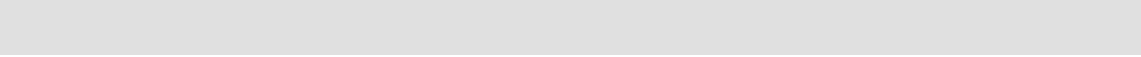




Assessor Information and Guidance

January 2019



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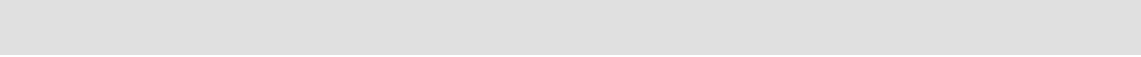
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1. Introduction to the Assessor Resource Kit

The Assessor Resource Kit (ARK) is a package of documents that has been prepared for Technical Assessors of the National Association of Testing Authorities, Australia (NATA). It is designed to provide information for all Technical Assessors involved in NATA's accreditation activities/programs for testing laboratories, calibration laboratories, inspection bodies, reference material producers, proficiency testing providers and human pathology laboratories.

The purpose of the ARK is threefold:

- to provide you with background information about NATA;
- to provide you with information to assist you with the preparation for assessments and your role when participating in them; and
- a detailed section covering assessment techniques that should guide you when conducting NATA assessments.

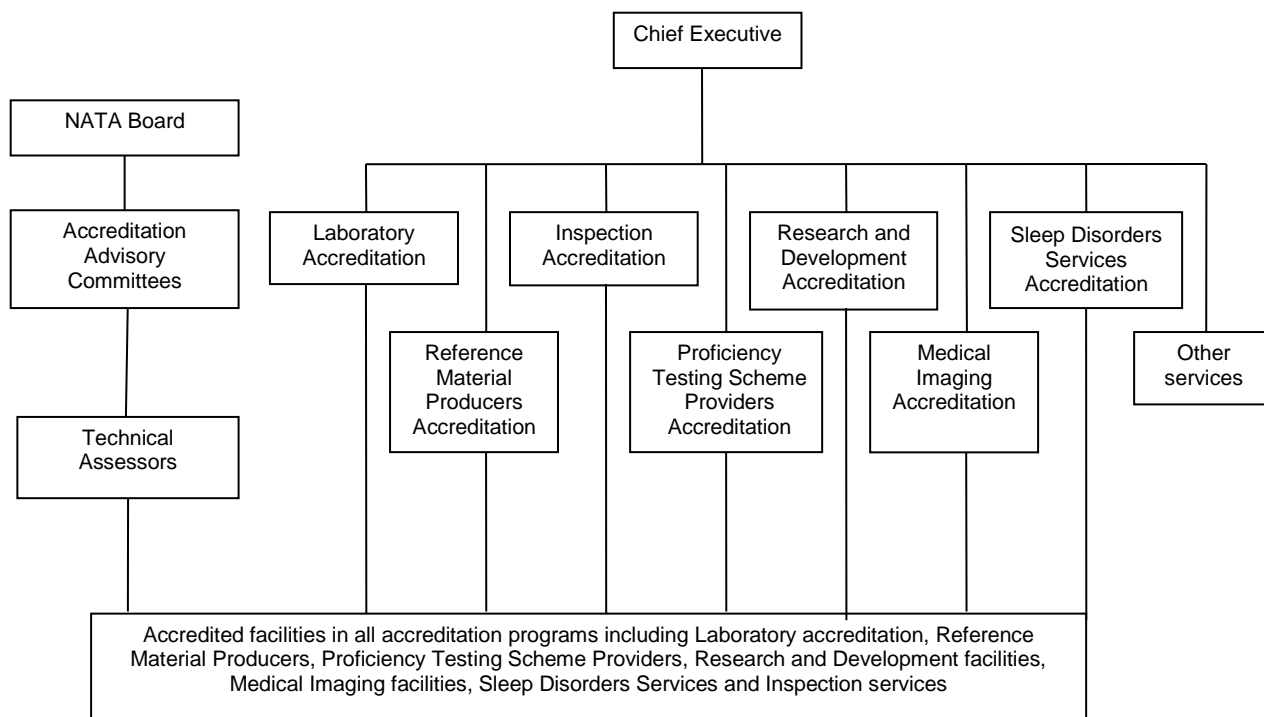
The ARK is both a training tool and a source of information. It is designed to be used in conjunction with attendance at the Technical Assessor Development Program provided by NATA's Training Services Group. It is also a useful stand-alone resource for Technical Assessors located overseas who are not able to attend a training course.

It is in NATA's interest to ensure that our Technical Assessors receive appropriate training and resource support. We would therefore be grateful for your feedback on the ARK, or any other matters relating to Technical Assessor training.

2. About NATA

Structure of NATA

The overall structure of NATA is shown in the following diagram:



The right-hand side of the diagram depicts the full-time secretariat of NATA. The left-hand side shows our representation and advisory resources. All of these external resources provide their input to NATA on an honorary basis.

NATA Board of Directors

The Board of Directors (the Board) is elected by the NATA members and is responsible for overseeing all of NATA's activities.

Accreditation Advisory Committees

The Board receives technical advice from specialist committees that it appoints. These committees are referred to as Accreditation Advisory Committees (AACs). There is an AAC for each area of accreditation.

The functions of AACs include:

- overview of relevant accreditation activities;
- establishment and review of accreditation criteria;
- submission of recommendations to the Chief Executive for granting, extending, continuing, and suspending accreditation;
- submission of recommendations to the Board for cancellation of accreditation; and
- provision of advice to the Board on appointment of Technical Assessors.

AAC members may be drawn from accredited facilities or other technical organisations and are appointed by the Board. Members are selected on the basis of technical expertise.

Technical Assessors

Each accreditation area/activity type has a panel of Technical Assessors appointed by the Board on advice of the relevant Accreditation Advisory Committee. Technical Assessors are selected on the basis of technical knowledge and expertise. As a member of an assessment team, the role of the Technical Assessor is to evaluate a facility's technical competence.

NATA staff

NATA employs more than 200 personnel nationally. The organisation's head office is in Sydney and State offices are located in Melbourne, Adelaide, Perth and Brisbane. Each State office has a Manager who is responsible for day-to-day administration of the office.

The Chief Executive is located in the Sydney office.

NATA's accreditation activities are grouped into sectors. The groupings have been established, where possible, based on natural alignments between individual areas or on the types of facilities that would be accredited under the group. Each sector is managed by a Sector Manager who has the overarching responsibility for the technical management of the accreditation area(s) within their sector. The Research and Development program has been excluded from the sector structure as facilities accredited within this program may reside in any given sector. A technical specialist (referred to as a Program Advisor) takes carriage of the technical management of this program.

Lead Assessors are employed to conduct assessment related activities and report to an assigned Accreditation Manager who is responsible for the operational service delivery aspects of accreditation work.

All staff report to the Chief Executive who is appointed by the Board.

NATA website (www.nata.com.au)

The website is our major communication tool both with accredited facilities (members) and Technical Assessors.

The website contains a section titled '[Technical Assessors Information and Guidance](#)' which contains information of relevance to Technical Assessors, including training.

The website is used to disseminate updates of all technical and information documents (such as this one) to members and Technical Assessors. Check the site regularly and in particular, before going out on your next assessment.

Memoranda of Understanding

NATA has in place several Memoranda of Understanding (MOUs). The most significant of these is the MOU in place with the Australian Government signed in 1988 and reconfirmed in 2018. A copy of the current MOU is available from the NATA website in the 'About Us' section under 'Working with Government'. There are other MOUs in place with various instrumentalities and government departments that are industry specific. If they have particular relevance to your

industry, the Lead Assessor will be aware of the policy issues and will provide guidance as required during an assessment visit.

International activities

MRAs, ISO/IEC 17011 and reports from overseas

NATA has a long history of experience in contributing to the development of laboratory and inspection accreditation around the world, and has been instrumental in initiating and enhancing many international advances. Our participation has many facets and this information can be found on the website in the 'Global Trading Network' section under the 'About Us' tab.

Mutual recognition arrangements

In the international accreditation arena, Mutual Recognition Arrangements (MRAs) are agreements between two or more parties. They cover the acceptance of endorsed test, calibration and inspection reports. Originally these agreements were developed on a bilateral basis between NATA and its counterpart organisation in another economy, the first one in the world being between NATA (Australia) and TELARC (now known as IANZ) in 1981. Currently NATA is party to multi-lateral arrangements in the Asia-Pacific area (APAC MRA) and globally, through the ILAC Arrangement.

In addition there are now government to government MRAs in place governing the acceptance of reports and certificates from accredited facilities in the economies that are signatories to the agreement.

The ILAC and APAC websites include a list of the economies and the organisations that are party to the APAC and/or ILAC arrangements. The listings are under constant revision as more economies and organisations join the arrangements.

You will find current information on ILAC and APAC on their websites:

- ILAC (International Laboratory Accreditation Cooperation) - www.ilac.org
- APAC (Asia Pacific Accreditation Cooperation) - www.apac-accreditation.org

ISO/IEC 17011

The international basis for the acceptance of equivalence of endorsed reports in the MRAs is ISO/IEC 17011 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*.

