

Today's Featured Speaker

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Judy is currently the Director of the Division of Laboratory Services, the division that is responsible for the oversight and administration of the CLIA program.

**Everything You Always
Wanted to Know About
CLIA's Waived Testing &
Competency for NON-Waived
testing!**

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Topics for Discussion



- CLIA Statistics
- Growth of Waived Tests & Laboratories
- CMS' Position on POC/Waived Testing
- CMS' Certificate of Waiver Project Data
- CMS' Next Steps for Waived Laboratories
- Questions???

Current CLIA Statistics

Total Number of Laboratories 221,793

Total Non-Exempt 215,057

– Compliance 19,404

– Accredited 15,864

– Waived 141,994

– Provider Performed Microscopy 37,795

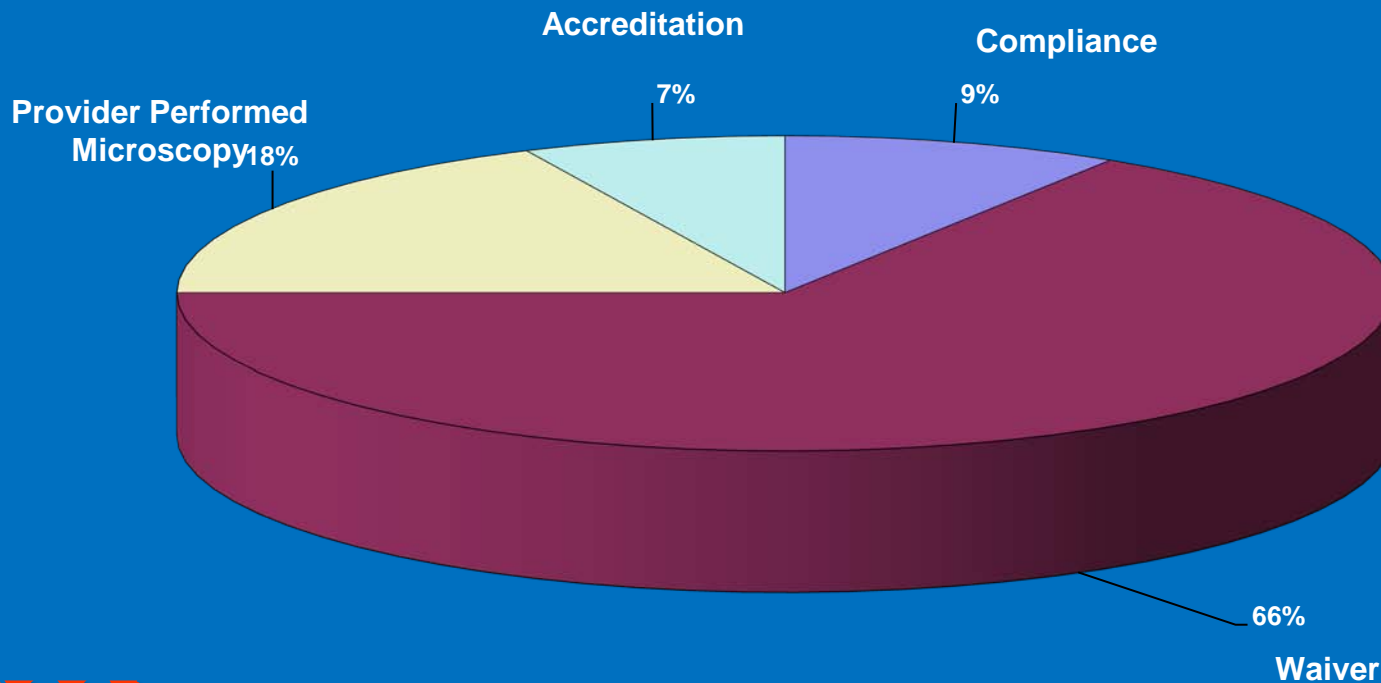
– Exempt 6,736

• NY 3,264

• WA 3,472

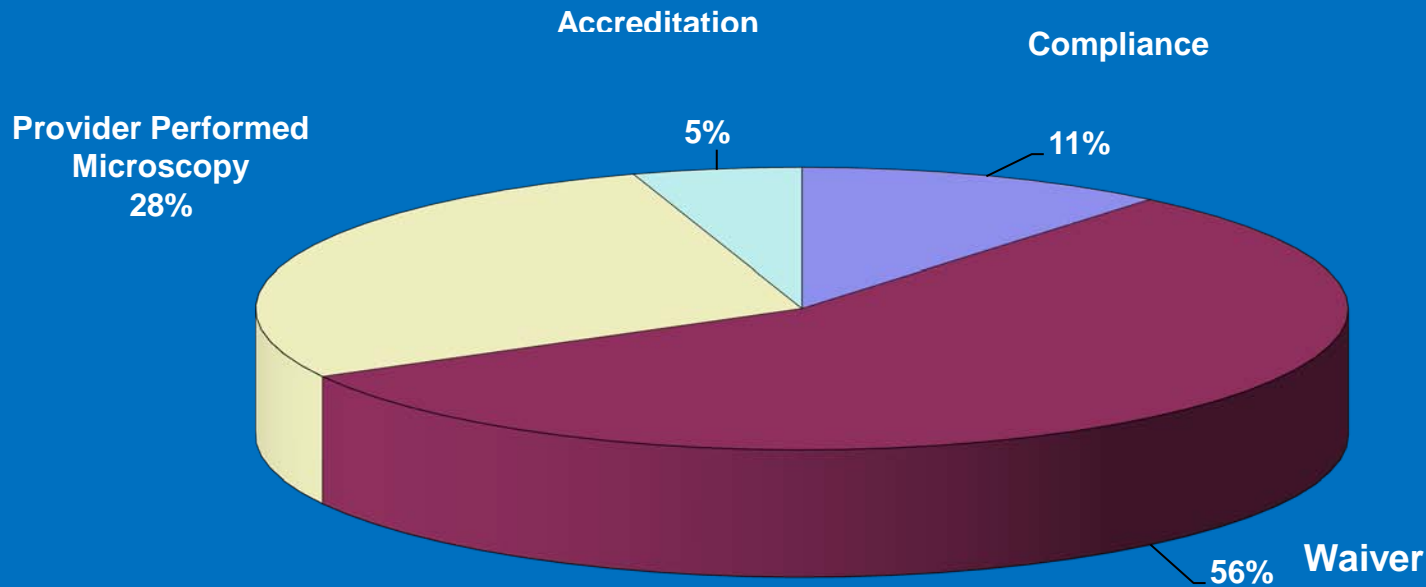
Current CLIA Statistics

CLIA Labs by Certificate Type (Non-Exempt Only)



