

The Why's & Wherefore's of CLIA Competency Evaluation

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Topics for Discussion

- Introduction
- Rationale for Competency Requirements
- Competency Regulations & Procedures
- Guidance & Problems to Avoid
- Questions

Introduction

- **Personnel Competency** introduced as a CLIA standard in 1992 regulations.
- Competency is required for all technical, supervisory & testing personnel.
- Various related requirements are interspersed throughout the regulations.
- Competency is NOT the same as a performance evaluation/training.

Rationale for Personnel Competency

- CLIA's intent is to ensure accurate, reliable & timely testing.
- Studies indicate that more education & training produce higher quality results.
- The means to confirm training effectiveness is competency evaluation.
- In CLIA, the laboratory director's qualifications are stringent due to the overall quality responsibility.

Rationale for Personnel Competency

- But qualifications for testing personnel are minimal, based on test complexity.
- Highlights importance of competency, regardless of education.
- Quality management includes personnel, processes, & procedures, as does competency.
- Competency is recognized by CLIA law.

Rationale for Personnel Competency

- CLIA survey experience indicates many problems caused by personnel errors.
- Many laboratory test mistakes may have a patient impact.
- Routine competency evaluations will help prevent errors.
- CMS permits flexibility in achieving compliance.

Competency Regulations

- 493.1413(b)(8)(9) & 1451(b)(8)(9)—
- Technical Consultant/Supervisor Responsibilities—
- *Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently.*

Competency Regulations

- 493.1413(b)(8)(9) & 1451(b)(8)(9)—
- Technical Consultant/Supervisor Responsibilities—
- *Evaluating & documenting individuals' performance at least 2X/yr. for the 1st yr. of testing & annually thereafter, unless method or instrument changes, prior to reporting patient results; re-evaluate w/ new tests systems.*

Competency Regulations

- 493.1235—Personnel Competency Assessment Policies—
- *As specified in the personnel requirements in Subpart M, the laboratory must establish & follow written policies & procedures to assess employee, & if applicable, consultant competency.*

Competency Regulations

- 493.1407(e)(12) & 1445(e)(13)—
Laboratory Director Responsibilities—
- *Ensure that policies & procedures are established for monitoring individuals who conduct pre-analytical, analytical & post analytical phases of testing to assure that they are competent & maintain their competency to process specimens, perform tests & report results promptly & proficiently, & whenever necessary, identify needs for remedial training or CE to improve skills.*

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.*

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *2. Monitoring the recording & reporting of test results*

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *3. Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records*

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *4. Direct observation of performance of instrument maintenance & function checks*

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and*

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *6. Assessment of problem solving skills*

Competency Assessment Guidance & Problems to Avoid

- Operator training prior to testing is critical & required.
- Competency assessments must demonstrate testing personnel (TP) are performing testing accurately.
- See TP responsibilities in regulations.
- Competency assessments must be documented.

Competency Assessment Guidance & Problems to Avoid

- Individual conducting competency assessments must be qualified.
- Competency is not PT!
- Competency records should match the laboratory's actual procedures performed by its personnel.
- When observing test performance, use the procedure manual (PM) /package insert (PI) to ensure PM is current.

Competency Assessment Guidance & Problems to Avoid

- Can use competency assessment for QA when confirming tests ordered match reported & charted results.
- Follow up on QC corrective actions will demonstrate problem solving ability.
- Checklists are only minimally ok.
- Competency for clinical & technical consultants & supervisors is based on their regulatory responsibilities.

Competency Assessment Guidance & Problems to Avoid

- Laboratory director serving as TC, CC, TS &/or GS isn't subject to competency requirements.
- Personnel who perform pre & post analytic activities & who are not listed in the regulations as required positions aren't subject to competency.
- But laboratory may want to do similar evaluations for QA or if a problem.

Competency Assessment Guidance & Problems to Avoid

- Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals.
- Pathologists should be evaluated by the laboratory director as technical supervisors.
- CMS permits (encourages) creativity in meeting competency requirements.