The accreditation operations of each participating accreditation body are evaluated against the principles outlined in this document. Teams of trained evaluators selected from within the MRA group do the evaluations. The evaluation team reviews the administrative arrangements in place as well as the conduct of accreditation activities, including witnessing a selection of assessments and surveillance visits.

On rare occasions, you may find yourself part of an assessment team being observed by one of these evaluation team members. If this happens you will be given guidance, training and information about what to expect and who will be involved. You should not make any changes to the way you normally participate in an assessment visit. The evaluation team are there to observe the NATA processes, not the outcome of a particular assessment visit.

3. The accreditation documents

NATA accreditation is based on the evaluation of a facility's technical competence, by applying criteria specific to each technical accreditation program and area. The criteria are detailed in the NATA Accreditation Criteria (NAC) packages. These documents are included as part of the ARK.

Each NAC includes the following documents:

- General NATA Documents;
- General Accreditation Criteria;
- General Accreditation Guidance;
- Specific Accreditation Criteria;
- Specific Accreditation Guidance;
- General Accreditation Forms; and
- Specific Accreditation Forms.

The General Documents, Criteria, Guidance and Forms are applicable to all accredited and applicant facilities as relevant, while the Specific Criteria, Guidance and Forms are applicable to only one given standard (program) and/or activity type.

The accreditation criteria and guidance documents are packaged to align with the accreditation standard (accreditation program) and industry classifications where relevant. In the scopes of accreditation NATA publishes, the industry classifications are identified as 'activity types'.

About NATA and accreditation

This information document outlines the general procedures relating to NATA accreditation, its administration, the accreditation programs offered by NATA and the international context of accreditation. A specific version of this document exists for the OECD GLP recognition program and for the Sleep Disorders Services program.

NATA Procedures for Accreditation

This is a general document applicable to all accreditation programs that explains NATA's accreditation policies and procedures.

Accreditation program standard

The NAC and ARK include the relevant current edition of the ISO or industry standard for the accreditation program being applied to a facility, or information on how to obtain the relevant document.

Laboratory accreditation: ISO/IEC 17025

ISO/IEC 17025 is the standard against which NATA's laboratory assessments are conducted*. The relevant requirements of the ISO 9000 series of standards applying to the quality systems for conformity assessment bodies are incorporated into ISO/IEC 17025. It has been prepared in five sections:

- General Requirements;
- Structural Requirements;

- Resource Requirements;
- Process Requirements; and
- Management Requirements.

***NOTE:** In Human Pathology, ISO 15189 is the standard against which NATA's laboratory assessments are currently conducted. This is an industry specific standard based on ISO/IEC 17025, for accreditation of medical pathology laboratories.

Medical Imaging: RANZCR Standards of Practice for Diagnostic and Interventional Radiology

Medical Imaging assessments are conducted against the current version of the RANZCR Standards of Practice for Diagnostic and Interventional Radiology. This is an industry specific standard that addresses the technical and management requirements as well as Commonwealth, State/Territory legislation applicable to the program.

Sleep Disorders Services: ASA Standards for Sleep Disorders Services

Sleep Disorders Services assessments are conducted against the ASA Standards for Sleep Disorders Services. This is an industry specific standard that addresses the technical and management requirements as well as Commonwealth, State/Territory legislation applicable to the program.

Reference Material Producers accreditation: ISO 17034

ISO/IEC 17025 may be used in conjunction with this international standard as the accreditation criteria against which assessments of NATA's Reference Material Producers are conducted.

Proficiency Testing Scheme Providers accreditation: ISO/IEC 17043

ISO/IEC 17043 is the standard against which assessments of NATA's proficiency testing scheme providers are conducted. ISO/IEC 17025 may be used in conjunction with this international standard.

Inspection accreditation: ISO/IEC 17020

ISO/IEC 17020 is the standard against which assessments of NATA's inspection bodies are conducted. It was originally prepared and published as EN 45004. The relevant requirements of the ISO 9000 series of standards applying to the quality systems for inspection bodies are incorporated into ISO/IEC 17020.

NATA General Accreditation Criteria (GAC)

These documents provide the general accreditation criteria that NATA facilities must comply with. The general accreditation criteria documents are applicable to all accreditation programs.

The GAC also includes the relevant Standard Application Document (SAD), e.g. *ISO/IEC 17025 Standard Application Document for accreditation of testing and calibration facilities*. This document provides interpretative criteria and recommendations for the application of the relevant standard for both applicant and accredited facilities.

From time to time it is necessary to amend or add to the criteria for accreditation. The NAC and ARK therefore contain provision for the filing of additional general accreditation criteria documents that may be issued detailing such amendments or additions.

All General Accreditation Criteria are published on the NATA website and can be found under 'Accreditation Information - Accreditation criteria and guidance' and each NAC package. The Lead Assessor will advise whether any new criteria has been issued or re-issued. You should also routinely visit the NATA website to check for any updates, especially prior to an assessment.

NATA Specific Accreditation Criteria (SAC)

For each accreditation activity type and program, NATA has produced specific accreditation criteria and annexes (where relevant) which provide interpretation of the relevant standard and additional criteria for a particular activity type and/or specific areas of testing that NATA applicant and accredited facilities must comply with.

The specific accreditation criteria and annexes contain:

- specific criteria relating to the activity type;
- technical information related to particular issues in the type of testing or program;
- a list of relevant reference literature.

The NATA Rules

The Rules take precedence over all other NATA documents and focus on NATA's constitution and conduct of affairs. They define the basic conditions that apply to all accredited and applicant facilities.

NATA General Accreditation Guidance and Specific Accreditation Guidance

In addition to the standard requirements and accreditation criteria, NATA produces a number of interpretive documents that provide guidance for applicant and accredited facilities. These include for example:

- equipment tables - general and reference equipment tables that include guidance on calibration and checking intervals and the associated procedures for commonly used equipment;
- documents which include interpretative information to assist facilities in relation to particular technical matters which do not form part of the accreditation criteria;
- informative documents;
- Proficiency Testing information;
- Measurement Uncertainty and Traceability information;
- the accreditation classification system for the accreditation program (also known as the 'Service Descriptors' for each activity type);
- checklists, worksheets and site notification forms.

4. Technical Assessors

Each accreditation program and activity type is supported by a panel of Technical Assessors. NATA identifies technical experts who have the required professional and personal qualities and invites them to join the panel of Technical Assessors relevant to their area of expertise.

Technical Assessors are drawn from both local and overseas:

- academic institutions;
- research establishments;
- government department laboratories and inspection services;
- industrial laboratories and inspection services;
- private laboratories and inspection services; and
- consultancies.

Technical Assessors are invited on the basis of their:

- professional expertise and experience;
- knowledge of testing and measurement or inspection;
- qualifications;
- understanding of facility management;
- analytical approach;
- ability to critically evaluate;
- ability to work as a member of a team;
- communication skills; and
- commitment to the accreditation process.

Following verbal acceptance of the invitation to join the panel, a new Technical Assessor receives a letter of invitation and a Technical Assessor record form. This form includes a confidentiality agreement and a list of the activity type and associated services or categories of inspection which the Technical Assessor feels competent to assess. This form is completed and returned to NATA for review and approval by the appropriate AAC.

After the form is processed and approved, the Technical Assessor is sent the Assessor Resource Kit (ARK) for their personal use. The ARK is used as the basis for course notes for the Assessor training course. It includes information to assist with assessments as well as a copy of relevant NATA Accreditation Criteria publications (see previous section).

Technical Assessor appointments are reviewed periodically, in consultation with the relevant Lead Assessors and Sector Manager, and a decision as to whether a Technical Assessor will continue their appointment is made based on the requirements of the program at the time.

Technical Assessors are requested to keep NATA informed of changes to their personal details, e.g. contact numbers, change of employer, changes to work experience. Keeping these details current assists with our assessment team selection.

Training for Technical Assessors

Technical Assessor Development Program

NATA's Technical Assessor Development Program (TADP) training sessions are provided for all appointed Technical Assessors free of charge (excluding travel and accommodation if they are required). Attendance at a TADP is a mandatory aspect of your commitment as a Technical Assessor.

The TADP is a one-day general session designed for all Technical Assessors involved in any of our accreditation programs.

The course covers the role of the Technical Assessor and the Lead Assessor as a member of an assessment team. It also covers preparation for and conduct of assessments including tips and hints on assessing skills.

On your initial appointment as a Technical Assessor, you will be automatically invited to attend the next appropriate TADP session in your locality. Technical Assessors must advise if they are unable to attend a TADP session to which they have been invited. Session dates and locations are available by contacting the NATA Training Services Group in the Sydney office or on the website. Continuing Technical Assessors are welcome to attend a TADP session as a refresher at any time.

After attending a TADP training session you will receive a Certificate of Attendance.

As the TADP training sessions are mandatory for new Technical Assessors, NATA reviews each Technical Assessor's status in our system on a regular basis. After two years it is our policy to reconsider the appointment of Technical Assessors who have not yet attended a TADP. Mitigating factors such as provision of TADP sessions by NATA in the locality, apologies received, etc. will be considered as part of that review.

It is understood that a Technical Assessor may be called upon to participate in an assessment before it is possible to attend a TADP. In such cases the Lead Assessor will provide appropriate guidance and direction. If possible, new Technical Assessors also participate in one or two assessments in the company of an experienced assessment team as part of their training.

