
AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS
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A Guide to Retroactive Case Reviews

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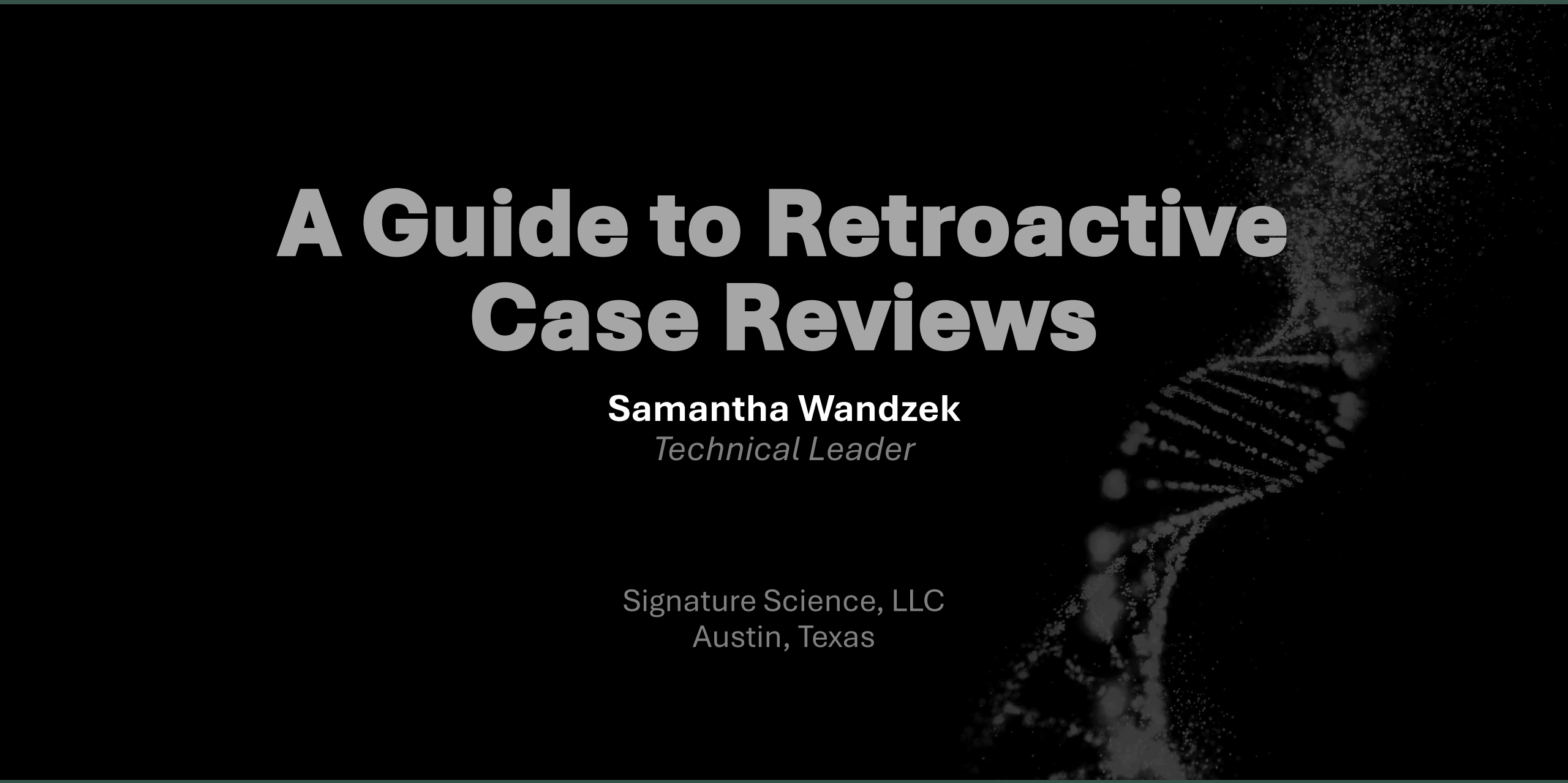
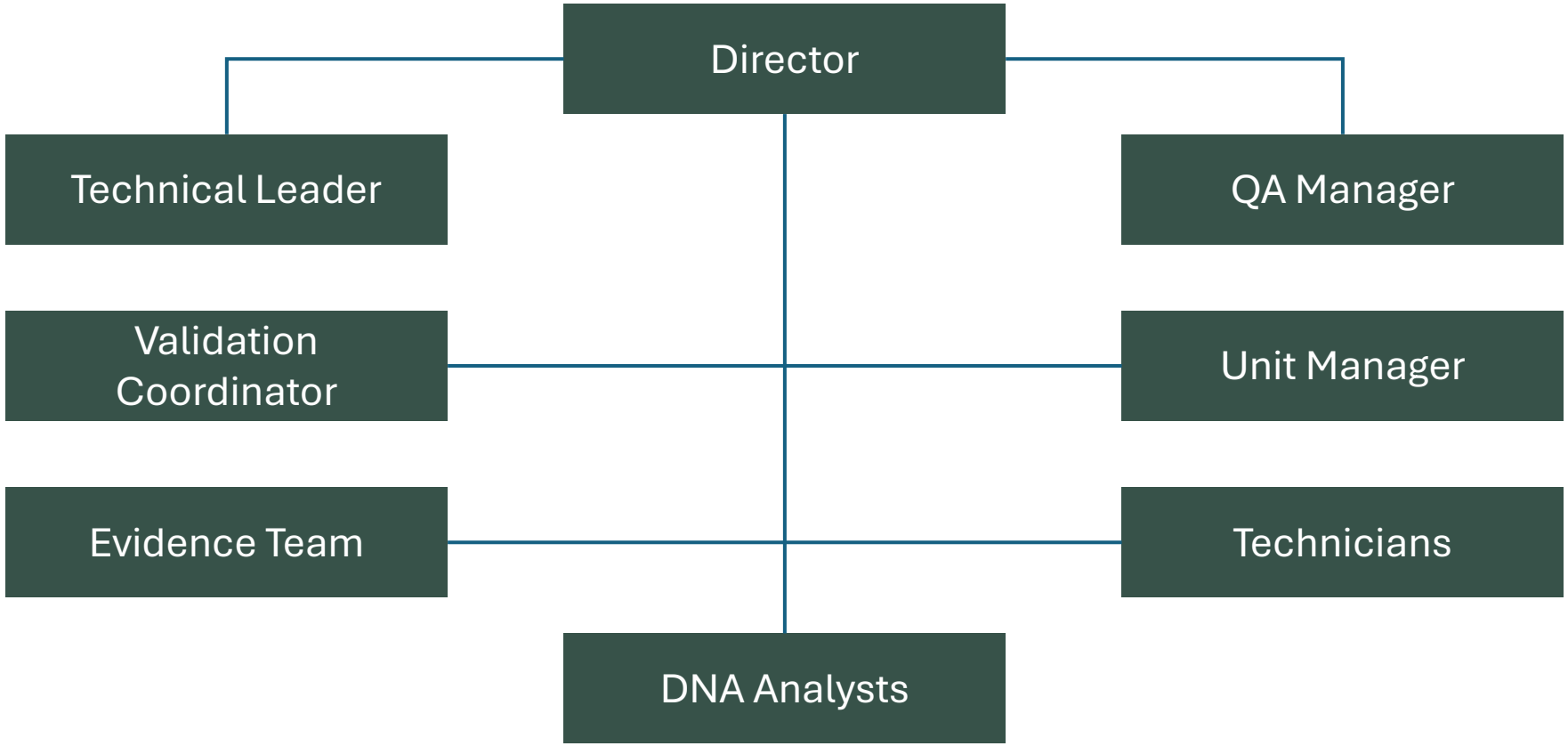


