

Twenty Years of CLIA

College of American Pathologists

February 20, 2008

R. Bruce Williams, MD

Chair, Commission on Laboratory
Accreditation

It Started Long Ago...

1949

- First chemistry Survey conducted
- CAP cooperates in AMA blood bank survey

1951

- First standard solutions offered

1958

- First bacteriology Survey conducted
- CAP sends brochure on cytology to all US physicians



History Timeline

1961

- Ad Hoc Committee on Laboratory Accreditation submits report recommending establishment of accreditation program

1962

- CAP Inspection and Accreditation Program established



1965

- First laboratory accreditation checklist compiled

History Timeline

1967

- Proficiency testing participation becomes a requirement for accreditation program
- Clinical Laboratories Improvement Act of 1967 passed
- JCAH adopts CAP laboratory accreditation standards

1969

- Inspection & Accreditation Program declared equivalent to CLIA-67 standards by HCFA

History Timeline

1973

- Laboratory accreditation cycle shortened from three years to two years

1978

- JCAH grants deeming authority for CAP Inspection & Accreditation Program

1979

- Inspection & Accreditation Program renamed Laboratory Accreditation Program (LAP)

History Timeline

1984

- First hormone receptor assay Survey offered

1986

- Joint inspection of blood banks initiated by CAP and American Association of Blood Banks

1988

- Clinical Laboratories Improvement Amendments of 1988 (CLIA-88) enacted



History Timeline

1988 con't

- CAP disseminates public information to women on importance of routine Pap smears in response to *Wall Street Journal* “Pap mill” expose and strengthens accreditation program for cytology
- CAP, AMA, AAFP, and ASIM establish the Commission on Office Laboratory Accreditation (COLA) for physician office laboratories
- Accreditation program first offered for forensic urine drug testing (FUDT)

History Timeline

1990

- Performance Improvement Program in Cervicovaginal Pathology (PAP) inaugurated

1992

- Reproductive biology accreditation program (RLAP) implemented

1994

- CAP receives deeming authority for LAP under CLIA-88



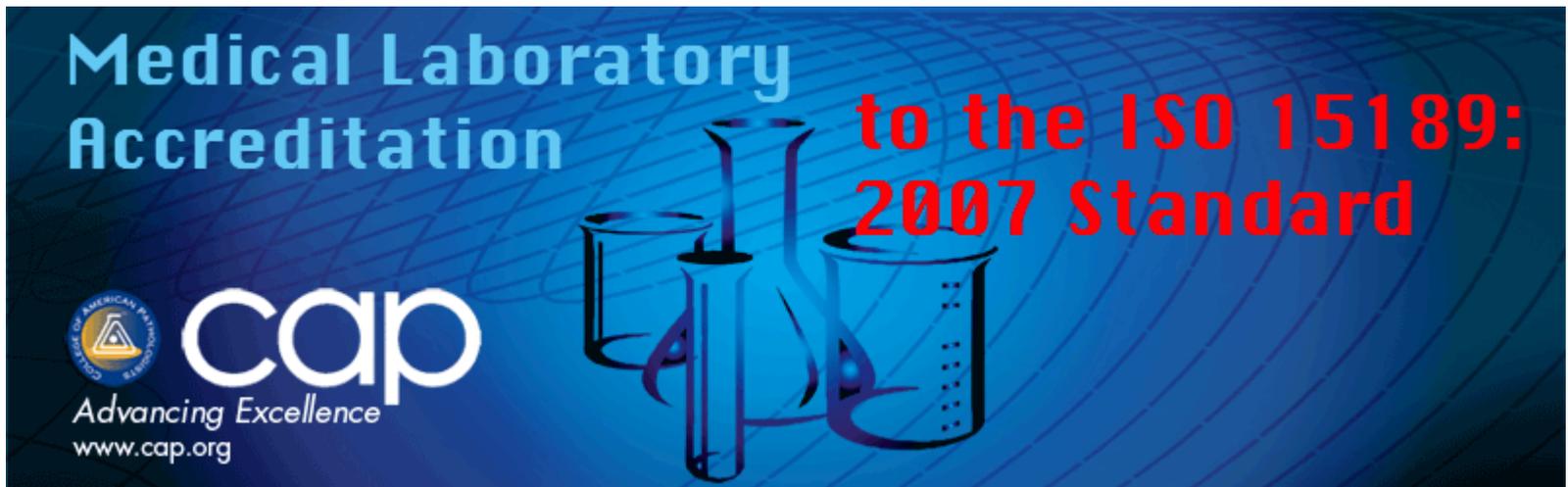
Recent History

- Complaints poster & whistle-blower policy
- Conflict of interest policies strengthened
- Inspector assignment done in-house
- Mandatory inspector training
- Independence of accreditation decision
- Unannounced inspections
- Participation in CMS Partners' group

