Today's Featured Speaker

Judy Yost, M.A., M.T.(ASCP) received her B.S. Degree at Wilkes College and her M.A. in hospital management from Central Michigan University. She is an American Society for Clinical Pathology certified Medical Technologist. She was the administrative director of progressively larger clinical laboratories and other clinical services in health systems prior to her employment at the Centers for Medicare & Medicaid Services (CMS).

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 Waived Testing & Competency Assessment for NON-Waived Testing!

Judith Yost, M.A., M.T. (ASCP)
Director
Division of Laboratory Services

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Topics for Discussion

- CLIA Statistics
- Growth of Waived Tests & Laboratories
- CMS' Certificate of Waiver Project Data
- CMS' Next Steps for Waived Laboratories
- Primer on Competency Assessment
- Contact Information
- Questions???

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Current CLIA Statistics

Total Number of Laboratories	**229,815**
Total Non-Exempt	**222,899**
– ***Compliance***	19,387
– ***Accredited***	15,697
– ***Waived***	150,256
– ***Provider Performed Microscopy***	37,559
– ***Exempt***	**6,916**
• *NY*	3,469
• *WA*	3,447

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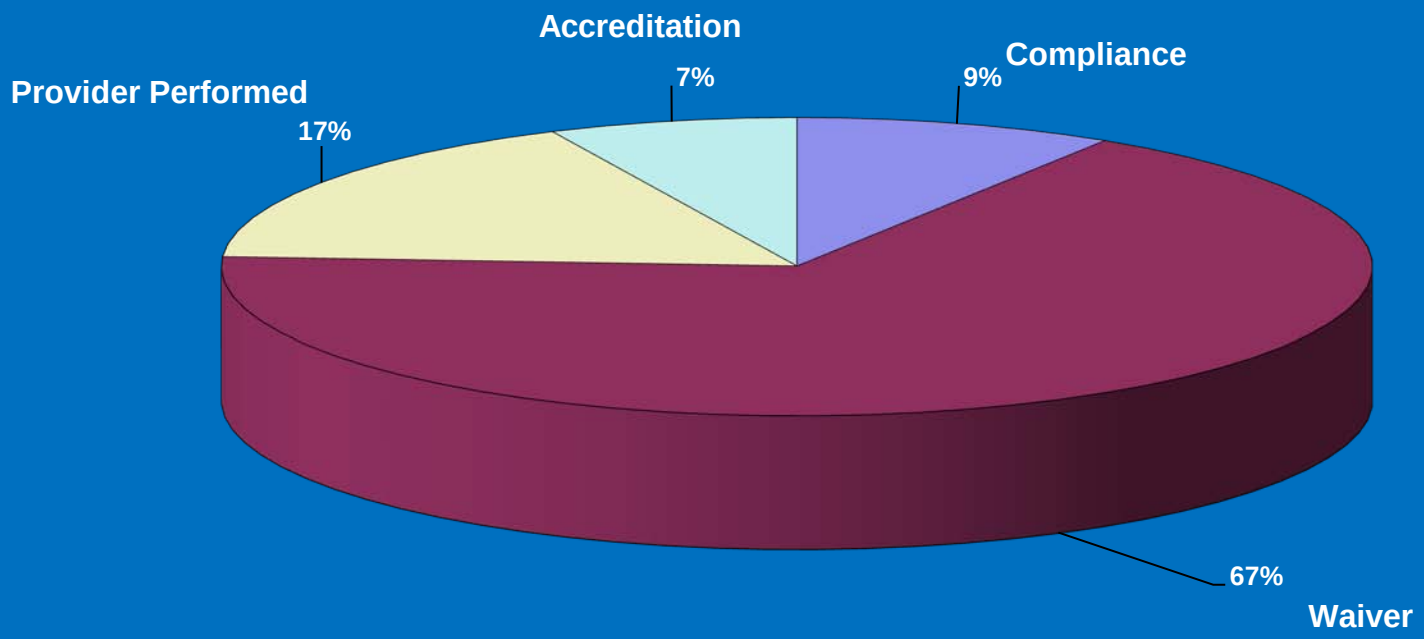
Current CLIA Statistics

CLIA Labs by Certificate Type
(Non-Exempt Only)



