



QMS Quick Learning Activity

Equipment and Calibration

ISO/IEC 17025:2017



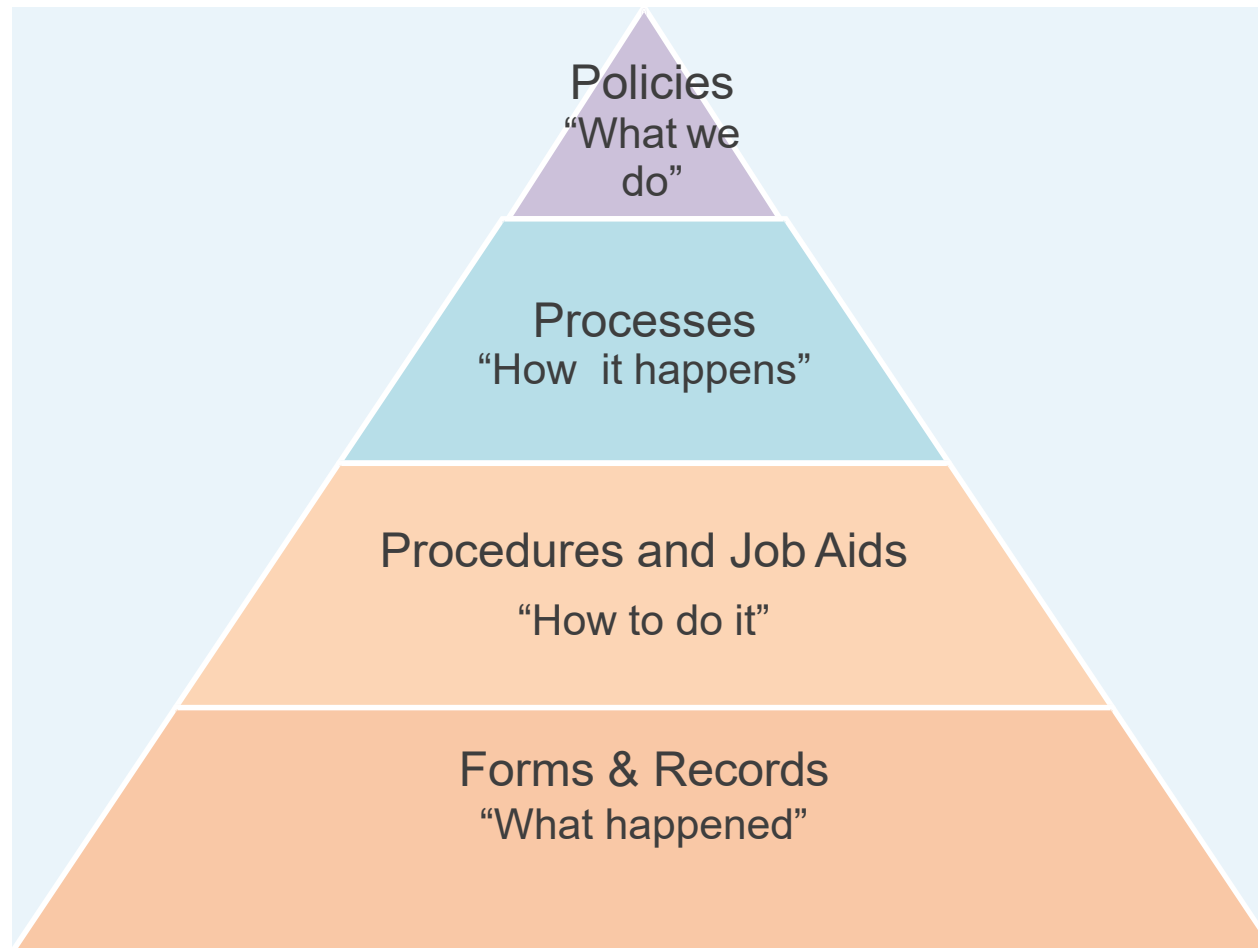
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Terms & Acronyms

