CMS CLIA Update 2009
Part II

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CLIA Update

Topics for Discussion:

- Current CMS CLIA Statistics
- Cytology PT NPRM & Performance Data
- CMS Top Survey Deficiencies
- CLSI EP-23: Alternative QC for Laboratories
- Partners in Laboratory Oversight
- PT Regulation Update Plan
- Waived Test Oversight Concerns
- Electronic Health Records (EHR) & CLIA
- CMS Basic Surveyor Training
- Questions & Answers

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Current Statistics

- **Total Number of Laboratories: 209,499**
  - ***Compliance*** 19,261
  - ***Accredited*** 16,238
  - ***Waived*** 129,219
  - ***Provider Performed Microscopy*** 38,383

  - ***Exempt*** **6,398**
    - *NY* 3,133
    - *WA* 3,265

CMS data base 12/2008

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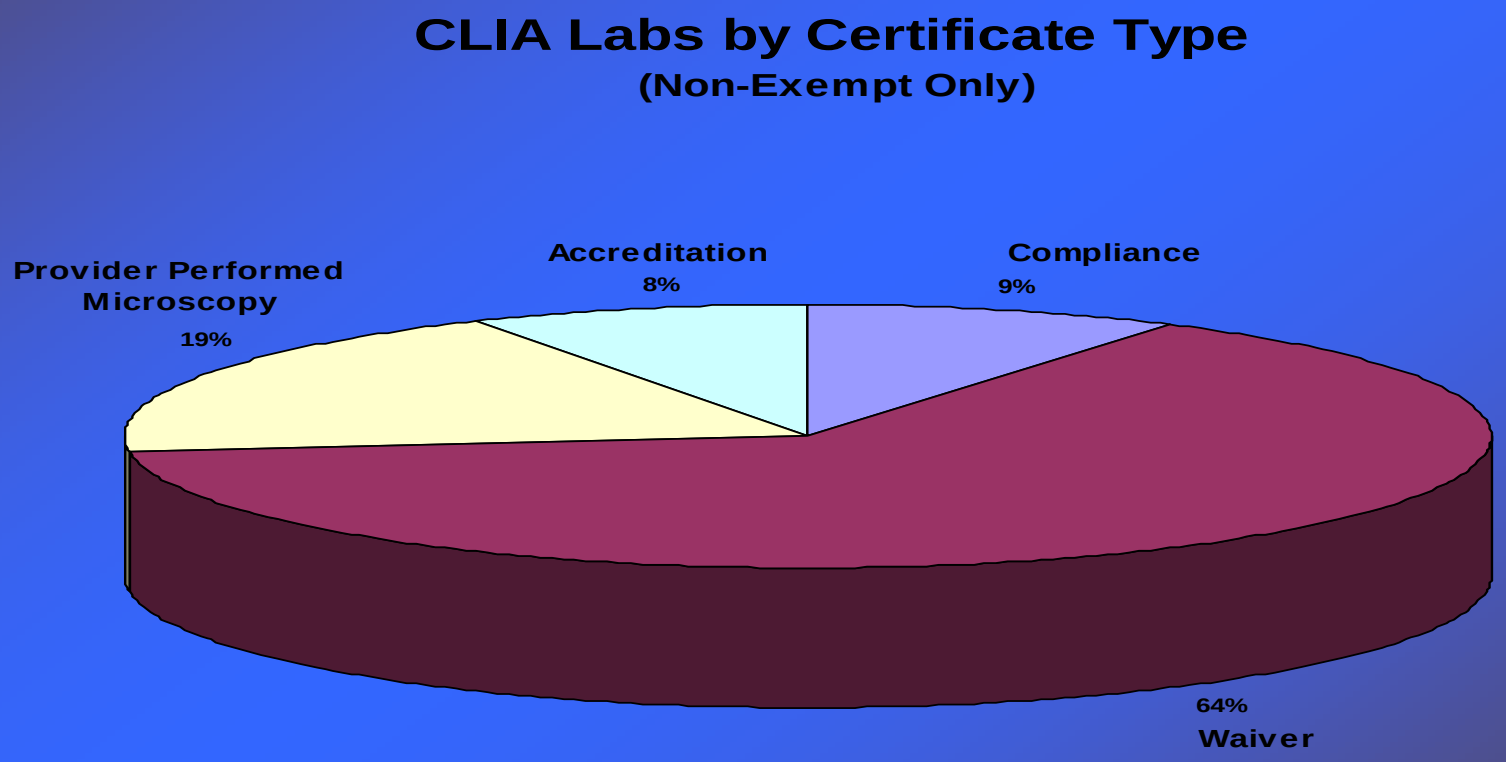
Current Statistics



