



February 9, 2017

Via E-mail to [lynn.garcia@fsc.texas.gov](mailto:lynn.garcia@fsc.texas.gov)

Ms. Lynn Garcia, General Counsel  
Texas Forensic Science Commission  
1700 North Congress, Suite 445  
Austin, TX 78701

Dear Ms. Garcia,

As a follow-up to our discussion on January 11, 2017, related to the questions posed by the Texas Forensic Science Commission to ANAB (ASCLD/LAB) in the letter dated July 26, 2016, I am providing a written response for submission to the Commission.

The questions posed by the Commission as a result of the assessment of the Austin Police Department Forensic Science Laboratory are repeated below.

1. Do assessors consistently consider whether a laboratory's protocols and underlying validation are based on sound scientific principles or do they limit their review to determining whether the laboratory has a protocol in place that it follows?

The purpose of an assessment is to evaluate the laboratory's compliance with the applicable accreditation standards and requirements. Laboratory protocols are assessed for compliance at each full assessment and during each FBI QAS audit. These assessments are conducted by assessors technically competent in the specific disciplines defined by a laboratory's scope of accreditation. Following implementation of a newly validated method, the validation study is assessed for compliance to applicable requirements during the next on-site assessment and/or in conjunction with a FBI QAS audit. As previously mentioned, the assessments are conducted by individuals technically competent in the specific discipline. Once a validation study has been reviewed, it is not typically re-assessed during subsequent visits either by ANAB or as part of a QAS audit.

The assessment is not limited to determining if a protocol is in place and being followed. The currently applicable standard requires not just that methods/procedures exist and are followed but that they are appropriate for the tests undertaken (ISO/IEC 17025:2005 5.4.1 and 5.4.2) and validated to determine that they are fit for the intended use (ISO/IEC 17025:2005 5.4.5).

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2. If it is not the accrediting body's role to establish or assess the foundational scientific validation of the analytical methodologies used by DNA labs which entities are responsible?

It is the role of the scientific community to establish the scientific foundation of analytical methodologies. It is the role of the accrediting body to assess a laboratory's compliance with applicable accreditation standards and requirements.

3. Should assessors re-review validation data from prior years considering one validation study may be relied upon to build subsequent studies and protocols?

The reliance on a previous validation study should be considered when developing a new validation study. The laboratory should evaluate the applicability of the previous study and any areas that need to be addressed should be incorporated into the new study.

The new ANAB Forensic Science Testing Laboratories Accreditation Requirements, currently in draft form, include a requirement for the laboratory to have a procedure for method validation. The requirement further specifies what needs to be included in the procedure.

4. Are assessors properly educated and trained to undertake the task of reviewing and assessing the reliability of the methods implemented in the laboratory?

Our assessors are technically competent in their disciplines but experience with reviewing validation studies does vary between individuals. We are evaluating how we can enhance our current process of reviewing validation studies. As mentioned above, the new ANAB Forensic Science Testing Laboratories Accreditation Requirements include specific requirements for method validation. Those requirements will assist assessors in evaluating method validation studies.

5. Is there a point at which SWGDAM "guidelines" become so widely accepted in the DNA community that they should be incorporated as supplemental accreditation standards and if so, is there a process for accomplishing that?

SWGDAM guidelines are not written as requirements documents. The SWGDAM guidelines documents themselves state that they contain "guidelines and not minimum standards." Guidelines frequently use the word "should" when establishing a recommendation. A recommendation does not equal a requirement. Applying SWGDAM guidelines as minimum technical requirements for the DNA discipline explicitly goes against the intended use of those documents.

6. What lessons have been learned in other audits of casework involving DNA mixture interpretation (such as the ANAB audit of the Washington, DC lab in April 2015 or ASCLD/LAB's recent assessment of the Broward County Sheriff's DNA lab)? Has a systemic root cause analysis been performed in those situations and what can we learn from them?

What we are learning from these assessments is that there is not as clear of a consensus in the DNA community regarding mixture interpretation as we may have thought and that the lack of published technical requirements for this discipline makes it possible for labs to apply inappropriate techniques. The lack of published technical requirements also allows for variation amongst assessors when determining whether a method is appropriate.

7. How can state-based oversight bodies like the Commission provide support for ASCLD/LAB, ANAB and other recognized accrediting bodies?

While state-based oversight bodies could choose to establish additional requirements of their own, it would not be ideal to have 50 different sets of requirements across the country. Collaborating at a national level to create discipline specific technical requirements that can be implemented in laboratories across the country is a good path forward. Encouraging laboratories to implement nationally accepted protocols in the various forensic disciplines would help to standardize practices across the country.

In addition to the responses to the Commission's questions above, I would also like to provide some clarifying information related to the accreditation process that the Commission may find helpful. ASCLD/LAB assessed the Austin Police Department Forensic Science Laboratory in 2005 and 2010 under the ASCLD/LAB Legacy Manual. The requirements under that program were substantially different than the current accreditation standard (ISO/IEC 17025:2005) and the ASCLD/LAB-International Supplemental Requirements for Forensic Science Testing Laboratories. The laboratory was not assessed against the current accreditation requirements until 2015. This should be taken into consideration when evaluating the laboratory's performance based on the current requirements.

Please continue to maintain an open line of communication with ANAB regarding issues or concerns that the Commission has related to accreditation. Our discussions generate valuable opportunities to further enhance the ANAB accreditation program.



Sincerely,

Pamela L. Sale  
Vice President, Forensics