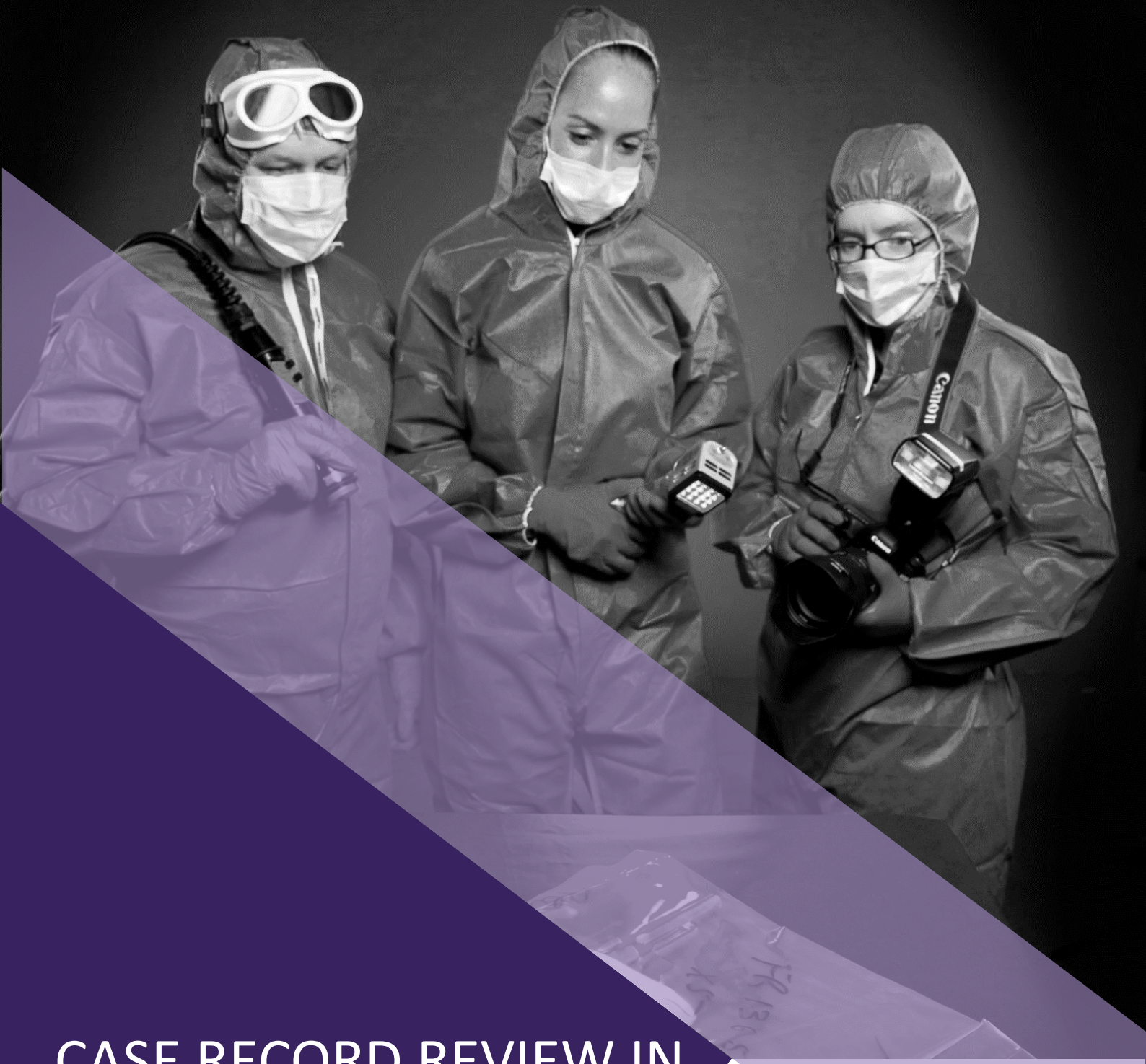

CASE RECORD REVIEW IN FORENSIC BIOLOGY

2019

ANZPAA
Australia New Zealand Policing Advisory Agency

NIFS
National Institute of Forensic Science Australia New Zealand

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CONTENTS

SCOPE

The purpose of this document is to provide advice in relation to the requirements for case record review in forensic biology and guidance for the development of laboratory procedures and practices. This document does not address expert testimony reviews, scientific literature reviews or reviews of the science underpinning forensic disciplines. While this document is predominantly designed for use in forensic biology laboratories, it is proposed that the content can be adapted for use in other forensic science disciplines.

