CLIA
CERTIFICATE OF WAIVER (CW) PROGRAM

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CLIAC Meeting

Atlanta, GA

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Objectives

- Provide the background and status of the CMS CW Project
- Solicit recommendations for oversight of CW laboratories

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Background

- CLIA Law – "Waived tests are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."
- Waived tests *have no routine oversight* under CLIA
- 209,499 labs enrolled in CLIA
  - 61% (129,219) = Waived

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Background - continued

- 1999: CO & OH visited 100 CW & PPMP laboratories; 50% had quality problems
- 2000-2001: MA, NY, PA, MS, NM, IA, AZ, ID visited 436 CW & PPMP laboratories; 32% had quality problems

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Background - continued

- **Institute an educational program for CW laboratories.**
- **Validate the effectiveness of the educational program**
- **Survey a percentage of waived laboratories annually to educate & collect information**

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CW Project Implementation

- Three year project initiated April 2002 to survey 2% of all waived labs each year
- More comprehensive questionnaire than pilot
- Evaluate effectiveness at conclusion of 3 years

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CW Project Implementation - continued

- **To facilitate education for the CW labs, CMS:**
  - **Created an educational program clearinghouse**
  - **Developed lab practices document**
  - **Collaborated with private organizations to develop/promote educational materials**

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CW Project Implementation - continued

- All 50 states- 897 Laboratories visited
- Alerted professional groups, e.g. AMA
- Training provided to surveyors
- Focused on education, information gathering
- Survey period – April to September

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Statistics from 2002-2007

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2002 Findings

- 2 cases of Immediate Jeopardy (IJ)
  - *(IJ) synonymous with imminent & serious risk to human health*
- 84% instructed personnel to retain current manufacturer PI (product insert)
- 90% instructed personnel to read & follow PI
- 60% instructed personnel to document test name, lot number, expiration date (note: good laboratory practice)

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2002 Findings- continued

- 44% laboratories had change in testing personnel in last 12 months
- 6% perform diagnostic glucose testing
- 99% of laboratories provide timely results
- 8% voluntarily enroll in PT

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2003 Findings

CW Survey Response	2002	2003
Did not have manufacturer instructions	11%	13%
Did not perform QC as required by manufacturer*	19%	24%
Did not follow manufacturer storage and handling	3%	3%
Personnel not trained/evaluated	21%	21%

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2003 Findings - continued

- 3 cases of IJ

  IJ: Rh slide testing, Rhogam administered to men

- 72% laboratories routinely check incoming PI to ensure there have been no changes in the product or procedure (73% in 2002)

- 49% documented test name, lot number, expiration date (note: good laboratory practice; 50% in 2002)

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2003 Findings - continued

CW Survey Response	2002	2003
Change in testing personnel	44%	43%
Perform diagnostic glucose testing	6%	3%
Provide timely results	99%	95%
Enrolled in proficiency testing	8%	10%

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CW- Risk of Harm

- Immediate Jeopardy (IJ) identified

2*	3	2
(897)	(1575)	(1742)
2002	2003	2004

*1 found from Complaint

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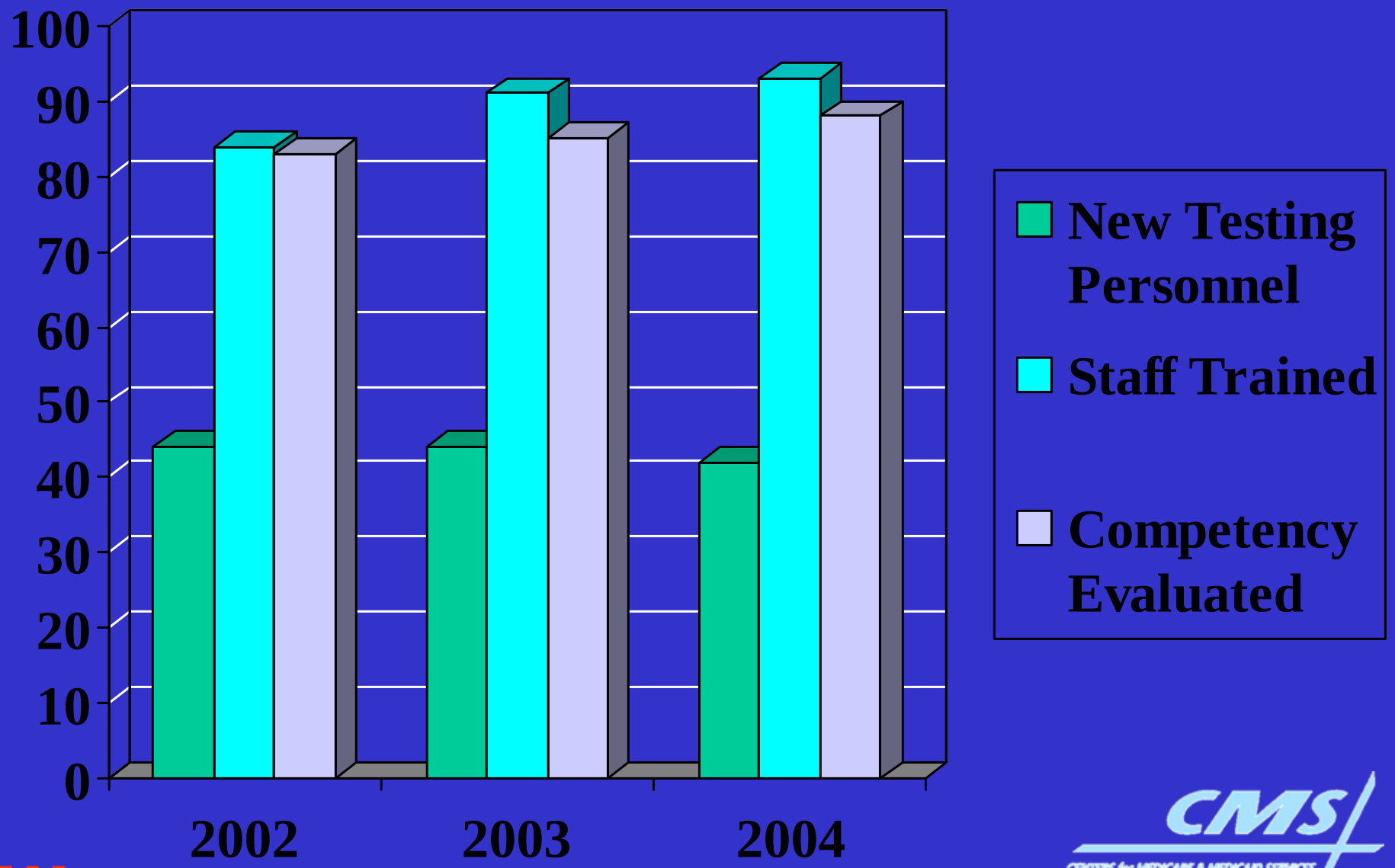
CW- Personnel & Training (%)