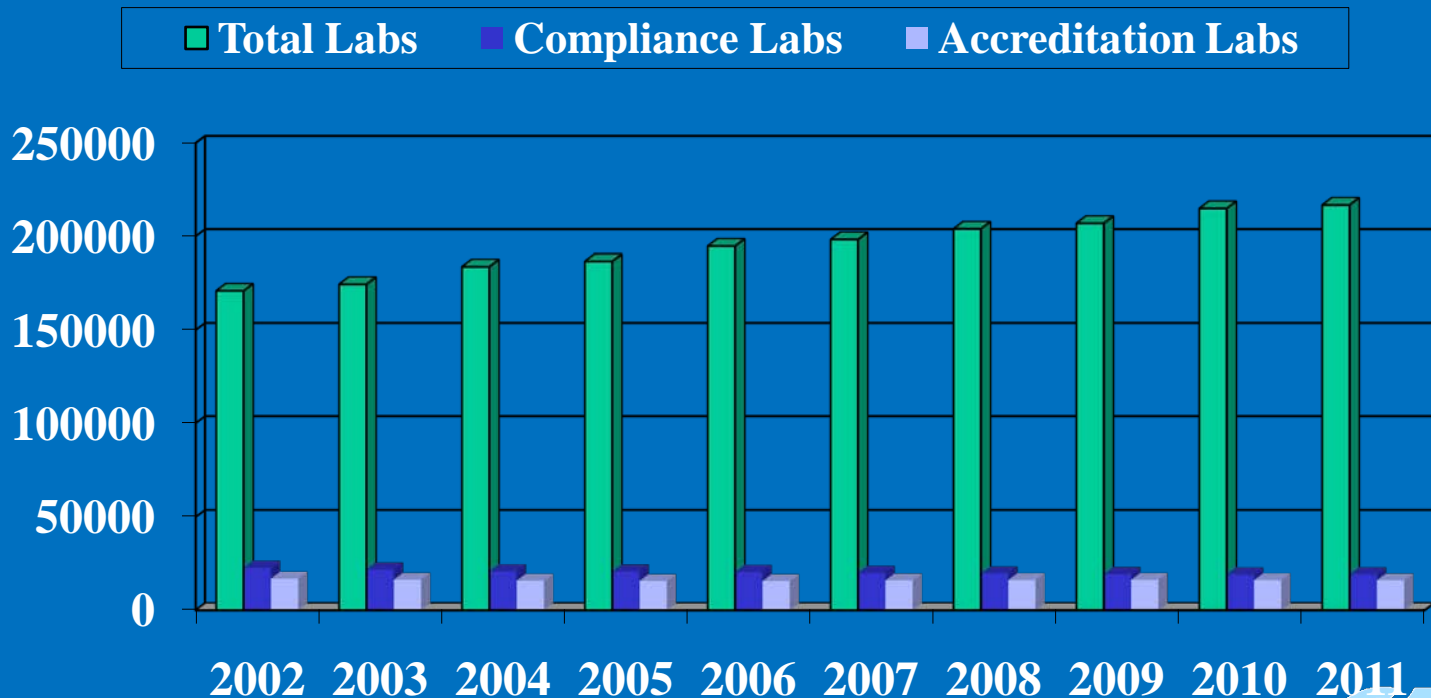
Current CLIA Statistics

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



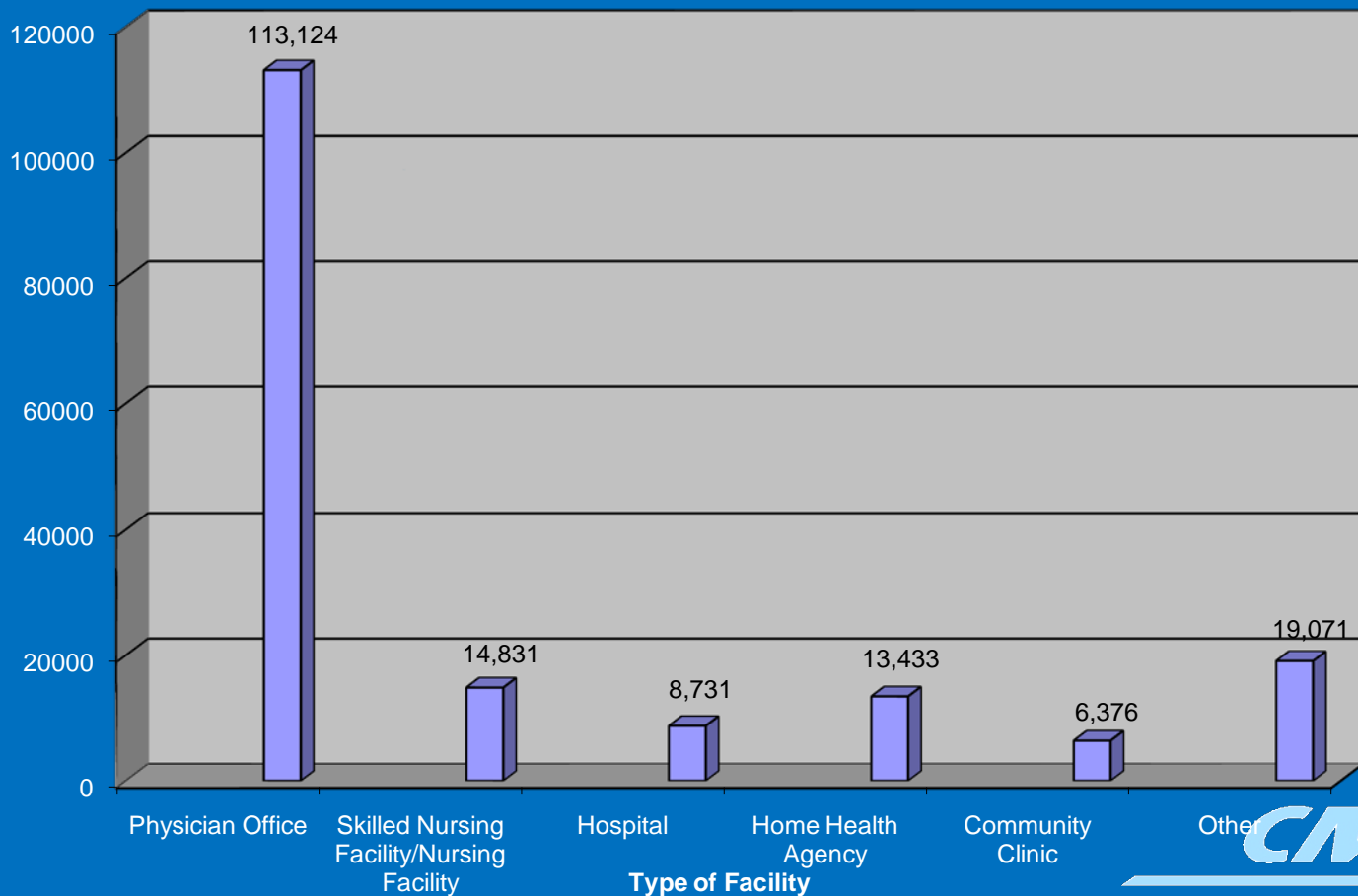
Current CLIA Statistics

Decade Trend



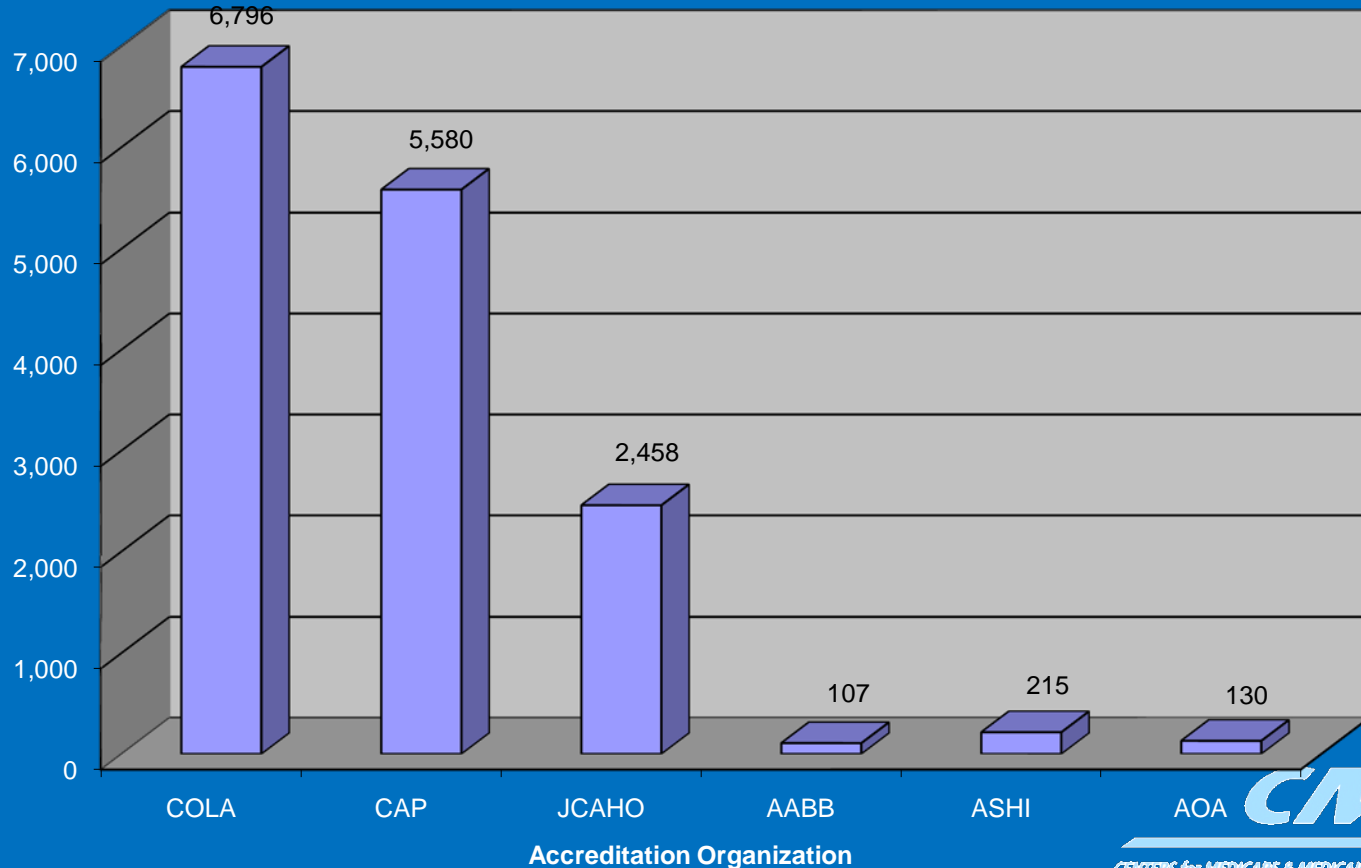
Current CLIA Statistics

Total CLIA Laboratories Registered Self-Selected Laboratory Types



Current CLIA Statistics

Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization



Growth of Waived Tests & Laboratories

By CLIA definition.....

Waived tests are;

“.....simple laboratory examinations & procedures which –

Employ methodologies that are so simple & accurate as to render the likelihood of erroneous results negligible;

Pose no reasonable risk of harm to the patient if the test is performed incorrectly”.

Certificate of Waiver (CW) Laboratory Requirements

The only standards for CW laboratories:

- *Follow manufacturer's instructions*
- Register with CMS
- Pay small certificate fee every 2 years

NOTE: Some CW labs are part of accredited facilities & are subject to their quality standards.

CMS Position on Waived/POC Testing

- Offers timely, efficient, convenient patient care
- Continues to increase
- Increased testing comes w/ issues:
 - ✓ Testing personnel less-trained; may not ID problems
 - ✓ No routine oversight w/ no funding/resources
 - ✓ Minimal manufacturer recommended QC
 - ✓ Pre & post analytical issues

