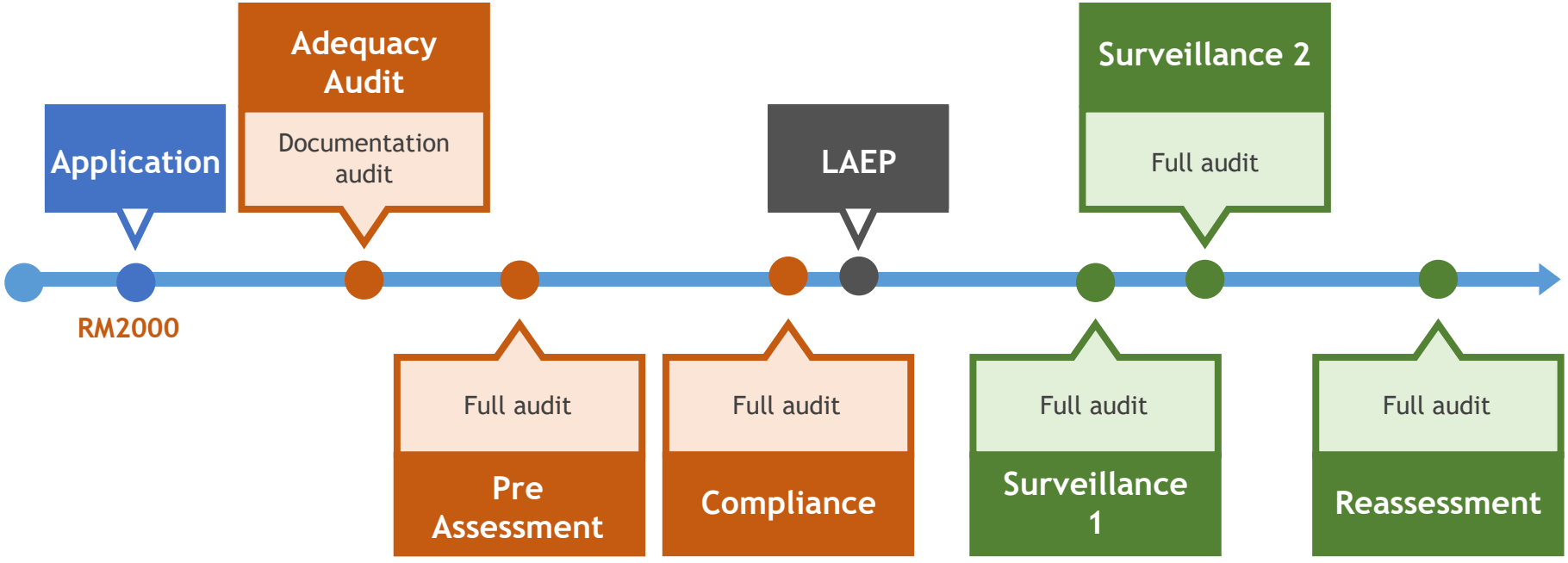
Full involvement (everybody) enables their abilities to be used for the organization's benefit.

PROCESS ORIENTATION

Desired result is achieved more efficiently when related resources and activities are managed as a process.

ACCREDITATION PROCESS

Lead assessor:
RM1000/day, or RM500/4 hrs
Assessors:
RM800/day, or RM400/4 hrs
Overseas assessors:
Actual prof. fee + Business class flight + accommodation



THE STRUCTURE

4. General requirements
   - Impartiality
   - Confidentiality
5. Structural requirements
6. Resource requirements
   - General
   - Personnel
   - Laboratory facilities and environmental conditions
   - Equipment
   - Metrological traceability
   - Externally provided products & services
7. Process requirements
   - Review of requests, tenders and contracts
   - Selection, verification & validation of methods
   - Sampling
   - Handling of test and calibration items
   - Technical records
   - Evaluation of measurement uncertainty
   - Assuring the validity of results
   - Reporting of results
   - Complaints
   - Nonconforming work
   - Control of data and information management
8. Management requirements
   - Options
   - Management system documentation (Option A)
   - Control of management system documents (Option A)
   - Control of records (Option A)
   - Actions to address risks and opportunities (Option A)
   - Improvement (Option A)
   - Corrective action (Option A)
   - Internal audits (Option A)
   - Management reviews (Option A)