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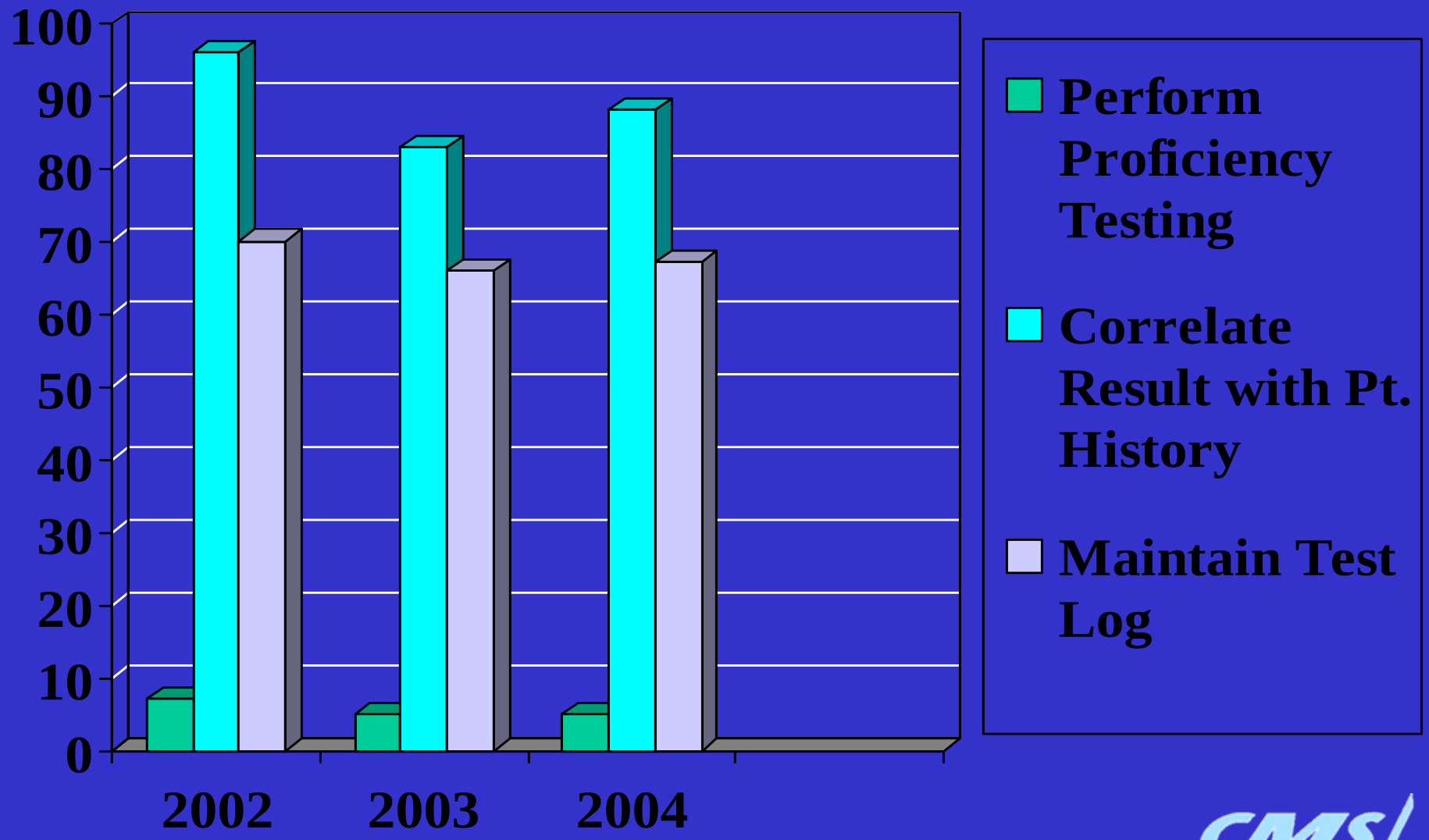
CW- Good Lab Practices (%)



