



QMS Quick Learning Activity

Equipment and Calibration

ISO/IEC 17025:2005

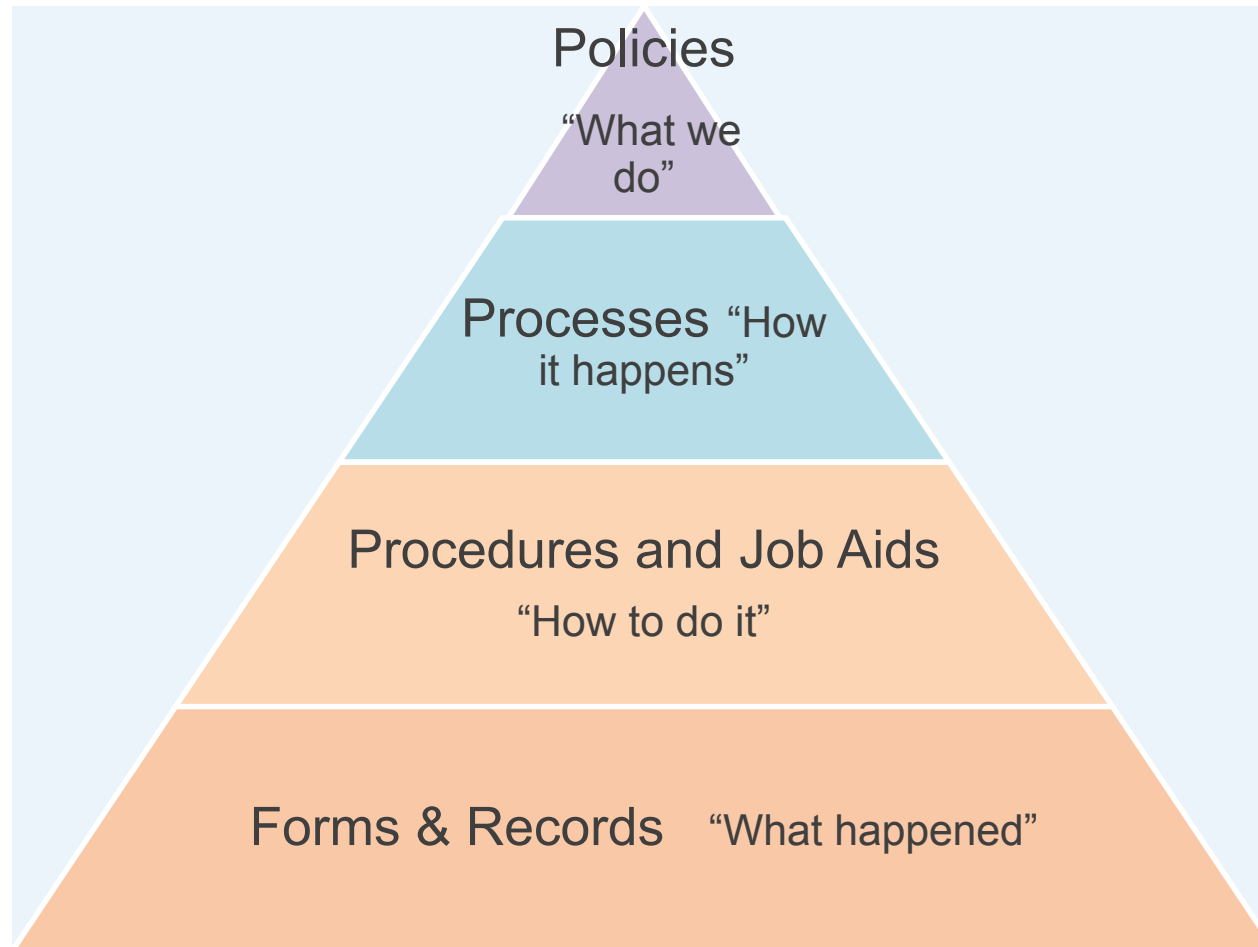


Terms & Acronyms

- **Calibration**-the comparison of two measurement devices or systems (one of known uncertainty (your standard) and one of unknown uncertainty (your test equipment))
- **Quality Critical 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 not traceable to the US National Institute Standard of Technology (NIST), but to the SI through NIST