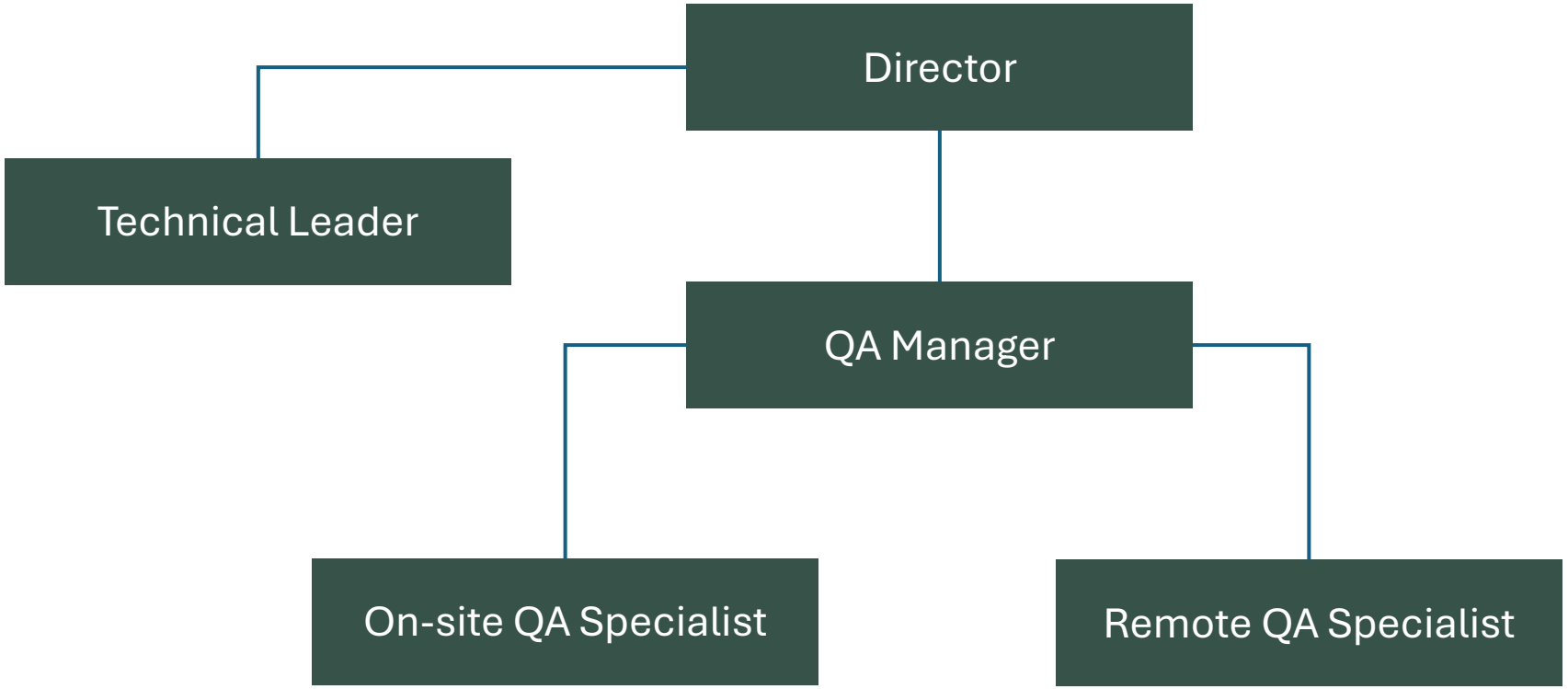
Introduction to Signature Science (SigSci)