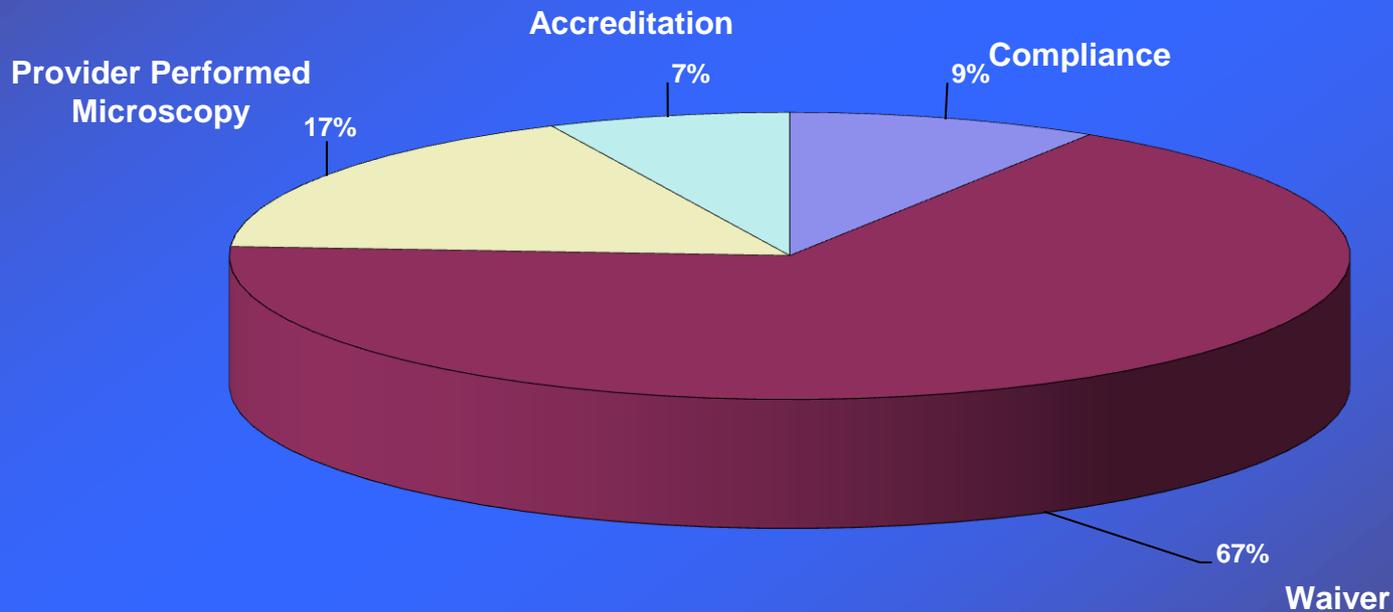
CMS CLIA DATA UPDATE

CMS CLIA DATA UPDATE

<u>Total Number of Laboratories</u>	<u>232,548</u>
<u>Total Non-Exempt</u>	<u>225,746</u>
– <u>Compliance</u>	19,319
– <u>Accredited</u>	15,787
– <u>Waived</u>	146,071
– <u>Provider Performed Microscopy</u>	37,767
– <u>Exempt</u>	<u>6,802</u>
• NY	3,336
• WA	3,466

CMS CLIA DATA UPDATE

CLIA Labs by Certificate Type (Non-Exempt Only)