In addition, from time to time, NATA may prescribe additional mandatory training requirements for Technical Assessors.

Technical forums

Industry specific technical forums are occasionally held (often in conjunction with a meeting of NATA members) where Technical Assessors can get together with others for technical training or to discuss technical issues arising from assessment activities.

Time commitment

Technical Assessors are completely free to accept or decline any invitation to participate in an assessment. We endeavour to minimise the amount of work asked of any Assessor. Normally, Technical Assessors participate in a maximum of two to four 'one day' assessments per year. Occasionally we ask a Technical Assessor to travel interstate, to rural locations or overseas. This may require a greater time commitment.

Conflicts of interest

Potential conflicts of interest must be advised to the arranging Lead Assessor when considering whether to accept an invitation to participate in an assessment.

The Assessor record form completed when you were first invited to join the Assessor panel includes a commitment that any conflicts of interest regarding an organisation you are invited to assess will be declared. Examples include:

- company alliances and commercial interests in the facility
- commercial arrangements, e.g. client/supplier relations
- intellectual property considerations
- consultancy arrangements (current and/or past)
- close personal associations (family and/or friends)

Professional ethics extends this principle to advising about any other possible conflicts of interest of which you may be aware.

When assembling an assessment team, NATA staff carefully considers each suitable Technical Assessor available for the assessment. However, we are not always aware of links you may have with the facility or other assessment team members. Please consider your involvement in the assessment from every possible angle. Advise the Lead Assessor of all potential conflicts of interest and discuss with them whether they may preclude you from participating in that particular visit.

Should you become aware of any conflict of interest during an assessment, please advise the Lead Assessor as soon as practicable.

Gifts and meals

The acceptance of dining invitations and gifts can be an area of concern for Technical Assessors. The following guidance may assist you with situations that might arise in the course of participating in assessment visits with NATA.

Any dining invitation or gifts proffered while participating in an assessment visit should be viewed as a hospitality token. However, they are not an obligation of the accreditation assessment process. Under no circumstance should gifts and meals ever be suggested to or expected of an organisation.

The provision of lunch by the facility is an acceptable time and cost-effective business practice. Occasionally company souvenirs are given e.g. corporate mugs, caps, etc. and when travelling in rural areas or interstate, evening meals may be offered. Provided they are not excessive in value these are acceptable.

Particularly when travelling overseas, small gifts may be given at the conclusion of an assessment visit as a token of appreciation for your time and effort. Often facility staff will offer to take you for evening meals or on local guided tours in spare time as a mark of hospitality and to allow you to experience more fully the richness of the local culture. Once again, provided these are not excessive in value they are in keeping with local business practices and thus acceptable.

It is up to you as individuals to make appropriate judgement when accepting or declining any gifts or dining invitations. Common-sense and awareness of usual business practice within the culture is the best guide. If you are in any way uncomfortable, discuss it with the Lead Assessor or gracefully decline.

Confidentiality

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 (or electronic based information) about the assessment, including briefing notes and report;
- any recommendations or discussions arising out of the assessment; and
- 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.

Some hints for maintaining confidentiality:

- 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;
- during the assessment, any use of a mobile phone should ideally be made outside of the laboratory and away from facility records and documentation, so that it cannot be misconstrued that pictures are being taken of laboratory documents; and
- at the completion of the assessment visit, return briefing material to the 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. In this case, when the job is completed, please return the Briefing Notes or destroy them.

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.

Promoting equity, valuing diversity

NATA respects the differences between employees and Technical Assessors, recognising that each person has individual skills and attributes to bring to their job and that different backgrounds, social and cultural experiences encourage innovation and flexibility within NATA.

NATA strives to create a working environment which is free from discrimination and harassment, including sexual harassment and workplace bullying.

NATA opposes discriminatory or harassing behaviours such as gestures, language and the display of materials that may offend, humiliate or intimidate another person, such as:

- sexual harassment involving inappropriate jokes, suggestive comments, unwelcome touching or physical assault or any other behaviour that is unwelcome and is of a sexual nature;
- bullying behaviour such as verbal abuse or physical intimidation;
- discriminatory or racist jokes, comments, nicknames, slang or other discriminatory behaviour that is unwelcome and humiliates another person.

Both the Lead Assessor and the Technical Assessor shall conduct NATA business in a professional manner in accordance with NATA's Equal Employment Opportunity, Discrimination and Harassment Policy (a copy may be obtained upon request).

If you have any questions or believe you have been exposed to discriminatory or harassing behaviour whilst conducting NATA business, please contact our Human Resources department or the General Manager, Operations and Technical immediately.

Work health and safety

At NATA we believe that promoting Work Health and Safety is essential if we are to develop an environment where our employees feel safe and valued and will therefore be able to make the most effective and efficient contribution to the achievement of our corporate goals and objectives.

It is the responsibility of the Lead Assessor and the Technical Assessor to conduct NATA business in accordance with NATA's Work Health and Safety Policies to protect their own health and safety and that of others.

When conducting an on-site assessment, the first prerogative is to comply with the customer's safety rules and conditions. The following should be adhered to at all times:

- always sign in and out, and if there is no receptionist on duty report your presence to a staff member. The same procedure should be followed upon leaving the premises;
- do not wander around the customer's site unaccompanied unless your contact person has given permission;
- whilst on site, if you recognise any potential hazard it should be reported to the customer contact person immediately; and
- in emergency situations, all NATA staff and Technical Assessors shall adhere to the safety and emergency procedures, all requests from the customer's emergency personnel and/or all requests from emergency personnel.

All Lead Assessors and Technical Assessors shall:

- ensure all Personal Protective Equipment is worn at all times as required by the client or as required by the task at hand;
- report to the customer contact person immediately should an accident occur on site involving NATA staff or Technical Assessors, as well as notify your manager upon returning to NATA; and
- adhere to all safety rules and procedures as prescribed by the customer.

Whilst conducting NATA business if you suffer an accident or injury please report the incident to our Human Resources department or the General Manager, Operations and Technical.

Drug and alcohol testing

Drug and alcohol testing at the workplace and on public roads has become common practice. While some have expressed concerns about the privacy implications of such testing, the community's attitude toward the balance between an individual's right to privacy and the urgent need to protect workers and the public at the workplace or on public roads from people who are under the influence of drugs and/or alcohol has changed to favour testing.

NATA takes workplace health and safety seriously and supports drug and alcohol testing at the workplace.

NATA expects staff and Technical Assessors to be free from any influence of drugs and alcohol at all times while they are carrying out their duties at NATA's or a customer's workplace or in transit to or from that workplace. NATA also expects staff and Technical Assessors to adhere to the customer's Smoke-free Environment policy.

The Assessment Information Document (AID) for initial assessments and reassessments and the Surveillance Visit Information Document (SVID) are important planning documents that ask for information on an organisation's drug and alcohol testing policy including whether such a policy may require the assessment team members to be tested.

NATA's Lead Assessors must ensure that this information is provided at the time the AID/SVID is submitted. Where assessment teams may be subject to drugs and/or alcohol testing, the Lead Assessor will advise you of this at the time arrangements are being made for the assessment and you will be given the opportunity to decline to participate in the visit.

The organisation performing the testing (or having the testing performed on its behalf) is not obliged to disclose the test results to NATA and cannot do so without the consent of the individuals tested.

Lead and/or Technical Assessors selected for on-site drug or alcohol testing must afford every co-operation to ensure the testing is conducted expeditiously and with as little interruption to the visit as possible.

Privacy policy

NATA respects and upholds the rights of individuals to privacy protection under the Australian Privacy Principles contained in The Privacy Act 1988. A copy of NATA's Privacy Policy can be obtained from the NATA website or by contacting one of the NATA offices. This policy describes how we manage the personal information we hold.

The personal information collected from individuals appointed as Technical Assessors will include your name; position; professional qualifications; business address; business telephone, mobile phone and fax numbers; home address, home telephone, fax and personal mobile phone numbers; email address; memberships of professional associations and employment history.

The information may be disclosed to NATA staff and committee members and it may be viewed by auditors as part of MRA evaluations of NATA. All parties have signed confidentiality agreements. The information may also be disclosed to government and regulatory authorities and other organisations, as required or authorised by law and/or with which NATA has an MOU or similar formal agreement.

From time to time, NATA receives requests from MRA partners for Technical Assessors. With your express consent, information may be disclosed to these accreditation bodies to enable them to contact you.

Insurance

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 Technical 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 and Baggage Insurance offered by car rental depots and/or agencies.

Please note: all insurance becomes void if a rental vehicle is abused (i.e. driven on a private road, an unsealed road or across a country property). All accidents involving rental vehicles must be reported immediately to the rental company. A copy of the accident report and bill of repairs should also be sent to the Lead Assessor.

- **Motor Vehicle Insurance:** NATA does not provide insurance to cover private motor vehicles for Technical Assessors. They must maintain their own comprehensive motor vehicle insurance.

NEVER sign any waivers or disclaimers that may be put to you in the course of your work with NATA. Immediately refer any such documents to NATA for review and attention.

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.

In the event of an insurance claim being required, please contact your nearest NATA office immediately for information and assistance with the claim process.

Consultation for legal matters

It is possible 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. 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, please immediately contact Tony Vandenberg, NATA's General Manager, Compliance and Governance on (03) 9274 8200.