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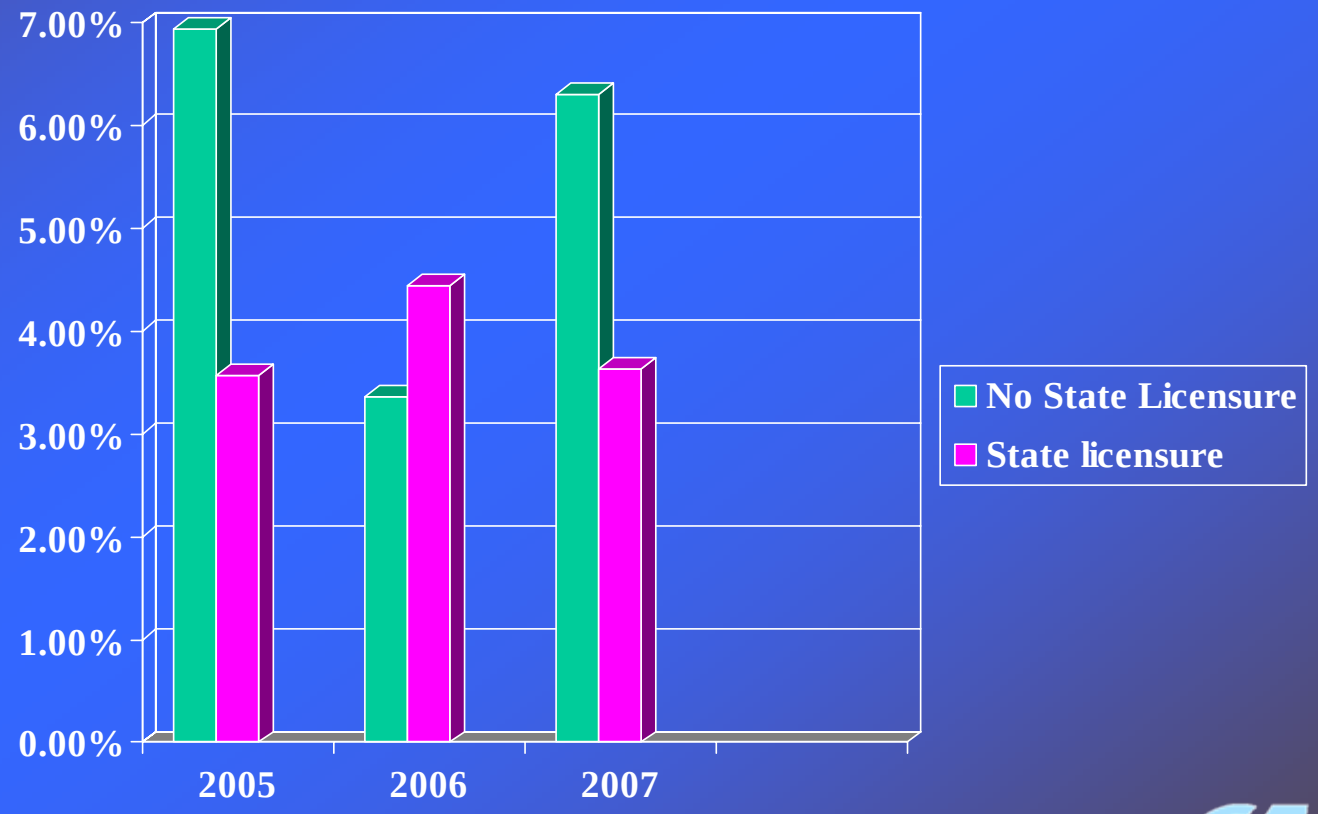
Percentage of CW Labs Performing Non-waived Tests
Source: CMS Database



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CW LABS - IJ

- 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 - IJ

- Recent case of IJ in CW lab:
  - Lab used all waived instruments
  - QC for HgA1C not performed per manufacturer's instructions
  - User manual for HgA1C instrument still wrapped in plastic
  - Testing personnel could NOT identify an invalid test on rapid strep and urine preg tests

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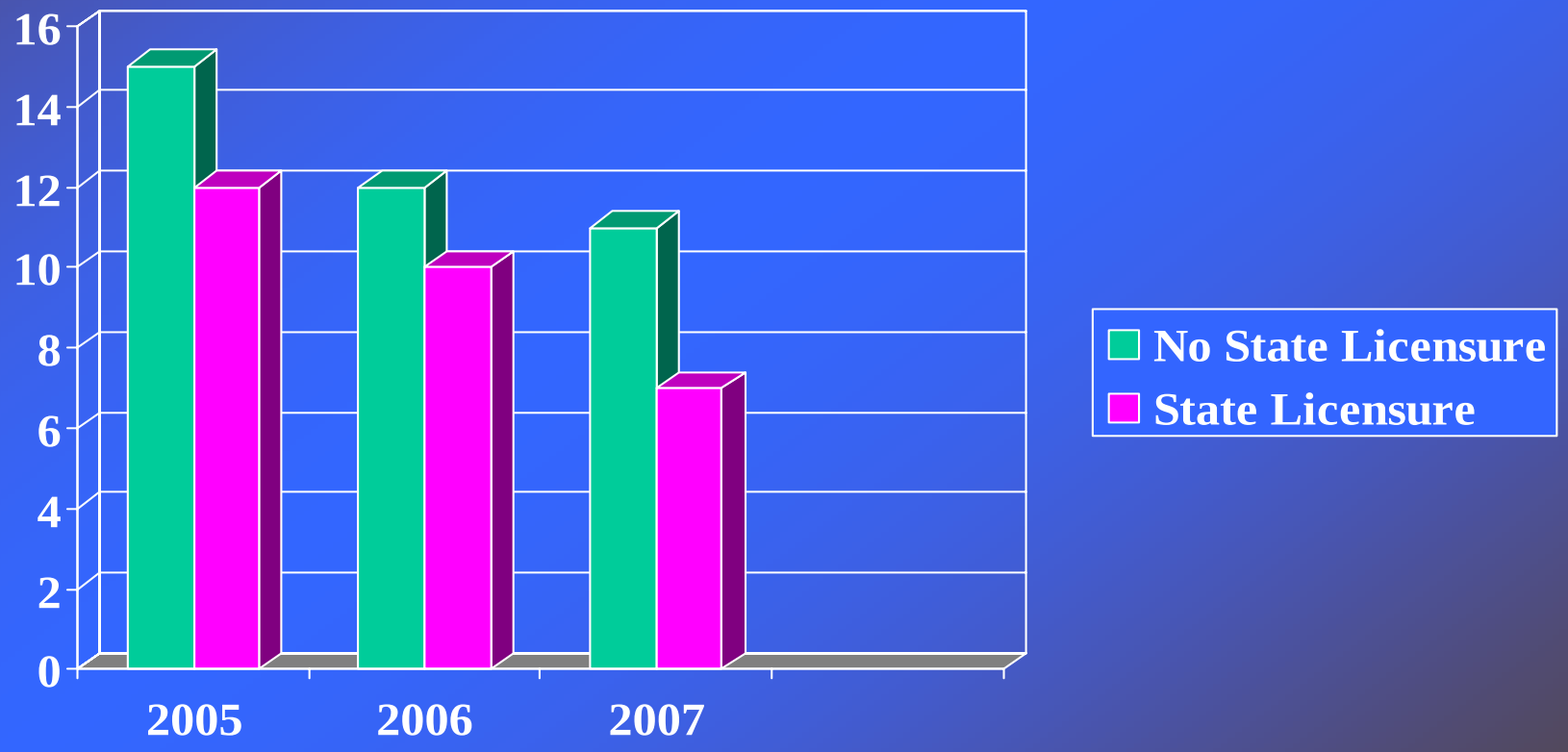
CW Labs that Did Not Have the Manufacturer's Instructions (%)