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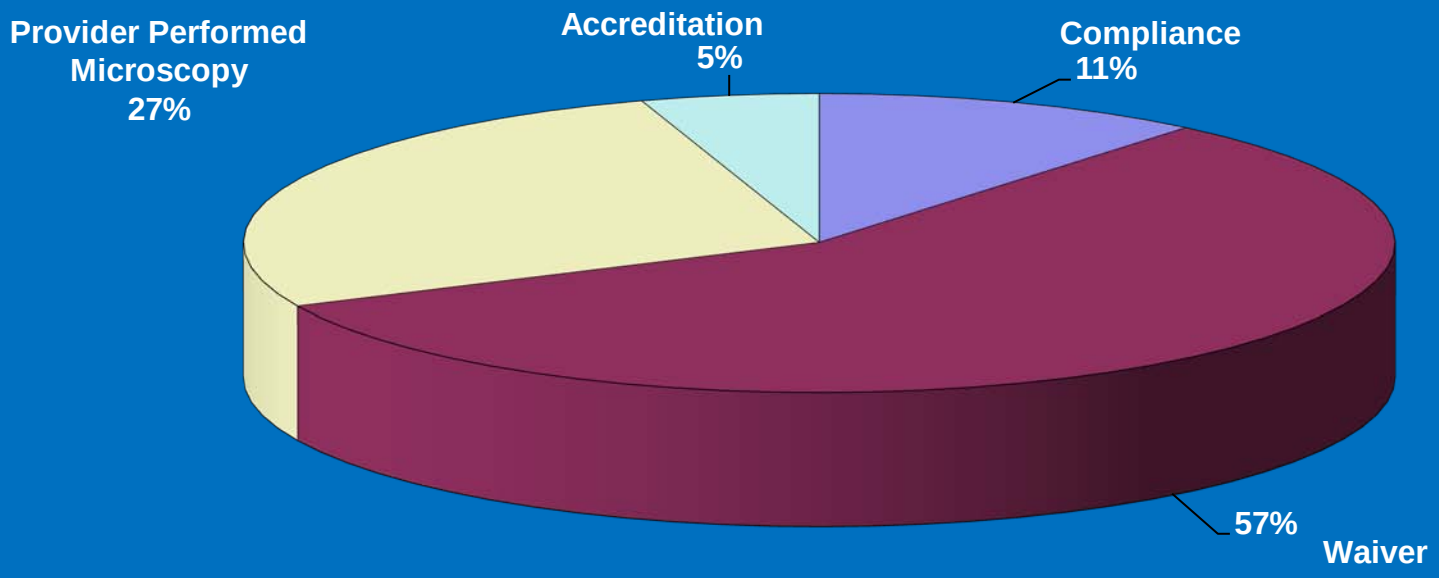
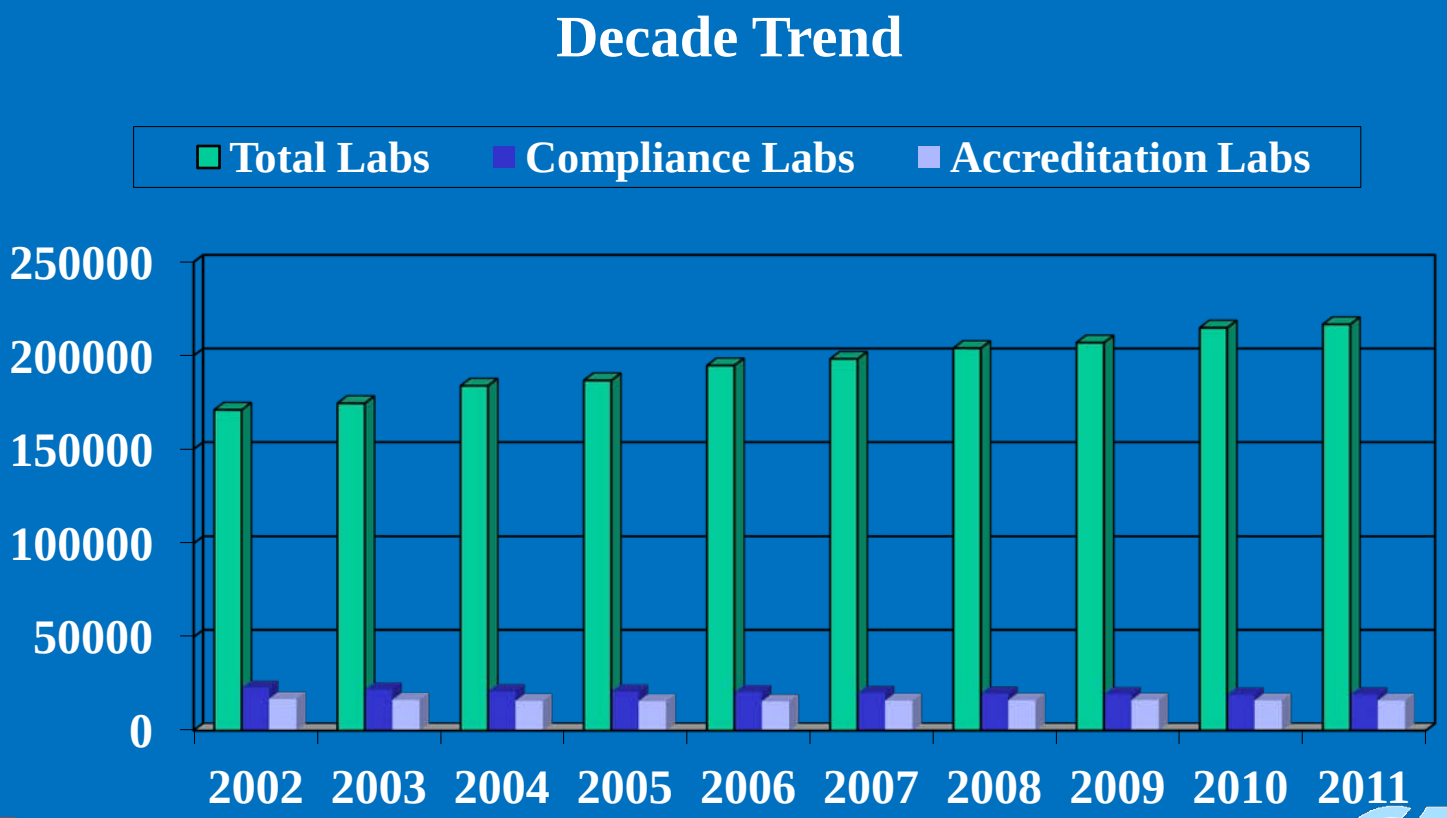
Current CLIA Statistics

