



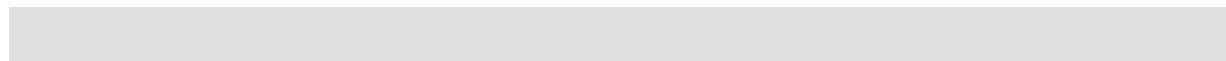
Specific Accreditation Criteria

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 not assessed)

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 (as they become available) in addition to the criteria included in the NAC for Legal (including Forensic Science). The following is currently available:

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

5 Structural requirements

5.3 The type and extent of the forensic science service provided must be defined and documented.

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

Note: The individual with direct operational 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. Where the forensic science facility is part of a parent organisation, the individual with direct operational control does not necessarily have to be the head of the parent organisation. Where the forensic

science facility operates multiple sites, it is acceptable for there to be one individual with responsibility for all sites with supervisors appointed at each site.

Where a facility operates multiple sites procedures must be in place to verify each site's continuing compliance with the management system.

Where the forensic science facility is part of a parent organisation, the facility must designate personnel who is/are responsible for coordinating the maintenance of the management system.

Where the organisation operates multiple sites the responsibilities and roles of personnel responsible for managing the quality output of these sites must be clearly defined.

The scope of responsibilities and authorities of personnel responsible for the management system must be clearly defined, including delegations. These personnel should ensure that these activities are undertaken in accordance with the procedures and within the timeframes specified by the management system and include, but not limited to, the following:

- maintenance of the management system documentation and associated operational procedures;
- monitoring of facility practices to verify continuing compliance with policies and procedures;
- evaluation of instrument calibration and maintenance records;
- periodic assessment of the adequacy of report review activities;
- ensuring the validation of new technical procedures;
- overseeing the investigation of technical problems, proposal of remedial actions and verification of their implementation;
- administration of proficiency testing and evaluation of results;
- selection, training and evaluation of internal auditors;
- scheduling and coordination of management system audits;
- maintenance of training records of facility personnel;
- training recommendations to improve the quality of facility staff;
- administration of court testimony monitoring, maintenance of records and provision of feedback on results;
- review of feedback received from customers;
- proposal of corrections and improvements to the management system.

6 Resource requirements

6.2 Personnel

6.2.2 Analysts/examiners must have tertiary qualifications and/or demonstrated experience in the relevant discipline.

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 assigned tasks. Pertinent training must be given to all trainees 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 competency assessment

Procedures for the conduct of staff evaluations should be available.

Staff records must include as a minimum:

- induction;
- relevant academic qualifications;
- participation in the facility's training program including relevant ongoing training;
- internal and external training courses undertaken;
- evaluation of continued competency;
- conferences, seminars, workshops etc. attended;
- relevant publications;
- authorisation to perform case work independently.

Access to current relevant literature must be available for each functional area.

Evidence of formal staff qualifications and membership of professional societies may be requested as part of the assessment process.

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's/examiner's objectivity, appearance, poise, performance under cross-examination 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 attendance.

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

6.3 Facilities and environmental conditions

6.3.1 The design of the facility should maximise facility functions and activities, safeguard physical evidence, protect the confidential nature of the facility's operation and provide a safe and healthy working environment.

Health and safety

The NATA assessment process emphasises the importance of safe facility practice, however, the review of health and safety issues during an assessment visit does not constitute a formal health and safety audit.

6.3.4

DNA Testing

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

A minimum of three separate, dedicated rooms are required for the:

- examination of items;
- extraction of DNA;
- amplification of DNA.

The PCR set-up area must not be in the DNA amplification room. For robotic platforms this may not apply provided contamination events can be detected. All equipment and reagents used in each room and in the PCR set-up area must be dedicated and not used elsewhere.

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

Where facilities are used to sample items for DNA, an environmental swabbing regime must be in place to monitor the effectiveness of cleaning protocols.

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

Policies and procedures on facility security must be documented. This must include the access allowed by customers or their representatives to the facility, exhibits and facility records. Examples may include access to relevant areas of the facility to witness tests/examinations, access either on-site or off-site to case records and provision of exhibits or samples for independent tests/examinations.