Source: CMS CLIA database 1/22/2009

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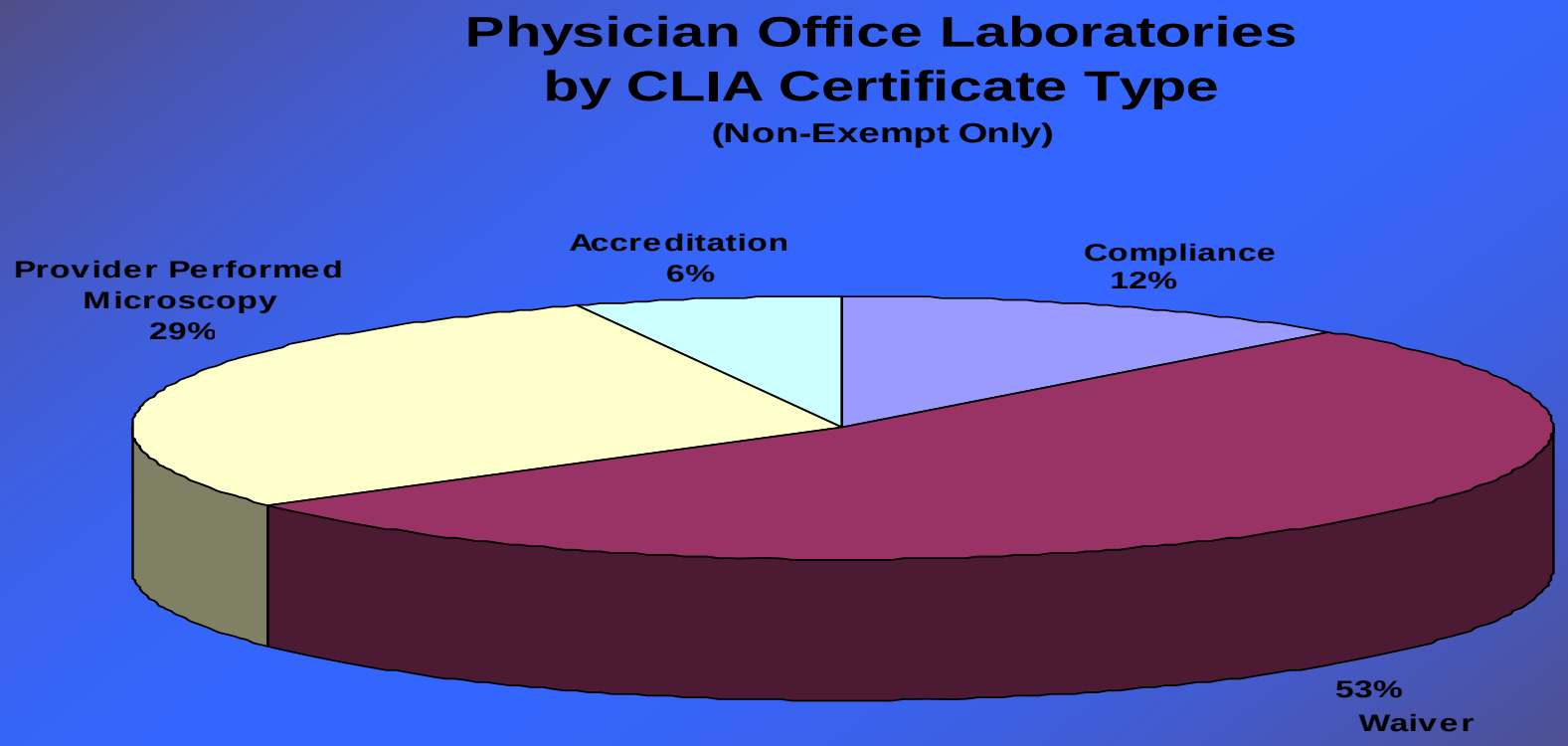
Current Statistics



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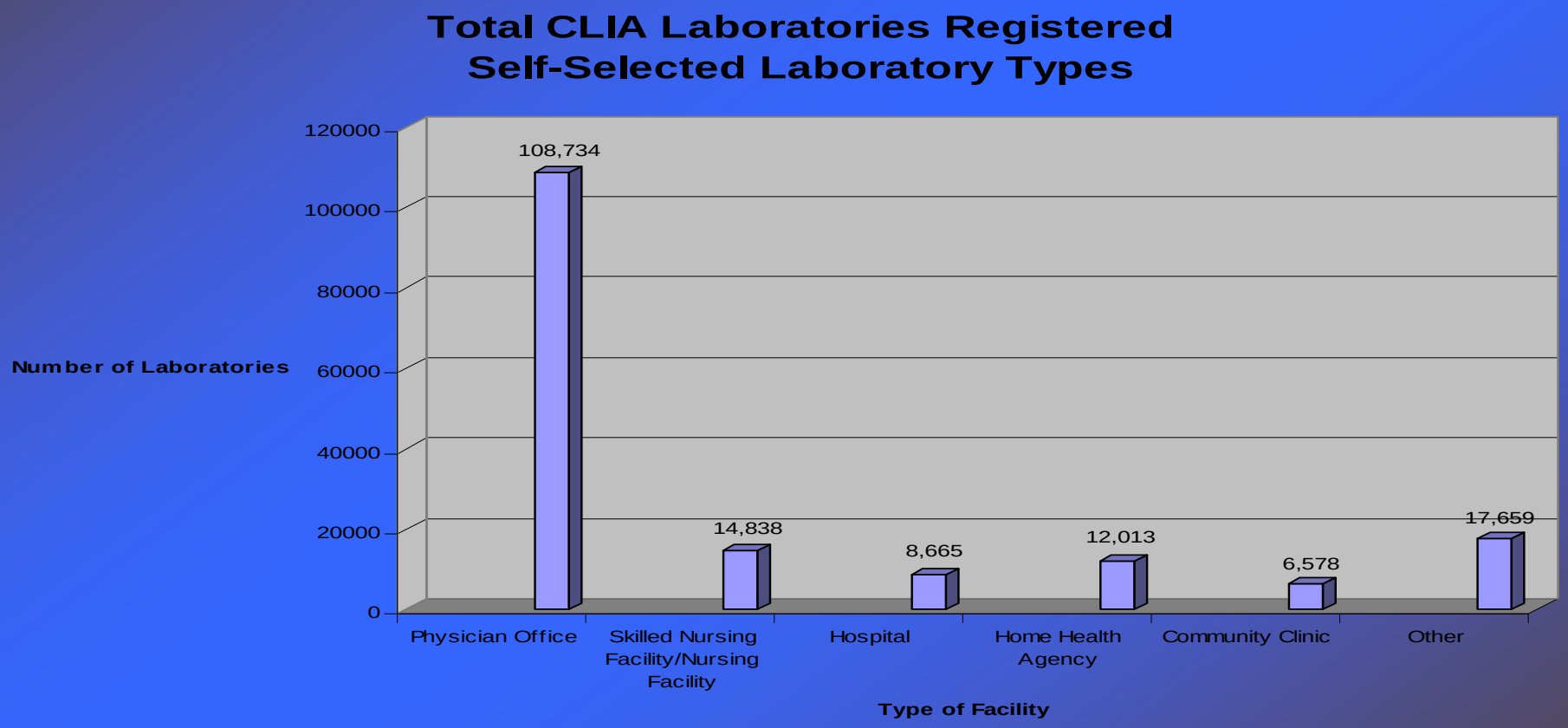
Current Statistics



