Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Legal (including Forensic Science) - Appendix

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ISO/IEC 17025 Application Document, Legal (including Forensic Science) - Appendix

In addition to the *ISO/IEC 17025 Standard Application Document* (SAD), this document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 for Legal (including Forensic Science) testing for both applicant and accredited facilities.

The clause numbers in this document follow those of ISO/IEC 17025:2017 but since not all clauses require interpretation, the numbering may not be consecutive.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Legal (including Forensic Science) (refer to *NATA Procedures for Accreditation).*

Forensic facilities may request assessment against the requirements of the following four Australian Standards in addition to the criteria included in the NAC for Legal (including Forensic Science):

AS 5388.1 Forensic analysis Part 1:	Recognition, recording, recovery, transport and storage of material (except section 6 Occupational health and safety - hazardous material which is excluded)
AS 5388.2 Forensic analysis Part 2:	Analysis and examination of material
AS 5388.3 Forensic analysis Part 3:	Interpretation
AS 5388.4 Forensic analysis Part 4:	Reporting

Forensic facilities may also request assessment against the requirements of the ISO 21043 Forensic Standards series in addition to the criteria included in the NAC for Legal (including Forensic Science):

ISO 21043-2 Forensic Sciences - Part 2: Recognition, recording, collecting, transport and storage of items (except Section 5.4 Health and Safety which is excluded)

ISO 21043-3 Forensic sciences - Part 3: Analysis

ISO 21043-4 Forensic sciences - Part 4: Interpretation

ISO 21043-5 Forensic sciences - Part 5: Reporting

This document does not apply to facilities accredited for compliance with the WADA *International Standard for Laboratories* (ISL).

This document also does not apply to facilities accredited for compliance with the *International Federation of Horseracing Authorities* (IFHA) and *National and State Racing Authority Rules*. Additional guidance is provided in ILAC G7 *Accreditation Requirements and Operating Criteria for Horseracing Laboratories*.

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This document does not apply to facilities accredited for compliance with AS/NZS 4308 and/or AS/NZS 4760 unless testing is performed for the Criminal Justice System. Advice on its applicability will be provided on a case by case basis.

5 Structural requirements

5.6 The authority of the individual with direct operational and/or technical control of the forensic science facility must be defined and be commensurate with their responsibilities.

Note*:* The individual with direct operational and/or technical control is expected to be knowledgeable of the scientific functions and forensic aspects of the facility's work, preferably through experience as a forensic scientist/analyst.
The individual, under whose direction the service operates must be clearly identifiable and accessible, provide leadership, including promoting ethical practice, and must have the authority to ensure and take responsibility for:

a. The implementation and maintenance of quality and management systems, including:
    a. Governance
    b. Policy
    c. Jurisdictional and legislative requirements
    d. Risks and opportunities
    e. Performance indicators
    f. Stakeholder feedback
    g. Business continuity

b. The range of services provided are:
    a. fit for purpose (including appropriate facilities and equipment);
    b. within the scope and competence of staff;

c. The provision of scientific consultation.

d. The suitability of outsourced service providers, including support services.

Note: Where the facility is part of a parent organisation, the individual with direct operational and/or technical control does not necessarily have to be the head of the parent organisation however, this individual must provide reporting to organisational executive that enables the organisation to have an appropriate level of oversight/governance of the management system compliance, outcomes and effectiveness.

The scope of responsibilities and authorities of personnel responsible for the management system must be clearly defined, including delegations.

6 Resource requirements

6.2 Personnel

6.2.2 Continuing professional development requirements for staff who participate in managerial and technical processes must be defined.

Analysts/examiners must have an appropriate qualification and/or demonstrated experience in the relevant discipline.

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6.2.5

Staff training

A training program for each discipline must be available.

Note: A facility's training program should emphasise and teach the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice within a specific area of work. Training should also include knowledge of forensic science across its wide spectrum and of criminal and civil law and procedures.

Where relevant, the training program must include presentation of evidence in court.

All analysts/examiners must be able to articulate concepts and provide opinion testimony relevant to the facilities scope of accreditation and their own personal authorisation. Pertinent training, including refresher training if required, must be given to all staff prior to appearance as an expert witness in court. This may include moot court, actual court observation and appropriate reading materials.