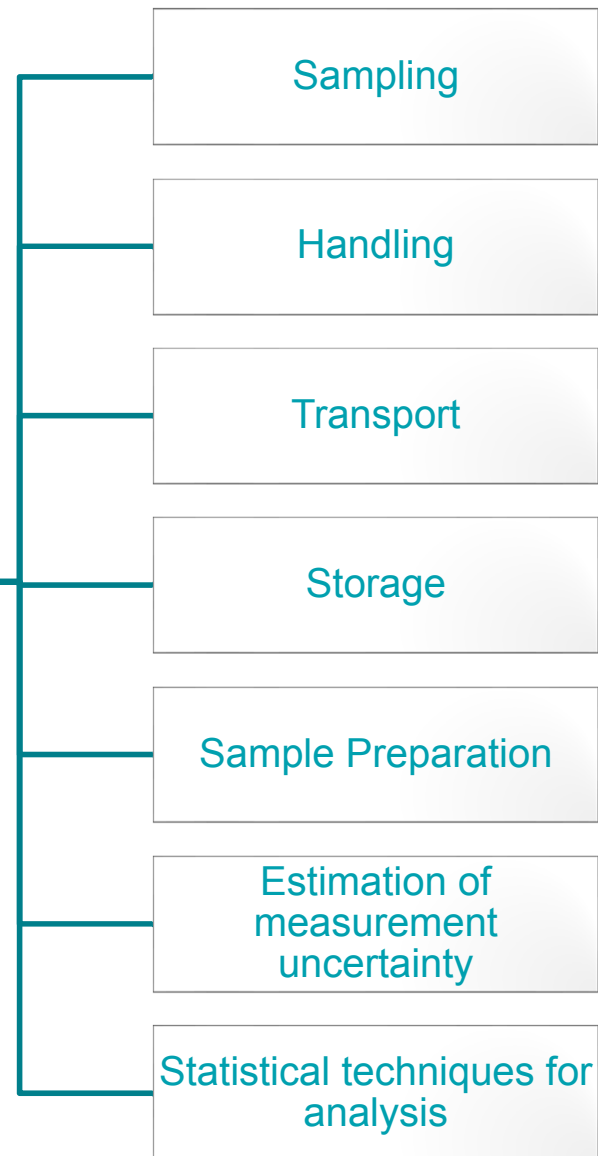


Some distinctions



Methods

The laboratory shall use appropriate methods that meet the needs of the customer and use procedures for all tests that should include these items:



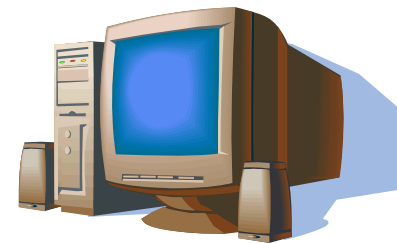
Equipment: Software (Control your Data!)

- Calculations (manual and electronic) and data transfers shall be subject to appropriate checks in a systematic manner
- When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of data the laboratory shall ensure that:
 - Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use
 - 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 data's
 - integrity
 - confidentiality
 - storage
 - transmission
 - processing
- Commercial software (e.g., word processing, database, statistical programming) is considered sufficiently validated
- Laboratory software and modifications to commercial software must be validated before use



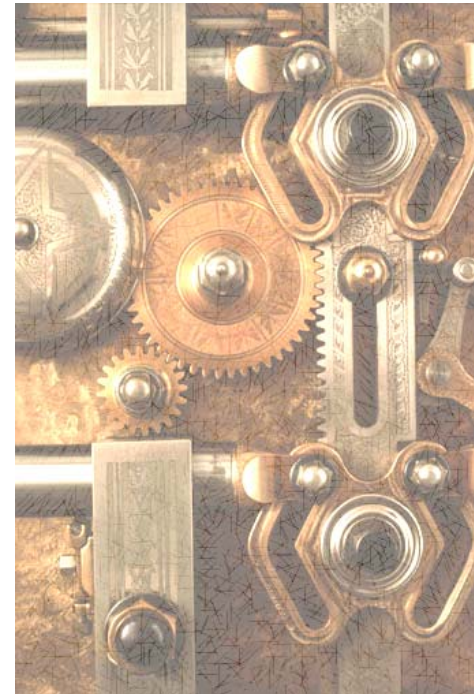
Quality Critical Equipment

- Those items of equipment necessary to perform a test and which have a significant effect on the uncertainty of measurement of test results
- The laboratory shall furnish equipment needed to perform Quality Critical Testing for:
 - Sampling
 - Measurement
 - Processing
 - Analyzing test data
- Equipment & Software:
 - Capable of achieving accuracy
 - Complies with specifications relevant to tests
 - Calibrated & checked prior to placing into service
 - Meets specification requirements
 - Complies with standard specifications
 - Records must be kept