- Multi-disciplinary scientific services company since March 2001
  - ~200 employees in four locations across the U.S.
- Forensics
- Biosecurity & emerging threats
- Infectious disease modeling/forecasting
- Chemical threat collection and detection
- Lab QA/data science/bioinformatics
- CBRNE training/exercises

Forensic DNA Casework Laboratory in Austin, Texas



Quality Assurance Team



Types of Documentation for Quality Incidents

- Case Notes
  - Comments within a LIMS (Laboratory Information Management System) generated report covering all DNA processing

Date/Time	Comments
02/24/2025 11:26 AM	SSLLC-FDL 24sec GF assay used on entire plate
02/24/2025 02:12 PM	First reads complete. Both positive controls failed. Data from this plate will not be reported. Applicable samples will be re-amped accordingly.
02/25/2025 08:17 AM	Second reads complete.

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Forensic DNA Laboratory
FFRM-020, Version 2
Effective Date: 14 July 2022

Case Notes Worksheet

Case #: LSS2024-03283 Date: 12/19/2024 Analyst: MB

Item #	Comment
1	Item was received on 12/12/24 but inadvertantly left under the custody of MB after intake, even though item was placed on SHF00010 once entered into the system. On 12/19/24 item was actually scanned to SHF00010 at approximitely 11am when the error was discovered.

- Separate document as needed depending on the situation
- Used for instrument or other issues that do not affect the overall outcome of the reported data

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Types of Documentation for Quality Incidents

- Incident Reports (IRs)
  - Typically used when sample(s) are not suitable for reporting
  - Referenced in case file and report

ADDITIONAL COMMENTS

1. See Appendix A for general information regarding serology screening for biological evidence and forensic DNA testing at this laboratory.
2. Please contact this analyst to determine if this case is eligible for additional serology and/or DNA analysis, including Y-STR testing.
3. See Incident Report 20250212-01 for additional information regarding Item(s) 1A.1-S.