Source: CMS CLIA database 1/22/2009

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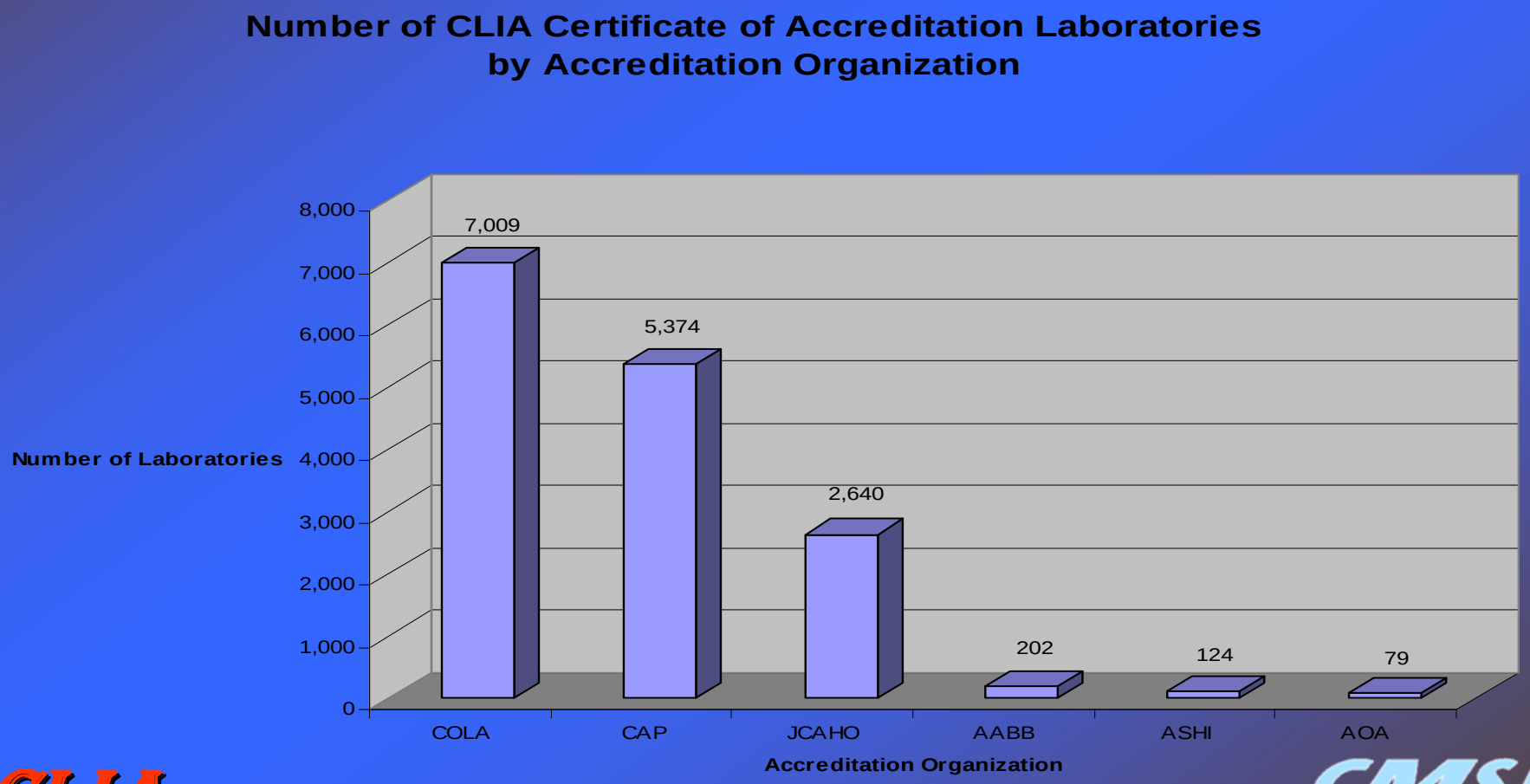
Current Statistics



Source: CMS CLIA database 1/22/2009

Cytology PT

Cytology PT Proposed Regulation:

- Proposed rule considered 17 CLIAC recommendations.
- Pub. by CMS Jan. ‘09; comments closed Mar. ‘09.
- Joint CDC/CMS collaboration.
- Contains questions; solicits comments & suggestions.
- 690 comments received; both pos. & neg.
- Comments analyzed; next steps in discussion.
- Stay tuned for further developments!
- www.cms.hhs.gov/CLIA/downloads/CMS-2252-P.pdf

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Cytology PT

Current Regulation	Proposed Regulation
10 Slides/Test	20 Slides/Test
2 Hours/Test	4 Hours/Test
Annual Test	Biennial Test
Test Composition:	***Test Composition***:
1 Unsatisfactory	1 Unsatisfactory
1 Normal	1 Normal
1 Low Grade (LSIL)	1 LSIL
1 High Grade (HSIL)/Cancer (CA)	2 HSIL or CA

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Cytology PT

Current Regulation	Proposed Regulation
1 Missed HSIL/CA=Auto. Fail	2 Missed HSIL or CA = Auto. Fail
Glass Slide Test Only	Glass Slide/New Tech.
Slide Field Valid. Not Req'd.	Slide Field Valid. Req'd.
Appeal Process Not Req'd.	Appeal Process Req'd.
Diff. Scoring Grids Path.& CT	Diff. Scoring Grids Path. & CT

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Cytology PT

Comparison of PT Performance, 1st Test

2005	91% passed
2006	95% passed
2007	96% passed
2008	97% passed

Value of cytology PT:

-Identifies those who shouldn't screen.