HOW TO READ THE STANDARD

"shall"= a requirement

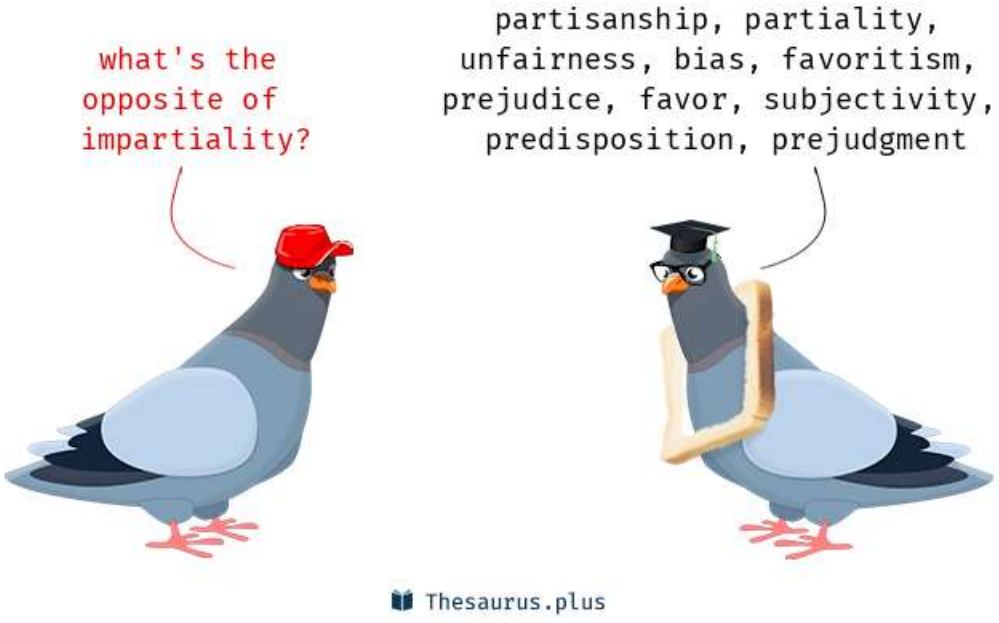
"should" = a recommendation

"may" = permission

"can" = possibility or a capability

GENERAL REQUIREMENTS

4.1 IMPARTIALITY *(+ risk)*



Impartiality is a principle of justice holding that decisions should be based on objective criteria, rather than on the basis of bias, prejudice, or preferring the benefit to one person over another for improper reasons.

4.2 CONFIDENTIALITY

- Emphasis on customer awareness
- Detail regarding specific cases where confidentiality could be affected
  - Responding to complaints
  - Releasing of information
  - Personnel, contractors, personnel of external bodies, individuals acting on lab's behalf

STRUCTURAL REQUIREMENTS

REQUIREMENT - LAB

- Legal entity (5.1)
- Identify management (5.2)
- Define and document activities (5.3)
- Activity (5.4)
- Structure, responsibility, authority and interrelationship of all personnel & procedure (5.5)
- Personnel with authority and resources (5.6)
- Communication & integrity (5.7)

Removed terms ‘technical management’ and ‘quality manager’

Revised standard consistently uses term ‘procedure’ when the intent is for lab to maintain documentation

RESOURCE REQUIREMENTS

6.2 PERSONNEL

- Personnel = internal + external
  - Act impartially, be competent and work in accordance with lab MS
- Competency
  - Document requirements for **each function** influencing the results of lab's activities. (6.2.2)
  - Competent to perform activities (6.2.3)
- Procedure(s) and record need to be maintained for personnel covering: determination and competence requirements; selection, training, supervision and authorisation and monitoring of competence (6.2.5)
- Authorisation of personnel to perform specific activities (6.2.6)

6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

- Requirement documented (6.3.2)
- Monitor, control and record (6.3.3)
- Measures to control facilities are to be implemented, monitored and periodically reviewed (6.3.4)
- Requirements are met if perform activities outside lab's permanent control (6.3.5)

6.4 EQUIPMENT

- Access to equipment (6.4.1) *+measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus*
- Procedure for handling, transport, storage, use and planned maintenance of equipment (6.4.3)
- 2 criteria that determine when calibration is required (6.4.6):
  - The measurement accuracy/uncertainty affects the validity of reported results, or
  - Calibration is required to establish the metrological traceability of reported results
- Establish, review and adjusted a calibration program as necessary to ensure confidents in the status of calibration (6.4.7)

6.4 EQUIPMENT

- All equipment which required calibration or has a defined period of validity must be labelled or otherwise identified (6.4.8)

  A calibration certificate/label shall not contain any recommendation on the calibration interval, except where this has been agreed with customer (7.8.4.3)
- OOS equipment – isolate/label/mark until verified (6.4.9)
- Procedure to conduct intermediate check (6.4.10)
- Reference values/correction factors from calibration/RM are updated and implemented (6.4.11)

6.5 METROLOGICAL TRACEABILITY

- Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (6.5.1)
- Traceable to SI unit (6.5.2)
- Demonstrate if not traceable to SI unit (6.5.3)