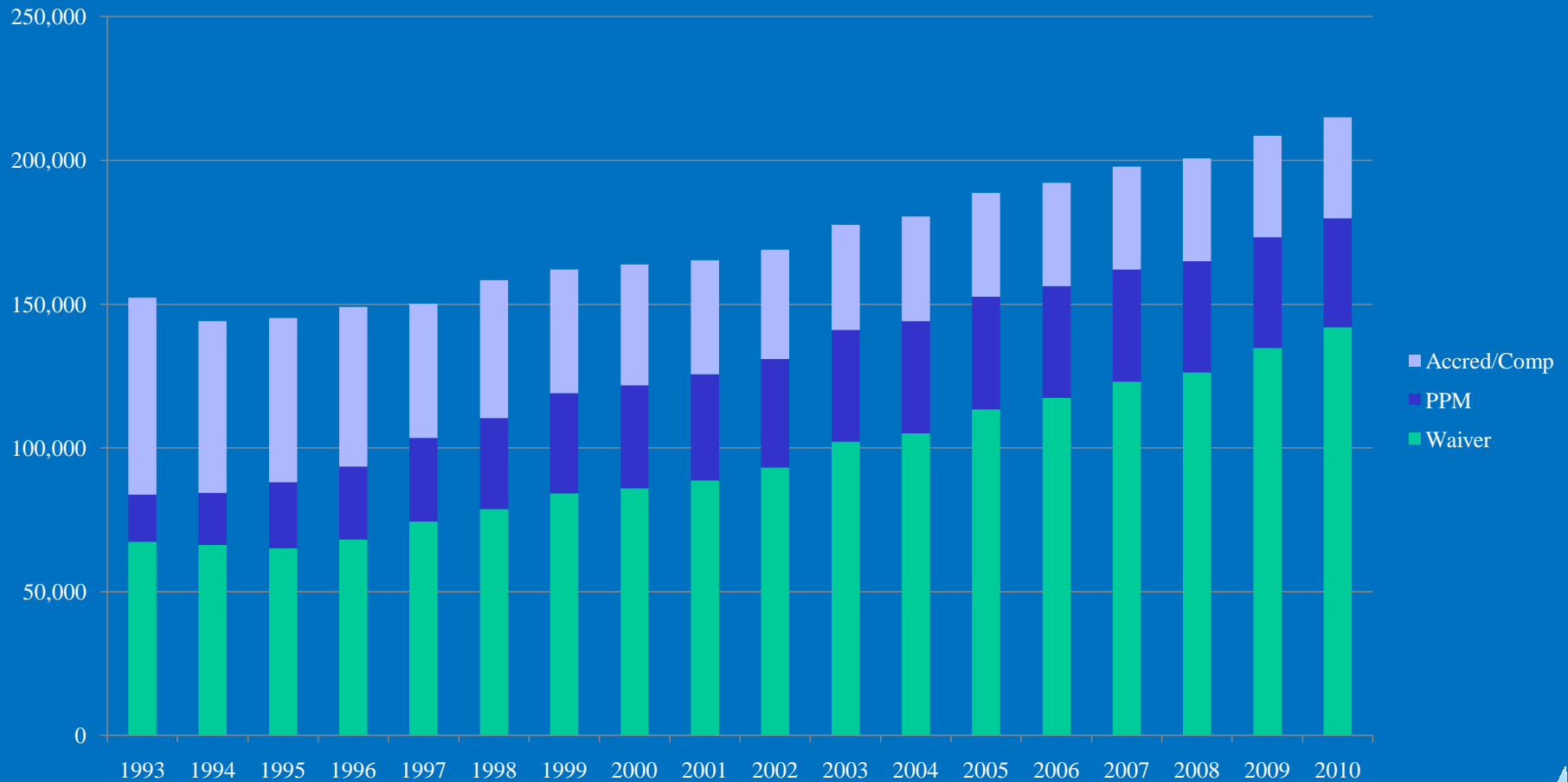


Growth of Waived Tests & CW Laboratories

Since 1992.....

- CLIA-waived tests have increased from 8 to > 100 tests.
 - **This represents 1000's of test systems!**
- The number of laboratories issued a CW has grown exponentially from 20% to 66% of the >220,000 laboratories enrolled. And it is growing.....

Growth of Waived Tests & CW Laboratories



Growth of Waived Tests & CW Laboratories

- Waived tests increased due to new, accurate & robust technologies designed by manufacturers
 - Meet FDA criteria for waiver
 - Tested under ideal conditions
 - Performed by individuals w/ some lab background



Growth of Waived Tests & CW Laboratories

- Huge growth in numbers & types of waived tests.
 - Most frequently performed tests in small labs
 - Tests typically done in POC settings
- Waived certificate is an incentive due to no government oversight & Medicare payment rec'd.
 - Creates less burden to the lab
 - Decreases costs to the lab
 - No PT/little QC
 - No routine survey
 - Lab makes \$\$\$

Certificate of Waiver (CW) Project

Due to concerns about complaints & growth of CW labs, in 1999 CMS:

- Began visits to 100 CW & PPM labs in CO & OH; **50% had quality problems!**
- As a result, CMS expanded this pilot to 8 more States--

Certificate of Waiver (CW) Project

2000- Present-- Expanded Pilot:

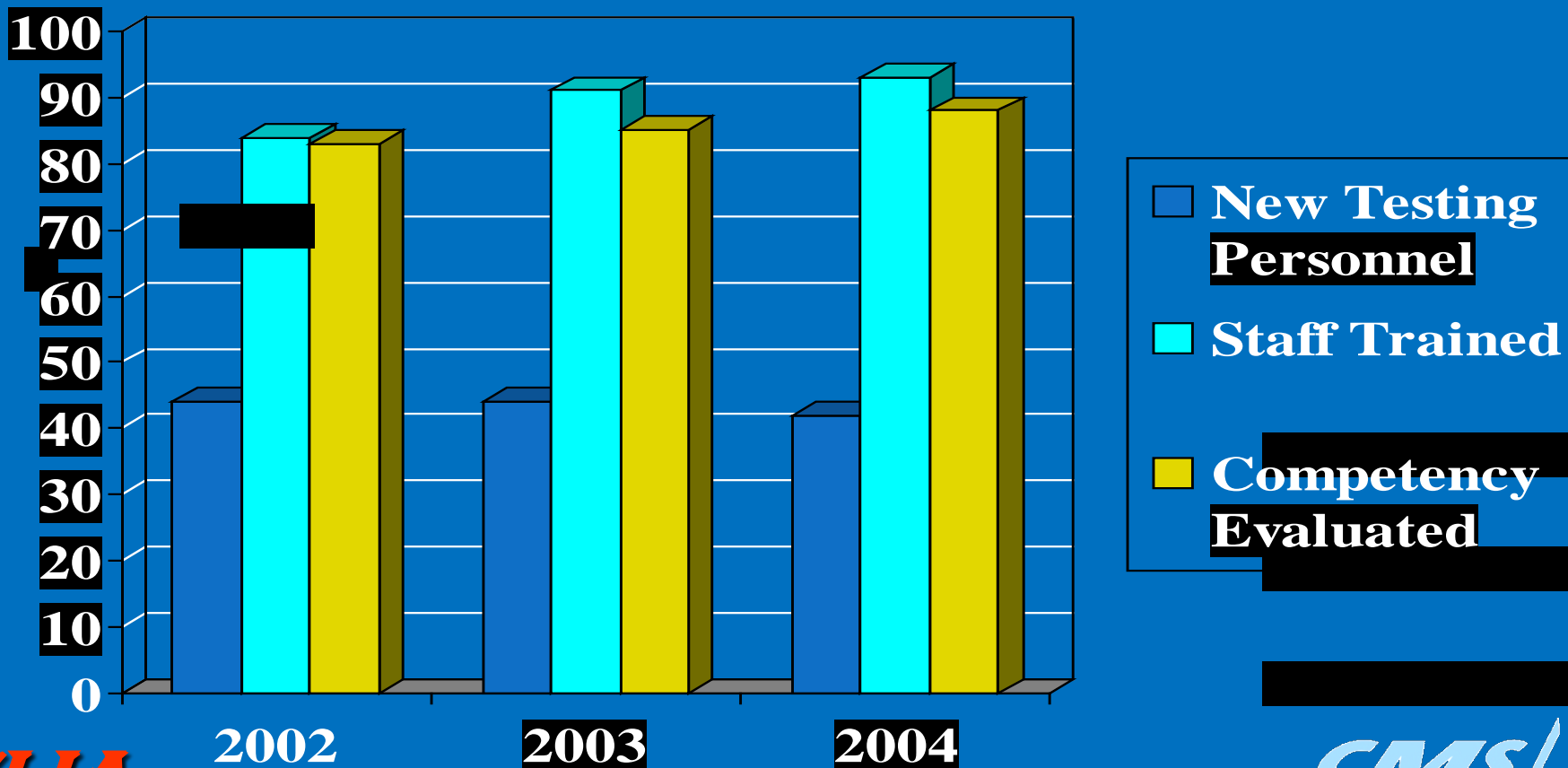
- Surveyors in MA, NY, PA, MS, NM, IA, AZ, ID visited 436 COW & PPMP laboratories; **32% had quality problems!**
- CMS-CLIA initiated an ongoing national project in 2002 to conduct educational visits for 2% of CW labs to collect data.
- Ea. lab responds to questions about its waived testing & rec. gd. lab practice info.

