



**ARTEL**

*Trust Your Results*

# Controls vs Calibration - Do you need both?

*George W Rodrigues, PhD  
Senior Scientific Manager  
Artel*

# Why Care?



# Controls



# Calibration



# Public Laws

## Congress

Clinical Laboratory Improvement Amendments  
(CLIA '88)

[www.cms.gov/clia/](http://www.cms.gov/clia/)

Food, Drug & Cosmetics Act

[www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/](http://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/)

# Federal Regulations

## CFR – Code of Federal Regulations

42 CFR Part 493 – Clinical- CLIA

21 CFR Part 820 – GMP- *In vitro* diagnostics

Also known as the QSR, Quality System Requirements.

# Program Requirements

## College of American Pathologists – CAP

[www.cap.org/apps/cap.portal](http://www.cap.org/apps/cap.portal)

## Clinical Pathology Accreditation - CPA (UK)

[www.ukas.com/services/addrreditation-services/medical-laboratory-accreditation-iso-15189](http://www.ukas.com/services/addrreditation-services/medical-laboratory-accreditation-iso-15189)

## Local Quality System Requirements



# Consensus Standards & Guides

## International Organization for Standardization - ISO

[iso.org](http://iso.org)

ISO 15189; ISO 17025

## ASTM International

[astm.org](http://astm.org)

Many equipment standards

## Clinical and Laboratory Standards Institute

[clsi.org/standards](http://clsi.org/standards)

Practices, guides, etc.

# Clinical & Laboratory Standards Institute

**General Laboratory Equipment**

**GP31-A: Laboratory Instrument Implementation,  
Verification, and Maintenance**

**QMS-23: General Laboratory Equipment Use,  
Verification and Maintenance**

# Regulatory Requirements

- Calibration of General Equipment <sup>A</sup>
- Calibration of Chemistry Analyzers <sup>B</sup>
- Test Control Material <sup>B</sup>
- Proficiency Testing <sup>C</sup>

References:

A CAP Checklists, ISO 15189, CLSI QMS

B 42 CFR 493.1267

C. 42 CFR Subparts H, I and K

# Why Do All This?

- Ensure analytical performance is acceptable within the required tolerance limits for intended use
- Comply with regulations
- Save time
- Save money
- Defend data integrity

# Controls & Calibration