-Demonstrates high quality of those who do.

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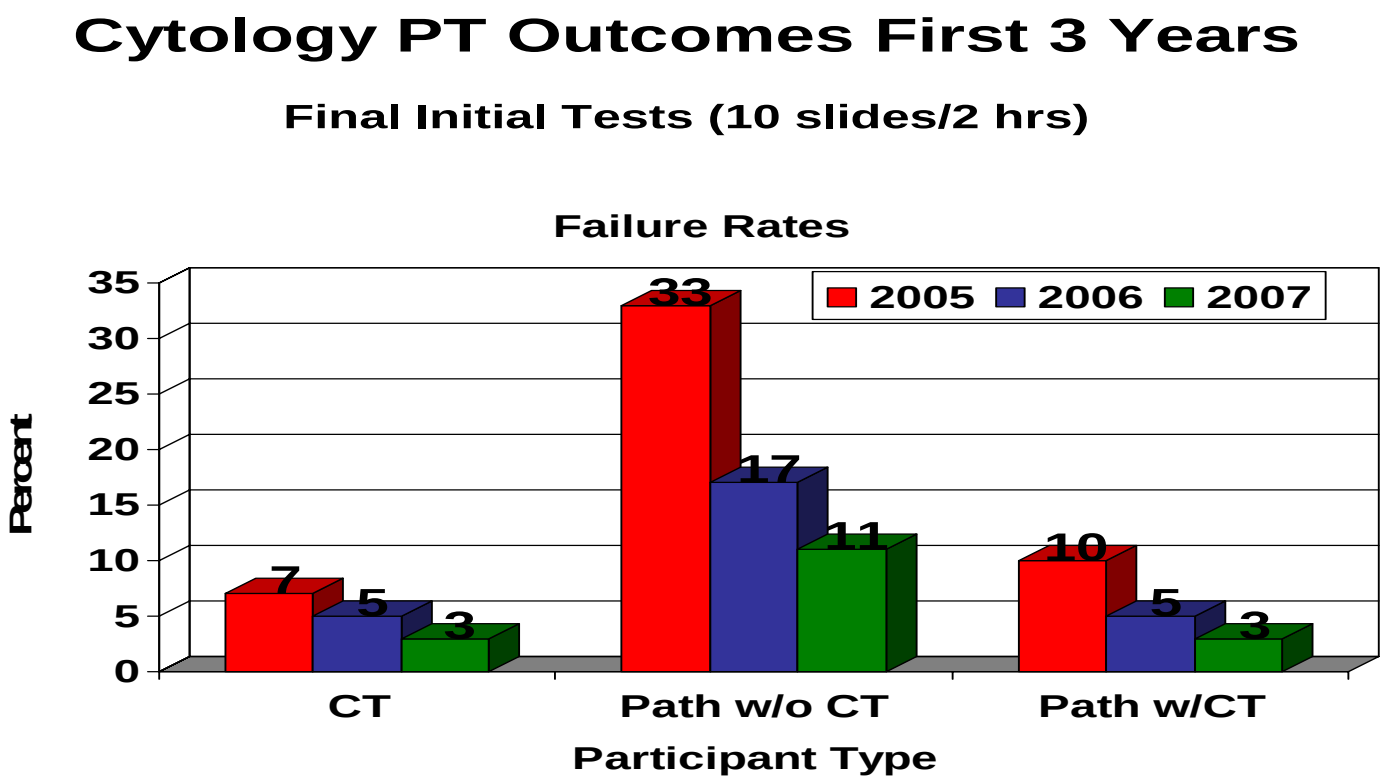
Cytology PT


Cytology PT Outcomes First 3 Years
Final Initial Tests (10 slides/2 hrs)
Failure Rates
2005
2006
2007
Percent
35
30
25
20
15
10
5
0
7
5
3
33
17
11
10
5
3
CT
Path w/o CT
Path w/CT
Participant Type

CMS' Top 10 Condition Level Deficiencies

Citation **% Labs Cited**

-Mod. complexity LD qualif./respons.----------0.8%
-Successful PT participation----------0.6%
-PT enrollment----------—0.4%
-Analytic Systems (QC)----------0.3%
-Mod. complexity TP----------0.3%

Source: CMS CLIA Database 6/09

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CMS' Top 10 Condition Level Deficiencies

Citation **% Labs Cited**

-Technical consultant qualif./respons-.----------0.2%
-High complexity director qualif./respons. ------0.2%
-Hematology----------0.1%
-Bacteriology----------0.07%
-Pre-analytic Systems----------0.06%

CMS CLIA Database 6/09

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CMS' Top 10 Overall Deficiencies

Citation **% Labs Cited**

- Policy for proper reagent storage--------—6.72%
- Verify accuracy non-PT'd tests---------—6.37%
- Analytic Systems' QA----------5.56%
- Follow mfgr's instructions----------5.55%
- Procedure manual----------4.77%

Source: CMS CLIA data base 12/08

Labs surveyed: 18,231

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CMS' Top 10 Deficiencies

Citation	% Labs Cited
• LD responsibility-QA plan	4.49%
• Gen lab systems QA	4.28%
• Use of expired reagents	4.26%
• Required elements for test reports	4.03%
• Mod. complexity LD qualif./respons.	3.88%

Source: CMS CLIA data base 12/08
Labs surveyed: 18,231

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Status Alternative QC Development

- ‘05 CLSI meeting sponsored by lab prof. orgs., gov’t., industry discussed **“QC for the Future”.**
  - *Labs need more info from manufacturers.*
  - *One-size-fits-all QC not good for diff. test systems/labs.*
- Two CLSI Evaluation protocol QC docs in development.
  - EP-23: Alternative, custom QC for labs (*Jim Nichols*)
  - EP-22: ISO risk mgt. for mfgrs. (*Greg Cooper*).
- CMS Interpretive Guidelines will be revised accordingly.
  - CMS hasn’t determined if EQC will remain.

