L7 Facilities and Equipment Management

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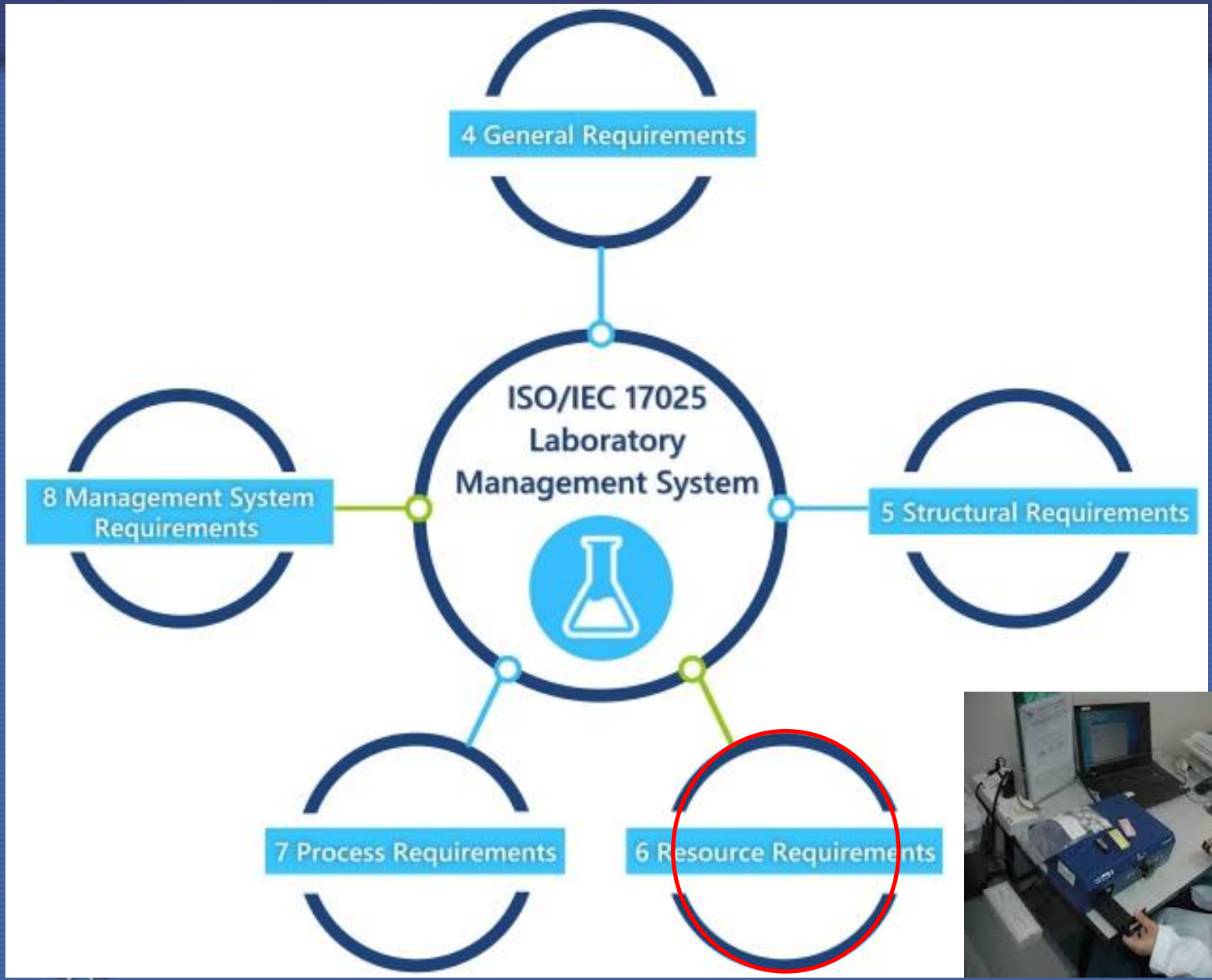
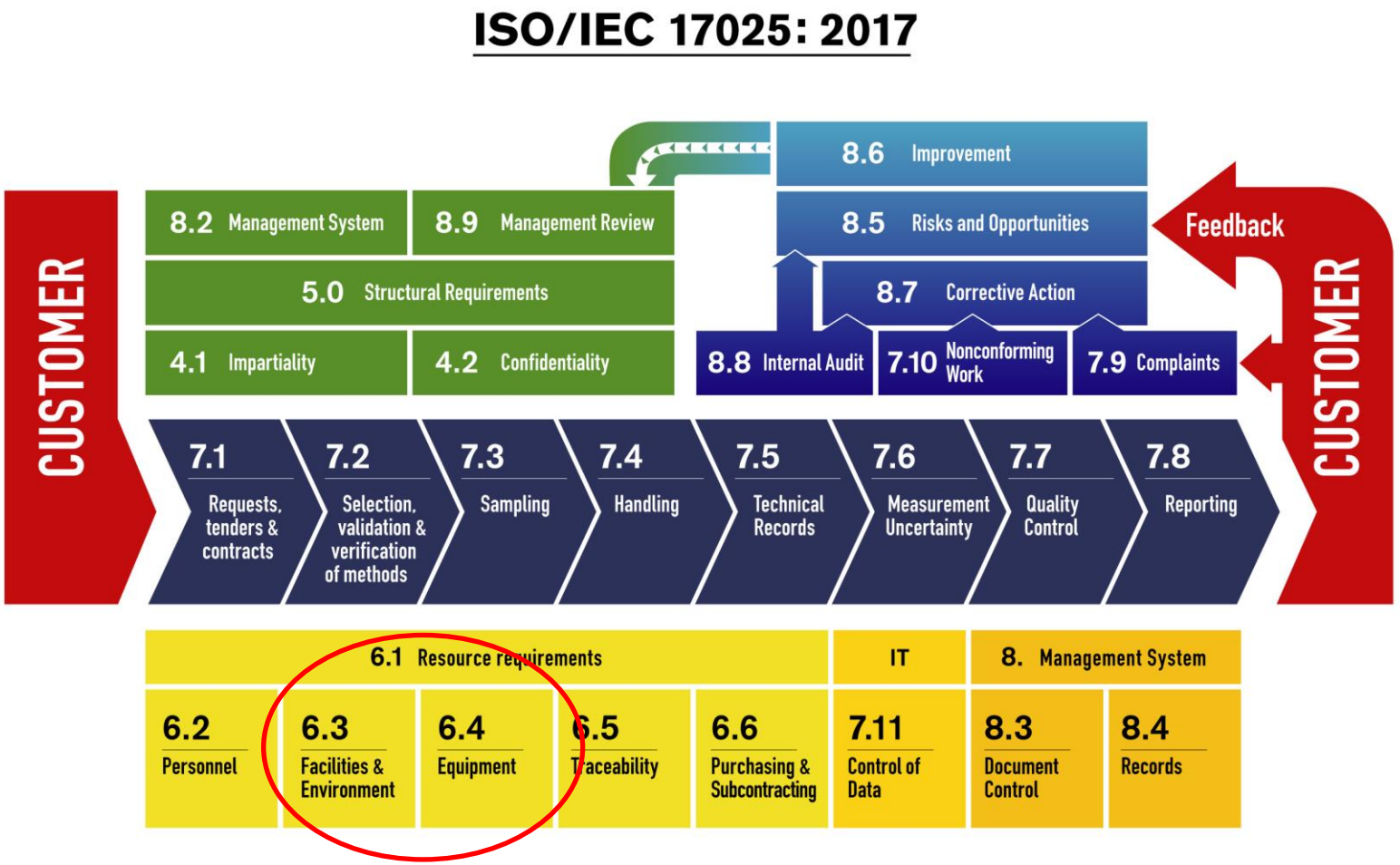
International Atomic Energy Agency