Initial competency assessment

Assessment of initial competency must be undertaken for all new staff in all applicable areas before such staff are authorised to work independently, including:

- an evaluation of knowledge of existing literature; and
- for crime scene examinations, the independent assessment of a crime scene.

The competency of an examiner must be assessed under conditions where the examination is conducted on ground truth known material so that the performance of the examiner can be assessed against an answer that is known to be correct. Where ground truth known material is not available, the closest approximation should be used (e.g. unknown material that has been examined independently by multiple examiners who have come to the same conclusion).

Ongoing Staff Competency

The facility must have a procedure determining the frequency of the review process for all individuals, including the need for retraining if necessary.

Court testimony monitoring

The facility must have a procedure covering the monitoring of testimony including:

- frequency of monitoring court testimony;
- who may conduct the evaluation;
- the evaluation of the analyst/examiner, performance as well as effectiveness of presentation (e.g. technical knowledge, ability to convey scientific concepts in understandable terms);
- the remedial action that is to be taken should the evaluation be less than satisfactory;
- the need for timely feedback to the analyst/examiner.

A facility may choose to use a combination of methods to perform the monitoring. This may include:

- review of transcripts;
- witness evaluation forms / testimony feedback forms;
- formal moot court completion.

A record must be kept of each evaluation including details of who conducted the evaluation and the date.

6.3 Facilities and environmental conditions

6.3.4

Molecular techniques

The facility must ensure that procedures and controls are implemented to minimise cross-contamination and that cross-contamination events can be detected and investigated.

The examination and sampling of items prior to nucleic acid testing must occur in a physically separate area to any downstream nucleic acid testing processes.

Pre-PCR and post-PCR DNA procedures must ensure the physical separation between each specific stage of testing is adequate to minimise the risks of contamination and follows unidirectional workflow.

In the event that the separation does not involve different physical locations (for example as with Rapid DNA instruments), then assessment and mitigation of any contamination risks must be implemented.

Reference items and samples must be processed separately from casework and evidentiary items by area and/or time.

All equipment and reagents used in each area must be dedicated and not used elsewhere.

There must be documented procedures for the cleaning and decontamination of facilities and equipment from nucleic acid product.

Note: In areas where handling is automated it may still be appropriate to implement an environmental swabbing regime to monitor the effectiveness of the contained systems.

When conducting molecular techniques an environmental swabbing regime must be in place to monitor the effectiveness of cleaning protocols in all areas where nucleic acid is handled.

In addition to general requirements for contamination control, the risk of contamination specific to Massively Parallel Sequencing (MPS) wet laboratory procedures must be mitigated.

Security and access

Security and access to areas where testing and calibration occur must be controlled.

Note: Topics to consider may include, but are not limited to, access to buildings, access by personnel, access by visitors, security during operational hours and non-operational hours, access to forensic samples (including all sub-samples), access to sensitive and confidential information such as case records and devices that grant access. Policies on access to to samples should consider chain of custody records.

6.4 Equipment

6.4.1 All critical reagents must be routinely checked for their reliability.

Standards and reagents must be labelled with sufficient information to allow traceability back to its original preparation.

6.4.13 Reference materials, certified reference materials and reference collections must be uniquely identified and records maintained.

Nucleic acid Reference materials

Population databases must be checked statistically for genetic dependence. Obvious deviations from expectations must be adequately addressed and considered when reporting results.

Databases used must be drawn from the appropriate population.

7 Process requirements

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 Test/examination methods and procedures used must be accepted in the field or supported by data gathered and recorded in a scientific manner. Procedures adopted must be demonstrably capable of generating valid results.

Where a facility introduces a validated method, it must first demonstrate the reliability of the procedure in-house (i.e. verify) against any documented performance characteristics of that procedure and that the method is fit for its intended use (fit for purpose).. As a minimum, the method must be tested using known samples which replicate casework-type samples, where possible under the laboratory's own conditions.

Records of method verification must be maintained for future reference.

Note: Where possible, if destructive tests are necessary, procedures should ensure that material is retained for reanalysis. In some circumstances e.g. trace evidence samples all of the sample may need to be analysed to provide a result, which is preferred to retaining some sample and not providing a result.

