# Houston Forensic Science Center

## INTEROFFICE MEMO

**To:** Dr. Peter Stout, Chief Executive Officer
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**From:** Erika Ziemak, Quality Director Erika Ziemak Digitally signed by Erika Ziemak Date: 2021.07.09 11:52:08 -05'00'

**Date:** July 9, 2021

**Re:** 2021 Internal Audit Report

The 2021 HFSC internal audit included all ANAB accredited disciplines: Latent Prints, Firearms, Seized Drugs, Forensic Biology, Crime Scene Unit, Multimedia and Toxicology. This audit was conducted by the Quality Division over an 11-week period from April to June 2021. The audit scope for these sections focused on the timeframe since their last internal audit.

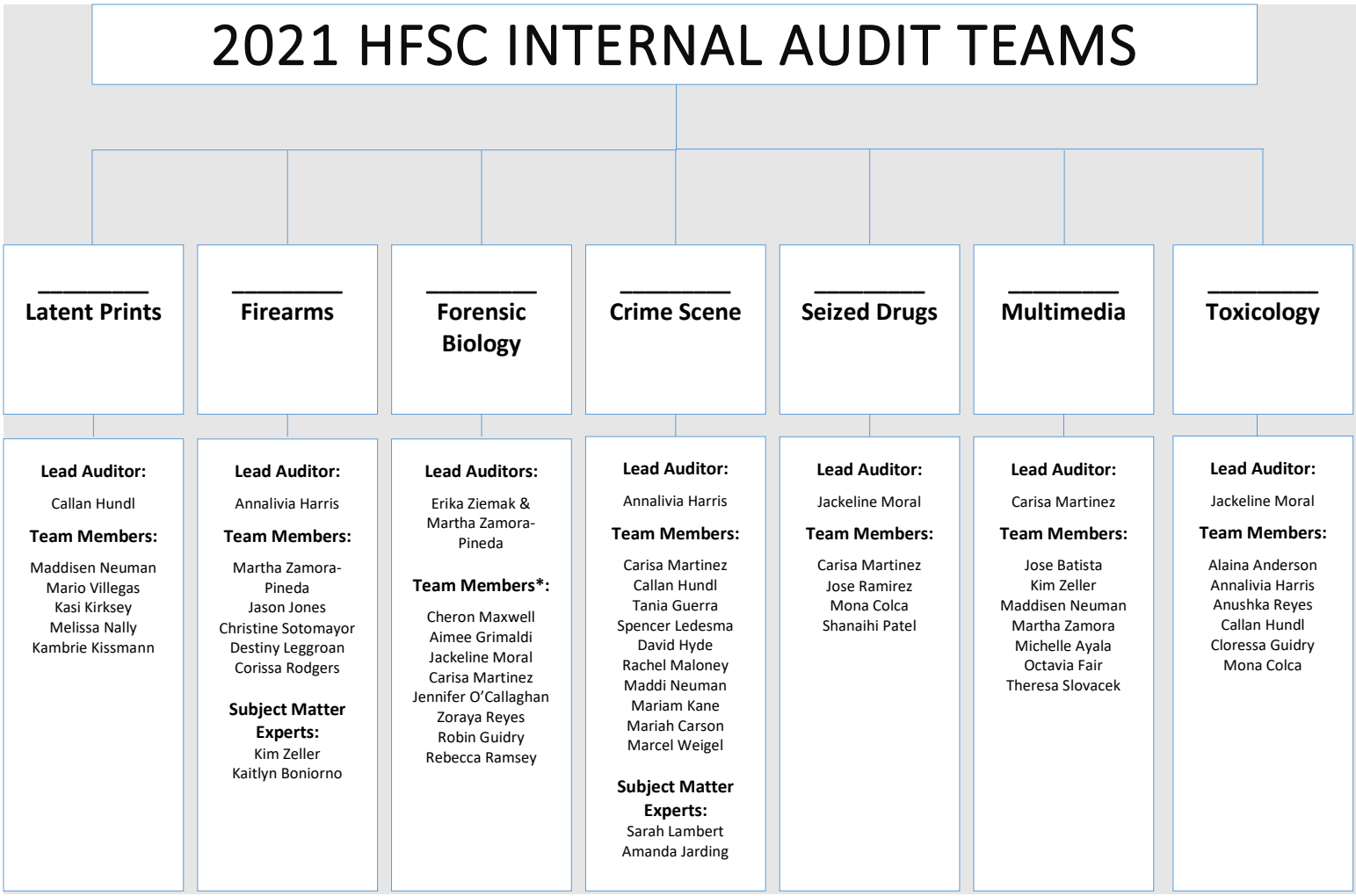
| Dates | Latent Prints | Firearms | Seized Drugs |
|---|---|---|---|
| **Audit Dates** | April 12 – April 16 | April 12 – April 16 | April 19 – April 23 |
| **Audit Scope** | April 2020 – March 2021 | June 2020 – March 2021 | April 2020- March 2021 |

| Dates | Forensic Biology | Crime Scene Unit | Multimedia | Toxicology |
|---|---|---|---|---|
| **Audit Dates** | May 10 – May 28 | May 17 – May 28 | June 14 – June 18 | June 21 – June 25 |
| **Audit Scope** | April 2020 – March 2021 | March 2020 – April 2021 | April 2020 – May 2021 | April 2020 – May 2021 |

The purpose of these audits was to verify compliance with the HFSC Quality Manual, sectional standard operating procedures and training programs, the ISO/IEC 17025:2017 standard, and the ANAB supplemental requirements as well as to directly observe a sample of accredited services within each discipline. In addition, the Forensic Biology section was also verified for compliance with the Quality Assurance Standards for DNA Testing Laboratories, effective July 2020.

The 2021 internal audit team was comprised of the Quality Division, and included technical and non-technical staff representatives, and in some instances also included subject matter experts from the section that was being audited.

# 2021 HFSC INTERNAL AUDIT TEAMS




* Due to the volume of case files reviewed in the Forensic Biology section during the internal audit, additional Forensic Biology staff members were tasked with assisting with case file reviews, but case file reviews were their only function.

As part of the LSS "Technical Review-Administrative Review (TR-AR)" project a postmortem review program was implemented. The number of cases selected for this postmortem review is statistically significant and the reviews are conducted by the technical sections. Cases that were reviewed as part of the postmortem review project, were not included as part of the internal audit case file review. Postmortem and internal audit case file review metrics are available in a PowerBi review dashboard.

The following sections of this report contain nonconformances, conforming with comment, and opportunities for improvement that were noted during the internal audit and are organized by technical section. Opportunities for improvement are suggestions given by the audit team to improve the quality management system as it pertains to each technical section. Nonconformances will be tracked through Qualtrax and assigned a quality report number to document the actions taken to address them. Qualtrax workflows are not needed for the listed conforming with comment and opportunities for improvement.

Direct observations were performed in each internal audit. The following table summarizes the number of direct observations performed in each technical section.

| Latent Prints | Firearms | Forensic Biology | Crime Scene Unit | Seized Drugs | Multimedia | Toxicology |
|---|---|---|---|---|---|---|
| 6 | 6 | 6 | 12 | 4 | 7 | 6 |

# Latent Prints

## Nonconformances

There were no nonconformances for the Latent Prints section.

## Conforming with comment

The following conforming with comment were noted during this audit:

| Conforming with comment #1 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.7.1.i:** "The administrative review includes: review of the test report for spelling and grammatical accuracy." |
| **Comment:** | Two grammatical errors were discovered during case file reviews. "Analysis" is spelled incorrectly on an item in Mideo for case 2020-10583. In case 2017-10733 the report says, "The above listed items was". |

| Conforming with comment #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.8.2.1:** "The following must be included on test reports unless an exception is documented by an acknowledged simplified report agreement: f: identification of the method used. |
| **Comment:** | The ACE-V methodology is not included on latent print comparison reports. This requirement was discussed prior to the audit between the quality division and latent print management. During the audit it was recommended to the latent print section to include this on their reports prior to the external assessment. As of 4/26/21 the method has been included on reports. |

| Conforming with comment #3 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.4.1.1.c:** "If there are issues with chains of custody in LIMS, a JusticeTrax or Porter Lee LIMS Request Form workflow shall be initiated in Qualtrax. Dates and times of transfers shall not be changed in the electronic chain of custody. Instead, a comment must be added to the corresponding transfers to document when the physical transfers occurred. Any comments made in the chains of custody transfers explaining the issue must be included in the workflow for approval. |
| **Comment:** | Based on information in a review DUI it was discovered that a comment to correct the chain of custody was not made nor was a workflow submitted as |

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| | documentation. A workflow has since been submitted by the examiner to have the comment added. |

# Opportunities for Improvement

The following opportunity for improvement was noted during this audit:

1. It was discovered during a case file review of a processing case that a Crime Scene Investigator filled out the “from” and “date” fields in a paper chain of custody for items they were sending to processing. The processor signed the form when taking it into their custody but there is no documentation of the identity of the CSI that is filling out the “from” and “date” fields in the form. The CSI lists the locker number in the “from” field. The CSU supervisors and the processors have been notified that going forward the CSI should be initialing next to the information they are writing on these forms.

2. During observations, the processor noticed that the reagent expiration date in a case he was reviewing was not correct. He had to get up from the photo lab computer and walk over to the hood to check the expiration date listed on the reagent bottle under the hood. The Quality Specialist had noticed earlier that day during case file reviews that this expiration date was not listed in the new reagent preparation log in Qualtrax and offered to add this as a field in the workflow for convenience. This field has been added to the workflow and will be more convenient for the reviewers to check and for case file reviews during audits as well.

3. The members of the internal audit team that conducted the evidence audit suggested to physically label the locations in the vault because they were not certain which location was where. Electronically located “evidence to be returned to submitter” items were found on a shelf and not in the bin. That same shelf contained items that were in a different electronic location.

4. It was discovered that one staff member did not have their badge/payroll number set up in JusticeTrax therefore they were not able to correctly run a custody inquiry on themselves. The Quality Manual recommends checking your personal custody periodically to ensure it is accurate. The Quality Specialist explained to the staff member how to set up their payroll number in JusticeTrax and how to run the custody inquiry.

5. One of the balances was still out of service in December of 2020 for the third month in a row. The latent print processor documented this in the monthly balance performance check for October and November but there was not an entry for December. In December, Mettler Toledo came to service and calibrate the balance and it was put back in service after this visit. On 4/15/21, the processor entered a workflow to document that the balance was still out of service during the December monthly check.

# Firearms

## Nonconformances

The following nonconformances were found for the Firearms section:

| Finding #1 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.4.7:** "Calibration/performance check records are maintained, preferably in a location near the instrument or equipment, or in Qualtrax." |
| **Finding:** | Prior to November 5, 2020 there are no IBIS tune-up logs for BRTX00000693. Additionally, for BRTXR0000699, a non-critical parameter failed 4 times prior to the vendor being notified and the issue being corrected. |

| Finding #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.11.6:** "When critical worksheets (e.g. Excel spreadsheets) are used in casework". |
| **Finding:** | The Firearms Section Trigger Pull Gauge Worksheet values for 'Shotgun' and 'Rifle' were switched. These values are used to calculate trigger pull uncertainty of measurement. The calculated uncertainty of measurement is included on reports when trigger pull determinations are reported. |

## Conforming with comment

The following conforming with comment were noted during this audit:

| Conforming with comment #1 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.4.1.1.d:** "chains of custody include the date of receipt or transfer and a description or unique identifier of the evidence. Staff members are responsible for ensuring evidence items have appropriate item descriptions recorded in LIMS." |
| **Comment:** | Trigger Pull Uncertainty of Measurement worksheets includes a time stamp. During the case record review of 2020-09848 and 2021-20350 it was noted that there was a discrepancy in the chain of custody time stamp and the UM timestamp that made it appear that the evidence was not in the analyst possession during the trigger pull UM measurement process. The origin of the time discrepancy should be identified, and the issue resolved. |

| Conforming with comment #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 8.2.1**: "HFSC ensures that its policies and procedures are available to all staff and are implemented at all levels of HFSC operations." |

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| **Comment:** | The HFSC Health and Safety Manual clause 13.6.2 states, “All primary containers of hazardous chemicals are clearly labeled to include: The identity of the chemical as it appears on the SDS.” There were two plastic bottles located in the Firearms basement lab area that were stored in a red carrying case along with a magnetic yoke. The contents of one bottle is dried, both bottles appear very old. Neither is labeled in a manner consistent with current labeling practices, and they are not stored in a safe manner. One bottle, which contains a small amount of red liquid, is labelled “Magnaflux Red Magnetic Particle Suspension Shake Well Before Using Kinderprint Co., Inc 800-227-6020”. The other bottle, which contains a dried dark grey material, is labeled “Magnaflux Black Magnetic Particle Suspension Shake Well Before Using Kinderprint Co., Inc. 800-227-6020”. |

# Opportunities for Improvement

The following opportunities for improvement were noted during this audit:

1. Photographs taken before and after serial number restoration would provide documentation of any physical changes to the condition of the firearm caused by the process. It would also provide reviewable data.