BACKGROUND

Forensic biology laboratories conduct case record reviews, which include technical and administrative reviews, as part of an overall quality management system in order to:

- ensure that correct results are reported
- ensure that laboratory procedures have been followed
- ensure that sound scientific principles have been applied
- meet standard or accreditation requirements
- reduce errors, identify process issues or identify personnel issues
- ensure that a product meets the clients' needs.

However, it has been reported that the application of peer review varies considerably across disciplines and agencies. There is a lack of empirical evidence to demonstrate the ability of a technical or administrative review to reduce errors, and a lack of guidelines and standards that regulate what should be included in these types of reviews, as well as how disputes or disagreements should be addressed and recorded.[1]

The 2017 Ross Inquiry into PathWest Laboratory Medicine WA highlighted anomalous results that were not detected during the peer review process, despite the laboratory having a strong quality culture with sound training and methodology in place. Although the majority of these anomalous results were restricted to transcription and typographical errors that did not impact the outcome of the case, these errors should have been detected during peer review. The inquiry made a number of recommendations that are relevant to this document, including the identification and removal of manual steps to reduce the chance of error, the introduction of a mandatory step that prevents results being released without review, and a proposal to develop a national methodology, including evaluation measures, for casefile and report peer review. [2]

The National Association of Testing Authorities (NATA) and the ANSI National Accreditation Board (ANAB) maintain accreditation programs for use by forensic science laboratories in Australia and New Zealand respectively. The programs establish specific criteria for compliance with ISO 17025: General requirements for the competence of testing and calibration laboratories in the forensic setting[3] that have been recently updated to reflect the risk-based thinking that has been introduced to ISO 17025.[4] Risk-based thinking has enabled the standard to place more emphasis on performance-based requirements and reduce prescriptive requirements. This signifies a need to review the historical approach taken to existing laboratory processes, many of which have developed over time and are often reactive in nature.

[1] KN Ballantyne, G Edmond, and B Found, "Peer review in forensic science," *Forensic Science International* 277 (2017): 66-76.

[2] A Ross, "Ross Inquiry into PathWest Laboratory Medicine WA," 2017, http://ww2.health.wa.gov.au/Reports-and-publications/Independent-PathWest-inquiry-completed - accessed 10 May 2019.

[3] National Association of Testing Authority (Australia), Specific Accreditation Criteria, ISO/IEC 17025 Application Document, Legal (including Forensic Science) – Appendix, July 2018; ANSI National Accreditation Board, ISO/IEC 17025:2017- Forensic Science Testing and Calibration Laboratories, Accreditation Requirements, 2019/04/29, AR 3125.

[4] International Organisation for Standardisation, ISO 17025, General requirements for the competence of testing and calibration laboratories, 2017, https://www.iso.org/standard/66912.html - accessed 10 May 2019.

DEFINITIONS

ADMINISTRATIVE REVIEW

A check that the non-technical aspects of a case record are correct, complete and documented according to procedures. This may include clerical checks, grammar and spelling, ensuring case identifiers and page numbers are present, as well as checks for comprehension of the intended audience.

ADMINISTRATIVE REVIEWER

Someone with enough awareness of procedures to review the non-technical components, which may include technical staff, managers or dedicated administrative staff.

PEER REVIEW

In forensic science, this term is used to describe the evaluation of the reports, examinations, notes, data and findings by others competent in the same field to assess that there is an appropriate and sufficient basis for the conclusions and/or opinions.[5]

This term is also used in science and academia to describe the process for the review of papers/articles that are submitted to scientific journals to be considered for publication.

TECHNICAL REVIEW

A check that processes, results, interpretations and opinions are scientifically sound, based on sufficient data and within the bounds of validated procedures. Where they extend beyond validated procedures, they should be within the bounds of validated scientific knowledge.

