مديرية الجودة والمواصفات الفنية في هيئة الطاقة الذرية الاردنية
وبالتعاون مع الهيئة العربية للطاقة الذرية
تعقد ورشة عمل بعنوان:

" إدارة المخاطر في المختبرات الإشعاعية و النووية حسب متطلبات الآيزو ISO 31000:2018"

محاضرة بعنوان :
المتطلبات العامة لكفاءة مختبرات الفحص و المعايرة
مواصفة الآيزو ISO17025:2017

Belal Al-Mrayat

EDUCATION
Master degree

- **Nuclear power engineering**

WORK
Jordan Atomic Energy Commission

- **Acting Head of Quality Control section**

SKILL
Quality

- **ISO 9001 Certified Lead Auditor.**

Messages from ISO/IEC 17025:2017

Message 1

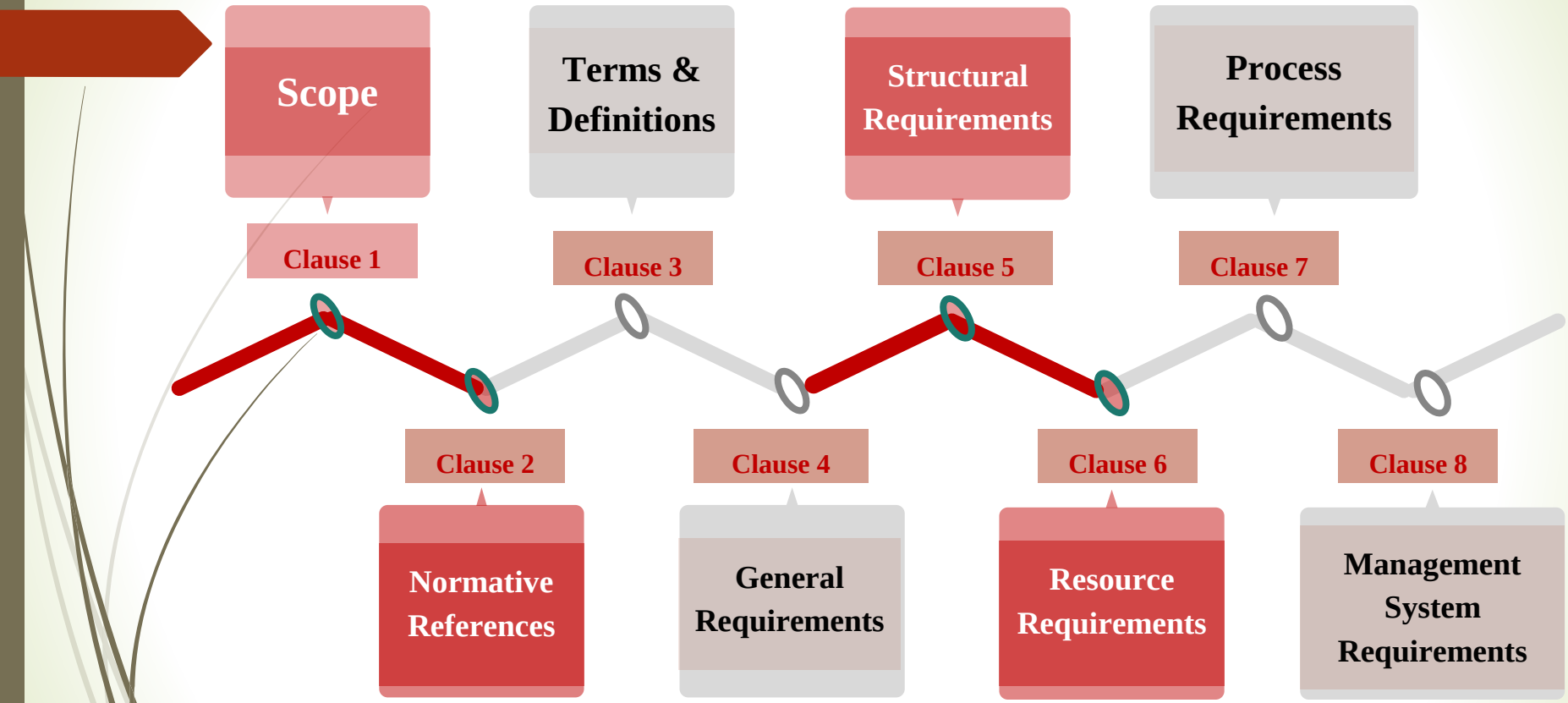
- Say what you do (PRC); Do what you say; Record what you do, Check the difference, Act on the difference

Message 2

- Do the right thing right the first time and every time to achieve consistent quality

Message 3

- Continual improvement is the way of life


Scope
Terms & Definitions
Structural Requirements
Process Requirements
Clause 1
Clause 3
Clause 5
Clause 7
Clause 2
Clause 4
Clause 6
Clause 8
Normative References
General Requirements
Resource Requirements
Management System Requirements

1. Scope:

- ❖ Cover the Requirements for competence, impartiality & operation of labs.
- ❖ It is applicable to all organizations performing Testing & Calibration

2. Normative References :

- ♣ ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM)1)
- ♣ ISO/IEC 17000, Conformity assessment — Vocabulary and general principles