2. It is difficult to locate cases involving infrequently used tests, such as barrel length uncertainty of measurement, serial number restoration, etc., for review purposes. Adding check boxes in JT would make it easier to search for these cases.

3. Several instances were noted where reviewers selected different levels of case complexity in the JusticeTrax review dynamic user interface (DUI). This creates issues when the data is pulled into the review dashboard. This creates issues when the data is pulled into the PowerBi review dashboard. One possible solution suggested by the Firearms Manager would be to create a field where the examiner selects the case complexity prior to review. This would improve the review DUI completion process by eliminating instances where technical and administrative reviewers select different case complexity levels.

4. Section 40 of the Firearms SOP lists reagents and controls used for the chemical serial number restoration technique. Reagents currently in use in the Firearms section were prepared in 2014. While the reagent logbooks document the preparation dates and the reagents are labeled, the lot numbers of the chemicals used to prepare the reagents are not documented in the logbook. It is recommended that new reagents be prepared, or prepared reagents be purchased commercially.

5. It is recommended that the lot number of the reagents and the controls used to check the serial number restoration reagents be added to the case record when they are used for serial number restoration.

6. Iron chips from Analytical Reference Materials International are used as a control. However, there is no lot number listed on the container. A lot number should be created and placed on the container.

# Seized Drugs

## Nonconformances

No nonconformances were identified for the Seized Drugs section during this internal audit.

Refer to Quality Report 2021-024, the required monthly check for the Seized Drugs balance MT #2 was not performed during the month of January 2021. This was discovered during the preparation for the Seized Drugs internal audit.

## Conforming with comment

The following conforming with comment was noted during this audit:

| **Conforming with comment #1** | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.4.3.1:** "If a reagent is transferred to a secondary container (e.g., a section prepares a bulk solution of a reagent then transfers it to smaller bottles for use by each analyst), the secondary container shall be labeled with the identity of the reagent and the date of preparation or lot number." |
| **Comment:** | During the internal audit, while inspecting the analyst's bench areas, it was discovered that there were two reagent bottles with the same screening chemical name ("Cobalt Thiocyanate"). During the section's internal audit prep, which occurred a week prior to the audit, the analyst changed all her bench area reagent labels to make sure they were legible to the internal auditors. She placed a "Cobalt Thiocyanate" pre-made label onto her "Ferricyanide" and "Cobalt Thiocyanate" reagent bottles. Prior to the end of the internal audit, the analyst disposed of the reagents and correctly relabeled the "Ferricyanide" reagent bottle. During the week of the internal audit, the analyst participated in an external virtual assessment, therefore no casework was completed using the mislabeled reagent bottle. |

## Opportunities for Improvement

No opportunities for improvement were noted during this audit.

# Forensic Biology

## Nonconformances

The following nonconformances were found for the Forensic Biology section:

| Finding #1 | |
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| **Requirement:** | **Quality Manual Clause 6.2.5f:** To promote continued competency, skills, and expertise, forensic practitioners are required to complete a total of 16 hours of continuing education and/or professional development within HFSC's performance review period. This continuing education requirement complies with ASTM Standard E2917.<br>**FBI Quality Assurance Standards Clause 16.1.1.1:** The continuing education hours shall be documented. Attendance at a regional, national, or international conference with content including topics relevant to the field of forensic DNA analysis shall be deemed to provide a minimum of eight hours of continuing education. |
| **Finding:** | At least one DNA contract worker did not complete the required continuing education requirements. |

| Finding #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.2.1:** All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.<br><br>**FBI Quality Assurance Standards Clause 15.5:** Internal and external audit documentation and, if applicable, corrective action(s) shall be reviewed by the technical leader to ensure that findings, if any, were appropriately addressed and this review shall be documented. |
| **Finding:** | Currently internal audit documentation is not directly provided to the technical leader for a documented review. External audit documentation was provided, but there is not a process in place to assure a documented review occurs. |

| Finding #3 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.5.1.5:** When a test result or observation is rejected, the reason for the rejection, the identity of the individual(s) rejecting the result or observation, and the date shall be recorded. |
| **Finding:** | Observations and/or test results are crossed out but the reason for the rejection is not recorded on most case files. |

| Finding #4 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 5.7a:** Section management shall ensure that attendance and documentation of topics discussed are made available for review. |
| **Finding:** | The review of meeting presentations/videos is not being documented for contract DNA workers. |

| Finding #5 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.5.1:** HFSC retains records of original observations derived from analyses, processing, and reviews (administrative and technical), records of derived data, and sufficient information to establish an audit trail. |
| **Finding:** | The ownership review checklist for one case was incomplete and the notification had already been issued. |

# Conforming with comment

| Conforming with comment #1 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.2.3:** If a forensic practitioner neither performs casework nor completes a proficiency test in a discipline for a period of 12 months or longer (the time may be less than 12 months based upon the discretion of the section manager and/or executive management), he or she must successfully complete a competency test prior to resuming casework in that discipline. |
| **Comment:** | Screening “post-leave” authorization memos are not specific as to what the analyst is authorized to perform. Missing contact DNA from “post-leave” memos. |

| Conforming with comment #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.5.1.5:** It should be clear from the case record who performed all stages of analysis/examination and the date each stage was performed. |
| **Comment:** | Manual additions to electropherograms are not dated. In some instances, it is difficult to determine when the DNA interpretation starts and ends. |

# Opportunities for Improvement

The following opportunities for improvement were noted during this audit:

1. HFSC Proficiency Test Results Form for proficiency test 20-5705-U2588C was not signed in a timely manner. Add daily, weekly reminders to Adobe PDF workflows to remind applicable staff members involved to sign documents in a timely manner.

2. Although not required in standard 13 of QAS, proficiency test spreadsheet kept by forensic biology does not keep track of which procedures analysts perform during each proficiency test.

Although not required in standard 13 of QAS, proficiency test spreadsheet kept by forensic biology does not keep track of which specific procedures analysts perform during each proficiency test.

3. Instrumentation QC documentation could improve to avoid confusion by specifying, specify areas that require signatures, dates, or not applicable.
4. It was recommended to have to add in the DNA maintenance SOP to refer to the DNA Analytical SOP or to add language to indicate what are acceptable results are while conducting a performance check or quality control check.
5. Ownership Review Checklist (Document ID: 61006) could be updated to include that the DNA types are supported by the raw and/or analyzed data (QAS 17.3.3.1) and that the verification of eligibility by a current CODIS user was performed (QAS 17.3.3.4).
6. A refresher is recommended to review the process for electronic COC transfers which do not occur at same time as physical transfers, the required Qualtrax workflow and role clarity.
7. Pagination of SAKs and reference case records have double page numbers.

# Crime Scene Unit

## Nonconformances

The following nonconformances were found for the Crime Scene Unit:

| Finding #1 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.7.1.i:** "The administrative review includes: review of the test report for spelling and grammatical accuracy." |
| **Finding:** | During the 2021 internal audit, the audit team identified defects in several case records. Defects requiring corrections were identified in 12 reports, 7 case notes and 2 scene diagrams. |

| Finding #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.2.1:** All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.<br><br>**Crime Scene Unit SOP Clause 11:** "Currency in an amount over $100 shall be submitted to the HPD Property Room by the end of the CSI's shift, unless other arrangements have been made and approved by a CSU supervisor and documented in the case record." |
| **Finding:** | A CSI collected over $100 from a scene and did not submit it to the property room by the end of shift, as required by the SOP. The CSI may have received approval to deviate from CSU management who were on scene, but this was not documented in the case record. |

## Conforming with comment

The following conforming with comment were noted during this audit:

| Conforming with comment #1 | |
|---|---|
| **Requirement:** | **Quality Manual clause 7.5.2:** "When striking out information on paper documents, a single line is drawn through the error and the error is initialed. Mistakes are not erased, made illegible, or deleted." |
| **Comment:** | An obliteration was observed in a case packet for 2020-13963. A currency form was scribed by a non-CSI. That person obliterated a mistake in their notes rather than using a single strike-through. This appears to be a onetime occurrence. Corrections made by CSIs in their case notes were observed by the audit team to conform to Quality Manual clause 7.5.2. |

| Conforming with comment #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.2.2.2:** "HFSC has a documented training program that provides knowledge and skills needed to perform specific forensic techniques, including testing and processing of evidence. Newly hired forensic practitioners, including contract employees and staff |

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|---|---|
| | performing accessioning activities, will complete appropriate training and demonstrate competence before beginning casework." |
| **Comment:** | Five CSU training binders were reviewed during the internal audit. Many of the check boxes in the training manuals had not been checked off or marked N/A. |

| **Conforming with comment #3** | |
|---|---|
| **Requirement:** | **Quality Manual Clause 8.3.2:** "Other section-specific documents such as worksheets require approval by section management and the Quality Division." |
| **Comment:** | Peer Review forms are not controlled and not always retained in the case record. Peer reviews quality as case related documentation subject to disclosure. These forms should be controlled and retained in the case record. CSU identified this issue and started retaining the Peer Review forms in the case record in January of 2021. |

| **Conforming with comment #4** | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.7.1.i:** "Review of reported results". |
| **Comment:** | The CSU Review sheet is not being utilized as intended. CSIs do not always sign the form documenting that they have made the corrections listed on the review form. |

| **Conforming with comment #5** | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.4.7:** "Calibration/performance check records are maintained, preferably in a location near the instrument or equipment, or in Qualtrax." |
| **Comment:** | CSU inspects their NIST traceable ruler annually, but the inspection is not currently being documented. |

# Opportunities for Improvement

The following opportunities for improvement were noted during this audit:

1. During a scene observation, an audit team member and a CSI discussed that fact that many CSIs have not had the opportunity to observe a full autopsy, although they routinely work with Medical Examiners from the Harris County Institute of Forensic Services (HCIFS).. CSU could coordinate with HCIFS to allow CSIs who would like to view an autopsy the opportunity to do so. Observing autopsies would improve CSIs knowledge of human anatomy, medical terminology, expand their investigation skills, and provide a greater understanding of how their work impacts other aspects of the criminal justice system.

2. A statement that all measurements are approximate could be added to the measurement log form.

3. CSU would benefit from having a large storage area in basement to secure oversized and/or large/awkward items of evidence.

