Forensic Science ISO/IEC 17025 Application Document

July 2015

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Forensic Science ISO/IEC 17025 Application Document

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 in the field of Forensic Science for both applicant and accredited facilities.

Applicant and accredited facilities must also comply with the ISO/IEC 17025 standard application document and any field annexes, policies and/or technical circulars (refer to *NATA Procedures for Accreditation).*

The following annexes apply to testing in the field of Forensic Science:

- Forensic Science Annex A: Parentage Testing for the Australian Family Law Act
- Forensic Science Annex B: Accreditation of forensic science facilities offering multi-site crime scene services

Forensic facilities may request assessment against the requirements of the following four Australian Standards

AS 5388.1 Forensic analysis Part 1: Recognition, recording, recovery, transport and storage of material (except section 6 occupational health and safety 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

If requested, criteria documented in these standards will also be used as additional accreditation criteria during assessment activities.

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

4 Management requirements

4.1 Organisation

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

4.1.5 a) 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.

4.1.5 i) Where the forensic science facility is part of a parent organisation, it may not be necessary for the facility to appoint its own quality manager. However a member of the forensic science facility's staff must be designated as being responsible for coordinating the maintenance of the quality management system.

Where the organisation operates multiple sites with the one quality manager responsible for all, the responsibilities and roles for managing the quality output of these sites must be clearly defined.

4.2 Management system

4.2.6 The scope of responsibilities and authority of the quality manager (however named) must be clearly defined and documented, including delegations.

The quality manager should ensure that these activities are undertaken in accordance with the procedures and within the timeframes specified by the management system.

The quality manager should ensure the following activities are undertaken:

- maintenance of the quality manual and associated operations documentation;
- 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.

4.6 Purchasing services and supplies

4.6.2 All critical reagents must be routinely tested for their reliability.

Standards and reagents must be labelled with:

- name of the reagent/standard;
- concentration, where appropriate;
- preparation date;

- identity of the preparer;
- unique identification (e.g. lot/batch number)

Note: Where only one batch may be prepared each day, the preparation date is sufficient to become the unique identifier.

and, where necessary:
- expiry date;
- storage conditions;
- hazard warning.

4.13.2 Technical records

4.13.2.1 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, autoradiographs, 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).

Fingerprints

A record must be kept of all latent prints submitted for NAFIS search.

Audio and visual processing

Processing stages which produce significant outcomes must be documented in sufficient detail to allow independent repeatability of the process employed. Other processing tasks, such as those performed to improve the subjective presentation of evidence, do not require the same level of detail, however sufficient information must be recorded to describe the type of processing employed.

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.

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.

4.13.2.3 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.

5 Technical requirements

5.2 Personnel

Analysts/examiners

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

5.2.2 Staff training

A documented training program for each discipline must be available and include:

- assessment of initial competency for all new staff in all applicable areas before such staff are authorised to work independently, including:
- an evaluation of knowledge of existing literature;
- examination and identification of known and unknown materials;
- for crime scene examinations, this must include the independent assessment of a crime scene.

Documented procedures for the conduct of staff evaluations should 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 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.

A library or access to current books, journals and other literature must be available for each functional area.

5.2.5 Staff training 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.

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

Staff Competency

The assessment of competency can be determined in a number of ways including:

- participation in proficiency testing and collaborative trials;
- review of results of QC samples and standards in test batches;
- direct observation of routine work procedures;
- evaluation of staff knowledge and understanding;
- independent assessment of work undertaken (e.g. crime scene);
- court testimony monitoring (refer below);
- peer review of case files;
- client feedback.

The facility must have a documented 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 documented 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;
- barrister feedback forms;
- formal moot court attendance.

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

5.3 Accommodation and environmental conditions

5.3.1 The design of the facility should maximise facility functions and activities, safeguard the 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. State and Territory authorities are responsible for occupational health and safety in facilities.

5.3.3 DNA Testing

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

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

5.3.4 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, 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.

5.4 Test and calibration methods and method validation

5.4.1 General

Documentation of methods and procedures 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 references.

5.4.2 Selection of test methods

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.

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

<u>Audio and video signal processing</u>

The method employed to copy a primary image for archive should be validated to ensure that the process produces a binary copy.

The choice of capture device, output device or image compression should be validated to ensure the purpose and requirement of the image are met or exceeded.

All images that will form part of a final report must have any digital processing tasks documented.

5.4.5 Validation of methods

Methods may be validated by comparison with other established methods using certified reference materials (where available) or materials of known

characteristics. NATA Technical Note 17 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). Facilities must ensure that the potential for cross contamination is minimised and that events can be detected and investigated.

5.4.6 Estimation of uncertainty of measurement

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

Additional information regarding uncertainty of measurement is available in both national and international forums and available on the NATA website as well as the ILAC (www.ilac.org) and APLAC (www.aplac.org) websites.