4 General Requirements
ISO/IEC 17025
Laboratory
Management System
8 Management System Requirements
5 Structural Requirements
7 Process Requirements
6 Resource Requirements

Structure


ISO/IEC 17025: 2017
8.6 Improvement
8.2 Management System
8.9 Management Review
8.5 Risks and Opportunities
Feedback
5.0 Structural Requirements
8.7 Corrective Action
CUSTOMER
4.1 Impartiality
4.2 Confidentiality
8.8 Internal Audit
7.10 Nonconforming Work
7.9 Complaints
CUSTOMER
7.1 Requests, tenders & contracts
7.2 Selection, validation & verification of methods
7.3 Sampling
7.4 Handling
7.5 Technical Records
7.6 Measurement Uncertainty
7.7 Quality Control
7.8 Reporting
6.1 Resource requirements
IT
8. Management System
6.2 Personnel
6.3 Facilities & Environment
6.4 Equipment
6.5 Traceability
6.6 Purchasing & Subcontracting
7.11 Control of Data
8.3 Document Control
8.4 Records

6.3 Facilities and environmental conditions

6.3.1 Facilities and environmental conditions suitable for laboratory activities and validity of results

6.3.2 The technical requirement for facilities and environmental condition documented

6.3.3 Environmental condition to be monitored, controlled and recorded as per specifications, methods, procedures etc

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6.3.4 Measures to control facilities implemented, monitored and periodically reviewed for i. Access, ii. Use of areas, iii. prevention of contaminations, iv. effective separation for incompatible activities

6.3.5 Follow above points for site laboratory

6.3 Facilities and environmental conditions

6.3 Facilities and environmental conditions

- The objective of this requirement is for the service to demonstrate that it has adequate facilities for the proper execution of activities.
- **Specific areas** for different activities: reading, irradiation, packaging, zeroing, … should exist
- Measures to control facilities may include **access** to and use of areas affecting activities, prevention of contamination and effective area separation, including sites or facilities outside of permanent control
- The dosimetry service premises should be installed in a low background radiation area – **background** must be checked

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6.3 Facilities and environmental conditions

- The detectors should be kept in reproducible environmental conditions of **temperature, humidity, lighting, power**, etc. as these may influence the measurements, e.g. response to fading, aging, self-irradiation dose, residual dose evaluation, etc. It is preferable to reduce the variations of environmental conditions rather than keeping records of performance. Environmental reference conditions (ambient temperature, relative humidity, light intensity, etc.) are also mentioned in the standards in relation to the performance tests.
- Don't forget that there is transport of dosemeters (postal, air transport (x-ray), temperature effects)
- Don't forget the in certain countries the temperature at the site might be different from the temperature in your lab