Future Improvements

2008

- CAP announces pilot implementation for ISO 15189 program



Medical Laboratory Accreditation

to the ISO 15189: 2007 Standard

 **cap**
Advancing Excellence
www.cap.org

CLIA-88

Landmark Legislation

- Recognized that quality laboratory practice was important to the health and welfare of the population
- Not “interstate only” as was CLIA-67
- Looked at all aspects of laboratory testing
 - Pre analytic
 - Analytic
 - Post analytic
- Resulted in improvements of quality lab practice
- Philosophies of both CAP and federal oversight became “in sync”

Structure of CAP LAP

- Scientific Resource Committees (US experts in all laboratory disciplines)
 - Ponder new technologies
 - Suggest relevant requirements to keep Program on cutting edge
 - Review requirements for accuracy, relevancy, and quality lab practice
- Commission on Laboratory Accreditation
 - Regional representation of pathologists who operate laboratories and know rules, regulations, and necessity for requirements
- Expert committees
 - Create checklists
 - Monitor proficiency testing
 - Handle complaints
 - Develop inspection education
 - Improve inspection process
 - Apply consistent accreditation decisions
- Oversight Council
 - Authority to aid with strategic planning, mission, and program direction



CAP Implementation of CLIA 88

- Discipline-specific checklists are the blueprint of quality practices for laboratories to follow, constantly evolve to reflect changes in technology
- Exceed CLIA requirements
 - Anatomic Pathology (Autopsy & Histology Processing)
 - Cytogenetics c.1976
 - Reproductive Biology c.1993
 - Molecular Pathology c.1993
 - Biochemical Genetics c.2009

More CAP Implementation

- Utilizes practicing lab professionals (true peers) in all disciplines
- Utilizes cadre of staff inspectors who perform inspections and assist peer inspectors to aid in uniformity and quality assessment
- Requires proficiency testing (PT) for regulated and unregulated analytes
- CAP Surveys offers PT for routine and esoteric tests

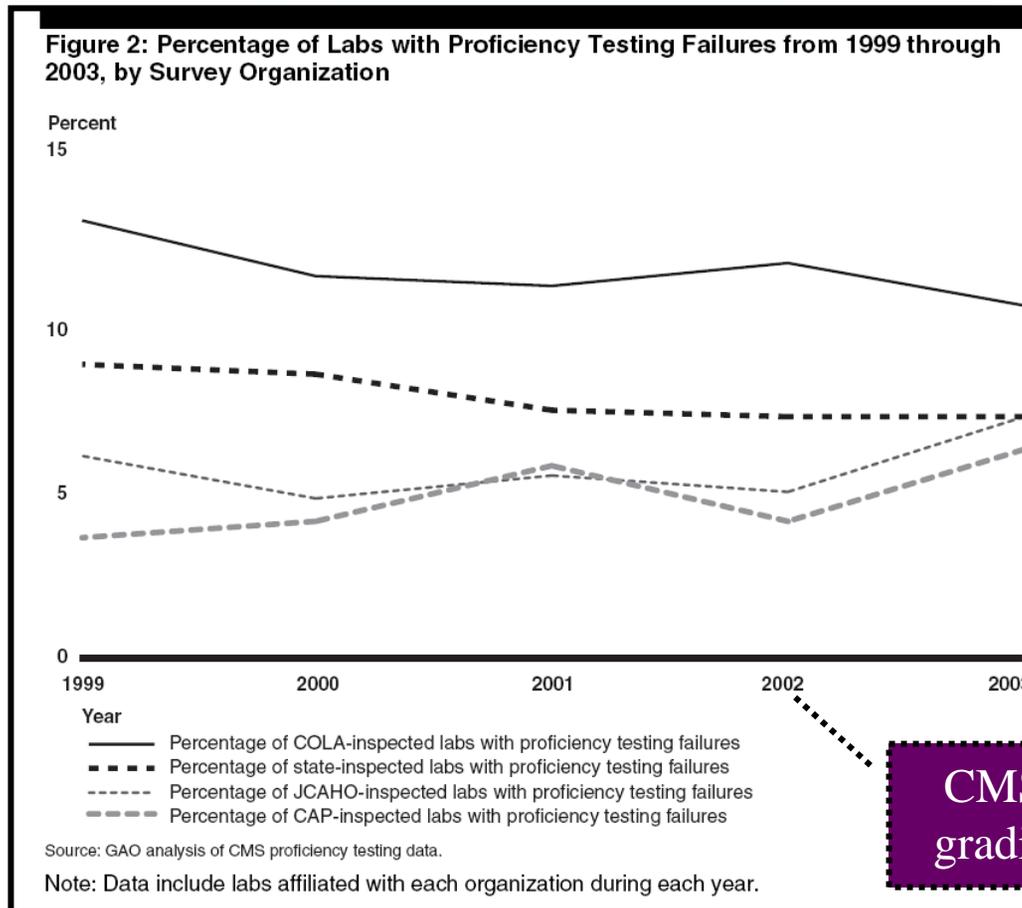
Not Just Talking Quality ...

