Brazoria County Sheriff's Office - Crime Laboratory

2023 - 17025T - Reassessment

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Data collected on 2023-08-08

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.

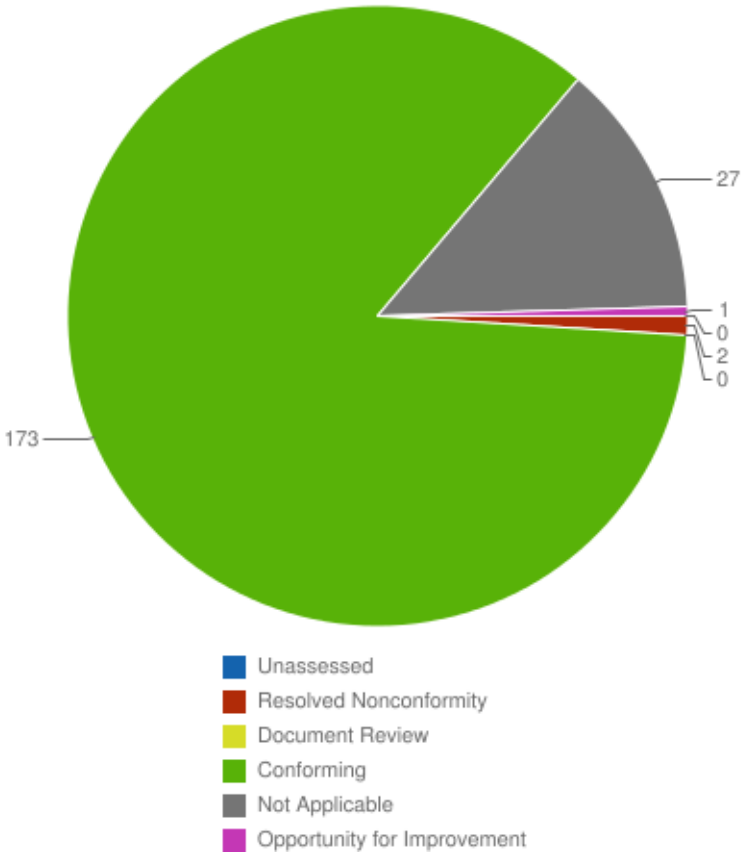
The accreditation activity also evaluates the laboratory’s conformance with their own management system requirements.

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

6.1 General

6.1 ISO/IEC 17025:2017

Opportunity for Improvement : 0

Requirement

Does the laboratory have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities?

Comments

The laboratory will greatly benefit from having the personnel and the facility to manage and perform its laboratory activities.

8.7 Corrective actions (Option A)

8.7.1 ISO/IEC 17025:2017

Resolved Nonconformity

Requirement

When a nonconformity occurs, does the laboratory:
a) react to the nonconformity and, as applicable:
- take action to control and correct it?
- address the consequences?
b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
- reviewing and analysing the nonconformity?
- determining the causes of the nonconformity?
- determining if similar nonconformities exist, or could potentially occur?
c) implement any action needed?
d) review the effectiveness of any corrective action taken?
e) update risks and opportunities determined during planning, if necessary?
f) make changes to the management system, if necessary?

Nonconformity Resolution Workflow

In two of the three seized drugs nonconformities reviewed the laboratory did not determine the causes of the nonconformity.

Corrective Action Closure Note: The Conformity Assessment Body performed cause and extent analysis, revised the Quality Action Plan procedure, and all forms associated with that process to include the determination of the cause, and reevaluated the 2022 and 2023 corrective actions. The revised Quality Action Plan procedure, all forms, and the reevaluation of the 2022, and 2023 corrective actions were reviewed. The nonconformity is resolved.

Nonconformity Resolution Workflow

In all three nonconformities reviewed the laboratory did not review the effectiveness of the corrective action taken.

Corrective Action Closure Note: The Conformity Assessment Body performed cause and extent analysis, revised the Quality Action Plan procedure, and all forms associated with that process to include the review of the effectiveness of any corrective action taken, and reevaluated the 2022 and 2023 corrective actions. The revised Quality Action Plan procedure, all forms, and the reevaluation of the 2022, and 2023 corrective actions were reviewed. The nonconformity is resolved.

8.8 Internal audits (Option A)

8.8.2 ISO/IEC 17025:2017

Resolved Nonconformity

Requirement

Does the laboratory:
a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits?
b) define the audit criteria and scope for each audit?
c) ensure that the results of the audits are reported to relevant management?
d) implement appropriate correction and corrective actions without undue delay?
e) retain records as evidence of the implementation of the audit programme and the audit results?

NOTE ISO 19011 provides guidance for internal audits.

Nonconformity Resolution Workflow

For the 2022, and 2023 internal audits, the laboratory did not implement appropriate correction and corrective action for its findings.

Corrective Action Closure Note: The Conformity Assessment Body performed cause and extent analysis, revised the Laboratory Operations Guide - Internal Audits, and reviewed all the nonconformances documented in the 2022 and 2023 Laboratory Internal Audit. The revised Laboratory Operations Guide - Internal Audits, and the review of all the nonconformances documented in the 2022 and 2023 Laboratory Internal Audit were reviewed. The nonconformity is resolved.