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8501 North Mopac Expressway, Suite 100
Austin, Texas 78759
Telephone: (512) 533-2000

INCIDENT REPORT #20XXXXXX-XX

To: Note to File

From: [NAME], DNA Technician
[NAME], Forensic DNA Analyst

Copy: Jamie Haas, QA Manager
Samantha Wandzek, Technical Leader

Date: [DATE]

Subject: **[TYPE OF INCIDENT]**

[Summary of Incident including impacted STACS batches]

[List affected cases with SigSci as well as agency number. Include specific samples as needed]

[Discuss rework done or could be done/resolution of incident]

Types of Documentation for Quality Incidents

- Corrective Action Report (CAR)
  - Systemic issues that need root cause analysis
  - Referenced in IR which is included in case file

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Forensic Laboratory
FFRM-010, Version 5
Effective Date: 7 August 2017

Corrective Action Report

Level 1 Nonconformity: A situation or condition that directly affects and has a fundamental impact on the quality of the work product or the integrity of the evidence.

Level 2 Nonconformity: A situation or condition which may affect the quality of the work but does not, to any significant degree, affect the fundamental reliability of the work product or the integrity of the evidence.

Section A—TO BE COMPLETED BY MANAGEMENT

Tracking #:	Type of Nonconformity (Level 1 or 2):	Date:
Situation/Condition:		
Potential Effect(s) of the Discrepancy:		
Requirement Source (e.g., SOP and Section, ANAB requirement, QAS reference):		
Individual(s) Responsible for Determining and Executing Corrective Action:		Response Due Date:

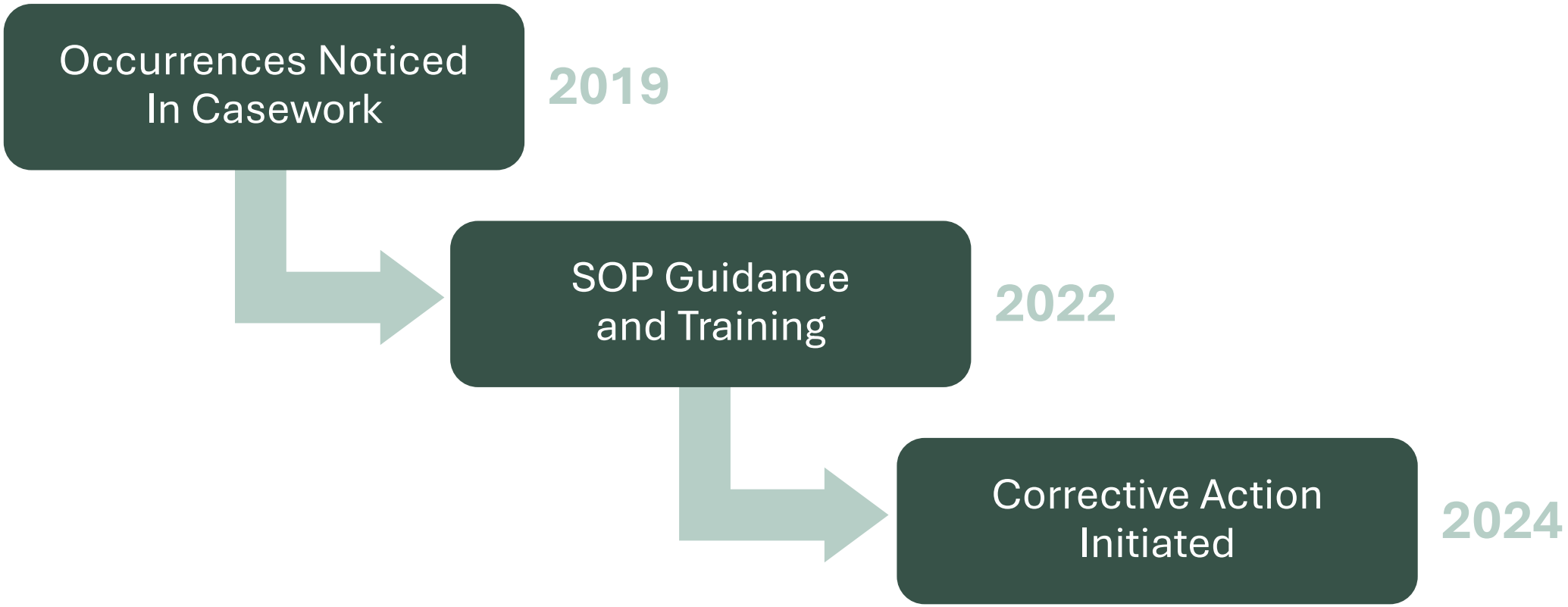
Section B—TO BE COMPLETED BY RESPONSIBLE INDIVIDUAL NAMED IN SECTION A

Root Cause Analysis:

Impact Table

		Risk or Impact on Quality →		
Level of recurrence ↓		**Low**	**Medium**	**High**
	Low	Case Note	IR	CAR
	Medium	IR	CAR	CAR
	High	CAR	CAR	CAR

How Was the Wide HPD Issue Flagged Internally?