# Multimedia

## Nonconformances

The following nonconformance was found for the Multimedia section:

| Finding #1 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.5.1:** HFSC retains records of original observations derived from analyses, processing, and reviews (administrative and technical), records of derived data, and sufficient information to establish an audit trail. Case records contain sufficient information to facilitate, if possible, the identification of the factors affecting uncertainty and to enable any test to be repeated under conditions as close as possible to those of the original. If examination records or original observations are made on nontraditional media (i.e., sticky notes, paper towels, gloves), then the original medium is retained in the case record. |
| **Finding:** | Original notes are written in a Word document and copied/pasted on the report template in JusticeTrax LIMS. The Word document is not retained in the case file record. If edits are suggested in TR/AR and documented in the Review DUI, the original report is not retained in the case record providing no way to confirm that the suggested revisions were made. If the revisions were made, the original report is not being retained in the case record and there is a loss of original observations.<br><br>When an extraction fails, the analyst adds a note in the report but the original extraction data proving the failure is not kept in the case record.<br><br>Evidence was transferred to another analyst for extraction. There are no notes from the analyst that conducted the extraction in the case file. What was performed and found by the other analyst was documented and reported by the primary analyst. |

| Finding #2 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.5.1.5:** The Crime Scene Unit, Multimedia, and Latent Print laboratories must keep all photographic images, regardless of photographic quality, taken during the examination process. These images are considered examination documentation that could be used in lieu of the evidence. The images must be included in the case record and stored in an approved HFSC repository such as LIMS, Caseworks (also called Mideo) or Dataworks. Computer hard drives and individual OneDrives are not approved repositories. |
| **Finding:** | Photographs of the evidence are uploaded into the case file record in a PDF document. The original photographs are stored temporarily (30 days) in the Multimedia network. The derivative item created contains the photographs; however, this item is given to the stakeholder and is not part of the case file. The date that the images were captured is not recorded and properties of the photos uploaded to the case file cannot be checked. |

| Finding #3 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 5.7:** Clear, concise, and professional communications should be a hallmark of forensic science and HFSC has established procedures for communicating results (see section 7.8). HFSC encourages regularly scheduled management and analytical section meetings that use a documented agenda. These meetings are essential to supporting the flow of communications, information exchange, creative brainstorming, and the recognition of exceptional performance. Section management shall ensure that attendance and documentation of topics discussed are made available for review. |
| **Finding:** | The section tries to hold monthly staff meetings. The section manager keeps meeting agendas but there is no documented process to ensure staff who were not in attendance are in receipt of the discussed information. The section manager keeps the meeting agendas, but no attendance is tracked nor maintained. |

# Conforming with comment

The following conforming with comment were noted during this audit:

| Conforming with comment #1 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.7.1:** All changes made to administrative and technical records because of verification, technical review or administrative review must be tracked in the case and/or the batch record. Section management will determine what tracking method is used. When non-electronic forms such as worksheets or checklists are used, these must be added to the case and/or the batch record. Electronic tracking is acceptable if a report can be run on the information.<br><br>Review documentation is an original observation and shall be retained as part of the technical record.<br><br>The administrative review includes:<br>· review of the test report for spelling and grammatical accuracy.<br>· review of all administrative records to ensure that the assigned case number is on each page.<br>· review of all examination records to ensure that the inclusion of the unique identifier, date, and identity of the person who performed each stage of analysis.<br>· review of the report to ensure that all key information (see 7.8.2 and 7.8.3) is included. |
| **Comment:** | There were two cases where the technical review or administrative review requested changes were not addressed. In one case the starting day was missing from the examination notes. The technical reviewer asked the analyst to add/correct the starting day; however, since this was not tracked, its unknown if the correction was made since the original notes are not kept in the case record. In the other case the investigator name is misspelled as Media instead of Medina. This was documented in the administrative review, but the correction was not made.<br>In one case a number (#2) is missing from the agency case number of the extraction log. |

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| | In one case the target location and meeting location are missing in the report. A workflow was initiated to amend the report before the closing meeting.<br>Photos from one case were uploaded by mistake in another case file. |

| **Conforming with comment #2** | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.7.1:** Forensic practitioners may not conduct a technical or administrative review on their own work product. |
| **Comment:** | An administrative review was completed by an analyst that assisted in the case. |

| **Conforming with comment #3** | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.7.1:** Technical reviews, administrative reviews, and batch reviews should be documented and tracked in review DUIs in JusticeTrax LIMS. |
| **Comment:** | On two cases the administrative review DUIs were not completed to document the reviews. The two DUIs were created before the closing meeting of the audit.<br>A case has two DUIs for the administrative review. It was not clear why two administrative reviews were completed. |

| **Conforming with comment #4** | |
|---|---|
| **Requirement:** | **Quality Manual Clause 7.5.2:** When striking out information on paper documents, a single line is drawn through the error and the error is initialed. Mistakes are not erased, made illegible, or deleted. |
| **Comment:** | In a training binder white-out was used on a supervised technical review sheet to cover a miswritten number and the technical reviewer's name. |

# Opportunities for Improvement

The following opportunities for improvement were noted during this audit:

1. Create a cover sheet with all case information before photographs are captured.
2. Create a photo log to document the total number of photographs taken in the case and ensure all are uploaded into the case file.
3. If a photograph is taken for items that have different parts, ensure the photo shows the details of each part instead of overlapping them.
4. Place a Do Not Touch sign near evidence laying out so it's clear that analysis is in process and item(s) should not be touched since there are people outside the section personnel (management) that have access to the section.
5. Analysts document communications with customer support and/or stakeholders in reports however it is recommended to upload the supporting documentation of that communication to the case record.

6. The section is referred to both the Multimedia Section and the Forensic Multimedia Unit in reports. It is recommended to provide consistency in the section's name.

7. Some report template headers cause formatting issues when copying and pasting. Consider amending the template report for consistency and to address this formatting issue.

8. For Digital Call-Outs more detailed accounts of what was done at scene and/or items of interest could make the review process more efficient.

9. Create a worksheet with all approved software/hardware used that analysts could fill out in real time. This worksheet can be saved to JusticeTrax (JT) as an attachment, and then only the relevant information could be copied onto the report. That way, the analysts would spend less time manually typing all softwares/hardwares and would have original case notes to attach to JT.

10. Search warrants are needed for all phone/computer extractions. If there is no search warrant, the analyst must contact the investigator. It would be beneficial if the section management could triage the cases and make sure the warrants are available for analysts to review before they are assigned cases.

11. Requests from investigators can be vague. Officers frequently ask for "all data" with little direction on what is needed. It would be beneficial if section management could help direct investigators and clarify their needs, especially when a manual extraction needs to be done. This would provide a buffer for analysts, help prevent bias, and reduce the workload of a vague request.

12. HPD has some Cellebrite capabilities and may try to extract data prior to submission to HFSC. This could affect HFSC's ability to process evidence. It is recommended to meet with HPD, HCDAO, and HCPDO to discuss the risks of non-forensic personnel performing this type of forensic service. There could be serious issues in court proceedings regarding validity of evidence if it is analyzed improperly.

13. Create a workflow in Qualtrax to track performance checks. This will allow the section to automatically save who performed the task, what equipment it was performed on and when the check was performed as well as send reminder emails to avoid missing a check.

14. When the section gets a new hire, it would be beneficial if Qualtrax tests for the section procedures were assigned to track and document required readings for each module completed.

15. When reviewing the training binders in several module checklists, there is reference to a number of cases created/reviewed/observed. It is recommended to record these exact cases in the training binder for future reference.

16. Create memos when mock trails are completed to formally document what was evaluated in the process, if the analyst performed successfully, or if further training is needed.

# Toxicology

## Nonconformances

No nonconformances were identified for the Toxicology section during this internal audit.

## Conforming with comment

The following conforming with comment was noted during this audit:

| Conforming with comment #4 | |
|---|---|
| **Requirement:** | **Quality Manual Clause 6.4.3.1:** "Reagents prepared in-house are labeled with the identity of the reagent, concentration (if applicable), date of preparation or lot number, and, as applicable, storage requirements." |
| **Comment:** | During the internal audit, while inspecting the reagent and standard refrigerator and freezer, it was noted that there were some reagent bottles that were not properly labeled. Although they were labeled as to their contents, the labeling did not adhere to the quality manual requirements. From further investigation, these reagent bottles were used for research and validation purposes for the LC-QQQ and did not have to adhere to the Quality manual requirements. Since the validation studies had been completed, these bottles were disposed by the Toxicology section. |

## Opportunities for Improvement

The following opportunity for improvement was noted during this audit:

1. The Alcohol Batch Worklist currently requires the analyst to manually write out all the calibrators, controls, internal standard solution, pipette, and instrument used in their analysis. For the controls, calibrators, and internal standard solution, they must document its identity, lot number for each solution and their expiration date. The audit team recommends that this form be improved by hard coding a list of the non-variable fields. By hardcoding these fields, the analyst reduces the manual writing process and will only fill out the lot number and expiration date for solutions and only the identity of the pipette(s) and instrument(s) used.

# HFSC Internal Audit Objective Evidence Checklist

2021 Internal Audit

## 4 General Requirements

### 4.1 IMPARTIALITY

#### 4.1.1 ISO/IEC 17025:2017

**Conforming**

Requirement

Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

Objective Evidence

HFSC Quality Manual Clause 4.1.1.

#### 4.1.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory management shall be committed to impartiality.

Objective Evidence

HFSC Quality Manual Clause 4.1.2.

#### 4.1.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

Objective Evidence

HFSC Quality Manual Clause 4.1.3.

#### 4.1.3.1 ANAB AR 3125

**Conforming**

Requirement

The management system shall:
a) have a code of ethics as part of the management's commitment to good professional practice;
b) ensure annual review of the document by all personnel and maintain a record of the review; and
c) ensure appropriate actions are taken when necessary.

Objective Evidence

HFSC Quality Manual Clause 4.1.3.1. Annual review of the Code of Ethics and/or Ethics training is maintained in Qualtrax. The HFSC Code of Ethics document is posted in Qualtrax.

### 4.1.4 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

Objective Evidence

HFSC Quality Manual Clause 4.1.4.

### 4.1.5 ISO/IEC 17025:2017

**Conforming**

Requirement

If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

Objective Evidence

HFSC Quality Manual Clause 4.1.4 and 4.1.5.

## 4.2 CONFIDENTIALITY

### 4.2.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

Objective Evidence

HFSC Quality Manual Clause 4.2.1.

### 4.2.2 ISO/IEC 17025:2017

**Conforming**

Requirement

When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

Objective Evidence

HFSC Quality Manual Clause 4.2.2.

### 4.2.3 ISO/IEC 17025:2017

**Conforming**

Requirement

Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

Objective Evidence

HFSC Quality Manual Clause 4.2.3.

### 4.2.4 ISO/IEC 17025:2017

**Conforming**

Requirement

Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

Objective Evidence

HFSC Quality Manual Clause 4.2.4.

## 5 STRUCTURAL REQUIREMENTS

### 5.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.
**NOTE:** For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

Objective Evidence

HFSC Quality Manual Clause 5.1.

### 5.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall identify management that has overall responsibility for the laboratory.

Objective Evidence

HFSC Quality Manual Clause 5.2. HFSC maintains an organizational chart of personnel.

### 5.2.1 ANAB AR 3125

**Conforming**

Requirement

There shall be a director, whose duties shall be defined.

Objective Evidence

HFSC Quality Manual Clause 5.2.1. Human Resources maintains job descriptions for each position.

### 5.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

Objective Evidence

HFSC Quality Manual Clause 5.3. HFSC's Scope of Accreditation document is posted to the external website.

### 5.4 ISO/IEC 17025:2017

**Conforming**

Requirement

Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall 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: An example of a regulatory authority is the Federal Bureau of Investigation for laboratories participating in the National DNA Index System (NDIS).

Objective Evidence

HFSC Quality Manual Clause 5.4. and DNA General SOP. The Forensic Biology section conforms to the requirements stated in the NDIS Operational Procedures Manual and in applicable FBI Quality Assurance Standards.

### 5.4.1 ANAB AR 3125

**Conforming**

Requirement

Laboratories shall conform to requirements in PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status.

Objective Evidence

HFSC Quality Manual Clause 5.4.1. Technical reports within the HFSC scope of accreditation contain the ANAB symbol.

### 5.4.2 ANAB AR 3125

**Conforming**

Requirement

If a laboratory performs testing or calibration under the authority of a statute, regulation or other legal requirement, the laboratory shall make this readily available.

Objective Evidence

HFSC Quality Manual Clause 5.4.2. Some HFSC sections are also accredited by the Texas Forensic Science Commission; that letter is posted to the external website.

### 5.5 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall:
a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;
b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

**ANAB NOTE** c) Documenting procedures to the extent necessary to ensure the consistent application of testing and calibration and the validity of the results includes analysis and data interpretation to arrive at a result, opinion or interpretation.

Objective Evidence

HFSC Quality Manual Clause 5.5. HFSC is outlined in the organizational chart maintained by Human Resources. Descriptions of position responsibilities (job duties/descriptions) are also maintained by Human Resources. HFSC maintains its policies and procedures as controlled documents which are in Qualtrax.