Certificate of Waiver (CW) Project

In 2002-2003:

- Change in testing personnel=43-44% of labs
- Provide timely results=95-99% of labs
- Chose to enroll in PT=8-10% of labs

Certificate of Waiver (CW) Project—Personnel & Training



Certificate of Waiver (CW) Project—Reports at CLIAC '04

The CDC reported issues found in CMS CW surveys correlate w/ CDC's studies.

New York State DOH reported similar findings from their visits.

Office of Inspector General also did a study with the same findings as CMS.

They all found the following:

CLIA

Certificate of Waiver (CW) Project-CDC Report at CLIAC'04

- High staff turnover in waived testing sites
- Lack of formal laboratory education
- Limited training in test performance & QA
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturers’ QC instructions (~55-60%)

Certificate of Waiver (CW) Project--2006



Initial visits

- Of 1947 labs visited, 69% were following the manufacturer's instructions.



Follow-up visits

- **85%** of labs not following manufacturers' instructions initially showed improvement after intervention.

Certificate of Waiver (CW) Project-- Serious Risk to Patient Health!!

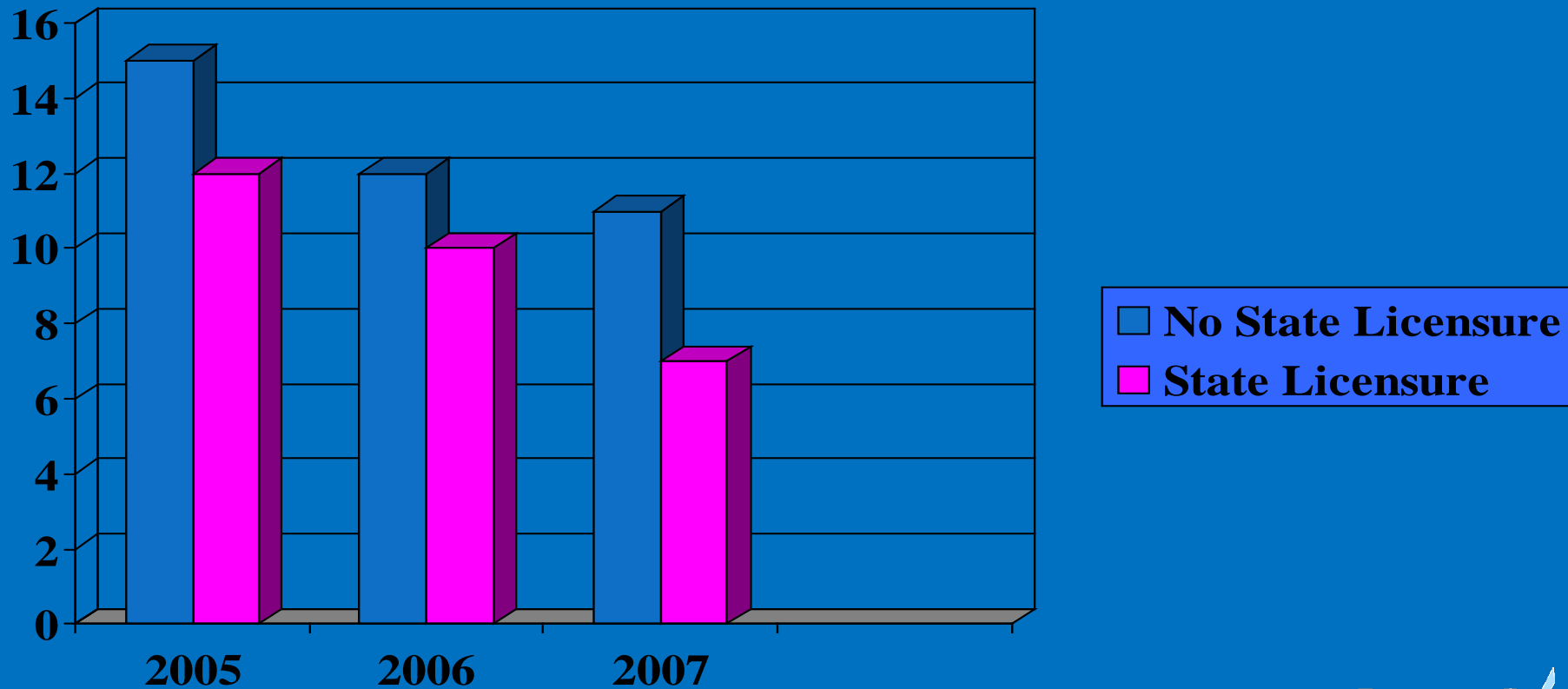
- FY 2005: 6/1678 surveys or <1% labs
- FY 2006: 6/1938 surveys or <0.5% labs
- FY 2007: 2/1737 surveys or <0.20% labs
- FY 2008: 3 out of 1902 surveys or <0.16% labs

- Consider if this is extrapolated to total CW lab population!