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Status Alternative QC Development

- CMS is working w/ CLSI to develop 2 guidance "Evaluation Protocol" documents.
  - Includes reps from labs, industry & gov't.
  - Utilizes consensus process.
  - Exciting, groundbreaking efforts nearly complete!
  - AOs interested, so all labs have standard policies.
- CLSI Subcommittee vote Fall '08; work ongoing.
- Labs should begin to learn & plan now!
- Will be phased in by CMS.

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PT Regulation Update

- Plan w/ milestones & timeline developed
  - Includes standards for: target values, grading criteria, PT providers, labs, PT referral, alternative assessment
  - Requires a proposed rule w/ comment & final
  - No firm ETA
- List of related issues compiled/discussed
- CDC/CMS met a full day in ’08 to discuss
- CLIAC recommendation to proceed rec’d. ‘08

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PT Regulation Update

- Use CLIAC WG w/ SMEs from affected parties
- Ongoing T/C occur w/ CDC & CMS
- Medicare data reviewed for test frequency
- PT providers' meeting convened Nov.'08
- Evaluating mechanisms for analyte selection.
  - Including genetic tests
- Considering alt. vehicles to publish analyte lists
- CDC planning CLIAC WG meeting early 2010.

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CMS Waived Test Concerns

- **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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Waived 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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Since 1992……

- CLIA-waived tests have increased from 8 to about 100 tests.
  - **This represents 1000's of test systems!**
- The number of laboratories issued a CW has grown exponentially from 20% to 64% of the >209,000 laboratories enrolled.

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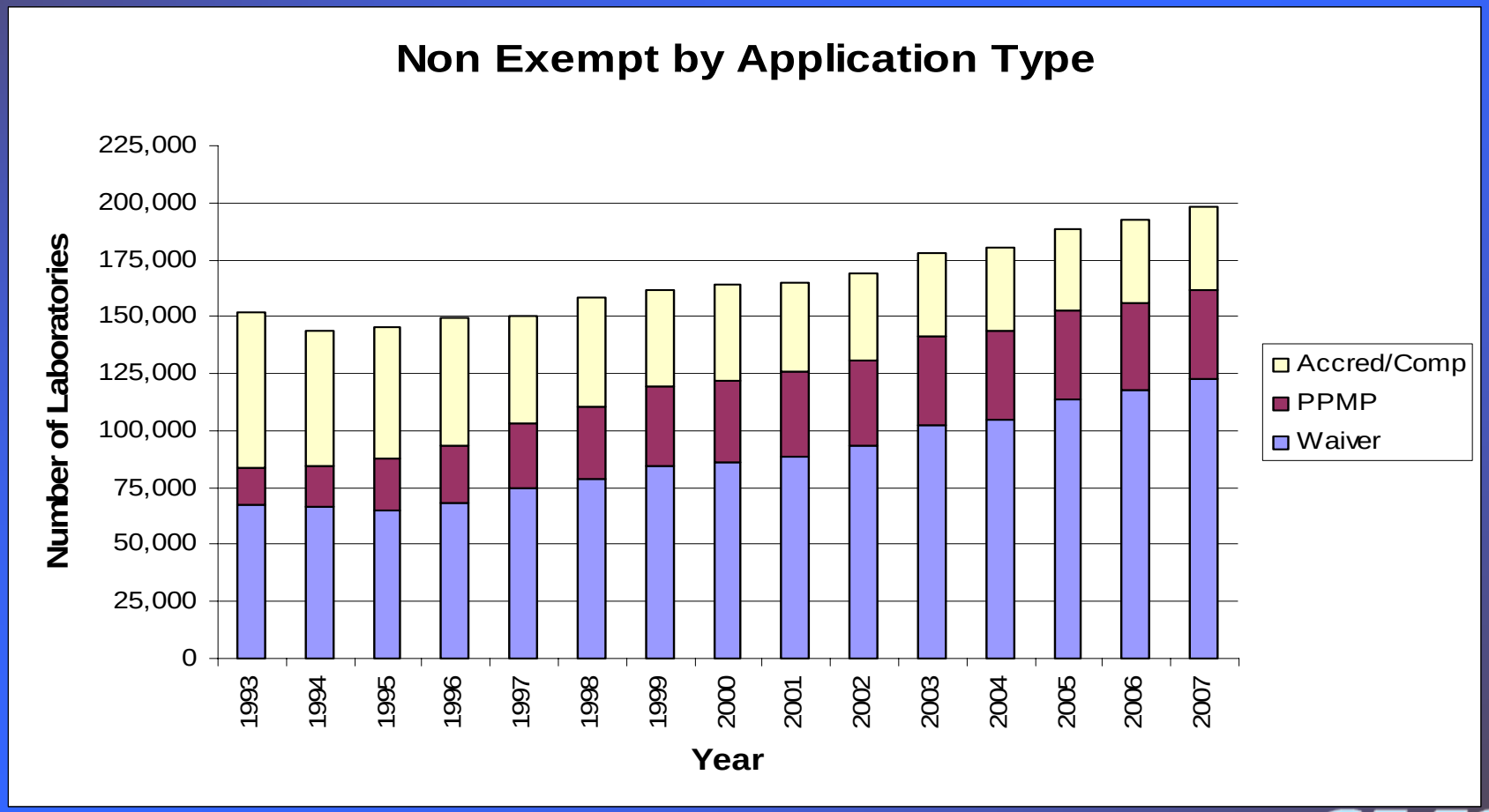
of Non Exempt Labs by Application Type



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CMS CERTIFICATE OF WAIVER (CW) PROJECT

- The only standard for CW laboratories is to *follow manufacturer's instructions* & register w/ CMS.
- As part of the CW project, each CW laboratory visited responds to questions about its waived testing practices.

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CMS CERTIFICATE OF WAIVER (CW) PROJECT DATA

1999 Pilot Project:

- CO & OH each visited 100 CW & PPMP laboratories; **50% had quality problems**!

