

Traceability and Standards for Quantitative PET Imaging

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Traceability

"property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties."

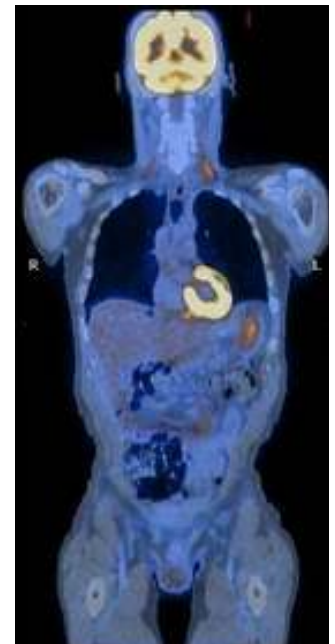
(International Vocabulary of Basic and General Terms in Metrology (VIM), BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, 2nd ed., 1993, definition 6.10)

Traceability, II

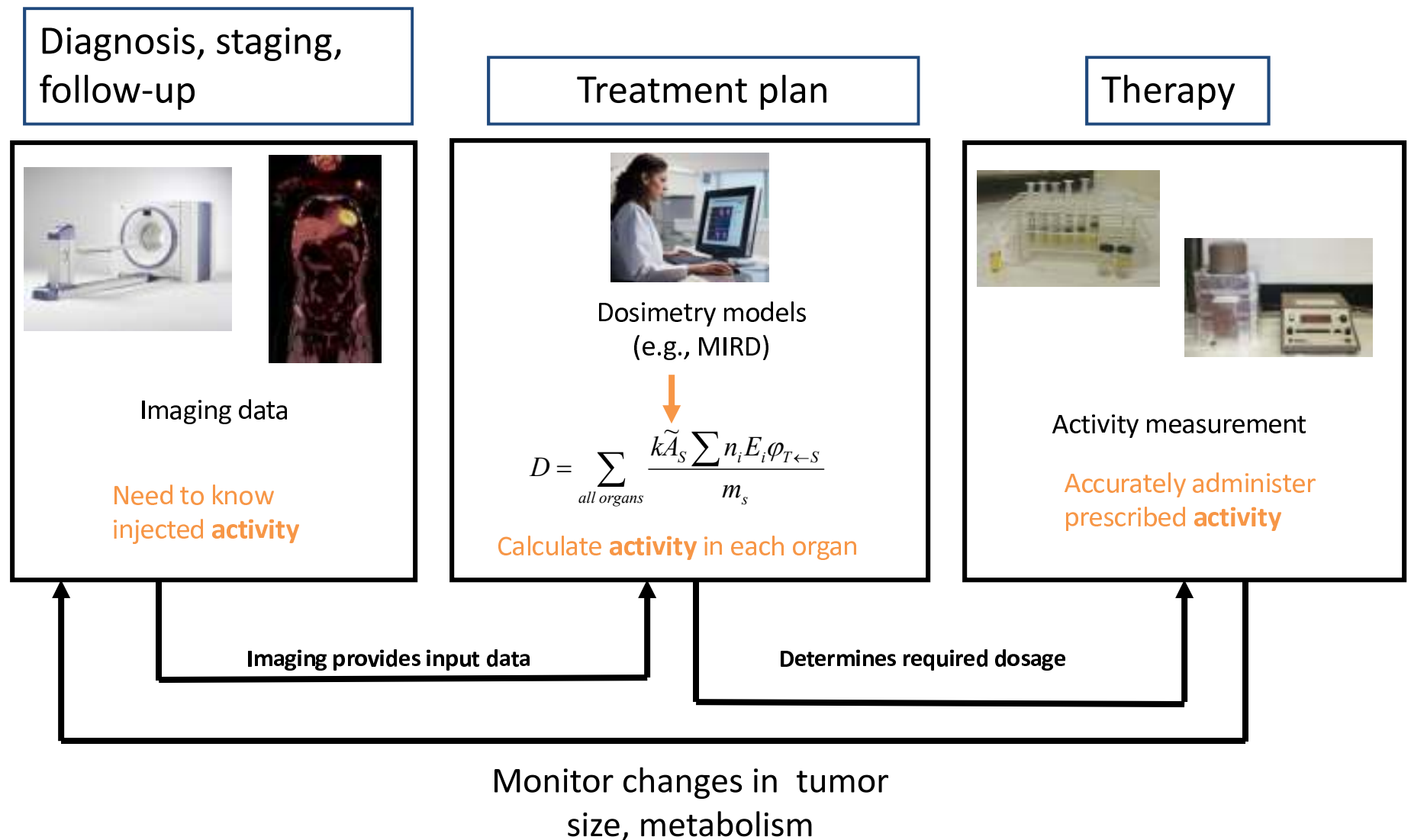
- New definition: comparisons -> calibrations
Requires
 - Unbroken chain
 - Uncertainty statement
 - All associated measurements to also be traceable to the SI (time, mass, length, etc)
- Refers to a measurement result, not an instrument, laboratory, or artifact source

Why traceability/standards for nuclear medicine imaging?