5. Assessment arrangements

Travel arrangements

NATA covers all reasonable costs associated with the conduct of assessment activities including accommodation and meals, travel and insurance.

NATA provides or arranges all transport. If, in order to perform an assessment, an overnight stay away from home is required, we reserve accommodation and pay for expenses. It is recommended that you carry a copy of the travel itinerary with you at all times to provide evidence of bookings and confirmation of payment arrangements. If you take your own car, a distance-based allowance is paid. Personal accident insurance is provided for the whole time of engagement in NATA's work.

NATA asks all Technical Assessors to:

- exercise good judgment with respect to travel expenses;
- check for accuracy of bills and other documents before authorising; and
- report all expenses promptly and accurately on the forms provided along with any other required documentation.

The following is a summary of NATA's current travel policy and is subject to change from time to time. Expansion or clarification may be obtained from any of NATA's Lead Assessors.

It is NATA's intention that all travel be undertaken in the most economical mode, consistent with the following:

Air travel

NATA's air travel policy objective for both domestic and international travel is to purchase air travel at the lowest expense level consistent with good business practice. Cheaper airfares with non-refundable restrictions will only be purchased for Technical Assessors in situations where, if the ticket is not used, the Assessor will travel the same route on NATA business within 12 months.

For domestic travel, economy class airfares are used. Economy class airfares are used for international travel where the destination is under seven hours from Australia. Where the destination is over seven hours from Australia, business class tickets are purchased.

NATA has no airline preference policy. However, domestic travellers are not permitted to insist on an airline purely to accrue frequent-flyer points.

When changes to travel plans are needed and this requires either cancellation or revision of reservations already made, please notify the Lead Assessor you have been dealing with as soon as possible.

Accommodation

NATA's policy objective for accommodation within Australia and overseas is to provide accommodation that is comfortable, convenient, meets business and personal needs and offers good value.

Hotel selection

When selecting accommodation the Lead Assessor refers to a list of approved accommodation. Listed hotels are in line with our policy objective as detailed

above. If you have any problems with the selected accommodation please do not hesitate to let the Lead Assessor know.

Hotel and meal expenses

A single room in a business class hotel/motel is the corporate standard. However, where the cost of a double room is the same as a single, every effort will be made to secure this booking.

When departing the hotel, please check the account carefully to ensure the charges incurred are correct. All expenses for which NATA is responsible will be charged back to NATA so do not pay for these. However, you are responsible for any personal extra expenses such as mini-bar consumption, in-house movies, lengthy personal phone calls, etc. and these should be paid for at the time of checking out.

If you dine in at the hotel restaurant, your meal expenses should be charged to your room account and NATA will pay for this and for all reasonable room service charges.

All other meals and reasonable expenses will normally be paid for by the Lead Assessor who is accompanying you. If arrangements have been made for you to travel alone, you may need to pay for them out of your personal funds. Please ensure that you obtain a tax invoice for the expense. NATA will reimburse you by cheque when you submit your Assessor Expense Record form with attached tax invoices substantiating the claim (see below).

Where a partner is accompanying you, if the hotel charges extra for your partner, you will be asked to pay the additional costs. Please discuss your intention to bring your partner with the Lead Assessor prior to the assessment.

Rental cars

Where the use of a rental car by a Technical Assessor is necessary, NATA will make the booking. When using a rental car, if possible, please fill it with petrol before returning it as the amount charged for petrol by the rental company is far in excess of the normal price. Petrol expenses can be claimed back on the Assessor Expense Record form.

Car rental will only be used when the efficient conduct of NATA business precludes the use of other means of transportation or car rental is the most economical option. For example, car rental would not normally be justified for transportation from the airport to the hotel if shuttle bus or taxi service is available.

If a rental car is to be collected from a pre-determined place (e.g. a hotel), then you must ring the nearest depot to let them know the car is ready to be collected. If this is not done, the rental car company will not pick up the car and further charges may be incurred.

Parking infringements, speeding fines and other driver related traffic offences incurred by Technical Assessors will not be reimbursed by NATA.

Selection of car

A medium sized vehicle is preferred due to petrol economy combined with reasonable comfort. Where it is necessary to use a larger or smaller vehicle please advise the Lead Assessor, and where possible, your request will be accommodated.

Rental car insurance

Refer to the Insurance section of this document.

Use of private car

It is expected that Technical Assessors will use the most cost effective means of transport. Under some circumstances, this may mean that a Technical Assessor will use their private car for transport. Queries regarding the most cost effective and efficient mode of transport for NATA assessments should be directed to the Lead Assessor.

Technical Assessors using private cars on NATA business will be reimbursed at a 'per kilometre' rate that is specified on the Assessor Expense Record form. Specific costs such as petrol and oil will not be directly reimbursed as they are considered to be included in the per kilometre rate.

To claim expenses on the use of a private vehicle, please fill in the Assessor Expense Record form (see below), indicating the kilometres travelled. This form should also be used for any other expenses incurred, for example parking fees and road tolls.

Technical Assessors using their own car for business must carry adequate car insurance as NATA does not insure a Technical Assessor's private vehicle. Parking infringements, speeding fines and other driver related traffic offences incurred by Technical Assessors will not be reimbursed by NATA.

Taxi eTickets

Taxi eTickets are used the same way as a credit card but are valid for one trip only. Where the Taxi eTicket is not used on the assessment, please return it to the Lead Assessor.

Meals

Where possible the Lead Assessor will pay for meals. Where a NATA employee is not present please pay for the meal with your personal funds and you will be reimbursed as detailed below.

Expense Claims

An Assessor Expense Record form will be provided as part of the Assessment Information package forwarded to you. This is to be used to claim for all reasonable expenses made by you that are not paid for either by the Lead Assessor or by directly charging back to NATA. Example expenses include:

- parking fees and road tolls;
- petrol expenses (only when using hire cars, not for private car use);
- kilometre rate (for private vehicle use only);
- meals paid for by you personally (note: if you are in the company of a Lead Assessor they will normally pay for your meal. If you dine at the hotel your meal should be charged back to your room account);
- emergency travel needs (e.g. personal toiletries, etc. if your luggage fails to arrive at your destination with you); and
- incidentals (to a maximum value of \$17.30 daily).

Tax invoice receipts must be obtained to substantiate all expenses not charged to a hotel. Please attach these to the claim form and forward them to the Lead Assessor immediately on your return from the assessment. For small amounts under \$10.00 (e.g. road tolls, parking usually paid by cash) receipts may be difficult to obtain and are not normally required.

Reimbursement EFT/cheques are normally raised during the second week of each month. Please submit your completed Assessor Expense Record form together with tax invoice receipts to the NATA Lead Assessor immediately following the assessment visit.

6. Roles and responsibilities of the assessment team

Role and responsibilities of the Lead Assessor

Prior to the assessment the Lead Assessor is responsible for:

- selecting the assessment team;
- liaising with Technical Assessors and facility staff, including activities to be witnessed as part of the visit;
- clarifying potential conflicts of interest regarding Technical Assessor selection;
- arrangement and confirmation of assessment logistics including date, time and duration;
- making appropriate travel arrangements and bookings;
- conducting the Document Review;
- preparing the briefing material and assessment program (timetable); and
- providing Technical Assessors with background briefing, checklists, relevant system documentation and any other information as appropriate.

At the assessment the Lead Assessor:

- facilitates the Team Briefing, Opening Meeting, Final Team Meeting and Closing Meeting;
- coordinates the evaluation of technical competence and examination of the quality system;
- examines the facility's quality system to ensure that the Management System Requirements and Resource Requirements are satisfied. (The Lead Assessor may however, call on the Technical Assessor's assistance, for example, to review the technical aspects of training records, internal audits, complaints, etc.);
- follows up on issues raised at previous assessments (where appropriate);
- provides information and answers questions regarding NATA's policies and practices;
- supports and is available to assist the Technical Assessors;
- ensures a balanced assessment is conducted;
- prepares the report on assessment; and
- presents the assessment team's findings to the facility staff at the Closing Meeting.

After the assessment the Lead Assessor:

- follows up on any required action;
- prepares the Report for submission to the Accreditation Advisory Committee Chair (or delegate); and
- finalises paperwork with regard to the assessment of the facility.

Role and responsibilities of the Technical Assessor

Prior to the assessment you must:

- advise the Lead Assessor of any potential conflicts of interest;
- prepare for the assessment (as outlined in What to do Before an Assessment); and
- maintain confidentiality.

At the assessment you will need to:

- review the technical criteria, Resource Requirements and Process Requirements (under the direction of the Lead Assessor). See What to Examine and Review (Technical Criteria);
- collect objective evidence;
- be thorough;
- be aware of the time constraints of the assessment process. If you need to take or make mobile phone calls because of an urgent or pressing matter during the assessment, please clear this with the Lead Assessor. It is best if mobile phones are turned off during the assessment, except at breaks;
- document findings clearly and concisely on the Assessor Record Sheet (or relevant activity type/program record sheet provided). Ensure your notes are accurate and legible for discussion with the Lead Assessor;
- provide technical advice to facility staff and the Lead Assessor;
- be aware of the importance of teamwork; and
- keep in touch with and seek direction from the Lead Assessor during the course of the assessment.