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



Source: CMS CLIA database 01/2012

Current CLIA Statistics



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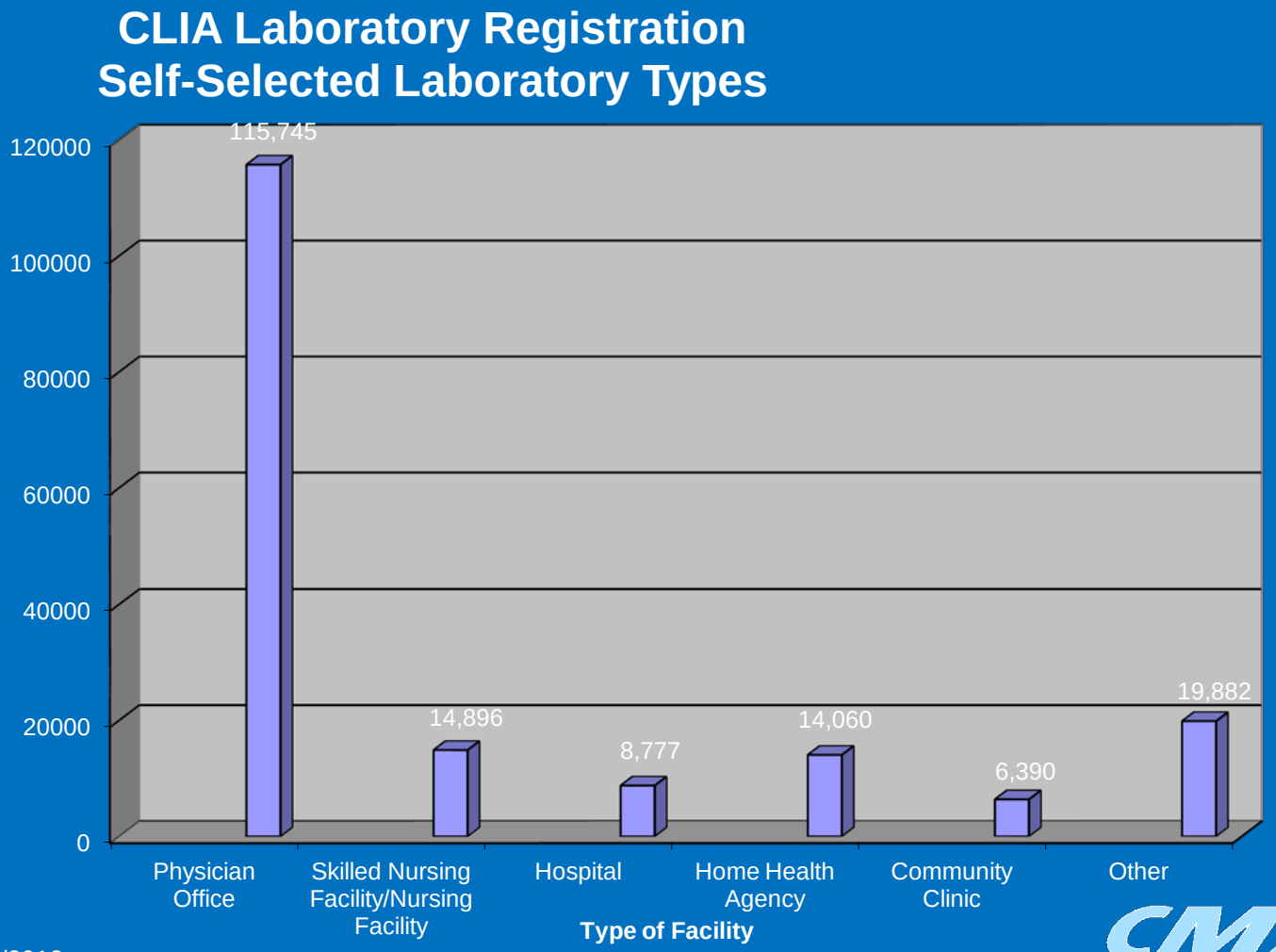
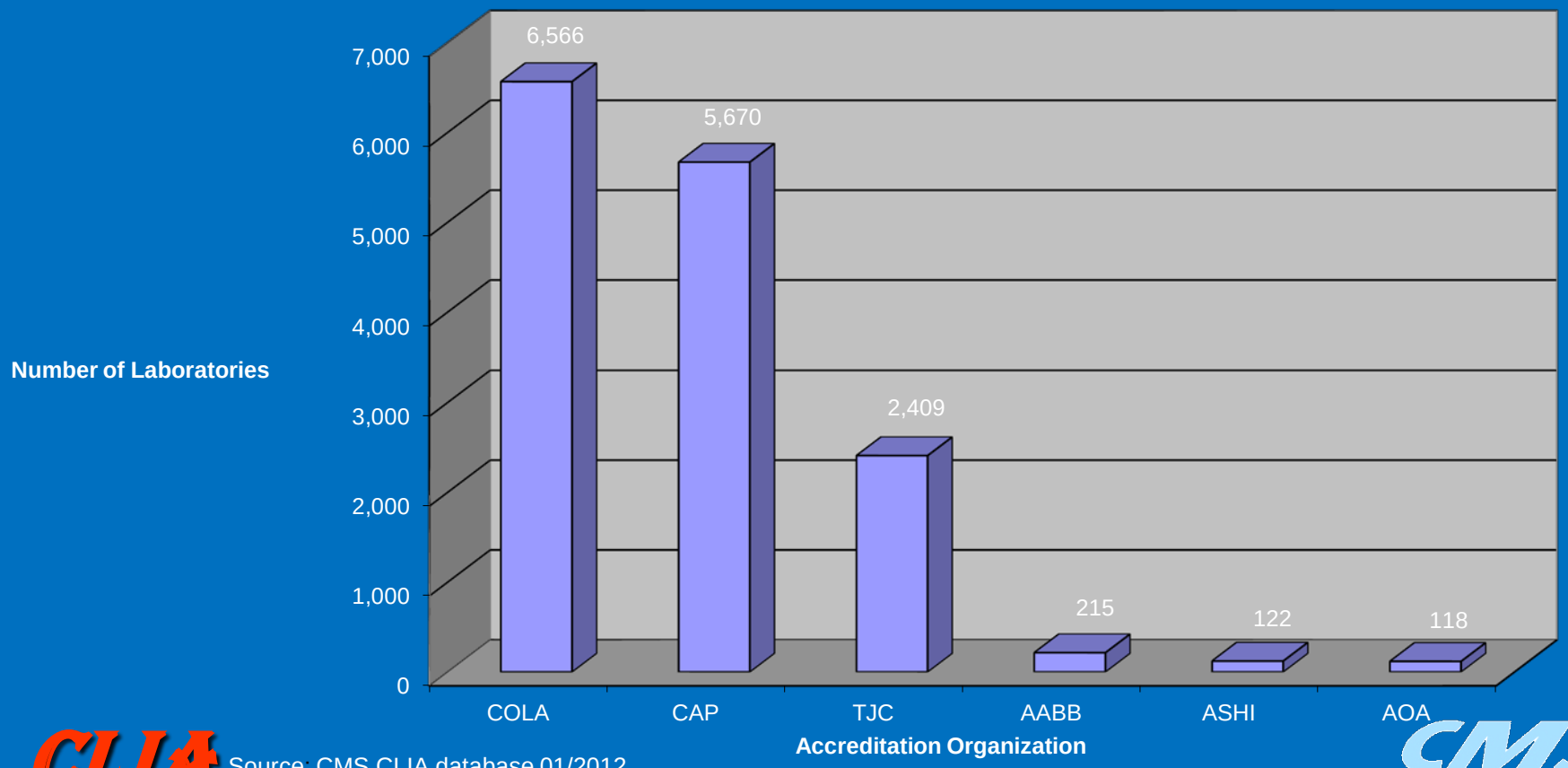
Current CLIA Statistics



Source: CMS CLIA database 01/2012

Current CLIA Statistics

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



Source: CMS CLIA database 01/2012

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".

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Certificate of Waiver (CW) Laboratory Requirements

The only standards for CW laboratories:

- F*ollow 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.

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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

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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 67% of the >230,000 laboratories enrolled. And it is growing…..

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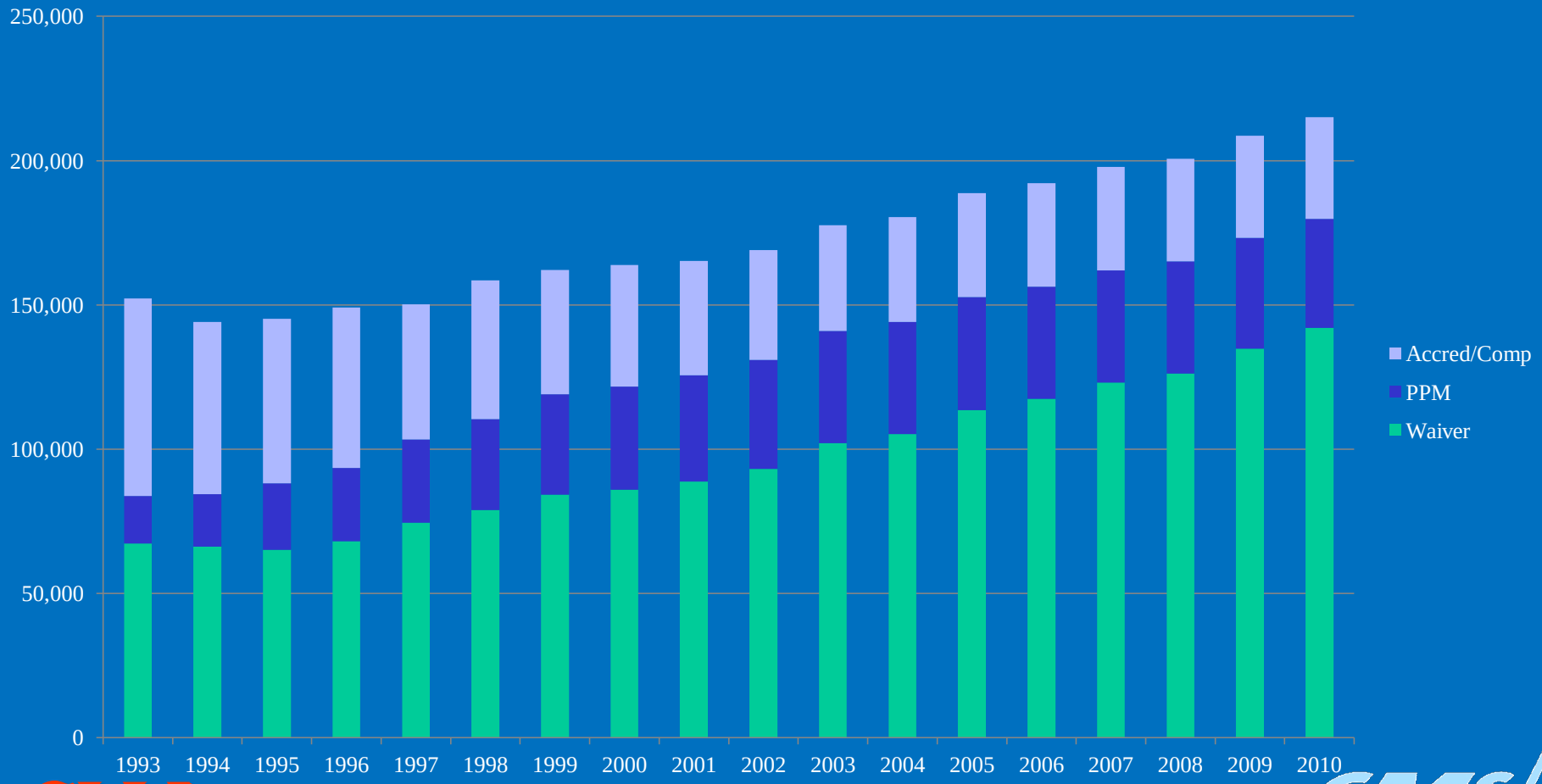
Growth of Waived Tests & CW Laboratories