5.5 Equipment

Audio and video signal processing

Hardware and software tools used must perform within a range of specifications that are suitable for the technical properties of the target signal. When selecting tools for audio and video signal processing, consideration should be given to the following properties:

- limitations of the physical, electronic or digital container format;
- frequency bandwidth or resolution for each signal element;
- limitations of noise and distortion (dynamic range);
- the level of artefacts introduced by the processing device;
- the specific processing method employed by each device, and
- whether alternative processing algorithms are available.

The signal monitoring and analysis equipment must be suitable for identifying the technical properties of a signal and for evaluating the results of each signal processing device.

Hardware and software devices used must be routinely and periodically verified to ensure that the device continues to perform to the required standard.

5.6 Measurement traceability

5.6.3.2 Reference materials

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.

5.7 Sampling

5.7.1 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.

5.8 Handling of test and calibration items

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

Electronically recorded evidence items must not be subject to any processes that cause permanent alteration. Where processing and/or analysis is required a working copy must be made.

Crime Scene

Photographic records (including video) of crime scenes or items taken from crime scenes are considered to be evidence.

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.

Audio and video signal processing

Operation of propriety hardware and software systems on the evidence item may be required if there are no alternative methods that can be used to access the recorded evidence. In these instances, such operation must not cause alteration to any audio and video content on the original evidence item.

5.8.2 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. It may, therefore, be a case number, a victim's name, or an address etc.

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

Fingerprints

If a latent fingerprint is recorded photographically, a legible identifier must be included in the photograph. An acceptable alternative would be appropriate identification recorded on a lift immediately after the lift is taken.

5.8.4 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.

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

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. It may be also possible to 'seal' or protect 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.

Electronic evidence

Depending on the nature of the investigation both physical and electronic containment may be required to ensure integrity is maintained.

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.

Proper security can be achieved by storing the evidence in locked cabinets, vaults, or rooms. If, during the process of examining evidence, an examiner needs to leave for a short time, such as for lunch, it is not necessary to pack up the evidence being examined if it is in a secure area (e.g. a limited-access facility room). This is also true for large and/or cumbersome items where it is advantageous to have the evidence remain out and there is controlled access to the 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 cars for short periods of time.

5.9 Assuring the quality of test and calibration results

5.9.1 Quality control

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;
- to characterise length-based polymorphisms using manual typing systems, markers which approximate the allele size range or ladders containing a majority of the known alleles must be used. Case samples must be bracketed by molecular weight size marker lanes. Each case sample must be no more than two lanes from a molecular weight size marker lane. For semi-automated typing systems, it is sufficient to include a suitable internal standard.

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.

Proficiency Testing

NATA's Proficiency Testing Policy Circular 2 requires each applicant or accredited facility to participate in appropriate proficiency testing, where available.

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 interlaboratory or intralaboratory 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.

Known PT providers are currently listed on the NATA website www.nata.com.au

Performance

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.

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. 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.

5.10 Reporting the results

5.10.1

The facility's policies and procedures for issuing reports must be documented. These must include:

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

5.10.2 Test reports

Report of tests/examinations must also include:

- the date of issue of the test report; and
- reference to other information where this may be relevant to the validity or application of results.

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.

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.

NATA references

Forensic Science Annex A:	Parentage Testing for the Australian Family Law Act
Forensic Science Annex B:	Accreditation of forensic science facilities offering multi-site crime scene services
NATA Policy Circular 2	Proficiency Testing Policy
NATA Technical Note 17	Guidelines for the Validation and Verification of quantitative and qualitative methods

Other references

Family Law Act

Family Law Regulations Form 5, Parentage Testing Procedure Report

SMANZFL: *Australasian Guidelines For Digital Imaging Processes*

Status of Children Act (NSW)

Children and Community Services Act (WA)

Guidance documents covering the implementation of specific accreditation requirements are also available from the ILAC (www.ilac.org) and APLAC (www.aplac.org) websites.

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

Amendment Table

The following amendments were made to the Forensic Science Application Document July 2013.

Please refer to this sheet in conjunction with the NATA Procedures for Accreditation and the associated ISO/IEC17025 Standard and Field Application Document and Annexes to ensure that you are familiar with these amendments.

AMENDMENT TABLE				
	Section or Title	**Clause amended**	**Amendment type**	**Amendment**
	Introduction		Addition	Inclusion of assessment against discipline specific Australian standards as accreditation criteria if requested
Section 4	Management requirements	4.1.5 a) note	Deletion	Removal of last sentence of paragraph two. Information included in ISO /IEC 17025
		4.1.5 i)	Amendment	Paragraph two. Change in emphasis regarding Quality Management at multiple sites
		4.2.6	Amendment	Inclusion of note into paragraph two. Highlighting that the quality manager has oversight of the listed activities and can delegate these roles
		4.13.1.2	Deletion	Deletion of 'Records pertaining to the analysis of samples for the National Criminal Investigation DNA Database (e.g. worksheets, test reports, electronic data analysis) must be retained indefinitely.' Information included in Standard Application Document
		4.13.2.1	Addition	Inclusion of observation surrounding use of scanned documentation
		4.13.2.1 a)	Deletion	Information included in Standard Application Document
		4.13.2.1 f)	Deletion	Information included in Standard Application Document
		4.13.2.1 j) i)	Deletion	Information included in Standard Application Document
		4.13.2.1 j) ii)	Deletion	Information included in Standard Application Document

