



# TECHNICAL ASSESSORS'

# NEWS

## IN THIS ISSUE:

Welcome from the CEO ..... 1  
 Assessor Training ..... 1  
 Completion of Assessor Record Sheets ..... 1-2  
 New Approach for Forensic Science Assessments..... 3  
 Insurance for NATA's Technical Assessors ..... 4  
 Assessments for Apheresis Units ..... 5  
 Technical Note 17 ..... 5

## WELCOME

I take great pleasure in introducing to you this first edition of NATA's newsletter for our Technical Assessors.

After receiving suggestions from members that a new publication in addition to NATA News would be a good way of ensuring regular and interactive communication between assessors and NATA, we surveyed our Technical Assessors to ascertain their feelings on the matter.

84.77% of respondents said they would be "interested in receiving a regular electronic newsletter, separate to the current NATA News." That's a pretty clear indication that Technical Assessors want their own publication and this newsletter is the result.

It's intended that the newsletter will come out quarterly, about a month after each issue of NATA News. All Technical Assessors are most cordially invited to submit any articles they would like to share with their colleagues.

Volunteer assessors underpin the NATA system of accreditation. Without the assistance of some 3000 volunteers, NATA would have no choice but to use



fee-based assessors and those costs would inevitably flow on to members.

I hope you enjoy this first issue. If you would like to send me any comments you may have I'd be happy to hear from you.

Best regards,

Jennifer Evans  
Chief Executive Officer

## ASSESSOR TRAINING



Last year NATA instigated the new position of Professional Development Manager (PDM) as part of the Integrated Accreditation Project. I have taken up this role.

My name is John Widdowson and I have been at NATA for many years – some may say too many. I have held positions within the Chemical, NDT, Construction Materials and Mechanical Testing fields. I also spent 9 years in NCSI conducting audits to ISO 9001.

The PDM role includes involvement in the training of Technical Assessors as well as NATA's technical staff.

In this first edition of the Technical Assessor newsletter I would encourage you to contact me with any ideas you may have about your initial or continued training.

My email address is [John.Widdowson@nata.com.au](mailto:John.Widdowson@nata.com.au)

I look forward to hearing from you.

John Widdowson  
Professional Development Manager

## COMPLETION OF ASSESSOR RECORD SHEETS

During each and every assessment you are asked to complete an Assessor Record Sheet (ARS) by the NATA Lead Assessor. You may ask yourself what are you required to complete and why do you need to do it? This article uses ISO/IEC 17025 as the basis, however, the principles and requirements apply equally to all other standards which we assess against.

Just as we require evidence of compliance from our accredited facilities, the same is required of NATA for our accreditation to ISO/IEC 17011 Conformity assessment

– *General requirements for accreditation bodies accrediting conformity assessment bodies.* If there is no evidence to show what was looked at, it might as well have not happened at all!

As such, the completion of the Laboratory Assessment Worksheet (LAW) by NATA staff and the completion of the ARSs by each technical assessor forms the basis of being able to determine compliance with ISO/IEC 17025 and also providing the evidence and examples where non-conformances are identified.

*continued on page 2*

## YOUR CONTRIBUTIONS ARE WELCOME

This is a great place to share some of all that experience you've gained, whether it's from working in the laboratory or while conducting assessments.

Stories, technical articles, photos, jokes – all contributions from our Technical Assessors are welcome.

Send them via email to: [corpcomm@nata.com.au](mailto:corpcomm@nata.com.au) or to: NATA Communications, PO Box 7507, Silverwater NSW 2128.



# COMPLETION OF ASSESSOR RECORD SHEETS (cont.)

So what do we require to be captured and recorded and what needs to be considered during the assessment process?

## Sample Receipt (Clause 5.8)

- Are there documented sample receipt procedures covering sample identification, sample handling, sample transport etc?
- Do request slips / contracts include sufficient information?
- Appropriate handling of specimens by staff witnessed
- Retention and storage of samples appropriate
- Rejection criteria for work
- How is subcontracted testing handled? (Clause 4.4)

*NB. It may be advantageous at this point to select particular accessions to conduct a traceability study from request to report.*

## Sampling (Clause 5.7) – where applicable

- Are there documented sampling procedures?
- Are there sampling plans?
- Is sampling carried out appropriately with records maintained?