The facility must have arrangements in place to detect unauthorised access, (all exterior entrance/exit points to the facility must be controlled in order to prevent access by unauthorised personnel and all security doors must have keys or other access devices limited to authorised personnel).

The entire exterior perimeter of a facility must inhibit unauthorised access. For example, in the absence of intrusion alarms, suspended ceilings which permit undetected entry to the facility are unacceptable.

The facility must be monitored during vacant hours. The action to be taken in the event that an unauthorised access to the facility is suspected must be documented.

Where a facility exists within a host agency facility, documented procedures may be required to permit out-of-hours entry for emergencies. Such arrangements are acceptable if they include, for example, the breaking of a storage seal to access a key or code and/or notifying an authorised staff member.

Each emergency access to the facility must be recorded.

Access to the operational area of the facility must be controllable and limited.

Visitors must not have unrestricted access to the operational areas of the facility. A record must be retained of all visitors to operational areas of the facility.

Persons other than facility staff who have a legitimate reason for requiring access to the operational areas of the facility (e.g. use of shared equipment, cleaners, contractors) may be given authorisation by the facility director for access to specific areas of the facility without the need to be 'accompanied' by a member of the facility's staff.

There must be documented procedures for the authorisation of such persons and a record must be maintained of their time spent in the facility. In general, it is expected that such persons will meet appropriate security standards as required by the facility and will be made aware of relevant procedures/requirements and of the limitations of their access.

Internal areas requiring limited/controlled access must have a lock system.

Short-term and long-term evidence storage areas require limited/controlled access.

Each access device (keys, magnetic cards etc.) must be uniquely identified and recorded in a register.

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.

DNA Reference materials

Population databases must be checked statistically for genetic dependence. Obvious deviations from expectations must be adequately addressed and taken into account 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.

Note: In forensic science, well established procedures are often found in peer-reviewed literature as well as in less formal documents obtained from conference proceedings and in-house facility manuals.

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. As a minimum, the method must be tested using known samples (e.g. proficiency test samples, samples from an external agency).

Records of method verification must be maintained for future reference.

If destructive tests are necessary, procedures must ensure that as much material as possible is retained for reanalysis.

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 suspect results;
- data/observations to be recorded and method(s) of analysis;
- literature; and
- references.

7.2.2 Validation of methods

7.2.2.1 Methods may be validated by comparison with other established methods using certified reference materials (where available) or materials of known characteristics. The *General Accreditation Guidance: Validation and verification of quantitative and qualitative test methods* provides guidance on procedures for validation and verification of analytical test methods.

Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the forensic science facility itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

DNA Testing

Where fully automated processes for DNA analysis are used, it must be ensured that the systems have been fully validated for the intended purpose (either by the manufacturer or in-house).

7.3 Sampling

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

Parentage Testing

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.

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 contamination issues and tamper proofing.

All evidence or samples must be sealed and identify the person sealing the evidence.

A container is properly sealed only if its contents cannot readily escape or become contaminated and only if entering the container results in obvious damage/alteration to the container or its seal. Compliance can be achieved in a variety of ways and the adequacy of each facility's procedures will need to be determined on a case-by-case basis. The use of tamper-evident tape may not be necessary if the critical factors are satisfied.

The use of uniquely numbered seals is acceptable provided readily available supporting records detail the person sealing the evidence.

If tape is used to seal containers it must be initialled or otherwise identified.

Heat sealed packages must have initials or other identification across the seal.

It is understood that facilities receive evidence from numerous sources making it difficult to ensure that all evidence submitted is properly sealed. 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.

Sealing large exhibits may be impractical or inappropriate. Accordingly, facilities must adopt procedures to ensure that the feature or area of the item subject to examination is protected from loss, deterioration and contamination. For example, items could be secured in limited access rooms, garages etc. Consider sealing and protecting by covering the section/part of the exhibit that is of interest.

