



May 13, 2022

**Division of Criminal Justice Services
Virtual Meeting¹**

10:02 AM – 11:44 AM

DRAFT MEETING MINUTES

DNA Subcommittee Members in Attendance:

Frederick Bieber, Ph.D.
Katherine Gettings, Ph.D.
Ken Kidd, Ph.D.
Jenifer Smith, Ph.D.
Bruce Weir, Ph.D.

DCJS Staff in Attendance:

Dean Defruscio
Jill Dooley
Colleen Glavin
Natasha Harvin-Locklear
Shelley Palmer
Brianna Robinson
Elizabeth Suparmanto

Dr. Weir opened the meeting by stating that the DNA Subcommittee is conducting its meeting virtually. Dr. Weir then conducted a roll call for attendance as the members of the Subcommittee attended from their own locations. A quorum was established with 5 members present (Bieber, Gettings, Kidd, Smith, and Weir; Eastman and Sozer were absent).

*Approximate
video times*

00:00:00 –
00:01:15

Dr. Weir then asked for a motion to approve the agenda. A motion to approve the agenda was made by Dr. Smith, seconded by Dr. Kidd, and approved unanimously.

00:01:15 –
00:02:05

The Chair then asked Subcommittee members for questions or comments on the minutes from the February 4, 2022, meeting of the Subcommittee. Dr. Gettings made a motion to accept the minutes, Dr. Smith seconded the motion, Dr. Kidd abstained. The motion passed.

00:02:05 –
00:03:11

¹ Due to the Coronavirus (COVID-19), and pursuant to Chapter 56 of the Laws of 2022 authorizing the meetings of any state agency, department, corporation, office, authority, board, or commission, as well as any local public body, or public corporation, or a committee or subcommittee or other similar body of such entity to be held remotely by conference call or similar service.

Approximate
Video Times

Next, the Subcommittee reviewed Accreditation/Laboratory updates from the Erie County Central Police Services Forensic Laboratory, Monroe County Crime Laboratory, New York State Police Crime Laboratory, and Onondaga County Center for Forensic Science. Representatives from the laboratories were available to answer questions as needed.

00:03:20 –
00:24:10

During Accreditation/Laboratory updates, the Subcommittee reviewed the final documentation from the ANAB reaccreditation assessment activity of the Erie County Central Police Services Forensic Laboratory. The Chair called for a motion to issue a binding recommendation to the Commission on Forensic Science to renew the New York State Accreditation of the Erie County Central Police Services Forensic Laboratory in the discipline of Biology for the period concurrent with its ANAB accreditation to expire August 31, 2026. Dr. Smith made the motion, Dr. Kidd seconded the motion, and the motion was approved unanimously.

00:03:20 –
00:07:55

The Subcommittee also reviewed the final documentation from the ANAB reaccreditation assessment activity of the New York State Police Crime Laboratory. The Chair called for a motion to issue a binding recommendation to the Commission on Forensic Science to renew the New York State Accreditation of the New York State Police Crime Laboratory in the discipline of Biology for the period concurrent with its ANAB accreditation to expire May 31, 2026. Dr. Bieber made the motion, Dr. Gettings seconded the motion, and the motion was approved unanimously.

00:08:49 –
00:22:20

The Chair then moved to Old Business. A verbal update was provided on the Partial Match and Familial Search programs. During the Familial Search update, the Subcommittee discussed the May 5, 2022, First Judicial Department in the Appellate Division ruling in the Matter of Stevens et. al., v. The New York State Division of Criminal Justice Services, the New York State Commission on Forensic Science, and the DNA Subcommittee of the New York State Commission on Forensic Science. The members expressed concern with the decision. Dr. Bieber made a motion for the Subcommittee to ask the Commission on Forensic Science to formulate and write to the Attorney General of New York to urge her to file an appeal forthwith and communicate the willingness of the Subcommittee to assist with preparing technical documentation. Dr. Smith seconded the motion, which was approved unanimously.

00:24:10–
00:43:50

There were no updates regarding CODIS Bulletins. Finally, the Subcommittee discussed a memorandum from the BIOTWG addressing the questions posed at the February meeting regarding proficiency testing. BIOTWG co-chair Craig O'Connor was available to address the memo and additional questions of the Subcommittee.

00:44:03 –
00:56:32

Next, the Subcommittee reviewed a laboratory disclosure from the New York City OCME Department of Forensic Biology.