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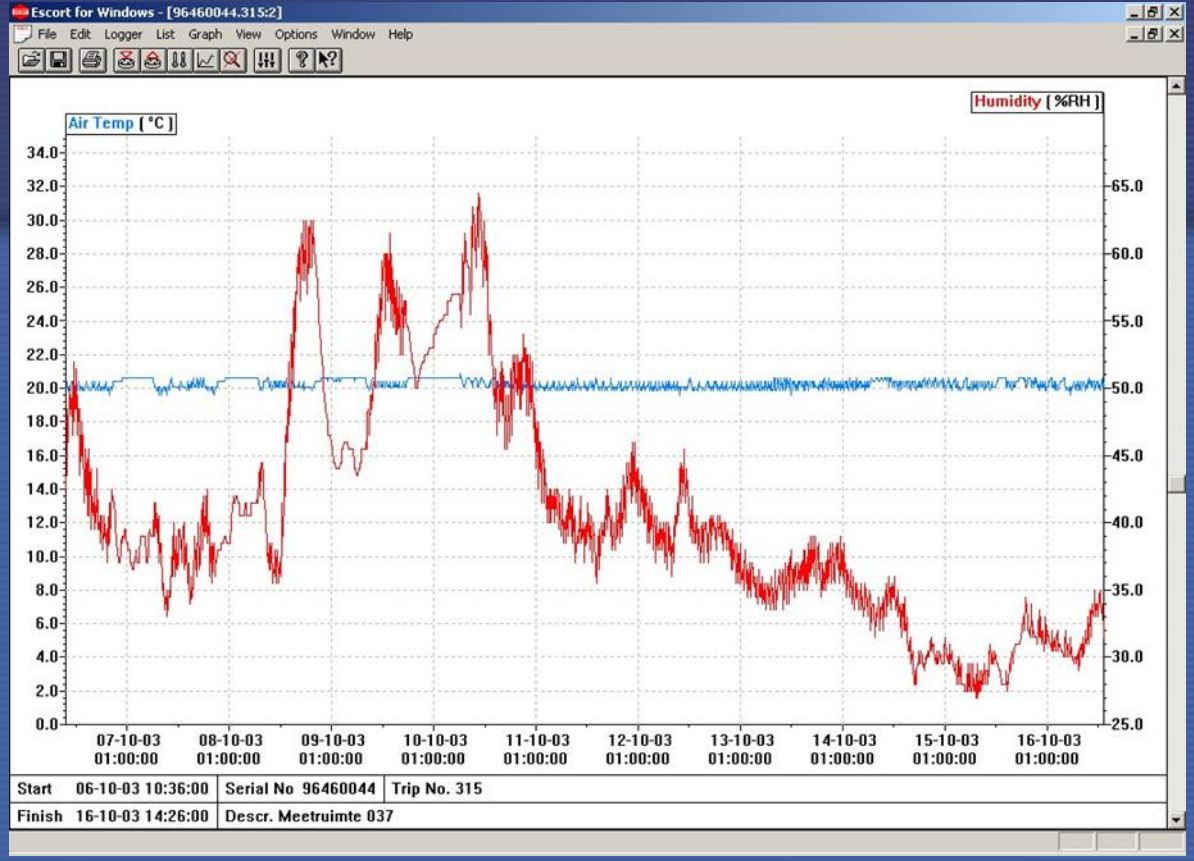
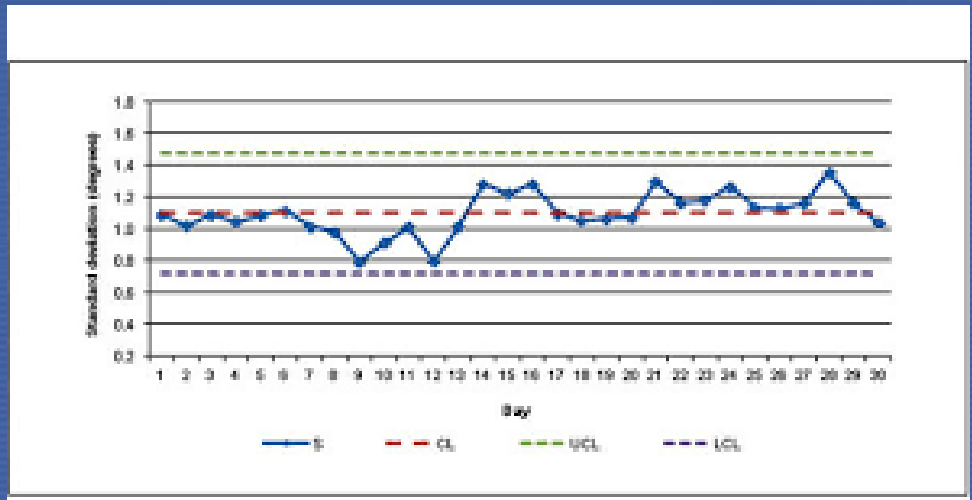
Environmental Conditions in Standards

Influence quantity	Passive dosimetry systems	Direct reading dosimeters
	IEC 62387:2020	IEC 61526:2010
Type of detector and type of dosemeter	All passive, TLD whole body	All active, whole body
Environmental conditions	Temperature: -10°C to +40 °C, Humidity 10% to 90%: 0.83 ≤ response ≤1.25 Fading, light, reader stability and power supply combined: 0.91 ≤ response ≤ 1.11	Temperature: -10 °C to + 40 °C: 0.83 ≤ response ≤1.25 humidity 40% to 90% : 0.90 ≤ response ≤ 1.10 power supply: 0.90 ≤ response ≤ 1.10 atmospheric pressure: 0.90 ≤ response ≤ 1.10 dose rate for dose meas.: 0.80 ≤ response ≤ 1.20

Logging





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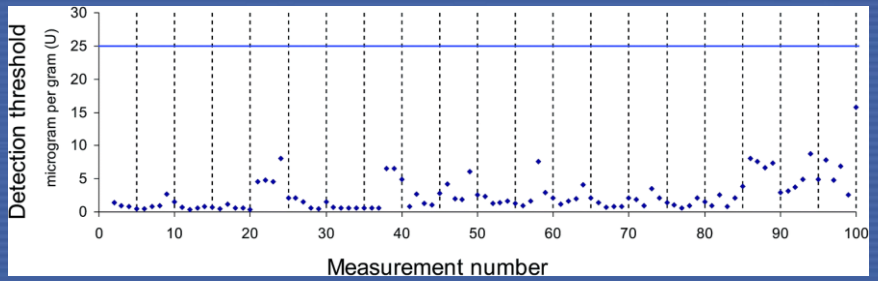
Logging

Visitors Log

[Organization Name]