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Growth of Waived Tests & CW Laboratories

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

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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 for the lab
  - Decreases costs to the lab
    - No PT or personnel stds/little QC
    - No routine survey

    --Lab makes $$$

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Certificate of Waiver (CW) Project

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

- Began visits to100 CW & PPM labs in CO & OH; **50% had quality problems!**
- As a result, CMS expanded this pilot to 8 more States—
- And then nationally

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Certificate of Waiver (CW) Project

- 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. good lab practice info.

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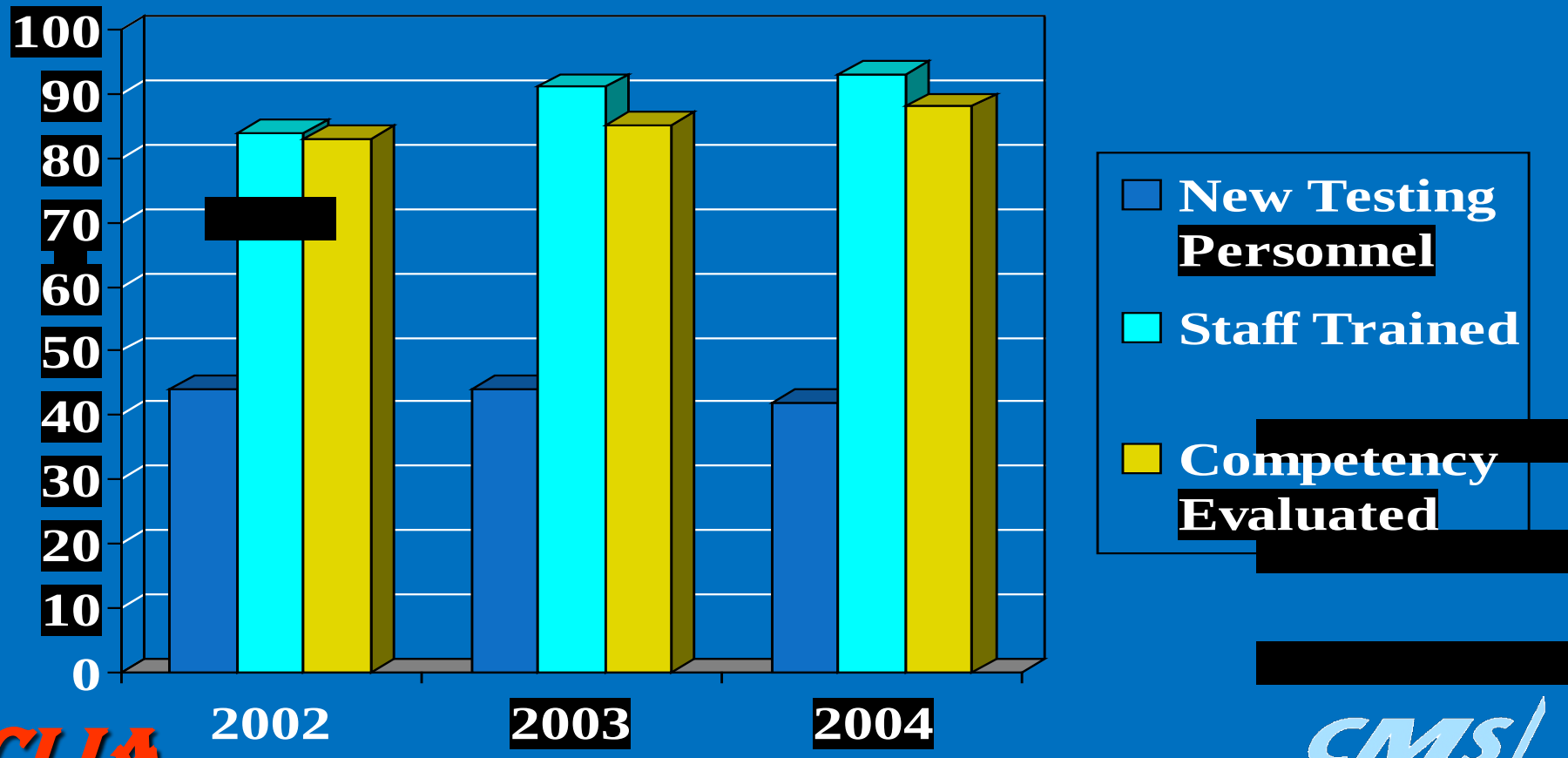
Certificate of Waiver (CW) Project—Personnel & Training



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CDC's Certificate of Waiver Findings-- CLIAC Report

- 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%)
- Similar to CMS, OIG. & NY State findings

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Certificate of Waiver (CW) Project—2006 & Ongoing

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.

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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!