00:56:37 –
00:59:48

Dr. Weir then requested a motion to enter Executive Session to discuss matters relating to a current investigation or matters that may lead to the appointment, promotion, demotion, discipline, or suspension of a person. Dr. Bieber made the motion, which was seconded by Dr. Smith and approved unanimously.

00:59:51 –
01:01:50

*Approximate
video times*

The Subcommittee adjourned into Executive Session with all present members in attendance. The Subcommittee discussed ongoing investigations, and no action was taken. Executive Session commenced at 11:12 AM and concluded at 11:41 PM. The Subcommittee reconvened the Open Meeting.

The Chair stated that no action was taken in Executive Session. Dr. Weir wanted to revisit his comments from earlier in the meeting regarding statistical calculations and reporting. He then made a motion to form a working group of 2 or 3 Subcommittee members to work in conjunction with the BIOTWG to examine the current procedures for calculating and reporting statistical strength of DNA evidence. Dr. Smith seconded the motion, and it was approved unanimously. The next meeting of the Subcommittee will take place on August 5, 2022, with the location to be determined. A motion to adjourn was made by Dr. Gettings, seconded by Dr. Smith, and approved unanimously.

01:01:50 –
01:04:03

Note: Video of the meeting is available at <https://www.youtube.com/user/nyspublicsafety>



Date July 12, 2022

John R. Clark
Monroe County Crime Laboratory
85 West Broad Street
Rochester, NY 14614

Dear Director Clark,

Congratulations! On July 11, 2022, ANAB renewed your organization's accreditation in the Field of Forensic Testing. This decision was based upon the documentation provided in the assessment report and in accordance with the recommendation of the Lead Assessor. ANAB is satisfied that your organization has met or exceeded the accreditation requirements and requirements of your own documented management system.

Accredited forensic service providers are expected to maintain the standards which were required to achieve accreditation and conform to [ANAB Terms and Conditions for Accreditation](#). The principal means used to monitor ongoing conformance include surveillance activities, proficiency testing reports submitted by approved test providers, and disclosure of significant events and nonconformities. The results of these monitoring activities will be considered when confirming the continuation of accreditation between assessments.

The planned surveillance activity and reassessment schedule is listed below:

- | | |
|--------------|------------------------------|
| • April 2023 | Surveillance Document Review |
| • April 2024 | Surveillance Assessment |
| • April 2025 | Surveillance Document Review |
| • April 2026 | Reassessment |

The provided ANAB accreditation symbol may be used to convey your accredited status. An accreditation symbol must not be used in any way which implies accreditation in any area outside of the scope of accreditation. If appropriate, the accreditation symbol may be used on your organization's website, reports, letterhead, business cards, and other official documents. Please refer to [PR 1018 Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status](#) for all required information. This policy also provides information on your ability to use a combined mark that contains the ANAB accreditation symbol and the International Laboratory Accreditation Cooperation (ILAC) mark.

The report and an electronic version of accreditation documents are included with this letter.

Achieving accreditation is the result of an extensive commitment of resources and much preparation by the management and personnel of the entire organization. I commend the efforts of all who were involved in this achievement. On behalf of ANAB, I extend my sincere congratulations to you. If you

have any questions or if ANAB might assist you in any way, please feel free to get in touch with us at qualitymatters@anab.org.



Brad Putnam
Director of Accreditation
ANSI National Accreditation Board

cc: Marcia Bledsoe, Quality Assurance Coordinator
ANAB Office



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Monroe County Crime Laboratory
85 West Broad Street, Rochester, New York 14614 USA

Fulfills the requirements of

ISO/IEC 17025:2017

ANAB Forensic Testing & Calibration AR 3125:2019

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories:2020

In the field of

Forensic Testing

This certificate is valid only when accompanied by a current scope of accreditation document.

The current scope of accreditation can be verified at www.anab.org.