Brief Visual of Issue

PER LOCUS LIKELIHOOD RATIOS

TABLE 1 OF 2

	NIST1036_AFAM 0.01b(1.0, 1.0)			NIST1036_ASIAN 0.01b(1.0, 1.0)		
LOCUS	Pr(E|Hp)	Pr(E|Hd)	LR	Pr(E|Hp)	Pr(E|Hd)	LR
D3S1358	9.89866E-5	1.11031E-4	8.91525E-1	4.77304E-5	4.90859E-5	9.72384E-1
vWA	3.76213E-5	8.31494E-5	4.52455E-1	6.09011E-5	1.61497E-4	3.77103E-1
D16S539	4.64930E-4	8.55850E-4	5.43237E-1	9.26428E-4	1.64841E-3	5.62014E-1
CSF1PO	2.39927E-3	3.30671E-3	7.25577E-1	2.59298E-3	3.59191E-3	7.21894E-1
TPOX	5.13635E-4	1.11457E-3	4.60839E-1	3.82780E-4	7.90291E-4	4.84353E-1
Yindel						
D8S1179	1.46872E-4	4.35994E-4	3.36867E-1	5.71943E-5	1.25224E-4	4.56737E-1
D21S11	8.49236E-6	1.34536E-5	6.31232E-1	1.37902E-4	2.67463E-4	5.15594E-1
D18S51	2.97870E-7	4.70777E-7	6.32719E-1	1.72932E-7	2.64093E-7	6.54815E-1
DYS391						
D2S441	2.05171E-4	1.03670E-3	1.97907E-1	2.05952E-4	9.33555E-4	2.20610E-1
D19S433	6.89390E-5	9.98317E-5	6.90552E-1	3.13018E-4	5.43828E-4	5.75583E-1
TH01	4.80731E-3	3.34560E-3	1.43691E0	1.07534E-2	6.75943E-3	1.59087E0
FGA	1.90672E-5	3.85122E-5	4.95096E-1	2.08327E-5	4.18238E-5	4.98106E-1
D22S1045	2.16924E-5	6.28761E-5	3.45003E-1	6.65004E-7	2.51521E-6	2.64393E-1
D5S818	3.58637E-3	2.99274E-3	1.19836E0	5.18638E-3	4.50789E-3	1.15051E0
D13S317	4.04458E-3	6.08891E-3	6.64254E-1	6.32881E-4	7.71803E-4	8.20003E-1
D7S820	2.22034E-4	3.24727E-4	6.83757E-1	4.01652E-4	4.77147E-4	8.41778E-1
SE33	6.65170E-6	1.33562E-5	4.98023E-1	5.06531E-6	9.65892E-6	5.24418E-1
D10S1248	1.73721E-4	4.04001E-4	4.30002E-1	1.94337E-4	4.75342E-4	4.08836E-1
D1S1656	5.52170E-4	7.58236E-4	7.28230E-1	3.85025E-4	6.04720E-4	6.36700E-1
D12S391	2.33073E-4	3.20522E-4	7.27167E-1	5.26623E-4	7.79340E-4	6.75730E-1
D2S1338	1.21401E-4	7.63963E-5	1.58909E0	6.28894E-4	4.96015E-4	1.26780E0
LR TOTAL			3.24328E-5			2.74558E-5
FACTOR OF N! LR			1.08116E-5			9.15245E-6
99% 1-SIDED LOWER HPD INTERVAL			6.77301E-6			9.17139E-17

Statistic One = 9.15245**E-6**

vs.

Reported Statistic Two = 9.17139**E-17**

Generally, expect one magnitude of difference; here we have eleven.