7.2.1.2 Methods, procedures and supporting documentation must include, where appropriate:

- description of the sample/item to be tested/examined;
- parameters or quantities to be determined;
- equipment/instrumentation required;
- descriptions of sample preparation methods, controls, standards and calibration procedures;
- a discussion of precautions, possible sources of error or limitations of the procedure;
- criteria for the rejection of results;
- data/observations to be recorded and method(s) of analysis;
- literature; and
- references.

7.2.2 Validation of methods

7.2.2.1 Method validation shall:

a. be conducted according to a validation plan;
b. include the associated data analysis and interpretation;
c. ensure raw data be retained and available for independent scrutiny to determine if the analysis was appropriate
d. establish the data and acceptance criteria required to report a result, opinion, interpretation, or statement of conformity;
e. identify limitations of the method; and
f. be approved by appropriate personnel.

Changes to associated data analysis and interpretation are considered changes to a validated method.

7.3 Sampling

7.3.1 Procedures for sampling must ensure that evidence/sample integrity is maintained.

<u>Parentage Testing</u>

Facilities undertaking parentage testing must make agencies collecting specimens aware in writing of their obligations under the Family Law Act, the associated Regulations, the Status of Children Act (NSW) and/or the Children and Community Services Act (WA). Additionally, for collections conducted in-house, these regulations must be followed.

7.4 Handling of test and calibration items

7.4.1 Procedures for the receipt of evidence must ensure that wherever possible, items stored in the facility are properly sealed.

When processing or analysing electronically recorded evidence items, procedures must be in place to minimise the risk of permanent alteration to the original recording. Where possible, processing or analysis must be conducted on a working copy.

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Firearms

Test fire ammunition is considered to be an artefact of the firearms examination process and may be treated as a facility-generated examination record rather than evidence.

7.4.2 Each individual item of evidence must be marked with unique identification. Should the item not lend itself to marking, its proximal container must be marked.

The identifier must unambiguously identify the case.

Labelling on caps/lids alone is not acceptable because of the risk of wrongly replacing lids during testing of batches of like samples.

7.4.3 Where the integrity of the evidence is potentially compromised (e.g. poorly sealed) this must be documented in the final report.

7.4.4

Sample/evidence integrity

The facilities procedures for maintaining the integrity of evidence or samples under its control must cover chain of custody, contamination issues and tamper proofing.

The conditions under which evidence will be accepted must be covered in the facility's acceptance criteria.

If the facility seals an exhibit there must be documented records of who sealed the evidence.

A chain of custody record (e.g. signature, date, time, description of evidence/sample) must be maintained which provides a comprehensive history of each evidence transfer over which the facility has control.

Storage conditions (e.g. temperature, humidity) must protect the integrity of the items as well as address security concerns.

7.5 Technical records

7.5.1 The records system must include all data and observations and any other analytical/examination or administrative records which support conclusions.

Note: Examples of administrative records include case-related conversations which support or impact on the outcome, evidence receipts, description of evidence packaging and seals, subpoenas and other pertinent information.

Note: Examples of analytical/examination records would include reference to procedures followed, tests conducted, standards and controls used, diagrams, printouts, electropherograms, photographs, digital records (including digital photographs, video and audio records), observations and results and reports of examinations.

In general, the records required to support conclusions must be such that in the absence of the analyst/examiner, another competent analyst/examiner or supervisor can evaluate what was done and interpret the data.

Unique identification (lot/batch number or preparation date) of standards and critical reagents must be recorded.

Where instrumental analyses are conducted, operating parameters must be traceable including those not specified in the method.

Instrument charts and graphs on analyses that are batched (e.g. blood alcohol determinations, drug screening) may be more appropriately kept in a central location as specified in the facility's procedure manuals.

Documented procedures must include a description of the storage of records, such as chromatograms, not stored in the case record.

Test observations or test results must be created or maintained in a permanent form. Where the original record or result may not be in a format that can be retained permanently (e.g. in pencil), it must be preserved by other means e.g. photography or scanning.

When a test result or observation is rejected, the reason(s) must be recorded (e.g. instrument or standard failure, a result off scale or outside acceptance criteria for the method).

<u>Case Record Management</u>

The facility must maintain a case record in a designated location(s) under a unique case designator.

The facility must have a system to uniquely identify, or link all records in or pertaining to the case record. There must be processes to ensure all case records are complete.

Note 1: Electronically-generated records satisfy the criteria if they include the printed unique identifier and the analyst/examiner/investigator's name or initials.

