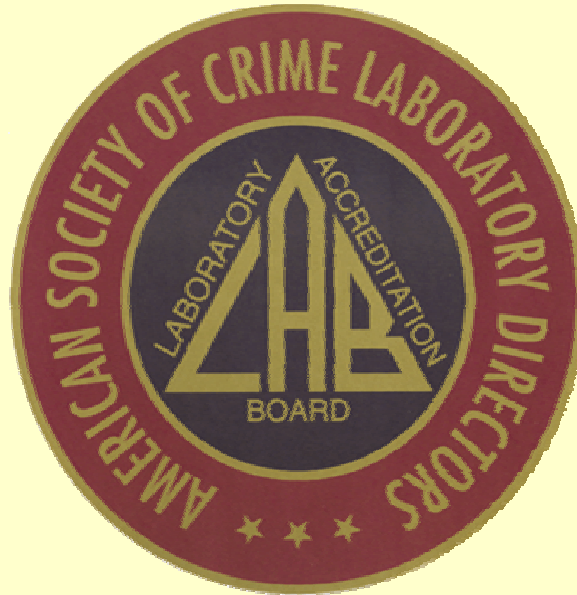


***American Society of Crime Laboratory Directors  
Laboratory Accreditation Board  
(ASCLD/LAB)***



***Promega 16<sup>th</sup> International  
Symposium on Human Identification***

***September 26-29, 2005  
Grapevine, Texas***

# ASCLD/LAB Accreditation Programs Legacy and *International*

## **Presentation Focus:**

- *Review Significant Changes from 2003 ASCLD/LAB Legacy Accreditation Manual to 2005 Accreditation Manual*
- *Review Timetable for Implementation of 2005 Legacy Manual*
- *Review Timetable for Updates to ASCLD/LAB-International Program Documents*
- *Additional Comments*

# *Dual-Track Accreditation Program*

- *On April 1, 2004, ASCLD/LAB began offering accreditation under two separate programs Legacy and International.*
- *ASCLD/LAB continues to offer accreditation under the existing program – Legacy Program. At this time the plan is to accept applications for accreditation under this program until April 1, 2009 and support the program until April 1, 2014.*
- *ASCLD/LAB is also accepting applications for accreditation under the **ASCLD/LAB-International Program** which is an ISO 17025 based accreditation program.*

# ASCLD/LAB-*International*

- *Based on ISO/IEC 17025*
- *Plus Supplemental Requirements based on Essential Requirements from ASCLD/LAB Legacy program and ILAC G 19 (Guidelines for Forensic Science Laboratories)*
- *Accreditation in the International program is for five years with **annual** Surveillance visits.*
- *Opens accrediting bodies up to 3<sup>rd</sup> party review.*



# **301 Laboratories currently Accredited by ASCLD/LAB**

as of 9-24-05

- *13 under ASCLD/LAB-International  
(significant number of applications)*
- *289 under ASCLD/LAB Legacy Program*
- *175 State*
- *80 Local*
- *23 Federal*
- *14 Private*
- *9 International*

# Significant Changes in the 2003 Manual

- *Twenty-two revisions to the ASCLD/LAB Legacy Accreditation Manual were approved by the Delegate Assembly.*
- *The 2005 Manual will be published and distributed by **October 1, 2005.***
- *ASCLD/LAB will accept applications under the 2005 manual immediately upon distribution.*
- *ASCLD/LAB will require all Legacy applications to be under the 2005 Manual on/or after **January 1, 2006.***

# *Summary of Relevant Revisions*

- *Documentation of Compliance must be maintained by the laboratory throughout the period of accreditation (five years).*
- *Standards for Individual Characteristic Databases (CODIS, NIBIN, AFIS) established.*
- *Defines Individual Characteristic Databases and Individual Characteristic Database Samples*

# *Relevant Changes continued....*

- *Annual Accreditation Audit Report due on anniversary of accreditation rather than April 1*
- *Reports of work must be generated.*
- *Reports must contain conclusions and opinions which address the purpose of the analysis.*
- *The significance of associations must be communicated clearly and properly qualified.*



# Relevant Changes continued....

- ***Serology** redefined as: A sub-discipline of biology, which is concerned with the identification of biological materials through the use of various tests.*