TECHNICAL REVIEWER

Someone with the required knowledge, skills and abilities, who is authorised to perform the technical review or has demonstrated expertise in the area.

VERIFICATION

Within the context of peer review in numerous pattern comparison forensic science disciplines, this term refers to a second check or independent repeat of a process, result or interpretation by someone with the required level of expertise.[6]

[5] International Organisation for Standardisation, ISO 21043-1, Forensic sciences: Terms and definitions, 2018. https://www.iso.org/standard/69732.html - accessed 10 May 2019.

[6] KN Ballantyne, G Edmond, and B Found, "Peer review in forensic science," *Forensic Science International* 277 (2017): 66-76.

PURPOSE OF REVIEW

A review step should be value adding, with the ultimate purpose in the context of forensic science to ensure that sound scientific principles have been applied.

For technical reviews in forensic biology, the purpose of the review is to ensure the opinions and interpretations presented are:

- supported by the data
- within the bounds of scientific knowledge and
- have the required level of quality assurance.

For administrative reviews in forensic biology, the purpose of the review is to ensure the records associated with the case are:

- labelled appropriately
- complete and
- provide the required level of comprehension by the intended audience.

Given the importance of case records in forensic biology, an approach that requires a review to be performed at every opportunity involving a check of every available record may be considered favourable. However, there is no evidence to support that this will ensure that the ultimate purpose is achieved. In fact, the opposite is likely to be true, given that extensive checking may introduce complacency and diffusion of responsibility (see human factors section). As a result, and in line with the updates to the relevant ISO standard, it is proposed that applying risk-based thinking to adopt a more proactive and performance-based approach to identifying review requirements will ensure that the system operates as efficiently as possible. It will also address the problems associated with onerous checklists and complicated process documents, which are discussed further in the human factors section of this document.

RISK-BASED THINKING

Risk-based thinking can be applied by forensic science laboratories to ensure that processes, products and services are fit-for-purpose and meet customer requirements. A risk-based approach involves the introduction of measures to eliminate or reduce the impact of risks identified as having the greatest potential impact on products and services.

As a general guide, evaluating the risks inherent to a particular task or process involves:

- clearly defining the objective(s) of the task to be performed
- identifying the risks to achieving that objective
- evaluating the risk level.

In the context of forensic biology, risk is influenced by the potential for an error to occur, the use of manual versus automated workflow processes and the potential for human factors to impact decision-making. In order to develop a risk-based approach for the technical and administrative review of casework casefiles and reports, consideration should be given to the:

1. components of the process
2. components of the case
3. intended purpose of the product
4. risk likelihood versus consequence.

1. COMPONENTS OF THE PROCESS

In a standard forensic biology workflow, components of the process that may be considered for review include:

Technical

- Checking the items received (chain of custody, integrity, condition, examinations not performed).
- Reviewing the examinations performed (procedures, samples collected, records).
- Ensuring that legislative requirements have been met.
- Reviewing the DNA analysis processes.
- Reviewing the DNA results assessment (number of contributors, STRmix™ output).
- Checking the statistical analysis.
- Ensuring quality checks have been performed (process controls, elimination database checks).
- Reviewing the interpretation of results and opinions expressed.

Administrative

- Reviewing the spelling and grammar.
- Ensuring that records are signed, dated and pages numbered where required.
- Checking the case related correspondence is present.
- Ensuring that the format of the report is consistent with laboratory and accreditation requirements.

It is important to note that while elements of the administrative review can be performed as part of the technical review, the reverse does not apply due to the skills and knowledge required.

2. COMPONENTS OF THE CASE

For a standard forensic biology case, the components that may impact a risk assessment of the review process include:

- Reporting Officer (experience, competency and frequency performing the task).
- Case Size and Complexity (number and type of items/examinations/results obtained).
- Type of Samples and Procedures Involved (number and variety of procedures as well as established vs novel).
- Priority (high profile or potential to become high profile, targeted or routine case).
- Potentially probative results (one or many of the same type).