## Staffing (Clause 5.2)

- Are qualifications and experience appropriate?
- Is there adequate supervision?
- Review of training procedures, records and evaluations of competency?

## Accommodation (Clause 5.3)

- Is there effective separation between incompatible areas?
- Is facility security appropriate?
- Is there monitoring and recording of environmental conditions (where applicable)?
- Is good housekeeping maintained?

## Methods and traceability (Clause 5.4)

- Witness the performance (where available) of testing against pre reviewed test methods to assess the competency levels of staff working within the facility
- Comments on the suitability and accuracy of methods (Australian Standards, Gold Standard methods, Manufacturer method etc)
- Are the methods appropriately detailed and clear to follow?
- Have new/modified methods been validated/verified to the extent necessary?
- Do staff have ready access to methods and follow as written?

- Has Measurement Uncertainty (MU) been estimated (where applicable)?

## Equipment and Calibrations (Clause 5.5 and 5.6)

- Is equipment fit for purpose, located appropriately and contain adequate identification?
- Is there a schedule for maintenance, checking and calibration? And records available?
- Where calibrations are required, have these been performed by NATA accredited providers and are they traceable?



- Are corrections appropriately made?
- Do electronic and hard copy records include all necessary information?
- Are transcriptions and calculations subject to checking?

## Reports (Clause 5.10)

- Are all required elements included in the report?
- Is the use of the NATA endorsement appropriate?
- Is the person releasing results appropriately authorised to do so?

## Internal Quality Control (Clause 4.6 and 5.9)

- Have purchased reagents, chemicals kits etc been appropriately QC checked prior to being placed into service?
- Does QC material match the matrices being testing and cover the analytical range of the test?
- Is the frequency of QC appropriate?
- Ensure there is appropriate internal review of QC results to note outliers and trends in results, including evidence of corrective actions taken.

## Proficiency Testing (PT) (Clause 5.9)

- Does the facility have a proficiency participation plan (including external and internal schemes where required)?
- Is PT adequate to cover the competencies covered by the scope of accreditation?
- Review of PT results, including review process and investigation into outliers
- Are PT samples handled by all staff and treated as routine sample (as far as practicable)?

## Records management (Clause 4.13)

- Are records available which ensures full traceability of the testing process?
- Is data recorded at the time of occurrence and records legible?
- Are the staff responsible for critical steps in the testing process identifiable?

- Are interpretations and opinions included in line with specific legislative requirements (where available)?
- Are subcontracted results and unaccredited test results clearly noted?
- Is there a procedure for the telephone release and electronic transmission of results?
- Are amended, supplementary and interim reports clearly identified?

Between the NATA Lead Assessor and Technical Assessor there must be evidence recorded that these key questions have been answered (essentially that the whole of ISO/IEC 17025 has been reviewed in full).

If you require a greater number of ARSs during the assessment, a supply is usually maintained by the Lead Assessor or photocopies of blank sheets can be obtained. We would rather have too many notes than too few.

## WE'D LIKE YOUR THOUGHTS ON 'TECHNICAL ASSESSORS' NEWS'

Are the contents interesting? Do you feel it's relevant to your role as a Technical Assessor? How many issues would you like to receive each year? And anything else you'd like to tell us.

Please send your response to us via email at [corpcomm@nata.com.au](mailto:corpcomm@nata.com.au) by 13 April. Your comments will be greatly appreciated.

# NEW APPROACH FOR FORENSIC SCIENCE ASSESSMENTS

As a result of feedback from NATA members, it has been highlighted that the reliance on case file reviews at assessments takes significant time with little value added in raising issues of risk to forensic science facilities.

Feedback provided also raised concern that the assessment team did not spend sufficient time reviewing actual technical activities. Accordingly, testing methods often were not appropriately reviewed and at times overlooked. Hence, a decision has been made to alter the way in which assessments are carried out. This will affect all future assessments that you will be involved in.

The focus of any accreditation activity is to confirm the technical competence of a facility, thus assuring confidence in the testing results produced. While reviewing reports and case files is a part of this process, the emphasis previously has been to sample a number of case files for each reporter appointed by the facility.

Assessments in 2012 will be organised differently and consequently the flow of the assessment process will change.

The altered assessment approach will result in no reduction in the rigour and technical review of facility processes and staff. The approach will ensure appropriate time is committed by the assessment team to review all of the technical requirements covered by section 5 of ISO/IEC 17025 *General requirements for testing and calibration laboratories* and the Forensic Science Field Application Document.