3. Terms & Definitions :

- ❖ given in ISO/IEC Guide 99 and ISO/IEC 17000 are applicable

Clause 4.0: General requirements

4.1 Impartiality : absence of bias

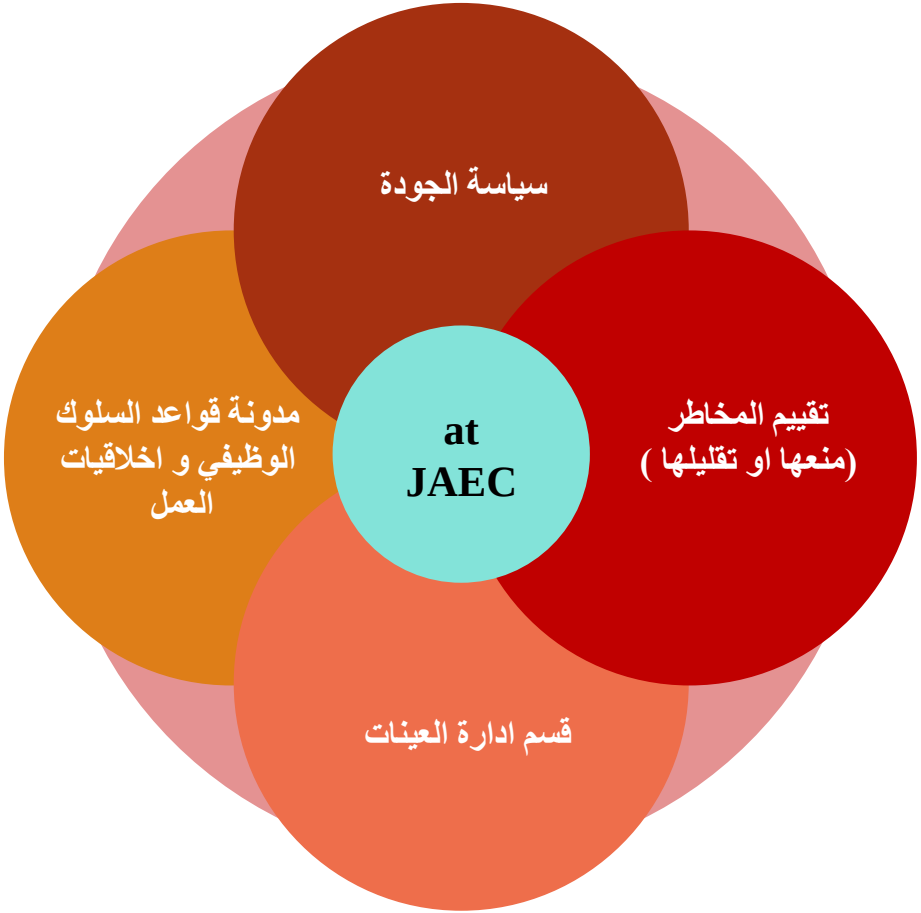
Conflict of interests

Accepting Gifts or Money.

Or any other offers to support malpractices.

- **The Lab shall not allow commercial, financial, or other pressures to affect impartiality.**
- **The Lab shall Identify the risks to eliminate and or minimize the risk.**

4.1 Impartiality at JAEC



يعمل أحد الموظفين في مختبر ما وفي المساء يعمل في مختبر آخر حيث يحصل على راتب أعلى بالإضافة لمكافأة على كل زبون جديد

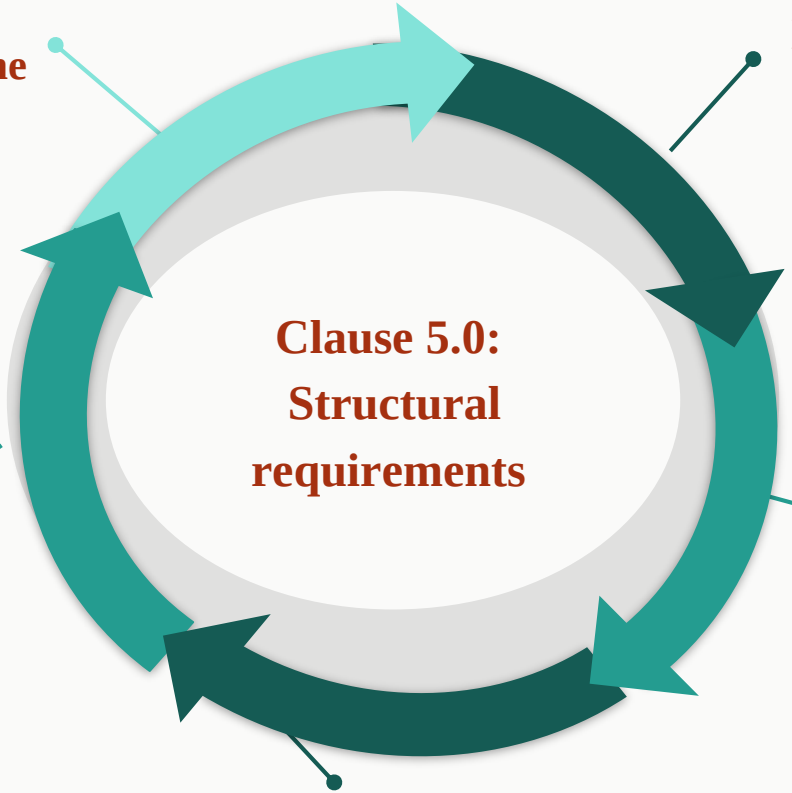
4.1 Confidentiality:

The protection of info & data to ensure it accessible only to authorized personnel and not made available or disclosed to unauthorized individuals or entities .