- Outcome Indicators of Quality
 - Proficiency Testing
 - Inspection Results



Proficiency Testing

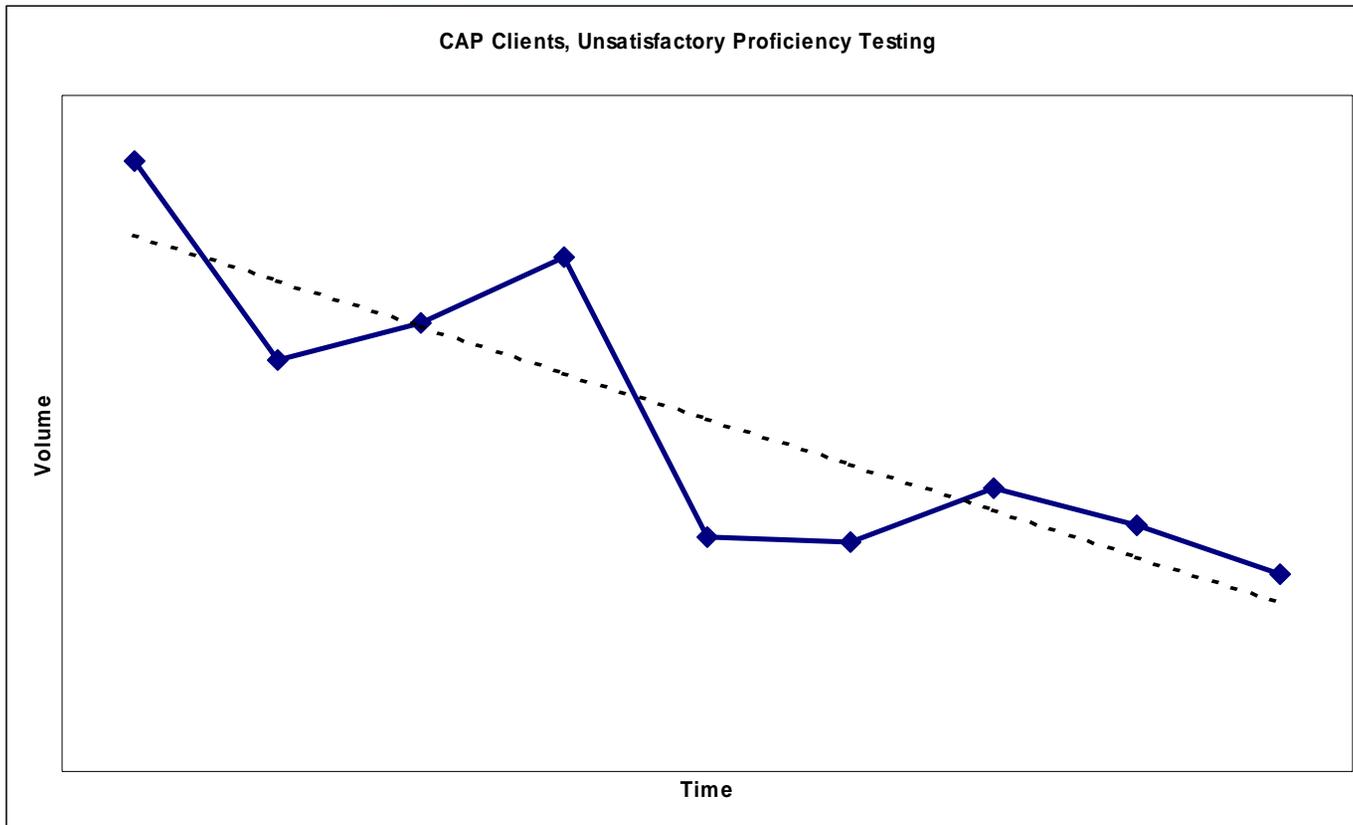
All labs that participate in the LAP required proficiency testing perform better over time