Note 2: Electronic document management/case management systems are acceptable as long as it is possible to verify the contemporaneous contents of the case record present at any time it would have been used to generate an interpretation or report.

Abbreviations are acceptable if they are readily comprehensible to a reviewer.

The facility must have a policy in place where scanned records are used in place of original records.

Considerations include how the scanned copy reflects the original, and client expectations and acceptance of scanned copies.

7.5.2 The requirement to initial and date all changes to original data generated by the facility is not required when notes are created contemporaneously. It must, however, be clear where contemporaneous notes begin and end.

Changes made to original electronic test records or data must also be traceable to the person making the change, the date the change was made and provide detail of the nature of the change.

7.6 Evaluation of measurement uncertainty

7.6.3 Evaluation of measurement uncertainty is required for all quantitative test results. This also applies where a qualitative result is issued based on a numerical value. For qualitative analyses and results, facilities are encouraged to have an understanding of the variability of all their results where this is possible.

Electronic evidence

The measurement uncertainty attached to the measurement of time using the system clock may need to be considered.

7.7 Ensuring the validity of results

7.7.1 The range of quality control activities available to facilities includes the use of:

- reference collections;
- certified reference materials;
- electronic reference sets;
- internally generated reference materials/collections;
- independent checks by other analysts/examiners;
- positive and negative controls;
- replicate testing/examination;
- alternative methods;
- spiked samples, standard additions and internal standards.

Depending on the particular test/examination, one or more of these examples may be appropriate.

Molecular techniques

The facility's quality control procedures must include the following where relevant:

- appropriate extraction negative control samples for pre-PCR processes and must be typed at every locus being tested. The facility must have a policy for the reporting of re-tested samples where the extraction negative has been exhausted due to previous typing;
- an amplification blank with each sample set;
- a human nucleic acid sample of known type introduced at or before the amplification step as a positive control and carried through the remainder of the typing.
- a control for the nucleic acid quantitation process

Case record review

A procedure must be available for the ongoing technical and administrative review of case records. 100% of case files must be both technically and administratively reviewed unless risk assessments have been completed for reducing this percentage. Evidence of the risk assessment must be available upon request. It is acceptable for administrative and technical reviews to be performed as part of one review process.

The procedure must include:

- who may conduct each type of review;
- the criteria to be used for each type of review;
- the number/percentage of case records to be reviewed where this is not 100%.
- details that the reported conclusions fall within the range of acceptable opinions of knowledgeable individuals in the field of forensic science or are supported by sufficient scientific data;
- the course(s) of action should a discrepancy be found.

Records of reviews conducted must be kept and include the identity of the reviewer and the date of the review. Use of initials or signature is satisfactory provided the reviewer can be clearly identified.

Any significant difference in the interpretation or opinions must be recorded.

It is important to note that a technical review, while important to the facility's quality assurance program, is not to be carried out to the extent that it shifts the perceived responsibility for the scientific findings from the examiner to the reviewer as it is the examiner who presents sworn testimony regarding the findings.

7.7.2 NATA requires each applicant or accredited facility to participate in appropriate proficiency testing (PT), where available (refer to *General Accreditation Criteria: Proficiency Testing*).

Where proficiency testing meets the needs of the facility, participation is mandatory and at least one test per technique and/or competency area covered in the scope of accreditation must be undertaken annually, where available. A facility must, unless exceptional circumstances exist and are recorded complete all proficiency tests for which it is enrolled and results are required to be submitted for every PT sample sent by the provider for each program the facility is enrolled in.

PT samples/items should be handled in the same way as routine casework as far as practicable. The facility's routine test procedures must be used. Additionally, the following requirements apply:

- performance in PT programs must be reviewed;
- feedback must be provided to all relevant staff; and
- where necessary, corrective action must be taken.

PT samples are expected to be representative of items examined in normal forensic case work. A PT sample may be apportioned among multiple examiners if doing so does not alter the character of the testing.

In addition to participating in external PT, or where external PT is unavailable, a facility should consider conducting inter-laboratory or intra-laboratory comparisons. This could include blind tests prepared internally (or externally) and circulated, or re-examination of a completed case by a different examiner.

To obtain the optimum benefit from PT, the facility should emphasise the educational aspects of the program and avoid a punitive approach when taking any corrective actions.