Pamela L. Sale, Vice President, Forensics

Expiry Date: 31 August 2026
Certificate Number: FT-0312





ANSI National Accreditation Board



SCOPE OF ACCREDITATION TO:
ISO/IEC 17025:2017
ANAB Forensic Testing & Calibration AR 3125:2019
FBI Quality Assurance Standards for Forensic DNA Testing Laboratories:2020

Monroe County Crime Laboratory

85 West Broad Street
Rochester, New York 14614 USA

FORENSIC TESTING

Expiry Date: 31 August 2026

Certificate Number: FT-0312

Discipline: Biology		
Component/Parameter	Item	Key Equipment/Technology
DNA Profile Determination	Short Tandem Repeat (STR) Y-Short Tandem Repeat (Y-STR)	Capillary Electrophoresis
Individual Characteristic Database	DNA Profile	National DNA Index System (NDIS)
Physical Comparison	DNA Profile	Software Program
Qualitative Determination	Body Fluid	Chemical Fluorescence Spectroscopy General Microscopy Immunoassay

Discipline: Fire Debris and Explosives		
Component/Parameter	Item	Key Equipment/Technology
Qualitative Determination	Explosive	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microcrystalline X-Ray Fluorescence Spectroscopy
Qualitative Determination	Fire Debris	Gas Chromatography Mass Spectrometry

Discipline: Firearms and Toolmarks		
Component/Parameter	Item	Key Equipment/Technology
Distance Determination	Firearm Physical Item	Chemical General Microscopy Measuring Equipment
Function Evaluation	Air Gun Firearm Silencer	Dead Weight Measuring Equipment Visual
Individual Characteristic Database	Ammunition	National Integrated Ballistic Information Network (NIBIN)
Physical Comparison	Ammunition Tool/Toolmark	General Microscopy Measuring Equipment Visual
Qualitative Determination	Ammunition Firearm Metal Nitrate Tool	Chemical General Microscopy Measuring Equipment Reference Collection
Serial Number Restoration	Physical Item	Chemical General Microscopy Magnetic Visual

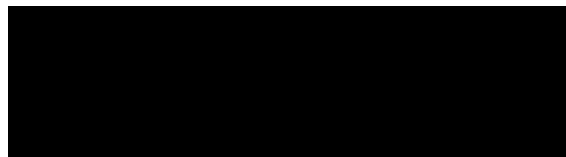
Discipline: Impressions		
Component/Parameter	Item	Key Equipment/Technology
Enhancement	Footwear Physical Item Tire	Chemical Software Program
Physical Comparison	Footwear Physical Item Tire	Software Program Visual
Qualitative Determination	Footwear Tire	Reference Collection

Discipline: Materials (Trace)		
Component/Parameter	Item	Key Equipment/Technology
Chemical/Physical Comparison	Coating Fiber/Textile Fractured Item General Unknown Glass Hair Tape	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microspectrophotometry Refractometry Thin-Layer Chromatography

		Visual X-Ray Fluorescence Spectroscopy
Qualitative Determination	Coating Fiber/Textile General Unknown Glass Hair Tape	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microspectrophotometry Reference Collection Refractometry Thin-Layer Chromatography Visual X-Ray Fluorescence Spectroscopy

Discipline: Seized Drugs		
Component/Parameter	Item	Key Equipment/Technology
Qualitative Determination	Botanical Liquid Solid	Chemical Gas Chromatography General Microscopy Infrared Spectroscopy Mass Spectrometry Microcrystalline Thin-Layer Chromatography Visual
Quantitative Measurement	Solid	Gas Chromatography
Weight Measurement	Botanical Liquid Solid	Balance

When published on a forensic service provider's Scope of Accreditation, ANAB has confirmed the competence required to develop and validate methods and perform on-going quality assurance for accredited activities. For a listed component/parameter, the forensic service provider may add or modify methods for activities without formal notice to ANAB for items and key equipment/technology listed. Contact the forensic service provider for information on the method utilized for accredited work.



Pamela L. Sale
Vice President, Forensics

Received by OFS
7/12/22



Monroe County Crime Laboratory

2022 - 17025T - Reassessment

Prepared by Lucy Davis

Audit Date

25 Apr, 2022

Data collected on 2022-04-25

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 the scope by discipline that was assessed for each location. The assessment plan, together with this report, provides a complete picture of the accreditation activity.

The ANSI National Accreditation Board (ANAB) evaluated the competence of the forensic service provider and conformance with all applicable accreditation requirements for the scope of accreditation listed 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 on-site activities.

REQUIREMENTS:

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

General requirements related to the forensic service provider'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.