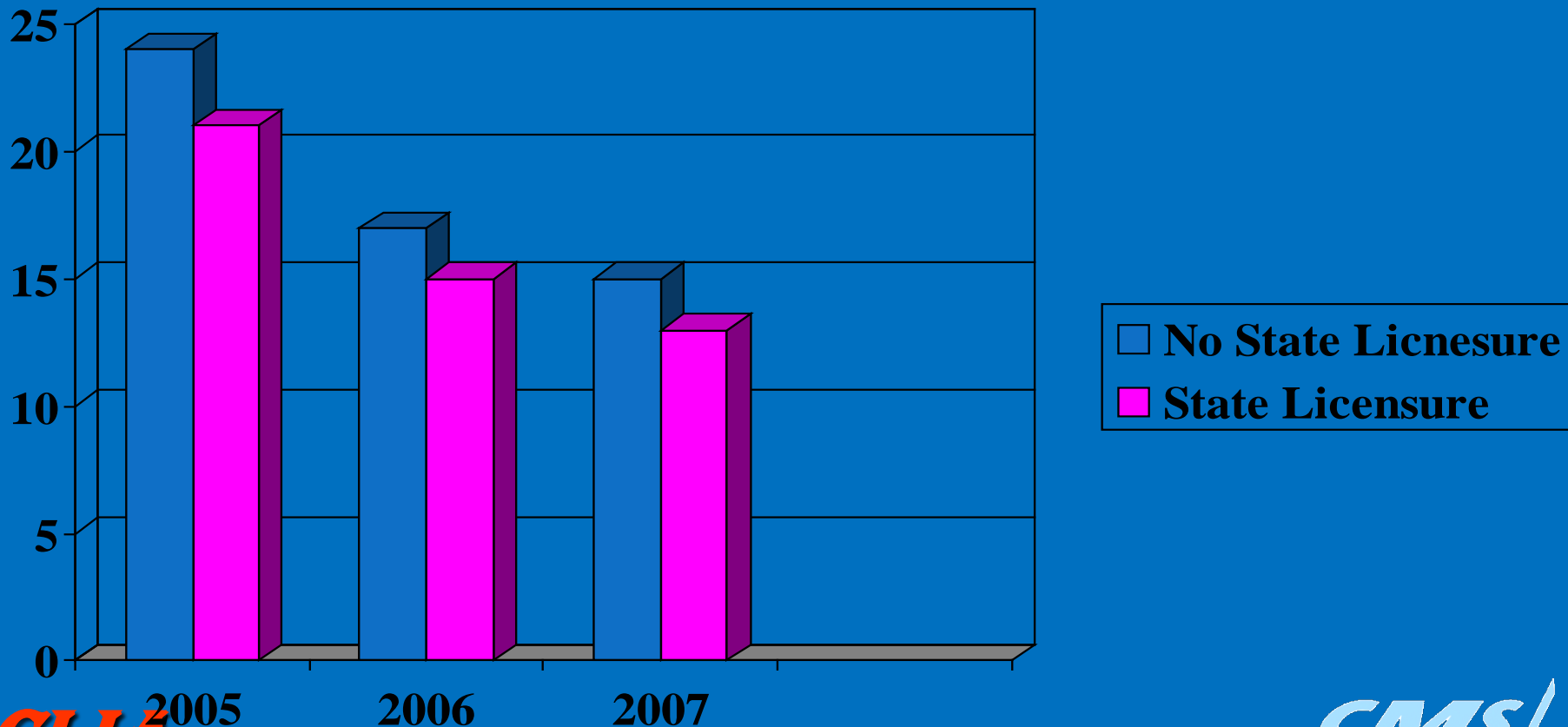
Certificate of Waiver (CW) Project -Labs Performing Non-Waived Tests



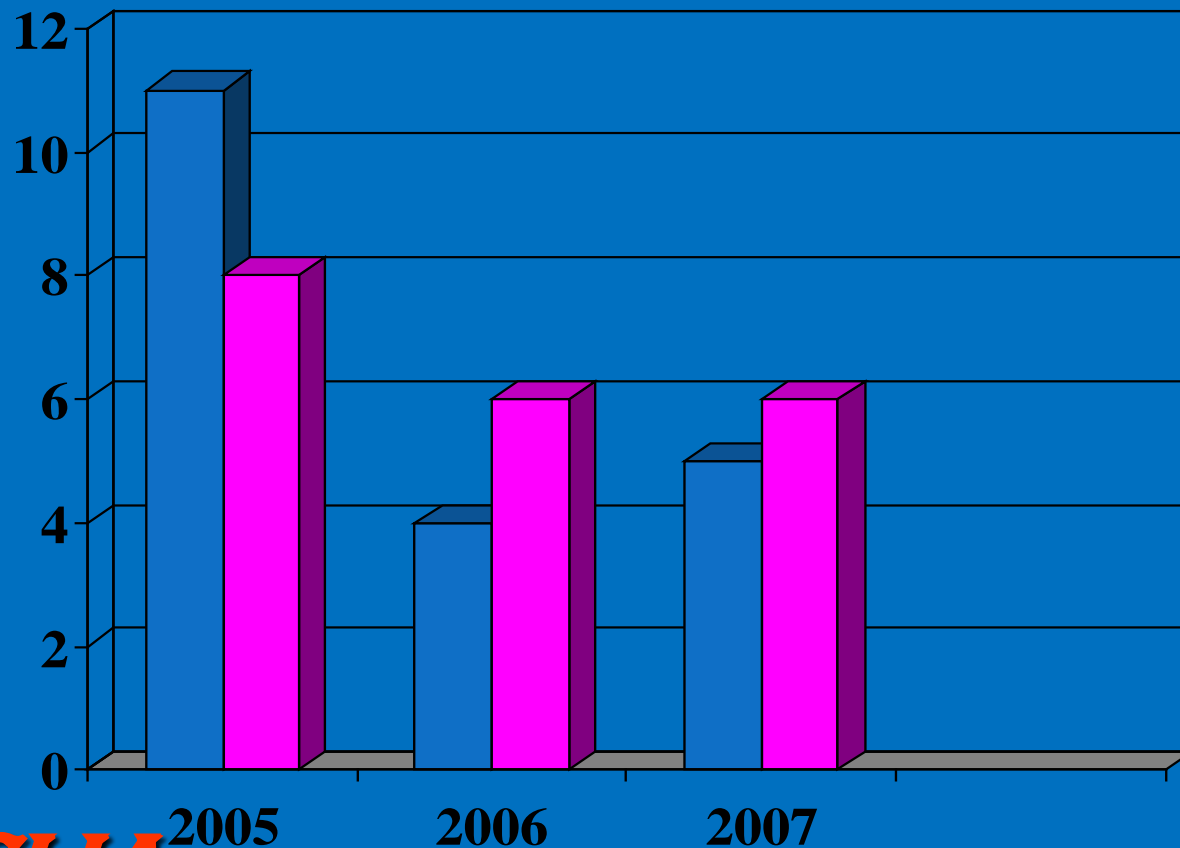
Certificate of Waiver (CW) Project- Labs w/o the Manufacturer's Instructions