After the assessment ensure you:

- maintain confidentiality;
- provide the Lead Assessor with advice on follow up action;
- complete the Assessor Expense Record Form and forward it to NATA as soon as possible following the assessment to enable prompt reimbursement of expenses; and
- return the briefing material to the Lead Assessor after you have finished with it.

NOTE: Following an assessment, you should only liaise with the Lead Assessor (not the facility under assessment) with regard to any follow-up action.

7. The purpose and types of assessments

Purpose

The purpose of an accreditation assessment is to:

- examine and evaluate the technical competence of a facility to perform the tests and/or other services covered by the Scope of Accreditation;
- evaluate the facility's documented management system to ensure compliance with the relevant requirements and criteria for accreditation;
- seek confirmation that the activities being performed by the facility conform to those documented in the management system and other documentation.

The assessment is conducted to establish whether an applicant or accredited facility satisfies NATA's criteria for accreditation. The assessment also serves to identify any requirements and criteria that are not satisfied, such that the facility's management can take action to achieve compliance.

NATA also endeavours to utilise national technical resources in the greatest public interest and, the peer review system helps by disseminating the most effective practice among organisations and to highlight differences in the interpretation of common procedures.

It is the role of the Lead Assessor to provide guidance to Technical Assessors on the appropriateness of their advice. It is essential that Technical Assessors clearly differentiate between personal preferences or opinions, acceptable practice and NATA's accreditation criteria.

The types of assessment

The types of assessment visits that may be conducted by NATA are as follows:

- Initial assessment - assessment of an applicant facility by a Lead Assessor and one or more Technical Assessors;
- Surveillance visit - a scheduled surveillance visit by a Lead Assessor only, to assess the facility for the management system requirements of the standard;
- Reassessment - a scheduled surveillance visit by a Lead Assessor and one or more Technical Assessors to assess the facility for the technical requirements of the standard;
- Variation - to assess new or additional tests, inspections and/or technical activities. These may be conducted as on-site variation visits or desktop reviews;
- Follow-up assessments - follow-up of issues raised during an earlier visit; and
- On-line surveillance - conducted as an office-based activity. Applies only to the Medical Imaging, Sleep and Human Pathology programs. The on-line surveillance activity is conducted to determine the continuing compliance with the accreditation criteria. Selected technical and management system requirements are reviewed, including the findings

from the previous visit. The activity may result in selected material being sent to a Technical Assessor for review and comment.

8. Preparing for assessments

The assessment team

The assessment team consists of at least one Lead Assessor and one or more Technical Assessors. The number of Technical Assessors will depend on the size of the facility being assessed and/or the scope of that facility's activities.

The Lead Assessor is responsible for selecting the assessment team and arranging and confirming assessment details.

Technical Assessors for each assessment are selected, on the basis of:

- technical expertise;
- the range of tests, inspections and/or other services performed by the facility;
- the Technical Assessor's background;
- the Technical Assessor's experience;
- avoidance of conflicts of interest;
- avoidance of commercial competition;
- no commercial relationships;
- previous employment of the Technical Assessor;
- assessment history of the facility;
- assessment history of the Technical Assessor;
- geographical location of the facility and the Technical Assessor;
- the facility's agreement; and
- the Technical Assessor's agreement.

Document review

In preparation for the assessment, the Lead Assessor may conduct a Document Review. This involves a thorough review of the facility's quality manual and relevant documents relating to the management system.

The purpose of the Document Review is to confirm that the policies and procedures, documented by the facility, meet NATA's accreditation criteria. It also provides the Lead Assessor with both an understanding of the facility's operation and an opportunity to identify any specific areas that will need review during the on-site assessment.

If you have any queries in relation to the document review process, please contact the Lead Assessor.

Briefing material

Once you have accepted the assignment, the Lead Assessor will send you information regarding the facility to be assessed. This information is referred to as the 'briefing notes' for the assessment.

Briefing notes may include:

- information on the purpose of the assessment;
- relevant background information on the facility;
- an assessment plan (where relevant);
- an Assessment Information Document (AID) completed by the facility being assessed. The AID details current staffing, tests being conducted, any requests for extensions to the Scope of Accreditation, etc.;
- available information on participation in proficiency testing (PT) programs (Note: This may not include all the PT carried out by the facility);
- copies of parts of the quality manual (only where relevant);
- details of the last assessment activity;
- other relevant information relating to both standard and non-standard test methods (as deemed appropriate and necessary);
- a Laboratory Assessment Worksheet (which may include details of the document review findings); and
- an Assessor Record Sheet(s) (or relevant activity type/program record sheet) for use during the assessment. These must be completed when witnessing particular tests or inspections (or parts of tests) during the assessment.

In some cases, for confidentiality reasons, an organisation may not provide details of in-house methods prior to the assessment. In such a situation, the Lead Assessor will discuss the situation with you and attempt to provide adequate information for your preparation.

What to do before an assessment

Once you receive your briefing material, you can begin your preparation for the visit. It is recommended that you review the briefing material immediately so that sufficient time is available to obtain any further information required by you prior to the visit.

To prepare for a visit:

- review the briefing material;
- refresh your knowledge of relevant standards or test methods;
- re-familiarise yourself with NATA's accreditation criteria including the use of the NATA endorsement in The Rules;
- review relevant sections of your Assessor Resource Kit;
- examine the scope of the assessment, be sure that your designated expertise is appropriate to cover the existing/requested Scope of Accreditation as well as any variation extensions that may have been requested by the facility;
- decide the tests or inspections to be witnessed; and
- undertake any other preparation that may be required.

Should you determine that you are not in a position to adequately assess all or part of the tests or inspections allocated to you, or have any other queries, please let the Lead Assessor know as soon as possible.

Cultural issues

You may be invited to participate in an assessment where cultural differences can be an issue, e.g.:

- overseas assessments;
- assessments where staff are from another culture;
- assessments where the parent controlling company is based overseas.

Where we are aware of them, the Lead Assessor will provide you with advice on local manners and etiquette. However, you can also take the lead given by the staff of the facility. Be sensitive to and respectful of their way of doing things; in particular be mindful of etiquette surrounding the following:

- introduction formalities and business card exchange practices;
- title/name addressing protocol, e.g. use of formal titles/names rather than familiar names, particularly in the presence of junior staff;
- English language use including tone and body language – avoid vernacular terms and never use slang;
- slow, clear enunciation and simple sentence structure where English may be a second language and/or interpreters are being used;
- directing attention and issues towards senior staff – avoid talking directly towards interpreters;
- senior/subordinate staff relations;
- loss of face – it is extremely important to ensure that people save face in a dignified manner without compromising the assessment findings;
- dining preferences and etiquette;
- dress code – business and casual;
- religious observances;
- working hours;
- general conversation topics, e.g. refrain from raising sensitive world topics and take care when making observations about local issues;
- international system comparisons - refrain from criticising their system or ours or making comparisons that show disrespect for either system.

Other cultures often place far more emphasis on seniority/respect awareness than is normal in Australian business culture. Be aware that you are in a significant position of authority and will be treated with a degree of deference and respect. The appropriate response is respect for their culture and people.

If you have any uncertainty, discuss it with the Lead Assessor. You can also consult the cultural section of the many excellent travel guides now available either hard copy or on the web.

9. Conducting assessments

Typical assessment sequence

Although each assessment will be different, the overall flow of assessments follows a consistent pattern involving five sequential phases:

1. Team briefing
2. Opening meeting
3. Evaluation of the technical competence of the facility and examination of parts of the quality management system
4. Final team meeting
5. Closing meeting

Team briefing

Prior to the assessment, the Lead Assessor will normally gather the assessment team for a team briefing. This may occur on the morning of the assessment, or where an assessment team has travelled considerable distance for the assessment, the team briefing may take place during the evening of the day before. The Lead Assessor will advise the meeting time and place prior to the assessment. There may also be situations where it is appropriate for the team briefing to be conducted over the telephone prior to the assessment.

The specific purposes of this meeting include:

- introducing the team members to one another;
- advising of any changes which have occurred in the organisation since the issue of the briefing material;
- resolving any remaining queries among the Technical Assessors;
- review of the assessment timetable and allocation of tasks for each assessment team member; and
- generating a spirit of teamwork within the group.

Opening meeting

On arrival at the facility, the assessment team meets with the relevant facility staff for the opening meeting. This meeting is critical to establishing the contractual framework of the assessment visit. The purpose of this meeting is to explain the assessment process and ensure that all the arrangements for the assessment are satisfactorily in place. During this meeting the Lead Assessor will:

- introduce the assessment team to the facility staff;
- explain the purpose and scope of the assessment;
- outline the sequence and timetable for the assessment including lunch and tea breaks;
- outline the assessment approach;
- reconfirm the existing Scope of Accreditation;
- clarify variations requested;

- confirm appropriate arrangements have been made for witnessing of test/inspections;
- confirm the availability of people to be interviewed and any time constraints on them;
- explain the classification of assessment findings;
- explain how any conditions for accreditation will be handled;
- assure those present of the confidentiality of the assessment;
- ensure that suitable guides for the assessment team have been arranged;
- ensure that a room or area has been set aside for the assessment team's use throughout the visit; and
- answer any questions from the organisation's representatives about the assessment.

Once the opening meeting is complete, the assessment can begin in accordance with the agreed assessment plan. Depending on the size of the facility, the range of tests and/or inspections being performed, the experience of the Technical Assessors and the size of the assessment team, the Lead Assessor and Technical Assessor(s) will usually work independently for some period. Generally, the Lead Assessor will review the management system documentation while the Technical Assessor will commence examination of technical operations.