The EPTIS database provides a comprehensive listing of proficiency testing (PT) providers, including their accreditation status and the PT schemes they offer https://eptis.org/.

7.8 Reporting of results

7.8.1 General

7.8.1.2 The facility's policies and procedures for issuing reports must include:

- prescribed formats for reports, certificates, witness statements etc.;
- issuing of preliminary or interim reports;
- reporting of results by telephone;
- electronic transmission of results and reports;
- retention of reports;
- authorisation to report;
- withdrawal of invalid reports.

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

7.8.2.1 It is noted that forensic science facilities may not be able to comply with all the reporting requirements. For example, Commonwealth and/or State/Territory legislation may require the issuing of certificates or statements in a prescribed format.

The laboratory must have a procedure for when and how to communicate preliminary or interim reports. The procedure must consider:

- identification of any results that need to be considered as preliminary or interim;
- the date and time of report issue;
- the test/examination result(s) given;
- the name of the person to whom the result(s) were given (where known);
- the name of the person issuing the result(s).

In such cases the recipient of the report must be informed that the report is preliminary or interim.

It is accepted that results supplied electronically to the National Criminal Investigation DNA Database may not need to comply with the requirements outlined in this subclause.

<u>Presumptive drug testing</u>

Where facilities perform presumptive drug testing (e.g. using portable spectroscopic techniques), a caveat must be included on the test report which indicates the result is to be used as a presumptive test only. Positive presumptive results must be confirmed using a suitable technique when used for evidentiary purposes.

Appendix: Notification to NATA of changes to facility processes.

This appendix outlines the requirements for Authorised Representatives to notify NATA within 14 days about changes that could impact accreditation status, as specified in Regulation 27.1 of the NATA Rules. It categorizes changes by their impact level and provides detailed examples.

Notification requirement overview: Members must inform NATA in writing within 14 days of changes in personnel, ownership, resources, management, premises, or functions that may affect accreditation conditions, including changes to Authorised Representatives or approved signatories. Any change potentially affecting sample analysis or result interpretation must be disclosed.

Categories of changes: Changes are grouped into software, procedure/technique/capability/workflow, consumables, laboratory equipment, policy, facility/personnel, proficiency test results, analysis/reporting, and management system/quality issues.

The following pages provide examples listed by category. Some changes might relate to more than one category. The examples are not exhaustive and other examples of where notification is required will apply.

NATA reserves the right to review any record or document which may be relevant to the assessment, including those in the "Green" column.

Where a major change is proposed NATA reserves the right to perform a supplementary assessment, including a variation assessment or desk-top variation, which will be considered on a case by case basis.

Minor changes must be notified in the Assessment Information Document (AID) prior to the next assessment.

Inconsequential changes should be notified at the assessment.

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[1]. SOFTWARE (irrespective of whether commercial, freeware, open-source or developed in-house, etc)

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
The introduction of new software that is used to analyse or interpret data. **e.g.** STRmix, FaSTR, DBLR, GMID-X **Introduction of a new version of software that includes a new capability such as AI / computer learning software and/or the introduction of an AI to support lights-out reporting** **New software / version change that requires the facility to amend its scope of accreditation** **Introduction of a new LIMS**	**A version upgrade to existing software used to analyse or interpret which does not include new capability.**	**The software is not used for analysis or interpretation** **Software used for management purposes or for tracking workload statistics (e.g. total case numbers, turn-around times)**

[2]. PROCEDURE / TECHNIQUE / CAPABILITY / WORKFLOW (Includes commercial products or those developed in-house)

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
Introduction of a new capability, competence or procedure not previously used by the laboratory **Where there are significant deviations from the manufacturer instructions for use or recommendations introduced.** **Amendment to an existing capability has decreased performance compared to the current method.** Examples • New DNA extraction chemistry (including moving to a different STR kit) • New DNA quantitation kit • New DNA profiling kit • Introduction of new analytical technology (e.g. MPS) • The new/revised method will result in a decreased amount of DNA recovered) • The way the product is used deviates from the manufacturer recommendations (e.g. a DNA profiling kit is used with reduced DNA input, altered cycle number, altered amplification volume, altered injection parameters, purification of amplified products)	**Minor amendment to an existing capability or test kit, scope of accreditation not changed, with at least performance equivalence to the current method** **Adding determinations/analytes to existing accredited methods** Examples • Conditions used to process samples have been altered (e.g. change to incubation time or temperature, or altered concentration of a key reagent) • The same core technology (e.g. DNA extraction chemistry), but using a newer product / version from the same manufacturer, or an alternative product from a different manufacturer. • The introduction of an improved method for exhibit sampling / DNA recovery • A change to the positive control used to monitor DNA extraction or amplification efficiency.	**The amendment has no relevance to analysis or interpretation** Examples • Update to lab policy to allow for the distribution of SOPs electronically

