

Definitions

- Quality – a high level of value or excellence (Merriam-Webster)
- Quality Assurance (QA)
 - Rules/procedures/activities that make sure you are doing things the correct way
 - Process oriented
 - Prevention of errors/mistakes/...
 - Preparatory Steps
- Quality Control (QC)
 - Testing the actual outcome
 - Product oriented
 - Detecting errors/mistakes/...
 - Corrective actions (best done while the activity is ongoing)

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Definitions continued



QC is used to verify the quality of the output.

Testing for quality is not assuring quality, it is controlling it.



QA is the process managing for quality.

Both QA and QC are necessary for ensuring quality in Exam 6.

Everyone needs to take an active role in order to ensure quality.

QA or QC?

Activity	QA or QC?
Central Training	
Manual of Operations	
Repeated Anthropometry measures	
Operations Committee	
Interview recordings	
IRB Review	
Equipment calibration	
QC Committee	

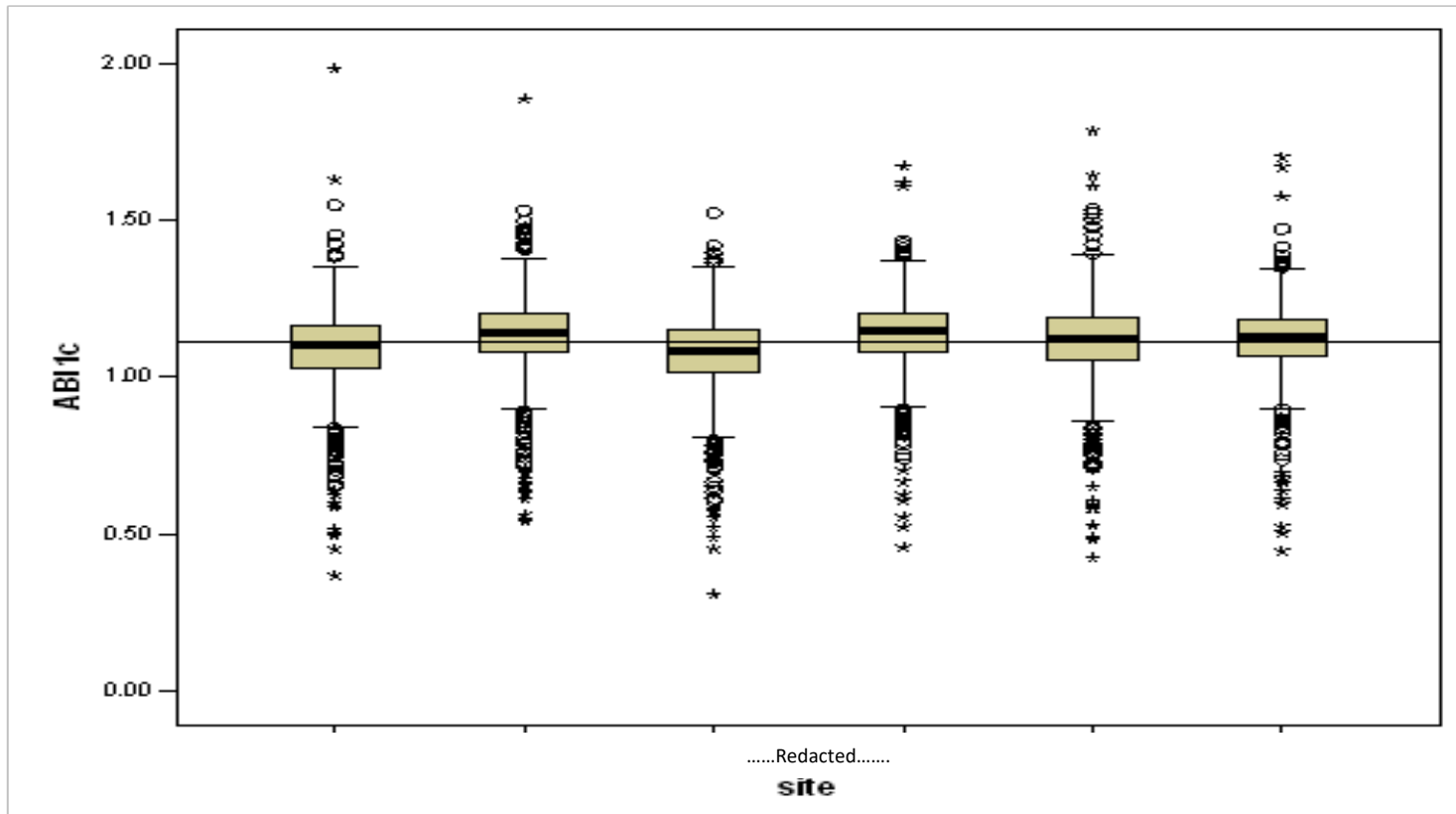
QA or QC?

