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DNA Quality Assurance Standards Audits Issues

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NIJ Disclaimer

- This project was supported by NIJ Award #2008-DN-BX-K073 awarded by the National Institute of Justice, Office of Justice Programs, U.S. Department of Justice. The opinions, findings, and conclusions or recommendations expressed in this publication/program/exhibition are those of the author(s) and do not necessarily reflect those of the Department of Justice."

Standards with the Most Findings -2010 (7/1/09 – 11/12/2010)

Standard 3.3 (new)

- Is the quality system as applicable to DNA reviewed annually (calendar year) independent of the audit required by Standard 15, and is the review performed under the direction and documented approval of the technical leader?

Standards with the Most Findings -2010, cont.

Standard 12.3.2 (new)

- 12.3.b - Does the administrative review include the following elements (any or all of which may be included within the technical-review process):
  - 12.3.2 - A review of the individual's biographical data, qualifying offense, and DNA profile generated from reanalysis, as applicable?

Standards with the Most Findings -2010, cont.

Standard 10.2 (new)

- Does the laboratory have and follow a documented program for conducting performance checks and calibrating equipment and instruments?

Standard 14.2 (new)

- Prior to implementation do all corrective actions have the documented approval of the technical leader?

Standards with the Most Findings -2010, cont.

Standard 7.1.1 (new)

- For evidence and sample identification:
  - a. Is all evidence marked with a unique identifier on the evidence package?
  - b. Does the laboratory clearly define what constitutes evidence and what constitutes work product?
  - c. Does the laboratory have and follow a method to distinguish each sample throughout processing?

Overturned Findings

Standard 3.1- For the DNA laboratory's quality assurance program:

3.1.1.15 - Outsourcing?

- If a laboratory is not outsourcing, they can state that in the quality assurance program and not have a documented procedure. For example, "If outsourcing of DNA samples is done, this position shall also be responsible for the approval of the technical specifications…."

Overturned Findings, cont.

Standard 3.3 - Is the quality system as applicable to DNA reviewed annually (calendar year) independent of the audit required by Standard 15, and is the review performed under the direction and documented approval of the technical leader?

- A finding stating that this hadn't been conducted was overturned because the laboratory submitted a corrective action stating that this was documented in the appendix section of the quality manual.

Overturned Findings, cont.

Standard 5.1.3.2 – For the review of scientific literature:

a. Does the laboratory have a program, approved by the technical leader, for the annual review of scientific literature that documents the ongoing reading of scientific literature?

- Finding under this section stated that the Technical Leader had not met the requirements for literature review in 2008. This was a finding from the previous year's audit (2009) and a corrective action was put in place. It is not appropriate to give a repeat finding that has a successful corrective action in place.

Overturned Findings, cont.

Standard 5.2.5 - Did each technical leader appointed or hired on or after July 1, 2009, document a review of the following:

5.2.5.1 - Validation studies and methodologies currently used by the laboratory?

5.2.5.2 - Educational qualifications and training records of currently qualified analysts?

- There was a finding because the interim technical leader had not reviewed the validation studies and educational qualifications. This interim TL was in place for 7 weeks. The finding was overturned since the interim TL was only in place for a limited duration, this is not considered an 'appointment' to that position.

Overturned Findings, cont.

Standard 9.6 – Does the laboratory have and follow written guidelines for the interpretation of data?

- The laboratory has 3 different methods for the calculation of OL alleles. One method was more difficult for mixture interpretation. The laboratory provided NDIS with documentation to demonstrate that the analyst followed the defined laboratory protocol.

Overturned Findings, cont.

Standard 9.6 – Does the laboratory have and follow written guidelines for the interpretation of data?

- The audit team observed a case file reports which contained mixture results that were reported as single contributors. Case files showed heterozygote profiles reported as homozygote due to one allele not satisfying the interpretation threshold.

Overturned Findings, cont.

- The laboratory sent their interpretation guidelines to NDIS and argued it was a difference in professional opinion. The results table had the 'homozygous " profiles, however the conclusion section of the report fully explained the profiles to be 'partial and no further interpretation could be made'

Overturned Findings, cont.

Standard 11.1.b - Does the laboratory maintain all analytical documentation generated by analysts related to case analyses?

- There was a finding because a laboratory was writing hand-written notes, then typing the information into a LIMS system followed by the destruction of the hand-written notes. The finding was overturned; analysts are allowed to transcribe their notes into a LIMS system.

Overturned Findings, cont.

Standard 11.2 - Do the laboratory reports include the following elements:

11.2.9 - Signature and title, or equivalent identification, of the person accepting responsibility for the content of the report?

- There was a finding because the laboratory had two signatures on the reports, one for the analyst and one for the technical reviewer. The finding was overturned because the report clearly delineated the roles of each person signing the report.

Overturned Findings, cont.