- **Calibration**-the comparison of two measurement devices or systems (one of known uncertainty [your standard] and one of unknown uncertainty [your test equipment])
- **Equipment**- Those items of equipment necessary to perform a test and which have a significant effect on the uncertainty of measurement of test results
- **SOP**-Standard Operating Procedure
- **Traceability**-the 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
- **Traceability to the SI (International System of Units)**- metrological traceability to a measurement unit of the International System of Units
 - Test equipment calibration is traceable to the SI through US National Institute Standard of Technology (NIST) (not traceable to NIST)



Some distinctions



Equipment

6.1 The laboratory shall have the following available which are necessary to manage and perform its laboratory activities.

Personnel

Facilities

Equipment

Systems

Support services



Equipment: LIMS and Software

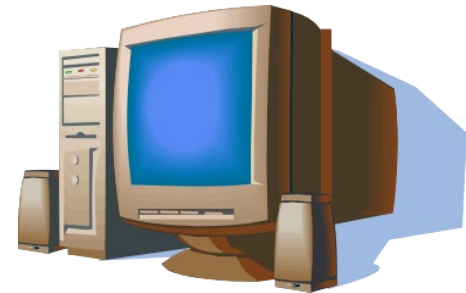
(Control your Data!)

- Calculations (manual and electronic) and data transfers **shall be checked in an appropriate and systematic manner.**
- Laboratory information management system(s) (LIMS) used for the collection, processing, recording, reporting, storage, or retrieval of data, the laboratory shall ensure that:
 - They are maintained in a manner that ensure the integrity of the data and information:
 - Excel spreadsheets with calculations only (documents)—**Lock the formula cells**
 - Excel spreadsheets with results after calculations (records)—**pdf the record** so no changes can be made



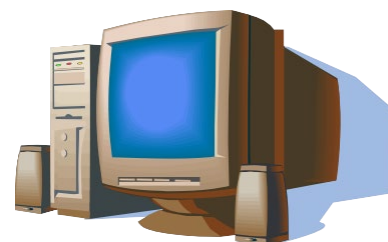
Protect Your Data!

- Establish and implement procedures to protect your LIMS and data from:
 - Unauthorized use
 - Unauthorized changes
 - Against tampering and loss
- Commercial software (e.g., word processing, database, statistical programming) is considered sufficiently validated
- Laboratory software and modifications to commercial off-the-shelf software must be authorized, documented, and validated before use



LIMS

- The LIMS shall be operated in an environment that complies with provider and laboratory specification, and which safeguard the accuracy of recording and (if manual) transcription
- The LIMS shall include recording system failures and appropriate immediate and corrective actions
- The laboratory shall ensure that external LIMS management providers shall comply with applicable ISO/IEC 17025 requirements
- All instructions, manuals, and reference data for the LIMS shall be available to personnel.



Equipment

- The laboratory shall have access to equipment that is required for the correct performance of laboratory activities and that can influence the results
- The laboratory shall establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.
- Equipment & Software:
 - Capable of achieving accuracy and/or measurement uncertainty to provide valid result
 - Verified prior to placing into service
 - Meets specification requirements
 - Records must be kept
 - Calibrated when
 - Measurement accuracy or uncertainty affects the validity of the reported results
 - To establish metrological traceability of the reported results

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Who should operate equipment?

- Equipment shall be operated by authorized personnel using up-to-date manuals containing:
 - Instructions for use and maintenance
 - Procedures for safe handling, transport, storage, use and planned maintenance to ensure proper functioning and to prevent contamination or deterioration
- Please see your *Equipment SOPs* for further guidance



Equipment Needs & Documentation

- All measurement and testing equipment have a significant effect on the validity and accuracy of test results
- All equipment that requires calibration shall be labelled, coded, or otherwise identified to indicate the status of calibration, including the last date of calibration and date of expiration or due date of next calibration
- Equipment sent out of the laboratory must be recalibrated or checked and shown to be satisfactory before placing into service