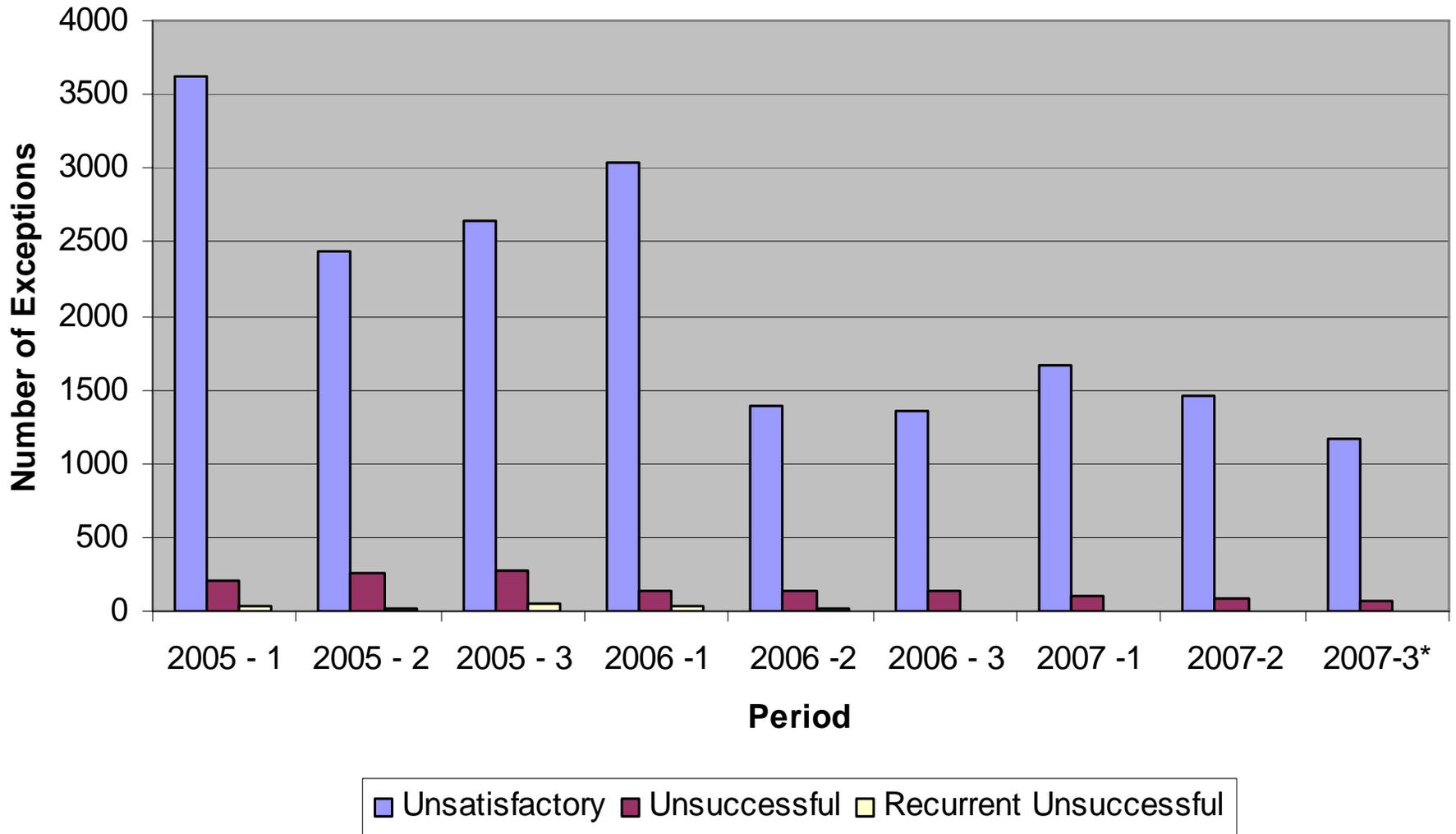
CMS changed grading criteria

Proficiency Testing