### 5.6 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:
a) 17025 implementation, maintenance and improvement of the management system;
b) 17025 identification of deviations from the management system or from the procedures for performing laboratory activities;
c) 17025 initiation of actions to prevent or minimize such deviations;
d) 17025 reporting to laboratory management on the performance of the management system and any need for improvement;
e) 17025 ensuring the effectiveness of laboratory activities.

Objective Evidence

HFSC Quality Manual Clause 5.6.

### 5.7 ISO/IEC 17025:2017

**Nonconformance**

Requirement

Laboratory management shall ensure that:
a) 17025 communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;
b) 17025 the integrity of the management system is maintained when changes to the management system are planned and implemented.

Objective Evidence

Multimedia: The section tries to hold monthly staff meetings. The section manager keeps meeting agendas but there is no documented process to ensure staff who were not in attendance are in receipt of the discussed information.

Forensic Biology: The review of meeting presentations/videos is not being documented for contract DNA workers.

## 6 RESOURCE REQUIREMENTS

### 6.1 General ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

Objective Evidence

HFSC Quality Manual Clause 6.1.

### 6.2 Personnel ISO/IEC 17025:2017

#### 6.2.1 ISO/IEC 17025:2017

**Nonconformance**

Requirement

All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

Objective Evidence

Crime Scene Unit: A Crime Scene Investigator collected over $100 from a scene and did not submit it to the Pr by the end of shift, as required by the SOP. The CSI may have received approval to deviate from CSU management who were on scene, but this was not documented in the case record.

Forensic Biology: Currently internal audit documentation is not directly provided to the technical leader for a documented review. External audit documentation was provided, but there is not a process in place to assure a documented review occurs.

### 6.2.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience

Objective Evidence

HFSC Quality Manual Clause 6.2.2.

### 6.2.2.1 ANAB AR 3125

**Conforming**

Requirement

Personnel who authorize results or express opinions and/or interpretations in the following disciplines shall meet the minimum educational requirements below.
Discipline: Mininum Educational Requirements
Biology Wildlife Forensics Fire Debris and Explosives Geological Materials Gunshot Residue Materials (Trace) Seized Drugs Toxicology: A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.
Bloodstain Pattern Analysis Firearms/T oolmarks Footwear and Tire Document Examination Friction Ridge Digital Evidence Video/Imaging Technology and Analysis Crime Scene Investigation Fire and Explosion Investigation: Meet the educational requirement(s) specified for competence (see ISO/IEC 17025:2017 6.2.2)
Anthropology Disaster Victim Identification Odontology Medicolegal Death Investigation: An advanced degree in anthropology, dentistry, or medicine
**NOTE 1** Minimum educational requirements apply to personnel working in any discipline for which training begins after the date of initial accreditation in that discipline under these requirements.
**NOTE 2** This table is not exhaustive and additional disciplines may be added as appropriate

Objective Evidence

HFSC Quality Manual Clause 6.2.2.1. Transcripts of required coursework are maintained in the staff member's quality file in Qualtrax.

### 6.2.2.2 ANAB AR 3125

**Conforming with Comment**

Requirement

The training program for each function influencing the results of laboratory activities, to the extent necessary based on job function, shall include:
a) ANAB the knowledge, skills, and abilities needed to perform work;
b) ANAB general knowledge of forensic science;
c) ANAB the application of ethical practices in forensic science;
d) ANAB criminal law, civil law, and testimony;
e) ANAB provisions for retraining;
f) ANAB provisions for maintenance of skills and expertise; and
g) ANAB 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 ANAB
NOTE 2 ISO/IEC 17025:2017, section 7.3 may be applicable to training programs.

Objective Evidence

Crime Scene Unit: Five CSU training binders were reviewed during the internal audit. Many of the check boxes in the training manuals had not been checked off or marked N/A.

### 6.2.3 ISO/IEC 17025:2017

**Conforming with Comment**

Requirement

The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

Objective Evidence

Forensic Biology: Screening “post-leave” authorization memos are not specific as to what the analyst is authorized to perform. Missing contact DNA from “post-leave” memos.

### 6.2.3.1 ANAB AR 3125

**Conforming**

Requirement

All personnel who perform testing or calibration shall be competency tested. Testing or calibration includes the review and authorization of results and expressing an opinion or an interpretation. The competency test shall include practical examination(s) that cover the spectrum of anticipated tasks related to the test or calibration. The competency test intended results shall be achieved prior to performing the tasks on a test or calibration item. NOTE Competency testing can be conducted for an individual task or a group of tasks covered by a module of a training program.

Objective Evidence

HFSC Quality Manual Clause 6.2.3.1.

### 6.2.3.2 ANAB AR 3125

**Conforming**

Requirement

Personnel who perform technical review of results or testimony, shall meet the competency requirements as specified in 6.2.3.1 for the testing or calibration tasks being reviewed.
NOTE Authorization of personnel includes all aspects of testing or calibration activities including, as applicable, the use of equipment.

Objective Evidence

HFSC Quality Manual Clause 6.2.3.2.

### 6.2.4 ISO/IEC 17025:2017

**Conforming**

Requirement

The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

Objective Evidence

HFSC Quality Manual Clause 6.2.4.

### 6.2.5 ISO/IEC 17025:2017

**Nonconformance**

Requirement

The laboratory shall have procedure(s) and retain records for:
a) determining the competence requirements;
b) selection of personnel;
c) training of personnel;
d) supervision of personnel;
e) authorization of personnel;
f) monitoring competence of personnel.

Objective Evidence

Forensic Biology: At least one contract worker did not complete the required continuing education requirements.

### 6.2.6 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:
a) development, modification, verification and validation of methods;
b) analysis of results, including statements of conformity or opinions and interpretations;
c) report, review and authorization of results.

Objective Evidence

HFSC Quality Manual Clause 6.2.6.

## 6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

### 6.3.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results. NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

Objective Evidence

HFSC Health and Safety Manual, HFSC Procedure Guide 500 Jefferson 18th Floor Laboratory Systems, HFSC Procedure Guide 500 Jefferson 18th Floor Generator Process, and the HFSC Business Continuity Plan. A health and safety audit was conducted on 2020 by the Quality Division, refer to the report for nonconformances and observations during this audit.

### 6.3.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented

Objective Evidence

HFSC Quality Manual Clause 6.3.2 and HFSC Health and Safety Manual

### 6.3.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

Objective Evidence

HFSC Quality Manual Clause 6.3.3.

### 6.3.4 ISO/IEC 17025:2017

**Conforming**

Requirement

Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:
a) access to and use of areas affecting laboratory activities;
b) prevention of contamination, interference or adverse influences on laboratory activities;
c) effective separation between areas with incompatible laboratory activities.

Objective Evidence

HFSC Quality Manual Clause 6.3.4. HFSC Security Manual. A security audit was conducted on 2020 by the Quality Division, refer to the report for nonconformances and observations during this audit.

### 6.3.4.1 ANAB AR 3125

**Conforming**

Requirement

There shall be a procedure that addresses security and access to areas where activities occur. NOTE Topics to consider may include, but are not limited to: access to building, access by personnel, access by visitors, security during operational hours and non-operational hours, and devices that grant access.

Objective Evidence

HFSC Quality Manual Clause 6.3.4.1 and HFSC Security Manual.

### 6.3.5 ISO/IEC 17025:2017

**Conforming**

Requirement

When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

Objective Evidence

HFSC Quality Manual Clause 6.3.5.

## 6.4 EQUIPMENT

### 6.4.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.
NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.
NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.

Objective Evidence

HFSC Quality Manual Clause 6.4.1

### 6.4.2 ISO/IEC 17025:2017

**Conforming**

Requirement

When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

Objective Evidence

HFSC Quality Manual Clause 6.4.2. and pertinent technical SOPs.

### 6.4.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

Objective Evidence

HFSC Quality Manual Clause 6.4.3. and pertinent technical SOPs.

### 6.4.3.1 ANAB AR 3125

**Conforming with Comment**

Requirement

In addition to the procedural requirements in ISO/IEC 17025:2017, clause 6.4.3, reagents prepared shall be labeled with, at a minimum, the identity of the reagent and the dale of preparation or lot number. Records shall be maintained identifying who made the reagent and the components used in preparation.

Objective Evidence

Seized Drugs: During the internal audit, while inspecting the analyst's bench areas, it was discovered that there were two reagent bottles with the same screening chemical name ("Cobalt Thiocyanate"). During the section's internal audit prep, which occurred a week prior to the audit, the analyst changed all her bench area reagent labels to make sure they were legible to the internal auditors. She placed a "Cobalt Thiocyanate" pre-made label onto her "Ferricyanide" and "Cobalt Thiocyanate" reagent bottles. Prior to the end of the internal audit, the analyst disposed of the reagents and correctly relabeled the "Ferricyanide" reagent bottle. During the week of the internal audit, the analyst participated in an external virtual assessment, therefore no casework was completed using the mislabeled reagent bottle.

Toxicology: During the internal audit, while inspecting the reagent and standard refrigerator and freezer, it was noted that there were some reagent bottles that were not properly labeled. Although they were labeled as to their contents, the labeling did not adhere to the quality manual requirements. From further investigation, these reagent bottles were used for research and validation purposes for the LC-QQQ and did not have to adhere to the Quality manual requirements. Since the validation studies had been completed, these bottles were disposed by the section.

### 6.4.3.2 ANAB AR 3125

**Conforming**

Requirement

Reference collections of data or materials which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, motor vehicle paints or headlamp lenses, drug samples, wood fragments, bullets, cartridges, DNA profiles, laboratory developed population databases) shall have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest

Objective Evidence

HFSC Quality Manual Clause 6.4.3.2

### 6.4.4 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.

Objective Evidence

HFSC Quality Manual Clause 6.4.4

### 6.4.5 ISO/IEC 17025:2017

**Conforming**

Requirement

The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

Objective Evidence

HFSC Quality Manual Clause 6.4.5

### 6.4.6 ISO/IEC 17025:2017

**Conforming**

Requirement

Measuring equipment shall be calibrated when:
the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or calibration of the equipment is required to establish the metrological traceability of the reported results.
NOTE Types of equipment having an effect on the validity of the reported results can include:
those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; those used to make corrections to the measured value, e.g. temperature measurements;
those used to make corrections to the measured value, e.g. temperature measurements;
those used to obtain a measurement result calculated from multiple quantities.

Objective Evidence

HFSC Quality Manual Clause 6.4.6.

### 6.4.7 ISO/IEC 17025:2017

**Nonconformance**

Requirement

The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

Objective Evidence

Firearms: Prior to November 5, 2020 there are no IBIS tune-up logs for BRTX00000693. Additionally, for BRTXR0000699, a non-critical parameter failed 4 times prior to the vendor being notified and the issue corrected.

Crime Scene Unit (Conforming with Comment): CSU inspects their NIST traceable ruler annually, but the inspection is not currently being documented.

### 6.4.7.1 ANAB AR 3125

**Conforming**

Requirement

The program for the calibration of equipment shall include a list of the equipment requiring calibration, specifications for the calibration laboratory, specified requirements for the calibration, and the interval of calibration.

Objective Evidence

HFSC Quality Manual Clause 6.4.7.1

### 6.4.8 ISO/IEC 17025:2017

**Conforming**

Requirement

All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

Objective Evidence

HFSC Quality Manual Clause 6.4.8 and through visual verification during the internal audit

### 6.4.9 ISO/IEC 17025:2017

**Conforming**

Requirement

Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

Objective Evidence

HFSC Quality Manual Clause 6.4.9.

### 6.4.10 ISO/IEC 17025:2017

**Conforming**

Requirement

When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure
ANAB AR NOTE When evaluating the need for intermediate checks, topics to consider include, but are not limited to: the calibration interval, the use of the equipment, the stability of the equipment, the method specifications, and risk associated with a failed check.

Objective Evidence

HFSC Quality Manual Clause 6.4.10.

### 6.4.11 ISO/IEC 17025:2017

**Conforming**

Requirement

When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

Objective Evidence

HFSC Quality Manual Clause 6.4.11.

### 6.4.12 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.

Objective Evidence

HFSC Quality Manual Clause 6.4.12.