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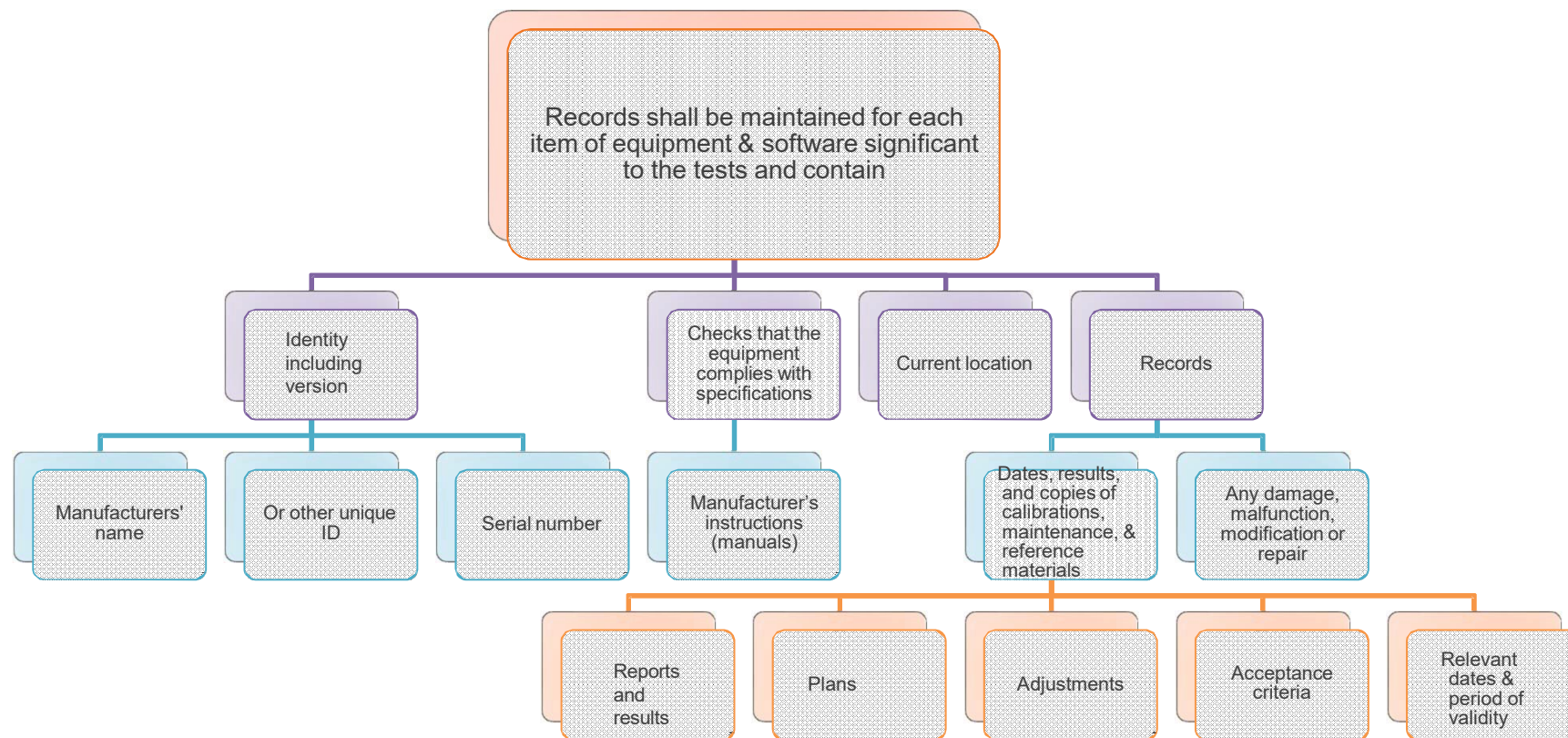
Equipment Needs & Documentation



- When calibration and reference material data include reference values or correction factors, the laboratory shall ensure these are updated and implemented
- The laboratory takes practicable measures to prevent unintended adjustments of hardware and software from invalidating results.
- Calibration and verification takes place at specified intervals through the use of traceable standards or appropriate reference materials or reference cultures