6.6 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

- Define requirements, select providers and evaluate/monitor the performance (6.6.2)
- Communicating the needs to providers (6.6.3)
  - Products and services
  - Acceptance criteria
  - Competence of personnel
  - Activities to be performed by lab/customer at the external provider's premises

PROCESS REQUIREMENTS

7.1 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

- Procedure – requirements, capability, resources, external providers, methods (7.1.1)

  Review can be performed in a simplified way for internal or routine customers

- Communication with customer (7.1.2, 7.1.4, 7.1.5)
- Decision rule (7.1.3)
- Cooperate with customer in clarifying the request and in monitoring lab's performance

  Provide reasonable access to relevant areas to witness
  Preparation, packaging and dispatch of items for verification

7.2 SELECTION, VERIFICATION AND VALIDATION OF METHODS

- Use appropriate method/procedures (7.2.1.1)
- Latest valid version (7.2.1.2)
- Select appropriate method and inform customer (7.2.1.4)
- Verify selected method before use (7.2.1.5)
- Planned method development (7.2.1.6)
- Validate non-standard method, lab-developed method and standard method used outside their intended scope/modified (7.2.2.1)

7.3 SAMPLING

- Sampling method must include:
  - Selection of samples or sites
  - Sampling plan (based on appropriate statistical method)
  - Preparation and treatment of sample(s) from a substance, material or product

7.4 HANDLING OF TEST/CALIBRATION ITEMS

- Procedure for transportation, receipt, handling, protection, storage, retention and disposal/return of items (7.4.1)
- System for identification of items (7.4.2)
- Include a disclaimer in the report indicating which results may be affected by deviation from specific conditions (7.4.3)
- Maintain, monitor and record environmental condition (7.4.4)

7.5 TECHNICAL RECORDS

- Amendment to technical records must be traceable to previous versions or to original observations. Original and amended data or files are to be kept, including date of alteration, an indication of the altered aspects and the identity of the personnel responsible (7.5.2)

7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

- All significant contributions to MU identified (7.6.1)
- Evaluation of MU for all calibrations, including lab which performs on its equipment, *i.e.* in house calibration (7.6.2)
- If method used precluded rigorous evaluation of MU, estimation shall be based on understanding on the theoretical principles or practical experience

7.7 ENSURING THE VALIDITY OF RESULTS

- Monitor validity of results by (7.7.1):
  - Use RM or QC materials
  - Use calibrated alternative instrument
  - Functional check of measuring and testing equipment
  - Working standards with control charts
  - Intermediate checks
  - Replicate tests/calibrations using same/different method
  - Retesting/recalibrations
  - Correlation of results for different characteristics
  - Review of reported results
  - Intra-laboratory comparisons
  - Testing of blind samples
- Participate in PT or other inter-laboratory comparison (7.7.2)

7.8 REPORTING OF RESULTS

- Results may be reported in a simplified way when agreed with customer. Any information listed in 7.8.2 – 7.8.7 that is not reported to the customer shall be readily available.
- When a statement of conformity to a specification or standard is provided, the lab must document the decision rule employed, taking into account the level of risk associated with the decision rule (accept for decision rule prescribed by customer/regulation/ normative documents) (7.8.6)

7.9 COMPLAINTS

- Description of the complaints handling process required to be available to any interested party on request (7.9.2)
- Outcomes required to be communicated to the complainant be made by, or reviewed and approved by, individual(s) **not involved** in the original laboratory in question

7.10 NONCONFORMING WORK

- Retain records of nonconforming work and actions as specified in 7.10.1 (7.10.2)
- Implement corrective action (7.10.3)

7.11 CONTROL OF DATA AND INFORMATION MANAGEMENT

- Information management system=collection, processing, recording, reporting, storage or retrieval of data -> validate for functionality before introduction (7.11.2)
- Ensure instructions, manuals and reference data relevant to lab information system are made readily available to personnel (7.11.5)
- Calculations and data transfer checked in an appropriate and systematic manner (7.11.6)

MANAGEMENT SYSTEM REQUIREMENTS (OPTION A)

OPTION A

- Management system documentation (8.2)
- Control of management system documents (8.3)
- Control of records (8.4)
- Action to address risk and opportunities (8.5)
- Improvement (8.6)
- Corrective action (8.7)
- Internal audit (8.8)
- Management review (8.9)

8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

- New requirements and introduces the concept of 'risk based thinking'
- Facilities must consider the risk and opportunities associated with lab activities in order to
  - Provide assurance that the management system achieves the intended outcomes
  - Enhance opportunities to achieve the lab's objective
  - Prevent/reduce undesired impacts and failures
  - Improvement
- **RISK REGISTER**

THANK YOU

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