Prior Wide HPD Training

- Limited guidance was given to analysts prior to 2022
- In 2022, standard operating procedure (SOP) and training materials were updated to include guidance on identifying, troubleshooting, or reporting of wide HPD intervals
  - The STRmix SOP was updated to include what a wide HPD is and how to potentially resolve it
  - A PowerPoint that explained what a wide HPD is with visual examples was discussed at a meeting with all analysts signed off to use the software

Corrective Action Trigger

- Reported statistic was exclusionary given the propositions

TABLE 2 OF 2

LOCUS	NIST1036_CAUC 0.01b(1.0, 1.0) Pr(E|Hp)	Pr(E|Hd)	LR
D3S1358	1.21570E-2	9.32362E-3	1.30389E0
vWA	8.24221E-3	2.30938E-3	3.56901E0
D16S539	3.69311E-2	2.02249E-2	1.82603E0
CSF1PO	1.26388E-2	1.64710E-2	7.67339E-1
TPOX	8.22349E-3	2.84821E-3	2.88725E0
YIndel			
D8S1179	2.01009E-5	1.50601E-4	1.33472E-1
D21S11	5.58651E-3	1.30033E-3	4.29623E0
D18S51	1.82741E-3	1.02201E-3	1.78806E0
DYS391			
D2S441	1.13771E-2	3.67100E-3	3.09919E0
D19S433	2.06279E-2	1.26847E-2	1.62620E0
TH01	8.41314E-3	8.00010E-4	1.05163E1
FGA	6.78243E-3	9.43798E-4	7.18632E0
D22S1045	2.14701E-2	9.10120E-3	2.35904E0
D5S818	7.49290E-2	4.14647E-2	1.80706E0
D13S317	8.64380E-3	2.23020E-3	3.87579E0
D7S820	6.53210E-3	4.03424E-3	1.61917E0
SE33	4.27489E-4	8.65053E-5	4.94176E0
D10S1248	5.72941E-3	2.13178E-3	2.68762E0
D1S1656	9.98134E-4	4.93355E-4	2.02315E0
D12S391	2.88083E-6	2.37011E-5	1.21548E-1
D2S1338	1.91452E-8	1.26547E-4	1.51290E-4
LR TOTAL			9.71877E1
FACTOR OF N! LR			4.85939E1
99% 1-SIDED LOWER HPD INTERVAL			9.79698E-5

Statistic One = 4.85939**E1**

vs.

<u>Reported</u> Statistic Two = 9.79698**E-5**

Flip from inclusionary statistic to exclusionary statistic given the propositions.

Actions Taken Following Issue Identification

- Client notifications and education
- Texas Forensic Science Commission notification
- Initiation of Corrective Action Process
  - Identification of affected cases
  - Resolution of affected cases
  - Prevention of recurrence

Client Notification

- Issued a memo to all current submitting agencies with notice of the retroactive case review
  - Explained the issue
  - Gave a timeline of events
  - Explained what SigSci anticipated the results of the review would be

Client Notification

- Met with attorneys as needed to explain in laymen's terms
  - Created a visual to make it easier to understand the ramifications

What if we missed a wide HPD?

Reported LR	New LR	Example Reported LR	Example New LR
Higher Exclusion	Lower Exclusion	3.55E-14 (1/LR) →2.81E+13	6.57E-5 (1/LR) → 1.52E+04
Exclusion	Inclusion	1.78E-10 (1/LR) → 5.59E+09	7.16E12
Lower Inclusion	Higher Inclusion	5.58E8	1.42E18

We DO NOT EXPECT:

- **a reported high inclusionary LR to become a new LR that is a lower inclusion**
- **a reported inclusionary LR to become a new LR that is exclusionary**

Example Reported LR	Example New LR
1.00E+18	1.00E+6
1.00E+6	7.59E-4 (1/LR) → 1.31E+03

The reported HPD LR is always the lowest LR calculated by the software.

Texas Forensic Science Commission (TFSC)

- Initiated in May 2005, the TFSC investigates allegations of professional negligence or professional misconduct and established licensing programs for forensic disciplines subject to accreditation in Texas
- Nine members currently
  - Seven scientists and two attorneys
- Signature Science is accredited by TFSC, and all staff must be licensed through them before performing work for Texas agencies
  - SigSci reported a self disclosure to TFSC regarding this issue

Initiation of Corrective Action Process

- Corrections (short-term fixes)
  - Prepare an amended report for the initial case that was identified
  - Perform retroactive case review for other affected cases
  - Issue additional amended reports as needed
- Corrective action (long-term fix)
  - Modify the document review checklist to add an assessment on whether the major technical guidance changes to SOPs could trigger the need for a retroactive case review