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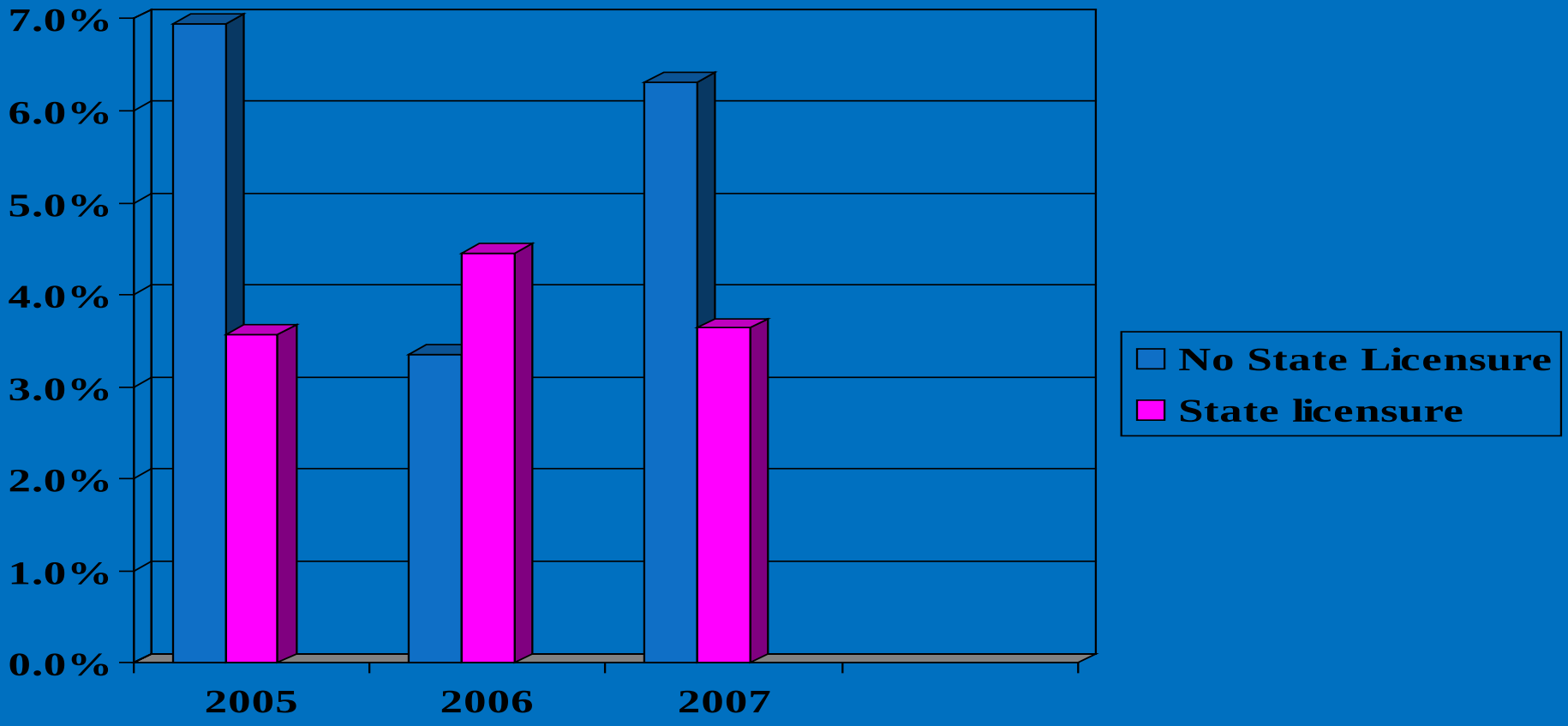
Certificate of Waiver (CW) Project -Labs Performing Non-Waived Tests



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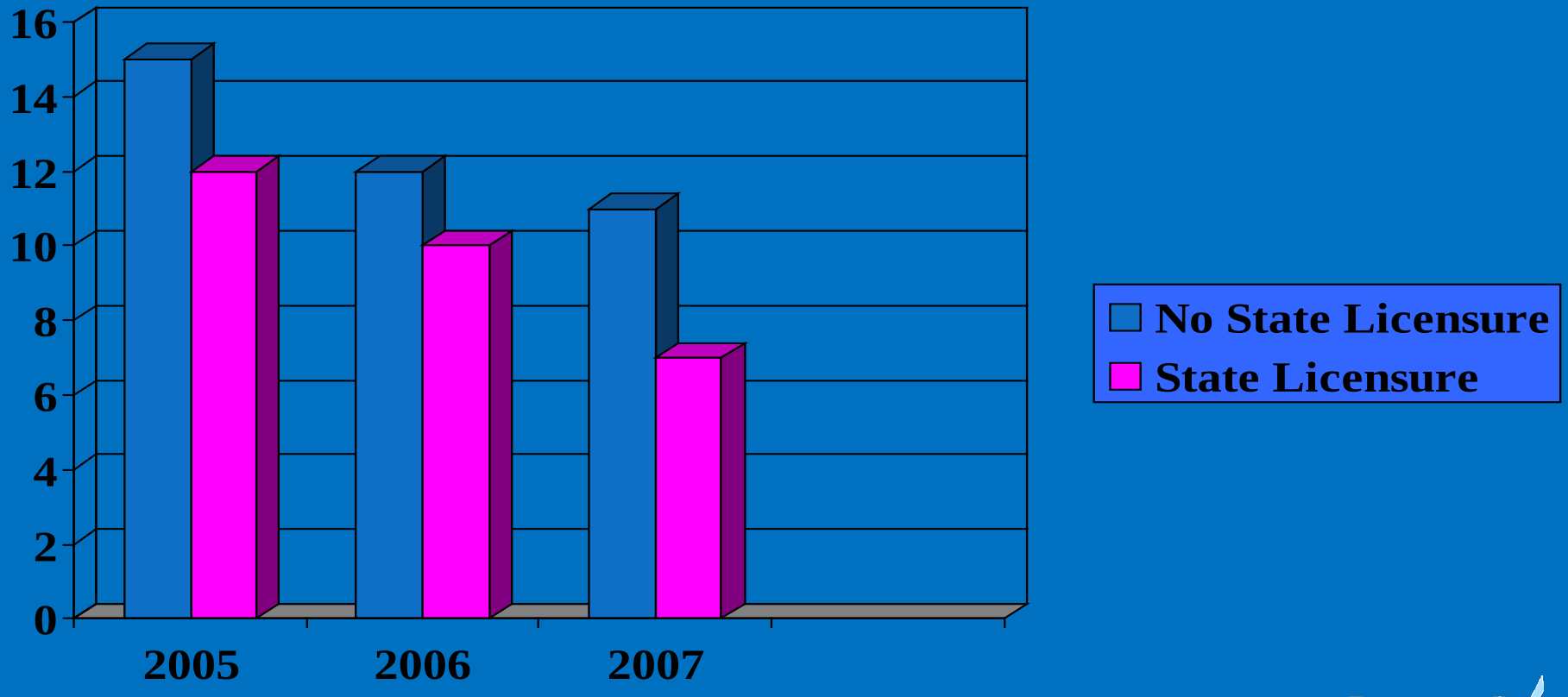
Certificate of Waiver (CW) Project-Labs w/o the Manufacturer's Instructions