13.1.4.1 – If a team approach is used, have all analysts, technicians, and technical reviewers been proficiency tested according to standard 13.1?

- An analyst transferred from another laboratory and is performing technical reviews and there was no documentation of an external proficiency test.
- The laboratory was not on-line with their DNA program.

Miscellaneous Information

- Identifiler and Identifiler Plus are considered different kits and if a laboratory moves from one kit to the other, they will have to perform an internal validation. A performance check will not suffice.
- If retesting is performed on a sample extracted prior to 7/1/2009 and the reagent blank was consumed in the original testing then the laboratory can use the old data from the reagent blank to show it was blank. However this will not apply if they are doing the analysis using a new technology that was not originally used on the sample.

Miscellaneous Information, cont.

- 11.2.7 Date issued? The date issued on a report can be laboratory defined.
  - If an analyst does work on a case (in a technician capacity) he/she does not have to be listed on the report (i.e. signature). This only need to be documented in the case file. Only the analyst taking responsibility for the analysis and interpretation of the case needs be listed in the report.

Miscellaneous Information, cont.

- For laboratories performing any Y based technology (quantitation and/or STR) - all Y kits are considered different technologies from Human Quant and/or nuclear STRs. Therefore, these methods must be performed on both proficiencies in the year. If a laboratory is doing Profiler and COfiler and Identifiler, then they only need to do each kit on one proficiency per year.

Miscellaneous Information, cont.

- Audit documents must be submitted 30 calendar days of receipt from the audit team

- If you contest or disagree with a finding, but complete the remediation, NDIS will not overturn the finding

Common Issues

- All N/A ratings must be explained
- Remember that some NO ratings have parent standards that will need to be rated NO as well
- Standard 5.2.3.1 and its subcategories must be satisfied in order to demonstrate that the technical leader is accountable for the technical operations. If not, then standard 4.1.2 must be rated NO in addition to standard 5

Common Issues

- 8.2 Have developmental validation studies preceded the use of a novel methodology for forensic DNA analysis?
- 8.3 Except as provided in Standard 8.3.1.1, have internal validation of all manual and robotic methodologies been conducted by each laboratory and reviewed and approved by the laboratory's technical leader prior to use?
- 8.4 Has the analyst or examination team successfully completed a competency test using the DNA analysis procedure prior to its incorporation into casework applications?

Common Issues

- If a laboratory has no new validations (developmental or internal) since their last external audit, how are 8.2, 8.3, and 8.4 rated?
  - 8.2 should be rated Yes or No – not N/A
  - 8.3 and 8.4 should be rated N/A with a comment

Common Issues

- Standard 6.1.4 - If a robotic workstation is used to carry out DNA extraction, quantification, PCR setup, and/or amplification in a single room, has the laboratory validated the analytical process in accordance with Standard 8?
  - a. If the robot performs analysis through amplification, is the robot housed in a separate room from that used for initial evidence examinations?
- Discussion - When robotic workstations are not used to carry out DNA extractions through PCR setup on casework samples in a single room, Standard 6.1.4 shall be marked "N/A."

Common Issues

- 8.5 - Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples prior to their incorporation into casework applications?
- 8.6 - Has the laboratory evaluated each additional or modified critical instrument by conducting a performance check prior to its use in casework?
- 8.7 - Has the laboratory evaluated software upgrades by conducting a performance check prior to use in casework?
  - a. Has new software or significant software modifications been documented and subjected to validation testing prior to use in casework?
- Regardless of the rating for these, a comment is ALWAYS required

Common Issues

- 9.5.4 - Does the laboratory use allelic ladders and internal size markers for VNTR sequence PCR- based systems?

- STRs are VNTRs – this should be rated YES in laboratories conducting STR typing

Common Issues

- 9.6.3 Does the laboratory have and follow specific documented statistical interpretation guidelines if genetic analyses that are not addressed by Standard 9.6.2 are being performed?
- 9.6.2 Has the 1996 National Research Council report and/or a court-directed method been used for the statistical interpretation of a DNA profile for a given population and/or hypothesis or relatedness, and are these calculations derived from an established population database(s) appropriate for the calculation?

Common Issues

- 10.2.1 At a minimum, are the following critical instruments or equipment performance-checked at least annually:
  - 10.2.1.5 Electrophoresis detection systems?
  - 10.2.1.7 Genetic analyzers?
- For most laboratories, standard 10.2.1.5 will be rated N/A with the following comment: Standard 10.2.1.5 is rated N/A since the laboratory does not use electrophoresis detection systems other than Genetic Analyzers

Auditor Training

- This is now available on-line through the FBI Virtual Academy at https://fbiva.fbiacademy.edu

- You will need to register

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Thank you.

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This project funded through NIJ Award or Cooperative Agreement # 2008-DN-BX-K073.
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