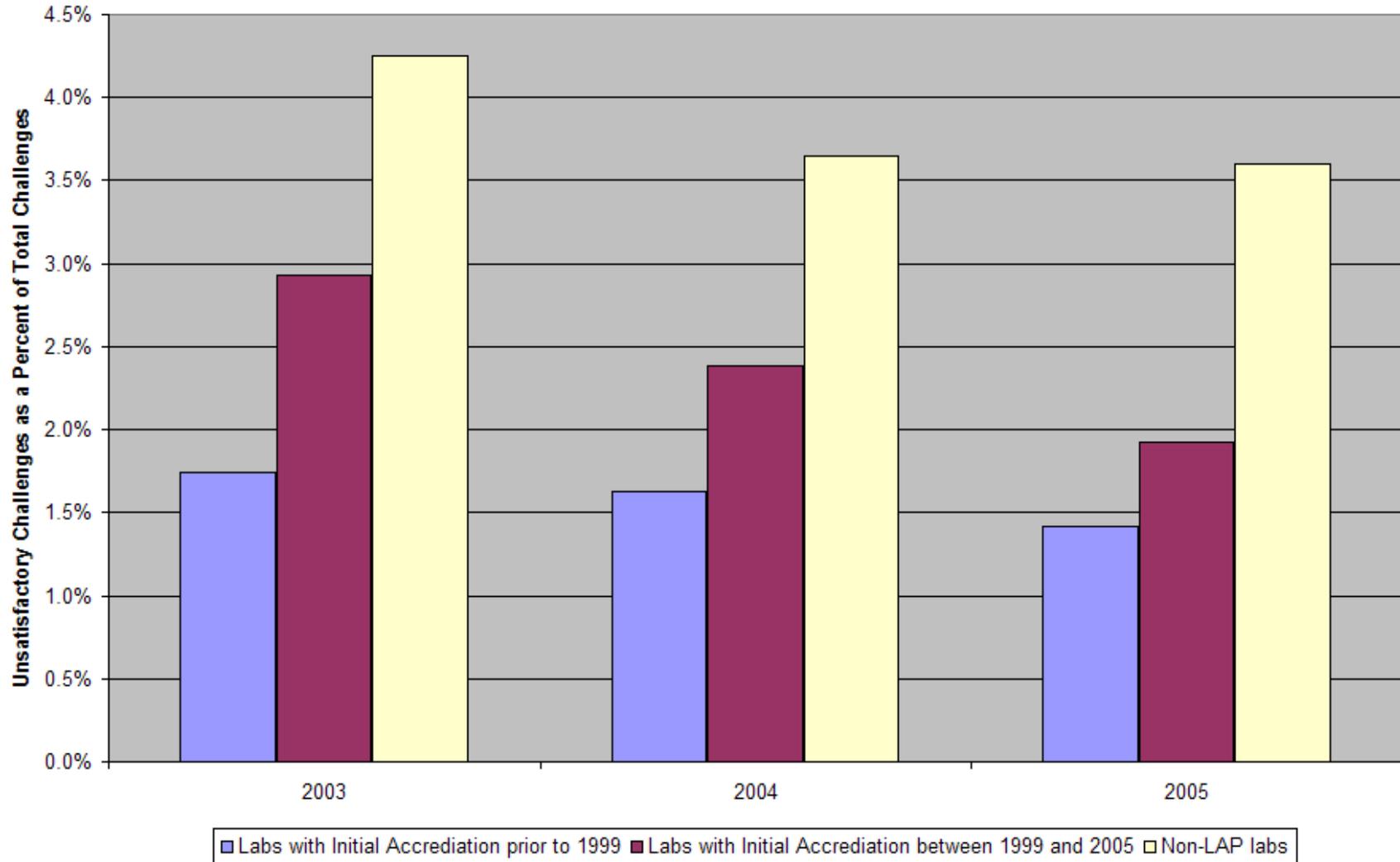
All labs that participate in CAP required proficiency testing perform better over time