Keep Records



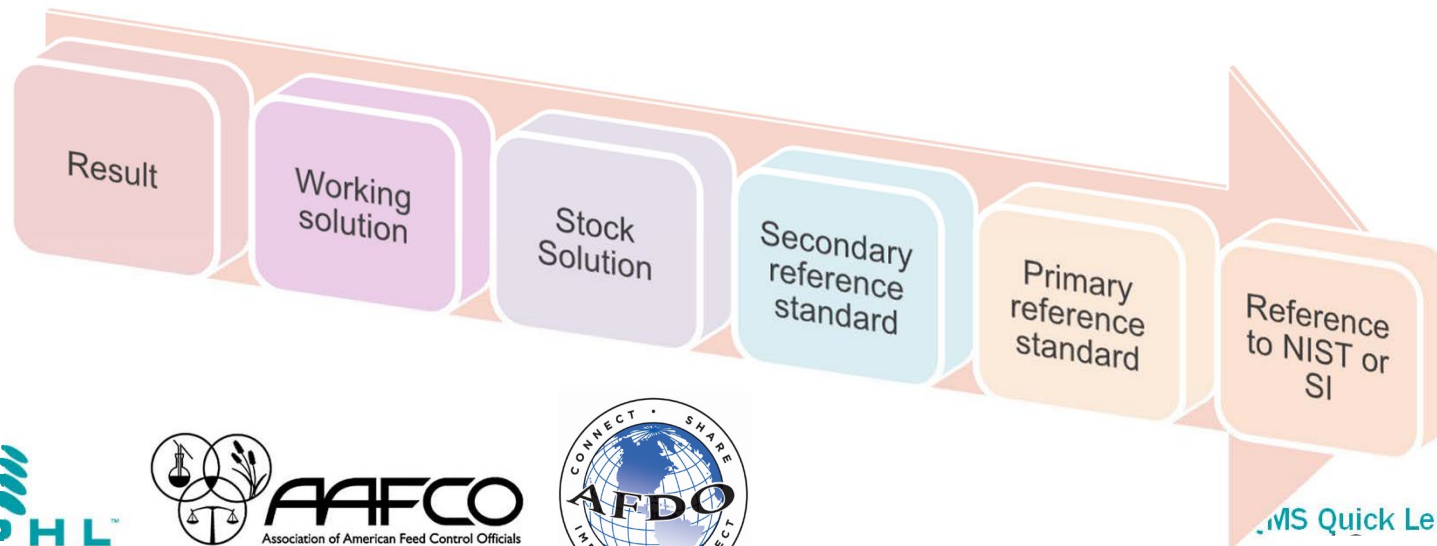
Defective Equipment

- Equipment that has been overloaded or mishandled, gives suspect results, is defective, or outside specified requirements shall be taken out of service, isolated or clearly marked as being out of service until it has been repaired & recalibrated, & verified.
- The laboratory shall examine the effect or deviation on test results and initiate management of nonconforming work procedure.