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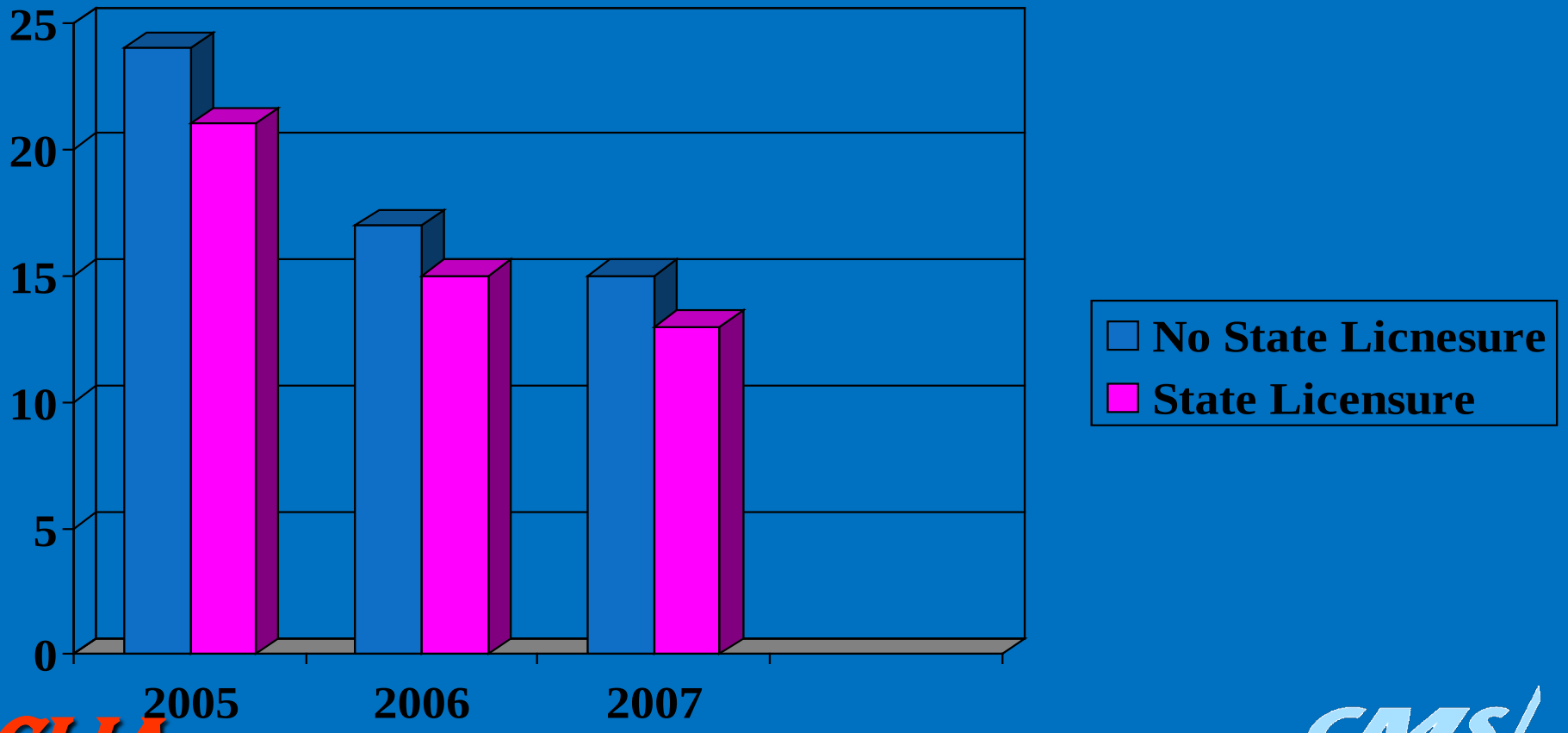
Certificate of Waiver (CW) Project- Labs Not Performing QC Initial Visit



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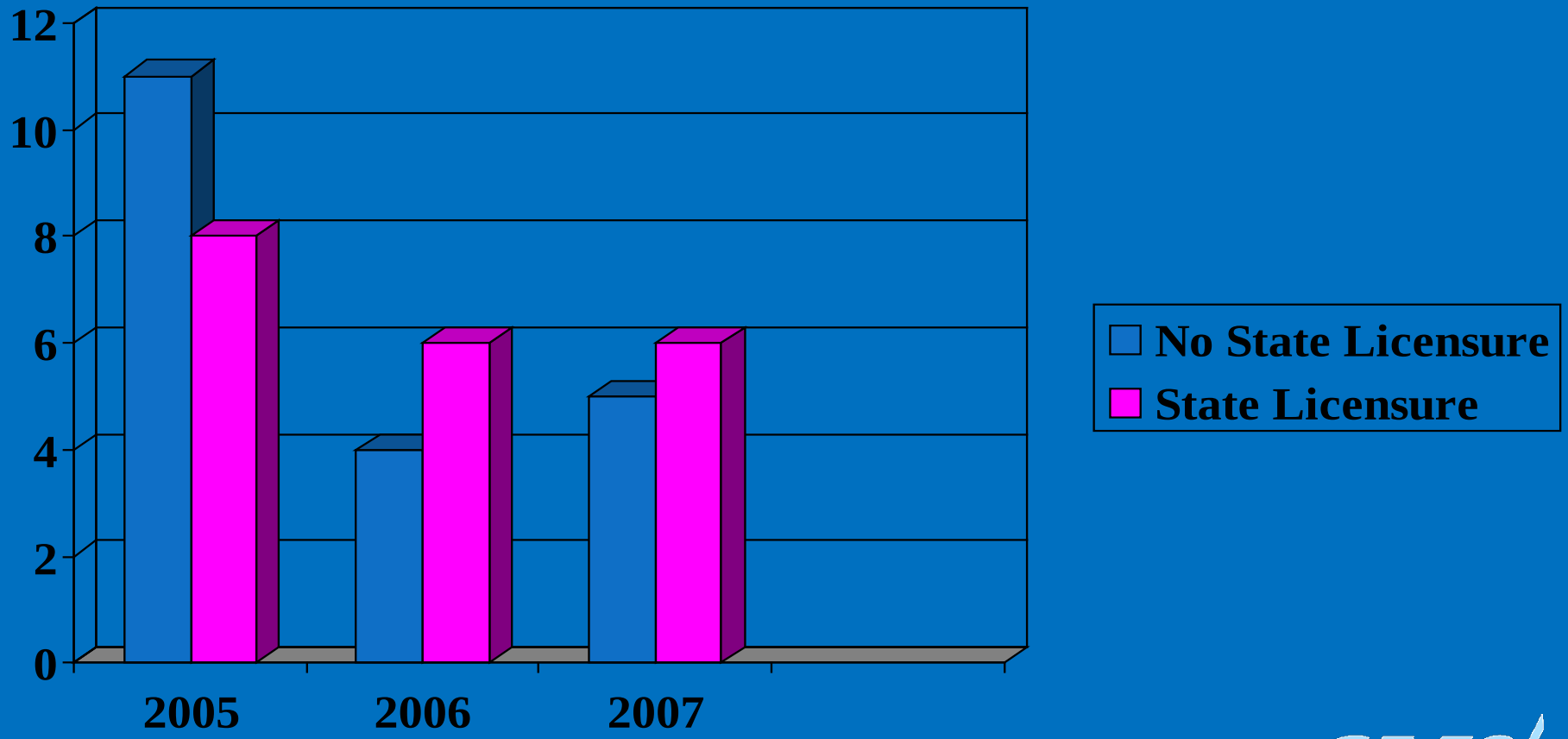
Certificate of Waiver (CW) Project-Labs Not Performing QC Follow Up Visit