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



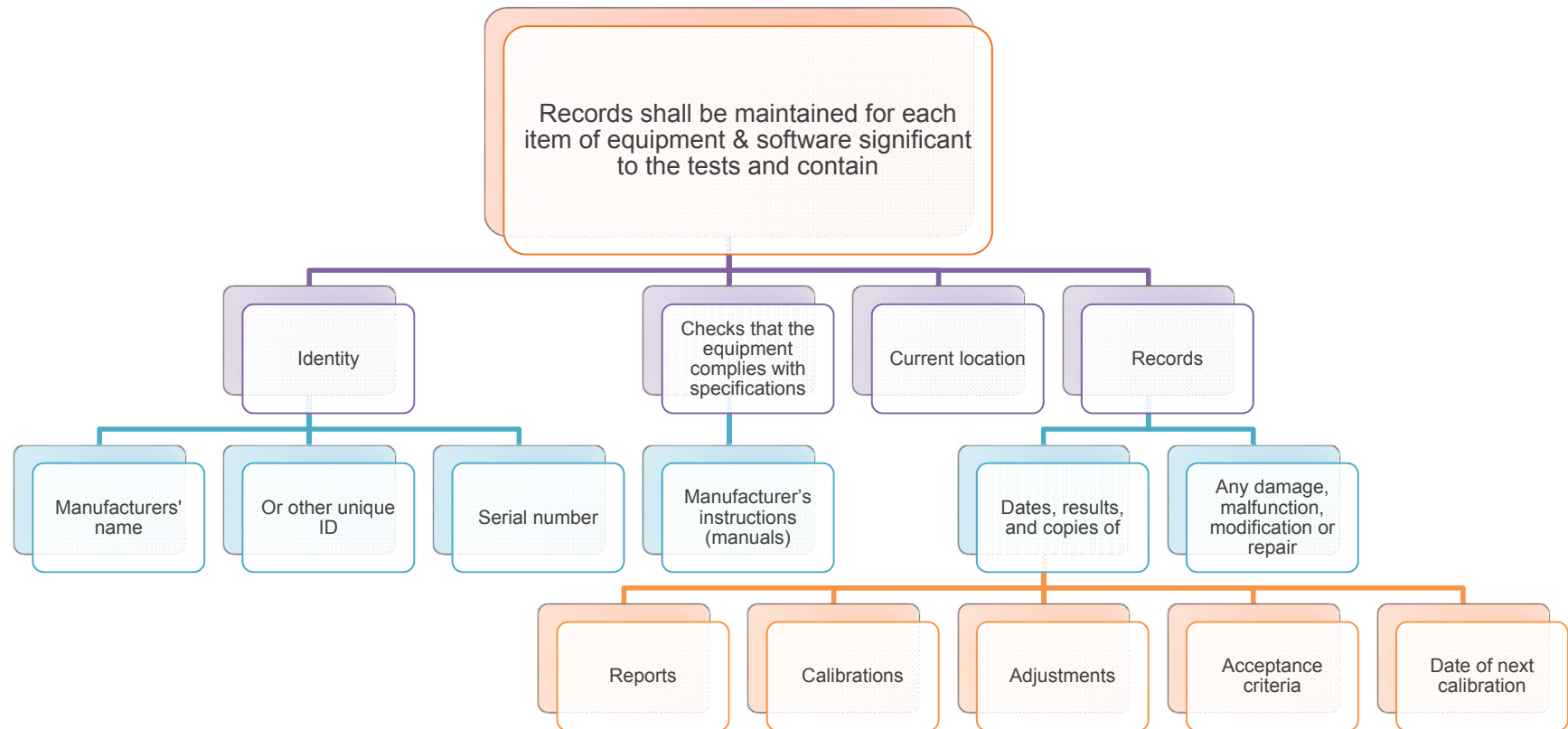
Equipment Needs & Documentation



- Intermediate checks (verifications) shall be carried out according to a defined procedure
- When calibrations show the need for correction factors, the laboratory should have procedures to show that copies (e.g., computer software) are correctly updated
- Hardware and software must be safeguarded from tampering that would invalidate the test 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 mishandled, gives suspect results, is defective, or gives suspect results shall be taken out of service and clearly marked as being out of service until it has been repaired & recalibrated.
- The laboratory shall determine if there has been an effect on previous test results and perform Corrective Action.



