

# Alternative Quality Control (CLSI Update)

# Changes in QC—“Analytic Systems”--2003

- Verification of performance specifications for mod. complexity tests.
- Clarification of calibration verification (checks).
- QC procedures—2 levels of ext.QC or EQC req'd.
- Initially all 3 were “educational”.
- Pertinent CMS “Brochures” on CLIA web site.

# Continue Educational QC, w/ Limited Scope



- *Retain QC (493.1256) as educational !*
  - Effective 12/31/2007
  - CMS labs had 2 ‘educational’ surveys;
  - Should understand & comply.
- **Discontinue as educational:**
  - Test method verification (493.1253)
  - Maintenance & Function Checks (493.1254)
  - Calibration & Cal. verif. (493.1255)

# CMS QC Survey Policy

- Until new QC policies are in place, labs will continue to receive “educational” surveys for *only* QC procedures at 493.1256.
- Labs not meeting QC stds. receive a **letter** urging them to correct, in lieu of deficiency;
  - *If serious quality issues, QC may be cited.*
- Existing requirements not met continue to be cited on a deficiency statement (CMS-2567).
  - **Calibration, cal ver. , test method verif., & function checks now in this category!!**

# CMS QC Survey Policy

- Accredited labs continue to meet their AOs QC standards.
- CMS is working w/ AOs to standardize inconsistent policies.
  - Through Partners in Laboratory Oversight.

# Status Alternative QC Development



- 2005 CLSI meeting sponsored by lab prof. orgs., government, industry & AOs, discussed a plan for **“QC for the Future”**.
  - *Labs need more info from manufacturers.*
  - *One-size-fits-all QC not good for diff. test systems/labs.*
- Two CLSI docs under development for QC.
  - *Alternative QC for labs (Jim Nichols) & risk management for manufacturers (Greg Cooper).*
- Interpretive Guidelines will be revised accordingly.
  - CMS hasn't determined if Options 1-3 will remain.

# Status Alternative QC Development

- CMS is working w/ CLSI to develop 2 guidance “Evaluation Protocol” documents.
  - Includes reps from labs, industry & gov’t.
  - Utilizes a consensus process.
  - Exciting, groundbreaking efforts!
- *Manufacturers’* - using ISO risk mgt. principles.
- *Laboratories’* - to design custom QC.
- CLSI Subcommittee vote—Fall ’08.



# Where to Find Info

- CMS Web site:

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

- “Laboratory Demographic Look- Up”

- Brochures, state/ regional contacts, application

- CMS Central Office, Baltimore

- 410-786-3531

- Judy Yost’s email:

- [Judith.yost@cms.hhs.gov](mailto:Judith.yost@cms.hhs.gov)



**THE END!!**

**THANK YOU!!**  
**QUESTIONS???**