Activity	QA or QC?
Central Training	QA
Manual of Operations	QA
Repeated Anthropometry measures	QC
Operations Committee	QA
Interview recordings	QC
IRB Review	QA
Equipment calibration	Both
QC Committee	Both

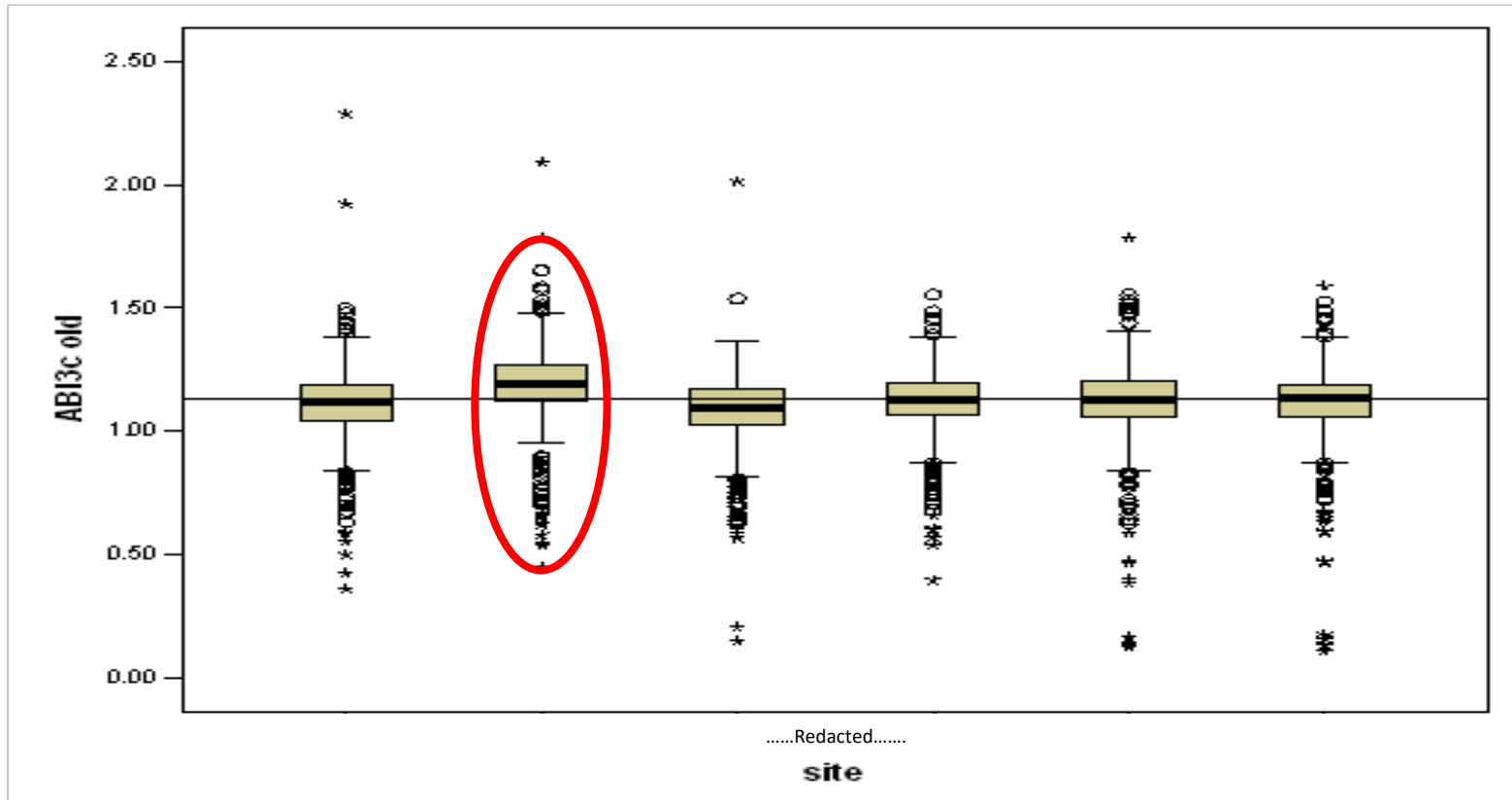
QA / QC Example from MESA

- Ankle Brachial Index (ABI)
- measurement of ankle BP / brachial BP.
- Supine
- Carefully designed and identical protocol and MOP at Exams 1 , 3, 5.

Exam 1 ABI by Field Center



Exam 3 ABI by Field Center



What changed between Exams 1 and 3?

- Efficient exam table introduced
- Lower extremities were not as well supported by the shelf
- Data were able to be corrected by taking into account estimated effect of gravity on ankle BP measures.

QC Plan for Exam 7

- Laboratory/Bioassay repeat measures
 - Specimens collected at prior exams for calibration
 - Replicate assays for excess variability in the measures
- Clinic Exam components
 - Lab blind duplicates
 - Repeat procedures (e.g. built into spirometry procedure)
 - Reading Center Quality Assessments (spirometry, imaging, glucose, polysomnography, actigraphy, heart monitor, ...)
 - Review of sampled Interview recordings
 - Review Cognitive Function Testing recordings
 - SC/Lead technician observation
 - Data checking (missing values; comparison with prior exam values)
 - Exam metrics (time to complete exam components, reporting, retention)
 - Calibration
- High Tech components
 - Described in individual training sessions

Roles and responsibilities

- Technicians
 - Become proficient in your procedures (includes certification)
 - Communicate questions and concerns right away
 - Take critique constructively
 - Participate in QC
- Study Coordinators and Leads
 - Train, certify, coach your team members
 - Forward questions and concerns to CC and Operations Committee
 - Calibration and maintenance (document)
 - Review and coach
 - Take and offer critique constructively