3. INTENDED PURPOSE OF THE PRODUCT

While results may be intended for different purposes, it is well accepted that all results of forensic analyses have the potential to be raised in court (i.e. utilised for evidentiary purposes). There are many occasions where the timeliness of results will influence their impact on a police investigation (i.e. utilised for investigative purposes), and this timeliness may need to be accompanied with caveats that highlight the limitations of the information.

A detailed discussion about the different types of information that may be used to generate investigative opportunities for police is out of scope for this document; however, a number of scenarios that may be encountered and the potential considerations for each are listed below:

Focus on timeliness using a similar process with a similar product delivered

A reduced level of review may be proposed to provide results considered to be more interim or investigative in a timely manner. This decision should be made with consideration of the risks associated with the information that is being provided and results should be accompanied by caveats that highlight the limitations and what inferences be drawn.

- Example: Releasing a DNA link for a reference DNA sample that is awaiting secondary confirmation.

Focus on alternative technologies using different processes with a different product delivered

The level of technical or administrative review should be tailored to the specific process that has been followed; however, this may be dependent on the availability of technical expertise and access to the information required to perform the review. Results should be accompanied by caveats that highlight the limitations associated with the information provided.

- Example: Predictive DNA analysis, which provides an indication of phenotype and/or biogeographical ancestry with an accompanying confidence level, which may involve analysis or expertise that is external to the forensic biology laboratory.

Focus on using the information available in different ways not intended for evidentiary purposes

The level of technical or administrative review should be tailored to the specific process that has been followed. This may be similar to the technical or administrative review performed for routine processing, dependent on the level of risk associated, and should be accompanied with caveats that outline the deviation from standard practice, limitations and what inferences can be drawn from the information.

- Example: Use of information below standard reporting thresholds that indicates a person of interest requires further investigation but is not suitable for evidentiary purposes.

4. RISK LIKELIHOOD VS CONSEQUENCE

Once all of the relevant factors have been identified and considered, a level of risk will need to be assigned. This may occur once for the process by reviewing all of the components and assessing the level of risk (actual or perceived) at a point in time. Alternatively, this may be performed each time a deviation from standard practice is performed. Ideally, an assessment of risk would be accompanied with data collected by the laboratory to inform decision-making. However, it is important to note that the absence of data does not preclude a risk assessment from being performed.

The level of risk that is attributed will depend on the balance of likelihood versus consequence. In the case of the technical and administrative review of casework casefiles and reports, this will be the balance of the likelihood of an error being present and detected by the review process, versus the consequence of results being released without the error being detected. The level of risk that can be accepted will be informed by organisational priorities and the current operating environment.

Example risk assessments are provided in **Appendix 1**.

HUMAN FACTORS

Human factors are an important consideration in the design of any technical or administrative review process, the impact of which can be reduced or mitigated through procedural steps. Below are some of the human factors that may be relevant, as well as potential strategies to manage them. The application of management strategies will need to balance effectiveness with practicality, as well as potential resource and cost implications.[7]

HUMAN FACTORS

Type	Definition
Authority bias	A power imbalance based on the level of standing of the first and second analyst that may influence decision making.
Confirmation bias	The tendency to agree with another person or expect a certain outcome because of previous experience, missing other relevant information.
Context bias	Access to case related information that is not required to undertake the forensic analyses (referred to as domain irrelevant information), which influences decision-making.
Diffusion of responsibility	An individual is less likely to take responsibility for action or inaction when others are present, or when they know checks will occur.
Expectation bias	The expectation of a certain outcome means that other viable explanations are not considered, or evidence not supporting an expectation is discounted.
Fatigue/Distraction	Reduced accuracy due to fatigue resulting from repetitive tasks.
In-group bias	The potential for a group of people that have worked closely for a period of time to think in a certain way and agree with each other.
Reactive devaluation	The situation in which the dislike for someone will mean that you are more critical of their work. Note: the opposite may also apply i.e. being less critical because of a positive opinion of someone.

[7] Camilleri A, Abarno D, Bird C, Coxon A, Mitchell N, Redman K, Sly N, Wills S, Silenieks E, Simpson E, Lindsay H. 2019. A risk-based approach to cognitive bias in forensic science. Science & Justice (in press).