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CW Labs that Did Not Follow Manufacturer's Instructions for Use of Appropriate Specimen

- FY 2005: No State Licensure: 2%
  State Licensure: Less than 1%
- FY 2006: No State Licensure: 2%
  State Licensure: Less than 1%
- FY 2007: No State Licensure: 3%
  State Licensure: Less than 1%

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CW Labs that Did Not Adhere to Manufacturer's Storage and Handling Instructions

- FY 2005: No State Licensure: 5%
  State Licensure: <1%
- FY 2006: No State Licensure: 3%
  State Licensure: <1%
- FY 2007: No State Licensure: 5%
  State Licensure: 2%

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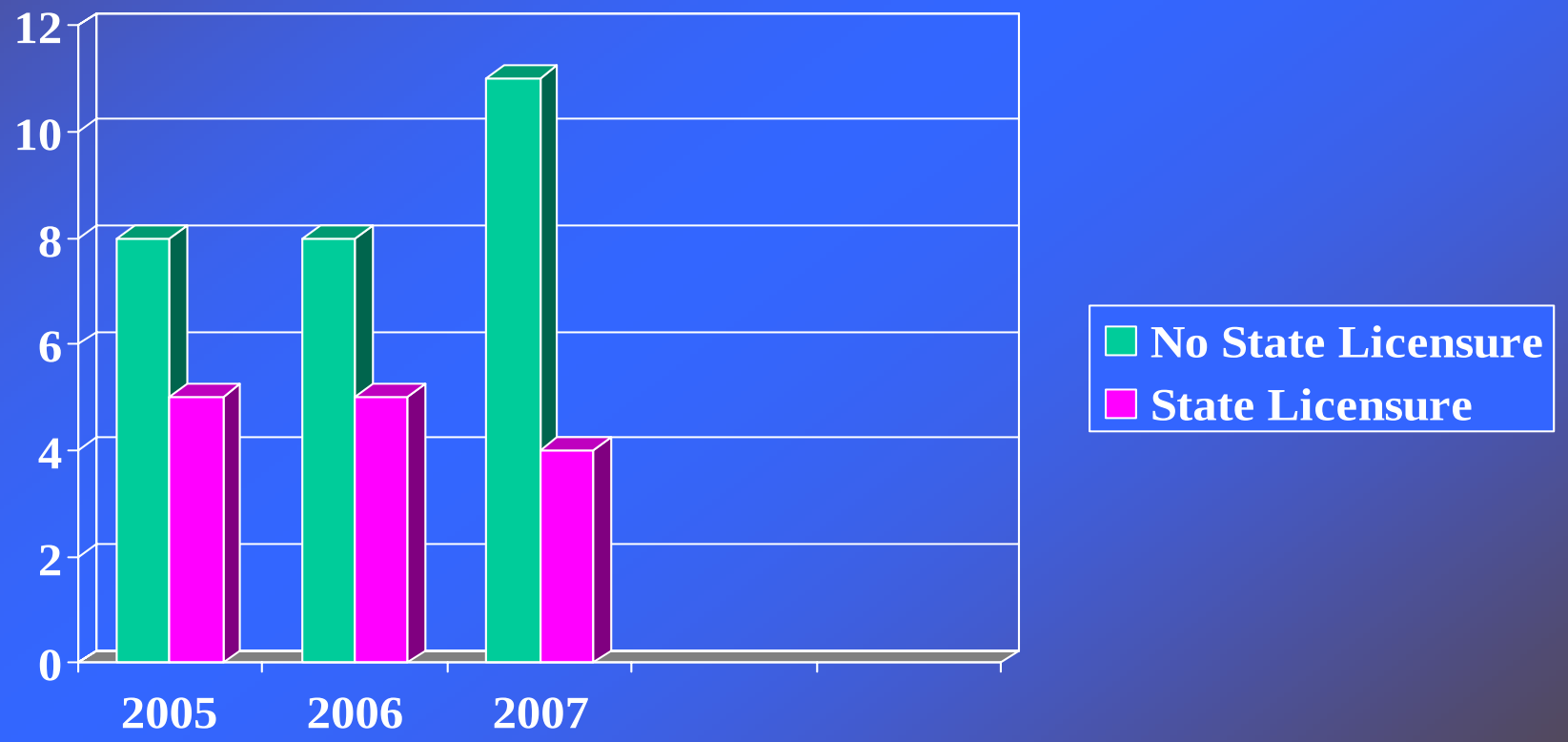
CW Labs that Did Not use Proper Expiration Date for Storage Method (%)