### 6.4.13 ISO/IEC 17025:2017

**Conforming**

Requirement

Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:
a) 17025 the identity of equipment, including software and firmware version;
b) 17025 the manufacturer's name, type identification, and serial number or other unique identification;
c) 17025 evidence of verification that equipment conforms with specified requirements;
d) 17025 the current location;
e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
h) details of any damage, malfunction, modification to, or repair of, the equipment.

Objective Evidence

HFSC Quality Manual Clause 6.4.13.

## 6.5 METROLOGICAL TRACEABILITY

### 6.5.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.
NOTE 1 In 150/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".
NOTE 2 See Annex A for additional information on metrological traceability.

Objective Evidence

HFSC Quality Manual Clause 6.5.1.

#### 6.5.1.1 ANAB AR 3125

**Conforming**

Requirement

The laboratory shall establish and maintain metrological traceability of its measurement results by utilizing products and services from suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials that are:
a) a National Metrology Institute that is a signatory to the BIPM1 - CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB)2; or
b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation; or
c) an accredited reference material producer that is accredited to ISO 170343,4 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material to be purchased.

Objective Evidence

HFSC Quality Manual clause 6.5.1.1 and through the use of external providers that fulfill the criteria defined above. Vendor evaluation forms filled out for calibration service providers.

#### 6.5.1.2 ANAB AR 3125

**Conforming**

Requirement

In situations where a supplier that meets 6.5.1.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased shall be confirmed. Objective evidence of the confirmation shall be available for review.

Objective Evidence

HFSC Quality Manual Clause 6.5.1.2.

### 6.5.1.3 ANAB AR 3125

**Not Applicable**

Requirement

For the purpose of establishing traceability of a measurement, an accredited laboratory may calibrate its own equipment that supports an accredited parameter on the scope if the related requirements in ISO/IEC 17025 and this document are met:
a) the calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel;
b) the calibration method shall be validated or verified prior to use;
c) certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties;
d) the calibration shall be carried out in an appropriate environment;
e) ANAB technical records of the calibration shall be established and maintained;
f) the laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts; and
g) a technical review of the technical records including any data transfers and calculations shall be completed by an individual other than the person(s) who performed the work.

Objective Evidence

N/A

### 6.5.1.4 ANAB AR 3125

**Conforming**

Requirement

If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material shall be evaluated for applicability of measurement traceability accreditation requirements.

Objective Evidence

HFSC Quality Manual Clause 6.5.1.4

### 6.5.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:
a) calibration provided by a competent laboratory; or NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.
b)certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
**NOTE 2** Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.
c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.
**NOTE 3** Details of practical realization of the definitions of some important units are given in the SI brochure.

Objective Evidence

HFSC Quality Manual Clause 6.5.2; and through review of calibration records during the internal audit.

### 6.5.3 ISO/IEC 17025:2017

**Conforming**

Requirement

When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metro logical traceability to an appropriate reference, e.g.:
a) certified values of certified reference materials provided by a competent producer;
b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

Objective Evidence

HFSC Quality Manual Clause 6.5.3.

## 6.6 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

### 6.6.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:
a) 17025 are intended for incorporation into the laboratory's own activities;
b) 17025 are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
c) are used to support the operation of the laboratory. NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

Objective Evidence

HFSC Quality Clause 6.6.1.

### 6.6.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a procedure and retain records for:
a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

Objective Evidence

HFSC Quality Clause 6.6.2.

### 6.6.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall communicate its requirements to external providers for:
a) 17025 the products and services to be provided;
b) 17025 the acceptance criteria;
c) 17025 competence, including any required qualification of personnel;
d) 17025 activities that the laboratory, or its customer, intends to perform at the external provider's premises.

Objective Evidence

HFSC Quality Manual Clause 6.6.3.

## 7 PROCESS REQUIREMENTS

## 7.1 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

### 7.1.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:
a) the requirements are adequately defined, documented and understood;
b) the laboratory has the capability and resources to meet the requirements;
c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;
**NOTE 1** It is recognized that externally provided laboratory activities can occur when: - the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full; - the laboratory does not have the resources or competence to perform the activities.
d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.
**NOTE 2** For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

Objective Evidence

HFSC Quality Manual Clause 7.1.1 and through review of requests during internal audit case file reviews.

### 7.1.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

Objective Evidence

HFSC Quality Manual Clause 7.1.2.

### 7.1.3 ISO/IEC 17025:2017

**Conforming**

Requirement

When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.
NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

Objective Evidence

HFSC Quality Manual Clause 7.1.3.

### 7.1.4 ISO/IEC 17025:2017

**Conforming**

Requirement

Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

Objective Evidence

HFSC Quality Manual Clause 7.1.4 and through review of requests during internal audit case file reviews.

### 7.1.5 ISO/IEC 17025:2017

**Conforming**

Requirement

The customer shall be informed of any deviation from the contract.

Objective Evidence

HFSC Quality Manual Clause 7.1.5.

### 7.1.6 ISO/IEC 17025:2017

**Conforming**

Requirement

If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

Objective Evidence

HFSC Quality Manual Clause 7.1.6.

### 7.1.7 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.
NOTE Such cooperation can include:
a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;
b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.

Objective Evidence

HFSC Quality Manual Clause 7.1.7, stakeholder surveys, and review of communication logs during internal audit case file reviews.

### 7.1.8 ISO/IEC 17025:2017

**Conforming**

Requirement

Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

Objective Evidence

HFSC Quality Manual Clause 7.1.8 and review of communication logs and requests during internal audit case file reviews.

### 7.1.9 ANAB AR 3125

**Conforming**

Requirement

The extent of database (e.g., DNA profiles, friction ridge, ballistics, biometrics) searches shall be communicated to customers and updated as needed.
NOTE 1 “extent” will be specific to the database but may include aspects of the scope or range of the search (e.g., local, state, national, international), the frequency of the search or if the customer is required to make a request to elevate the scope of the search or to have a search performed.
NOTE 2 This may be communicated on a case-by-case basis, in the report, or in a general customer communication.

Objective Evidence

HFSC Quality Manual Clause 7.1.9 and informational brochures available on HFSC external website.

## 7.2 SELECTION, VERIFICATION AND VALIDATION OF METHODS

### 7.2.1 SELECTION, VERIFICATION OF METHODS

#### 7.2.1.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. NOTE "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

Objective Evidence

HFSC Quality Manual Clause 7.2.1.1.

#### 7.2.1.1.1 ANAB AR 3125

**Conforming**

Requirement

The laboratory shall use appropriate methods and procedures for all associated data analysis and interpretation.

Objective Evidence

HFSC Quality Manual Clause 7.2.1.1.1.

#### 7.2.1.1.2 ANAB AR 3125

**Conforming**

Requirement

All test methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s).
NOTE 1 Characteristics include, but are not limited to, alleles in a DNA profile, friction ridge detail in a latent print, striation detail on a bullet, features of handwriting, or criteria for evaluation of mass spectrometry fragments and ratios in a seized drug sample or a toxicology sample extract. NOTE 2 This requirement is not focused on the process of assessing an unknown in order to identify the test item that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known prior to the assessment of the unknown.

Objective Evidence

HFSC Quality Manual Clause 7.2.1.1.2.

#### 7.2.1.1.3 ANAB AR 3125

**Not Applicable**

Requirement

For laboratories whose scope of accreditation includes calibration:
a) measuring instrument calibration methods shall assess accuracy (bias and precision) of the instrument across a range of values that meets the needs of the customer; and
b) the source of material(s) used to calibrate a measuring instrument shall be different from that used to adjust a measuring instrument and that used to verify calibration status.
**NOTE 1** a) “needs of the customer” include regulatory or statutory limits.
**NOTE 2** b) Preference should be given to material(s) from different manufacturers, followed by different lot numbers of material from the same manufacturer.

Objective Evidence

N/A

### 7.2.1.2 ISO/IEC 17025:2017

**Conforming**

Requirement

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

Objective Evidence

HFSC Quality Manual Clause 7.2.1.2.

### 7.2.1.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details

Objective Evidence

HFSC Quality Manual Clause 7.2.1.3.

### 7.2.1.4 ISO/IEC 17025:2017

**Conforming**

Requirement

When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used

Objective Evidence

HFSC Quality Manual Clause 7.2.1.4.

### 7.2.1.5 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

Objective Evidence

HFSC Quality Manual Clause 7.2.1.5 and verification and validation studies located in Qualtrax.

### 7.2.1.6 ISO/IEC 17025:2017

**Conforming**

Requirement

When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

Objective Evidence

HFSC Quality Manual Clause 7.2.1.6.

### 7.2.1.7 ISO/IEC 17025:2017

**Conforming**

Requirement

Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. NOTE Customer acceptance of deviations can be agreed in advance in the contract.

Objective Evidence

HFSC Quality Manual Clause 7.2.1.7.

## 7.2.2 VALIDATION OF METHODS

### 7.2.2.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items. NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:
a) calibration or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

Objective Evidence

HFSC Quality Manual Clause 7.2.2.1

#### 7.2.2.1.1 ANAB AR 3125

**Conforming**

Requirement

The laboratory shall have a procedure for method validation that:
a) includes the associated data analysis and interpretation;
b) establishes the data required to report a result, opinion, or interpretation;

Objective Evidence

HFSC Quality Manual Clause 7.2.2.1.1.

#### 7.2.2.1.2 ANAB AR 3125

**Conforming**

Requirement

The associated data interpretation is considered part of a validated method. When changes are made, then ISO/IEC 17025:2017, 7.2.2.2 applies.

Objective Evidence

HFSC Quality Manual Clause 7.2.2.1.2.

### 7.2.2.2 ISO/IEC 17025:2017

**Conforming**

Requirement

When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed. NOTE Changes to associated data analysis and interpretation are considered changes to a validated method.

Objective Evidence

HFSC Quality Manual Clause 7.2.2.2.

### 7.2.2.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements. NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

Objective Evidence

HFSC Quality Manual Clause 7.2.2.3

### 7.2.2.4 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall retain the following records of validation:
a) the validation procedure used;
b) specification of the requirements;
c) determination of the performance characteristics of the method;
d) results obtained;
e) a statement on the validity of the method, detailing its fitness for the intended use.

Objective Evidence

HFSC Quality Manual Clause 7.2.2.4.

## 7.3 SAMPLING

### 7.3.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

Objective Evidence

HFSC Quality Manual Clause 7.3.1.

### 7.3.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The sampling method shall describe:
a) the selection of samples or sites;
b) the sampling plan
**ANAB AR 3125** b).1 Statistical sampling at a stated level of confidence shall be used if an inference will be made to report on the whole population.
c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.
**NOTE 1** When received into the laboratory, further handling can be required as specified in 7.4.
**NOTE 2 (ANAB AR3125)** The intent of ISO/IEC 17025 is that the activity of sampling occurs prior to the item being submitted to the laboratory. A laboratory can choose to perform further sampling after receipt of the item, in which case the requirements for sampling are applicable.

Objective Evidence

HFSC Quality Manual Clause 7.3.2.

### 7.3.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:
a) reference to the sampling method used;
b) date and time of sampling;
c) data to identify and describe the sample (e.g. number, amount, name];
d) identification of the personnel performing sampling;
e) identification of the equipment used;
f) environmental or transport conditions;
g) diagrams or other equivalent means to identify the sampling location, when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan.

Objective Evidence

HFSC Quality Manual Clause 7.3.3

## 7.4 HANDLING OF TEST OR CALIBRATION ITEMS

### 7.4.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.

Objective Evidence

HFSC Quality Manual Clause 7.4.1, Client Services/Case Management (CS/CM) IAPE accreditation, and HFSC CS/CM SOP.

### 7.4.1.1 ANAB AR 3125

**Conforming with Comment**

Requirement

For all test items received except known origin individual characteristic database samples, the procedure shall:
a) address requirements for storage, packaging, and sealing of items to: 1. protect the integrity of all items; and 2. require items to be re-sealed as soon as practicable;
b) address measures to be taken to secure unattended items;
c) require chain-of-custody for: 1. all items received; and 2. items that are collected or created and preserved for future testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, trace evidence, DNA extracts);
d) require chain-of-custody to securely and accurately identify: 1. the individual(s) or location(s) receiving or transferring the item(s); and 2. the item(s) being transferred; and 3. the chronological order of all transfers, minimally including the date;
e) require communication to the customer regarding the disposition of all items received; and
f) ANAB address communication to the customer regarding items collected or created and preserved for future testing.
**NOTE 1 c)** An item being tracked could contain multiple components and be tracked as one item.
**NOTE 2 d)1)** Documentation of internal transfers does not need to include use of personal storage locations.