The information you will receive prior to an assessment and the discussions held with the NATA lead assessor will be different to current practise, as follows:

- A specific test list will be requested from facilities;
- The information that you will receive will provide details of exactly what testing is undertaken, by what method/technique, the method utilised and an indication of the frequency of testing;
- Upon receipt of this information, you will be contacted by the Lead Assessor to discuss what specific testing you would like to witness being performed (or if not possible, discussed on the day). These methods may then be requested from the facility prior to the assessment for your review or reviewed during the assessment whilst on-site; and
- The information gathered from all assessors will result in an assessment plan being generated to ensure that all key activities are assessed.

This structured approach allows NATA to appropriately capture what is reviewed at each visit, ensuring all key activities and associated competencies are reviewed and the methods adopted for those competencies sampled.

As technical assessors, you will be requested to ensure that the supplied 'Assessor Records Sheets' (ARS) are completed with sufficient

detail on what was assessed. The following information is required to be captured, including what complies with the accreditation requirements and what does not:

- what was observed/performed by the staff of the facility;
- which staff were engaged during the process;
- which methods were reviewed; and
- which case files were reviewed.

This record is retained by NATA and serves as the source of evidence of what was assessed.

It is expected that technical assessors will spend a greater amount of time in the laboratory setting, discussing work scenarios and processes with staff. It is therefore expected that staff will be available throughout the day to assist the assessment team.

For greater clarification. The flow of the assessment day is likely to be as follows (depending on size and complexity of testing undertaken):

## **Entry discussions with senior management**

Discussion surrounding services provided, key activities performed, any changes to testing, staffing and processes. This will also be the time to clarify any work commitments by facility staff which need to be accommodated by the assessment team.

## **Review of specimen or evidence handling and storage**

Depending on the set-up of the facility a review of initial receipt, chain of custody, storage and destruction will be reviewed by the entire assessment team. Where these are handled by different departments, the assessment team will split up and review these areas.

## **Witness/discussion of specific methods within each defined area of competency**

The review will include assessment of authorised staff to perform the testing in line with documented procedures and/or standard practice, quality control procedures, accommodation, equipment, record maintenance and continuity of sample identity etc.

This process will be repeated for each core competency to be assessed.

## **Record review**

This will involve review of completed case files (refer below), proficiency testing records, staff training records etc.

## **Compilation of interim report**

This will be done by the NATA lead assessor with assistance from the technical assessors based on the assessment findings and evidence recorded in the ARS.

## **Exit discussion**

It is during the exit discussion that the assessment findings are presented. The facility staff are encouraged to question or clarify any issues in the report which are unclear or any misunderstandings that may have occurred.



## CASE FILE REVIEWS

The focus of the assessment team will be to ensure that the facility has internal processes and procedures in place for monitoring case file reviews, both technically and administratively. As noted, not all case reporters will continue to be reviewed. The selection of reporters and associated cases will be dependent on each facilities specific situation. For example:

- only a sample of select cases from a sample of reporters will now be reviewed;
- if new reporters have been appointed since the last NATA visit, then a number of these may also be sampled;
- where concerns are raised then more cases or reporters may be sampled to determine the extent of any non-conformance(s).

An exception to this is for parentage testing conducted in accordance with the Australian Family Act 195 Regulation 21N(5). For such testing, all reporters nominated by the facility will be reviewed at each reassessment.

Prior to each assessment, the NATA Lead Assessor will ensure a brief discussion with all assessors to confirm the assessment plan and the new process of assessment to be followed.

Please use the NATA Lead Assessor as a resource and ask as many questions regarding the process as necessary. Given time, this approach will become familiar to both the facilities and assessors involved.