Evidence to be stored and transported in vehicles must be appropriately packaged. Alternative arrangements must be made for items of evidence collected from crime scenes that cannot be packaged in such a way that loss or contamination would be evident.

An examiner in the process of examining evidence who needs to store it temporarily in a secure area need not seal the evidence each time it is stored.

Containers must be closed for overnight storage to protect evidence from accidental loss or contamination.

Sample/evidence storage

A secure area for overnight and/or long-term storage of evidence either physical or electronic must be available.

High value and high risk items in the process of being examined and requiring overnight storage must be secured with limited access.

Note: High value/ high risk items may include illicit drugs, firearms, money, explosives etc.

Appropriate security for this type of evidence is achieved by storing it in locked cabinets, vaults or rooms. If an examiner needs to leave the controlled access area for a short time whilst in the process of examining this type of evidence or whilst examining large and/or cumbersome items, it is not necessary to pack up the evidence if it is in a secure area. Items of evidence, other than high value and high risk items which are in the process of being examined may be left in examination areas overnight, providing the areas are adequately secured and staff with access to the areas are aware of the need to ensure that such items be protected from loss, damage or contamination.

Additional protective measures may be required for items being examined for trace evidence to minimise the possibility of loss or cross-transfer of evidence.

When not in the direct possession of the crime scene investigator (or authorised representative), evidence collected from crime scenes must be stored in a secure area.

Unattended cars are not considered secure storage areas for evidence. It is accepted, however, that during the course of a normal shift, a crime scene investigator will be required to attend a number of jobs. In such cases, it may be acceptable to store exhibits in unattended and locked cars for short periods of time.

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.

Where appropriate, observations or test results must be preserved by photography or electronic scanning (e.g. electrophoretic runs, physical matches, quantitation results). Photocopies may also be suitable (e.g. thin-layer chromatography results, questioned documents).

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).

Case Record Management

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. The total number of pages in the case record must also be clearly identified.

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

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

Where records are scanned, it should be determined if these can replace the hard copy record. Consideration will need to be given to client expectations and acceptance of an 'original' that is scanned.

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.

7.6 Evaluation of measurement uncertainty

7.6.3 Evaluation of measurement uncertainty is required for all quantitative tests. This also applies where a qualitative result is issued based on a numerical value. For qualitative analysis, 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 Assuring 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.

DNA Testing

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

- an extraction negative sample with each set of extractions 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 DNA sample of known type introduced at or before the amplification step as a positive control and carried through the remainder of the typing.

DNA profiling data must be typed independently by two authorised scientists, who must then agree on the DNA typing results to be reported. Alternatively, a validated expert system and one authorised scientist can be used.

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 skill set must be undertaken annually, where available. A facility must complete all proficiency tests for which it is enrolled.

Note: A skill set can be viewed as a transferrable skill to similar scenarios. For example in fingerprints it can be considered that one skill exists for the purposes of proficiency testing and reviewing competency, whereas criminalistics have multiple distinct skills depending on the techniques employed.

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 a number of 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.

A link to the EPTIS database is provided on the NATA website (www.nata.com.au). The EPTIS database provides a comprehensive listing of proficiency testing (PT) providers, including their accreditation status and the PT schemes they offer.

7.7.3 A facility's performance in PT will be assessed on-site, during assessments and surveillance visits. Evidence of review of returned results and any corrective action taken in response to outliers is also required to be available and will be reviewed by the NATA assessment team.

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.

Where preliminary or interim reports are issued by telephone, the following must be recorded in the case record:

- the date and time of the telephone call;
- the test/examination result(s) given;
- the name of the person to whom the result(s) were given;
- the name of the person issuing the result(s) by telephone.

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.

Presumptive drug testing

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.

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

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
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General Accreditation Guidance	Validation and Verification of quantitative and qualitative methods
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Other Publications

Family Law Act

Family Law Regulations Form 5, Parentage Testing Procedure Report

Status of Children Act (NSW)

Children and Community Services Act (WA)

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.

Amendment table

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

Section or Clause	Amendment
Introduction	Addition of reference to ISO 21043 Forensic standards