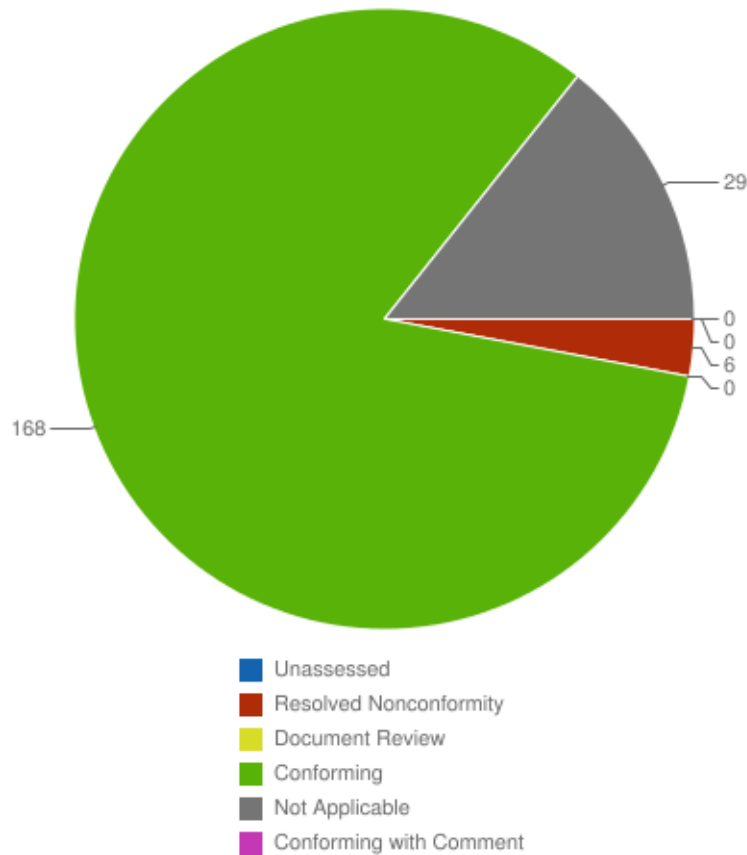
The accreditation activity also evaluates forensic science provider's conformance with their own management system requirements.

ASSESSMENT RESULT:

Based on the assessment techniques and sampling reviewed during the assessment activity, the assessment team found that the forensic service provider demonstrated competence to operate a management system that fulfills all applicable accreditation requirements, including those specified within their management system.

Any comments (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

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

7.8.2.1 ISO/IEC 17025:2017

Resolved Nonconformity

Obligation

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 title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling")?
- the name and address of the laboratory?
- the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities?
- unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end?
- the name and contact information of the customer?
- identification of the method used?
- a description, unambiguous identification, and, when necessary, the condition of the item?
- 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?
- the date(s) of performance of the laboratory activity?
- the date of issue of the report?
- 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?
- a statement to the effect that the results relate only to the items tested, calibrated or sampled?
- the results with, where appropriate, the units of measurement?
- additions to, deviations, or exclusions from the method?
- identification of the person(s) authorizing the report?
- 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).

Add Nonconformity Resolution Workflow

The laboratory has two methods to conduct sampling in Seized Drugs. The reports only indicate that "a hypergeometric sampling plan was used for the analysis" and does not define which of the two available plans were used.

Corrective Action Closure Note: The laboratory provided the Corrective Action form, cause analysis, revision of procedure "Reporting v2022.1", and a report issued 6/8/2022. The cause was determined that in June 2019, the laboratory started using two different hypergeometric sampling plans. When they transitioned to the ISO/IEC 17025:2017 requirements in 2020, they did not understand that the sampling method used was required to be included in the reports. They reviewed the 83 reports that were issued from 6/1/2019 to 5/3/2022. They determined that not including the specific sampling method used during the analysis in issued reports would have no affect on previously reported cases because the reported values would have been the same, just that the customer would not know which method was used. They sent a letter to all clients that had received reports without the sampling method defined and stated if they required the specific method used in their cases to contact the laboratory. They revised their procedures to place a footnote with the reported results pointing to the report footnotes that specified which method was used. They provided a report to confirmed this correction and the provided revised procedures defining the new procedure for reporting. The laboratory provided documentation of review of staff and sign off of the new procedure. This nonconformity is resolved.

7.8.3 Specific requirements for test reports

7.8.3.2 ISO/IEC 17025:2017

Resolved Nonconformity

Obligation

Where the laboratory is responsible for the sampling activity, do test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results?

Add Nonconformity Resolution Workflow

The laboratory has two methods to conduct sampling in Seized Drugs. The reports only indicate that "a hypergeometric sampling plan was used for the analysis" and does not define which of the two available plans were used.