Objective Evidence

Latent Prints: Based on information in a review DUI it was discovered that a comment to correct the chain of custody was not made nor was a workflow submitted as documentation. A workflow has since been submitted by the examiner to have the comment added.

Firearms: Trigger Pull Uncertainty of Measurement worksheets includes a time stamp. During the case record review of 2020-09848 and 2021-20350 it was noted that there was a discrepancy in the COC time stamp and the UM timestamp that made it appear that the evidence was not in the analyst possession during the trigger pull UM measurement process. The origin of the time discrepancy should be identified, and the issue resolved.

### 7.4.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

Objective Evidence

HFSC Quality Manual Clause 7.4.2.

### 7.4.2.1 ANAB AR 3125

**Conforming**

Requirement

The system used to identify items shall cover all items received.

Objective Evidence

HFSC Quality Manual Clause 7.4.2.1 and through observation of the analysis of casework during the internal audit.

### 7.4.3 ISO/IEC 17025:2017

**Conforming**

Requirement

Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

Objective Evidence

HFSC Quality Manual Clause 7.4.3.

### 7.4.4 ISO/IEC 17025:2017

**Conforming**

Requirement

When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

Objective Evidence

HFSC Quality Manual Clause 7.4.4, HFSC Procedure Guide 500 Jefferson 18th Floor Laboratory Systems, and HFSC Procedure Guide 500 Jefferson 18th Floor Generator Process.

## 7.5 TECHNICAL RECORDS

### 7.5.1 ISO/IEC 17025:2017

**Nonconformance**

Requirement

The laboratory shall 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. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

Objective Evidence

Multimedia: Original notes are written in a Word document and copied/pasted on the report template in JusticeTrax LIMS. The Word document is not retained in the case file record. If edits are suggested in TR/AR and documented in the Review DUI, the original report is not retained in the case record providing no way to confirm that the suggested revisions were made. If the revisions were made, the original report is not being retained in the case record and there is a loss of original observations.
When an extraction fails, the analyst adds a note in the report but the original extraction data proving the failure is not kept in the case record.
Evidence was transferred to another analyst for extraction. There are no notes from the analyst that conducted the extraction in the case file. What was performed and found by the other analyst was documented and reported by the primary analyst.

Forensic Biology: The ownership review checklist for one case was incomplete and the notification had already been issued.

### 7.5.1.1 ANAB AR3125

**Conforming**

Requirement

Define the technical record(s) to be retained if all related technical records are not maintained.

Objective Evidence

HFSC Quality Manual Clause 7.5.1.1.

### 7.5.1.2 ANAB AR3125

**Conforming**

Requirement

Where abbreviations or symbols specific to the forensic service provider are used, the meaning of the abbreviations or symbols shall be defined.

Objective Evidence

HFSC Quality Manual Clause 7.5.1.2.

### 7.5.1.3 ANAB AR3125

**Conforming**

Requirement

Technical records to support a report (including results, opinions, and interpretations) shall be such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data.

Objective Evidence

HFSC Quality Manual Clause 7.5.1.3.

### 7.5.1.4 ANAB AR3125

**Conforming**

Requirement

Records shall be created or maintained in a permanent manner.

Objective Evidence

HFSC Quality Manual Clause 7.5.1.4.

### 7.5.1.5 ANAB AR3125

**Nonconformance**

Requirement

If an observation, data, or calculation is rejected, the reason, the identity of the individual(s) taking the action and the date shall be recorded in the technical record

Objective Evidence

Multimedia: Photographs of the evidence are uploaded into the case file record in a PDF document. The original photographs are stored temporarily (30 days) in the Multimedia network. The derivative item created contains the photographs; however, this item is given to the stakeholder and is not part of the case file. The date that the images were captured is not recorded and properties of the photos uploaded to the case file cannot be checked.

Forensic Biology: Observations and/or test results are crossed out but the reason for the rejection is not recorded on most case files.

Forensic Biology (Conforming with Comment): Manual additions to electropherograms are not dated. In some instances, it is difficult to determine when the DNA interpretation starts and ends.

### 7.5.1.6 ANAB AR3125

**Conforming**

Requirement

If an adjustment or repair is performed due to a calibration that does not meet specifications, pre and post adjustment repair data shall be retained. NOTE See related clause 180/IEC 17025:2017, 7.8.4.1.d)

Objective Evidence

HFSC Quality Manual Clause 7.5.1.6.

### 7.5.2 ISO/IEC 17025:2017

**Conforming with Comment**

Requirement

The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

Objective Evidence

Crime Scene Unit: A obliteration was observed in a case packet for 2020-13963. A currency form was scribed by a non-CSI. That person obliterated a mistake in their notes rather than using a single strike-through. This appears to be a onetime occurrence. Corrections made by CSIs in their case notes were observed by the audit team to conform to Quality Manual clause 7.5.2.

Multimedia: In a training binder white-out was used on a supervised technical review sheet to cover a miswritten number and the technical reviewer's name.

## 7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

### 7.6.1 ISO/IEC 17025:2017

**Conforming**

Requirement

Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

Objective Evidence

HFSC Quality Manual Clause 7.6.1.

### 7.6.1.1 ANAB AR3125

**Conforming**

Requirement

The method of analysis for evaluation of measurement uncertainty shall:
a) require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;
b) include the process of rounding the expanded uncertainty;
c) require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and
d) specify the schedule to review and/or recalculate the measurement uncertainty.

Objective Evidence

HFSC Quality Manual Clause 7.6.1.1

### 7.6.2 ISO/IEC 17025:2017

**Not Applicable**

Requirement

A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

Objective Evidence

N/A

### 7.6.3 ISO/IEC 17025:2017

**Conforming**

Requirement

A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.
**NOTE 1** In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.
**NOTE 2** For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.
**NOTE 3** For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

Objective Evidence

HFSC Quality Manual Clause 7.6.3.

### 7.6.3.1 ANAB AR3125

**Conforming**

Requirement

Measurement uncertainty shall be evaluated, or estimated when applicable, for all reported quantitative results. NOTE An item descriptor that includes a number is not considered a result. This difference should be clear to the reader of the report.

Objective Evidence

HFSC Quality Manual Clause 7.6.3.1.

### 7.6.4 ANAB AR3125

**Conforming**

Requirement

The following records shall be maintained for each evaluation and estimation of measurement uncertainty:
a) ANAB statement defining the measurand;
b) ANAB statement of how traceability is established for the measurement;
c) ANAB the equipment (e.g., measuring device[s] or instrument[s]) used;
d) ANAB all uncertainty components considered;
e) ANAB all uncertainty components of significance and how they were evaluated;
f) ANAB data used to estimate repeatability, intermediate precision, and/or reproducibility;
g) ANAB all calculations performed; and
h) ANAB the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

Objective Evidence

HFSC Quality Manual Clause 7.6.4.

## 7.7 ENSURING THE VALIDITY OF RESULTS

### 7.7.1 ISO/IEC 17025:2017 & ANAB AR 3125

**Nonconformance**

Requirement

The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:
a) use of reference materials or quality control materials;
b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s] of measuring and testing equipment;
d) use of check or working standards with control charts, where applicable;
e) intermediate checks on measuring equipment;
f) replicate tests or calibrations using the same or different methods;
g) retesting or recalibration of retained items;
ANAB AR3125 g.1) When a verification of a result is carried out:
a) it shall be conducted by an individual who is currently authorized to perform the testing;
b) a record of the verification shall be made and the record shall identify who performed the verification, when it was performed, and the result of the verification;
c) the resolution of any discrepancy shall be recorded.
ANAB NOTE a) See requirements of 6.2.6 in ISO/IEC 17025:2017
h) correlation of results for different characteristics of an item;
i) review of reported results;
ANAB AR3125 i.1 There shall be a procedure for the technical review of technical records, including reports, and testimony. The procedure shall:
1. require the individual performing the technical review to have been competency tested to perform the testing or calibration work that is being
2. preclude an individual from technically reviewing their own work;
3. define the method to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review;
4. define the method to be used to ensure testimony in each discipline is reviewed;
5. define the method to be used to conduct and record the review;
6. ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record;
7. ensure conformance with methods and applicable management system documents; and
8. describe a course of action to be taken if a discrepancy is found.
ANAB NOTE 1 An individual conducting the technical review need not be an employee of the forensic service provider, currently proficiency tested or currently performing the work.
ANAB NOTE 2 An individual who performs a verification can also perform a technical review. ANAB NOTE 3 The sampling rate may vary for different disciplines.
j) 17025 intra-laboratory comparisons;
k) 17025 testing of blind sample(s).

## Objective Evidence

Crime Scene Unit: During the 2021 internal audit, the audit team identified defects in several case records. Defects requiring corrections were identified in 12 reports, 7 case notes and 2 scene diagrams.

Crime Scene Unit (Conforming with Comment): The CSU Review sheet is not being utilized as intended. CSIs do not always sign the form documenting that they have made the corrections listed on the review form.

Latents Prints (Conforming with Comment): Two grammatical errors were discovered during case file reviews. “Analysis” is spelled incorrectly on an item in Mideo for case 2020-10583. In case 2017-10733 the report says, “The above listed items was”.

Multimedia (Conforming with Comment): Two cases where the TR or AR requested changes and changes were not addressed. In one case the starting day was missing from the examination notes. The technical reviewer asked the analyst to add/correct the starting day; however, whether the correction was made or no can’t be tracked since no original was uploaded/kept in the case file. In the other case the investigator name is misspelled as Media instead of Medina. This was documented in the administrative review, but the correction was not made. In one case a number (#2) is missing from the agency case number of the extraction log. In one case the target location and meeting location are missing in the report. A workflow was initiated to amend the report before the closing meeting. Photos from one case were uploaded by mistake in another case file.

Multimedia (Conforming with Comment): An administrative review was completed by an analyst that assisted in the case.

Multimedia (Conforming with Comment): On two cases the administrative review DUIs were not completed to document the reviews. The two DUIs were created before the closing meeting of the audit. A case has two DUIs for the administrative review. It was not clear why two administrative reviews were completed.

### 7.7.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:
a) participation in proficiency testing; NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of 150/IEC 17043 are considered to be competent.
b) participation in inter-laboratory comparisons other than proficiency testing.

Objective Evidence

HFSC Quality Manual Clause 7.7.2.

### 7.7.2.1 ANAB AR 3125

**Conforming**

Requirement

The process for monitoring performance by comparison with results of other forensic service providers shall at a minimum:
a) ensure successful completion of at least one proficiency test for each discipline prior to accreditation being granted in that discipline; and
b) ensure each location on the scope of accreditation successfully completes, per calendar year, at least one proficiency test for each discipline in which accredited services are provided, with authorized release of the test results to ANAB from the test provider.
**NOTE 1** Calibration and Testing scopes of accreditation are separate within the Toxicology discipline. The above requirements apply to each scope of accreditation.
**NOTE 2** For proficiency tests taken at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

Objective Evidence

HFSC Quality Manual Clause 7.7.2.1

### 7.7.3 ISO/IEC 17025:2017

**Conforming**

Requirement

Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

Objective Evidence

HFSC Quality Manual Clause 7.7.3.

### 7.7.4 ANAB AR3125

**Conforming**

Requirement

The performance of personnel shall be monitored. This monitoring shall ensure that all personnel who influence the results of testing or calibration activities shall successfully complete at least one intralaboratory comparison, interlaboratory comparison or proficiency test per calendar year in each discipline on the scope of accreditation in which the individual conducts work. In the event that the preceeding options are not available or appropriate, observation-based performance monitoring is acceptable.
**NOTE 1** The monitoring should be varied over time to cover all aspects of assigned job functions, but does not have to include all aspects of the work performed each time.
**NOTE 2** Solely perfonning verifications (7.7.1.f).1) or solely reviewing and authorizing results (7.8.1.1) are considered to influence results and are subject to these requirements.
**NOTE 3** Calibration and Testing scopes of accreditation are separate within the Toxicology discipline. The above requirements apply to each scope of accreditation.
**NOTE 4** For performance monitoring conducted at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

Objective Evidence

HFSC Quality Manual Clause 7.7.4. HFSC's proficiency testing and blind quality control program.