MANAGEMENT STRATEGIES

Type	Impact
Blind review	A blind review process for subjective decision making steps should be explored. This does not require a full repeat of the process and may be a stepwise recording of notes before comparison to the final conclusion of the first analyst. To minimise efficiency impacts, areas assessed as high risk may be subjected to blind review while areas assessed as low risk may be open review.
Fatigue management	Reviews can be segmented across individuals, time or processes to reduce fatigue issues for large cases. There may also be potential to reduce the requirements of a final review where there have been multiple reviews throughout a process, in order to reduce fatigue.
Feedback loops/Corrective actions	Issues raised through reviews should be monitored, and results fed back to all relevant staff to ensure that error trends are addressed, and that the review process is targeting appropriate points in the process (i.e. suitable corrective action has been applied).
Review mechanisms	Checklists can be useful memory prompts to ensure checks are performed; however, correct structuring and attention to the length of checklists is important to prevent them becoming 'tick and flick' exercises. Substituting checkboxes with a requirement to enter specific details in areas assessed as high risk may assist.
Rostering	A rostering system allows for the random allocation of technical and administrative reviewers to reduce the potential for an analyst to 'shop' for a reviewer that is likely to agree.
Sequential unmasking	Stepwise introduction of context information as required to reduce the potential for the information to influence decision making.
Third independent reviewer	Utilising an independent third reviewer for adjudicating on disagreements or conducting further reviews, chosen from a roster or random draw amongst authorised individuals, may minimise bias and increase error detection.
Training and standardisation/ Automation	Standardisation and automation of processes can reduce the level of subjectivity, which will also reduce the potential for differing opinions to be an issue at the review stage.

PERSONAL RESPONSIBILITY OF AUTHOR

It is important to note that the inclusion of a technical or administrative review step does not shift the responsibility for the content of a casework casefile or report from the author to the reviewer. The reporting scientist must take ownership of the task, and not rely on others to detect potential errors. Research in other domains has found that although a second check may reduce error rates in certain tasks, it does not eliminate error. The best person to identify an error is the person that has performed the activity, so it is important to ensure that a self-check precedes any peer check, and all staff are aware of the need for personal responsibility for completeness and accuracy.

MANAGING DISAGREEMENTS

An effective review process will identify issues that need to be resolved, the majority of which will be considered minor, resulting from human error and easily rectified through feedback to the first analyst. On some occasions, the issues identified may be more contentious and the result of a difference of opinion. Again, some of these may be resolved through discussions between the first and second analysts, while others may be more difficult to resolve. As a result, it is important that laboratories have a clear policy in relation to what constitutes a disagreement, how it should be managed, and what recording and disclosure requirements apply.

TYPES OF DISAGREEMENTS

The nature of the discipline will likely inform the types of disagreements that may arise. For the pattern comparison disciplines, a large number of subjective decision making steps are involved, which have the potential to generate differences that may require discussion. In the analytical disciplines including forensic biology, procedures are often more detailed and prescriptive; however, there are still a number of subjective decision making steps that may generate disagreement. Below are three possible scenarios that may be encountered in relation to disagreements, accompanied by considerations that may be useful in the development of a laboratory procedure.

Scenario 1 – *Impact on final outcome with resolution between the parties*

In this scenario, alternate opinions are proposed given the same data but an agreed approach is reached after discussion between the two analysts. When this occurs, consideration should be given to the level of recording and disclosure that may be required. Further information is provided in the relevant sections below.

Scenario 2 – *Impact on final outcome without resolution between the parties*

In this scenario, alternate opinions are proposed given the same data but an agreed approach cannot be reached. Often, a third person is consulted and the considerations for enlisting a third opinion are discussed further in the management strategies section below. A laboratory procedure will generally specify a preference for reporting where there are two equally viable options proposed. The use of certain terminology (such as conservative) can be problematic, so it is imperative that guidance is provided to ensure that the preferred approach is clear. The decision will be dependent on the information available, so a decision may need to be reassessed where additional information is received.