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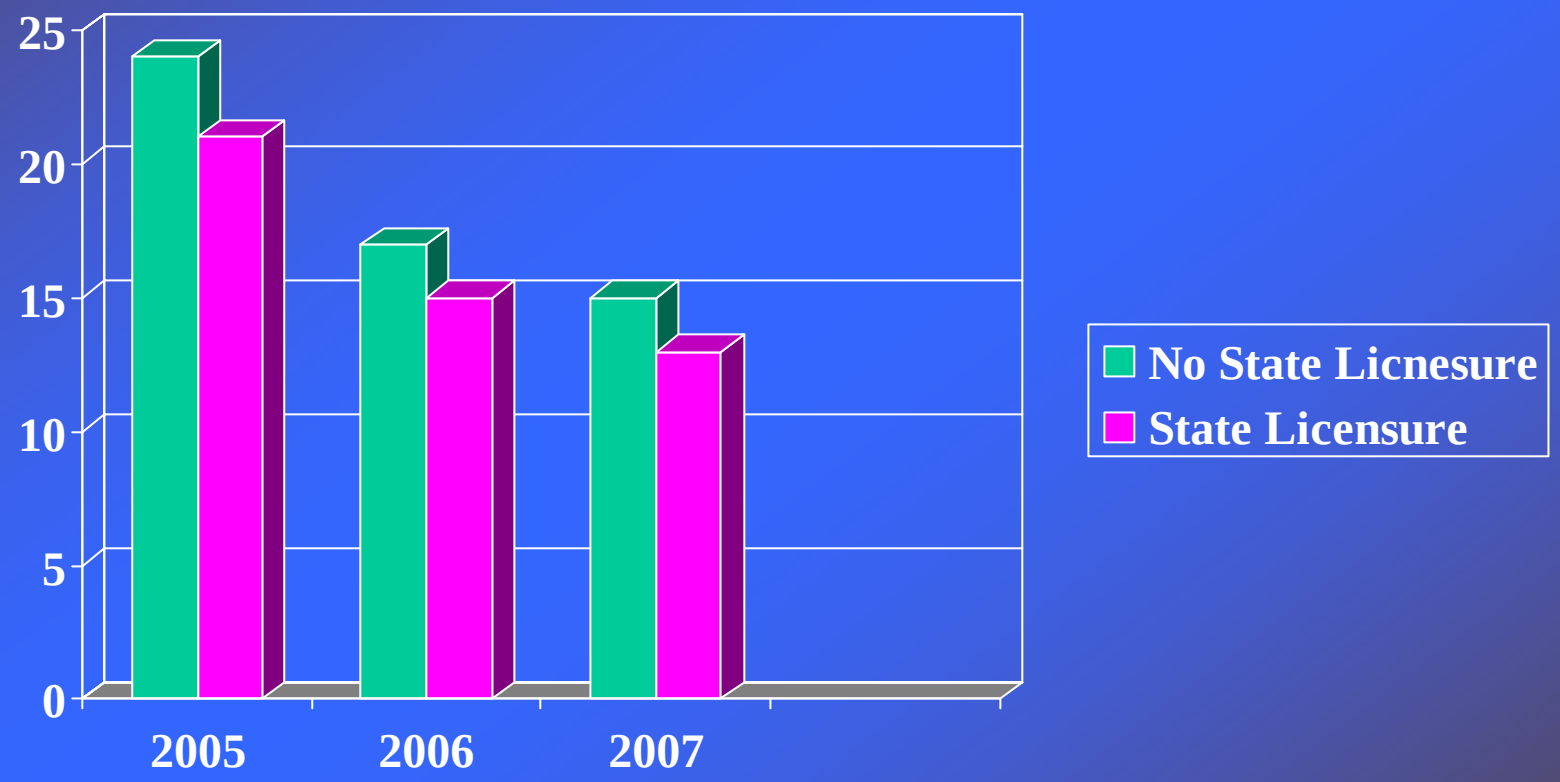
(%) CW Labs that Were Not Performing Required Quality Control on Initial Visit



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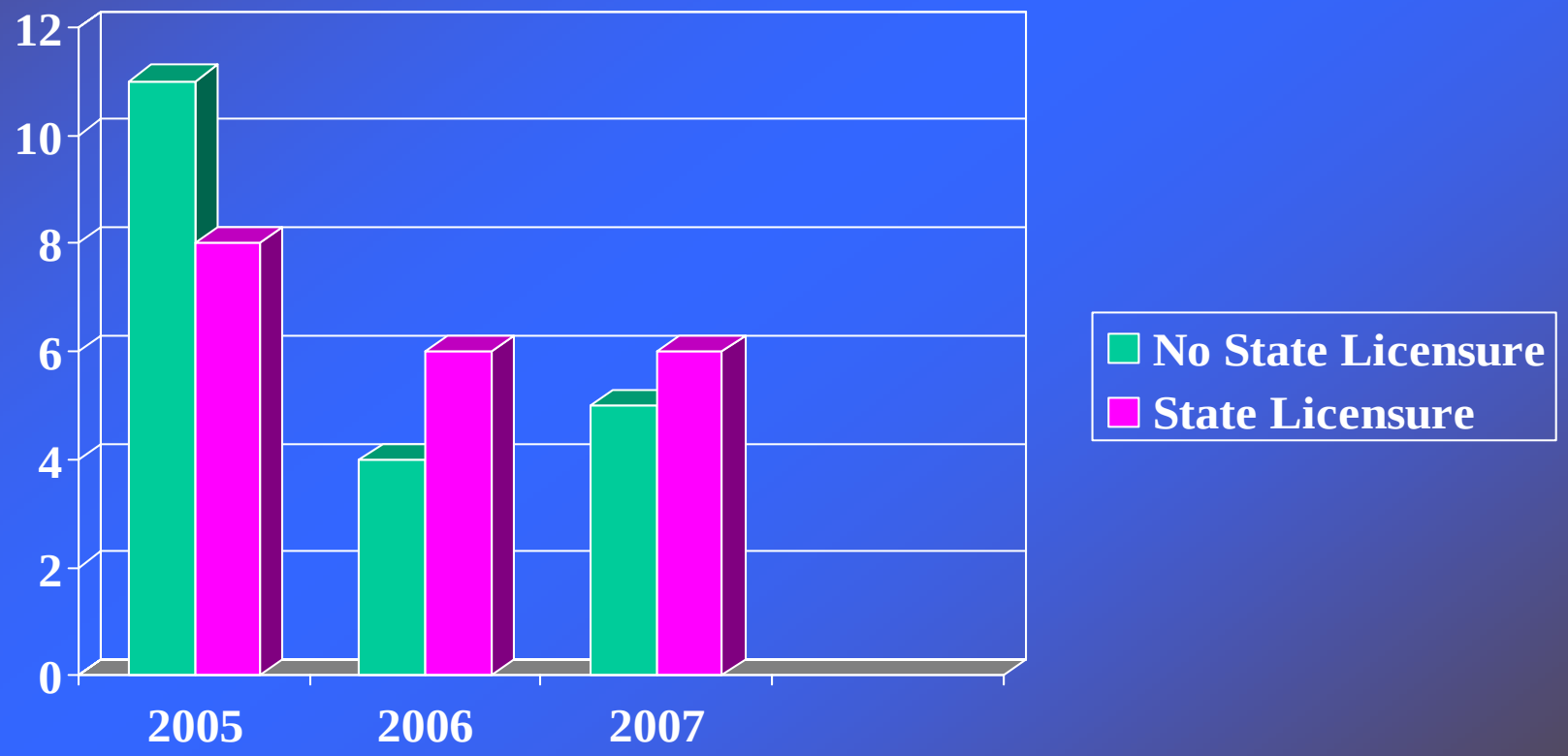
Labs that Were Not Performing Required Quality Control After Follow Up Visit (%)