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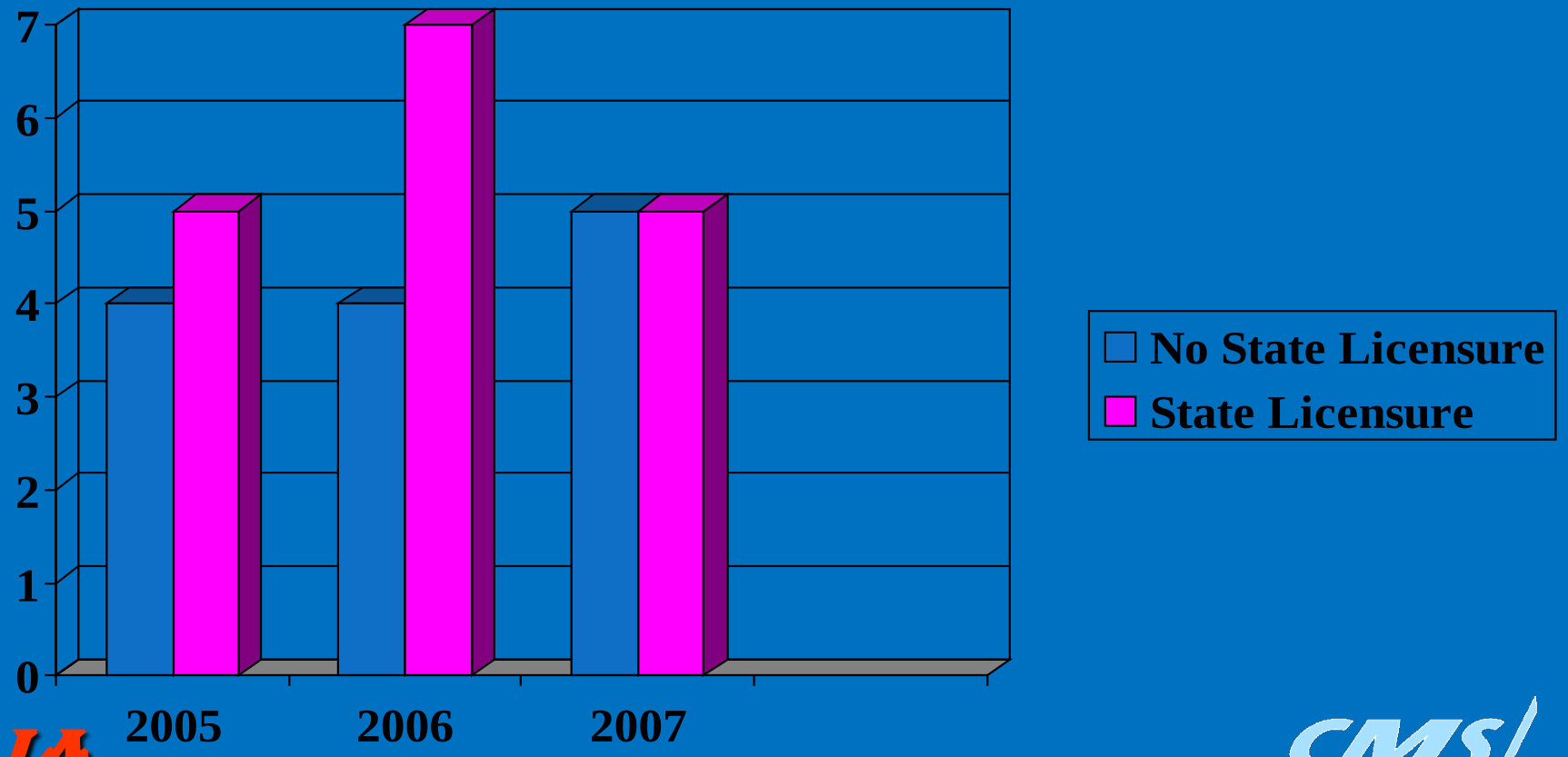
Certificate of Waiver (CW) Project-Labs Participate in Voluntary PT



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

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

*package insert

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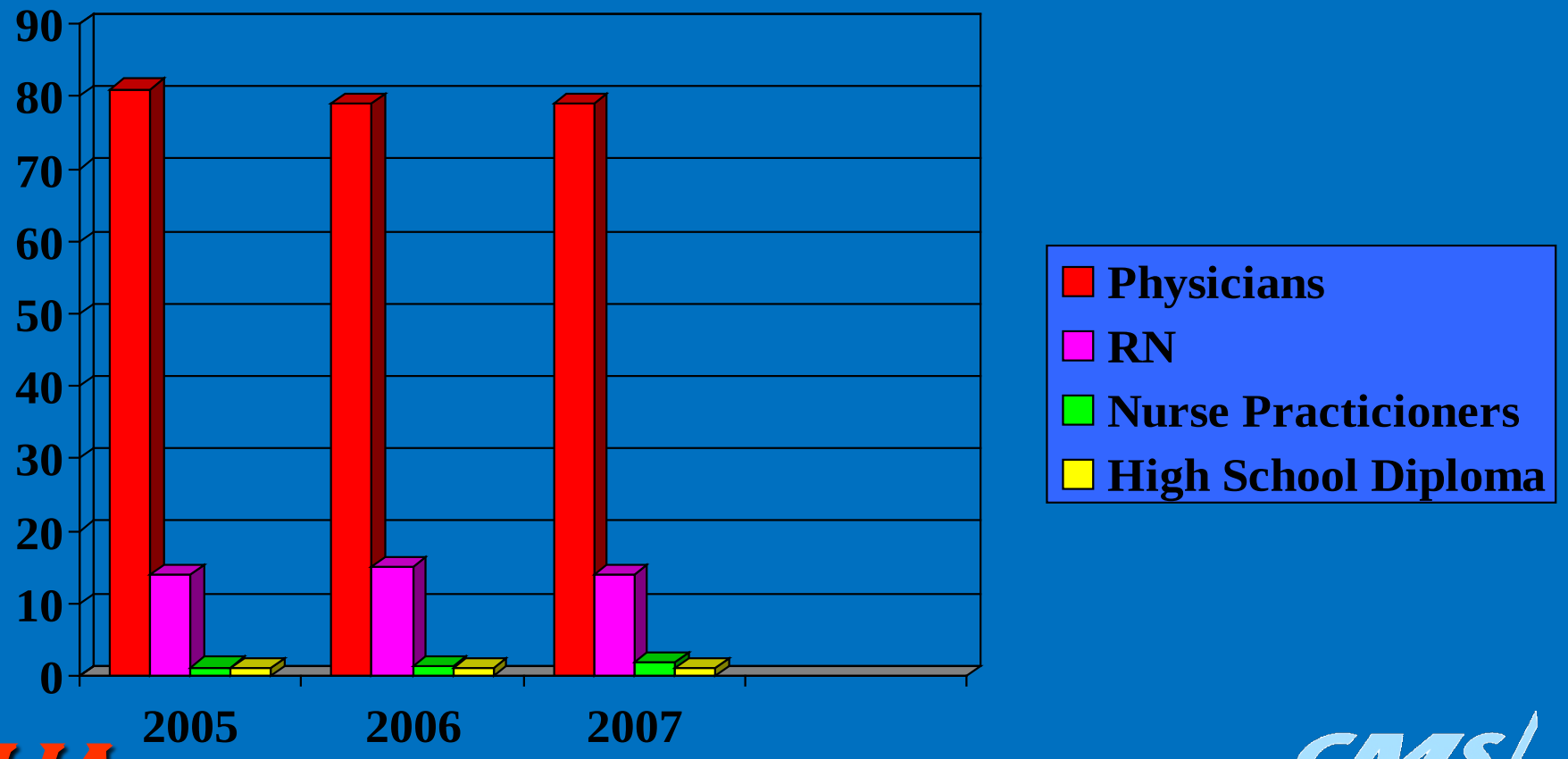
Certificate of Waiver (CW) Project- Lab Directors