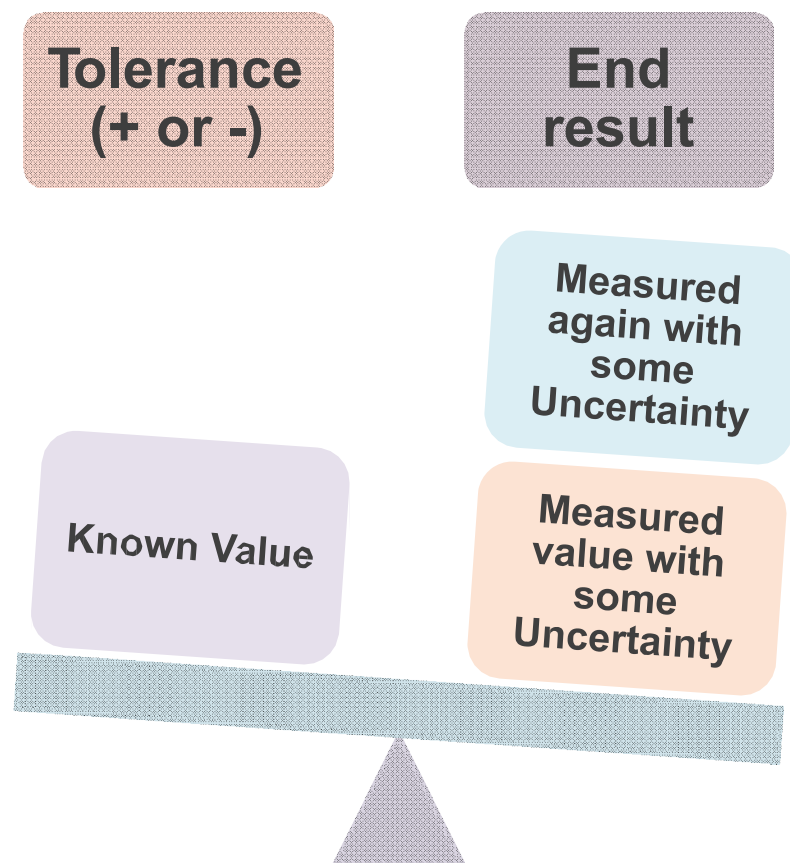
Metrological Traceability & Equipment

- The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.
 - traceable standards
 - or appropriate reference materials
 - or reference cultures
- Traceability applies to measuring and test equipment unless you can prove that it is a minor component of measuring uncertainty. In this case, you must provide the uncertainty of the instrument.



What is Calibration?

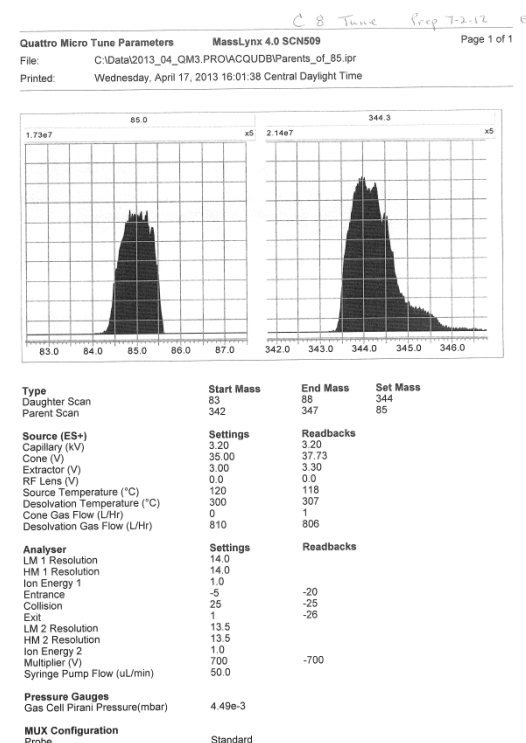
- A response to a known value which establishes a relationship between the known value and an indicator and established tolerance
- "I have the result, I know what it should be—what is my answer in relation to the known value and how much can I tolerate the difference?"