أثناء زيارة أحد الزبائن لاستلام تقرير نتائج عيناته ، طلب منك بشكل ودي تزويده بنتائج زبون أخر

Identify Management has overall responsibility & the integrity of MS

legal entity or part & legally responsible

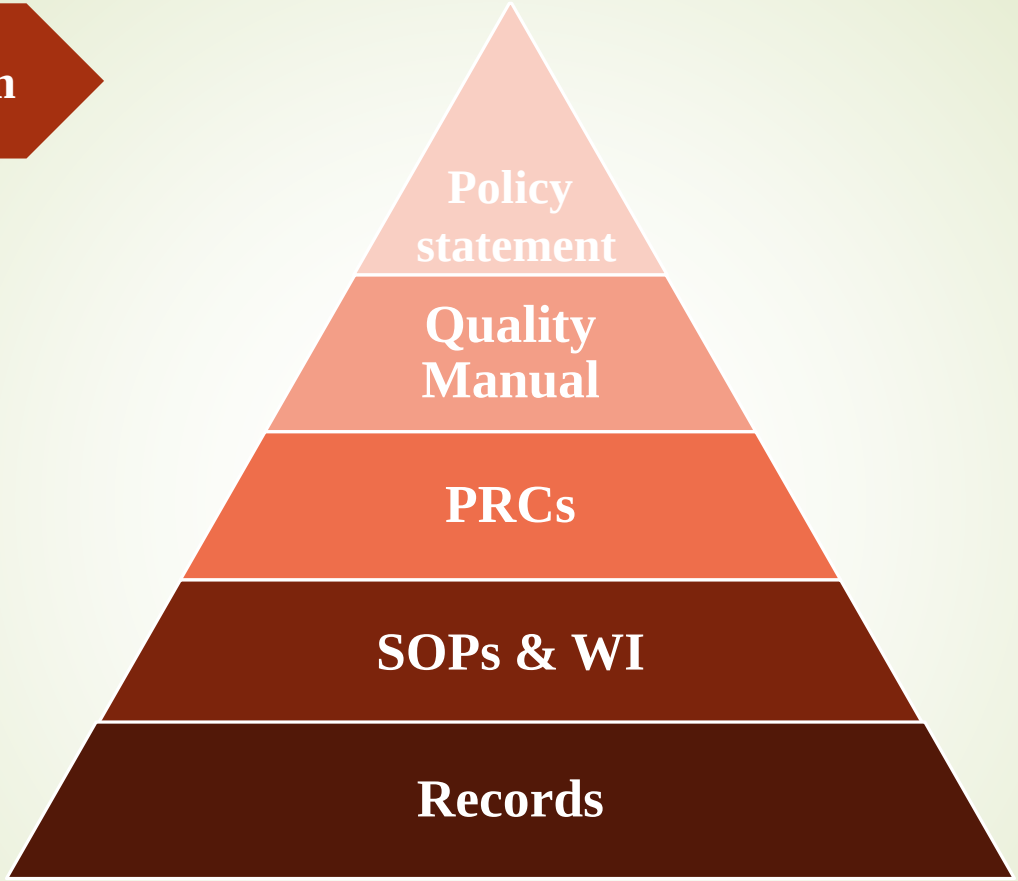


Range of lab Activities

Personnel
the responsibilities and the authorities

Organization Structure & Relationships

Management system



Overall hierarchy of the quality management system at JAEC


Authority Vs Responsibility

6. Resource Requirements

6.1 General Resource Requirements

To be able to achieve accreditation, LAB must have :

6.2 Personnel

- PRC
- Impartiality & Integrity
- Education, Training, Experience & skills
- Staff Competency
- Training needs
- Duties , Authorities and Responsibilities
- Staff Records
- Delegation

6.3 Facilities and environmental conditions

- **Suitable facilities and environmental conditions**
- **The requirements shall be documented in SOPs or PRCs**
- **Shall , Monitoring , controlling ,implementation measures and periodically review**
- **Activities outside lab**

6.4 Equipment

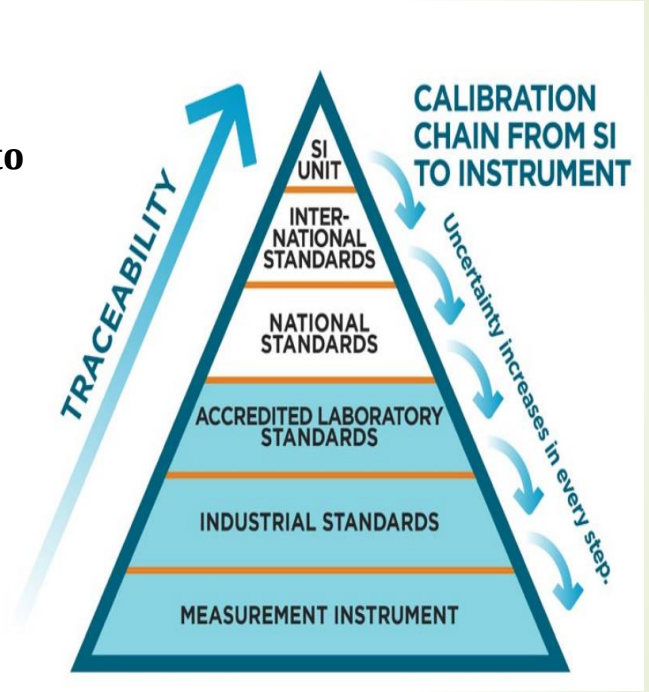
- Availability of **Instruments, Software, Standards, RM, reference data, Reagents, Consumables or auxiliary apparatus** for performing activities
- PRCs for Handling ,Transport, Storage, Use and Maintenance
- Verifying requirements to achieve accuracy and measurement uncertainty
- calibration and verification (metrological traceability)
- **Equipment cards** , out of services .