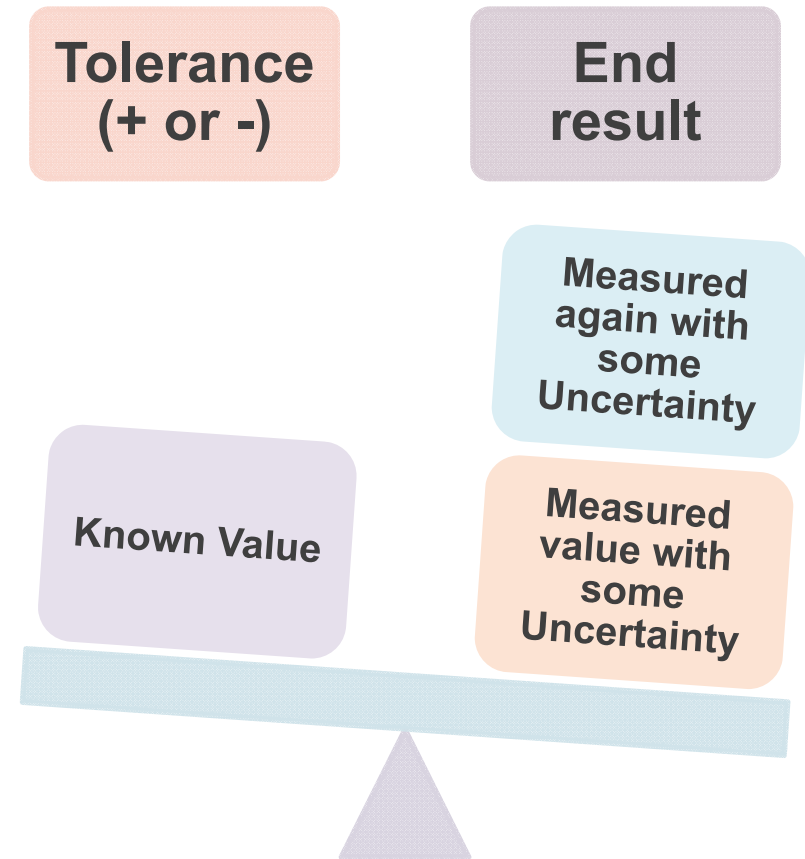
Measurement Traceability & Equipment

- All measurement and testing equipment that has a significant effect on the validity and accuracy of test results should be calibrated or verified at specified intervals through the use of
 - 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?

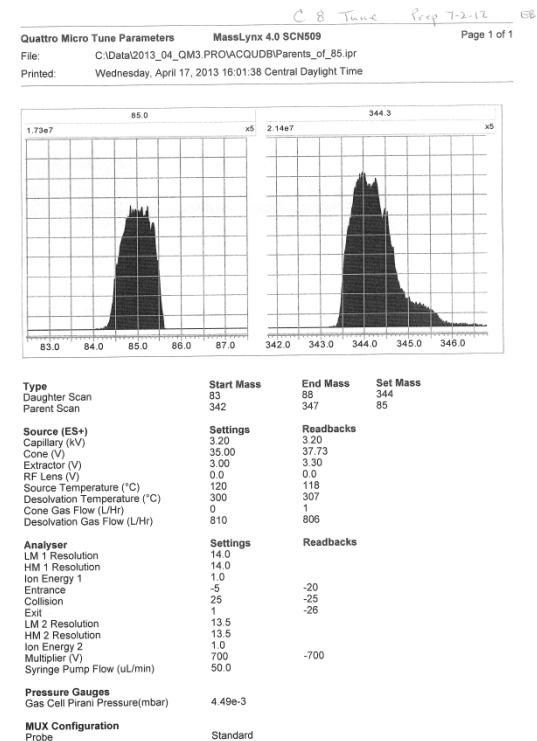
- A response to a known value which establishes a relationship between the known value and an indicator and established tolerance
- I have the result, I know what it should be—what is my answer in relation to the known value and how much can I tolerate the difference?