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CW Labs that Were Not Performing Required Calibration or Function Checks

- FY 2005: No State Licensure: 3%
  State Licensure: 4%
- FY 2006: No State Licensure: 2%
  State Licensure: 3%
- FY 2007: No State Licensure: 1%
  State Licensure: 3%

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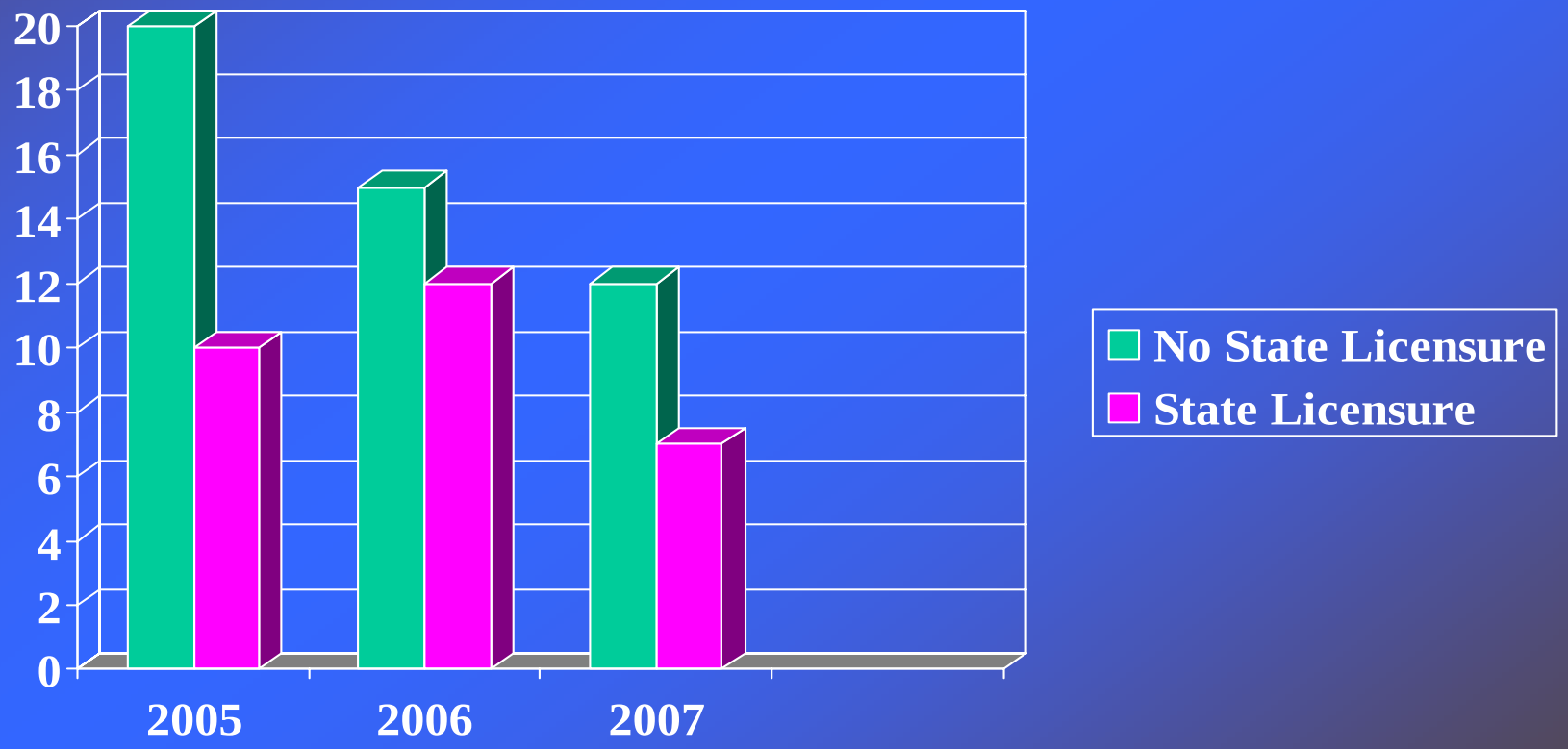
CW Labs that Were Not Reporting Patients' Test Results as Recommended by Manufacturer (%)



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CW Labs that Were Not Performing Required Instrument Maintenance

- FY 2005: No State Licensure: 2%
  State Licensure: 2%
- FY 2006: No State Licensure: 1%
  State Licensure: <1%
- FY 2007: No State Licensure: 1%
  State Licensure: 1%

