Kentucky State Police Division of Forensic Services

2024 - 17025T - Reassessment

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Data collected on 2024-05-13

ANSI National Accreditation Board

United States

Description

This assessment report summarizes the outcome of the recent accreditation activity. A separate document, the assessment plan, provides information on the type of activity (*e.g.,* reassessment, surveillance activity, scope extension), the date(s) of the activity, the assessment team members, the requirement documents and refers to the scope of the discipline(s) assessed for each location. The assessment plan, together with this report, provide a complete picture of the accreditation activity.

The ANSI National Accreditation Board (ANAB) evaluated the competence of the laboratory and conformance with all applicable accreditation requirements for the scope of accreditation referenced in the assessment plan. Objective evidence of implementation was assessed. The results of an assessment activity are based on a sample of records, locations, and personnel that were available at the time of the activity. Witnessing is an additional technique used in most activities.

REQUIREMENTS:

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories & ANAB Accreditation Requirements for Forensic Testing and Calibration (AR 3125) evaluated over the accreditation cycle are summarized in the following broad categories:

General requirements related to the laboratory's commitment to impartiality and confidentiality in its activities.

Structural requirements related to the range of activities, management structure, the authority, roles and responsibilities of personnel. Documented procedures which ensure a consistent application of activities and the validity of results.

Resource requirements related to the impartiality of personnel. Requirements for a training program, competency testing, authorizations, and ongoing monitoring to ensure the competence of personnel. Facility and security suitability for activities. Records and procedures for equipment to ensure proper functioning and where applicable, establishment of metrological traceability. Requirements for externally provided products and services.

Process requirements related to the handling of test and calibration items in a manner to maintain the integrity of the item. Requirements for chain-of-custody of items to be tested and appropriate methods and procedures. Ensuring the required performance of the methods along with monitoring the validity of the results. Requirements to ensure results are supported by sufficient technical records and are reported accurately, clearly, unambiguously, and objectively. Procedures for nonconforming work and a documented process for handling complaints. Requirements related to the laboratory information management system protection and integrity of data and information.

Management system requirements related to policies and objectives appropriate for the scope of activities. Requirements to control internal and external documents and records. Requirements to address risks and opportunities and timely, well-documented corrective actions. Requirements for an internal audit program and management reviews.

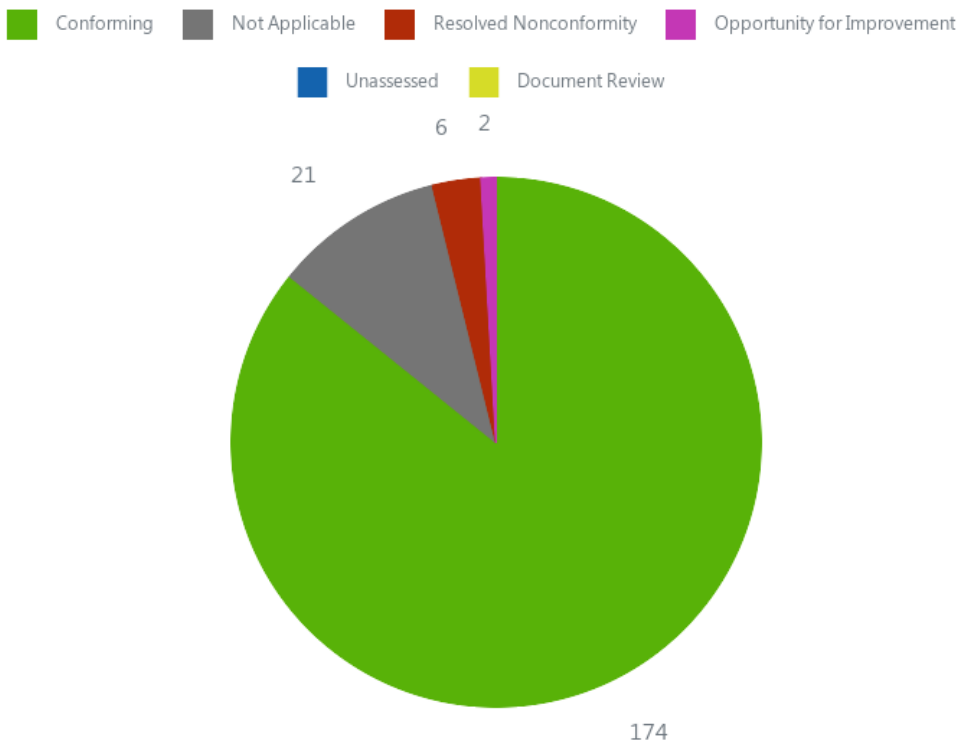
The accreditation activity also evaluates the laboratory’s conformance with their own management system requirements.