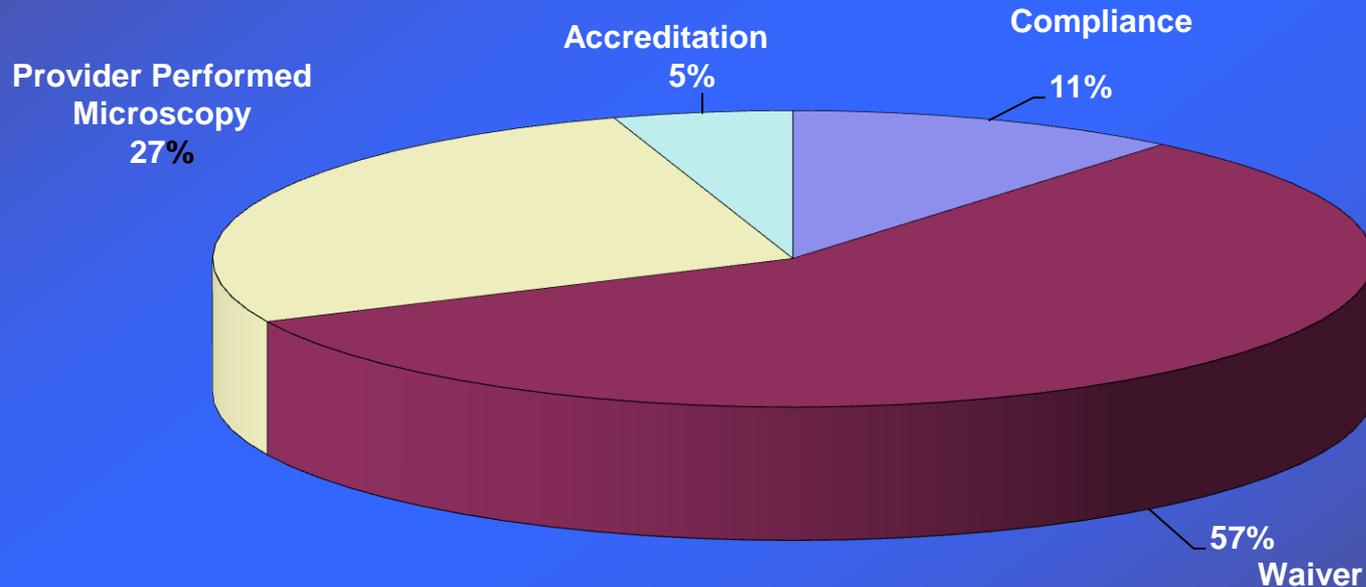


Source: CMS CLIA database 06/2011



CMS CLIA DATA UPDATE

Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)