Examples of some of the common approaches in place are:

- Report the more conservative result – The term conservative generally refers to the result that provides the least weight of evidence. In forensic biology, where evaluative reporting is used for the majority of opinions/interpretations, this could be considered to be the likelihood ratio that is closest to one. The benefits of this approach include the use of caution where there is uncertainty, given it is often the less contentious or probative result that is being presented. The limitations of this approach include the potential to misunderstand the term conservative and how it was applied within the case, as well as risks associated with selecting the most conservative result based on the information available at the time, which may not be all of the relevant information required to perform this assessment effectively.

- Report the result that favours defence – The purpose of this approach is to reduce the strength of evidence for the presumed prosecution hypothesis or increase the strength of evidence for the presumed defence hypothesis, in an attempt to acknowledge the uncertainty in the result. Again, it is important to highlight that this approach can only be performed for the presumed prosecution and defence hypotheses, which may not be consistent with those actually being proposed by prosecution and defence. This approach may also lead to questions in relation to bias favouring the defence.
- Report the result as unsuitable due to uncertainty – In this approach the potential for a result to be used in a case is removed by reporting as unsuitable. While this approach concedes the uncertainty demonstrated by the difference of opinion, it does have the potential to remove evidence that may have been of value for either the prosecution or defence case. In a court setting, it also removes the potential for the jury to use other information that the scientist is not aware of, to assess the result within the broader case context.
- Report the result with two options – Presenting both options acknowledges there is more than one valid conclusion and leaves the decision to the Court. This may be problematic if the court is not in a position to perform the assessment, if different members of the jury prefer different results, or if confusion is created where an expert is unable to provide guidance as to which result is more reliable. There is also the potential for an analyst to be in the position where they are required to discuss a result that they do not support, which may only have been included to address feedback from a second analyst during the review process.

Scenario 3 – *No impact on final outcome with or without resolution between the parties*

In this scenario, the suggested changes do not impact the opinion being presented. As such, procedures to mediate and disclose requirements may be less extensive and/or less critical to develop.

MANAGEMENT STRATEGIES

Where a disagreement arises that cannot be resolved through a simple conversation between analysts, it is important to consider opportunities for further work that may provide clarity. In a forensic biology laboratory, this may include additional testing or reanalysis of existing results. It is important that the workplace has a culture that supports expressing all views, as human factors significantly impact the management of disagreements. This is especially relevant for the situation where a third opinion is consulted. Attempts should be made to randomise this process through a rotating roster, to avoid intentionally (or unintentionally) introducing additional human factor biases. Consideration should also be given to a review panel, or seeking advice from someone external to the agency. Throughout this process it is important to consider the preferred approach to reporting by the laboratory, as this may inform which of the options is more appropriate.

RECORDING REQUIREMENTS

Good record keeping is a key component of a quality laboratory protocol; however, when it comes to the recording of disagreements, there is limited guidance as to what constitutes the minimum requirements. Generally, it is accepted that significant disagreements and the process undertaken to address them should be recorded to allow for review and discussion if required. However, there is more variation when it comes to the recording of disagreements that are not considered to have an impact on the final opinion. Ultimately, each laboratory is responsible for identifying the appropriate level of recording of disagreements, which should be performed in consideration of both accreditation and client requirements.

DISCLOSURE REQUIREMENTS

When determining the level of disclosure of disagreements required, it is important to consider whether the laboratory will make the information available routinely, or only by request. There are a number of reasons why a laboratory may choose to disclose disagreements routinely:

- Demonstrate transparency.
- Increase confidence by allowing critical review.
- Demonstrate the robustness of the process.
- Code of conduct or accreditation requirements.

There are also a number of reasons why a laboratory may choose to only make the information available on request:

- No impact on the final interpretation or opinion presented.
- Potential for misunderstanding of the impact of the difference of opinion.
- Requirement for a mechanism to explain and record the difference of opinion.
- Potential for the perception of an error where there is not one.
- Resourcing implications.

Ultimately, each laboratory is responsible for the process that is followed and the level of disclosure employed, which should be developed in consideration of scientific, accreditation and client requirements.