Certificate of Waiver (CW) Project- Labs Not Performing QC Initial Visit

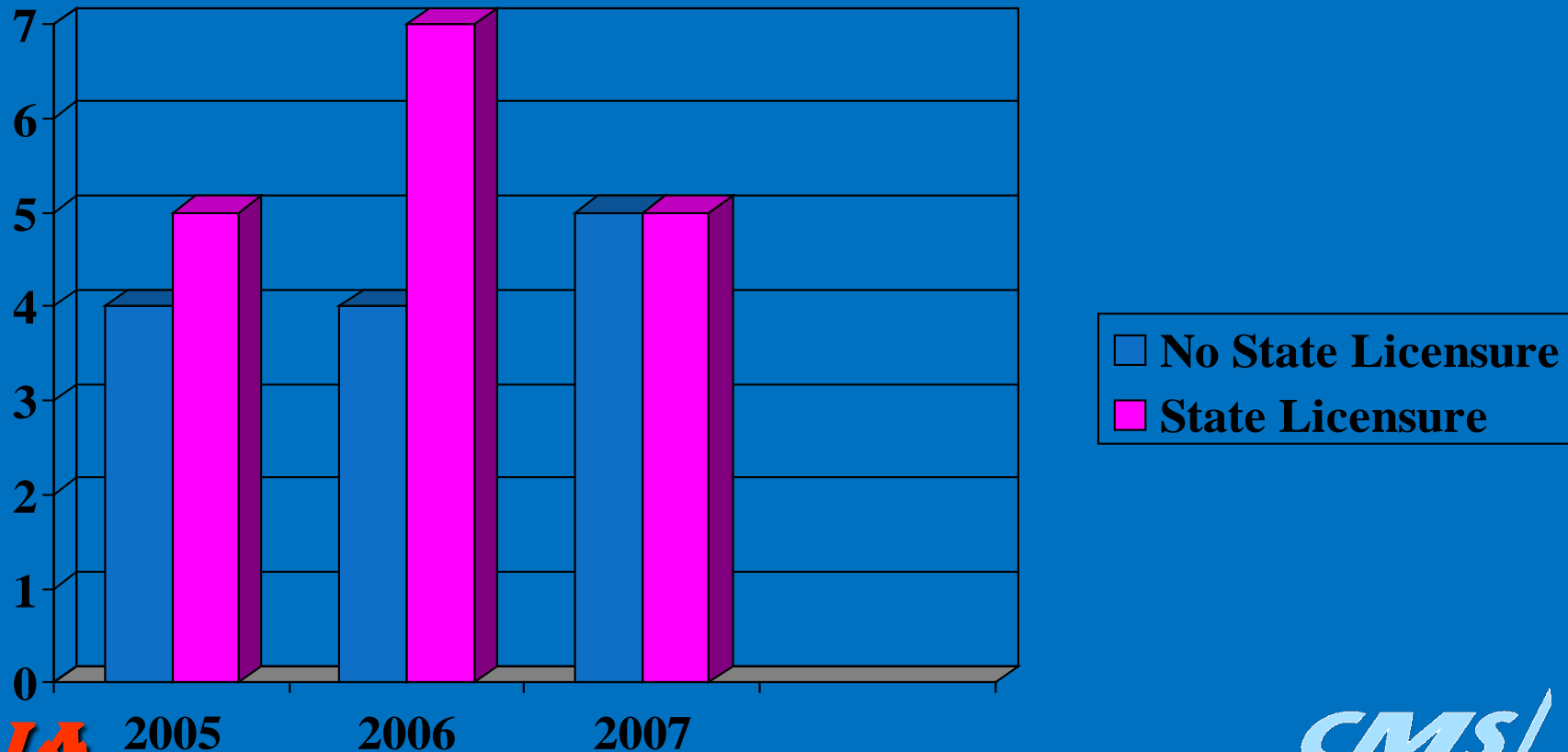


Certificate of Waiver (CW) Project- Labs Not Performing QC Follow Up Visit



□ No State Licensure
■ State Licensure

Certificate of Waiver (CW) Project- Labs Participate in Voluntary PT

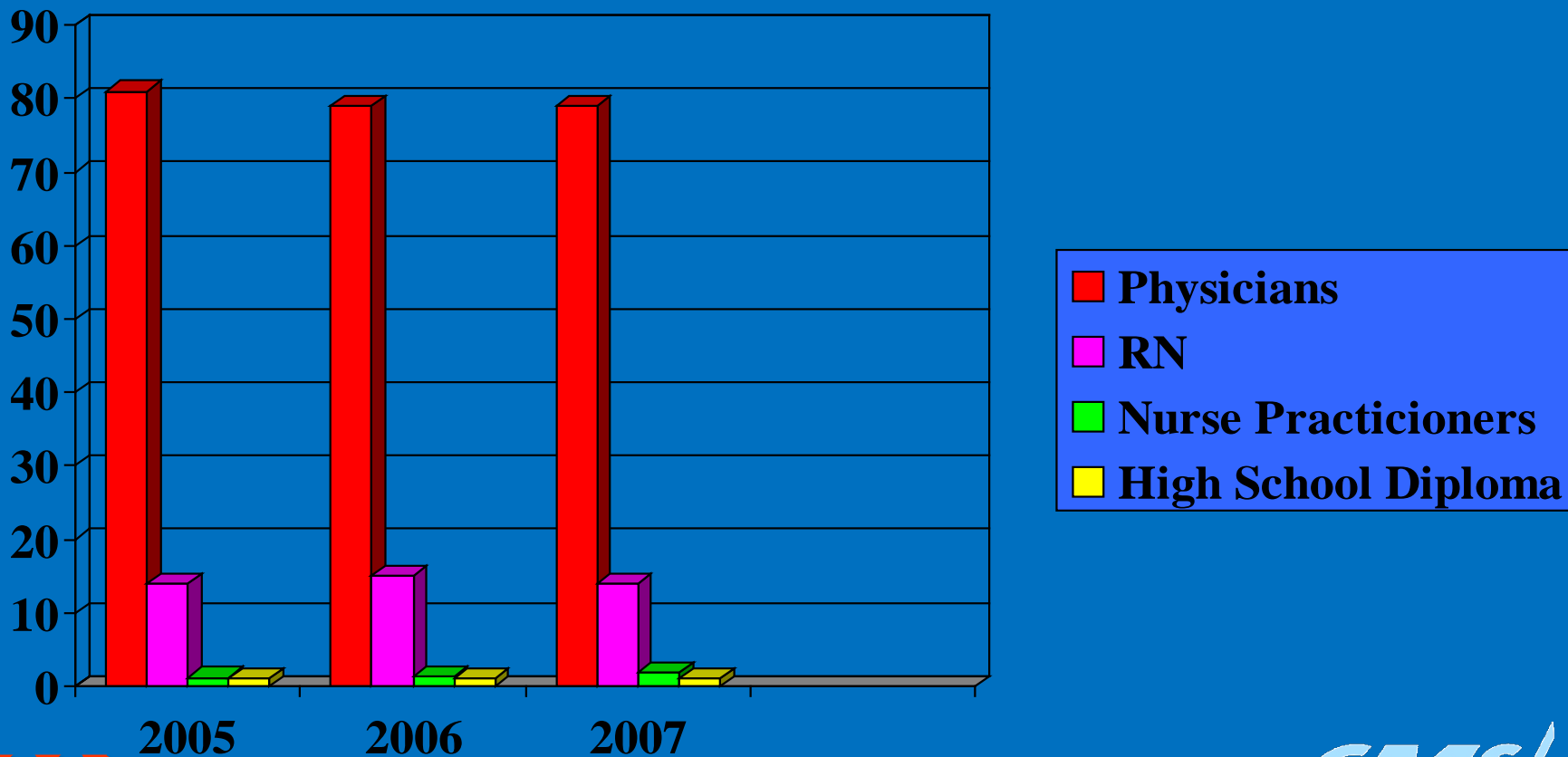


Certificate of Waiver (CW) Project- Performance w/ Voluntary PT Enrollment

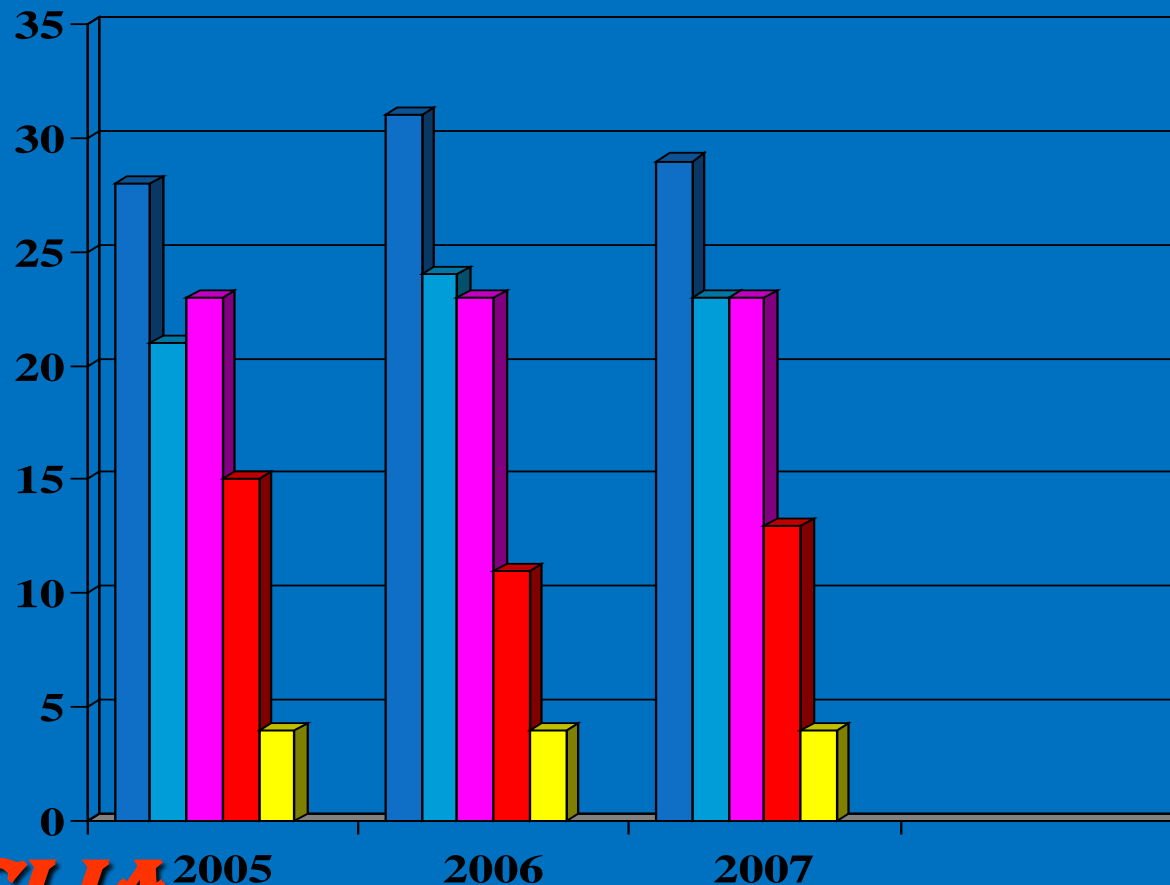
| <u>CMS Survey Response</u> | <u>PT</u> | <u>No PT</u> |
|--|-----------|--------------|
| • Lab has current PI* | 98% | 88% |
| • Performs required QC | 95% | 75% |
| • Performs function checks/ Calibration | 75% | 62% |
| • Performs confirmatory test | 25% | 15% |

*package insert

Certificate of Waiver (CW) Project- Lab Directors



Certificate of Waiver (CW) Project- Testing Personnel



Certificate of Waiver (CW) Project--Summary

The CW Project has:

- Raised the awareness of the need to follow manufacturer's instructions for testing
- Identified labs testing beyond the scope of the lab's waived certificate
- Provided education about CLIA, laboratory testing & Good Lab Practices
- Confirmed that labs w/ routine oversight perform significantly better & improve over time.



Next Steps for Waived Testing..



- Number of CW labs increasing exponentially
- Education is effective, but resources are lacking
- CMS developed an “Issue” paper w/ multi-faceted recommendations for agency mgt.
- CMS to convene w/ Partners to develop long & short term plans.

Next Steps for Waived Testing.....

Short term

- Continue CW project indefinitely
- Provide edu. materials w/ ea. new ap, on web site, w/ on-site visits; update CE clearinghouse
- Initiate test menu collection w/ apps
- Collaborate w/ Partners/CDC to ID add'l. efforts
- Enlist support of med., mfgr. & patient advocacy orgs.
- Evaluate data from AO/ES w/ CW standards
- Coordinate w/ FDA on overlapping issues
- Publish comprehensive report

Long term-Change the CLIA law to improve oversight

Where to Find Info:

- CMS CLIA Web site:
 - www.cms.hhs.gov/clia/
 - NEW FEATURE: “Lab Demographic Look- Up”
 - Brochures, state contacts, application, guidelines
- CMS Central Office, Baltimore
 - 410-786-3531
- Judy Yost’s email:
 - Judith.yost@cms.hhs.gov



Questions??

THANK YOU!!



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:
- *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:
- *Monitoring the recording & reporting of test results*

Regulatory Procedures for Competency Evaluation

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

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *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:
- *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 Contact Information

- CMS/CLIA web site:

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



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