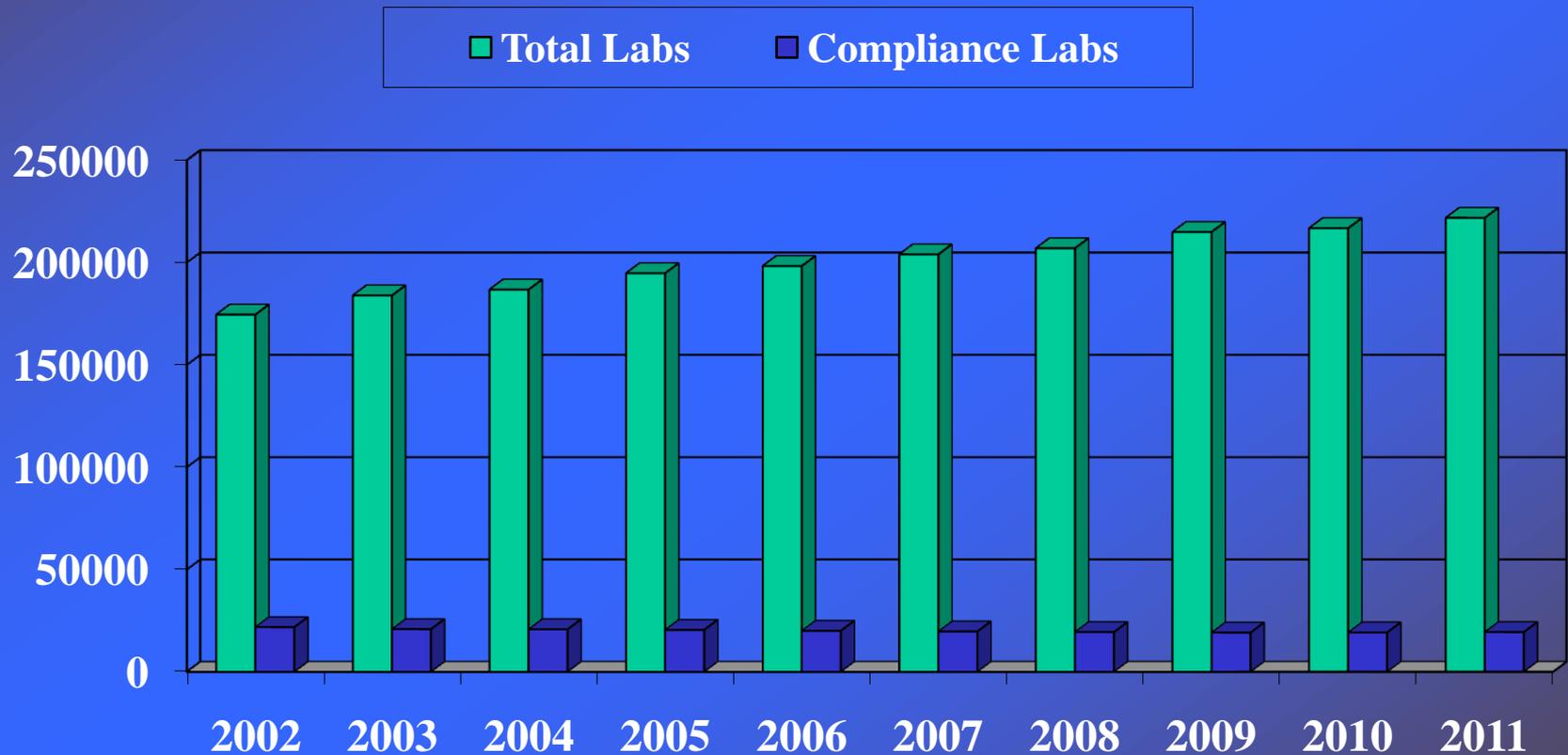


Source: CMS CLIA database 06/2011



CMS CLIA DATA UPDATE

Decade Trend

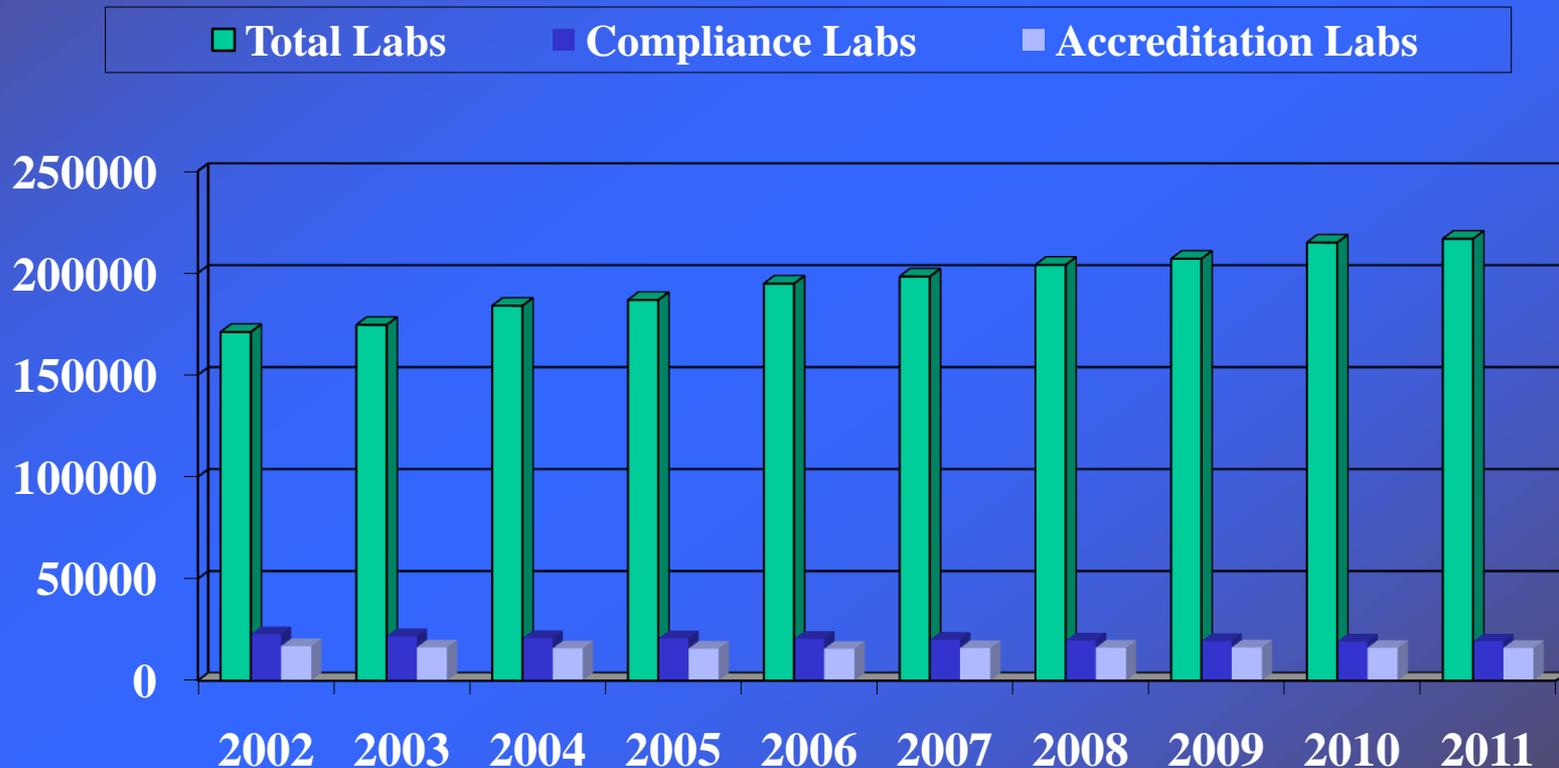


Source: CMS CLIA database 12/14/2010



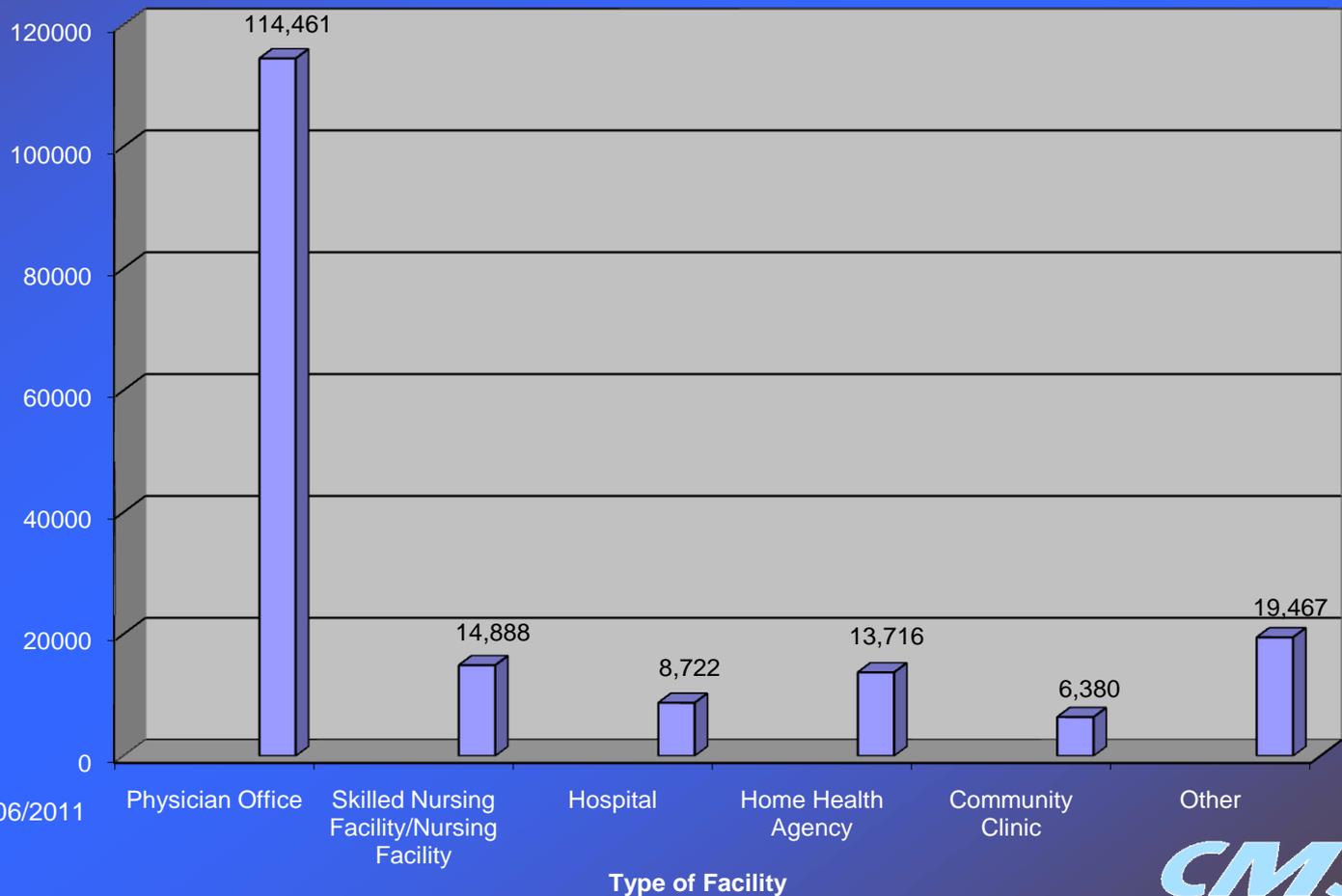
CMS CLIA DATA UPDATE

Decade Trend



CMS CLIA DATA UPDATE

CLIA Laboratory Registration Self-Selected Laboratory Types

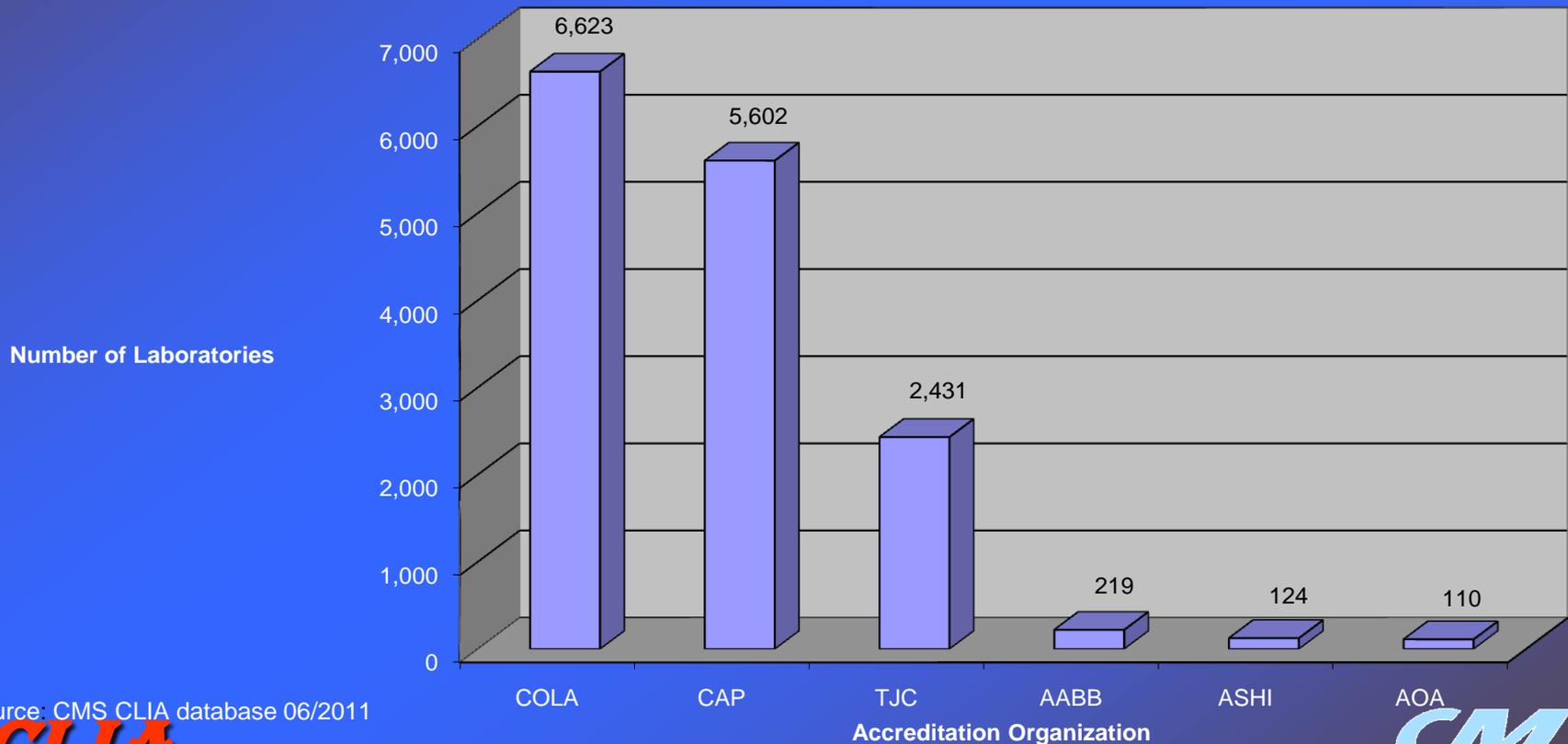


Source: CMS CLIA database 06/2011



CMS CLIA DATA UPDATE

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



Source: CMS CLIA database 06/2011



CMS CLIA DATA UPDATE

Transfusion Fatalities

Type	FY 2010	FY 2009
TRALI (Transfusion Related Acute Lung Injury)	36	31
Hemolytic (Immune)	9	12
TACO (Transfusion Related Circulatory Overload)	5	9
Bacterial Contamination	5	6
Other (Anaphylactic, Graft vs. Host Disease, Babesiosis, Hyperhemolysis Syndrome, Allergic, Non-Immune Hemolytic, Unknown)	16	17
TOTAL	71	75

CMS CLIA DATA UPDATE

Transfusion Fatalities

	FY 2010	FY 2009
Investigations	4	11
2567's	0	7

2567's issued

Specimens mixed up in the lab

Specimen drawn from the wrong patient

Testing errors—missed antibodies

Wrong FFP type issued

Wrong patient transfused

CMS CLIA DATA UPDATE

Top 10 Condition Deficiencies

<u>Citation</u>	<u>% Labs Cited</u>
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-Mod. complexity LD qualif./respons.	4.2%
-Successful PT participation	3.2%
-PT enrollment	1.8%
-Analytic Systems (QC)	1.7%
-Mod. complexity TP	1.5%