# INSURANCE FOR NATA'S TECHNICAL ASSESSORS

NATA maintains insurance cover which includes our voluntary Technical Assessors when conducting work on behalf of NATA. This insurance provides coverage in a number of areas including:

- Public Liability and Professional Indemnity Insurance: Technical Assessors are indemnified when performing tasks on behalf of NATA.
- Group Personal Accident Insurance: This insurance covers voluntary Technical Assessors anywhere in the world when engaged in voluntary work authorised by and under the control of NATA. This includes travel to and/or from such training/work.
- Corporate Travel Insurance: Technical Assessors are covered when on authorised business travel from the time the person leaves their residence or business and is continuous for a full 24 hours until the assessor's return. This insurance covers the following categories up to pre-set limits:
  - Death & Disablement; Weekly Injury Benefit; overseas medical expenses; additional/cancellation/curtailment expenses; luggage; personal effects; travel documents; additional money cover; personal liability; kidnap & ransom; loss of deposits; legal costs; extra territorial workers compensation.
- Rental Vehicle Insurance: NATA has insurance to cover the excess payable for rental vehicle damage. Therefore, you should not accept the Excess Reduction Insurance or the Personal & Baggage Insurance offered by Avis car rental depots and/or agencies. Please note: all insurance becomes void if an Avis vehicle is abused (ie. driven on a private road, an unsealed road or across a country property). All accidents involving rental vehicles must be reported immediately to Avis on 1800 257 247. A copy of the accident report and bill of repairs should also be sent to the NATA lead assessor.

NATA does not provide insurance to cover private motor vehicles for Technical Assessors. They must maintain their own comprehensive motor vehicle insurance.

Assessment team members are in a position of privilege with respect to information about the facility under assessment. Confidentiality is essential. All Technical Assessors sign a declaration of confidentiality prior to participating in a NATA assessment and must maintain strict confidentiality regarding all aspects of the facility's operation.

Information to keep confidential includes:

- All assessment arrangements including the name of the facility to be assessed and other technical assessors involved.

- Paperwork about the assessment, including briefing notes and report.
- Any recommendations or discussions arising out of the assessment.
- Any information about the facility and its operation obtained during the course of an assessment that would otherwise not normally be available to you.

Breaches of confidentiality are viewed very seriously by NATA and as a minimum will jeopardise a Technical Assessor's participation in any future assessment activity. Technical Assessors should also note that if you act outside of the remit of work assigned to you by NATA, our insurance will not cover you.

Some hints for maintaining confidentiality are:

- Remember, all matters associated with the assessment are confidential.
- Upon receipt of the briefing notes, keep the information in your own office area (or at home). Keep it together and out of sight from others.
- Do not discuss any of the information about the assessment with others, including your work colleagues.
- At the completion of the assessment, return briefing material to the NATA lead assessor for disposal. The information should only be retained in a situation where you are likely to be involved in some follow-up advice.

From time to time you will be asked to review and update the information we retain regarding your professional expertise. At this time we normally take this opportunity to obtain a re-affirmation from you regarding your commitment to:

- declare any potential conflicts of interest; and
- maintain confidentiality at all times.



On technical issues keep within your scope of expertise/knowledge. It is inappropriate to comment on another technical assessor's performance or findings.

Outside of a tribunal/court environment you are obliged to continue maintaining strict confidentiality about accreditation visits or assessment matters.

Technical assessors should be aware that the NATA assessment process and/or assessment findings can become the subject of legal proceedings. As a consequence, Technical Assessors may be asked to provide affidavits or even appear in court.

In such cases, NATA will provide all necessary assistance and support.

If you are contacted by a legal office for advice, comment or a scientific opinion or you are subpoenaed for a legal appearance that in any way relates to NATA, NATA accredited facilities and/or an accreditation visit that you participated in, or if you require further information regarding the above matters, please contact NATA's General Manager, Compliance and Governance (Tony Vandenberg) on (03) 9274 8219.

## Consultation for legal matters

It is possible, although this is a rare occurrence, that Technical Assessors may be requested/paid to give advice or a scientific opinion to consulting solicitors. They may also be subpoenaed as an Expert Witness in legal matters, e.g. tribunal or court appearances.

As a general principle in these circumstances, it is judicious to limit your responses to questions or general comments and scientific opinion to those areas relating to your scope of expertise and knowledge only.

If you are aware that the matter relates to NATA, NATA accredited facilities and/or an accreditation visit that you participated in please keep in mind the following:

## NATA's accreditation processes

It is not appropriate under any circumstances to comment on any NATA policy or procedures relating to NATA's accreditation processes. Questions along these lines should be reflected back to the examiner for reference to appropriate NATA staff. This applies whether you are in a tribunal/court environment or in general discussion with anyone.