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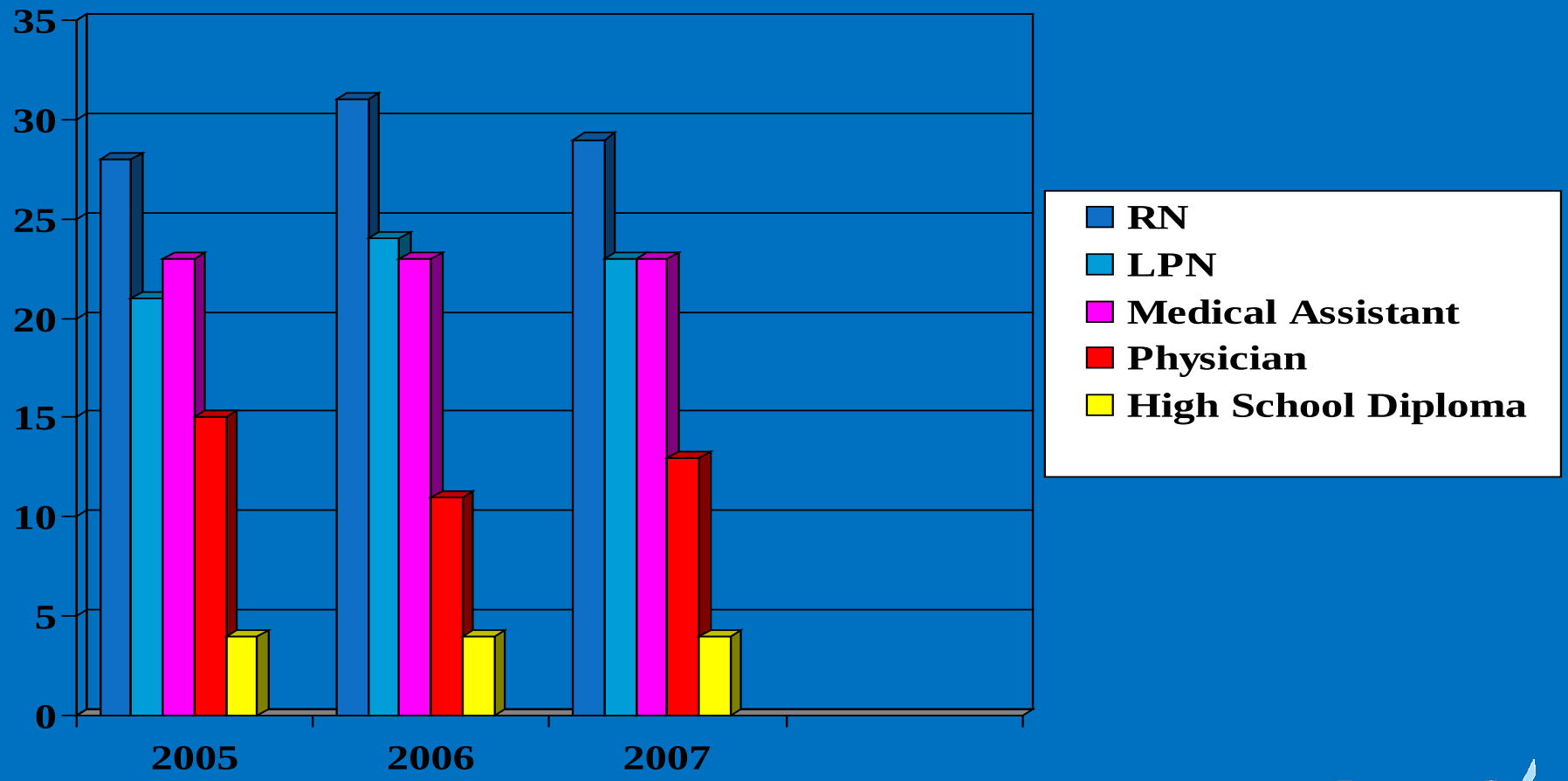
Certificate of Waiver (CW) Project- Testing Personnel



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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.

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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.

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Next Steps for Waived Testing…..

Short term

- Continue CW project indefinitely
- Provide edu. materials; 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
- Establish a measure of impact of pre-visit education

Long term-Change the CLIA law to improve oversight

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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

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Questions??

THANK YOU!!

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The Why's & Wherefore's of CLIA Competency Evaluation For Non-Waived Testing

Judith Yost M.A., M.T.(ASCP)
Director,
Division of Laboratory Services

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Topics for Discussion

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

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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.

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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.

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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.

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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.

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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.*

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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.*

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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.*

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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.*

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Regulatory Procedures for Competency Evaluation

1. Competency for all tests performed must include:

- *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.*

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Regulatory Procedures for Competency Evaluation

2. Competency for all tests performed must include:

- *Monitoring the recording & reporting of test results*

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Regulatory Procedures for Competency Evaluation

3. Competency for all tests performed must include:

- *Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records*

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Regulatory Procedures for Competency Evaluation

4. Competency for all tests performed must include:

- *Direct observation of performance of instrument maintenance & function checks*

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Regulatory Procedures for Competency Evaluation

5. 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*

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Regulatory Procedures for Competency Evaluation

6. Competency for all tests performed must include:

- *Assessment of problem solving skills*

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Competency Assessment Guidance

- Operator training prior to testing is critical & required; see TP responsibilities in regulations.
- Competency assessments must demonstrate testing personnel (TP) are performing testing accurately.
- Competency assessments must be documented.
- Can combine elements; do over time.

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Competency Assessment Guidance

- Individual conducting competency assessments must be qualified (TS/GS or TC).
- Use existing Quality System & work/procedures
- 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.

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Competency Assessment Guidance

- 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.

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Competency Assessment Guidance

- 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.

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Competency Assessment Guidance

- 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.

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CMS/CLIAContact Information

- **CMS/CLIA web site:**

www.cms.hhs.gov/clia/

Includes App, Regulations, Guidelines, Brochures

- **CMS/CLIA Central Office:**

410-786-3531

- **Judy Yost's Email:**

judith.yost@cms.hhs.gov

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09302009 SUMMARY PERSONNEL QUALIFICATIONS – MODERATE COMPLEXITY- PPM PROCEDURES

EDUCATION	TRAINING/EXPERIENCE	BOARD CERTIFIED/ELIGIBLE	REGULATION
LABORATORY DIRECTOR			
State Licensed Lab Director (N/A in TX)			493.1357 (a)
State Licensed Physician **MD, DO, DPM**			493.1357 (b)(1)
State Licensed Midlevel Practitioner **Nurse midwife** **Nurse practitioner** **Physician Assistant**			493.1357 (b)(2)
State Licensed Dentist **DDM, DDS**			493.1357 (b)(3)
TESTING PERSONNEL			
State Licensed Physician **MD, DO, DPM**			493.1363 (b)(1)
State Licensed Midlevel Practitioner **Nurse midwife** **Nurse practitioner** **Physician Assistant**			493.1363 (b)(2)
State Licensed Dentist **DDM, DDS**			493.1363 (b)(3)

Summary Personnel Qualifications