### 7.7.5 ANAB AR3125

**Conforming**

Requirement

The process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing shall at a minimum:
a) ensure that results are not known or readily available to the participant being monitored;
b)ensure use of approved methods;
c) establish criteria for determining successful completion prior to the monitoring activity;
d) require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity; and
e) for calibration laboratories, require intralaboratory comparisons, interlaboratory comparisons and proficiency tests to be performed using a breath alcohol measuring instrument that was calibrated by the person performing the comparison or test
**NOTE c)** See requirements of 7.5 in ISO/IEC 17025:2017 and this document

Objective Evidence

HFSC Quality Manual Clause 7.7.5., proficiency testing, blind quality control program, HFSC's transcript review project, and testimony evaluation.

### 7.7.6 ANAB AR3125

**Conforming**

Requirement

There shall be a plan that will:
a) demonstrate conformance with the requirements stated in clause 7.7.2.1.b) and 7.7.4; and
b) ANAB ensure inclusion of a representative sample of the components/parameters and equipment/technologies within each discipline listed on the scope of accreditation.

Objective Evidence

HFSC Quality Manual Clause 7.7.6.

### 7.7.7 ANAB AR3125

**Conforming**

Requirement

To satisfy the proficiency test requirements in clauses 7.7.2.1.a) and b), the forensic service provider shall:
a) where available and appropriate for the work conducted, use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLA5 and has the applicable proficiency test(s) on its scope of accreditation, or
b) where not available or not appropriate for the work conducted, gain approval from ANAB for alternative means by which the laboratory's performance can be assessed.
c) submit results to the proficiency test provider, if applicable, on or before the agreed upon due date.

Objective Evidence

HFSC Quality Manual Clause 7.7.7.

### 7.7.8 ANAB AR3125

**Conforming**

Requirement

The following records shall be maintained for all intralaboratory comparisons, interlaboratory comparisons, proficiency tests and observation-based monitoring:
a) discipline(s) monitored;
b) design of the monitoring activity;
c) expected results;
d) location, when more than one location is associated with a single accreditation certificate;
e) records submitted to a proficiency test provider, when applicable;
f) appropriate technical records;
g) evaluation of results and action taken for unexpected results; and
h) feedback on individual performance provided to the participant.

Objective Evidence

HFSC Quality Manual Clause 7.7.8.

## 7.8 REPORTING OF RESULTS

## 7.8 GENERAL

### 7.8.1.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The results shall be reviewed and authorized prior to release.

Objective Evidence

HFSC Quality Manual clause 7.8.1.1. and through case file reviews.

#### 7.8.1.1.1 ANAB AR3125

**Conforming**

Requirement

The authorizer of results shall review the technical record and document the review

Objective Evidence

HFSC Quality Manual clause 7.8.1.1.1.

### 7.8.1.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

**NOTE 1** For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.
**NOTE 2** Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

Objective Evidence

HFSC Quality Manual Clause 7.8.1.2. and laboratory reports.

### 7.8.1.2.1 ANAB AR3125

**Conforming**

Requirement

The results shall be provided in a written report. NOTE The reporting of results does not include testing of known origin samples for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.

Objective Evidence

HFSC Quality Manual clause 7.8.1.2.1 and laboratory results

### 7.8.1.2.2 ANAB AR3125

**Conforming**

Requirement

There shall be a procedure for reporting of results that:
a) identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for partial work performed;
b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement;
**NOTE b)** Associations for multiple results may be qualified by a single statistic or qualitative statement if the statistics are identical or, where applicable, meet or exceed a defined minimum threshold
c) requires communicating the reason(s) in the report when the reported results are inconclusive;
d) requires reporting of the initial database entry (e.g., CODIS, AFIS, NIBIN); and
e) requires reporting of an association resulting from a database search ( e.g., CODIS, AFIS, NIBIN).

Objective Evidence

HFSC Quality Manual Clause 7.8.1.2.2 and laboratory reports.

### 7.8.1.2.3 ANAB AR3125

**Not Applicable**

Requirement

The documented process for reporting of results of calibration shall:
a) identify what information will be reported in the calibration certificate; and
b) require the issuance of an endorsed calibration certificate if requested by the customer.

Objective Evidence

N/A

### 7.8.1.3 ANAB AR3125

**Conforming**

Requirement

When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

Objective Evidence

HFSC Quality Manual Clause 7.8.1.3. Simplified report agreements and acknowledgment documentation are maintained in Qualtrax.

### 7.8.1.3.1 ANAB AR3125

**Conforming**

Requirement

When results are reported in a simplified way, the agreement with the customer shall specify which information in 7.8.2 through 7.8.7 of ISO/IEC 17025:2017 will not be included in a written report or through electronic access. The requirements 7.8.2 through 7.8.7 in this document are applicable even if the forensic service provider reports results in a simplified way.

Objective Evidence

HFSC Quality Manual Clause 7.8.1.3. Simplified report agreements and acknowledgment documentation are maintained in Qualtrax.

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

### 7.8.2.1 ISO/IEC 17025:2017

**Conforming with Comment**

Requirement

Each report .shall 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) 17025 a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");
b) 17025 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 laboratory's 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.
**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.
**NOTE 3 i)** Date(s) may be reflected as a range of dates or the date of each activity.
**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)

Objective Evidence

Latent Prints: The ACE-V methodology is not included on latent print comparison reports. This requirement was discussed prior to the audit between the quality division and latent print management. During the audit it was recommended to the latent print section to include this on their reports prior to the external assessment. As of 4/26/21 the method has been included on reports.

### 7.8.2.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

Objective Evidence

HFSC Quality Manual Clause 7.8.2.2 and through case file reviews

## 7.8.3 SPECIFIC REQUIREMENTS

### 7.8.3.1 ISO/IEC 17025:2017

**Conforming**

Requirement

In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:
a) information on specific test conditions, such as environmental conditions;
b) 17025 where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: -it is relevant to the validity or application of the test results; -a customer's instruction so requires, or -the measurement uncertainty affects conformity to a specification limit;

7.8.3.1.c).1 ANAB The measurement uncertainty shall:
a) be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;
b) include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;
c) be in the format of y ± U;
d) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and
e) be reported to the same level of significance (i.e., same number of decimal places or digits) as the measurement result.
d) where appropriate, opinions and interpretations (see 7.8.7);
e) 17025 additional information that may be required by specific methods, authorities, customers or groups of customers.
ANAB NOTE 1 a) A legal requirement is created, imposed, and enforced by a third-party external to the laboratory agency.
ANAB NOTE 2 c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.
ANAB NOTE 3 e) Reducing or simplifying a fraction is not a change in level of significance.

Objective Evidence

HFSC Quality Manual Clause 7.8.3.1.1. and laboratory reports with uncertainty of measurement for quantitative measurements.

### 7.8.3.1.1 ANAB AR3125

**Conforming**

Requirement

If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, the forensic service provider shall:
a) have objective evidence of the regulation, statute, case law or other legal requirement; and
b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

Objective Evidence

HFSC Quality Manual Clause 7.8.3.1.1 and laboratory reports with uncertainty of measurement for quantitative measurements.

### 7.8.3.2 SO/IEC 17025:2017

**Conforming**

Requirement

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

Objective Evidence

HFSC Quality Manual Clause 7.8.3.2 and through case file reviews

## 7.8.4 REPORTING SAMPLING-SPECIFIC CERTIFICATES ISO/IEC 17025:2017

### 7.8.4.1 ISO/IEC 17025:2017

**Not Applicable**

Requirement

In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:
a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent); NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.
**7.8.4.1.a).1 ANAB** The measurement uncertainty shall:
a ) include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, and the coverage probability;
b) be in the format of y ± U;
c) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and
d) be reported to the same level of significance (i.e., same number of decimal places or digits) as the measurement result.
**ANAB NOTE c)** For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.
b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
c) a statement identifying how the measurements are metrologically traceable (see Annex A);
d) 17025 the results before and after any adjustment or repair, if available;
e) 17025 where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
f) 17025 where appropriate, opinions and interpretations (see 7.8.7).

Objective Evidence

N/A

### 7.8.4.1.1 ANAB AR 3125

**Not Applicable**

Requirement

If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a calibration result or prohibits including measurement uncertainty in the calibration certificate, the forensic service provider shall:
a) have objective evidence of the regulation, statute, case law or other legal requirement; and
b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the calibration result.

Objective Evidence

N/A

### 7.8.4.2 ISO/IEC 17025:2017

**Not Applicable**

Requirement

Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

Objective Evidence

N/A

### 7.8.4.3 ISO/IEC 17025:2017

**Not Applicable**

Requirement

A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

Objective Evidence

N/A

### 7.8.4.4 ANAB AR 3125

**Not Applicable**

Requirement

If applicable, a label (in addition to the calibration certificate) attached to a calibrated breath alcohol measuring instrument shall not give the impression that the breath alcohol instrument itself is approved and shall include:
a) the name of the accredited calibration laboratory or its accreditation certificate number;
b) the unambiguous identification of the item calibrated;
c) the date of the current calibration; and
d) cross reference to the calibration certificate issued in respect to the calibration.

Objective Evidence

N/A

### 7.8.5 REPORTING SAMPLING-SPECIFIC CERTIFICATES ISO/IEC 17025:2017

**Conforming**

Requirement

Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall 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;
**7.8.5.d).1 ANAB** If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.
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.

Objective Evidence

HFSC Quality Manual Clause 7.8.5.

### 7.8.6 REPORTING STATEMENTS OF CONFORMITY

#### 7.8.6.1 ISO/IEC 17025:2017

**Conforming**

Requirement

When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions] associated with the decision rule employed, and apply the decision rule.
**NOTE:** Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

Objective Evidence

HFSC Quality Manual Clause 7.8.6.1.

#### 7.8.6.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall report on the statement of conformity, such that the statement clearly identifies:
a) to which results the statement of conformity applies;
b) which specifications, standards or parts thereof are met or not met;
c) the decision rule applied (unless it is inherent in the requested specification or standard).
**NOTE:** For further information, see ISO/IEC Guide 98-4.

Objective Evidence

HFSC Quality Manual Clause 7.8.6.2. and through case file reviews.

### 7.8.7 REPORTING OPINIONS AND INTERPRETATIONS

#### 7.8.7.1 ISO/IEC 17025:2017

**Conforming**

Requirement

When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.
NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.

Objective Evidence

HFSC Quality Manual Clause 7.8.7.1., through case file reviews and review of personnel quality files and training records.

#### 7.8.7.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

Objective Evidence

HFSC Quality Manual Clayse 7.8.7.2 and through case file reviews.

#### 7.8.7.3 ISO/IEC 17025:2017

**Conforming**

Requirement

When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

Objective Evidence

HFSC Quality Manual Clause 7.8.7.3 and through case file reviews.

### 7.8.8 AMENDMENTS TO REPORTS

#### 7.8.8.1 ISO/IEC 17025:2017

**Conforming**

Requirement

When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

Objective Evidence

HFSC Quality Manual Clause 7.8.8.1 and through case file reviews and through the Qualtrax IR/CAR reporting workflow.

#### 7.8.8.2 ISO/IEC 17025:2017

**Conforming**

Requirement

Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement ''. Amendment to Report, serial number ... [or as otherwise identified]", or an equivalent form of wording.
Such amendments shall meet all the requirements of this document.

Objective Evidence

HFSC Quality Manual Clause 7.8.8.2., through case file reviews and through the Qualtrax IR/CAR reporting workflow.

### 7.8.8.3 ISO/IEC 17025:2017

**Conforming**

Requirement

When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Objective Evidence

HFSC Quality Manual Clause 7.8.8.2 and through case file reviews and through the Qualtrax IR/CAR reporting workflow.

## 7.9 COMPLAINTS

### 7.9.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.

Objective Evidence

HFSC Quality Manual Clause 7.9.1.

### 7.9.2 ISO/IEC 17025:2017

**Conforming**

Requirement

A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

Objective Evidence

HFSC Quality Manual Clause 7.9.2.