Regulated Analyte Performance

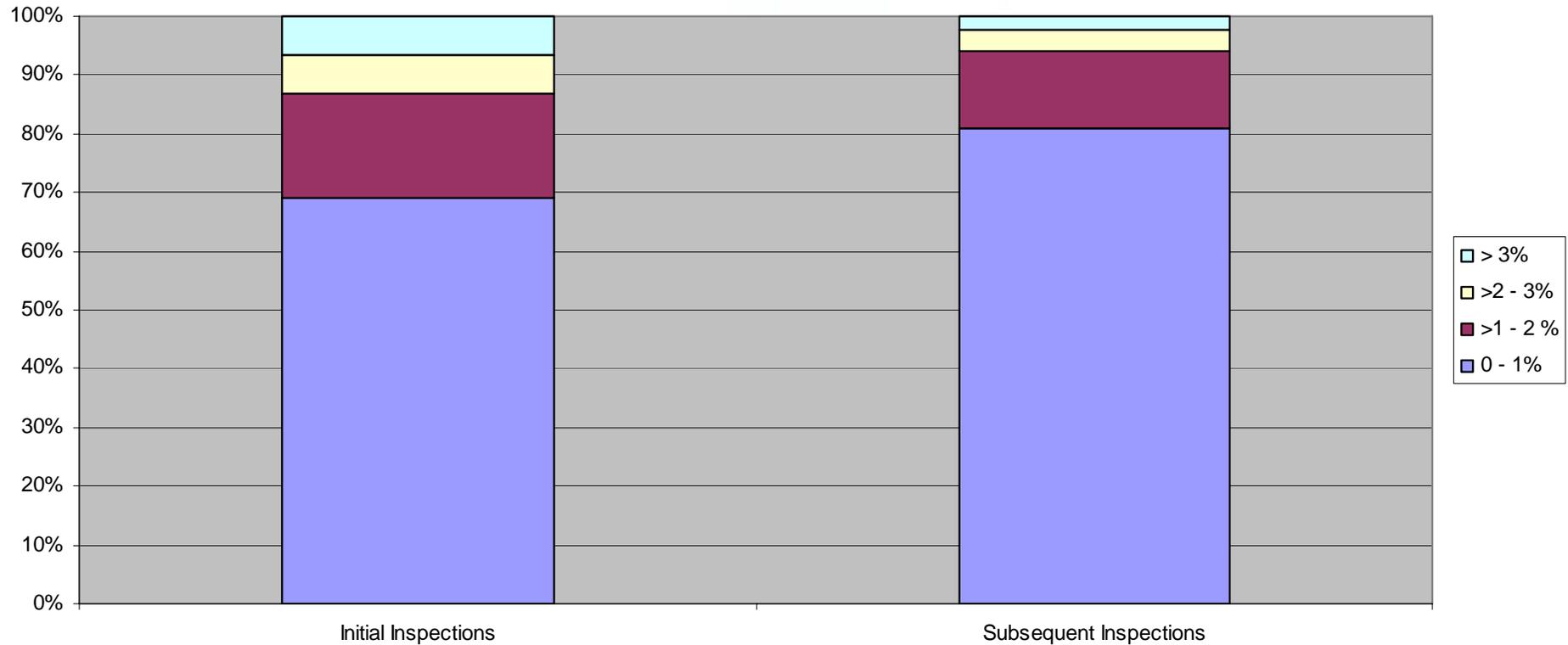


Unsatisfactory Proficiency Testing Performance



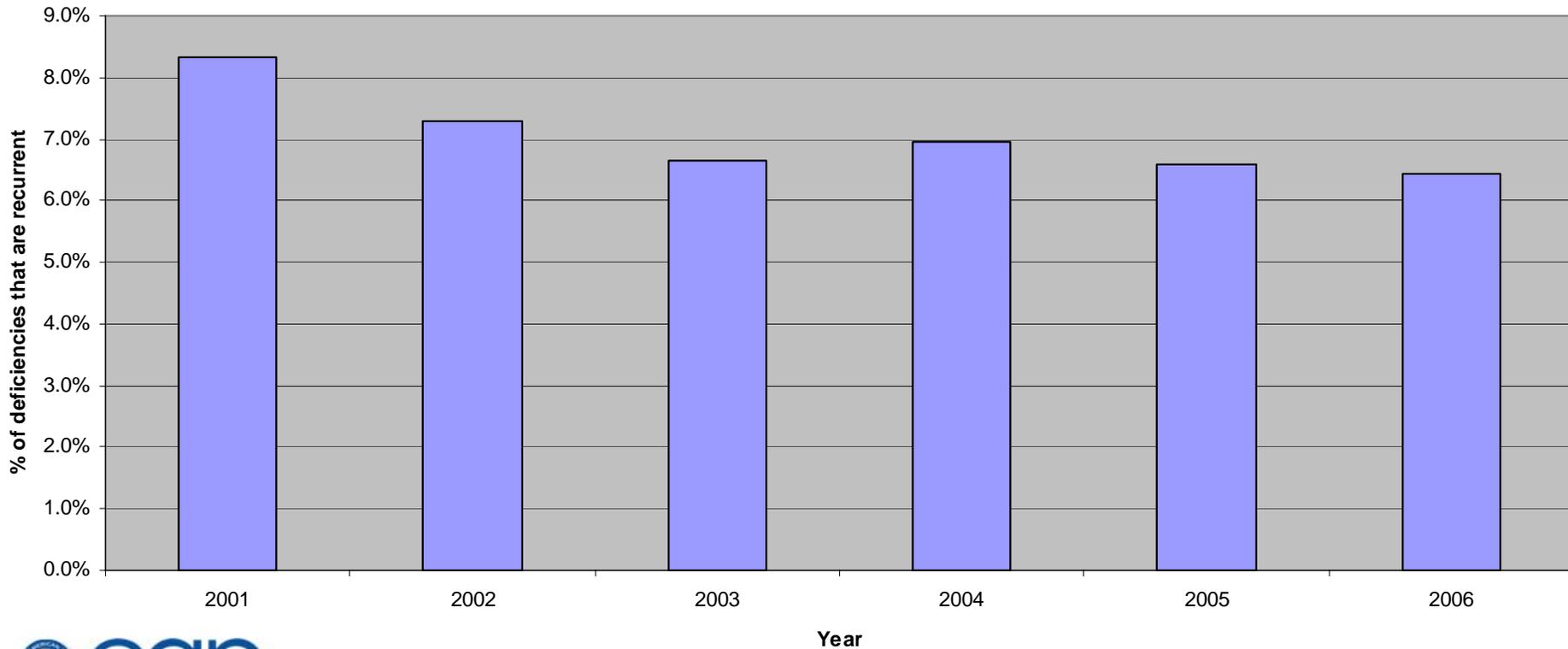
Decrease in Deficiencies Post Initial Accreditation

Percentage of Phase II Deficiencies
2002-2007 Inspections



Decrease in Recurring Deficiencies

Recurrent Deficiencies as a Percent of Total Deficiencies



CAP Areas of Collaboration with Other Agencies

- Commission on Cancer (CoC)
 - Accepted CAP Cancer Protocols
- American Society of Clinical Oncology (ASCO)
 - HER2 requirements & other predictive markers
- United Network of Organ Sharing (UNOS)
 - Collaboration for organ donation programs
- American Society of Reproductive Medicine (ASRM)
 - Co-sponsors reproductive accreditation program
- Liaisons with specialty societies for PT (ACMG, AACC, ASHI)
- The Joint Commission
- AABB
- Select State Agencies
- Other CMS Partners

Future Opportunities for Quality in Laboratories

- Reevaluate and reconsider advisability of increasing numbers of waived test approvals
- Include esoteric testing such as cytogenetics and molecular in current CLIA-88 framework

Not Just Talking Quality, But Investing in Quality