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• Interpretation and reporting of five-person mixtures (previously limited to four-person)		

[3]. CONSUMABLE (Includes commercial products or those developed in-house)

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
The performance of the consumable has had a significant impact upon analysis or interpretation **A change of consumable which is used to provide a new capability/competence.**	**The performance of the consumable has had a potential or minor impact upon analysis or interpretation** **A change by the manufacturer to an existing consumable that causes a variation to previously validated parameters e.g. the composition of the provided buffer.** Examples The lab switches to a different brand or type of swab or adhesive tape used to recover biological material from exhibits, and performance of the consumable has the potential to impact results (e.g. the amount of DNA recovered). Introduction of a new chemistry or assay to test for the presence of biological fluids (e.g. HemaTrace or RSID).	**The performance of the consumable has no relevance to analysis or interpretation** Examples A different brand of microcentrifuge tube or pipette tip not affecting previously validated parameters of the technique (e.g. introduced because the new brand is DNA-free, or supply is more reliable). A different brand of scalpel blade used to excise stains for subsequent DNA testing.

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[4]. LABORATORY EQUIPMENT

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**

New equipment where the performance of the equipment is directly relevant to the analytical process or the interpretation of results.
 	
Examples
• The introduction of MPS
 	
• A new brand or model of equipment not used by the laboratory before, such as:
  • Liquid handling robot involved in DNA testing
  • Thermal cycler, Genetic Analyser,
  • Quant instrument.
  • Alternate light source.
  • Punch machine for FTA card sampling
	Updates, upgrades or replacement/duplication of existing equipment where the performance equipment is directly relevant to the analytical process or the interpretation of results.
	
	Examples
	• Replacement of an existing (aged / broken) asset with an identical model (like-for-like)
	• Additional asset (like-for-like addition to the fleet)
	• Change to deck layout of an automated liquid handling robotic platform
		The equipment has no little or no relevance to analysis or interpretation
		
		Examples
		• Autoclave
		• Manual pipette
		• Heating block (not a PCR thermal cycler)
		• Drying oven
		• Centrifuge
		• Computer linked to an item of lab equipment (assuming that the relevant software did not change)

[5]. POLICY CHANGE (a change to business rules)

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
Internal and/or external policy changes which has or could have a significant impact on the service provided, the competence of the facility, impartiality or impact its ability to meet accreditation criteria. **Outsourcing or cessation of a function or service covered by the scope of accreditation.** Examples The decision to implement a DNA quantitation threshold, whereby samples below a certain DNA quant value are not progressed for further testing. The decision to alter analytical threshold values (e.g. limit of detection or limit of quantitation values for DNA profile interpretation).	**The policy change has insignificant impact to analysis or interpretation** Examples The laboratory makes a change to the way training is delivered to staff.	**The policy change has no relevance to analysis or interpretation** Examples • Agreement between the laboratory and the client to destroy volume crime swabs after testing is complete, rather than return them to the client. • Exhibit acceptance / rejection criteria developed in consultation with stakeholder(s). • Agency-specific policy regarding prioritisation of work or service delivery that affects turn-around / response times (but does not change the analytical processes) • Amending operational hours to align to client requirements. • Amendment to the policy for reference sample retention times.

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[6]. FACILITY / PERSONNEL CHANGE

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
Changes to senior and/or key personnel that have the potential for significant impact to operations Examples A change to the Executive Director (or however named) who is the senior accountable individual for the forensic service (or the person who is accountable for the facility if the scope is more than forensic services) A change to the Authorised Representative (if not the same as the Executive Director **Significant changes/renovations to the facility buildings that have the potential for significant impact to operations** **Additional sites requiring accreditation** **The laboratory relocates to a new facility or new premises (including the relocation to a different area within the same facility)**	**Changes to the facility or personnel that have some potential for impact to operations** Examples: The laboratory expands its footprint in the existing facility. The laboratory alters the configuration or usage of operational laboratory areas. Changes in other forensic personnel.	**Changes to the facility or personnel that have no impact on operations** Examples: The laboratory makes a minor configuration change that has no impact or relevance to operational processes.