6.5 Metrological Traceability

Documented unbroken chain of calibrations, each contributing to measurement uncertainty and linking them to reference.

Results will traceable to the SI units in one of these 3 ways:

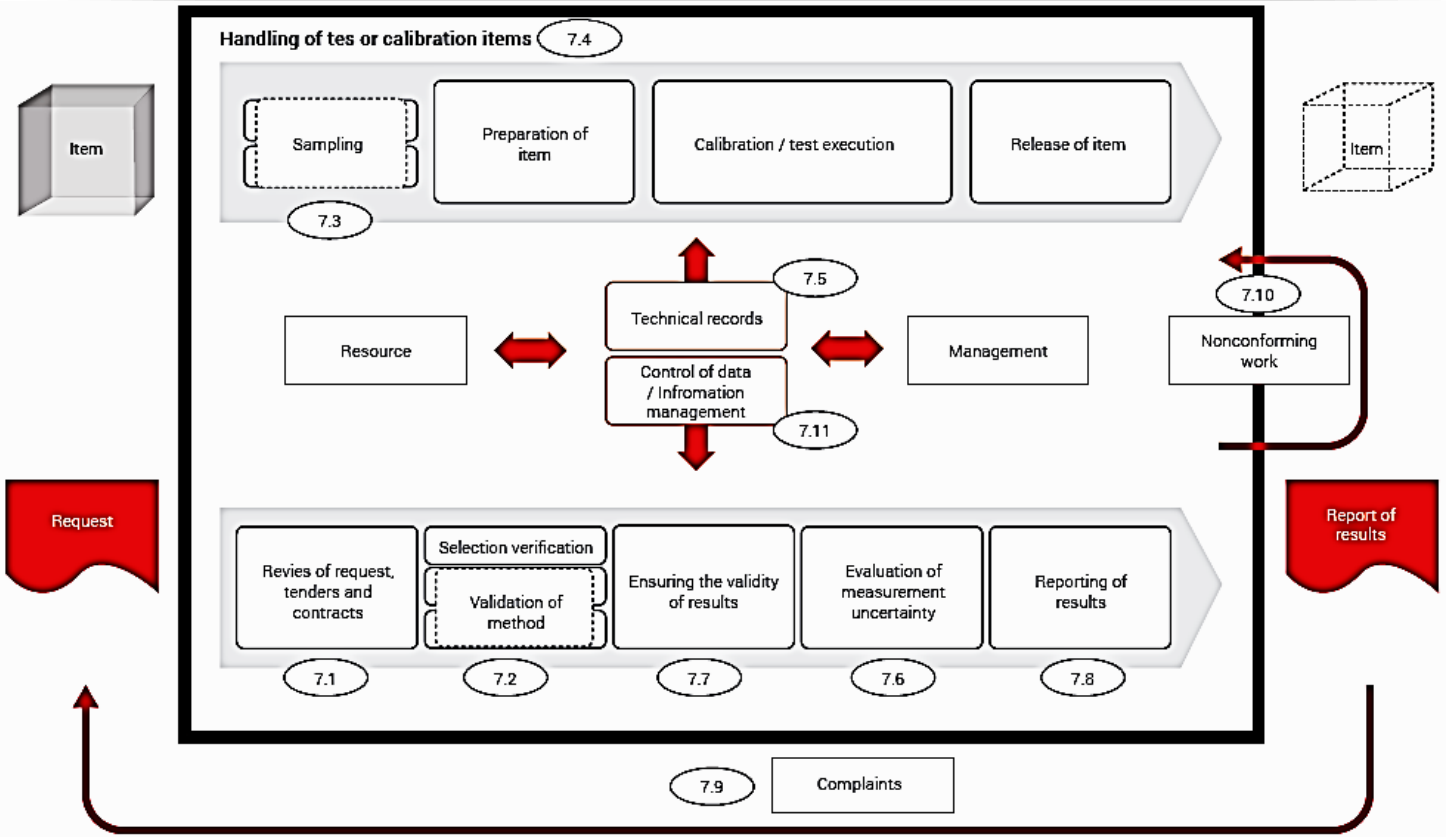
- **Calibration by a competent lab**
- **Certified values of CRM provided by 17034.**
- **Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards**



6.6 Externally Provided Products and Services

- PRC for requirements
- ensure only satisfactory products and services
- Evaluation of suppliers

7. Process Requirements



7.1 Tenders & Contracts

- **PRC**
- **communication with the customer**
- **ensure that customer’s needs are met**
- **inform the customer ALL details**