## Assessment visit matters

When answering questions about a specific accreditation visit that you may have participated in, be prudent with your response. In a tribunal/court appearance, restrict your answers on administrative and liaison matters with NATA to those pertaining to the contact you have and/or that you were directly involved with on the day.

## ASSESSMENTS FOR APHERESIS UNITS

NATA began its accreditation program for Apheresis Units in August 2009. Units are accredited to ISO 15189:2007 and the NPAAC Standard – *Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells:2009*.

NATA has now trained 11 apheresis nurses and Bone Marrow Coordinators to be Technical Assessors and although this was new for them it has worked well. This ensures that one of the benefits of the NATA/RCPA Accreditation process – that of peer review – was extended to this new area.

To reduce costs associated with an initial assessment, a decision was made not to do Advisory Visits and to assess the Apheresis Units in conjunction with the BMT Laboratories.

The Apheresis Unit is assessed the day prior to the BMT Laboratory. This gives the assessment team adequate opportunity to review both the collection and the subsequent processing, storage and release of the stem cells in the laboratory.

Approximately 97% of the units identified initially have been accredited or are in the



process of accreditation and the standard of these units is high.

Costs from application to initial accreditation are approximately \$6,000 to \$7,000.

The reassessment interval depends on the date of the reassessment of the BMT Laboratory that processes and stores the stem cells.

Costs associated with the reassessment of the apheresis unit are covered by the annual

membership fee, from the date of accreditation pro rata to 30 June in the first year. The annual fee for 2011-2012 is approximately \$3000.

The current fee schedule is available from the NATA website-[www.nata.com.au](http://www.nata.com.au)

If you have any queries you can contact Wendy Harris at [wendy.harris@nata.com.au](mailto:wendy.harris@nata.com.au) or telephone 02 9736 8264

## TECHNICAL NOTE 17 UPDATE

Technical Note 17 Validation and Verification of Chemical Test Methods has been replaced by Technical Note 17 Guidelines for the validation and verification of quantitative and qualitative test methods. The new version of the Technical Note, which describes the aspects of a method that should be considered when undertaking method validation or method verification, is intended to be applicable to most fields of testing rather than chemical testing alone as was the case with the previous version.

A test method must be shown to be fit for purpose so that a facility's customers can have confidence in the results produced by its application. Method validation and verification provides objective evidence that a method is fit for purpose, meaning that the particular requirements for a specific

intended use are fulfilled.

For these reasons, method validation and verification are essential requirements of accreditation to ISO/IEC 17025 and ISO 15189. Accordingly, facilities accredited to these Standards must demonstrate the validity of all methods used by validating all in-house and modified standard methods and verifying standard methods. Validation is always a balance between costs, risks and technical possibilities. The extent of validation required will depend on the status of the method under consideration and the needs relating to its intended application.

Users of this Technical Note should note that although there are many publications and methods for validating and verifying different methods, no one method is universally agreed and approaches other than those set

forth in this guideline may be applicable and acceptable. The guideline cannot as such be regarded as a procedure for method validation or verification in connection with the facilities' compliance with the requirements of ISO/IEC 17025 and ISO 15189. It is the responsibility of the facility to choose the validation or verification procedure and protocol most suitable for the desired outcome. However, it is important to remember that the main objective of validation or verification of any testing method is to demonstrate that the method is suitable for its intended purpose.

A number of examples from different fields of testing have been provided throughout the document.

### The National Association of Testing Authorities, Australia

#### New South Wales

PO Box 7507  
Silverwater NSW 2128  
7 Leeds St  
Rhodes NSW 2138  
Ph: 1800 621 666 (free call)  
Fax: 02 9743 5311

#### Victoria

Level 1,  
675 Victoria Street  
Abbotsford Vic 3067  
Ph: 03 9274 8200  
Fax: 03 99421 0887

#### Queensland

PO Box 1122  
Archerfield BC  
QLD 4108  
628 Ipswich Rd  
Annerley QLD 4103  
Ph: 61 7 3721 7300  
Fax: 61 7 3848 3660

#### Western Australia

Suite 7  
Business Centre  
Technology Park  
2A Brodie Hall Drive  
Bentley WA 6102  
Ph: 08 9486 2800  
Fax: 08 9486 2828

#### South Australia

Unit 1  
13-15 King William Rd  
Unley SA 5061  
Ph: 08 8179 3400  
Fax: 08 8271 7601