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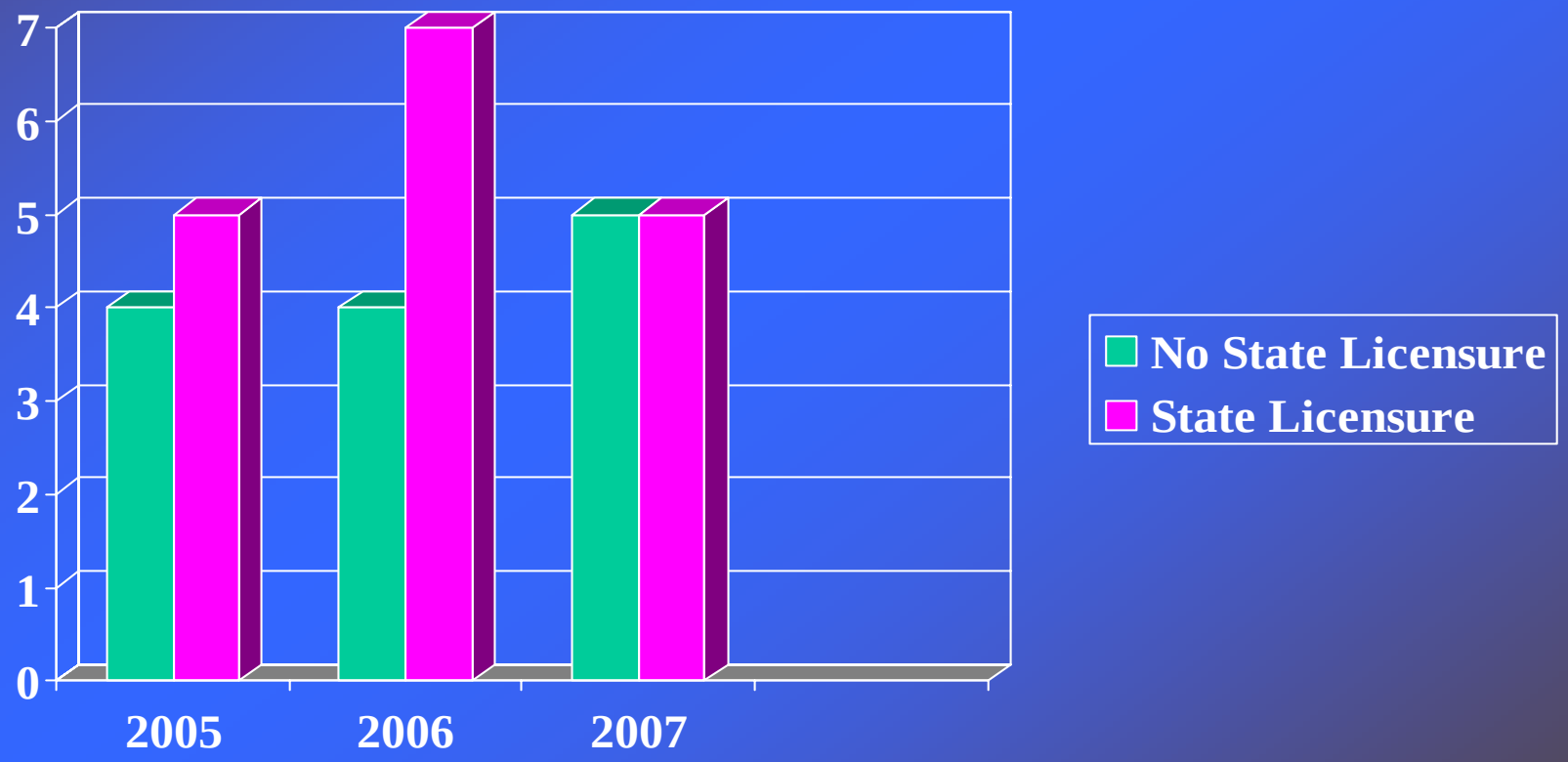
CW Labs that Participate in Voluntary Proficiency Testing (%)



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CW Performance Based on 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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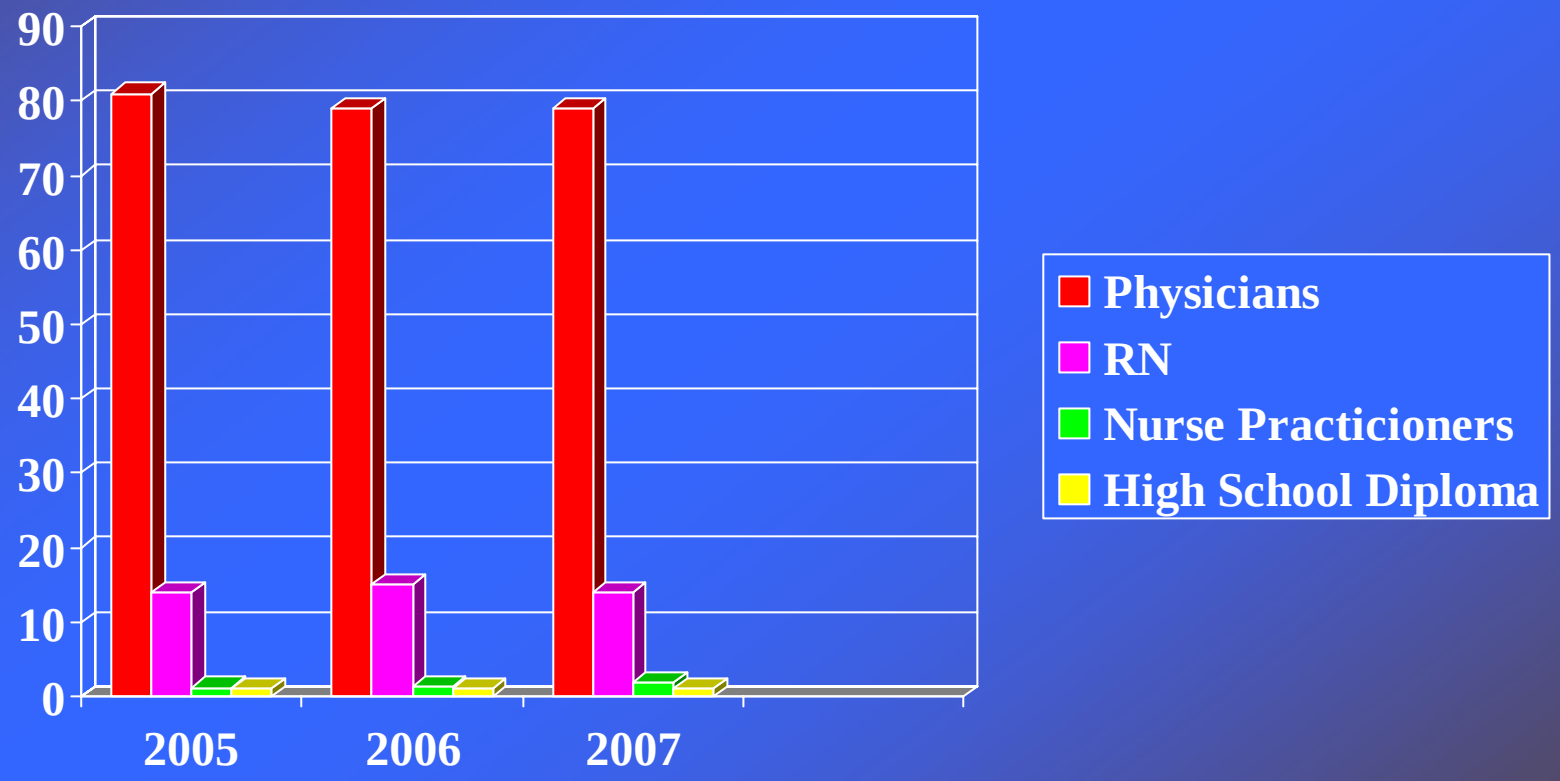
Who Are the CW Lab Directors? (%)