Evaluation of technical competence/examination of the quality system

The essential purpose of this phase of the on-site visit is to establish that activities within the scope of the accreditation are being competently conducted at a technical level and in accordance with the documented quality system.

It is important throughout the assessment process that the members of the assessment team limit their activities to work covered by the scope of the facility's accreditation and the criteria included in the NATA Accreditation Criteria Publications.

For each function or activity, the assessment team examines all the important features, and audits:

- relevant documentation (including its currency);
- appropriateness of methods and procedures;
- suitability of equipment, machinery or instruments (including their calibration);
- metrological traceability;
- suitability of the environment and supporting services;
- adequacy of personnel (number, training, skills, etc.);
- monitoring of processes/quality control measures;
- handling and identification of samples, specimens or test items; and
- recording and reporting of results.

Throughout the assessment, each member of the assessment team will conduct their evaluation in slightly different ways. However, as a Technical Assessor you must always:

- keep within the scope of your assigned assessment tasks, including the agreed timetable;
- collect and record specific evidence to support your observations on the Assessor Record Sheet (or other activity type/program specific document) including:
 - for conforming situations, a note to this effect and the sample size taken;
 - for non-conforming situations, details such as what was incorrect and the record/report/equipment identifiers;
 - for observations, note any areas for improvement or positive feedback;
- be objective and impartial in collection of this evidence;
- be alert for indications of other evidence that might need to be probed; and
- use the Assessor Record Sheet (or other relevant activity type/program record sheet) to record observations/conclusions concerning tests or inspections witnessed in the course of the assessment.

What to audit (technical criteria)

Where appropriate, the following criteria are examined by the Technical Assessor under the guidance of the Lead Assessor during an assessment.

Staff training and competence

As a routine aspect of every assessment visit, an appropriate range of tests or inspections should be witnessed to ensure that:

- staff are familiar with test/inspection methods and are capable of carrying them out;
- appropriate training and education has been provided;
- staff are appropriately supervised and technical direction is provided; and
- staff understand test/inspection principles and limitations according to their responsibility.

Testing/inspection environment

For controlled environments the assessment team need to ensure that:

- relevant monitoring equipment is appropriately located and calibrated;
- the potential for contamination or interference is minimised;
- lighting provided is adequate;
- ventilation is adequate;
- benches/test areas are 'fit for purpose';
- access to the facility and storage areas is controlled; and

- consumables are stored appropriately.

Management of equipment

Management of equipment is reviewed to ensure that:

- the facility has all the necessary equipment;
- equipment is operating correctly and is maintained in good working order;
- operating instructions are adequately documented and available;
- staff are competent in the use of the equipment;
- safeguards are in place to prevent accidental adjustments that could invalidate results;
- equipment that is damaged or requiring calibration is kept out of use;
- appropriate checks are done on borrowed equipment;
- all significant items of equipment are uniquely identified, and relevant records kept; and
- appropriate preventive maintenance programs are in place.

Calibration and measurement traceability

Where equipment has an effect on accuracy or validity of results, the assessment team must ensure that:

- the initial calibration, recalibrations and performance checks are appropriate;
- the calibration schedule includes all relevant equipment;
- the frequency of recalibrations and performance checks are appropriate; and
- the traceability of reference standards and equipment involving physical measurements is appropriate.

Reference materials and metrological traceability

It is important to ensure that (where applicable) reference materials used are:

- identified appropriately;
- traceable to national/international standards of measurement, or to national/international standard reference materials (where possible); and
- stored correctly.

In-house calibrations and performance checks

In-house calibrations and performance checks are reviewed to ensure they:

- meet the requirements of NATA's policy on 'Equipment Assurance, in-house Calibration and Equipment Verification';
- are carried out by trained staff;
- are appropriately documented; and

- are recorded accurately.

Method documentation and validation

All methods should be reviewed to ensure they:

- are documented clearly, in sufficient detail, suitable for a new staff member with basic training (or for the lowest level of experience of staff who will be involved);
- are readily available and used by staff; and
- have appropriate document control.

Non-standard or in-house methods should be reviewed to ensure:

- client agreement; and
- records of validation are adequate.

Measurement uncertainty

The method of calculating measurement uncertainty should be examined (if appropriate).

Document control of methods

Test methods are examined to ensure:

- a formal mechanism to update national/international standard methods is in place;
- only current versions of methods are in use (unless superseded methods are required legally or by a contract);
- extracts from methods are under document control;
- no unauthorised amendments are made to methods; and
- there are no obsolete copies of methods in use.

Sampling and handling of test/calibration items (or samples)

Sampling techniques are examined to ensure:

- documented procedures are available to staff at the sampling location;
- sampling is statistically valid (if appropriate);
- staff are adequately trained; and
- adequate records are kept.

Sample identification is reviewed to ensure:

- identification is unique for each sample;
- identification is legible and permanently applied;
- identification is linked to records;
- where relevant, a procedure is in place for subsampling and the identification of subsamples is appropriate; and

- where samples are unsuitable for testing, or identification is in doubt, the client is contacted.

Sample handling is examined to ensure:

- sample receipt, registration, preparation, and disposal is carried out as per the procedure;
- procedures are in place to prevent deterioration of test items; and
- if preconditioning or storage under specific conditions is required, conditions are monitored and records are kept.

Monitoring the validity and reliability of test results

Records of external monitoring (quality assurance) are reviewed to ensure:

- participation in all appropriate proficiency programs. (For calibration activities, the laboratory's performance in a measurement audit carried out just prior to the assessment is reviewed); and
- corrective actions are carried out where necessary.

NOTE: Laboratories are asked to provide details of proficiency programs in which they have participated in the AID.

Records of internal monitoring (quality control) are reviewed to ensure:

- the internal quality control program covers all accredited tests and involves all relevant staff;
- tests are monitored using replicate testing by the same or different operators;
- results are reviewed and corrective action is carried out where necessary;
- statistical techniques are applied correctly;
- infrequently performed tests are performed routinely to maintain competence; and
- the performance of equipment is monitored appropriately.

Records and reports (and records traceability)

Records are examined to ensure:

- traceability of all steps including test requests, sample registrations and raw data; and
- records and documents are retained.

Test/inspection records are examined to ensure:

- sufficient information is recorded to allow critical review of the results and for traceability;
- they are legible;
- corrections to errors are authorised;
- they are securely stored for a defined period, protected against loss or deterioration, and confidentiality is maintained;

- the integrity of data capture and transfer in computer controlled equipment;
- the validation of computer software; and
- appropriate evidence of checking calculations and data transfers.

Test/inspection reports are examined to ensure:

- they contain the content as required by the relevant accreditation standard (for example, ISO/IEC 17025), the relevant Specific Accreditation Criteria document and the test or inspection method;
- any variations to methods are clearly noted;
- subcontracted results are clearly identified;
- when a statement of conformity to a specification or standard is provided, the decision rule applied takes into account the level of risk and is documented;
- only authorised personnel are permitted to express opinions and interpretations and the basis upon which the opinions and interpretations has been made is documented;
- appropriate use of NATA's logo and endorsement;
- integrity and confidentiality is maintained when transmitted electronically; and
- where there is any doubt about the validity of issued results, the report is amended and the client is notified.

What to audit (management criteria)

The following are some of the specific issues typically examined by the Lead Assessor. In addition, adherence to the facility's own procedures is examined. You may be asked to review some aspects of the management system and records at a technical level. The Lead Assessor will seek your input as appropriate.

- organisation and management structure
- responsibilities, authorities, competence requirements and interrelationship of personnel
- requests, tenders and contracts
- externally provided products and services
- internal audits
- management reviews
- actions to address risks and opportunities
- complaints, corrective actions and non-conforming work
- control of data and information management
- training and competence records
- control of documents
- equipment

Clarifying anomalies

Inevitably, the process of gathering information during the assessment will uncover events or activities which seem at variance with the management system, the designated work instruction or test method, or your expectations. At this point, you should pause and probe carefully:

- find out the facts is it really wrong?
- if so, do they know it is wrong?
- can they give (or can you find) an explanation for it happening?
- is this an isolated event or is it occurring elsewhere as well?
- is it an aberration or is it a symptom of a deeper problem?
- why didn't their quality audits detect this?

Decisions on observations

Before confirming the observation as a condition for accreditation, you need to apply a twofold test to the facts you have acquired.

- can this apparent deficiency be expressed in words or phrases taken directly from NATA's Accreditation Criteria or from the facility's management system or technical documents?
- was tangible evidence obtained in the form of specific observations or records which would support the claim (e.g. record/report number)?

If both of these conditions are met, chances are you have identified a genuine condition. This must be discussed with the Lead Assessor.

Matters of technical opinion

It sometimes happens that a Technical Assessor is not satisfied with the technical correctness of some aspect of the facility's methods or activities. In such cases, the Technical Assessor must always try to decide the issue on the basis of evidence.

- what evidence does the facility have that what it is doing is satisfactory?
- what evidence exists that what the facility is doing is not satisfactory?

A facility is never required to change its work practices on the basis of the personal opinion of a Technical Assessor. If a decision cannot be made according to previous precedent or policy known to the Lead Assessor, Sector Manager or Program Advisor, it may be appropriate to refer the matter to the relevant AAC or another technical expert. This would occur after the assessment.