AMENDMENT TABLE				
	Section or Title	**Clause amended**	**Amendment type**	**Amendment**
		4.13.2.1 l)	Addition	Inclusion of 'or link' records to a case file
			Deletion	Removal of 'may include an index'. This is a facility decision
			Deletion	Deletion of 'It is acceptable for physical records such as chromatograms, photographs, impressions/moulds etc. to be stored in the case record in a bag/envelope secured to prevent loss which contains an itemised description of contents, case number, analyst's identification and that the bag/envelope itself is identified as part of the case file' Information included in ISO /IEC 17025
Section 5	Technical requirements	5.2.1	Deletion	Technical management section deleted as this is a duplication of 4.1.5
		5.2.2 b)	Deletion	Removal of requirements relating to human resources policies and procedures. Not criteria of ISO/IEC 17025
		5.2.5	Amendment	Requirement for 12 monthly Court attendances has been altered for the facility to determine frequency.
		5.3.1	Deletion	Removal of first paragraph. Information included in ISO /IEC 17025
		5.3.4 e)	Deletion	out-of-hours monitoring to the ability to review and audit access records. This is adequately covered.
		5.4.5	Deletion	Deletion of first paragraph. No criteria contained
		5.4.5	Addition	Inclusion of validation requirements for fully automated DNA instrumentation.
			Editorial	Inclusion of note referencing Technical Note 17 and removal of validation parameters.
		5.4.6	Amendment	Change in emphasis to highlight that quantitative assays require MU to be established
		5.8.1	Deletion	The facility must have a documented sample / evidence control system. Information included in ISO /IEC 17025
		5.8.1	Editorial	Editorial alignment of comments to the discipline
		5.8.2	Editorial	Removal of unique case designator to unique identifier
		5.8.4	Deletion	The latter could be achieved by storing the item under tamper evident seal - no criteria included.
		5.8.4	Editorial	Editorial rearrangement of comments

AMENDMENT TABLE				
	Section or Title	**Clause amended**	**Amendment type**	**Amendment**
		5.8.4 c)	Deletion	Removal of last sentence of paragraph two which does not contain any criteria
			Addition	Inclusion of criteria to have records when staff seal the evidence received
			Addition	Requirement to record and report on any incorrectly sealed evidence received
		5.8.4 Fingerprints	Deletion	Removal of fingerprints section as no special requirements exist.
		Sample evidence/ storage a)	Editorial	Editorial change to expand 'illicit drugs' to cover other high value and high risk items.
		5.9	Deletion	Removal of reference to Technical Circular 15 which has been withdrawn.
		5.9.1 Proficiency Testing	Amendment	Incorporation of Technical Circular 20 into accreditation criteria
		Case record review	Addition	Inclusion of 100% technical and administrative reviews unless a risk assessment has been conducted. This replaced 'all or most' previously included.
			Addition	Inclusion that any differences in interpretation must be recorded.
DNA Annex			Editorial	Technical Requirements incorporated into body of document
		5.3.3	Deletion	Deletion of the following requirements as these are not unique molecular requirements and information is included in ISO /IEC 17025 and the Application Document • There must be documented procedures for the cleaning and decontamination of facilities and equipment from DNA and PCR product DNA. • The facility must demonstrate that all functions of the automated system are protected against sample contamination. • A positive and negative plate control must be used for each automated extraction run. • Automated workstations that are used to carry out DNA extractions through to PCR set-up may be located in a single room on the same platform.

AMENDMENT TABLE				
	Section or Title	**Clause amended**	**Amendment type**	**Amendment**
		5.4.1	Deletion	Facilities must have documented policies for the interpretation of data for each method of DNA analysis. The basis for concluding that samples have the same or different profiles, or that the results of the analysis are inconclusive or uninterpretable, must be established. Information expected of ISO /IEC 17025
		5.4.2	Deletion	In instances where there may be only one attempt at typing (e.g. due to insufficient sample), it must be ensured that the DNA Polymerase and kits have been tested prior to use. Information expected of ISO /IEC 17025
			Deletion	Where appropriate, precision (e.g. measurement of fragment lengths) must be determined by repetitive analysis to establish criteria for matching. Information expected of ISO /IEC 17025
		5.6.3.2	Amendment	Change form Australian database to appropriate database.
			Addition	Inclusion of 'and authorising scientist' when using validated expert reporting systems.
			Editorial	Annex B produced which replace Policy Circular 43 - Multi-Site crime Scene Services