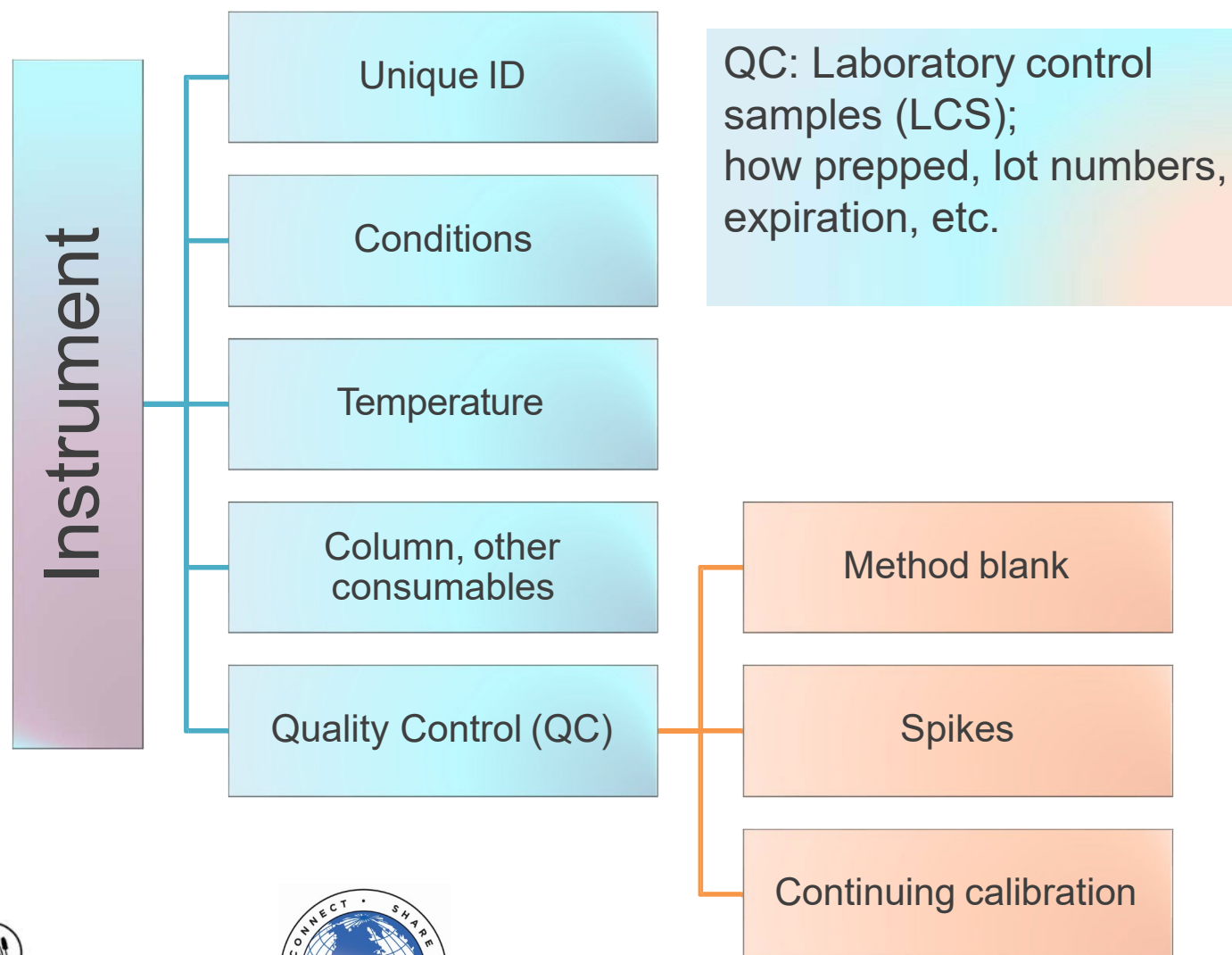
Intermediate Checks

- There need to be defined procedures and schedules for carrying out checks needed to maintain confidence in the calibration status of:

- Reference standards
- Primary standards
- Working standards
- Transfer standards
- Reference materials