Final team meeting

After the examination of the technical and management criteria is complete, the assessment team meet for the Final Team Meeting. This meeting is to enable the Lead Assessor to collate the findings of the assessment team into an interim report for presentation to the facility's representatives at the Closing Meeting. The Assessor Record Sheet you have completed will be collected by the Lead Assessor.

In the relatively short time that is available for this team meeting, the following tasks must be completed.

- each member of the team must table the evidence they recorded in support of their observations.
- the team must evaluate the significance of each of these observations and decide how to classify them.
- the team must review all other assessment findings to ensure that the facility meets NATA's accreditation criteria.

Assessment report

The Lead Assessor prepares the overall report on the assessment but will seek assistance from you with its preparation and guidance on the appropriate coding of your findings. Your Assessor Record Sheet will be collected and retained on file, so please consider legibility and phrasing when completing it.

You should also take the opportunity to offer positive feedback to the facility where appropriate.

Codes used in Assessment Reports by the Lead Assessor include:

- O an observation. This may include recommendations for improvement of what is acceptable practice or a reminder or flag for follow-up or review at the next visit
- M indicates a Minor Condition
- C indicates a Condition

Classification of conditions

As assessments may disclose a number of deficiencies ranging from relatively minor to very serious, some form of classification enables the significance of these deficiencies to be put into proper context.

A Condition (coded as 'C'):

- contributes directly to the reliability of the test or inspection result, e.g. inadequate staff training;
- has the potential to compromise the test or inspection result because it is always there, e.g. calibration deficiency, staff inexperience in relation to the test, inadequate quality control;
- it is a systematic problem, i.e. it is identifiable and not random (e.g. the document control system does not ensure that all copies of manuals are current);
- contributes directly to how the result may be interpreted by the client, e.g. sampling deficiencies;
- an issue that has been raised previously as an 'M' but not been fully or appropriately addressed.

All 'Cs' must be addressed and evidence of this provided by the facility prior to accreditation being granted (or continued).

A Minor Condition (coded as 'M'):

- does not contribute directly to the reliability of the test result but is still a requirement for accreditation, e.g. staff have received appropriate training but this has not been recorded.
- a non-compliance/deficiency that is not constant, i.e. it is random or infrequent, e.g. only a few staff training records have been found to be out of date.

A response on action taken or intended will be required for an 'M' but evidence of this will not be sought for accredited facilities. Confirmation that the issue was addressed will be followed up at the next assessment. For applicants and scope extensions, both 'Cs' and 'Ms' must be addressed and evidence of action taken provided prior to accreditation being granted or scopes extended.

Guidance on the expression of conditions

It is essential that any condition is expressed clearly and in accordance with good audit practice. An acceptable condition statement is:

- a non-blaming statement of fact;
- based on objective evidence recorded on the assessor record sheet or assessment worksheet; and
- directly related to a specific requirement for accreditation or a method/technique for which accreditation is currently held or sought.

Closing meeting

Following the final team meeting, the assessment team and relevant facility staff gather for the Closing Meeting. The purpose of this meeting is to present a summary of the findings of the assessment team to the representatives of the facility and to allow discussion of the findings.

The structure of the meeting is determined by the Lead Assessor, but the sequence below is generally followed.

- restate the purpose and scope of the assessment (as outlined in the Opening Meeting);
- talk through the contents of the report, explaining particularly the circumstances and justification for each of the assessment observations classified as conditions and minor conditions;
- invite the facility staff to comment on these findings, and resolve any concerns or differences of viewpoints expressed;
- agree on a response date (usually four weeks);
- when agreement is reached, a signed copy of the interim report will be left with the facility as its record of the assessment outcome; and
- describe the next steps in the process, including the transmission of the assessment report to the AAC and the actions to be taken by the facility and NATA to enable continued accreditation or the granting of accreditation.

The meeting will conclude with an acknowledgment of the cooperation and courtesy extended to the assessment team throughout the visit.

10. After the assessment (follow-up action)

Corrective action

When an assessment reveals a condition or deficiency in the facility's activities, it is important that the facility takes immediate action to rectify the problem. Corrective action is concerned with finding the cause (or causes) of the problem and taking appropriate action to ensure the problem will not occur again.

Corrective action involves:

- fixing the initial problem and reviewing all work to determine what other work may have been affected;
- investigation to identify the real cause(s) of the problem(s);
- deciding what action must be taken to eliminate the cause;
- taking the action and making whatever changes are needed in the facility's quality system and technical documentation; and
- continued monitoring to ensure that the action is taken and that it is effective.

Note: Examples of this process will often be seen during the on-site assessment and should be followed through at that visit.

Verification of corrective action

Before accreditation can be granted (or continued) NATA needs to be satisfied that the condition(s) identified during the assessment have been effectively corrected. It is the nature and magnitude of the condition(s) that determine the type of verification activity needed.

In the simplest case, documented evidence of action taken may satisfy NATA's criteria.

In a serious situation, a follow-up visit may be required prior to the next surveillance visit. Normally this will involve a visit specifically to examine the areas of concern disclosed by the original assessment. However, in some rare situations (where the facility has been suspended), the range of Condition(s) is so great that a complete reassessment is required.

In most circumstances, the Lead Assessor involved in the original assessment is directly involved in the review of the corrective action undertaken by the facility. Where appropriate, the Lead Assessor will seek advice (or confirmation of a satisfactory response) from the Technical Assessor involved in the assessment.

11. Assessment techniques

An assessment is a fact-finding mission. As a Technical Assessor, your role is to gather evidence about the facility's compliance (or otherwise) with NATA's Accreditation Criteria.

During the course of the assessment, the assessment team must:

- gather all the information it needs about the facility;
- be constantly evaluating its findings against the facility's stated management system and operating procedures; and
- identify, through objective evidence, any breakdown in the management system or departures from operating procedures.

To do all of this in the time available, the assessment team must gather the information as efficiently and effectively as possible. The assessment team must be thorough and objective in the way it gathers this information and conclusions must be based on objective evidence.

From your own professional background and experience, you will know the critical aspects of procedures and should pay special attention to these aspects in your examination of the facility.

Effective information gathering

In every assessment situation there are several means of gathering information effectively including:

- asking questions;
- listening to the answers;
- observing activities;
- examining facilities; and
- reviewing records.

Each of these techniques will be used during every assessment and will sometimes be used simultaneously. All are important tools for the assessment team in the quest for gathering information about the facility thoroughly, effectively and efficiently.

Questioning

When using questions to obtain information during an assessment, there is a range of techniques that should be used.

Open questions help:

- produce answers of substance;
- gather information effectively and efficiently; and
- keep the dialogue flowing.

The six questions that will give the information effectively and efficiently are:

Who

What

When ?

How ?

Where ?

Why ?

Direct or closed questions require a 'yes' or 'no' answer so should be used to:

- obtain a definite answer;
- establish something factual;
- clarify detail; and
- bring discussion back on track.

Here are some examples:

“Are you the person who normally carries out this test?”

“Do you know who does....?”

“This part of the process says XYZ and this part says ABC, which is correct?”

Hypothetical questions are helpful because they pose the unusual, can be used to test understanding of a process or allow coverage of testing or inspection that may not be in progress during the assessment.

“What would you do if?”

“If ABC were to happen, what would this mean to XYZ?”

Clarifying questions help to prevent misunderstandings obtain more detail from the interviewee.

“I don't quite understand. Could you please explain?”

Talk through the topic

Talking through the topic (rather than asking a question directly) may help to:

- avoid questioning the obvious;
- provide reassurance while you examine;
- avoid unnecessary periods of silence; and
- build a bridge for further questions.

“Now let me see - this method sheet shows the method title, the method reference number, the date of issue, the authorising officer's signature ...”

Confirm answers to questions

Confirming answers to questions provides reassurance that you have understood what was said. However, be careful that you do not come across as doubting. Answers to questions can be confirmed by:

- asking the same question from a different perspective;
- asking the same question of a different person;
- observing activities; and
- examining records.

Periodically summarise

‘So you left school, worked for two years on building sites, and then went to university and got your degree. What happened next?’

Periodically summarising is a useful technique because it:

- helps you clarify your own thoughts;
- reassures the interviewee that you are listening and understanding what they are saying;
- provides the opportunity for correction; and
- builds a bridge to the next topic.

Vary your pattern

This can be achieved by:

- starting questioning with the ‘show and tell’ technique;
- filling any gaps with key questions; and
- using a combination of open questions, direct questions, and hypothetical questions and clarifying questions.

The ‘**Show and Tell**’ technique is an assessment technique that combines both observing and listening. It:

- requires attentive observation and listening;
- tends to be non-threatening;
- gathers more information; and
- requires thorough preparation.

Allow some periods of silence during question time. A period of silence can:

- give the interviewee time to think;
- place the interviewee under pressure to respond; and
- generate tension (so use with care).

Use your quiet time effectively

During the assessment, there may be periods of quiet time. This time can be used to:

- collect your thoughts;
- write your notes;
- listen to your co-assessor; or
- prepare for the next part of the assessment.

Questions to avoid

Self-answering questions should be avoided because they:

- lead to the expected answer; and
- place unnecessary pressure on the interviewee.