[7]. PROFICIENCY TEST RESULTS

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
Advise of significant PT outliers immediately and any immediate cause and/or action taken and provide a timeframe for the results of the complete investigation and corrective action where perfromed. Note: Significant may be any result which would affect results or conclusions if transferred to actual casework.	**The outcome of a proficiency test has deviated slightly from the expected result with little significance.** Examples • There is a minor discrepancy between the results provided by the laboratory and the official results provided for the proficiency test, examples might include the detection of a drop-in allele in a DNA profile, or not reporting an allele that has dropped-out / below threshold. However, the conclusions reached by the laboratory are still consistent with the conclusions provided by the PT provider.	**The outcome of a proficiency test is as expected (noting that performance in proficiency tests will be subject to review at assessment).**

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[8]. ANALYSIS / REPORTING

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
Significant incorrect results / conclusions have been reported **The introduction of Activity Level Reporting, evaluative reporting, likelihood ratios or other new mechanisms by which results are reported to end-users** Examples: • A result or conclusion provided in a report that has already been issued is later found to be incorrect • A significant contamination event has occurred that has resulted in the loss of many results, or has impacted conclusions expressed in reports • Report formats are changed due to regulatory amendments e.g. parentage testing forms	**There is a minor error in a report, but the results and conclusions are not affected** Examples: • A typographical error is detected in a report that has already been issued (e.g. a minor error to the spelling of complainant name) (this would be captured and disclosed to NATA by way of the log of quality incidents) • There is a one-off contamination event affecting a batch of samples but the issue was detected and there was no impact on results reported.	**The issue has no impact and results and conclusions are not affected** Examples: • A change is made to the report template / format

[9]. MANAGEMENT SYSTEM / QUALITY ISSUES

Major **Advise NATA immediately**	**Minor** **Advise NATA at next assessment**	**Inconsequential** **No requirement to notify NATA**
Any quality investigation/audit/etc. that identifies significant systemic issues / nonconformities with the operation of the laboratory which have or could have affected results. **The laboratory becomes subject to any external review (i.e. a COI)** **Any changes which may affect the scope of accreditation** **Outsourcing of critical processes such as management system activities, method validations, technical/administrative case file reviews etc** **Significant restructures which could impact the facilities ability to meet accreditation criteria** **Enactment and/or cessation of the facilities business continuity plan (BCP)** **Identified pressures which have or could compromise impartiality**	**Internal changes to management system procedures such training programs, complaints procedures etc** Examples • A typographical error is detected in a report that has already been issued (e.g. a minor error to the spelling of complainant name) (this would be captured and disclosed to NATA by way of the log of quality incidents) • There is a one-off contamination event affecting a batch of samples, due to issues with automated platform (but the issue was detected and there was no impact on results reported)	**The issue has no impact on the service**

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[PUBLIC]

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

AS 5388.1 *Forensic analysis Part 1: Recognition, recording, recovery, transport and storage of material*

AS 5388.2 *Forensic analysis Part 2: Analysis and examination of material*

AS 5388.3 *Forensic analysis Part 3: Interpretation*

AS 5388.4 *Forensic analysis Part 4: Reporting*

ISO 21043-2 *Forensic Sciences - Part 2: Recognition, recording, collecting, transport and storage of items*

ISO 21043-3 Forensic sciences – Part 3: Analysis

ISO 21043-4 Forensic sciences – Part 4: Interpretation

ISO 21043-5 Forensic sciences – Part 5: Reporting

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

NATA Publications

NATA Accreditation Criteria (NAC) package for Legal (including Forensic Science)

General Accreditation Criteria Proficiency Testing Policy

Other Publications

Children and Community Services Act (WA)

Family Law Act

Status of Children Act (NSW)

Amendment table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Whole document	Whole document has undergone extensive review with the removal of much of the prescriptive nature of the document.
Appendix	Inclusion of new appendix

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