- Reference to a common standard helps to understand instrumental variability
- Investigate sources of instrumental variability to focus on biological effects
- Realistic statistical (quantitative) assessment of effect
- Comparability of clinical data from multiple centers
- Dosimetry



Needs for traceability in diagnostic and therapeutic nuclear medicine



Variability in activity values derived from PET-CT images

- Between clinical sites
 - Activity calibration of injected activity or of activity in phantom
 - Conversion of image intensity to activity
 - Different protocols for acquisition, reconstruction, analysis
- Between scanners
 - Conversion of image intensity to activity
 - Different reconstruction algorithms
- Between scans
 - Activity calibration of injected activity or of activity in phantom
 - Conversion of image intensity to activity



“But we calibrate with phantoms!”

- Activity contents are often not calibrated to the same standard
- Phantom activity calibration is not always linked to calibration of injected activity (to patient)
- If they are linked to each other, they are usually still not linked to a common standard.

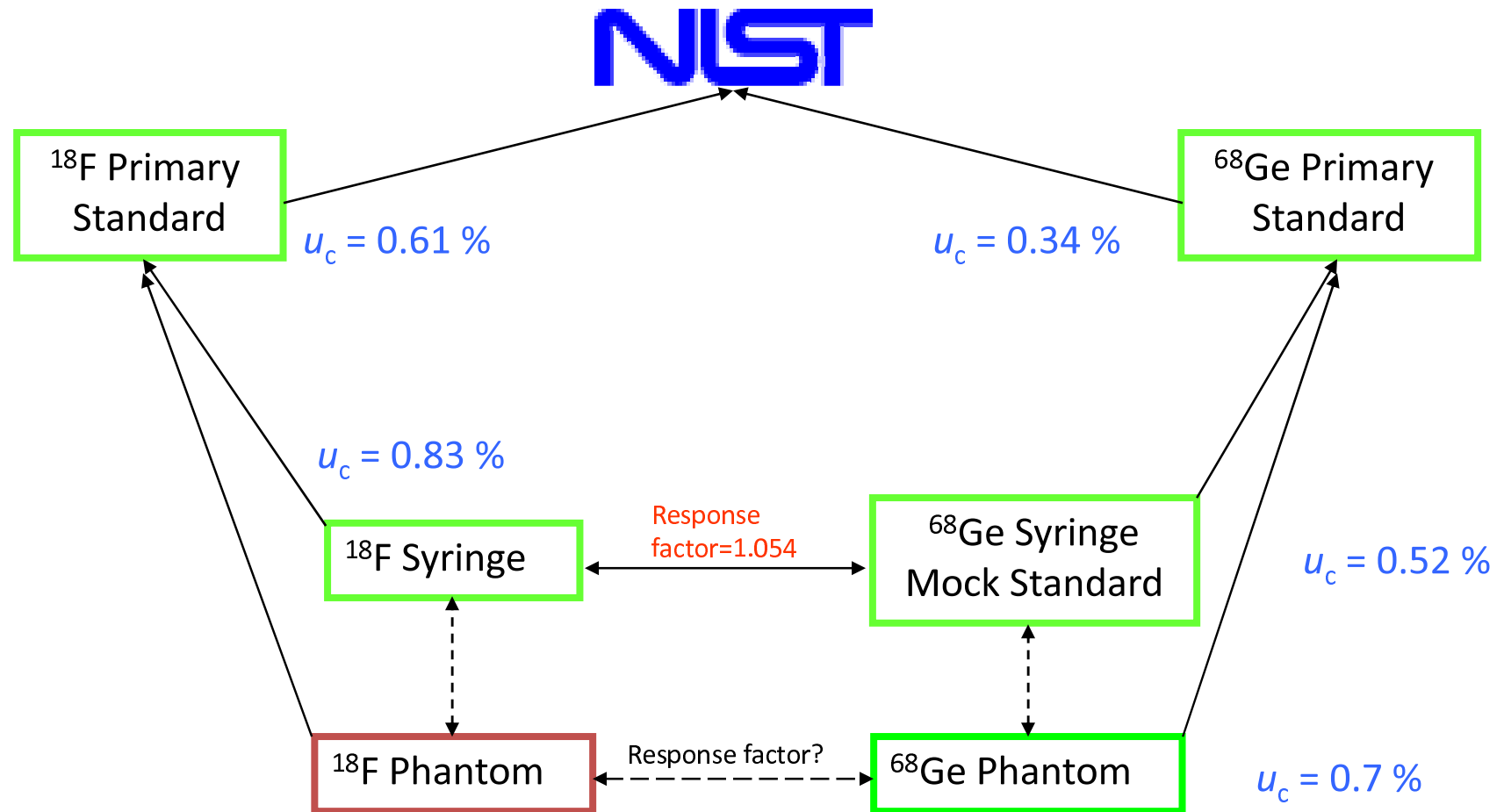
What about SUV?