CMS CLIA DATA UPDATE

Top 10 Condition Deficiencies

<u>Citation</u>	<u>% Labs Cited</u>
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-High complexity director qualif./respons.	-----1.3%
-Technical consultant qualif./respons.	-----1.0%
-Hematology	-----0.6%
-Gen. Lab Systems QA	-----0.3%
-Gen. Lab Systems preanalytic	-----0.3%

CMS CLIA DATA UPDATE

Top 10 Deficiencies

Citation

% Labs Cited

- Policy for proper reagent storage-----5.8%
- Analytic Systems' QA-----5.5%
- Verify accuracy non-PT'd tests-----5.5%
- Follow mfgr's. instructions-----4.9%
- Procedure manual-----4.6%

CMS CLIA DATA UPDATE

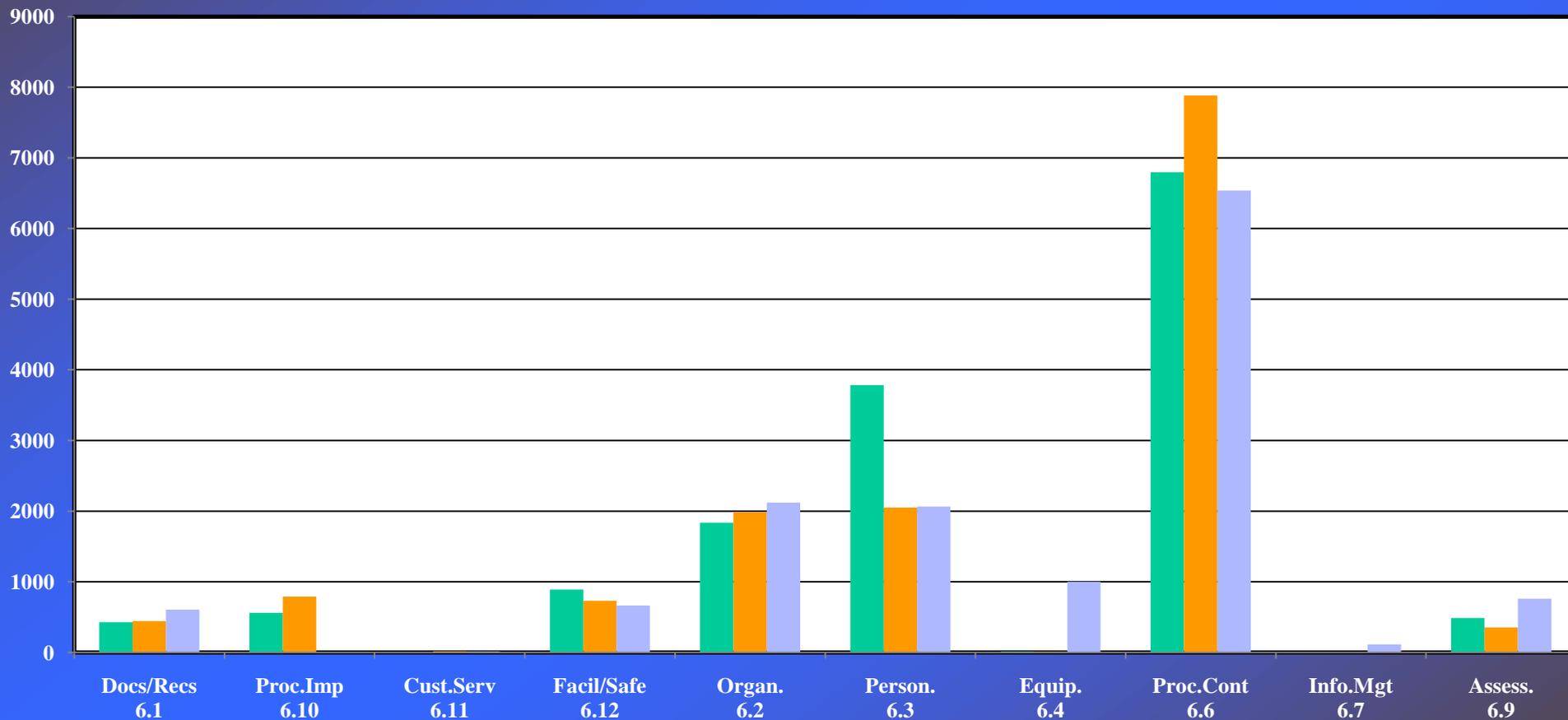
Citation

% Labs Cited

- LD responsibility-QA plan-----4.4%
- Mod. complexity LD qualif./respons.-----4.2%
- Calibration verif.-----4.2%
- Use of expired reagents-----4.1%
- Gen lab systems QA-----3.7%