REVIEW ASSESSMENT METHODOLOGY

The optimal way to assess the value of a review step is to collect data specific to the process in question. It is important to note that this may be in two forms; either by recording each time an error is detected during a review step to highlight the areas in which a review performs well, or by collecting data to inform error rates to highlight the parts of a process that are prone to error. A discussion about the collection of data to inform error rates is out of scope for this document. However, the potential to identify the areas in which a review step performs well, in an effort to inform a more risk-based review process is discussed further below.

It is anticipated that the data collection process would not need to be onerous, and could be facilitated through a laboratory information management system if the required information is recorded. In the absence of an existing mechanism to record the information, it is proposed that a simple survey instrument is completed each time a technical or administrative review is performed, for a set period of time or set number of casework casefiles and reports, would be enough to make informed decisions in relation to the checks required. It should be noted that if any changes to the required checks are made, routine reassessment of the errors that are being detected would need to be undertaken. The table below provides an example of the components of a survey instrument that may be included in an assessment of the value of technical and administrative review for casework casefiles and reports in forensic biology. Where an assessment is required to determine if the error is minor, major or critical, this should be performed in consideration of the impact on the final interpretation or opinion being presented.

	IMPACT ON FINAL INTERPRETATION/OPINION		
Type	Minor	Major	Critical
Spelling, grammar, clerical checks			
Transcriptions			
Examination records			
Biological fluid identification			
Appropriate testing performed			
DNA processing			
DNA typing			
Number of contributors			
STRmix™ analysis			
Final opinion/interpretation			
Other			

CONCLUSION

A risk based approach to determining administrative and technical review requirements that considers human factors, has a clear disagreement management process and assesses the effectiveness of the process, will ensure that forensic laboratories have processes that are fit for purpose and achieve the desired outcome of a review system that operates efficiently and effectively.

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APPENDIX 1 – EXAMPLE RISK ASSESSMENTS

EXAMPLE A – TASK-SPECIFIC RISK TABLES

The following risk matrices have been adapted from process documents developed by NSW Health Pathology Forensic and Analytical Science Service and may be a useful point of reference as an example of how risk tables can be adapted to evaluate risk of error in case record review. These risk tables are task-specific and would be utilised when assessing whether or not a review is to be performed for a specific case. A case example has been provided for reference, which relates to whether or not a technical review should be performed for a high profile armed robbery case.

In assessing the likelihood and consequence of error, all forms of error are considered, including both minor errors that do not impact on the direction or magnitude of the opinion, and major errors which have the potential to cause an incorrect opinion. It should be noted that an assessment that an error is likely or possible does not imply that major errors will occur, simply that an error of any type may occur.

LIKELIHOOD OF ERROR

EXPERIENCE

FREQUENCY PERFORMING THE TASK	YEARS OF EXPERIENCE PERFORMING THE TASK		
	1-2 years	**2-5 years**	**> 5 years**
Frequent	*Possible*	*Unlikely*	*Highly Unlikely*
Occasional	*Likely*	*Possible*	*Unlikely*
Infrequent	*Likely*	*Likely*	*Possible*

Case example *– The reporting scientist has 3 years of experience reporting the case type and performs the equivalent task frequently. Likelihood of error =* ***Unlikely***

CASE COMPLEXITY

VOLUME OF DATA	EXAMINATION COMPLEXITY			
	Simple	**Routine**	**Complex**	**Very complex**
Very Large	*Possible*	*Likely*	*Likely*	*Highly Likely*
Large	*Possible*	*Possible*	*Likely*	*Likely*
Moderate	*Unlikely*	*Possible*	*Possible*	*Likely*
Small	*Unlikely*	*Unlikely*	*Possible*	*Possible*
Very Small	*Highly Unlikely*	*Unlikely*	*Unlikely*	*Possible*

Case example *– The case has a large amount of data that would be considered very complex i.e. complex mixed DNA profiles. Likelihood of error =* ***Likely***

CONSEQUENCE OF ERROR

FACTORS		IF YES:
High media or political interest?	Y/N	Catastrophic
Related to terrorism or organised crime?	Y/N	Major
High priority case?	Y/N	Moderate

Case example *– The case is high priority due to an increase in offences of that type in the area. Consequence of error =* ***Moderate***