SigSci's Approach to Identifying Affected Cases

- Retroactive review of all issued reports that contain a likelihood ratio

I	K	M	O	P
Pop. 1	Pop. 1 SubSource LR (poin	Pop. 1 SubSource LR (HPD lowe	LOG DIFFERENCE	INCLUSION TO EXCLUSION
NIST1036_AfAm	1.689748999	0.937413466	0.25589101	TRUE
NIST1036_AfAm	1.177872427	0.554726636	0.327019236	TRUE
NIST1036_AfAm	1.352458707	0.635290055	0.328151958	TRUE
NIST1036_AfAm	1.068575788	0.491469633	0.337308641	TRUE
NIST1036_AfAm	1.124889174	0.492718581	0.358510797	TRUE
NIST1036_AfAm	1.188270885	0.475482843	0.397780605	TRUE
NIST1036_AfAm	2.685926241	0.705510551	0.580590569	TRUE
NIST1036_AfAm	11.8740006	0.617092907	1.284246512	TRUE
NIST1036_AfAm	2.440198721	0.068425258	1.552208748	TRUE
NIST1036_AfAm	2601.303481	3.24161E-05	7.904430284	TRUE

- Staff members assigned to cases for first and second reviews
  - Around a dozen DNA Analysts who are signed off to use the statistical software that generated the issue are part of the review
    - Evaluation of Forensic Biology Report and data generated by the software
    - Use of Excel as aid for cases from 2021 on created from STRmix™ data folder

SigSci's Approach to Identifying Affected Cases

Case number	Submitting Agency	Author	TR (If amended needed)	Wide HPD (Y/N)	Amended report needed (Y/N)	Flip from inclusion to exclusion (Email SOW ASAP)	Check 1 (assigned)	Check 1 (date complete)	Check 2 (assigned)	Check 2 (date complete)	Notes	S drive location (if needed)
LSS2020-12345	City, Texas	Jane Doe	John Doe	Y	Y	SOW emailed 1/1/2025	Joe Schmoe	1/1/2025	SOW	1/1/2025		
LSS2020-12346	City, Texas	John Doe	N/A	N	N	N/A	Jane Doe	11/30/2024				

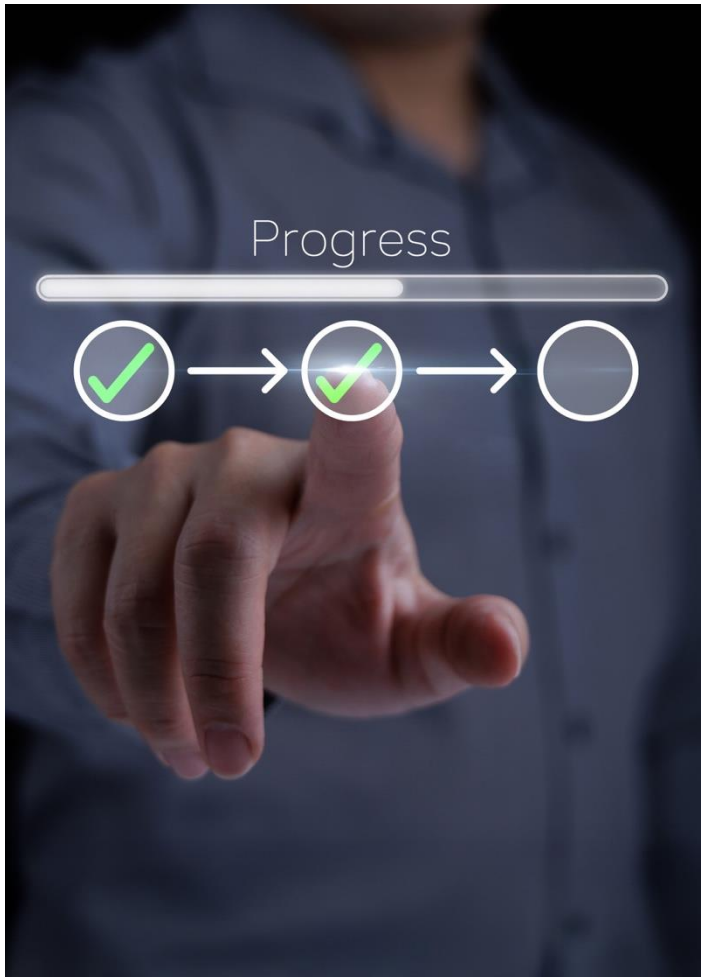
- Use of an Excel spreadsheet separated by year

How Did SigSci Go About Resolving the Cases?

