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

Promega 16th 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 3rd 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

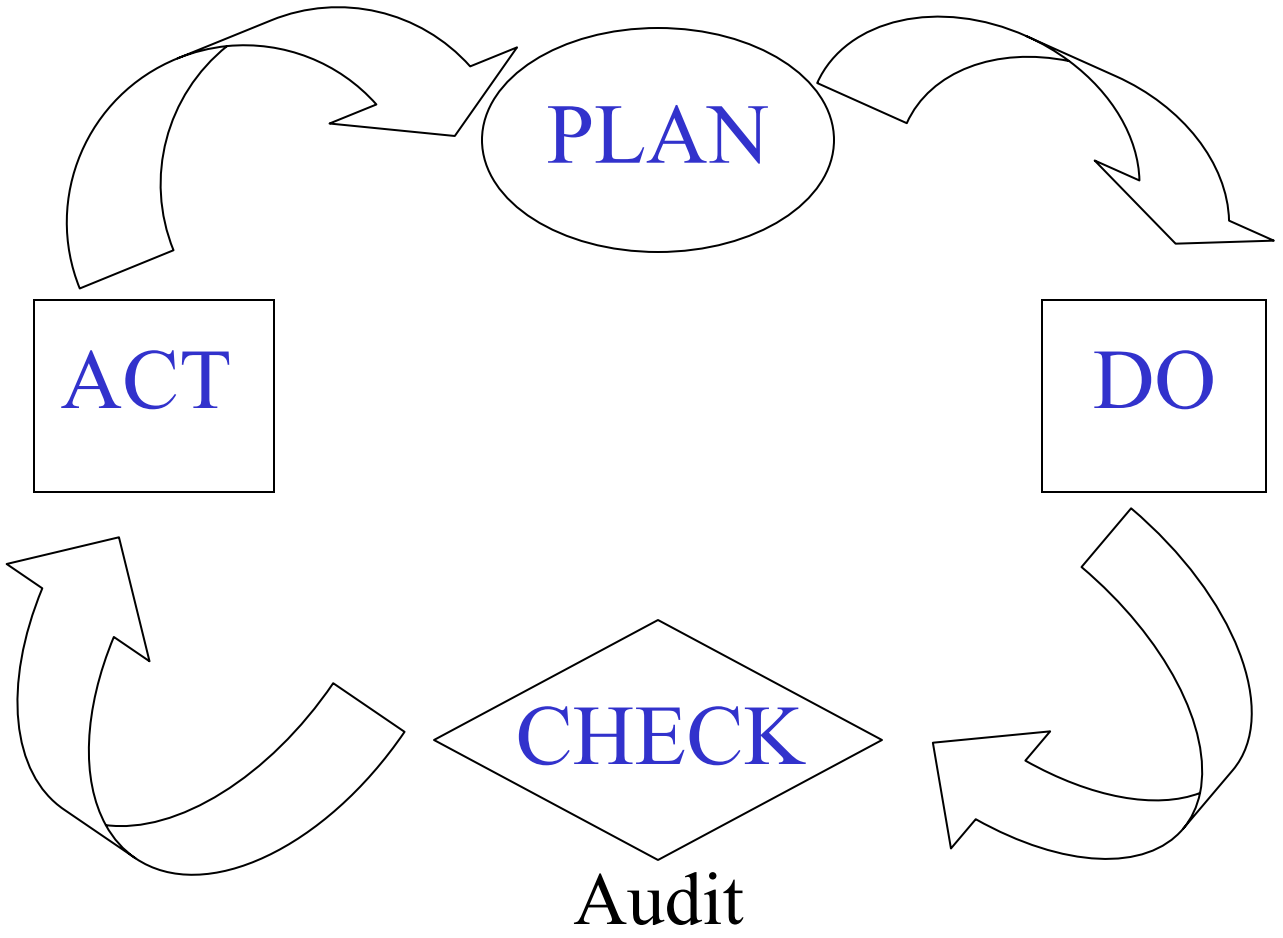
International Program:

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 1and 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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