RISK RATINGS

OVERALL LIKELIHOOD RATING

1	2	3	4	5
Highly Unlikely	*Unlikely*	*Possible*	*Likely*	*Highly Likely*

Case example *– Experience = Unlikely. Complexity = Likely. For the overall likelihood rating the highest likelihood is selected =* ***Likely***

OVERALL CONSEQUENCE RATING

1	2	3	4	5
Insignificant	*Minor*	*Moderate*	*Major*	*Catastrophic*

Case example *– The highest consequence is selected =* ***Moderate***

RISK MATRIX

LIKELIHOOD	**CONSEQUENCE**				
	Insignificant	**Minor**	**Moderate**	**Major**	**Catastrophic**
Highly Unlikely	*Low*	*Low*	*Low*	*Low*	*Medium*
Unlikely	*Low*	*Low*	*Low*	*Medium*	*Medium*
Possible	*Low*	*Low*	*Medium*	*Medium*	*High*
Likely	*Low*	*Medium*	***Medium***	*High*	*High*
Highly Likely	*Medium*	*Medium*	*High*	*High*	*Extreme*

Example *– The overall risk rating =* ***Medium***

Whether or not this level of risk is accepted (review not performed) will be subject to policies and procedures developed within each organisation.

EXAMPLE B – DEVELOPING RISK ASSESSMENT TABLES

The following risk matrices may be a useful point of reference as an example of how risk tables can be adapted to evaluate risk of error in case record review.

1. Having identified the risk and given the existing (or proposed) controls in place to prevent the risk from eventuating (or to contain its potential consequences), identify the worst realistic primary consequence of an instance occurring. A consequences table (such as the example below) can be used to determine the 'best fit' for the scenario being assessed:

CONSEQUENCE				
1 *Insignificant*	**2** *Minor*	**3** *Moderate*	**4** *Major*	**5** *Catastrophic*
Example – administrative error in report issued with no impact on reported result/opinion.	Example – minor technical error in report issued with no impact on reported result/opinion.	Example – technical error in report issued impacting the reported result/opinion. No wrongful inclusion/exclusion of an individual.	Example – technical error in report issued resulting in a wrongful inclusion/exclusion of an individual.	Example – multiple technical errors in report issued resulting in multiple wrongful inclusions/exclusions of individuals.

**In considering the potential consequence in terms of the impact on the reported result/opinion, it may also be valuable to consider the potential impact on compliance with procedures in terms of accreditation and the perception of the laboratory.*

2. Using existing data or other sources, and considering the existing (or proposed) controls in place, assess the likelihood of an instance occurring and having the consequences assessed in step 1. A likelihood table (such as the example below) can be used:

RATE OF OCCURRENCE	**LIKELIHOOD**				
	1 *Highly Unlikely*	**2** *Unlikely*	**3** *Possible*	**4** *Likely*	**5** *Highly Likely*
Per unit	1 in 100,000 or more	1 in 10,000	1 in 1,000	1 in 100	1 in 10
Time scale of occurrence	Once in more than 2 years	Once every 2 years	Once every 12 months	Once every 6 months	Once a month or more

3. Use the ratings determined in step 1 and step 2 to establish the overall risk level using the matrix below. The risk table should include some reference as to the risk tolerance and conditions for each level (an example is provided below):

LIKELIHOOD	**CONSEQUENCE**				
	Insignificant	**Minor**	**Moderate**	**Major**	**Catastrophic**
Highly Unlikely	*Low*	*Low*	*Low*	*Low*	*Medium*
Unlikely	*Low*	*Low*	*Low*	*Medium*	*Medium*
Possible	*Low*	*Low*	*Medium*	*Medium*	*High*
Likely	*Low*	*Medium*	*Medium*	*High*	*High*
Highly Likely	*Medium*	*Medium*	*High*	*High*	*Extreme*

RISK TOLERANCE AND CONDITIONS			
Low	**Medium**	**High**	**Extreme**
Acceptable – controls must be adequate.	Tolerable – controls must be adequate and reviewed regularly for efficacy.	Intolerable – controls must be improved as soon as practicable and monitored to ensure efficacy (review risk regularly).	Intolerable – controls must be improved immediately and closely monitored (monitor risk continuously).

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