Date	Visitors Name	Time IN	Time OUT	Notes/Remarks
16/12/2015	Mr. Adam Smith	10:16:00 AM	11:14:00 AM	Mr. Stephan's guest
16/12/2015	Peter Phillips	10:36:00 AM	10:55:00 AM	Information desk



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Example: accommodation and the laboratory environment - IMS

- The dosimetry service should ensure that appropriate conditions for staff, equipment and procedures are attained. Activities that are not directly related to the performance of dosimetry service operations should be separated to avoid unnecessary interference.
- The dosimetry service premises should be installed in a low background radiation area, dust free and temperature controlled environment.
- The detectors should be kept in reproducible conditions of temperature, humidity, lighting, background radiation, etc. as these may influence the measurements, e.g. response to fading, aging, self-irradiation dose, residual dose evaluation, etc.
- Environmental reference conditions (ambient temperature, relative humidity, light intensity, etc.) are also mentioned in the standards in relation to the performance tests.
- A preventive maintenance programme should be instituted to minimize the chance that equipment will fail at a critical time, such as in an emergency.

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Equipment: the main things – example of IMS

- The dosimetry service should be with the necessary items of equipment to carry out its task.
- Staff should be trained to use the equipment
- Maintenance records should be kept for all pieces of equipment in use
- The equipment should be identified and calibrated and labeled to indicate for example, the status of calibration, calibration date, maintenance date, etc.
- Calibrations should be metrologic traceable
- Accommodation and the laboratory environment should be sufficient
- Quality Control of the equipment should be made
- A record should be kept of software versions used for testing, calibrating and sampling and respective updates should be kept for example, for dosemeter reading, processing and storage, databases, etc.

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6.4 Equipment

6.4 Equipment

6.4.1 All items are available as listed below for the correct performance of laboratory activities and which can influence the result

- Measuring instruments
- Software
- Measurement standards, reference materials (recommendation for manufacturer must have ISO 17034)
- Reference data, reagents, consumables
- Auxiliary apparatus
- A procedure for handling, transport, storage, use and planned maintenance of equipment as listed above is required.

6.4 Equipment

6.4.2 If equipment is used outside permanent control, the laboratory to ensure that the requirements for equipment is meet

6.4.3 Document and implement procedure for handling, transport, storage, use and planned maintenance of equipment to prevent contamination or deterioration

6.4.4 Verify that equipment conforms with specified requirements before being placed or returned into service

6.4.5 The equipment is capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result

6.4 Equipment

6.4.6 Periodic calibration of measuring equipment to ensure validity and metrological traceability of reported results

6.4.7 Establish a calibration programme review and adjust

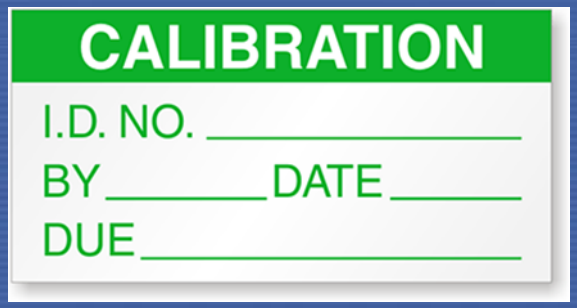
6.4.8 Identify calibration status for reference to user

6.4.9 Overloading or mishandling and or defective equipment is identified and isolate until repaired and verified. Examine effect of defect or deviation and initiate procedure of non conforming work

6.4.10 Intermediate check is carried out as per procedure

6.4.11 Apply reference values or correction factors as given in calibration data

6.4.12 Take measures to prevent unintended adjustments of equipment from invalidating results.



6.4 Equipment

6.4.13 Record for each equipment to retain as including listed below

- The identity of equipment, include software and version
- The manufacturer's name, type identification, serial number or other unique identification
- Check of verification that equipment complies with the specification
- The current location
- Calibration date, results and copies of reports, certificate of all calibration, adjustment, acceptance criteria, due date and calibration interval
- Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity
- The maintenance plan and maintenance records
- Any damage, malfunction or repair to the equipment

6.4 Equipment

- The service should be equipped with the necessary equipment to carry out its task – this equipment should be kept up to date.
- Equipment includes: **readers, irradiators, software, dosemeters, detectors, consumables** (incl. e.g. N_2) and auxiliary apparatus such as ovens for annealing, …
- All equipment shall be:
    - Uniquely identified and labelled indicating status of calibration or period of validity
    - Periodically calibrated (see further), verified (Quality Control, see further) and maintained
- **Records/Logbooks** of calibration, quality control, maintenance, instrument incidents, … should be available

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Identification and logbook of equipment

Each item, be it instrument, software or calibration standard should be entered into a list to be identifiable.