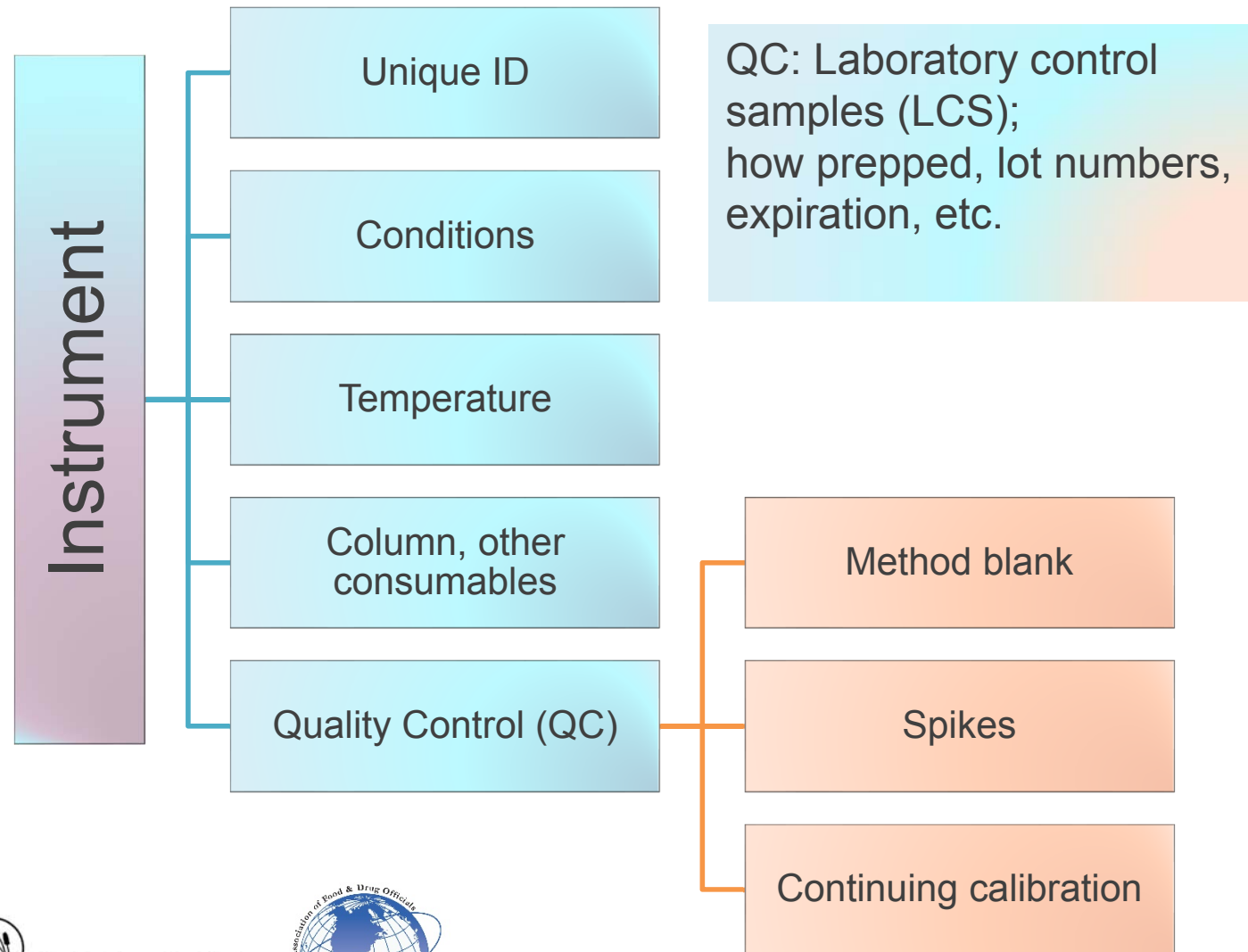
Intermediate Checks

- 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



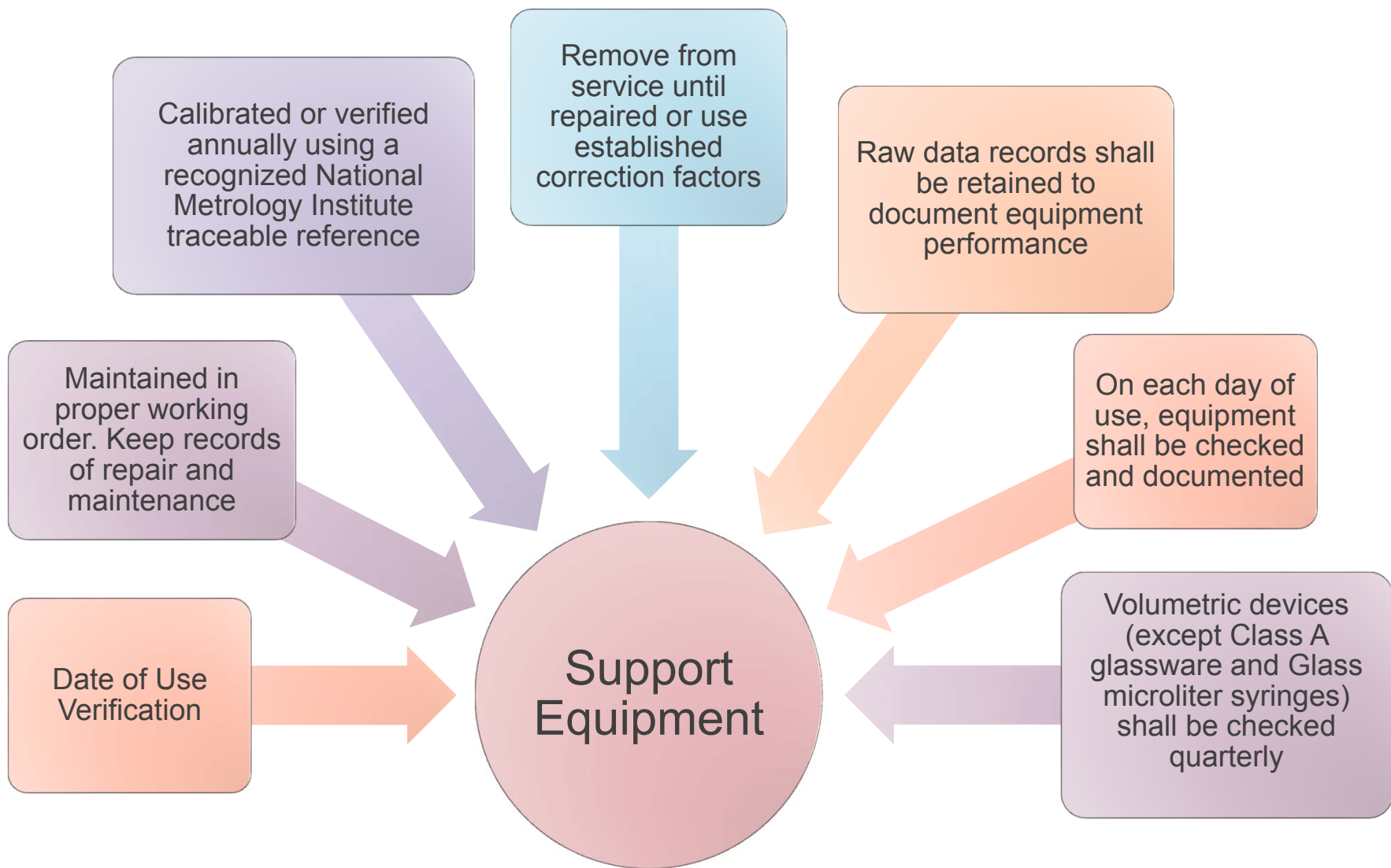
Things to Document for Analysis



Support Equipment that require calibration

- Not test equipment, but includes:
 - Balances
 - Ovens
 - Refrigerators
 - Freezers
 - Incubators
 - Water baths
 - Temperature measuring devices
 - Thermal/pressure sample preparation devices
 - Volumetric dispensing devices (including automatic dilutor/dispensing devices)
- If quantitative results are dependent on their accuracy





Some questions to ask

- *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

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<https://www.iso.org/standard/39883.html>



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