### 7.9.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The process for handling complaints shall include at least the following elements and methods:
a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
b) tracking and recording complaints, including actions undertaken to resolve them;
c) ensuring that any appropriate action is taken.

Objective Evidence

HFSC Quality Manual Clause 7.9.3.

### 7.9.4 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

Objective Evidence

HFSC Quality Manual Clause 7.9.4.

### 7.9.5 ISO/IEC 17025:2017

**Conforming**

Requirement

Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

Objective Evidence

HFSC Quality Manual Clause 7.9.5.

### 7.9.6 ISO/IEC 17025:2017

**Conforming**

Requirement

The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

**NOTE:** This can be performed by external personnel.

Objective Evidence

HFSC Quality Manual Clause 7.9.6.

### 7.9.7 ISO/IEC 17025:2017

**Conforming**

Requirement

Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

Objective Evidence

HFSC Quality Manual Clause 7.9.7.

## 7.10 NONCONFORMING WORK

### 7.10.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are defined;

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

Objective Evidence

HFSC Quality Manual Clause 7.10.1.

### 7.10.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

Objective Evidence

HFSC Quality Manual Clause 7.10.2.

### 7.10.3 ISO/IEC 17025:2017

**Conforming**

Requirement

Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

Objective Evidence

HFSC Quality Manual Clause 7.10.3.

## 7.11 CONTROL OF DATA AND INFORMATION MANAGEMENT

### 7.11.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall have access to the data and information needed to perform laboratory activities.

Objective Evidence

HFSC Quality Manual Clause 7.11.1.

### 7.11.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE 1 In this document “laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

Objective Evidence

HFSC Quality Manual Clause 7.11.2

### 7.11.2.1 ANAB AR 3125

**Conforming**

Requirement

There shall be a plan for validation of computer software developed by the user and records of the validation shall be maintained.

Objective Evidence

HFSC Quality Manual 7.11.2.1.

### 7.11.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory information management system(s) shall:
a) be protected from unauthorized access;
b) be safeguarded against tampering and loss;
c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
d) be maintained in a manner that ensures the integrity of the data and information;
e) include recording system failures and the appropriate immediate and corrective actions.

Objective Evidence

HFSC Quality Manual Clause 7.11.3.

### 7.11.4 ISO/IEC 17025:2017

**Conforming**

Requirement

When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

Objective Evidence

HFSC Quality Manual Clause 7.11.4.

### 7.11.5 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

Objective Evidence

HFSC Quality Manual Clause 7.11.5.

### 7.11.6 ISO/IEC 17025:2017

**Nonconformance**

Requirement

Calculations and data transfers shall be checked in an appropriate and systematic manner.

ANAB NOTE: This requirement does not apply if the calculation or data transfer is secure and not subject to human error.

Objective Evidence

Firearms: The Firearms Section Trigger Pull Gauge Worksheet values for ‘Shotgun’ and ‘Rifle’ were switched. These values are used to calculate trigger pull uncertainty of measurement. The calculated uncertainty of measurement is included on reports when trigger pull determinations are reported.

### 7.11.6.1 ANAB AR 3125

**Conforming**

Requirement

The technical record shall indicate the check was performed and who performed the check. When possible, this check shall not be conducted by the person who performed the calculation(s) or the data transfers.
**NOTE:**This check may be part of a technical review

Objective Evidence

HFSC Quality Manual 7.11.6 and through case file reviews.

## 8 MANAGEMENT SYSTEM REQUIREMENTS

### 8.1 OPTIONS

#### 8.1.1 GENERAL ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.
**NOTE:** See Annex B for more information.

Objective Evidence

HFSC follows option A; HFSC Quality Manual Clause 8.1.1.

#### 8.1.2 ISO/IEC 17025:2017

**Conforming**

Requirement

Option A
As a minimum, the management system of the laboratory shall address the following:
— management system documentation (see 8.2);
— control of management system documents (see 8.3);
— control of records (see 8.4);
— actions to address risks and opportunities (see 8.5);
— improvement (see 8.6);
— corrective actions (see 8.7);
— internal audits (see 8.8);
— management reviews (see 8.9).

Objective Evidence

HFSC Quality Manual Clause 8.1.2.

#### 8.1.3 ISO/IEC 17025:2017

**Not Applicable**

Requirement

Option B
A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.

Objective Evidence

N/A

#### 8.1.3.1 ANAB AR 3125

**Not Applicable**

Requirement

In order for Option B to be available to a forensic service provider, the provider must maintain an accredited ISO 9001 certification. The certification body, which certified the provider to ISO 9001, must be accredited for ISO 9001 by an IAF
MLA signatory accreditation body for management systems. Any forensic service provider that does not meet this criterion must choose Option A.

Objective Evidence

N/A

#### 8.1.3.2 ANAB AR 3125

**Not Applicable**

Requirement

The Option A requirements under 8.2 through 8.9 in this document are also applicable to forensic service providers who choose Option B.

Objective Evidence

N/A

### 8.2 MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

#### 8.2.1 ISO/IEC 17025:2017

**Conforming with Comment**

Requirement

Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

Objective Evidence

Firearms: The HFSC Health and Safety Manual clause 13.6.2 state, "All primary containers of hazardous chemicals are clearly labeled to include: The identity of the chemical as it appears on the SDS." There were two plastic bottles located in the Firearms Section basement lab area that were stored in a red carrying case along with a magnetic yoke. The contents of one bottle is dried, both bottles appear very old. Neither is labeled in a manner consistent with current labeling practices, and they are not stored in a safe manner. One bottle, which contains a small amount of red liquid, is labelled "Magnaflux Red Magnetic Particle Suspension Shake Well Before Using Kinderprint Co., Inc 800-227-6020". The other bottle, which contains a dried dark grey material, is labeled "Magnaflux Black Magnetic Particle Suspension Shake Well Before Using Kinderprint Co., Inc. 800-227-6020".

#### 8.2.1.1 ANAB AR 3125

**Conforming**

Requirement

The following words (to include forms of the same word) used in ISO/IEC 17025:2017 or in this document require addressing the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify

Objective Evidence

HFSC Quality Manual Clause 8.2.1.1.

#### 8.2.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

Objective Evidence

HFSC Quality Manual Clause 8.2.2.

#### 8.2.3 ISO/IEC 17025:2017

**Conforming**

Requirement

Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

Objective Evidence

HFSC Quality Manual Clause 8.2.3.

### 8.2.4 ISO/IEC 17025:2017

**Conforming**

Requirement

All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

Objective Evidence

HFSC Quality Manual Clause 8.2.4.

### 8.2.5 ISO/IEC 17025:2017

**Conforming**

Requirement

All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

Objective Evidence

HFSC Quality Manual Clause 8.2.5.

## 8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS

### 8.3.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.
**NOTE:** In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

Objective Evidence

HFSC Quality Manual Clause 8.3.1.

### 8.3.2 ISO/IEC 17025:2017

**Conforming with Comment**

Requirement

The laboratory shall ensure that:
a) documents are approved for adequacy prior to issue by authorized personnel;
b) documents are periodically reviewed, and updated as necessary;
c) changes and the current revision status of documents are identified;
d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
e) documents are uniquely identified;
f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

Objective Evidence

Crime Scene Unit: Peer Review forms are not controlled and not always retained in the case record. Peer reviews quality as case related documentation subject to disclosure. These forms should be controlled and retained in the case record. CSU identified this issue and started retaining the Peer Review forms in the case record in January of 2021.

## 8.4 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS

### 8.4.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.

Objective Evidence

HFSC Qualiy Manual Clause 8.4.1.

### 8.4.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.
**NOTE:** Additional requirements regarding technical records are given in 7.5.
**ANAB NOTE 2:** Contractual obligations for records retention include legal requirements and customer expectations.

Objective Evidence

HFSC Qualiy Manual Clause 8.4.2.

## 8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (OPTION A)

### 8.5.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:
a) give assurance that the management system achieves its intended results;
b) enhance opportunities to achieve the purpose and objectives of the laboratory;
c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
d) achieve improvement.

Objective Evidence

HFSC Quality Manual Clause 8.5.1.

### 8.5.1.1 ANAB AR 3125

**Conforming**

Requirement

Risks and opportunities related to health and safety shall be considered.

Objective Evidence

HFSC Quality Manual Clause 8.5.1.1.

### 8.5.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall plan:
a) actions to address these risks and opportunities;
b) how to:
— integrate and implement these actions into its management system;
— evaluate the effectiveness of these actions.
**NOTE:** Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

Objective Evidence

HFSC Quality Manual Clause 8.5.2.

### 8.5.3 ISO/IEC 17025:2017

**Conforming**

Requirement

Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.
**NOTE 1** Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.
**NOTE 2** Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

Objective Evidence

HFSC Quality Manual Clause 8.5.3.

## 8.6 IMPROVEMENT (OPTION A)

### 8.6.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall identify and select opportunities for improvement and implement any necessary actions.
**NOTE:** Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

Objective Evidence

HFSC Quality Manual Clause 8.6.1 and Preventive action reports are maintained in Qualtrax.

### 8.6.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service.
**NOTE:** Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

Objective Evidence

HFSC Quality Manual Clause 8.6.2 Survey feedback (and applicable responses) and preventive action reports are maintained in Qualtrax.

## 8.7 CORRECTIVE ACTIONS (OPTION A)

### 8.7.1 ISO/IEC 17025:2017

**Conforming**

Requirement

When a nonconformity occurs, the laboratory shall:
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.
**ANAB g)** The process for corrective action shall establish a reasonable timeframe for completion for each corrective action.

Objective Evidence

HFSC follows option A; HFSC Quality Manual Clause 8.7.1.a-g.

### 8.7.2 ISO/IEC 17025:2017

**Conforming**

Requirement

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Objective Evidence

HFSC follows option A; HFSC Quality Manual Clause 8.7.2.

### 8.7.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall retain records as evidence of:
a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
b) the results of any corrective action.

Objective Evidence

HFSC Quality Manual Clause 8.7.3.a-b. Nonconformances, actions taken, and follow-up reports are tracked and maintained in Qualtrax.

## 8.8 INTERNAL AUDITS (OPTION A)

### 8.8.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:
a) conforms to:
— the laboratory's own requirements for its management system, including the laboratory activities;
— the requirements of this document;
**ANAB a).1** Internal audits shall provide information on whether the management system conforms to the requirements of this document.
b) is effectively implemented and maintained.

Objective Evidence

HFSC Quality Manual Clause 8.8.1.a-b.

#### 8.8.1.1 ANAB AR 3125

**Conforming**

Requirement

Internal audits shall be conducted at least annually, as well as prior to the initial accreditation assessment.

Objective Evidence

HFSC Quality Manual Clause 8.8.1.1.

#### 8.8.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory shall:
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;
**ANAB b).1** Internal audits shall include direct observation of a sample of accredited services within each discipline.
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.

Objective Evidence

HFSC Quality Manual Clause 8.8.2.a-e.

### 8.9 MANAGEMENT REVIEWS (OPTION A)

#### 8.9.1 ISO/IEC 17025:2017

**Conforming**

Requirement

The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

Objective Evidence

HFSC Quality Manual Clause 8.9.1 and HFSC 2020 Management Review & Update to Management Review Report.

#### 8.9.1.1 ANAB AR 3125

**Conforming**

Requirement

Management reviews shall be conducted at least annually, as well as prior to the initial accreditation assessment.

Objective Evidence

HFSC Quality Manual Clause 8.9.1.1 and HFSC 2020 Management Review & Update to Management Review Report.

#### 8.9.2 ISO/IEC 17025:2017

**Conforming**

Requirement

The inputs to management review shall be recorded and shall 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; and
o) other relevant factors, such as monitoring activities and training.

Objective Evidence

HFSC Quality Manual Clause 8.9.2 and HFSC 2020 Management Review & Update to Management Review Report

### 8.9.3 ISO/IEC 17025:2017

**Conforming**

Requirement

The outputs from the management review shall record all decisions and actions related to at least:
a) the effectiveness of the management system and its processes;
b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
c) provision of required resources;
d) any need for change.

Objective Evidence

HFSC Quality Manual Clause 8.9.3 and HFSC 2020 Management Review & Update to Management Review Report.