7.2 Selection , Verification and Validation

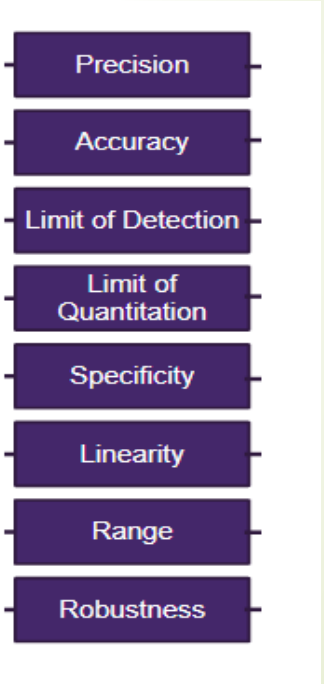
7.2.1 Selection and Verification

- use suitable methods and PRCs for activities, uncertainty evaluation and statistical techniques for data analysis .
- available to all personnel
- use the latest valid version.
- communicate with customer.

7.2.2 Methods Validation

- **is a process that is used to demonstrate the suitability of an analytical method for an intended purpose.**

- **Methods types:**
  standard , non-standard, and laboratory-developed
- **Method validation needs :**
  expertise , time, money , staff, equipment availability, & samples matrix
- **When ?**
  -new method -revised method -used in different lab - QC
- **Why ?**
  -to increase reliability and trust and to prove the truth



7.3 Sampling

Sampling methods must describe:

- ❑ The selection of samples or sites
- ❑ The sampling plan
- ❑ The preparation and treatment of samples
- ❑ Sampling method
- ❑ Date and time of sampling
- ❑ Sample description
- ❑ Personnel
- ❑ Environmental or transportation conditions
- ❑ Location

7.4 Handling of Test and Calibration Items

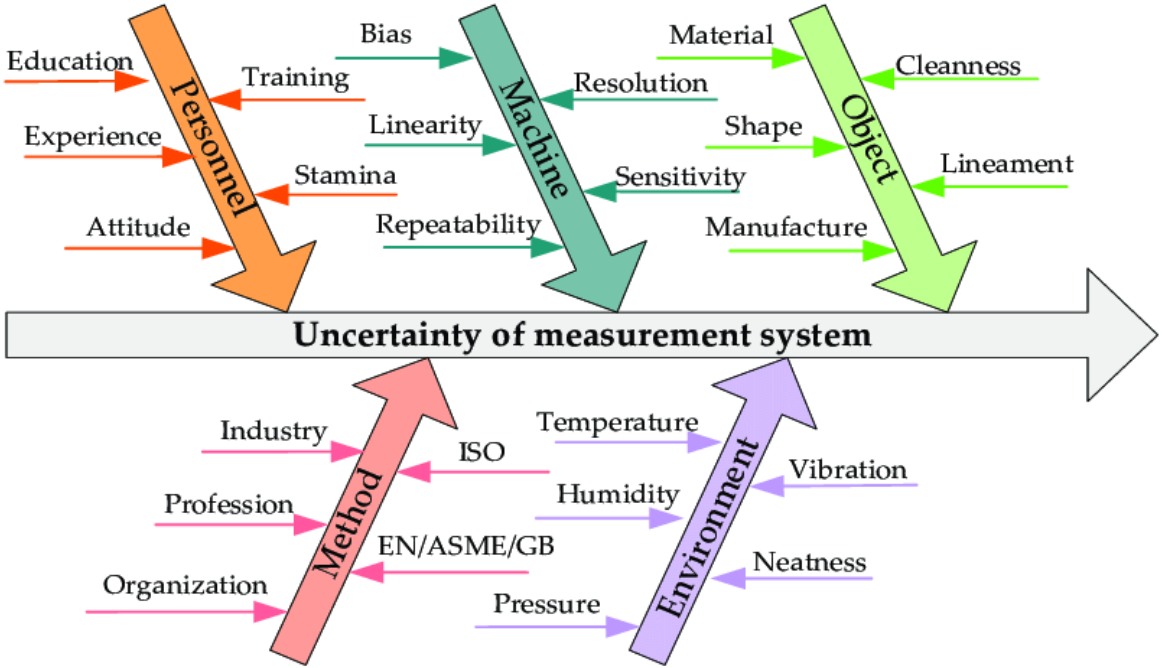
- **The laboratory must have a PRC to cover :**

transportation, receipt, handling, protection, storage, retention, and disposal or return .

7.5 Technical Records

- any Info or data that could affects results & its uncertainty
- any info enable the repetition of the lab activity under conditions as close as possible to the original