ASSESSMENT RESULT:

Based on the assessment techniques and a sample of the objective evidence reviewed during the assessment activity, the assessment team found that the laboratory demonstrated competence to operate a management system that fulfills all applicable accreditation requirements, including those specified within their management system.

Any opportunities for improvement or nonconformities identified during this assessment activity are noted below. All nonconformities will be resolved prior to an accreditation decision by ANAB and a summary provided in a subsequent assessment activity report.

Summary of Comments



Audit Comments

5. Structural requirements

5.4 ISO/IEC 17025:2017 — Resolved Nonconformity

Requirement

Are laboratory activities carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition? Does this include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility?

ANAB NOTE: Example of regulatory authorities are the Federal Bureau of Investigation for laboratories participating in the National DNA Index System (NDIS) and state forensic science commissions providing accreditation.

Nonconformity Resolution Workflow

Specific to QAS-DB 8.1, 8.3, 8.3.1 (2 & 3), 8.3.2, 8.3.3., 8.3.4 and 8.3.4.a. The laboratory made a protocol modification, which required new reagents to be used in conjunction with a direct amplification typing test kit and altered the steps of the procedure, that had an impact on the efficacy of the PCR process or the detection of DNA types. The laboratory did not perform an internal validation study as required by QAS-DB 8.3.3 and the QAS Guidance Document.

Corrective Action Closure Note: The laboratory has contested the finding with NDIS. This nonconformity is resolved.

6.2 Personnel

6.2.2.2 ANAB Accreditation Requirement

Opportunity for Improvement : 0

Requirement

Does the training program for each function influencing the results of laboratory activities, to the extent necessary based on job function, include:
a) the knowledge, skills, and abilities needed to perform work?
b) general knowledge of forensic science?
c) the application of ethical practices in forensic science?
d) criminal law, civil law, and testimony?
e) provisions for retraining?
f) provisions for maintenance of skills and expertise? and
g) criteria for acceptable performance?

NOTE 1 Past work experience and training may be substituted for portions of the training program to the extent that it has been demonstrated to be relevant and sufficient.

NOTE 2 ISO/IEC 17025:2017, section 7.3 may be applicable to training programs

Comments

The Fire Debris training program including the the Interpretation Procedures are very broad. There is a risk to the laboratory that without additional documentation to the training program, the transfer of knowledge will not be maintained.

7.2.1 Selection and verification of methods

7.2.1.1.1 ANAB Accreditation Requirement

Resolved Nonconformity

Requirement

Does the laboratory use appropriate methods and procedures for all associated data analysis and interpretation?

Nonconformity Resolution Workflow

Within the toxicology discipline, several Blood Alcohol reports reported out a numerical value for a level either above or below its established linear calibration curve. By reporting out this numerical value, they cannot interpret the data with any statistical significance.

Corrective Action Closure Note: The laboratory updated the Tox Blood Alcohol SOP to require the analyst to not report out any values outside the calibrated range. Review of the updated procedure and four reports shows the lab is in compliance. This nonconformance is resolved.

7.2.1.2 ISO/IEC 17025:2017

Resolved Nonconformity

Requirement

Are all methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and made readily available to personnel (see 8.3)?