- Situation dependent based on the possible cause
- Amended reports have been/will be issued for all affected cases
  - Re-evaluation using statistical software
  - Additional DNA testing for samples not resolved by re-evaluation

What Is the Status of the Review?

- Over 2300 reports need to be evaluated
  - To date, about ~1/4 of the cases have undergone at least a first review
  - Due to the large number of cases that need to be reviewed, amendments are focusing on reports where an exclusionary statistic has been reported, but additional work may lead to an inclusionary statistic being reported
    - 10 amended reports issued so far

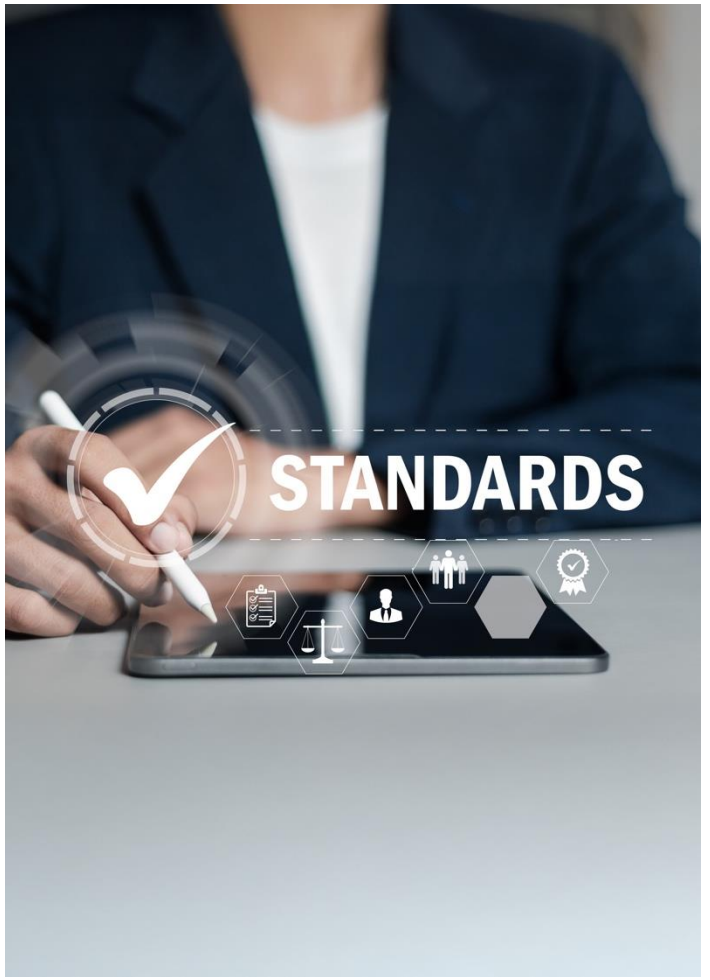


What Else Is SigSci Doing?

- Continued training for staff
- Corrective action will include a review of all cases through the end of 2024 as well
- Validating new version of STRmix™ software that will eliminate one known issue
- Possibility for small scale reviews in later years as well depending on 2024 outcome

Training After CAR

- All new analysts must review:
  - A standard operating procedure that explains what a wide HPD is and how to potentially resolve it
  - A PowerPoint that explains what a wide HPD is with visual examples
- Incorporation of STRmix™ focus topics
- Incorporation into STRmix™ oral exam
  - A STRmix™ run is given that includes a wide HPD



What Could Have Made the Review Easier?

- Organization of run folders from the beginning of the software being used
  - Could have used Excel tool to only evaluate which cases had flags to investigate
- Initial query of reports could have included a feature to pull out submitting agency
  - Cases dating from 2020 on (when SigSci went paperless) do not have the agency in the report name
- Assign initial reviews only
  - Some analysts started to do second reviews before first reviews were finished

Polling Questions

- Has your laboratory had to disclose an issue to its stakeholders before?
  - Yes
  - No
  - I don’t know
- If your lab has made a self disclosure before, do you think the lab gained benefits in the long run because of the lessons learned?
  - Yes, definitely
  - Maybe
  - No, definitely not

Summary

- Issues arise in every lab
  - It's not the issue that defines the lab's quality and character; it's how the lab addresses the issue
- Communication is key
  - External (with clients and stakeholders)
  - Internal (with analysts)
- Careful assessments of the root cause(s) are critical to ensuring that similar issues do not occur in the future

It's good to learn from your mistakes. It's better to learn from other people's mistakes.

– Warren Buffet

Samantha Wandzek

Contact Me

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