- As a result of findings in CO & OH, CMS expanded the pilot to the 8 other States.

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CMS CERTIFICATE OF WAIVER (CW) PROJECT DATA

2000-2001 Expanded Pilot:

- Surveyors in MA, NY, PA, MS, NM, IA, AZ, ID visited 436 COW & PPMP laboratories; **32%** had quality problems.

Present

- CMS-CLIA initiated CW Project April 2002 to survey 2% of CW labs per year & it's ongoing.

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2004 CDC Findings Include…

- 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%)
- CDC & NY studies correspond to CMS’.

(Presentation CLIAC_Waived testing update_Sept 2004.)

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CMS CW Project Data
FY 2006

Initial visits

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

Follow-up visits

Of 414 labs revisited for not following manufacturer's instructions, 353 or ***85% improved upon revisit.***

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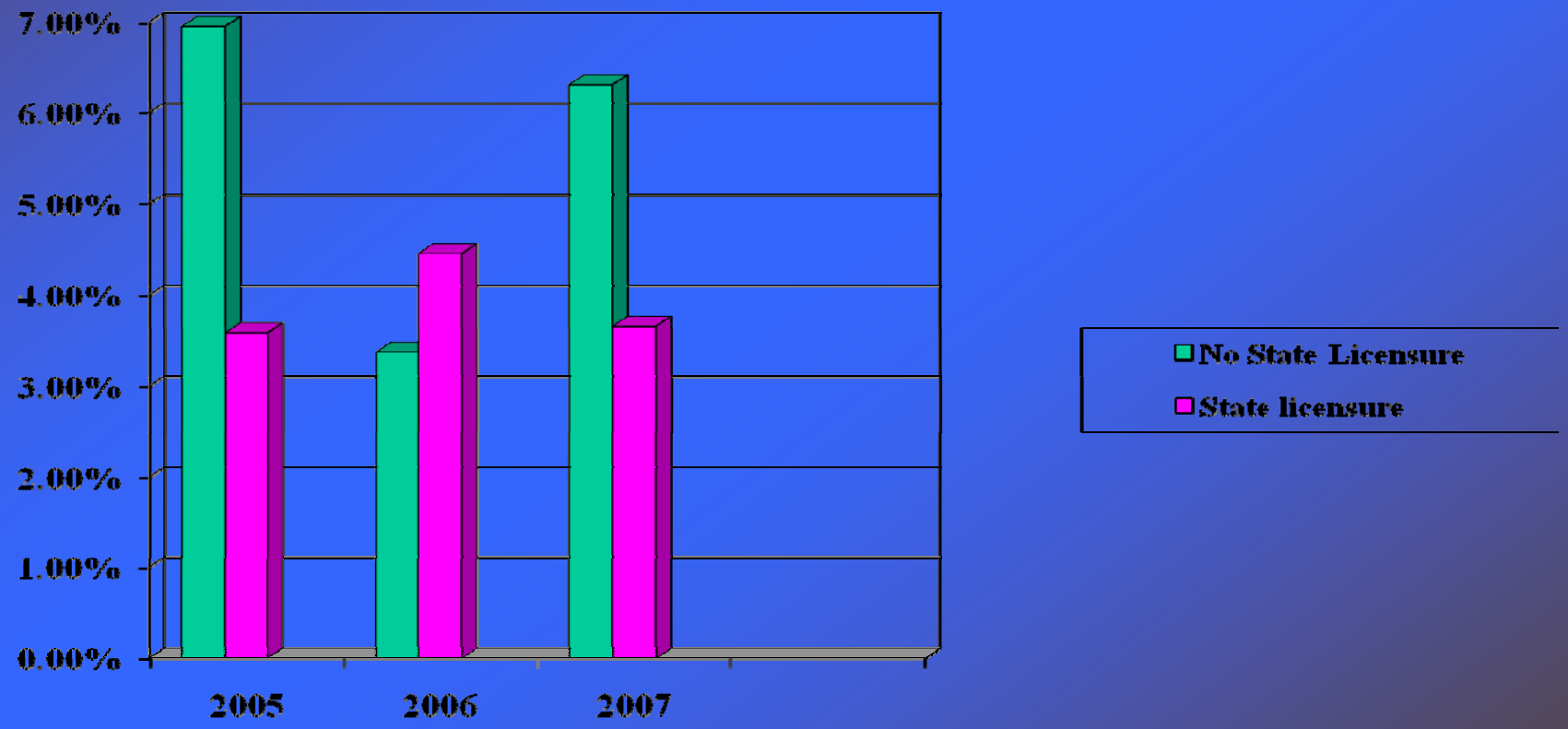
Percentage of CW Labs Performing Non-waived Tests



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CMS CW Project– IJ Risk of Harm

- FY 2005: 6 out of 1678 surveys or <1%
- FY 2006: 6 out of 1938 surveys or <0.5%
- FY 2007: 2 out of 1737 surveys or <0.20%