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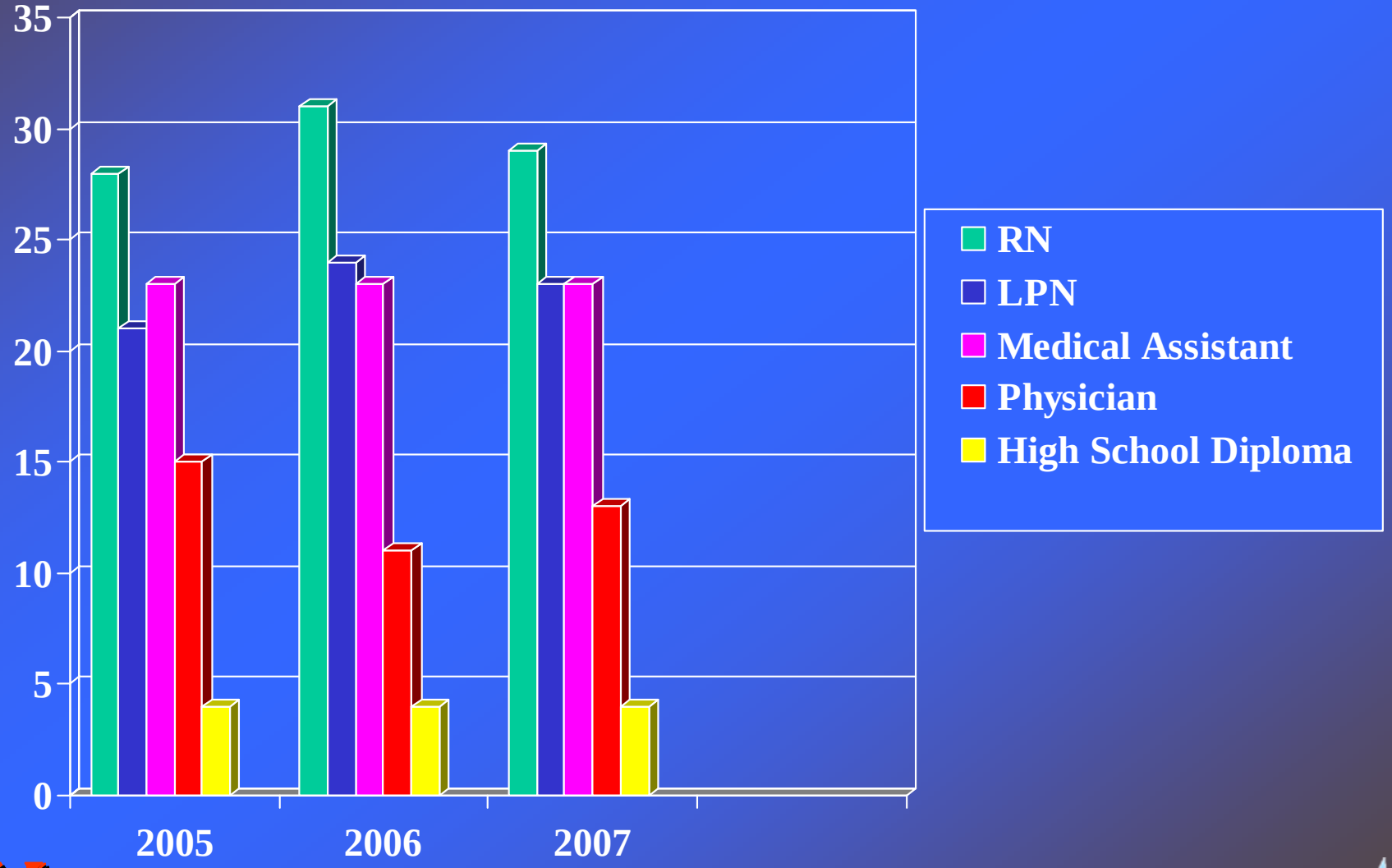
Who are the CW Testing Personnel? (%)



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WARNING
Fraud labs masked as CW labs

For example:

- Lab applies for CLIA CW in one State
- Mailing address in another State
- Lab billed Medicare for $400k for both waived and non-waived testing
- When surveyors visit lab, no lab at address
- CLIA certificate is then terminated

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SUMMARY
CMS Visits Are Definitely Worthwhile!

The CW Project has:

- Raised the awareness of following the manufacturer's instructions for testing
- Identified labs testing beyond the scope of their waived certificate
- Provided labs education about CLIA, laboratory testing and Good Lab Practices

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Next Steps

- Possible continuation of project
- Collaboration with CMS Partners
- Possible changes to the CLIA Law
  - Definition of waived test
  - PT requirement
  - Personnel requirements
  - Routine oversight (surveys)

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THE END

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