7.6 Evaluation of MU

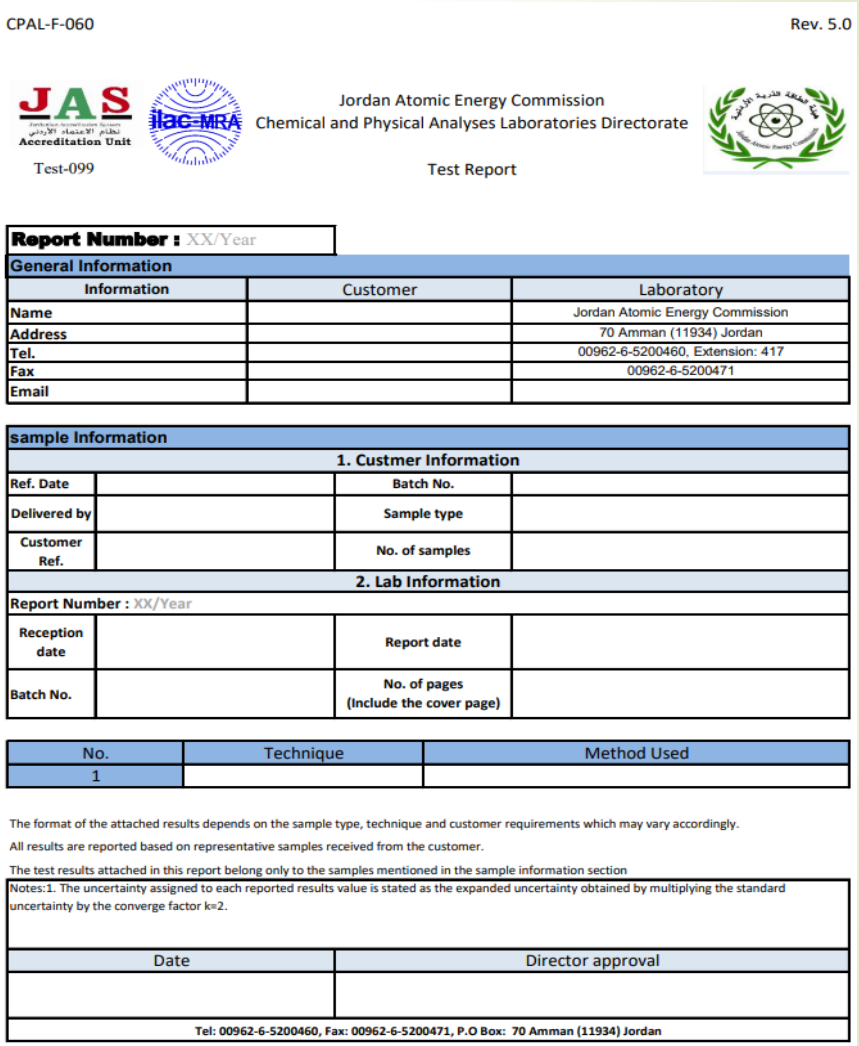


7.7 Ensuring the Validity of Results

- Top priority , lab shall have a PRC for monitoring the validity of results.
- RM/CRM- QC materials
- Calibrated instruments , functional checks
- Trends & statistical techniques
- Retesting/replicate/recalibration
- Review of results
- PT/ILC
- Blind sample

7.8 Reporting of results

- The results shall be approved & reviewed &submitted accurately, clearly, and objectively & contain all related info.
- Title ، lab name & address ،location ،customer name & contact, method ،sample description, four dates ,results with units & uncertainty, signs , any other notes.
- Test or calibration conditions or any other info



CPAL-F-060 Rev. 5.0

JAS Accreditation Unit — Test-099 — ilac-MRA

Jordan Atomic Energy Commission
Chemical and Physical Analyses Laboratories Directorate

Test Report

Report Number : XX/Year

General Information

Information	Customer	Laboratory
Name		Jordan Atomic Energy Commission
Address		70 Amman (11934) Jordan
Tel.		00962-6-5200460, Extension: 417
Fax		00962-6-5200471
Email		

sample Information

1. Custmer Information

Ref. Date		Batch No.	
Delivered by		Sample type	
Customer Ref.		No. of samples	

2. Lab Information

Report Number : XX/Year

Reception date		Report date	
Batch No.		No. of pages (Include the cover page)	

No.	Technique	Method Used
1		

The format of the attached results depends on the sample type, technique and customer requirements which may vary accordingly.

All results are reported based on representative samples received from the customer.

The test results attached in this report belong only to the samples mentioned in the sample information section

Notes:1. The uncertainty assigned to each reported results value is stated as the expanded uncertainty obtained by multiplying the standard uncertainty by the converge factor k=2.

Date	Director approval

Tel: 00962-6-5200460, Fax: 00962-6-5200471, P.O Box: 70 Amman (11934) Jordan

7.9 Complaints

- PRC for receive, evaluate & make decisions on how to handle complaints

QA-F-006 Customer Feedback Rev. 6.0

عميلنا العزيز

تمكف هيئة الطاقة الذرية الاردنية بشكل دوري على تحسين خدماتنا للعملاء و معالجة اي مشاكل او ملاحظات فورا. نطلب من فضلكم تعبئة النموذج ادناه و تزويدنا بأي مشاكل او شكاوى او ملاحظات سواء سلبية او ايجابية.

شكرا مقدما لتعاونكم , نتطلع دائما للحفاظ على علاقة جيدة معكم.

الجزء الأول : معلومات عامة .

اسم العميل :	
عدد العينات :	
تاريخ التقييم:	
المختبر مقدم الخدمة :	☐ مختبرات التحاليل الفيزيائية و الكيميائية ☐مديرية مختبرات البحوث و المعلومات . ☐مختبر معايرة قياس الجرعات القياسية الثانوية. ☐مختبر الديترونات.