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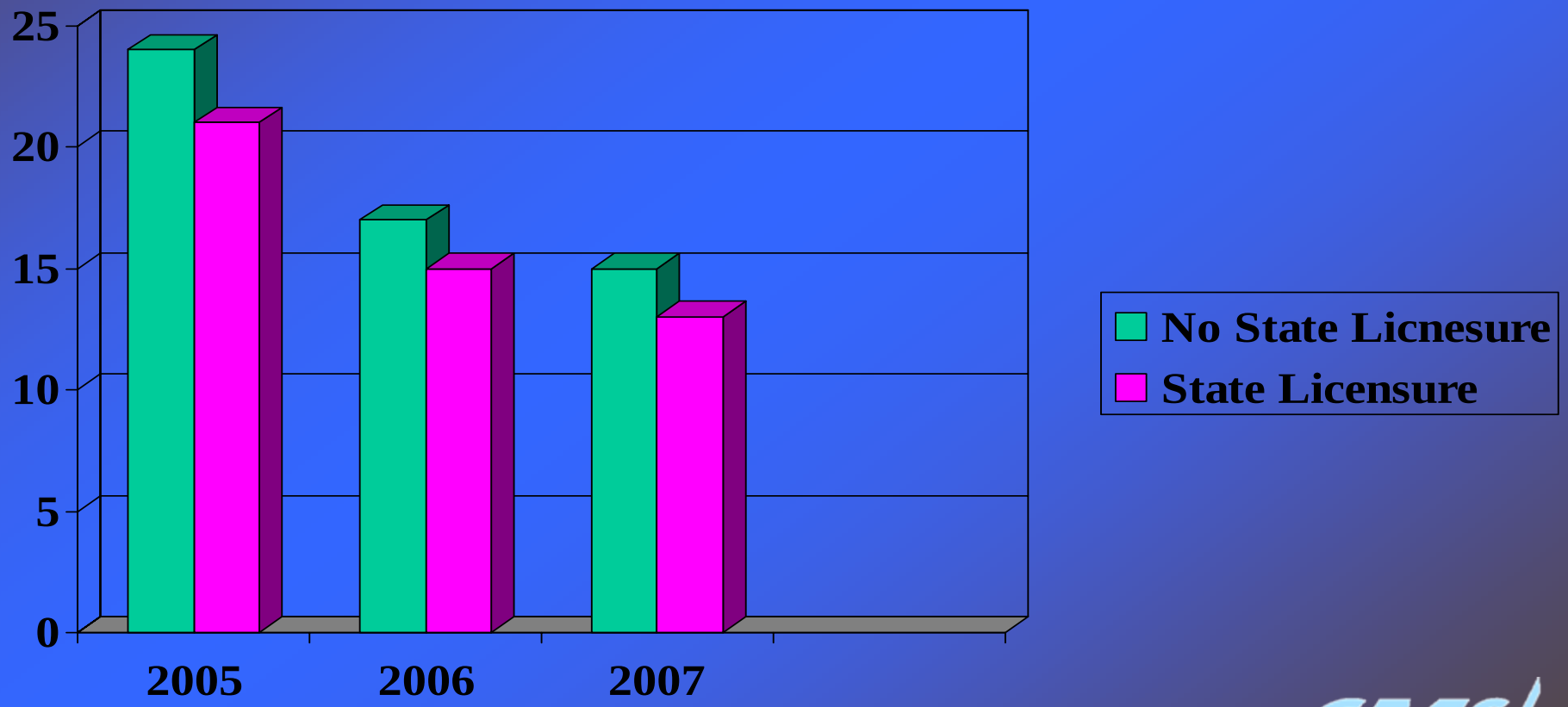
CW Labs that Were Not Performing Required QC on Initial Visit



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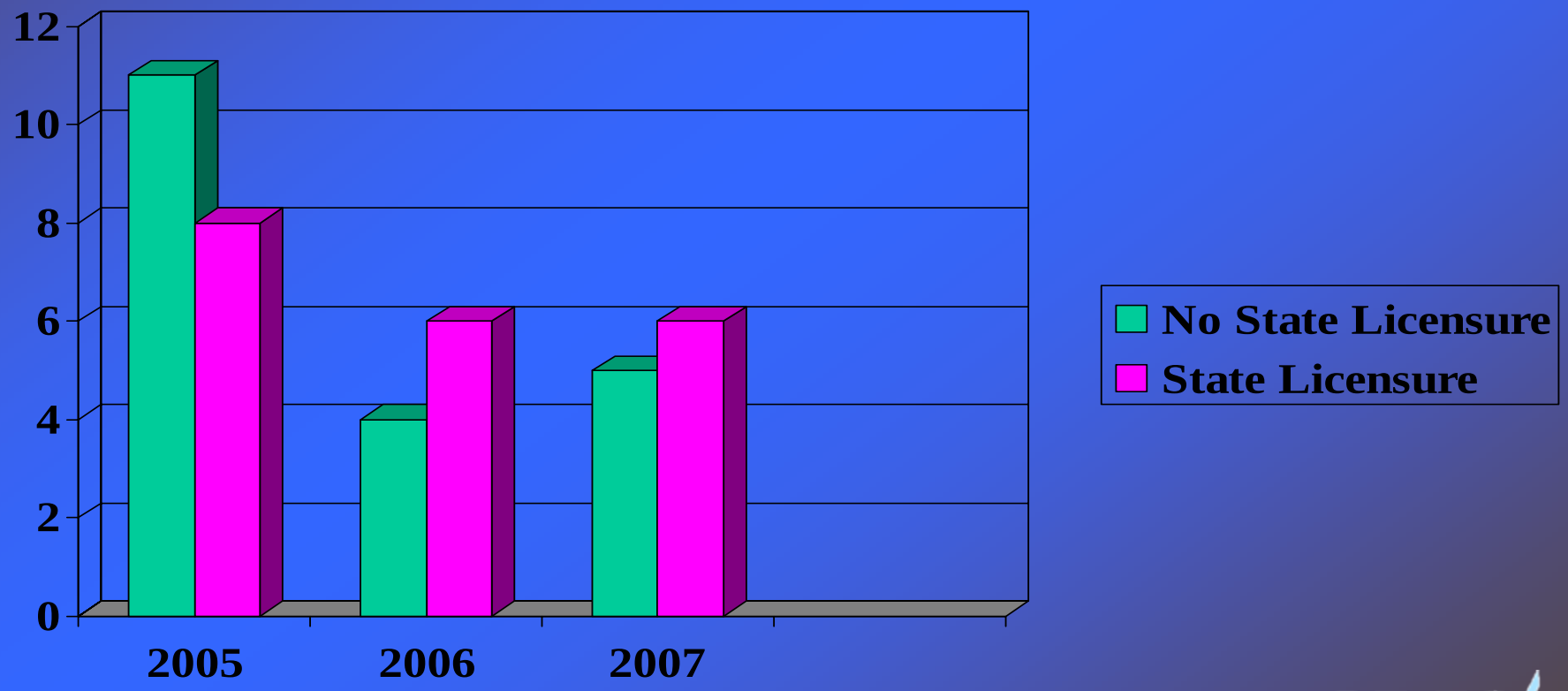
Labs that Were Not Performing Required QC After Follow Up Visit