- Depends on:
 - Measurement of injected activity (might be traceable)
 - Mass (might be traceable)
 - Time (usually not all measurement are)
 - Calibration of scanner (no traceability)
- Assessment of uncertainty?
- Consistency of calculation across manufacturers?

Absolute measurements?

- Only way to ensure traceability for all measurements
- Is it possible?
- Can it be done with modest amount of effort?
- Dosimetry community seems most interested

Linking phantoms, patient activity to common standard



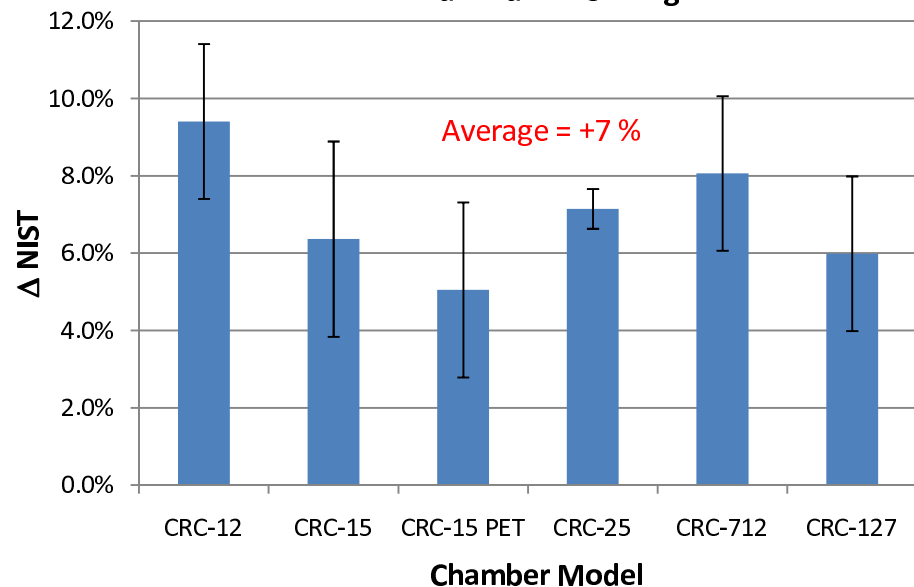
Goal at beginning: uncertainty in phantom calibration $\leq 1\%$

Traceable activity calibrator standards

- Developed by RadQual, LLC
- Calibration methodology developed by NIST in collaboration with RadQual
- Based on ^{68}Ge , calibrated for both ^{68}Ge and ^{18}F (equivalent activity)
- Multicenter trial with NIST-calibrated sources -> some commercial chambers are wrong by up to 9 %.

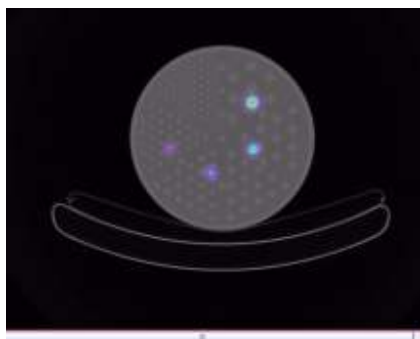


Difference in Activity Calibrator Reading from NIST Value at Manufacturer's Setting for ^{18}F



Calibrated phantom standards

- Epoxy-based
- All traceable to NIST primary standards
- New design has nominal volumes of 2-22 mL
- Standard uncertainty on activity $\sim 0.7\%$ for ^{68}Ge
- IAEA Cooperative Research Project
 - Absolute image quantification for dosimetry
 - 12 clinical sites globally
 - PET arm: ^{68}Ge (for ^{18}F)
 - SPECT arm: ^{133}Ba (for ^{131}I)



NIST

Conclusion

- Traceability is nonexistent for nearly all image-based measurements in NM
- Comparability of data questionable
- Open questions for discussion
 - How are current clinical results affected by lack of traceability?
 - Can absolute quantification be achieved?
 - Is it necessary?
 - What other mechanisms for ensuring traceability can be developed?