# Relevant Changes continued....

- *Evidence, physical defined as: Anything detectable by sensory, physical, chemical, optical or electronic means, including those things in a digital or multimedia form, that provides factual information about crime.*

# Relevant Changes continued....

- *A laboratory which must be accredited to satisfy legislation such as the “Justice for All Act” may seek accreditation in DNA only for a two-year period.*
- *The accreditation in a single discipline is for two years after which the laboratory must seek accreditation in all disciplines in which it provides services.*

# Updates to International Program Documents

- *ISO/IEC 17025: 2005 was published by ISO in May 2005.*
- *The ASCLD/LAB-International Supplemental Requirements document will be revised to align it with the new ISO/IEC 17025 document and the 2005 Legacy Manual.*
- *Target publication date for the new ASCLD/LAB-International Supplemental Requirements document is January 1, 2006.*
- *Compliance with ISO/IEC 17025:2005 and the 2006 Supplemental Requirements will be phased in during 2006.*

# FBI Quality Assurance Standards

- *In 2000, ASCLD/LAB signed an agreement with the FBI that for all ASCLD/LAB inspections involving DNA analysis, the FBI's DNA Audit Document will be used as a supplement to ASCLD/LAB standards for both the Legacy and International Programs.*
- *ISO/IEC 17025 ASCLD/LAB Supplement to 4.1.2 Note regarding FBI Audit Document use when DNA is part of laboratories scope.*

# Criteria File

*Useful in preparing for and conducting the on-site.*

## *Legacy Program:*

- *Must be completed by the laboratory and made available prior to on-site inspection*
- *A file (electronic or hard copy) which documents compliance with each of the criteria of the accreditation program*
- *Available in interactive format on the ASCLD/LAB website*

# Conformance File

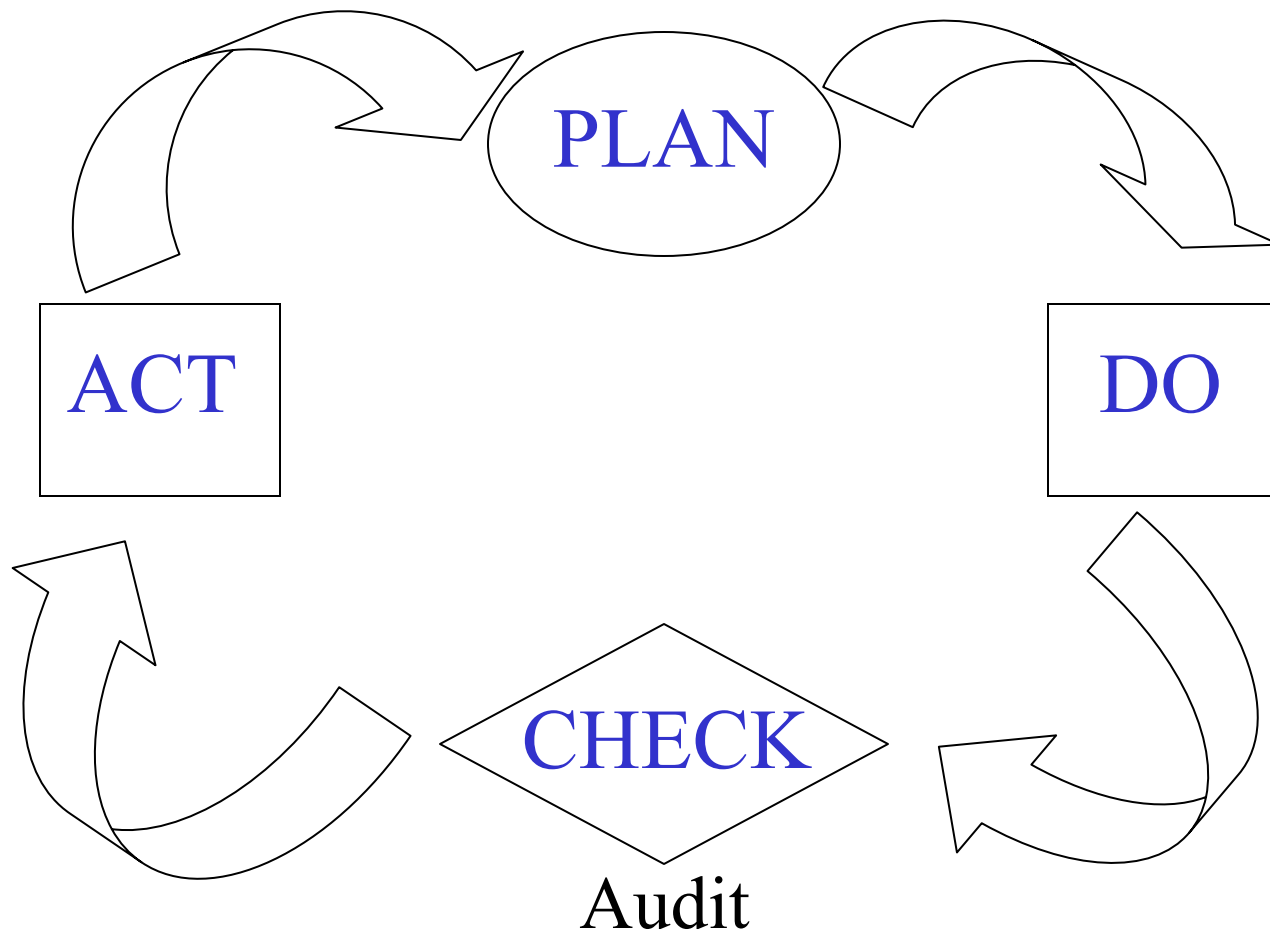
## International Program:

*Includes all applicable documentation of conformance with each requirement or the location of the policies and procedures that reflect conformance.*

- Allows feedback to laboratory prior to setting visit*
- **Must be created by the laboratory and made available prior to on-site assessment.***
- Part of the laboratories internal audit or GAP analysis which assists in identifying missing elements and readiness for the on-site assessment.*
- Optional pre-assessment visit by lead assessor (not required) to conduct a gap-analysis.*

# Process Managing (*Deming*)

## *Laboratory Inspection/Assessment*





# ASCLD/LAB Audit Process

- *Internal audits to assure a consistent high quality product.*
- *Legacy - Draft inspection reports are audited post inspection.*
- *International – Assessment reports are audited prior to Summation Conference with the laboratory.*
- *FBI DNA Quality Assurance Audit Document is audited by an FBI Trained Auditor. Newly added audit process.*

# Audit-Draft Inspection Report (Legacy)

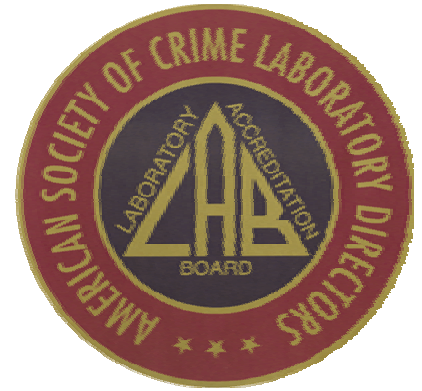
- *At the completion of the inspection, a Draft inspection report is formulated.*
- *The Draft report is pre-decisional, pending consideration of the Board of Directors.*
- *No report is left.*
- *The “draft” report to the ASCLD/LAB Executive Director.*
- *The report is forwarded to staff inspectors and Board Coordinator who will participate in an audit, for comment and questions.*
- *All comments received are compiled and discussed during an Audit Committee conference usually within a week.*
- *Audited Report sent to the laboratory.*

# Audited Summary Assessment Report (*International*)

- *A Quality Review Panel will conduct an audit of the Summary Assessment Report, consisting of the CAR's for each non-conformity (level 1 and 2).*
- *Prior to the summation conference and presentation of the Report to the laboratory director.*
- *A copy is left with the laboratory.*
- *Full assessment report will be completed by the Lead Assessor within 15 days of the Summation Conference.*

# Sampling Plan

- *ISO 17025 Clause 5.7.1*
- *“The laboratory shall have a sampling plan and procedures for sampling.....”*
- *Based on appropriate statistical methods*
- *ASCLD/LAB Supplemental Note 3.*



# Further Information

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