Corrective Action Closure Note: The laboratory provided the Corrective Action form, cause analysis, revision of procedure "Reporting v2022.1", and a report issued 6/8/2022. The cause was determined that in June 2019, the laboratory started using two different hypergeometric sampling plans. When they transitioned to the ISO/IEC 17025:2017 requirements in 2020, they did not understand that the sampling method used was required to be included in the reports. They reviewed the 83 reports that were issued from 6/1/2019 to 5/3/2022. They determined that not including the specific sampling method used during the analysis in issued reports would have no affect on previously reported cases because the reported values would have been the same, just that the customer would not know which method was used. They sent a letter to all clients that had received reports without the sampling method defined and stated if they required the specific method used in their cases to contact the laboratory. They revised their procedures to place a footnote with the reported results pointing to the report footnotes that specified which method was used. They provided a report to confirmed this correction and the provided revised procedures defining the new procedure for reporting. The laboratory provided documentation of review of staff and sign off of the new procedure. This nonconformity is resolved.

7.8.5 Reporting sampling - specific requirements

7.8.5 ISO/IEC 17025:2017

Resolved Nonconformity

Obligation

Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, do reports include the following, where necessary for the interpretation of results:

a) the date of sampling?

- b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate)?
- c) the location of sampling, including any diagrams, sketches or photographs?
- d) a reference to the sampling plan and sampling method?
- e) details of any environmental conditions during sampling that affect the interpretation of the results?
- f) information required to evaluate measurement uncertainty for subsequent testing or calibration?

Add Nonconformity Resolution Workflow

The laboratory has two methods to conduct sampling in Seized Drugs. The reports only indicate that "a hypergeometric sampling plan was used for the analysis" and does not define which of the two available plans were used.

Corrective Action Closure Note: The laboratory provided the Corrective Action form, cause analysis, revision of procedure "Reporting v2022.1", and a report issued 6/8/2022. The cause was determined that in June 2019, the laboratory started using two different hypergeometric sampling plans. When they transitioned to the ISO/IEC 17025:2017 requirements in 2020, they did not understand that the sampling method used was required to be included in the reports. They reviewed the 83 reports that were issued from 6/1/2019 to 5/3/2022. They determined that not including the specific sampling method used during the analysis in issued reports would have no affect on previously reported cases because the reported values would have been the same, just that the customer would not know which method was used. They sent a letter to all clients that had received reports without the sampling method defined and stated if they required the specific method used in their cases to contact the laboratory. They revised their procedures to place a footnote with the reported results pointing to the report footnotes that specified which method was used. They provided a report to confirmed this correction and the provided revised procedures defining the new procedure for reporting. The laboratory provided documentation of review of staff and sign off of the new procedure. This nonconformity is resolved.

7.10 Nonconforming work

7.10.2 ISO/IEC 17025:2017

Resolved Nonconformity

Obligation

Does the laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f)?

Add Nonconformity Resolution Workflow

The records were not available for review of some nonconforming work actions demonstrating all actions taken, evaluation conducted of the significance of the nonconforming work, and where necessary, the customer was notified.

Corrective Action Closure Note: The laboratory provided Preventive and Corrective Action forms, cause analysis, additional documentation to supplement original preventive actions taken, 2022 Assessment Non conformance meeting minutes, and revised "Quality Manual v2022-2" and "Case Management and Minimum Testing procedure v2022.1". While the original cause and effect was reviewed for the issue in the initial nonconformity was documented, the documentation of that review was not complete. The cause of the limited documentation was determined to be due to personnel changes and documents being held in multiple locations. Original preventive action and cause analysis forms were revised to provide additional detail concerning the actions taken that had not be documented originally. This included additional information related to cases reviewed at the time of the original preventive action and the evaluation of impact of analysis on previous results conducted at the time. The laboratory did an additional review of cases from the timeframe and identified 2 additional cases that required notification of attorneys. During this review additional preventive actions were identified and implemented including moving the weighing bench where the item is evidence was dropped, adding additional lighting to that work area, adding a shield to the weight table, and placing brighter bulbs in the room for better vision. The 2022 Assessment Non conformance meeting document date 5/6/2022 supplements the corrective action report providing detailed discriptions of actions taken originally and the additional actions during the second review.