الجزء الثاني : ما مدى رضاكم حول النقاط التالية :

1- الخدمة بشكل عام : ممتاز ☐ جيد ☐ متوسط☐ ضعيف ☐ غير راضي ☐	**2- سهولة إنجاز المهمة والتعاون:** ممتاز☐ جيد ☐ متوسط☐ ضعيف☐ غير راضي☐
3- كفاءة الفحوصات: ممتاز☐ جيد ☐ متوسط☐ ضعيف☐ غير راضي☐	**4- تكلفة الفحوصات:** ممتاز☐ جيد ☐ متوسط☐ ضعيف☐ غير راضي☐
5- الوقت المحدد لاستلام النتائج: ممتاز☐ جيد ☐ متوسط ☐ ضعيف ☒ غير راضي☐	

الجزء الثالث : الاقتراحات و التوصيات :

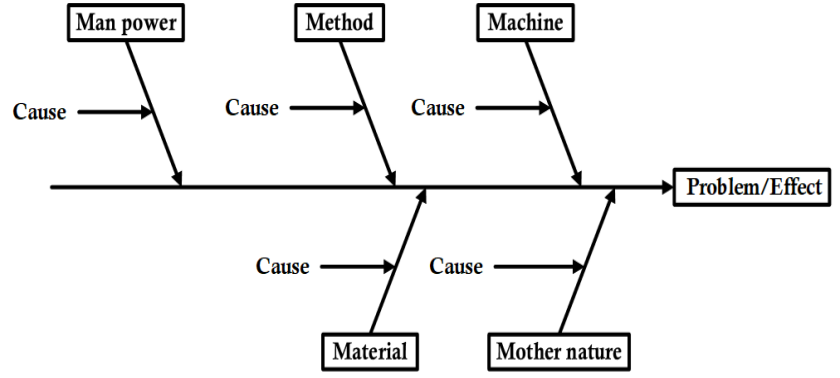
هل هناك أي اختبارات أو خدمات جديدة تود أن تقدمها المختبرات التحليلية؟
في حال الجواب نعم , يرجى الكتابة هنا .

يرجى كتابة اي اقتراحات او شكاوى او توصيات لديكم هنا :

الرجاء ارسال النموذج الى قسم ضمان الجودة في هيئة الطاقة الذرية الاردنية الى البريد الالكتروني التالي :
QA.info@jaec.gov.jo

7.10 Nonconforming work

- **It is the failure to meet one or more of the requirements.**
- **Requirements can be related to customers, regulatory or legal bodies, ISO standard, or the organization's requirements .**
- **A corrective action is the action conducted to prevent recurrence of a nonconformance.**

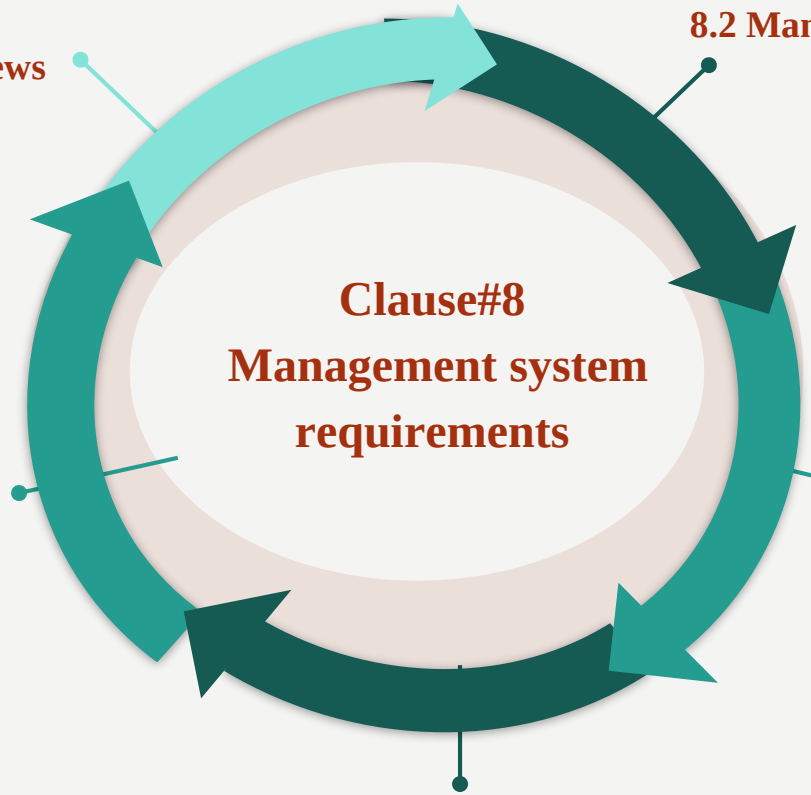


7.11 Control of data and information management

- **Labs need to verify that they have the necessary access to data and information needed to perform all of its activities.**