Nonconformity Resolution Workflow

There are several procedures within the Friction Ridge discipline that are not being kept up to date.

Corrective Action Closure Note: The lab updated the seven Friction Ridge procedures that were not up to date. Review of all seven procedures. This nonconformance is resolved.

7.5 Technical records

7.5.1 ISO/IEC 17025:2017

Opportunity for Improvement : 0

Requirement

Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original? Do the technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results? Are original observations, data and calculations recorded at the time they are made and identifiable with the specific task?

ANAB NOTE Options for recording observations include, but are not limited to: written notes, photography, drawing, photocopying, and scanning.

Comments

The lab would benefit from ensuring items that are tested within the Materials discipline are uniquely identified such that another analyst could re-examine the same items that were originally tested.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 ISO/IEC 17025:2017

Resolved Nonconformity

Requirement

Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:
a) a title (e.g. ÒTest ReportÓ, ÒCalibration CertificateÓ or ÒReport of SamplingÓ)?
b) the name and address of the laboratory?
c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratoryÕs permanent facilities, or in associated temporary or mobile facilities?
d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end?
e) the name and contact information of the customer?
f) identification of the method used?
g) a description, unambiguous identification, and, when necessary, the condition of the item?
h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results?
i) the date(s) of performance of the laboratory activity?
j) the date of issue of the report?
k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results?
l) a statement to the effect that the results relate only to the items tested, calibrated or sampled?
m) the results with, where appropriate, the units of measurement?
n) additions to, deviations, or exclusions from the method?
o) identification of the person(s) authorizing the report?
p) clear identification when results are from external providers?

NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

ANAB NOTE 2 A legal requirement that dictates the information to be included in a report is a valid reason to not include one or more listed report elements.

ANAB NOTE 3 i) Date(s) may be reflected as a range of dates or the date of each test or calibration.

ANAB NOTE 4 o) Authorization of the report does not have to be performed by the same person(s) who authorized the results. (see ISO/IEC 17025:2017 7.8.1.1).

Nonconformity Resolution Workflow

Element c)-Biology: Rapid DNA laboratory work is being performed at the Jefferson Laboratory and the Rapid DNA interpretation is being performed at the Central Laboratory, there is no indication on the reports from the Central Laboratory that the laboratory work was done at the Jefferson laboratory.

Element i)-Friction Ridge: All reports reviewed in the Friction Ridge discipline did not contain any start dates of performance of laboratory activity.

Corrective Action Closure Note: Element c)-Review of five Biology reports with the new language that indicates where the work was performed and review of an email notification to the staff of the changes. This nonconformity is resolved.
Element i) Review of five reports shows that the start date is now on each Friction Ridge report. This nonconformity is resolved.

7.8.7 Reporting opinions and interpretations

7.8.7.2 ISO/IEC 17025:2017 — Resolved Nonconformity

Requirement

Are the opinions and interpretations expressed in reports based on the results obtained from the tested or calibrated item and clearly identified as such?

Nonconformity Resolution Workflow

All cases reviewed within the Materials discipline that contained an opinion or interpretation, the opinion or interpretation was not clearly identified in the report.

Corrective Action Closure Note: The lab revised the report template to now include a header of "Results and Opinions". Review of several reports from various disciplines shows the reports clearly identify any result or opinion made. This nonconformance is resolved.

8.3 Control of management system documents (Option A)

8.3.1 ISO/IEC 17025:2017 — Resolved Nonconformity

Requirement

Does the laboratory control the documents (internal and external) that relate to the fulfilment of this document?

NOTE In this context, ÒdocumentsÓ can be policy statements, procedures, specifications, manufacturerÕs instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

Nonconformity Resolution Workflow

The Firearms discipline is using the AFTE Training Manual for all training activities and is not controlling the document.

Corrective Action Closure Note: The lab has now controlled the Firearms Training Manual and makes reference to the AFTE training Manual. Review of the updated manual and Qualtrax workflow. This nonconformance is resolved.