Revisions in the "Case Management and Minimum Testing v2022.1" procedure included using transfer vessels to move items to and from the balance or camera station. It also requires more detail in the case notes on discriptions of the item and packaging of evidence to include pictures if required. Revision of the "Quality Manual v2022.2" includes ensuring all corrective action documents are available to all parties involved and at least one meeting will be held to discuss corrective actions with effected staff and documentation of the meeting. All documentation including meeting minutes, attendees, action items, procedural changes, cases reviewed, material reviewed, LIMS information, follow-up documentation, and effectiveness of the corrective action will be saved to the laboratory network. The laboratory provided documentation of review of staff and sign off of the new procedures. This nonconformity is resolved.

8.7 Corrective actions (Option A)

8.7.1 ISO/IEC 17025:2017

Resolved Nonconformity

Obligation

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?

Add Nonconformity Resolution Workflow

The records were not available for review of a corrective action demonstrating the evaluation of the cause of the nonconformity, determining if similar nonconformities existed, and the review of the effectiveness of the corrective action taken.

Corrective Action Closure Note: The laboratory provided Corrective Action forms, cause analysis, additional documentation to supplement original corrective actions taken, 2022 Assessment Non conformance meeting minutes, and revised "Quality Manual v2022-2" and "Case Management and Minimum Testing procedure v2022.1". While the original cause and effect was reviewed for the issue in the initial actions documented, the documentation of that review was not complete. The cause of the limited documentation was determined to be due to personnel changes and documents being held in multiple locations. Original corrective action and cause analysis forms were revised to provide additional detail concerning the actions taken that had not be documented originally and additional actions limited after the second review. This included additional information related discussion with the attorneys and determination if additional actions were required. The laboratory confirmed the initial case had been closed without going to trial. The laboratory did an additional review of the case discrepancy log and it was determined that the previous technical leader had reviewed some cases, but not all. The laboratory identified the cases analyzed during that time period and determined there were no other discrepancies requiring additional review. During this review additional preventive actions were identified and implemented including purchasing new laboratory coats better suited for analysis and ordering tube holders that had a better fit for tubes used. The 2022 Assessment Non conformance meeting document supplements the corrective action report providing detailed descriptions of actions taken originally. Revisions in the "Case Management and Minimum Testing v2022.1" procedure included using transfer vessels to move items to and from balance or camera station. It also specifies more detail in the case notes for descriptions of the item and packaging of evidence to include pictures if required. Revision of the "Quality Manual v2022.2" includes ensuring all corrective action documents are available to all parties involved and at least one meeting to be held with to discuss with effected staff and documentation of the meeting. All documentation including meeting minutes, attendees, action items, procedural changes cases reviewed, material reviewed, LIMS information, follow-up documentation, effectiveness of the corrective action will be saved to the laboratory network. The laboratory provided documentation of review of staff and sign off of the new procedure. This nonconformity is resolved.

8.9 Management reviews (Option A)

8.9.2 ISO/IEC 17025:2017

Resolved Nonconformity

Obligation

Are the inputs to management review recorded and include information related to the following:

- a) changes in internal and external issues that are relevant to the laboratory?
- b) fulfilment of objectives?
- c) suitability of policies and procedures?
- d) status of actions from previous management reviews?
- e) outcome of recent internal audits?
- f) corrective actions?
- g) assessments by external bodies?
- h) changes in the volume and type of the work or in the range of laboratory activities?
- i) customer and personnel feedback?
- j) complaints?
- k) effectiveness of any implemented improvements?
- l) adequacy of resources?
- m) results of risk identification?
- n) outcomes of the assurance of the validity of results?
- o) other relevant factors, such as monitoring activities and training?

Comments

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Add Nonconformity Resolution Workflow

The 2021 Management Review did not include information related to the suitability of policies and procedures and the status of actions from the previous management review.

Corrective Action Closure Note: The laboratory provided the Corrective Action form, cause analysis, the 2021 revised Management Review, and meeting notes from a quarterly meeting of staff to discuss the suitability of procedures and effectiveness of action items from 2020. The cause of the nonconformity was determined to be that general discussions were included in the 2021 review but the topics were not fully addressed in the final document. With the change to ISO/IEC 17025:2017 they believed the general information was sufficient. There was no effect on the quality of the laboratory's work because the nonconformance is related to the documentation of the issues and the management staff could provide the information during the assessment. Minutes were provided from a management meeting on 6/16/2022. During the meeting they reviewed changes in policies and procedures that occurred in 2021 and confirmed they were suitable. They also included a review of actions defined in the 2020 Management Review not discussed in the 2021 Management Review and the status or completion of those actions. They also revised their Management Review Report form to include more detail on these items and to have all actions to be summarized at the end of the report. This nonconformity is resolved.