Measurement instruments list

No.	Measurement instrument	Type	Operator	Calibration interval	Calibration procedure	Calibration authority	Calibration standard
V-47/1	Detector GeLi 7%	LG	AAAAA	before each measurement series	WI-47/1	Gamma Spectroscopy Lab.	Mixed radionuclide set No 12
V-47/2	Multichannel Analyzer	Inspector 1200	AAAAA		none		
V-47/3	Gamma Analysis Software	Genie 2000	AAAAA		none		
V-47/4	Computer	Scenic Pro M7 350	AAAAA		none		

Identification and logbook of equipment

Additional data to be recorded:

Measurement instruments list

No.	Date start of service	Date out of service	Producer	Supplier	Serial No.	Location	Date of delivery
V-47/1	14.03.2001		AAAAA	CCCCCC	Detector 225648	FC 1-4	Oct 2000
V-47/2	14.03.2001		AAAAA	CCCCCC	9941039	FC 1-4	Oct 2000
V-47/3	14.03.2001		BBBBB	BBBBB	Software Version 2.1	FB 1-4	Oct 2000
V-47/4	14.03.2001		AAAAA	CCCCCC	YBJF 105269	FB 1-4	Oct 2000

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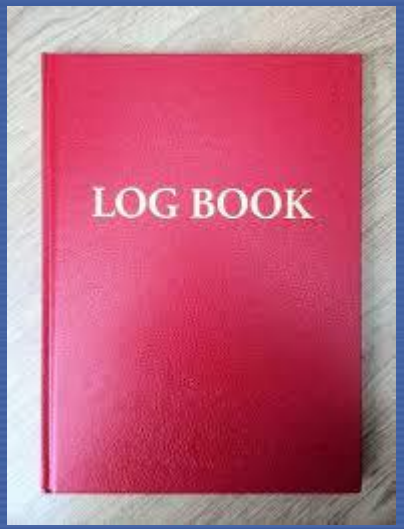
Logbook

- Per instrument:
  - Date
  - Any calibration, verification, damage, malfunction, modification or repair to the equipment



Measuring equipment calibration

- Before being put into service
- Afterwards in regular intervals or before use
- After adjustment
- After repair
- After being used outside of the testing laboratory by outside personnel
- See specific lecture on traceability

Calibration and Verification

- Reproducibility of the calibration should be controlled e.g. monthly by **verification** (quality control QC) of the calibration. The verification can be done under simplified conditions. For example, the verification is done using dosemeters irradiated free-in-air, instead of on a phantom, with a ^{137}Cs source. This can be done using your own irradiator that does **not** have to be accredited.

- The metrological traceability of calibration cannot be achieved through this verification, but it can be used for QC purposes to verify the reproducibility of calibration or the reader. The verification of calibration can follow for example a QA-procedure, where the action limits for the stability/reproducibility of the calibration factors are stated, based on expertise, statistical data and experience of the laboratory

6.5 Metrological traceability

See separate lecture

6.6. Externally provided product and services

6.6.1 Ensure that only suitable externally provided products and services that affect laboratory activities are used.

6.6.2 Have procedure and retain records for

- Review and approve purchasing,
- Selection, evaluation and re evaluation of external provider
- Inspection or verification
- Taking actions arising from evaluations, monitoring of performance and re-evaluations

6.6.3 Communicate its requirements to external providers, for:

- The products and services to be provided;
- The acceptance criteria;
- Competence, including any required qualification of personnel;
- Activities that the laboratory, or its customer, intends to perform at the external provider's premises.

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6.6. Externally provided product and services – example of IMS

- These are mainly: reader manufacturer/maintenance, dosemeter supplier, SSDL, software supplier, irradiator, proficiency test supplier, consumables supplier
- Dosemeters should be checked initially and controlled afterwards – a element correction factor ECC should be available e.g. every 5 years.
- Check batch homogeneity:
  - Usually exposed to some internal irradiator Sr-90 and read out.
  - Calculate average and check standard deviation
  - Eliminate outliers (this is destroy these dosemeters)
- Yearly evaluation of your suppliers