CMS CLIA DATA UPDATE

Partners' Deficiencies 2007-9

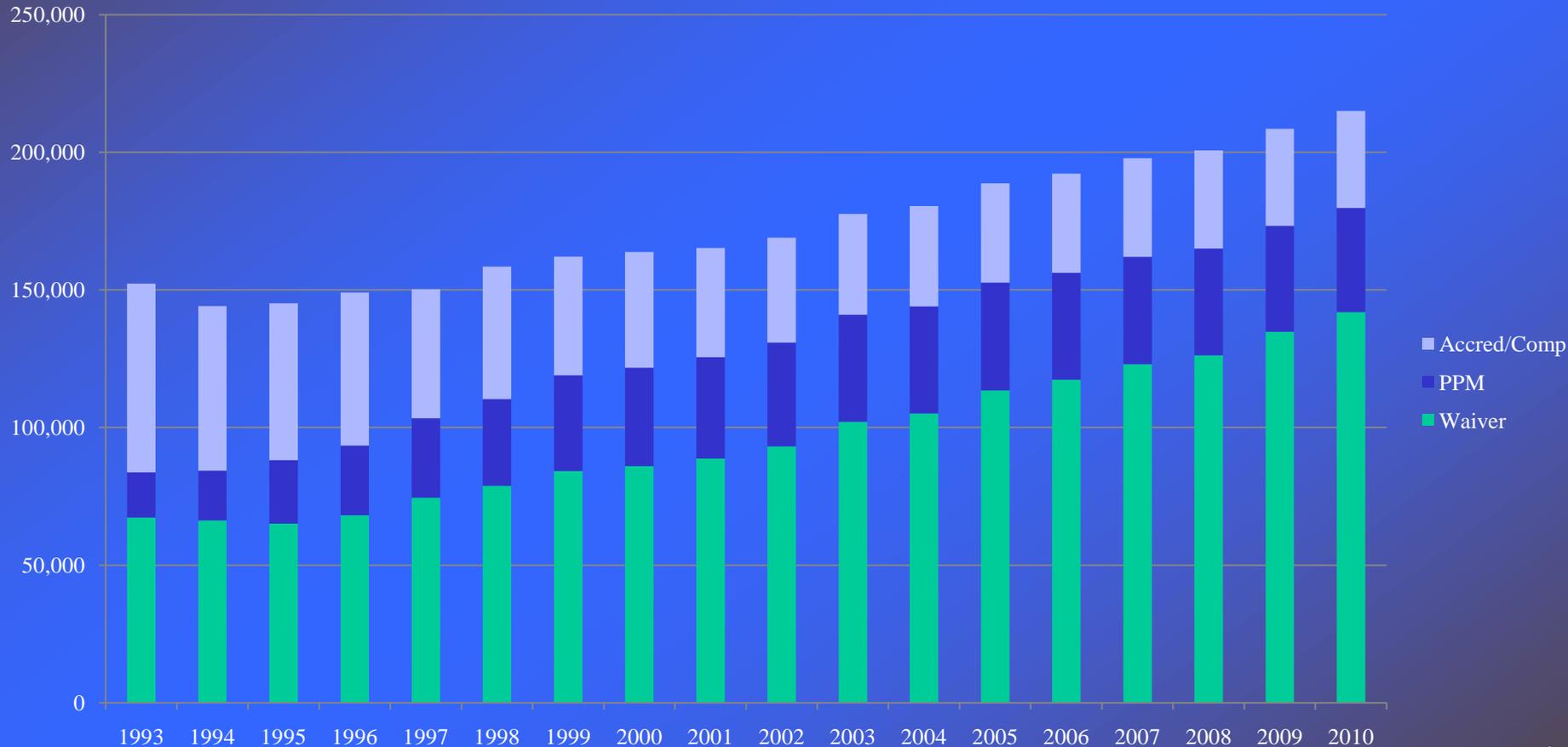


Quality System Essentials



CMS CLIA DATA UPDATE

Waived Lab Growth



CMS/CLIA Contact Information

- CMS/CLIA web site:

<http://www.cms.hhs.gov/clia/>

Includes States, Regulations, Guidelines

- CMS/CLIA Central Office:

410-786-3531

- Judy Yost's Email:

judith.yost@cms.hhs.gov



CLIA

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CENTERS for MEDICARE & MEDICAID SERVICES

THE END!!

THANK YOU!!

Questions??????