“You calibrate this regularly, don’t you?”

Trick questions should never be used during assessments because they destroy credibility, create resentment and close off communication.

Consider this example:

Assessor: “Do you rotate stock annually?”

Facility staff member: “Yes”

Assessor: “It is supposed to be a six-monthly rotation!”

Ambiguous questions should be avoided because they create confusion.

For example: “Are you sure that this is the best set of QC data?”

It is important to phrase questions carefully and clearly.

Compound questions:

- are usually directive;
- are not helpful; and
- generate more confusion.

For instance: “If you found a box on the floor, would you check its contents, label it for quarantine or put it back on the shelf?”

Irrelevant questions are to be avoided because they:

- waste time; and
- create diversions.

Consider this example: “How much did the new computer system cost you?”

Questions directed to the wrong person should be avoided as they waste time and can generate both confusion and tension.

Listening

Asking the right question is just the start of the information-gathering process. It is only when the answer begins that the information starts flowing back to us. If we are not listening, we are going to miss some of it.

We aren’t listening when we are:

- waiting to say something ourselves;
- thinking of our response to the answer while they are still speaking;
- jumping to conclusions or making assumptions;
- thinking about something else; or
- get bored and switch off.

Poor listening can result in:

- conveying disinterest to the other party;
- missing important details; and
- missing the interactions.

To be a good listener it is important to:

- focus on the speaker;
- be willing to see things from another's point of view;
- remain calm if 'attacked', rather than being defensive; and
- accept the person (if not their actions).

To show we are listening:

- be sensitive to the speaker's feelings;
- ask relevant questions;
- use minimal encouragers;
- mirror the mode and pace of the other person's speech; and
- use appropriate body language and eye contact.

Observing activities

You will obtain a great deal of information from the questions you ask and the answers you receive.

However, what is documented in the procedures or told to the assessment team may not be occurring in practice. This may be because:

- the answers given to the assessment team may not be the truth. (Deliberate deception happens occasionally, but not very often. Honest misunderstandings are far more common);
- there may be special variants of procedures which have not been documented in the manual and were not elicited during the discussions; and
- unknown to the supervisors, staff may not be following the standard procedures through carelessness, ignorance or inadequacies in the system or the resources available to them.

In addition, there will be aspects of the implementation of the management system and the procedures which cannot be explored by discussion and can only be established by examination.

Benefits of observing activities

Observing activities will help you to:

- see whether or not prescribed procedures are being followed;
- determine whether or not staff have the skills required to perform tasks;
- evaluate the effectiveness of the training and supervision provided;
- evaluate adequacy of resources available;

- detect defects in the equipment, for example, equipment instability; and
- confirm the answers to questions asked earlier.

What to observe

Routine work

Observing the normal routine work of the facility is better than witnessing a special demonstration. Seeing people working at their normal tasks and undertaking on-going activities will enable you to appraise the real standard of a facility's operation.

Work not being performed can be discussed in the hypothetical sense. It is also possible to arrange the performance of a test or inspection by requesting this prior to the assessment. This should be discussed with the Lead Assessor.

Special demonstrations

Sometimes, the assessment team will want to witness work which is not a normal part of the daily routine. On these occasions, the facility will have to provide a special demonstration for the purpose.

The facility should always be advised in advance of any requests of this nature. Items may have to be diverted from other tasks so providing advice in advance will enable the facility to make appropriate arrangements prior to the assessment. Advising the facility in advance gives them time to brush up on their techniques.

If a test or inspection is too lengthy to see from start to finish, it is acceptable to ask to see just the critical phases which are of special interest.

Dealing with tension

An assessment is a stressful experience for staff at every level in the organisation. Pride, reputation, and status are all at stake and some people may even feel that their jobs are at risk. Most of us don't look forward to examinations of any kind. These factors can lead to an assessment being a time of tension.

Tension during an assessment can lead to:

- defensive responses;
- reluctant communication;
- occasional aggression; and
- poor performance.

To reduce tension in an assessment situation:

- be human;
- put people at ease;
- project an appropriate image; and
- recognise your own tension.

Maintaining a professional approach

Throughout the assessment it is important to maintain a professional approach.

Ensure your preparation is thorough and complete and your appearance is appropriate and professional.

To **project the right image**, ensure you:

- are courteous and constructive;
- maintain an objective and unbiased approach;
- remain calm and self-controlled; and
- maintain a balanced perspective.

To **maintain a professional approach**, it is important that you stay on track during the assessment. To do this:

- avoid diversions, however interesting;
- follow your plan (as far as possible);
- manage your time; and
- keep control of your part of the assessment.

Throughout the assessment, ensure you:

- are prepared to probe to find the information you need; and
- are satisfied with the information you have obtained and with your findings.

But always remember:

An assessment is a fact-finding mission, not a fault-finding safari.

Teamwork

Teamwork is essential. During an assessment, teamwork involves a common purpose among the Technical Assessor(s) and with the Lead Assessor. It involves a mutual understanding of team roles, and a willingness to surrender individuality to the team unit.

To work as a team:

- support one another;
- don't interrupt one another;
- don't undermine anyone in the team; and
- respect each Technical Assessor's approach.

Be aware of the other team member's needs by allowing time for:

- everyone to collect their thoughts;
- clarifying questions; and
- technical support.

If you disagree with a comment or suggestion made by another Technical Assessor or the Lead Assessor, be sure you:

- ascertain whether or not the issue is important enough to be raised;
- determine whether or not it can wait and be raised at another time;
- in consultation with the Lead Assessor, call a team meeting if necessary; and
- never have an argument with a fellow Technical Assessor or Lead Assessor in front of others.

Keeping the assessment flowing

It is important for all members of the assessment team to keep the assessment flowing.

To keep the assessment flowing:

- examine a systematic sequence of activities;
- avoid back-tracking unnecessarily;
- maintain an orderly flow of questions;
- avoid long unnecessary periods of silence; and
- project quiet confidence.

When things seem wrong

During an assessment, you may come across something that seems wrong. When this happens it is important to carefully clarify the situation.

To clarify anomalies:

- be specific about the anomaly or inconsistency;
- challenge the specific issue, not the person;
- avoid judgemental or dogmatic descriptions; and
- avoid absolutes (such as never, always).

12. Contacts

Contact addresses, telephone and facsimile numbers of the NATA offices may be found on the NATA website (www.nata.com.au):

Program and Sector contacts

| Activity/Industry Type | Sector contact |
|---|--|
| Agribusiness | Neil Shepherd Life Sciences Sector Manager Melbourne |
| Environment | |
| Food & Beverage | |
| Animal Health | |
| Healthcare, Pharmaceutical & Media Products | |
| | |
| Materials | Diane Hobday Infrastructure Sector Manager Melbourne |
| Infrastructure & Asset Integrity | |
| Manufactured Goods | |
| | |
| Legal | Andrew Griffin Legal & Clinical Services Sector Manager Melbourne |
| Human Pathology | |
| Human Testing for Workplace and/or Community Screening | |
| Medical Imaging | |
| Sleep | |
| Diagnostic Imaging Accreditation Scheme | |
| | |
| Calibration | Paul McMullen Calibration Sector Manager Melbourne |
| Proficiency Testing Scheme Providers | |
| Reference Materials Producers | |
| | |

| | |
|--|--|
| Inspection Accreditation | Julian Wilson Inspection Sector Manager Sydney |
| | |
| Research and Development Accreditation | Jenny Pyke Program Advisor Melbourne |
| | |
| OECD Good Laboratory Practice Compliance | Louise Calder Program Advisor Sydney |

Enquiries

In addition to the State Managers, the following staff are able to assist you with enquiries you may have:

| | |
|------------------|--|
| Jennifer Evans | Chief Executive Officer |
| Susan Harry | General Manager, Stakeholder Relations |
| Eric Lo | General Manager, Business Services |
| Regina Robertson | Senior Advisor, International |
| John Styzinski | General Manager, Operations and Technical |
| Tony Vandenberg | General Manager, Compliance and Governance |

Using email to contact NATA staff

If you wish to contact any NATA staff member by email their address is as follows:

firstname.surname@nata.com.au

Amendments

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

| Section | Amendment |
|--|---|
| 1. Introduction to the Assessor Resource Kit | Minor updates to wording in introductory paragraph. |
| 2. About NATA | Updated NATA staff numbers, MOU date and website references. Updated references to APLAC - now APAC. |
| 3. The accreditation documents | Minor updates to wording for consistency with the rest of the document and updated website references. |
| 4. Technical Assessors | Minor updates to wording consistent with the rest of the document. Updated reference to The Privacy Act 1988. Updated references to Avis to rental company. |
| 5. Assessment arrangements | Minor updates to wording consistent with the rest of the document. |
| 6. Roles and responsibilities of the assessment team | Minor updates to wording consistent with the rest of the document |
| 7. The purpose and types of assessments | Updated description of variation visit. Replaced reference to Medical Testing with Human Pathology. |
| 8. Preparing for assessments | Minor updates to wording consistent with the rest of the document. |
| 9. Conducting assessments | Minor updates to wording consistent with the rest of the document. Updated the process for 'M' and 'C' conditions to include scope extensions. |
| 11. Assessment techniques | Minor updates to wording consistent with the rest of the document. |
| 12. Contacts | Updated Sector Contacts and Enquiries tables. |