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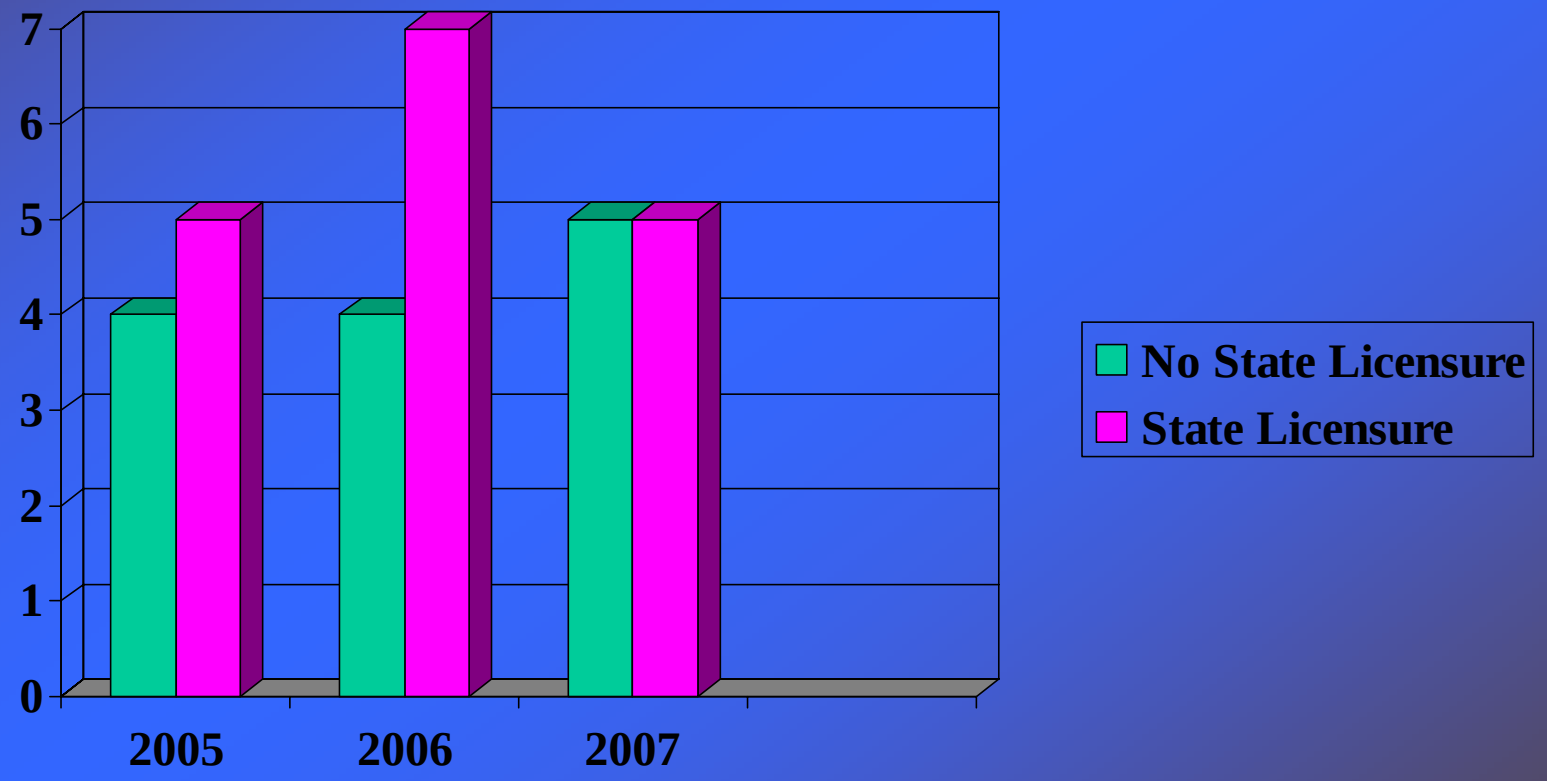
CW Labs that Participate in Voluntary Proficiency Testing



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Performance of CW Labs Performing Voluntary Proficiency Testing

CW Survey Response	PT	No PT
Lab has current manufacturer's instructions	98%	88%
Performs required QC	95%	75%
Performs required function checks or calibration	75%	62%
Performs confirmatory testing	25%	15%

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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 w/ related studies.

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Partners in Laboratory Oversight

- Meet approx. twice/year
- Successfully resolve problems, coordinate, communicate, improve policy consistency
- Developed performance measures for AO/ES/CMS lab oversight programs:
  - Survey timeliness
  - PT monitoring/referral policy
  - Survey deficiency frequency comparisons
  - Repeat deficiencies
  - Complaints

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Electronic Health Records

- Laboratory test result transmission is prototype
- CLIA requires results to State authorized person;
- Or individual who will use them
- CLIA requires certain data elements
- CLIA requires accurate, timely, reliable & confidential transmission regardless of mechanism
- Issues: State laws, incompatible systems, lab responsibilities, oversight of intermediaries & switches

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CMS Surveyor Basic Training

- Required for all ‘new’ surveyors, State or CMS regional
- One week long: Monday-Friday Nov. 2009
- Provides everything from background/history, to survey process, assessing compliance, citing deficiencies, policies , enforcement, etc.
- Utilizes scenarios, examples, exercises—practical application of regulations
- Opportunity to interact w/ faculty (CMS RO/CO)

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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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THE END!!

THANK YOU!!

QUESTIONS???

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