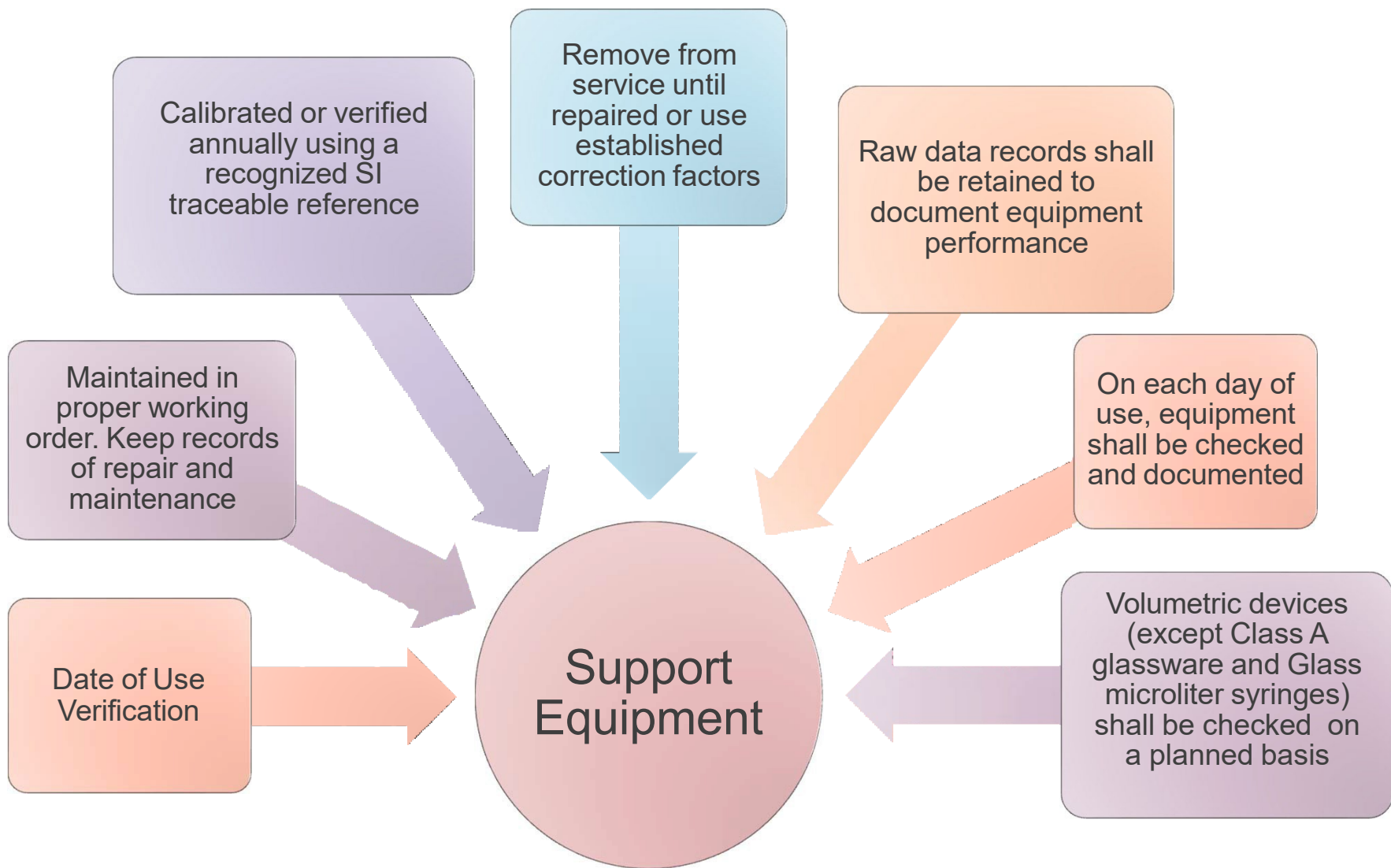
Things to Document for Analysis



Support Equipment that require calibration

- Support equipment requiring calibration includes:
 - Balances
 - Ovens
 - Refrigerators
 - Freezers
 - Incubators
 - Water baths
 - Temperature measuring devices
 - Thermal/pressure sample preparation devices
 - Volumetric dispensing devices (including automatic dilutor/dispensing devices)
 - Centrifuges
- If quantitative results are dependent on their accuracy





Some questions to ask for equipment

- *Is there a system with a procedure on commissioning equipment, verifying its performance, and calibration prior to use?*
- *What is the plan/procedure for continuing calibration and verification of the equipment's performance?*
- *Are there records that show the continuing calibration and verification is ongoing on regularly scheduled intervals?*
- *Are there labels that a user may see immediately to determine the status of the regular checks and calibrations?*



References

- ISO/IEC 17025:2017
 - <https://www.iso.org/standard/66912.html>