8.1 Options
8.2 Management system documentations.

8.8 Internal audits.
8.9 Management reviews



8.3 Control of management system documents
8.4 Control of records.

8.7 Corrective actions

8.5 Actions to address risks and opportunities.
8.6 Improvement.

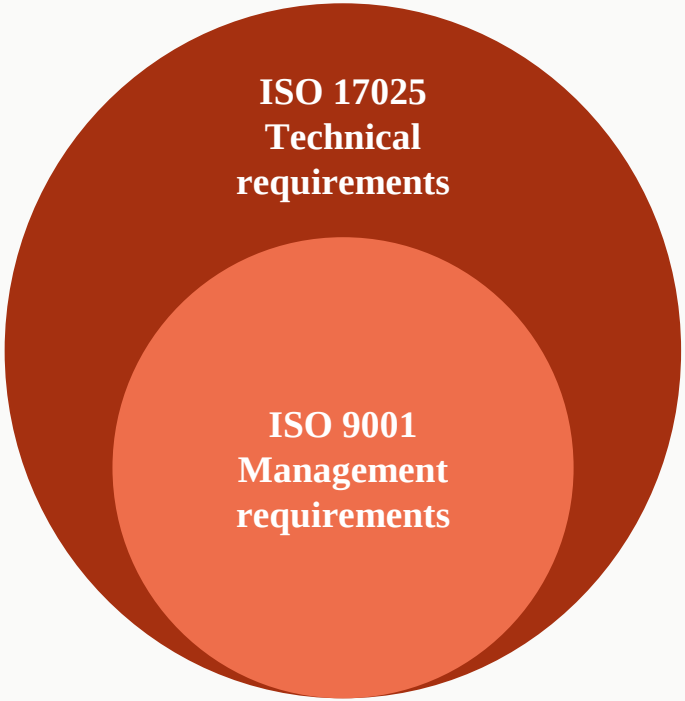
Options

Option A:

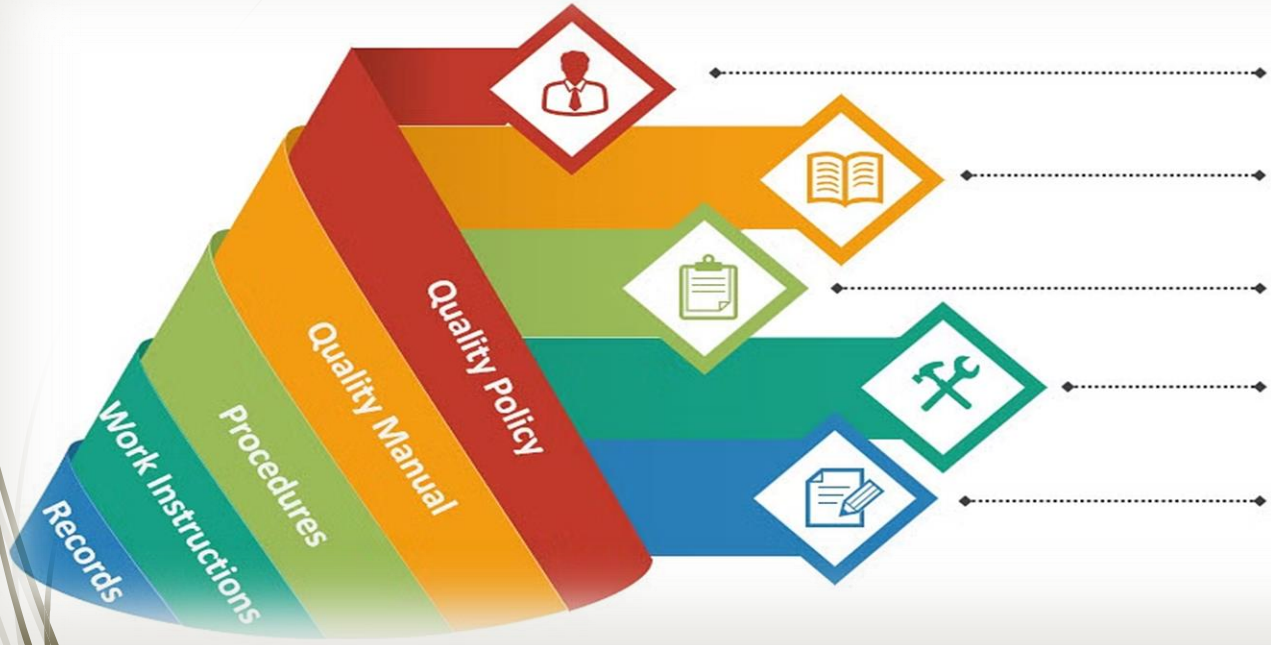
Compliance with the provisions of all clauses of 17025

Option B:

Laboratories implementing a management system in accordance with ISO 9001 need to comply with clauses 4-7 of ISO/IEC 17025.



Management system documentations.



Quality Policy
The overall direction regarding quality.

Quality Manual
The Why? organizations commitment, system description

Procedures
The What? When? Where? Who? Overall procedures.

Work Instructions
The How?, Detailed instructions to work.

Records
Objective Evidence?, Recorded data, for example filled-in forms.

Actions to address risks and opportunities

- **The laboratory shall consider the risks and opportunities associated with the laboratory activities**

Improvement

The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

- **Review of Quality policy, objectives.**
- **Customer feedback and complaints.**
- **PT and ILC.**
- **Management review meeting.**
- **Risk analysis.**

Corrective action

The laboratory shall have a PRC to handle the nonconformity cases.

Internal audit

The lab shall conduct internal audits at planned intervals to check the compliance of the QMS.

Management reviews

The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

Management reviews shall cover the following :

Changes in issues that are relevant to the laboratory.

Fulfilment of objectives,

Suitability of policies and procedures;

Status of actions from previous management reviews;

Outcome internal audits;

Corrective actions;

Assessments by external bodies;

Changes in the volume and type of the work or in the range of laboratory activities;

Customer feedbacks and complaints;

Effectiveness of any implemented improvements;

Results of risk identification;

Adequacy of resources;

“Thank You”