



# Laboratory Accreditation – A Brief History

CLIAC/CDC  
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# *Laboratory accreditation...*

*The historical foundation, rules and influencers that directed development, and today's environment*

# Timeline 1847-1926

- ▶ 1847 – American Medical Association (AMA) established
- ▶ 1899 – American Hospital Association (AHA) established
- ▶ 1913 – American College of Surgeons (ACS) established - Chicago
- ▶ 1915 – American College of Physicians (ACP)
- ▶ 1922 – American Society of Clinical Pathologists (ASCP)
- ▶ 1926 – ACS publishes Manual of Hospital Standardization
  - Volunteers survey hospital, including laboratory

# Timeline 1943 - 1951

- ▶ 1943 - American Medical Association (AMA) recognizes pathology as the practice of medicine
- ▶ 1945 – ASCP Committee recommends formation of a separate "academy of pathology"
- ▶ 1946 - College of American Pathologists (CAP) established - Chicago
- ▶ 1946 – Government begins funding hospital construction relying upon ACS certification
- ▶ 1951 – The Joint Commission on Accreditation of Hospitals is created from the AMA, AHA, ACS, ACP, and Canadian Medical Association

# Timeline 1952 - 1965

- ▶ 1952 – CAP establishes a liaison committee with the JCAH
- ▶ 1956 – JCAH begins using employed surveyors instead of volunteers recommended by the AHA & government
- ▶ 1960 – Voluntary government program implemented to reimburse hospitals for care of indigent patients if JCAH accredited
- ▶ 1965 – Medicare legislation passes under LBJ
  - Laboratory defined as an “essential” service
  - Continued to be included in organization’s survey

# Timeline 1960's - 1973

- ▶ Late 1960's – Deaths related to misread PAP smears
- ▶ 1967 – CLIA legislation passed by Congress
- ▶ JCAH adopts laboratory standards for QC & personnel (as part of hospital survey)
  - NCCLS founded (now CLSI)
- ▶ 1972 – Social Security Act requires DHHS to validate JCAH findings
- ▶ 1973 – SSA validations strictly facility, building codes, fire safety

# Timeline 1978 - 1987

- ▶ 1979 – JCAH adds full time laboratory surveyors to cadre
- ▶ 1982 – Accreditation cycle changed from two to three years for all JCAH programs
- ▶ 1987 – JCAH name change to JCAHO (*Hospitals becomes Healthcare Organizations*)
  - 1966 - 2000 JCAHO adds accreditation for Long Term Care, Behavioral, Hospice/Home Care, Ambulatory, Office-based Surgery, Assisted Living

# Timeline 1987 - 1995

- ▶ 1987 – Cytology PAP shacks hit the media again
- ▶ 1988 – Amendments to CLIA '67 initiated
- ▶ 1988 – Commission on Office Laboratory Accreditation (COLA) established
- ▶ 1990 – Proposed CLIA '88 rule published
- ▶ 1992 – Final CLIA '88 rule published
  - Phase in of requirements that impact POLs
  - Biennial inspections required (all other JCAHO programs still triennial)
- ▶ December 1993 – COLA receives deemed status for CLIA
- ▶ January 1995 – JCAHO receives deemed status for CLIA
- ▶ February 1995 – CAP receives deemed status for CLIA

# Timeline 1996 - 2007

- ▶ 1994 – JCAHO publishes an independent standards manual for laboratories (from the hospital manual)
- ▶ 2000 – Test categorization responsibility transferred from CDC to FDA
- ▶ 2003 – Final CLIA goes into effect (cal verification, equivalent QC)
- ▶ 2007 – JCAHO changes name to The Joint Commission

# CLIA '67

- ▶ Problems in cytology labs
- ▶ Regulated labs engaged in interstate commerce
- ▶ POL's largely unregulated
- ▶ Mandated efforts to assure the quality of clinical laboratory testing

# CLIA'88

- ▶ Amended CLIA-67 by expanding the Department of HHS's authority from regulation of laboratories that only accepted and tested specimens in interstate commerce to the regulation of any laboratory that tested specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.
- ▶ Specific concerns were raised about the validity of cholesterol screening and the accuracy of Pap smear results.
- ▶ Set QC standards for non-waived testing
- ▶ Reduces QC frequency in most of the subspecialties.
- ▶ Studies show most lab errors are pre-analytical.

# CLIA 2003

- ▶ Introduced concept of EQC
- ▶ To monitor the accuracy and precision of the complete analytical process;
- ▶ To detect immediate errors that occur due to test-system failure, adverse environmental conditions, and operator performance; and
- ▶ To monitor over time the accuracy and precision of test performance that may be influenced by changes in test-system performance and environmental conditions, and variance in operator performance.

# The Joint Commission

- ▶ Continues to meet all CMS Deeming requirements for CLIA Program. Remains equivalent to or more stringent than CLIA requirements.
- ▶ Participates in the Centers for Medicare and Medicaid Services (CMS) Partners in Laboratory Oversight project. The goal of this partnership is to promote more effective oversight of our nation's laboratories and drive continuous improvement in quality and patient safety in laboratories.
- ▶ Shares relevant survey findings with The Joint Commission's Cooperative Partners as well as with CMS.
- ▶ Improved coordination of its for-cause surveys
- ▶ Improved complaint sharing with The Joint Commission's Cooperative Partners and CMS.
- ▶ Enhanced its proficiency testing monitoring for unsuccessful events.

# The Joint Commission

- ▶ All Joint Commission surveys are unannounced with a few exceptions.
- ▶ Added new and revised Accreditation Participation Requirements (APRs) to establish processes for employees and the public to identify quality or safety concerns. The APR also outlines protections for whistleblowers.
- ▶ Improved its "Immediate Threat" reporting process to CMS. This process conforms to CLIA-defined timelines.
- ▶ Notifies CMS of substantive changes in The Joint Commission standards and survey processes prior to implementation in the field.
- ▶ Improved its data management of CLIA-related deficiencies which facilitates easier identification of repeat survey deficiencies.

# The Future

- ▶ Focus on new, emerging technologies.
- ▶ Identify best practices.
- ▶ Focus on reduction of error in the pre- and post-analytical phases.
- ▶ Improved oversight of point-of-care testing.
  
- ▶ The Joint Commission is examining a more integrated approach to laboratory and clinical issues.



"Always laugh when you can. It is cheap  
medicine." - Lord Byron